



MNU - User Manual

User Manual

Version 5.4

Revision History			
Version	Data	Description	Author
1.0	19/07/2019	First version	Leonardo Eifert Catanante
1.1	02/08/2019	Included: "Grant regulatory user profile"	Ricardo Ferreira Borges
1.2	16/09/2019	Included is the possibility of extending the deadline for fulfilling requirements for processes of this type. "TOXICOLOGY" (except wooden preservatives) An appendix with specific guidelines on the petitioning process for import/export matters (PAF) is included.	Bruno Zago França Diniz
1.3	15/10/2019	Layout change and inclusion of information relating to Bruno To PagTesouro as an online payment option.	Zago França Diniz
1.4	18/11/2019	Inclusion of information regarding authorization of amendment by a third party and amendment by a third party	Bruno Zago França Diniz
1.5	15/01/2020	Inclusion of information about express shipping in Beneficiary's CNPJ name and CPF.	Bruno Zago França Diniz
1.6	14/02/2020	Cosmetics Registration and Cosmetics Registration in the category "Hair Straightener for Dyed Hair - Grade 2" and Transfer of Ownership	Ricardo Ferreira Borges
1.7	26/03/2020	The configuration instruction for the "User" profile has been removed. "Regulatory Petition" until the functionality is Operating as expected.	Bruno Zago França Diniz
1.8	28/05/2020	Inclusion of information regarding the Amendment of Legal Representative and Technical Representative for Operating Permits and Special Permits	Ricardo Ferreira Borges
1.9	23/06/2020	Re-inserted link configuration instruction representation "Regulatory Petition User"	Bruno Zago França Diniz
2.0	30/06/2020	The information regarding the payment, pending protocol, open requirements, and processes tabs has been updated. and specific guidelines for cosmetics registration included specific guidelines for the free certificate of practice and sanitary certificate of vessel, general petitions from the General Management of Ports, Airports and	Ricardo Ferreira Borges

		Borders, applicant update before analysis is complete, and registration of sanitizing products.	
2.1	09/12/2020	Updated information has been provided regarding the functionalities for transferring ownership, third-party amendments, registration and notification of sanitizing products, and changes to expressions of interest in sanitizing products. Updated information regarding requirement viewing and fulfillment. Added information regarding support for Pix as a payment method via PagTesouro.	Bruno Zago França Diniz
2.2	10/12/2020	Inclusion of the "Troubleshooting" section.	Ricardo Ferreira Borges
2.3	11/02/2021	Inclusion of information regarding the Embryo Production Registry, Pesticide Residue Study Registry, and Accreditation and Qualification of Bruno Zago França Diniz and Public Health Laboratories. Reordering of Specific Guidelines in the manual by alphabetical order.	Ricardo Ferreira Borges
2.4	03/05/2021	Update of information regarding general requests from the General Management of Ports, Airports and Borders (GGPAF).	Bruno Zago França Diniz and Ricardo Ferreira Borges
2.5	08/06/2021	Inclusion of information relating to the import and export form for LPCO and LI.	Bruno Zago França Diniz and Ricardo Ferreira Borges
2.6	30/09/2021	Update on information regarding the PIX payment method.	Bruno Zago França Diniz
2.7	07/10/2021	Inclusion of information regarding the use of Single Sign-On. via Gov.Br to access the system	Bruno Zago França Diniz
2.8	09/12/2021	Clarification regarding the validity period of tokens for third-party addendums and transfer of ownership.	Bruno Zago França Diniz
2.9	08/07/2022	Inclusion of information regarding service evaluation.	Ricardo Ferreira Borges
3.0	23/12/2022	Inclusion of information regarding the validation of attached file names, information related to changes in company name or address in operating permits, and information regarding the registration and notification of health products.	Ricardo Ferreira Borges
3.1	30/06/2023	The "Troubleshooting" section has been updated with guidance on the new Subject Inquiry feature and how to view or file a case or petition. a petition linked to this process or petition occurs	Bruno Zago França Diniz Ricardo Ferreira Borges

		excluding accessing the request using the same CNPJ that filed the process or petition. Inclusion of the possibility of issuing receipts for manual petitions and for petitions previously filed through the old Electronic Petitioning System.	
3.2	14/08/2023	Update on viewing information Requirements can be found in the Open Requirements tab. Update to the section on ownership transfer with specific information for Toxicology processes.	Ricardo Ferreira Borges Bruno Zago França Diniz
3.3	28/08/2023	Update to 50MB maximum file size Bruno Zago França Diniz allowed for annex not requested.	
3.4	18/09/2023	Inclusion of information regarding automatic purging. drafts that have been inactive for more than 13 months.	Bruno Zago França Diniz
3.5	04/12/2023	Evolution of the import/export form by Express shipment including a field for entering the quantity of units, and its respective validation, and information regarding the importation of <i>Cannabis</i> .	Ricardo Ferreira Borges
3.6	05/07/2024	Inclusion of information regarding the drug notification form (medical gases)	Bruno Zago França Diniz
3.7	04/09/2024	Inclusion of information relating to the form of notification and registration of food	Ricardo Ferreira Borges
3.8	02/10/2024	Update to the <i>Cannabis</i> Import Form including automatic validation information	Bruno Zago França Diniz
3.9	04/10/2024	Inclusion of information regarding the AFE/AE grant form.	Ricardo Ferreira Borges
4.0	01/11/2024	Updating the cosmetics registration form	Ricardo Ferreira Borges
4.1	31/12/2024	Inclusion or exclusion of a brand, exclusion of a manufacturer, and alteration of a food manufacturing step.	Ricardo Ferreira Borges
4.2	06/03/2025	Inclusion of information regarding the form for expanding or reducing the activity or class of the Operating Authorization. Reorganization of specific guidelines. Exclusion of guidelines for the decentralized protocol for Operating Authorization in PAF, Certification of Good Storage Practices in PAF, and Accreditation of Vaccination Services.	Ricardo Ferreira Borges

4.3	31/03/2025	Updating information related to the food registration and notification form.	Ricardo Ferreira Borges
4.4	03/04/2025	Updating information related to the cosmetics registration and notification form, and adding information regarding changes and migrations of notifications and expressions of interest.	Ricardo Ferreira Borges
4.5	25/06/2025	Inclusion of the workflow for issuing certificates and documents	Ricardo Ferreira Borges
4.6	05/08/2025	Adding the favorites tab	Ricardo Ferreira Borges Bruno Zago França Diniz
4.7	14/10/2025	Inclusion of new fields in the Health Products form and issuance of AFE/AE Certificate.	Ricardo Ferreira Borges Bruno Zago França Diniz
4.8	14/11/2025	Update to the section regarding Forms of Operating Permit to reflect the activity Food Registry	Bruno Zago França Diniz
4.9	05/01/2026	Inclusion of new information regarding prioritization options and rare diseases (applicable only to medications).	Bruno Zago França Diniz
5.0	13/03/2026	Update of information regarding system access profiles, and inclusion of details about the "Financial" profile. Inclusion of information relating to Clinical Drug Research forms.	Bruno Zago França Diniz
5.1	29/05/2026	Inclusion of information regarding the versioning of specific forms and the corresponding alert messages in the Drafts tab.	Bruno Zago França Diniz
5.2	16/06/2026	Updating the information on the Payment and tabs Open requirements, minor corrections to specific food forms.	Bruno Zago França Diniz
5.3	29/07/2026	Update of information regarding specific medical device forms (formerly "health products") to include new fields to be completed.	Bruno Zago França Diniz
5.4	09/09/2026	Inclusion of the product registration and notification workflow. tobacco derivatives	Ricardo Ferreira Borges

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USER MANUAL

ACCESS TO THE SYSTEM

This manual aims to instruct the user in the best possible way on how to use the system.

Access the link <https://solicita.anvisa.gov.br>

The Solicita System works exclusively on more modern browsers, such as Microsoft Edge, Google Chrome, or Mozilla Firefox.



Solicita now offers two login options:

- Traditional access via user email and password
- Access via Gov.Br

Access via Gov.Br uses the user's registration on the [Gov.Br portal](#), which needs to be up-to-date and active, combined with the user's registration with Anvisa, for the correct display of the represented companies.

Step-by-step instructions and answers to frequently asked questions about this access can be [found here](#).

Access to the system depends on the user being linked to at least one CNPJ (Brazilian company tax ID) and having granted their user one of the system's profiles. For more information on granting and managing profiles, [Consult the Anvisa Registration manual](#).

Access to the Solicita system is possible with the following profiles:

- Security Manager or Legal Representative – Grants full access to the system. The user can access documents associated with requests made only by the user **themselves**.
- Regulatory Petition User Link – Grants full access to the system. The user can access documents associated with requests made by **any user linked to that CNPJ (Brazilian tax ID)**.
- Financial Profile – Allows **exclusive** access to the "Payment" tab for payment of pending transactions.

The "Financial" profile grants access only to the "Payment" tab, where the user can click the "Select Payment" action button to access both GRU generation and payment via PagTesoouro.

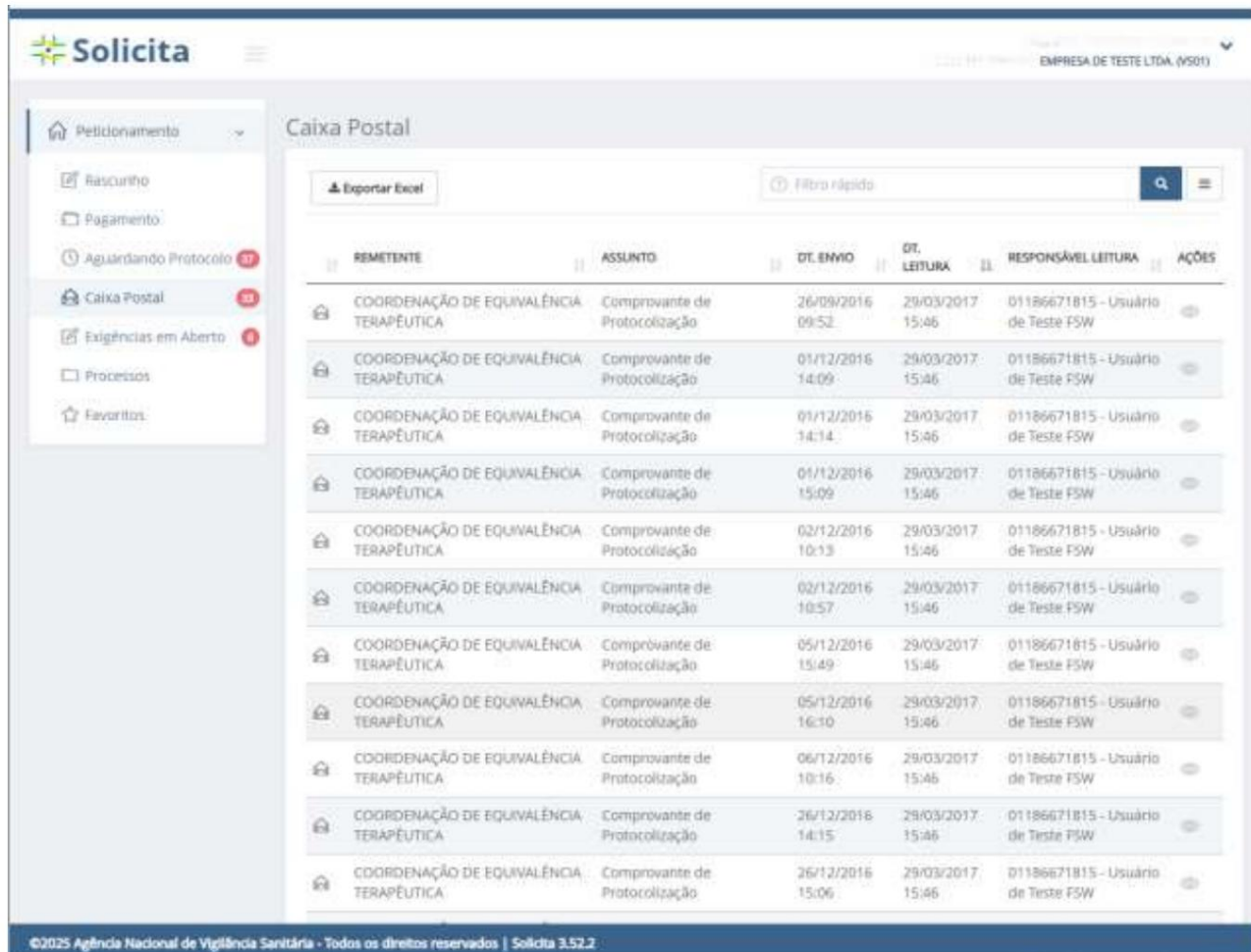


PROCESSO	Nº TRANSAÇÃO	DESCRIÇÃO	QTD	VALOR	DT. VENCIMENTO	DT. VENCIMENTO	AÇÕES
237145000	00176	Assistência de importação por meio de REMESSA ESPRESSA, de até 26 unidades de volume e destino para fins regulatórios.	237145000	R\$ 177,00	23/03/2024 15:54	25/03/2024 15:54	Selecionar Pagamento
237145000	00176	Assistência de importação por meio de REMESSA ESPRESSA, de até 26 unidades de volume e destino para fins regulatórios.	237145000	R\$ 177,00	23/03/2024 15:54	25/03/2024 15:54	
237145000	00176	Assistência de importação por meio de REMESSA ESPRESSA, de até 26 unidades de volume e destino para fins regulatórios.	237145000	R\$ 177,00	23/03/2024 15:54	25/03/2024 15:54	

Important! This profile should not be used in conjunction with other profiles available for Solicita. Similarly, if a user already has one of the other profiles, granting the Financial profile will not result in any changes to the access granted by the other profiles.

2. Home Screen

The home screen will display two main sections:

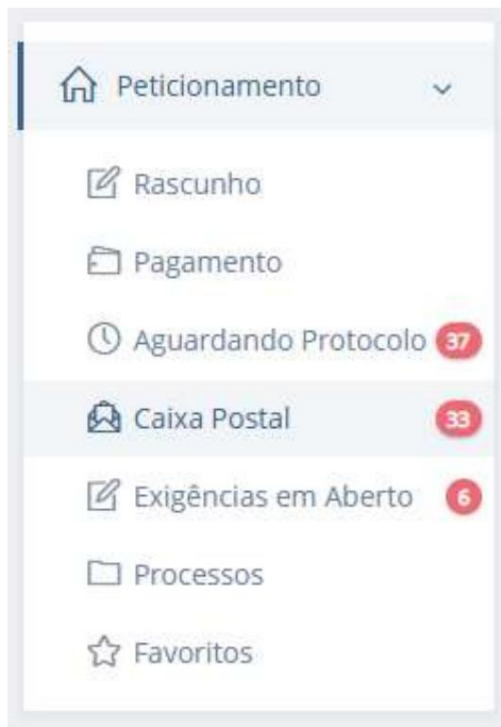


The screenshot shows the Solicita system interface. On the left is a sidebar with navigation options: Petiçãoamento, Rascunho, Pagamento, Aguardando Protocolo (37), Caixa Postal (33), Exigências em Aberto (6), Processos, and Favoritos. The main area is titled 'Caixa Postal' and contains a table of requests. At the top of the table is an 'Exportar Excel' button and a 'Filtro rápido' search bar. The table has columns for REMETENTE, ASSUNTO, DT. ENVIO, DT. LEITURA, RESPONSÁVEL LEITURA, and AÇÕES. The data rows show multiple requests from 'COORDENAÇÃO DE EQUIVALÊNCIA TERAPÊUTICA' with subject 'Comprovante de Protocolização', sent on various dates in 2016 and 2017, and read by 'Usuário de Teste FSW'.

REMETENTE	ASSUNTO	DT. ENVIO	DT. LEITURA	RESPONSÁVEL LEITURA	AÇÕES
COORDENAÇÃO DE EQUIVALÊNCIA TERAPÊUTICA	Comprovante de Protocolização	26/09/2016 09:52	29/03/2017 15:46	01186671815 - Usuário de Teste FSW	
COORDENAÇÃO DE EQUIVALÊNCIA TERAPÊUTICA	Comprovante de Protocolização	01/12/2016 14:09	29/03/2017 15:46	01186671815 - Usuário de Teste FSW	
COORDENAÇÃO DE EQUIVALÊNCIA TERAPÊUTICA	Comprovante de Protocolização	01/12/2016 14:14	29/03/2017 15:46	01186671815 - Usuário de Teste FSW	
COORDENAÇÃO DE EQUIVALÊNCIA TERAPÊUTICA	Comprovante de Protocolização	01/12/2016 15:09	29/03/2017 15:46	01186671815 - Usuário de Teste FSW	
COORDENAÇÃO DE EQUIVALÊNCIA TERAPÊUTICA	Comprovante de Protocolização	02/12/2016 10:13	29/03/2017 15:46	01186671815 - Usuário de Teste FSW	
COORDENAÇÃO DE EQUIVALÊNCIA TERAPÊUTICA	Comprovante de Protocolização	02/12/2016 10:57	29/03/2017 15:46	01186671815 - Usuário de Teste FSW	
COORDENAÇÃO DE EQUIVALÊNCIA TERAPÊUTICA	Comprovante de Protocolização	05/12/2016 15:49	29/03/2017 15:46	01186671815 - Usuário de Teste FSW	
COORDENAÇÃO DE EQUIVALÊNCIA TERAPÊUTICA	Comprovante de Protocolização	05/12/2016 16:10	29/03/2017 15:46	01186671815 - Usuário de Teste FSW	
COORDENAÇÃO DE EQUIVALÊNCIA TERAPÊUTICA	Comprovante de Protocolização	06/12/2016 10:16	29/03/2017 15:46	01186671815 - Usuário de Teste FSW	
COORDENAÇÃO DE EQUIVALÊNCIA TERAPÊUTICA	Comprovante de Protocolização	26/12/2016 14:15	29/03/2017 15:46	01186671815 - Usuário de Teste FSW	
COORDENAÇÃO DE EQUIVALÊNCIA TERAPÊUTICA	Comprovante de Protocolização	26/12/2016 15:06	29/03/2017 15:46	01186671815 - Usuário de Teste FSW	

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The sidebar, where you can choose which features you want to use:



And the results section, where it is possible to identify documents that meet the criteria of each of the boxes



DESCRIÇÃO	DT. CRIAÇÃO	DT. EDIÇÃO	RESPONSÁVEL EDIÇÃO	AÇÕES
8122 - FARMACIA FARMACIA Biotec - CANCELAMENTO DE BOM FIM DE MANUFATURA PARA FARMACIA Biotec...	08/07/2019 10:08	08/07/2019 10:08	Usuário de Foneix Biotec	
11996 - FARMACIA Biotec - CANCELAMENTO DE BOM FIM DE MANUFATURA PARA FARMACIA Biotec...	08/07/2019 10:08	08/07/2019 10:08	Usuário de Foneix Biotec	
4077 - FARMACIA Biotec - CANCELAMENTO DE BOM FIM DE MANUFATURA PARA FARMACIA Biotec...	08/07/2019 10:08	08/07/2019 10:08	Usuário de Foneix Biotec	

3. SKETCHING SCREEN

Upon accessing the system, if there are no new messages in the mailbox, the first screen that will be displayed is... the drafts screen:

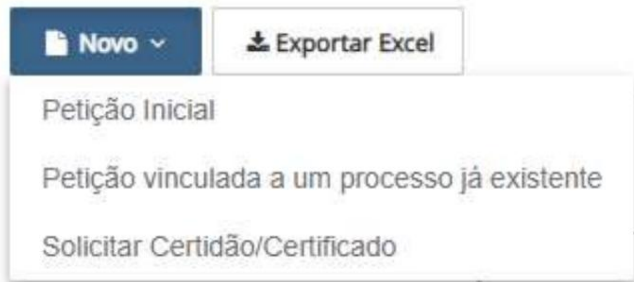


DESCRIÇÃO	DT. CRIAÇÃO	DT. EDIÇÃO	DT. EXCLUSÃO AUTOMÁTICA	RESPONSÁVEL EDIÇÃO	AÇÕES
8122 - EQUIPAMENTO - Notificação de Dispositivos Médicos Classe II	06/07/2023 16:22	12/08/2023 14:52	12/10/2024 16:22		
7027 - AE - ALTERAÇÃO - FARMACIA DE MANUFATURA - ENDEREÇO	17/08/2023 19:24	12/09/2023 14:31	12/10/2024 14:31		
4077 - Registro de Suplementos Alimentares Contendo Propaganda em seu Embalagem	11/09/2023 15:36	12/09/2023 14:14	12/10/2024 14:14		
10303 - PRODUTO BIOLÓGICO - Solicitação de Transferência de Titularidade do Registro (Código de Em...	12/09/2023 16:58	12/09/2023 16:58	13/11/2023 09:54		
4134 - Registro de Novos Alimentos e Novas Ingredientes	13/09/2023 09:15	13/09/2023 09:15	13/10/2024 09:15		

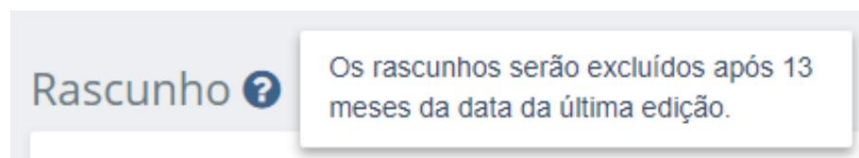


When activated

It will be possible to register a new initial process/petition or a new secondary petition/petition linked to an existing process, **provided it is linked to the CNPJ used to access the request.**



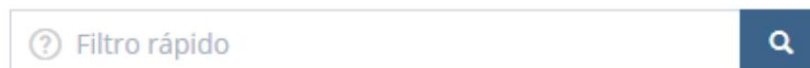
Important! All drafts are automatically deleted 13 months after the date of the last edit. The deletion date is displayed to the user in the "Automatic Deletion Date" column. This date is automatically updated every time a draft is edited and saved.



When activated

It will be possible to export the drafts present in the rows to Excel.

present at the bottom of the form



When you fill in the magnifying

and activate the

glass field, the lines below will show drafts that have any field that meets the search criteria included in the quick search field.



When activated

Advanced search criteria will be displayed.



In advanced search, the search criteria are:

- Description – Displays results related to the subject code or subject description of the sketch;
- Responsible for Editing – Displays results related to the person responsible for the last edit to the draft or, if no changes occurred after the draft was created, the user responsible for creating the draft;
- Creation Date – Displays results related to the draft's creation date. When filling in the In the Start and End fields, it is possible to perform searches within a defined period.
- Automatic Deletion Date – Displays results related to the automatic deletion date of sketch.

When using more than one field, the result displayed on the screen will be the combined result of the selections in each field.

The results section has the following structure:

Descrição	DT. CRIAÇÃO	DT. EDIÇÃO	DT. EXCLUSÃO AUTOMÁTICA	RESPONSÁVEL EDIÇÃO	AÇÕES
9024 - EQUIPAMENTO - Notificação de Dispositivo Médico Classe II	04/07/2023 14:22	12/09/2023 14:32	12/10/2024 14:32		 
7927 - AT - ALTERAÇÃO - FARMÁCIA DE MANIPULAÇÃO - ENDEREÇO	17/08/2023 15:24	12/09/2023 14:31	12/10/2024 14:31		 
4077 - Registro de Suplementos Alimentares Contendo Probióticos em Formas	11/09/2023 15:36	12/09/2023 14:14	12/10/2024 14:14		 
10303 - PRODUTO BIOLÓGICO - Substituição de Transfêrência de Titularidade de Registro (Código de Em...	12/09/2023 14:58	12/09/2023 14:58	12/11/2023 09:54		 
4234 - Registro de Novos Alimentos e Novos ingredientes	13/09/2023 09:15	13/09/2023 09:15	12/10/2024 09:15		 

The fields display the following information:

- Description - Field displaying the subject code and subject description.
- Creation Date - Field displaying the date the draft was created.
- Edition Date - Field displaying the date the draft was edited;
- Automatic Deletion Date – Field displaying the date for automatic deletion of the sketch;
- Responsible for Editing - Field displaying the name of the person responsible for the last modification. done in draft form;
- Actions – Enables the execution of three actions.

Change button



- Allows editing of a draft.

View button



- Allows viewing a draft without the possibility of editing.

Delete button



Allows you to delete a draft.

When accessing a previously saved draft, the system performs several checks before allowing the user to proceed:

- If the checklist items associated with the subject have been modified since the last save

After reopening the draft, a message will be displayed, as shown below, and it will not be possible to proceed with sending that draft. The company must save its documents and information and start a new draft on that subject:



- If the draft relates to a secondary petition and the previously selected original petition has had its ownership changed to another CNPJ (Brazilian tax ID), a message will be displayed, as shown below, and it will not be possible to proceed with sending that draft. The company must save its documents and information and start a new draft on that subject:



- If the draft relates to a specific form and this form has been updated by

After creating a draft, Anvisa will display a message, as shown below, and it will not be possible to proceed with sending that draft. The company must save its documents and information and start a new draft on that subject:

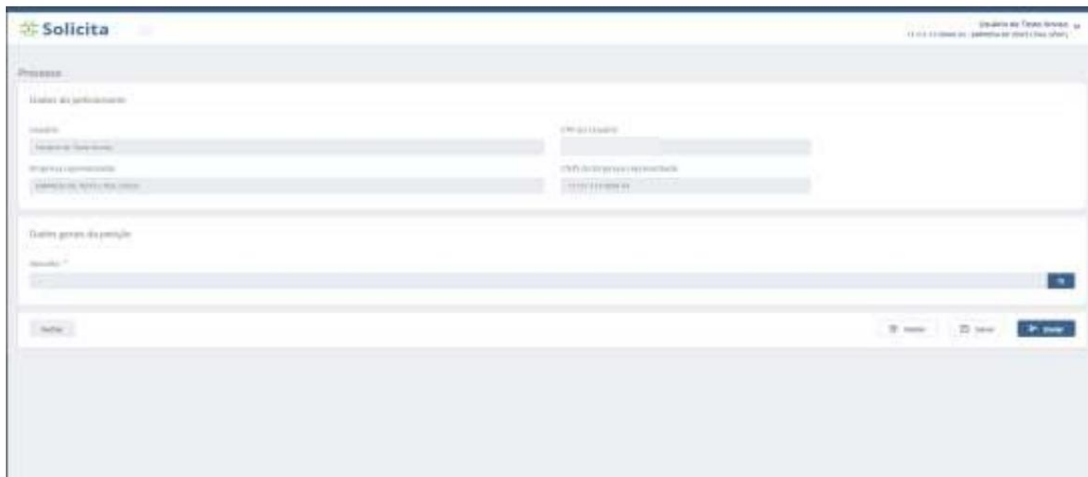


4. CREATING A DRAFT OF A PRIMARY PETITION

By selecting the "Initial Petition" option under "New".



After clicking on "initial petition," a page will open with forms relevant to the petition.



This page initially has two sections. The first section displays the petitioner's information, which is pre-filled with their name, CPF (Brazilian individual taxpayer registration number), the name of the chosen company, and its respective CNPJ (Brazilian company taxpayer registration number). The second section contains general petition information, with a field indicating the chosen subject matter of the process and a...

Use the search , to open the subject search screen, where the search will be performed and then button to select the subject.

At the bottom there are 4 buttons, which are:

-  A pop-up will appear confirming the closing of the petition, informing that... All unsaved data will be discarded.



- 
 This will check if the form has been filled out correctly; if not, a message will be displayed in red at the top of the screen indicating that corrections need to be made.



- 
 This will save the process with the currently filled data; selecting at least the subject is mandatory. If something prevents saving, a message will appear informing you of the problem, as in the following example:



- 
 Send the process.

By pressing the button  Next to the "Subject" field, the following screen will open.



On this screen, you can see the "Select" option, which, when clicked, will open a list of Activities/Product Types where you can select the desired one:

Atividade/Tipo de produto

Selecione

Selecione

Toxicologia

Portos, Aeroportos e Fronteira

Empresas

Medicamento

Alimento

Produtos para Saúde (Correlatos)

Código

You can enter the code for the desired subject to search.

Descrição

In which a

Description of the research topic.

Serviço

This section allows you to select the desired service from those listed for Anvisa on the Gov Br Portal. You can search for a service by typing part of its name (using the "auto-complete" feature). When you select a service, the related petition topics will be displayed as a result. This feature is still under construction and may have inconsistencies.

 Pesquisar

Button to confirm the search using the entered and/or selected information, which can also be used with empty fields, thus opening and displaying the list of responses with all the existing issues

Selecionar assunto

Atividade/Tipo de produto

Selecione

Serviço

Código

Descrição

Pesquisar

Código	Atividade/Tipo de Produto	Descrição	
11396	Medicamento	DINAMIZADO – (CLONE) - Histórico de Mudanças do Produto COM inclusão de modificação exclusiva HMP	→
11535	Medicamento	PRODUTO DE CANNABIS (FITOTERÁPICO) - Autorização Sanitária (com concentração de THC até 0,2%)	→
11536	Medicamento	PRODUTO DE CANNABIS (FITOTERÁPICO) - Autorização Sanitária (com concentração de THC acima de 0,2%)	→
11537	Medicamento	PRODUTOS DE CANNABIS (FITOFÁRMACO) - Autorização Sanitária (com concentração de THC até 0,2%)	→
11538	Medicamento	PRODUTOS DE CANNABIS (FITOFÁRMACO) - Autorização Sanitária (com concentração de THC acima de 0,2%)	→
287	Cosmético	Registro de Produto Grau 2 - Nacional	→
2871	Cosmético	Registro de Produto Grau 2 - Importado	→
3874	Saneantes	Registro de Produto de Risco 2 - Inseticida para Empresas Especializadas	→
4007	Alimento	Registro de Água Mineral Natural e Água Natural	→
4030	Alimento	Registro de Novos Alimentos e Novos Ingredientes IMPORTADO	→

Exibindo 1 a 10 de 180 itens

«

1

2

3

4

5

...

18

»

10

▼

To select the desired subject from the results list, click the arrow to the right of the desired item.

Note: If there are more than 10 results, you can navigate between the results pages using the navigation bar that will appear below the results list, or use the selector on the side of the bar to display a larger number of topics on the search screen.

Page 21/286

« 1 2 3 4 5 ... 18 » 10 ▼

After selecting the desired subject, the fields in the "General Petition Data" block will be automatically completed, and up to 3 blocks will appear: "Form Templates," "Legal Basis," and "Documentation," already filled with initial data.

Modelos de Formulários:

NOME DO FORMULÁRIO	Arquivo	Download
Formulário FP 1 F	Arquivos - Formulário de Petição 1 (Formulário)	
Formulário FP 2 F	Arquivos - Formulário de Petição 2 (Formulário)	
Formulário FP 3 F	Arquivos - Formulário de Petição 3 (Formulário)	
Ficha de Cadastro de Empresas	Arquivos - Ficha de Cadastro de Empresas	
Formulário FP 1 F	Arquivos - Formulário de Petição 1 (Formulário)	

In the "Form Templates" section, you can download form templates for completion which, once filled out, can be linked to the corresponding item in the "Documentation" section.

Solicita

Cadastre dados da petição

Assunto:

Para: Solicitante: Perfil do Solicitante: Natureza da Petição:

Tipos de documentos:

Modelos de Formulários:

NOME DO FORMULÁRIO	Arquivo	Download
Formulário FP 1 F	Arquivos - Formulário de Petição 1 (Formulário)	
Formulário FP 2 F	Arquivos - Formulário de Petição 2 (Formulário)	
Formulário FP 3 F	Arquivos - Formulário de Petição 3 (Formulário)	
Ficha de Cadastro de Empresas	Arquivos - Ficha de Cadastro de Empresas	
Formulário FP 1 F	Arquivos - Formulário de Petição 1 (Formulário)	

In the "Documentation" section, you can see the columns "No.," which displays the item number, "Item," which displays the item name/title, "Required," where "Yes" will be displayed if including file(s) is mandatory for that item, "Files," where the files selected for each item will be displayed, and "Actions," where...

In each item, there will be a button.

The system will apply a filter that will automatically replace any invalid characters that may be in the composition of each file name with an underscore (_). Invalid characters include

Programming language delimiters (& and control/ " " < >), line breaks and tabs (\n \r \t), characters invisible characters (ESC, DEL, null, end of text, ...), among others. This change does not alter the content of the files.

Depending on the subject code selected, other information blocks may be available in the petition form; see the final sections of the Manual for specific guidance on each form.

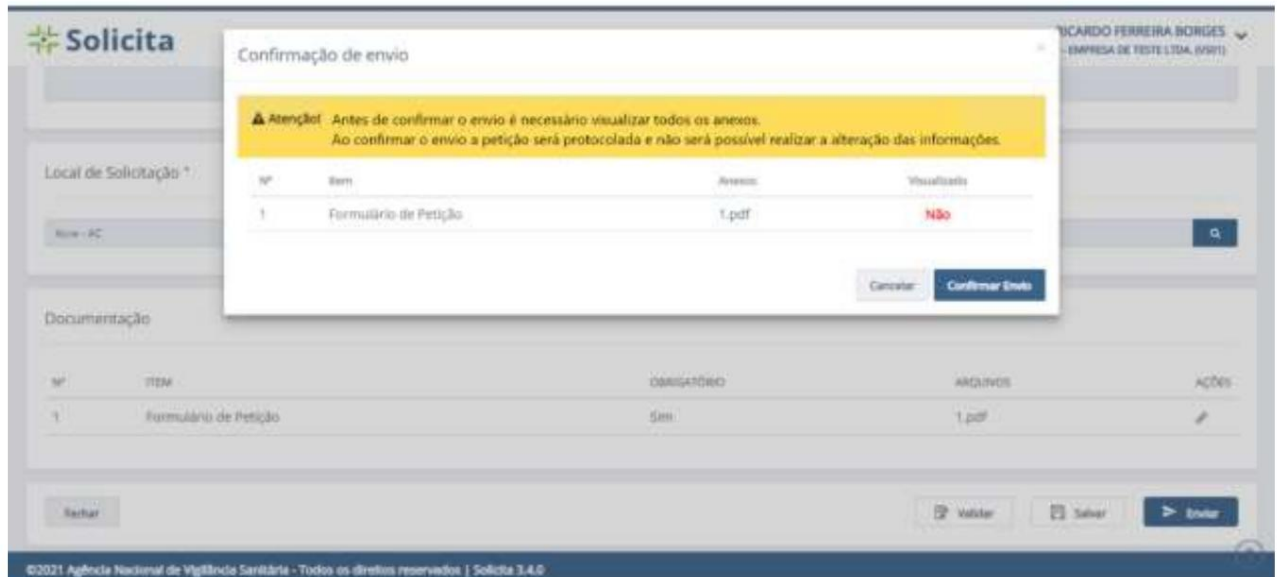
By clicking the button  A screen will open allowing you to attach one or more relevant files to...

The files can be up to 50 MB and have the extensions jpg, jpeg, bmp, png, pdf, doc, docx, xls, and xlsx.

É permitido anexo de arquivos dos tipos jpg, jpeg, bmp, png, pdf, doc, docx, xls e xlsx. Limitados a 50MB.

[Selecione o\(s\) arquivo\(s\)](#)

When you click submit, if everything is correct, a submission confirmation box will appear.



Solicita

Local de Solicitação: 1

Nome: AC

Documentação

Nº	ITEM	OBRIGATORIO	ARQUIVOS	AÇÕES
1	Formulário de Petição	Sim	1.pdf	

Botões: Salvar, Validar, Salvar, Enviar

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displaying the documentation items with the names of the inserted attachments.

Confirmar Envio

To confirm the submission, you must first click on attachments so , click on the names of that you can preview the files. After clicking, the "Presented" field will change from **No** to **Yes**.



Solicita

Local de Solicitação: 1

Nome: AC

Documentação

Nº	ITEM	OBRIGATORIO	ARQUIVOS	AÇÕES
1	Formulário de Petição	Sim	1.pdf	

Botões: Salvar, Validar, Salvar, Enviar

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After . It will not be possible to make any changes to the documents.

If the request requires a fee, a window will appear with information about the petition awaiting payment.



Petição aguardando pagamento

Favorecido:	74.535.250/0001-62 - EMPRESA TESTE BB
Assunto:	4110 - Avaliação de inclusão de coadjuvantes de tecnologia, exceto enzimas
Número de Transação:	38452019

[Selecionar Pagamento](#)

Concluir



The button . When clicked, it opens the window below.



Pagamento

Escolha a forma de pagamento:



Gerar Boleto



PagTresouro
(Pagamento Online)

Gerar boleto: Ao emitir a GRU a empresa está ciente de que será necessário efetuar o pagamento da guia na rede bancária e aguardar o prazo de compensação bancária que poderá ser de até dois dias úteis.

Pag Tesouro (Pagamento on line): Por meio desta funcionalidade será possível ser direcionado a página web do Banco do Brasil a fim de permitir a validação do pagamento de forma imediata caso utilize a opção "débito em sua conta". Ressalta-se que as empresas que optarem pelo "débito na conta da sua empresa" e que tenham em seu contrato junto ao Banco a necessidade de mais de uma assinatura, apenas após a confirmação desta será possível ter o pagamento validado. Para esta opção, após a validação do pagamento a protocolização da petição se dará em até 30 minutos.

Agência Nacional de Vigilância Sanitária - Fomento ao desenvolvimento econômico ANVISA-ATONCE - 0003-942-0702 - nacional
Setor de Indústria e Suprimentos (SIS) - Praça S. Aires Espinosa, 57 - Brasília, DF - CEP: 71228-020 e 71228-220

ANVISA
Agência Nacional de Vigilância Sanitária

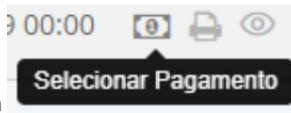
Showing the payment options: Generate Boleto, which allows you to print the GRU for payment; and PagTesouro, which allows payment by Credit Card or using Pix.

By selecting the "Generate Boleto" option, you will be able to print the GRU for payment. Clicking on

Concluir

You will be redirected to the draft screen again. The request has been completed.

But if it hasn't been paid yet, it will be available in the "Payment" tab, and the payment can be made by clicking [the appropriate button/method].



the button

Again, the option to Generate Boleto or PagTeseouro can be selected.

When selecting the PagTeseouro option, the following options are displayed:

- Credit Card, where you can choose one of the available payment providers. Depending on the Choose, no prior registration is required.
- Pix, where a QR Code will be generated to finalize the payment. The full code will also be displayed for use on the institution's website.



After completing the necessary actions, the user is redirected back to the PagTeseouro page:


 Pagamento realizado com sucesso.

Detalhes do Pagamento

Identificação do pagamento 4B6vbQFKg08P27GLO8LmN0	Data e hora do pagamento 07/08/2019 19:00:55
Descrição 141 - ANM-TAXA VISTORIA FISCALIZACAO	Instituição financeira Simulador BB
CNPJ do contribuinte 74.535.250/0001-02	Nome do contribuinte EMPRESA TESTE BB
Número da transação 31908070000000143	Valor pago R\$ 3.514,32

Imprimir
Concluir



Concluir

Clicking on

You will be redirected to the draft screen again.

If the request does not require payment of a fee, a success message will be displayed with the petition details.

Petição enviada com sucesso
✕

Favorecido:	11.111.111/0001-91 - EMPRESA DE TESTE LTDA. (VS01)
Assunto:	11396 - DINAMIZADO - (CLONE) - Histórico de Mudanças do Produto COM inclusão de modificação exclusiva HMP
Número de Transação:	34072019
Protocolo:	25352003690201916
Processo:	25351001503201961
Expediente:	0004612191
Tipo de Documento:	Processo
Protocolizador:	- Usuário de Teste Anvisa em 15/07/2019 10:55:36

 Imprimir Comprovante

Concluir

By clicking on

 Imprimir Comprovante

The page ready for printing the receipt will open.



Mozilla Firefox

https://solicita-homolog.anvisa.gov.br/solicita/imprimir?wicket-crypt=sHIVDRBV88I



AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA

COMPROVANTE DE PROTOCOLIZAÇÃO ON-LINE

Protocolo:
25352003690201916

Expediente:
0004612191

Número de Transação:
34072019

Tipo de Documento:
Processo

Número do Processo:
25351001503201961

Favorecido:
11.111.111/0001-91 - EMPRESA DE TESTE LTDA. (VS01)

Assunto:
11396 - DINAMIZADO – (CLONE) - Histórico de Mudanças do Produto COM inclusão de modificação exclusiva HMP

Protocolizado On-Line via Peticionamento Eletrônico por:
- Usuário de Teste Anvisa em 15/07/2019 10:55:36

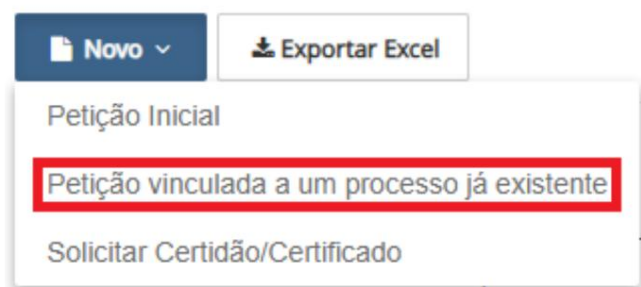
Imprimir

Upon completion, you will be redirected to the drafts screen again.

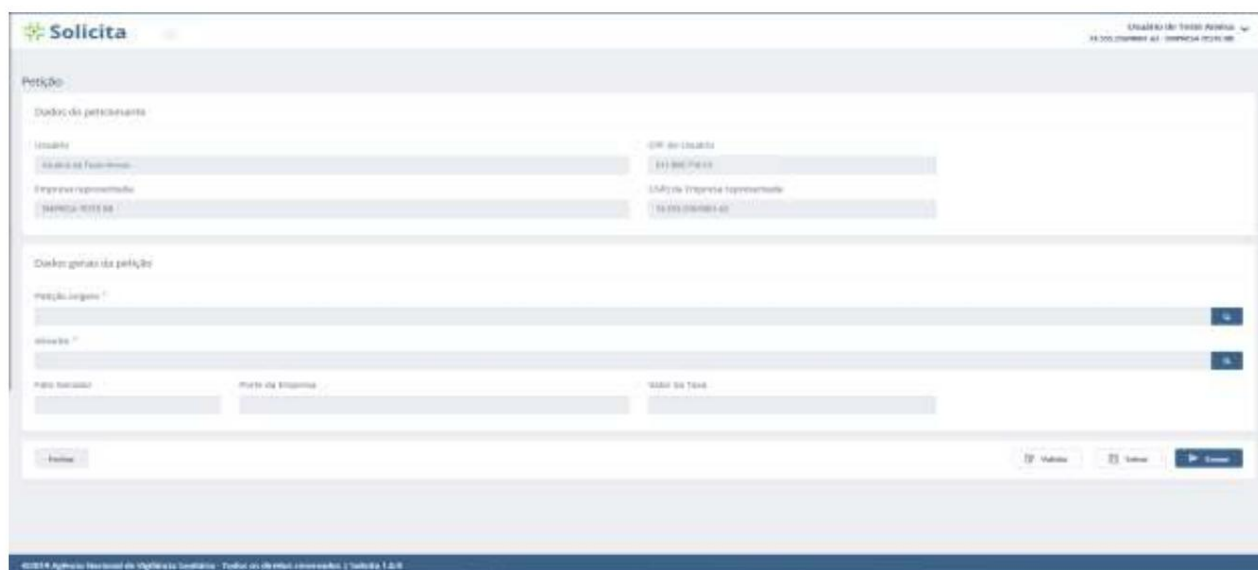
5. CREATING A DRAFT PETITION LINKED TO AN EXISTING PROCESS

Note: This step can also be done via the processes tab, linking the petition directly to the desired process.

To create a draft petition linked to an existing case, on the Draft screen select New and then "Petition linked to an existing case".



After clicking, a new tab will open in your browser, similar to the following example:



Initially, it is possible to identify two blocks of information: the first containing the petitioner's data, as in the initial petition process, and a second containing the general data of the petition.

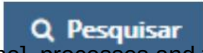


By clicking the button  Next to the "Origin Petition" field, a window will be available for Research and selection of the petition to which the request will be linked.

Selecione a petição desejada ×

Processo	Assunto	Expediente
0 / 100		





By entering the desired data and clicking [button name], processes and files corresponding to the searched criteria will be listed, **provided they were submitted by the accessed CNPJ [Brazilian tax ID]**.

Note: fields can be left blank to search all processes, or you can fill in only the desired fields, searching according to the data entered.



To select the desired process, click next to the process. From this point on, the steps will be the same as those required to fill out an initial petition, starting with selecting the subject matter.

Important!

- If the selected source petition does not have an associated service, the “activity/product type” field will be pre-filled with the same option as the initial petition. Pay attention to whether the linked petition you want to file is of a different product type and adjust the filter selection as needed; the “select” option is equivalent to clearing the filter.
- The Digital Service selector, when the screen accessed is a petition linked to an existing process, loads the available services taking into account the digital service of the parent petition. For example, when starting a linked petition in a Cosmetic Registration process, whose service is Request Cosmetic Registration, the services available for the linked petition include Amend, Cancel, and Renew Cosmetic Registration, among others.
- Petitions related to an investigation dossier are only available to receive a secondary petition once a requirement has been issued by Anvisa or when the petition has been published.
- Depending on the subject code selected, other information blocks may be available.
available in the petition form.
- When indicating a secondary petition/petition linked to a process as the “Original Petition,” it will only be possible to link requests for amendments, withdrawals, appeals, and corrections to that petition.
petitions, as per the notice displayed on the screen:

Selecionar assunto

⚠ Atenção! Esta funcionalidade permite a solicitação de aditamento, aditamento por terceiro, desistência a pedido, recurso e retificação.

Atividade/Tipo de produto

Alimento

Serviço

Código

Descrição

Pesquisar

6. CREATING A DRAFT OF A CERTIFICATE/CERTIFICATE

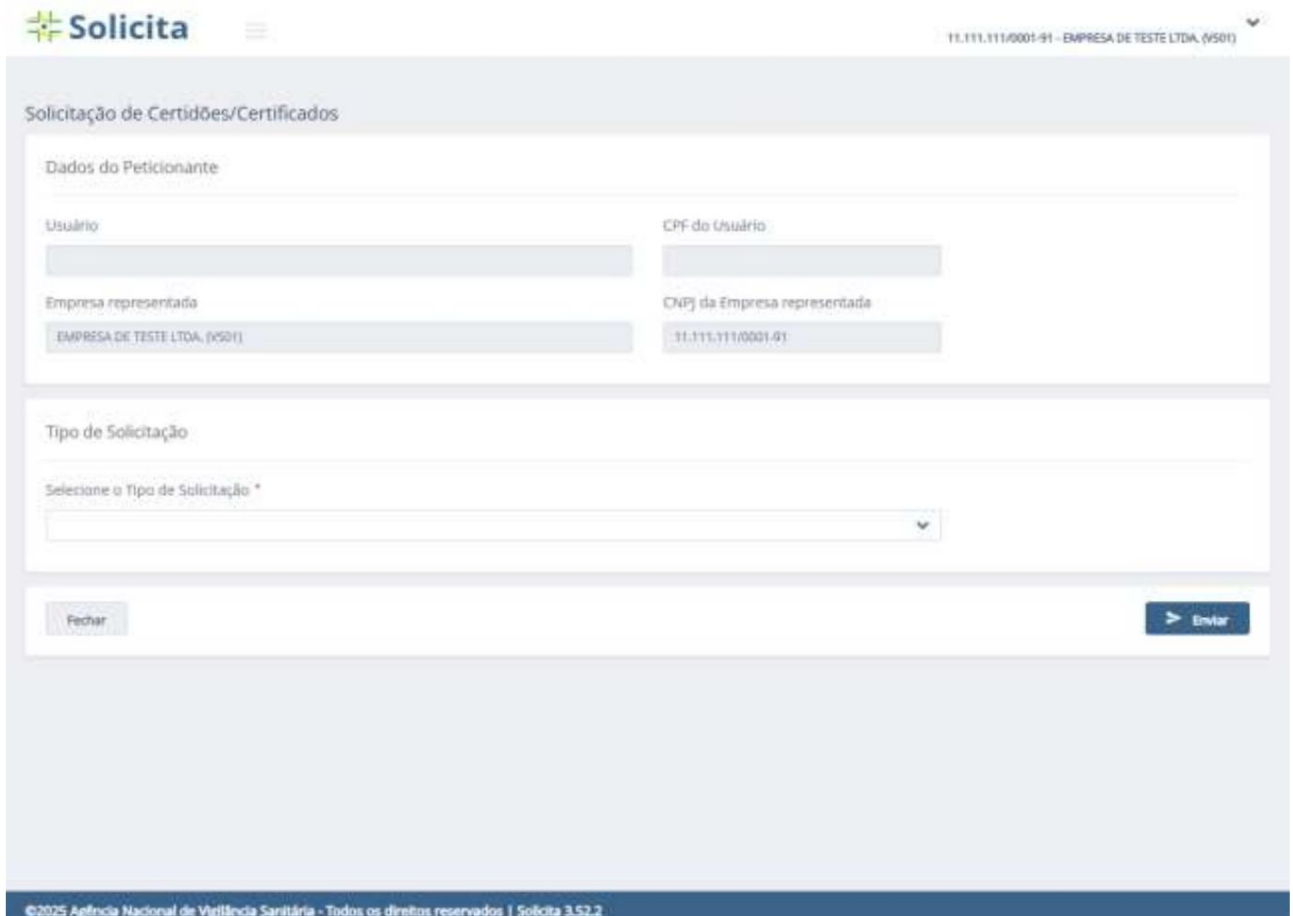
To create a draft of a certificate/certificate request, on the Draft screen select New and then “Request Certificate/Certificate”.



Important! Not all product types are yet available for issuance through the self-service Request system.

In cases where the product type has not yet been made available, the message "Issuance is not yet available for this product type" will be displayed.

After clicking on “Request Certificate”, a new tab will open in your browser similar to the one shown below:



Initially, it is possible to identify two blocks of information, the first containing the petitioner's data:

Solicitação de Certidões/Certificados

Dados do peticionante

Usuário	CPF do Usuário
Empresa representada	CNPJ da Empresa representada
EMPRESA DE TESTE LTDA. (V501)	11.111.111/0001-01

The second one with the "Type of Request":

Tipo de Solicitação

Selecione o Tipo de Solicitação *

First, select whether you want to issue a certificate or document related to an operating permit or a product:

Tipo de Solicitação

Selecione o Tipo de Solicitação *

Autorização de Funcionamento (AFE ou AE)

Produto

Fechar

Enviar

Certificate of Authorization to Operate (AFE or AE)

When selecting Operating Authorization (AFE or AE), the field "Select the authorization for issuing the Certificate" will be enabled.

Selecione a Autorização para Emissão do Certificado *

The system will display the valid AFEs or AEs for the represented company. If the company does not have an active AFE or AE, the system will display the message: "The company does not have an active AFE or AE at the moment. The AFE/AE Certificate is an optional document and can only be requested after the Authorization has been granted. To request the granting of the AFE or AE, go to: Draft > New > Initial Petition."

After selecting the desired AFE or AE, the system will display the following information on the screen: "authorization number", "activity and class", "process number" and "process subject". The system will also display the type of document that will be displayed, taking into account the type of authorization selected (AFE or AE).

Selecione o Tipo de Documento *

AFE - Certificado de Autorização de Funcionamento

 **Pré-Visualizar**

You will be able to preview the document that will be issued by clicking the button; a new tab will open with the chosen certificate template pre-filled for verification of the information available in the Anvisa database. If you identify any discrepancies, please contact the responsible department before requesting the issuance of the certificate.

Important! Please note that the request to correct the database must be made before requesting the issuance of the certificate, since it is not possible to make changes to the generated document after the request has been submitted.

Once the information is correct, click the checkbox next to the text "I declare that the information is correct and up-to-date, and I am aware that, after the issuance request, it will not be possible to change the information in the issued document."

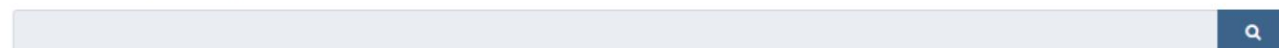


If the request requires payment of a fee, a window will appear with information about the petition awaiting payment, just as shown in the "Initial Request" section. If no fee is required, the system will complete the petitioning process.

Product certificate or certification

When selecting a product, the field "Select a product for issuing Certificates" will be Enabled.

Selecione um produto para emissão de Certidões ou Certificados *



By clicking the button  Next to the field above, a window will be available for searching and selecting the product for which you wish to issue a certificate.

The user can then search for the desired product by entering the process number or the regularization number. At least one field must be filled in to perform the search. By clicking on



The product(s) corresponding to the searched criteria will be listed, **provided that they are owned by the accessed CNPJ (Brazilian tax ID) and that are active.**

Selecione

×

Número do Processo

25351420018200970

Número da Regularização

Pesquisar

Nome do Produto	Nº Regularização	Nº Processo	Assunto	
ENXAGUATÓRIO BUCAL ANTI-SÉPTICO DENTALC LEAN HORTELÃ H2CLEAN	229740007	2535142001820 0970	REG. COSMÉTICOS - Registro de Pr oduto - Nacional	→



To select the desired process, click next to the process. From this moment on, the data of the chosen process will be displayed in the section "Request Data - Issuance of Certificate/Certificate – Product"

Dados da Solicitação - Emissão Certidão/Certificado - Produto

Nome do Produto

PROTETOR SOLAR FPS 30 MED SUN

Número da Regularização

214850190

Número do Processo

25351417175200919

Assunto do Processo

REG. COSMÉTICOS - Registro de Produto - Nacional

Selecione o Tipo de Documento *

In the "Select Document Type" field, select the type of document you wish to issue. After selection, the system will choose the subject matter and automatically calculate the fee amount according to the company size and the event that generated the transaction.

Assunto

2873-COSMÉTICOS - Certificado de Livre Comercialização de produto

Fato Gerador Porte da Empresa Valor da Taxa

0900 GRANDE - GRUPO I R\$ 0,00

Tipo de Isenção

Microempreendedor Individual (MEI)

If a document template is chosen that includes trademark information for the country, a field will be enabled for including the "Product name abroad" and the "country" to which the product will be exported.

Identificação do País para o qual o produto será exportado

NOME DO PRODUTO NO EXTERIOR	PAIS	AÇÕES
Nenhum item foi adicionado.		

+ Adicionar

Limpar Tudo

+ Adicionar

To enter information, click on information.

to display a modal for inserting the

Informe o nome do produto no exterior e o país para exportacao

Nome do produto no Exterior *

País *

0 / 100

Adicionar Cancelar

Enter the "Product Name Abroad" and the "Country" and click as many times as necessary.

Adicionar

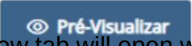
This process can be repeated.

Identificação do País para o qual o produto será exportado

NOME DO PRODUTO NO EXTERIOR	PAIS	AÇÕES
Teste	AFEGANISTÃO	 

The name and country entered can be deleted by clicking on  or edited by clicking on .

After entering the desired document type, it will be possible to preview the document that will be issued.

Using the button , a new tab will open with the chosen certificate template pre-filled for verification of the information available in the Anvisa database. If you identify any discrepancies, please contact the responsible department before requesting the issuance of the certificate.

Important! Please note that the request to correct the database must be made before requesting the issuance of the certificate, since it is not possible to make changes to the generated document after the request has been submitted.

Once the information is correct, click the checkbox next to the text "I declare that the information is correct and up-to-date, and I am aware that, after the issuance request, it will not be possible to change the information in the issued document."



If the request requires payment of a fee, a window will appear with information about the petition awaiting payment, just as shown in the "Initial Request" section. If no fee is required, the system will complete the petitioning process.

Access to a certificate or document

For both operating permits and product applications, after the petition is completed, a secondary file will be generated which can be consulted in the processes tab of Solicita. The certificate can be obtained by accessing this file, as shown below:

PROCESSO - 25351143996201825
 287 - REG. COSMÉTICOS - Registro de Produto - Nacional





287 - REG. COSMÉTICOS - Registro de Produto - Nacional [0204361181] -
 16/03/2018 - Publicado deferimento

- 2106 - REG. COSMÉTICOS - Recadastramento de Produtos Infantis no SGAS (RDC 237/2018) [4370471214] - 05/11/2021 - Anuído
- 2874 - COSMÉTICOS - Certificado de Livre Comercialização para exportação de produto [0505759250] - 16/04/2025 - Distribuído para a área responsável
 - Certidão/Certificado - 16/04/2025
- 2874 - COSMÉTICOS - Certificado de Livre Comercialização para exportação de produto [0505766256] - 16/04/2025 - Distribuído para a área responsável
- 2874 - COSMÉTICOS - Certificado de Livre Comercialização para exportação de produto [0505843251] - 17/04/2025 - Distribuído para a área responsável

Instructions for validating the issued document can be found in the footer of every page:



Documento emitido eletronicamente em **28/02/2025** pela Agência Nacional de Vigilância Sanitária - ANVISA. A validade desse documento pode ser verificada em <https://consultas.anvisa.gov.br/#/autenticadocumentos> inserindo o código **XXXXXX** e o hash **YYYYYYYYYYYYYYYYYYYY**

1 / 2

7. PAYMENT TAB

When you select the "Payment" option on the side screen, the following screen will be displayed:



This tab displays transactions that are awaiting payment or payment processing and whose due date is after the current date. "Overdue" transactions will not be displayed in this tab, as payment is no longer possible.

Important! This tab is updated internally by the system every 30 minutes. Therefore, for a recently completed transaction, it may take up to 30 minutes to appear. If the company needs the payment processed urgently, it is suggested that the payment flow be initiated directly on the completion screen.

Regarding the submission of the petition. The time of the last update is displayed at the top of the screen: "The last update occurred at hh:mm:ss".

On the screen, there is a button listed immediately after



which generates an Excel file with the petitions awaiting expedited payment. same, one filter

below processing. and a button to open the filter advanced:



The advanced filter form includes the following fields and options:

- Numero do Processo**: Text input field.
- Nº Transação**: Text input field.
- Descrição**: Text input field.
- Guia**: Text input field.
- Valor**: Text input field.
- DI. Emissão**: Date range selector with 'Inicio' and 'Fim' fields.
- DI. Vencimento**: Date range selector with 'Inicio' and 'Fim' fields.
- Nome do Produto**: Text input field.
- Numero de Conhecimento**: Text input field.
- Numero de Conhecimento de Carga**: Text input field.
- Numero da AFE/AE**: Text input field.
- Serviço Digital**: Text input field.
- Indicador**: Text input field.
- Limpar** and **Procurar** buttons at the bottom right.

When activated, this displays the advanced filter that can be used to search for a payment by:

- Transaction number - Displays results related to the transaction number.
- Description - Displays results related to the transaction description.
- Guide - Displays results related to the guide number.
- Value - Displays results related to the transaction value.
- Issue Date – Displays results related to the issue date between the selected dates.
- Due Date - Displays results related to the due date between the given dates.
chosen
- Product Name – Displays results related to the product name (if available)
- Bill of Lading Number – Displays results related to the bill of lading number (also known as AWB), applicable only to petitions and processes related to import/export.
- Knowledge Number – Displays results related to the knowledge number (if any); this identifier was provided for physical/manual petitions after the documentation was delivered to the Agency and before the process or file number was generated.
- AFE/AE Number – Displays results related to the AFE/AE number. Applicable only to Processes and petitions related to Operating Permits or Special Permits.
- Digital Service – Displays results related to the selected digital service. This filter is still under construction and will be populated as more Anvisa services are listed on the Gov Br portal, therefore it may present inconsistencies.

MNU - User Manual

The payment list has the columns "Transaction No.", "Description", "Guide", "Amount", "Issue Date", "Date". "Due Date" and "Actions," which displays the possible action buttons for each payment, namely:



Allows you to choose the payment type when issuing a duplicate GRU or granting access to...
Treasurer



Print the transaction statement.

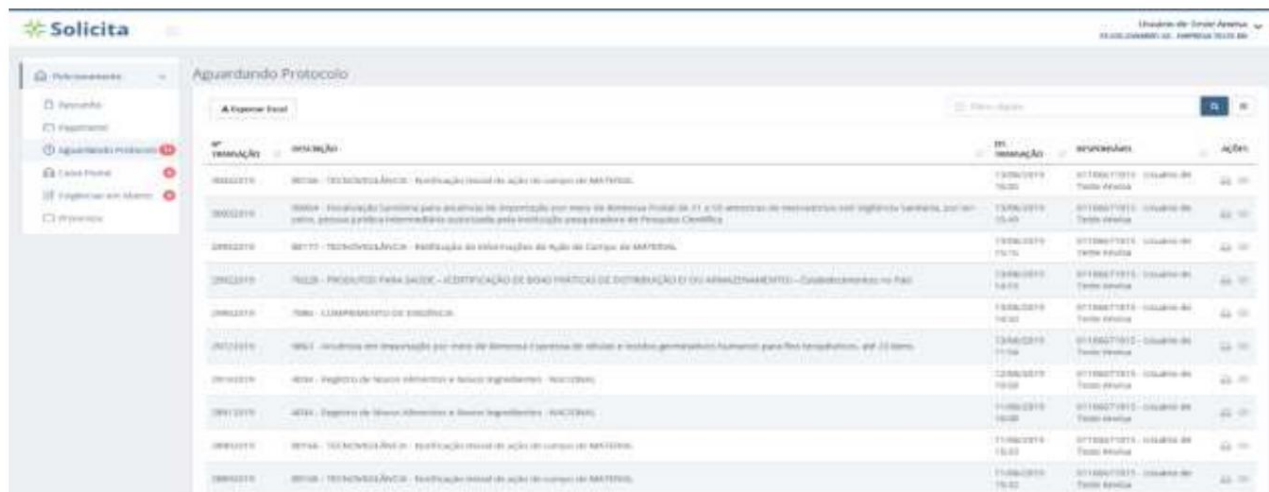


Allows you to view the request.

Nº TRANSAÇÃO	DESCRIÇÃO	GUIA	VALOR	DT. EMISSÃO	DT. VENCIMENTO	AÇÕES
7335632019	80101 - TECNOLOGIA - Anúncio para veicular publicidade contendo alerta à população de EQUIPAMENTOS	881033/2019	R\$ 1.2410,00	19/07/2019 00:00	18/08/2019 00:00	[D] [E] [V]
7355192019	80101 - TECNOLOGIA - Anúncio para veicular publicidade contendo alerta à população de EQUIPAMENTOS	988071/2019	R\$ 1.2410,00	22/07/2019 00:00	21/08/2019 00:00	[D] [E] [V]
7390032019	80102 - TECNOLOGIA - Anúncio para veicular publicidade contendo alerta à população de MATERIAIS DE USO MÉDICO	985782/2019	R\$ 1.2410,00	22/07/2019 00:00	21/08/2019 00:00	[D] [E] [V]

8. ABA AWAITING PROTOCOL

Selecting the "Awaiting Protocol" option in the side menu will display a page similar to the example below:



Nº Transação	Descrição	Data	Status	Ações
00000001	00000 - FOLHA FISCAL - FOLHA FISCAL DE AGUARDANDO PROTOCOLO	15/05/2019	00000 - FOLHA FISCAL	00000 - FOLHA FISCAL
00000002	00000 - FOLHA FISCAL - FOLHA FISCAL DE AGUARDANDO PROTOCOLO	15/05/2019	00000 - FOLHA FISCAL	00000 - FOLHA FISCAL
00000003	00000 - FOLHA FISCAL - FOLHA FISCAL DE AGUARDANDO PROTOCOLO	15/05/2019	00000 - FOLHA FISCAL	00000 - FOLHA FISCAL
00000004	00000 - FOLHA FISCAL - FOLHA FISCAL DE AGUARDANDO PROTOCOLO	15/05/2019	00000 - FOLHA FISCAL	00000 - FOLHA FISCAL
00000005	00000 - FOLHA FISCAL - FOLHA FISCAL DE AGUARDANDO PROTOCOLO	15/05/2019	00000 - FOLHA FISCAL	00000 - FOLHA FISCAL
00000006	00000 - FOLHA FISCAL - FOLHA FISCAL DE AGUARDANDO PROTOCOLO	15/05/2019	00000 - FOLHA FISCAL	00000 - FOLHA FISCAL
00000007	00000 - FOLHA FISCAL - FOLHA FISCAL DE AGUARDANDO PROTOCOLO	15/05/2019	00000 - FOLHA FISCAL	00000 - FOLHA FISCAL
00000008	00000 - FOLHA FISCAL - FOLHA FISCAL DE AGUARDANDO PROTOCOLO	15/05/2019	00000 - FOLHA FISCAL	00000 - FOLHA FISCAL
00000009	00000 - FOLHA FISCAL - FOLHA FISCAL DE AGUARDANDO PROTOCOLO	15/05/2019	00000 - FOLHA FISCAL	00000 - FOLHA FISCAL
00000010	00000 - FOLHA FISCAL - FOLHA FISCAL DE AGUARDANDO PROTOCOLO	15/05/2019	00000 - FOLHA FISCAL	00000 - FOLHA FISCAL

On the screen, there are buttons listed in the table below, a quick filter.



, which generates an Excel file containing the protocols

and a button  to open the advanced filter



which, when activated, displays the advanced filter with the following search options:

- Transaction Number - Displays results related to the transaction number.
- Description - Displays results related to the transaction description.
- Responsible Party - Presents results related to the responsible party.

- Transaction Date - Displays results relating to the transaction date within the entered period.

The protocol listing has the columns “Transaction No.”, “Description”, “Transaction Date”, “Responsible Party”, and “Actions”.

Nº TRANSAÇÃO	DESCRIÇÃO	DT. TRANSAÇÃO	RESPONSÁVEL	AÇÕES
30042019	80156 - TECNOMONITORIA - Notificação inicial de ação de campo de MATERIAL	13/06/2019 16:05	RTS - Usuário de Teste Anvisa	 
30032019	90064 - Fiscalização Sanitária para análise de importação por meio de Rede de Pontos de 25 a 50 amostras de mercadorias sob Vigilância Sanitária, por terceiros, pessoa jurídica intermediária autorizada pela Instituição pesquisadora de Pesquisa Científica	13/06/2019 15:09	RTS - Usuário de Teste Anvisa	 
29952019	80177 - TECNOMONITORIA - Retificação de informações de Ação de Campo de MATERIAL	13/06/2019 15:16	TS - Usuário de Teste Anvisa	 
29922019	70228 - PRODUTOS PARA SAÚDE - (CERTIFICAÇÃO DE BOAS PRÁTICAS DE DISTRIBUIÇÃO E/OU ARMAZENAMENTO) - Estabelecimentos no País	13/06/2019 14:53	RTS - Usuário de Teste Anvisa	 
29902019	7086 - CUMPRIMENTO DE EXIGÊNCIA	13/06/2019 14:50	TS - Usuário de Teste Anvisa	 

You can perform some actions by clicking the action buttons:



: Opens a window to print the extract with the petition data.

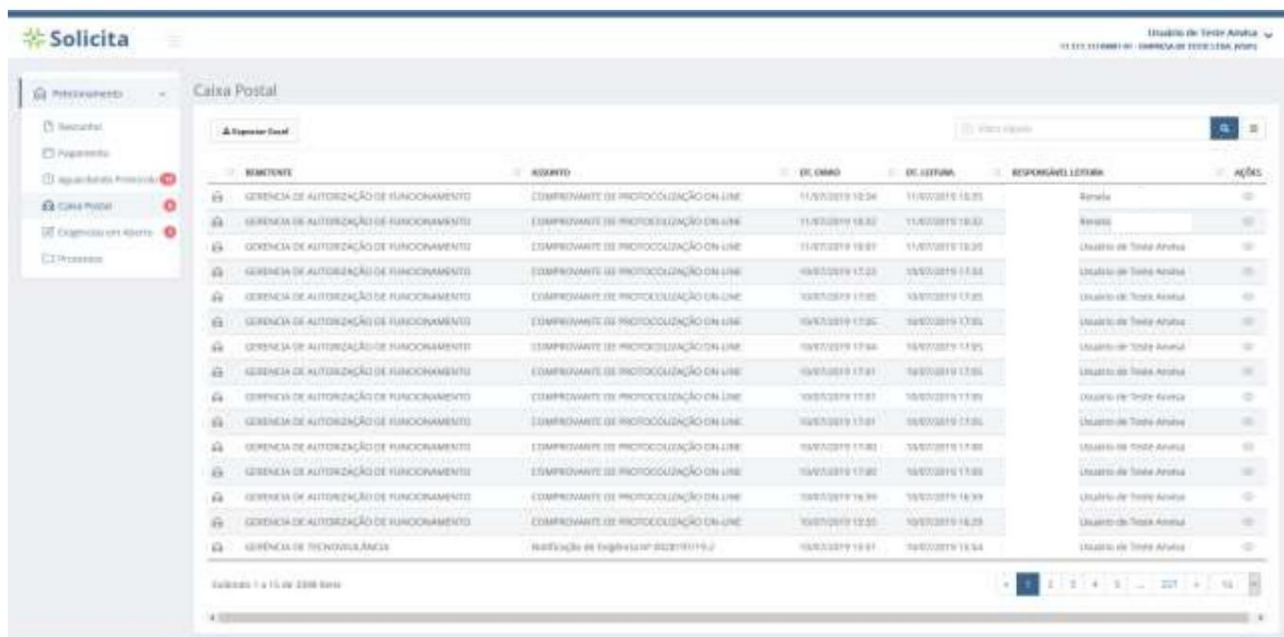


This opens the petition in a new tab, with details and on a page similar to the action of opening a new petition. This button is only displayed for workflows initiated in Solicita, and only for the user who filed the petition or for users who have the Regulatory Petition User link. In cases where an amendment has been made by a third party, the field may be disabled if the third party chooses not to share the information with the applicant of the process or petition.

9. ABA P.O. BOX

By selecting the “Mailbox” option in the side menu, a screen will open listing read and unread messages related to the company's CNPJ (Brazilian tax ID) used to access Solicita. Whenever there is an unread message and the user attempts to access any functionality, they will first be directed to the mailbox.

Starting in July 2020, messages of the type “Proof of Filing” will have the requirement to be read removed, so that these messages will no longer prevent the use of other system functionalities while they remain unread. This exception applies only to messages of this type; other messages will continue to require reading before allowing the use of other system functionalities.



REMITENTE	ASSUNTO	DE	ENVIO	DE	LEITURA	RESPONSÁVEL LEITURA	AÇÕES
GERENCIA DE AUTORIZAÇÃO DE FUNCIONAMENTO	COMPROVANTE DE PROTOCOLOÇÃO ON LINE	11/07/2019 12:34	11/07/2019 12:35			Renata	
GERENCIA DE AUTORIZAÇÃO DE FUNCIONAMENTO	COMPROVANTE DE PROTOCOLOÇÃO ON LINE	11/07/2019 12:32	11/07/2019 12:32			Renata	
GERENCIA DE AUTORIZAÇÃO DE FUNCIONAMENTO	COMPROVANTE DE PROTOCOLOÇÃO ON LINE	11/07/2019 12:31	11/07/2019 12:31			Usuário de Teste Anônimo	
GERENCIA DE AUTORIZAÇÃO DE FUNCIONAMENTO	COMPROVANTE DE PROTOCOLOÇÃO ON LINE	10/07/2019 17:23	10/07/2019 17:23			Usuário de Teste Anônimo	
GERENCIA DE AUTORIZAÇÃO DE FUNCIONAMENTO	COMPROVANTE DE PROTOCOLOÇÃO ON LINE	10/07/2019 17:22	10/07/2019 17:22			Usuário de Teste Anônimo	
GERENCIA DE AUTORIZAÇÃO DE FUNCIONAMENTO	COMPROVANTE DE PROTOCOLOÇÃO ON LINE	10/07/2019 17:21	10/07/2019 17:21			Usuário de Teste Anônimo	
GERENCIA DE AUTORIZAÇÃO DE FUNCIONAMENTO	COMPROVANTE DE PROTOCOLOÇÃO ON LINE	10/07/2019 17:20	10/07/2019 17:20			Usuário de Teste Anônimo	
GERENCIA DE AUTORIZAÇÃO DE FUNCIONAMENTO	COMPROVANTE DE PROTOCOLOÇÃO ON LINE	10/07/2019 17:19	10/07/2019 17:19			Usuário de Teste Anônimo	
GERENCIA DE AUTORIZAÇÃO DE FUNCIONAMENTO	COMPROVANTE DE PROTOCOLOÇÃO ON LINE	10/07/2019 17:18	10/07/2019 17:18			Usuário de Teste Anônimo	
GERENCIA DE AUTORIZAÇÃO DE FUNCIONAMENTO	COMPROVANTE DE PROTOCOLOÇÃO ON LINE	10/07/2019 17:17	10/07/2019 17:17			Usuário de Teste Anônimo	
GERENCIA DE AUTORIZAÇÃO DE FUNCIONAMENTO	COMPROVANTE DE PROTOCOLOÇÃO ON LINE	10/07/2019 17:16	10/07/2019 17:16			Usuário de Teste Anônimo	
GERENCIA DE AUTORIZAÇÃO DE FUNCIONAMENTO	COMPROVANTE DE PROTOCOLOÇÃO ON LINE	10/07/2019 17:15	10/07/2019 17:15			Usuário de Teste Anônimo	
GERENCIA DE AUTORIZAÇÃO DE FUNCIONAMENTO	COMPROVANTE DE PROTOCOLOÇÃO ON LINE	10/07/2019 17:14	10/07/2019 17:14			Usuário de Teste Anônimo	
GERENCIA DE AUTORIZAÇÃO DE FUNCIONAMENTO	COMPROVANTE DE PROTOCOLOÇÃO ON LINE	10/07/2019 16:39	10/07/2019 16:39			Usuário de Teste Anônimo	
GERENCIA DE AUTORIZAÇÃO DE FUNCIONAMENTO	COMPROVANTE DE PROTOCOLOÇÃO ON LINE	10/07/2019 12:55	10/07/2019 12:55			Usuário de Teste Anônimo	
GERENCIA DE FISCALIZAÇÃO	Notificação de Exigência nº 022/2019-2	10/07/2019 12:07	10/07/2019 12:54			Usuário de Teste Anônimo	

On the screen, there is a button just below it, a quick filter.

 Exportar Excel

which outputs an Excel file with the listed messages

 Filtro rápido and a button  to open the filter advanced, what, to the to be activated, it presents the advanced filter



which can be used to search for a message by:

- Sender - Displays results related to the sender.
- Subject - Displays results related to the message's subject.
- Recipient - Displays results related to the person responsible for reading the message.
- Submission Date - Displays results related to the submission date within the selected period.
- Reading date - Displays results relating to the reading date within the selected period.

The message list has the columns "Sender", "Subject", "Date Sent", "Date Read", "Responsible".

"READING" and "ACTIONS", which has a button that opens a new browser tab.

which, when activated, opens the detailed message in

10. ABA OPEN REQUIREMENTS

By clicking on "Open Requirements" in the side menu, the screen will be displayed.



Processo	Requisição	Atividade/Procedimento	Exigência	Exigência	DT. Emissão	DT. Limite	Responsável Letura	DT. Limite para Cumprimento	Ações
25.9129547732147	12204 - Medicamento - Revólver processual	Medicamento	48577622	48577622	14/09/2022	14/09/2022	XXXXXXXXXX - Nome do Usuário	14/09/2022	
25.9129547732147	155 - SMCAR - Registro de Medicamento Similar	Medicamento	152165217	481881527	08/11/2022	08/11/2022	XXXXXXXXXX - Nome do Usuário	08/11/2022	
25.9141886252147	75576 - Acompanhamento das Ações de Recolamento	Empresa	087735237	087735237	25/07/2022	25/07/2022	XXXXXXXXXX - Nome do Usuário	25/07/2022	
25.9129547732147	105 - SMCAR - Registro de Medicamento Similar	Medicamento	152165217	152428226	28/09/2022	28/09/2022	XXXXXXXXXX - Nome do Usuário	28/09/2022	
25.91711887331512	8882 - Produto Farmacêutico - Avaliação toxicológica de produto com ingredientes ativos já registrado no País	Toxicologia	051386181	050255226	14/09/2022	14/09/2022	XXXXXXXXXX - Nome do Usuário	14/09/2022	

This screen displays any requirements issued by Anvisa in processes or petitions related to the company's CNPJ (Brazilian tax ID) used to access Solicita, or requirements for which the logged-in company is the recipient. Requirements can be viewed for requests made through Solicita, the Electronic Petitioning System (available at <http://www9.anvisa.gov.br/peticionamento/sat/global/acesso.asp>), as well as processes and petitions initiated by Anvisa itself.

This screen displays unmet requirements from processes or petitions that have not been finalized and that were submitted from August 1, 2019 onwards. Therefore, requirements that remain unmet in processes and petitions that have reached a "finalized" document status, such as approved, published approval, petition closed, withdrawal at the request of the applicant, or canceled, for example – that is, where Anvisa's action on the request has already been finalized – will no longer be displayed in the open requirements tab. Only those related to processes and petitions filed by the company, as well as those issued in documents created by the Agency, such as investigation dossiers, are displayed.

On the screen, there is a button in the table below it, a quick filter.

 **Exportar Excel**

which generates an Excel file with the open requirements.

 **Filtro rápido**

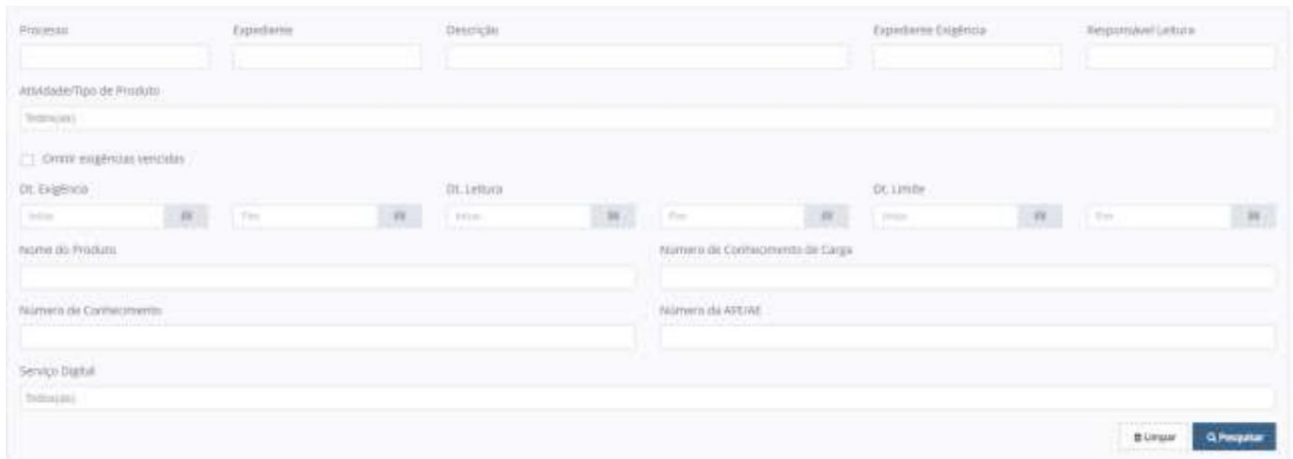


and a button



to

Open the advanced filter, which, when activated, displays the advanced filter with the fields for filtering:



- Process - Displays results related to the process number.
- File Number - Displays results related to the file number
- Description - Presents results related to the requirement description.
- Requirement File Number - Displays results related to the requirement file number.
- Responsible for Reading - Presents results related to the person responsible for reading.
- Activity/Product Type - Displays results related to the product type
- Omit overdue requirements - Displays results that are not overdue
- Requirement Date - Shows results related to the requirement date within the selected period.
- Reading Date - Displays results related to the reading date within the selected period.
- Deadline Date - Displays results related to the deadline date within the selected period.
- Product Name – Displays results related to the product name (if available)
- Bill of Lading Number – Displays results related to the bill of lading number (also known as AWB), applicable only to petitions and processes related to import/export.
- Knowledge Number – Displays results related to the knowledge number (if any); this identifier was provided for physical/manual petitions after the documentation was delivered to the Agency and before the process or file number was generated.
- Digital Service – Displays results related to the selected digital service. This filter is still under construction and will be populated as more Anvisa services are listed on the Gov portal.
- Br.
- AFE/AE Number – Displays results related to the AFE/AE number. Applicable only to Processes and petitions related to Operating Permits or Special Permits.

The Requirements listing table has the columns “Process”, “Description”, “Activity/Type of

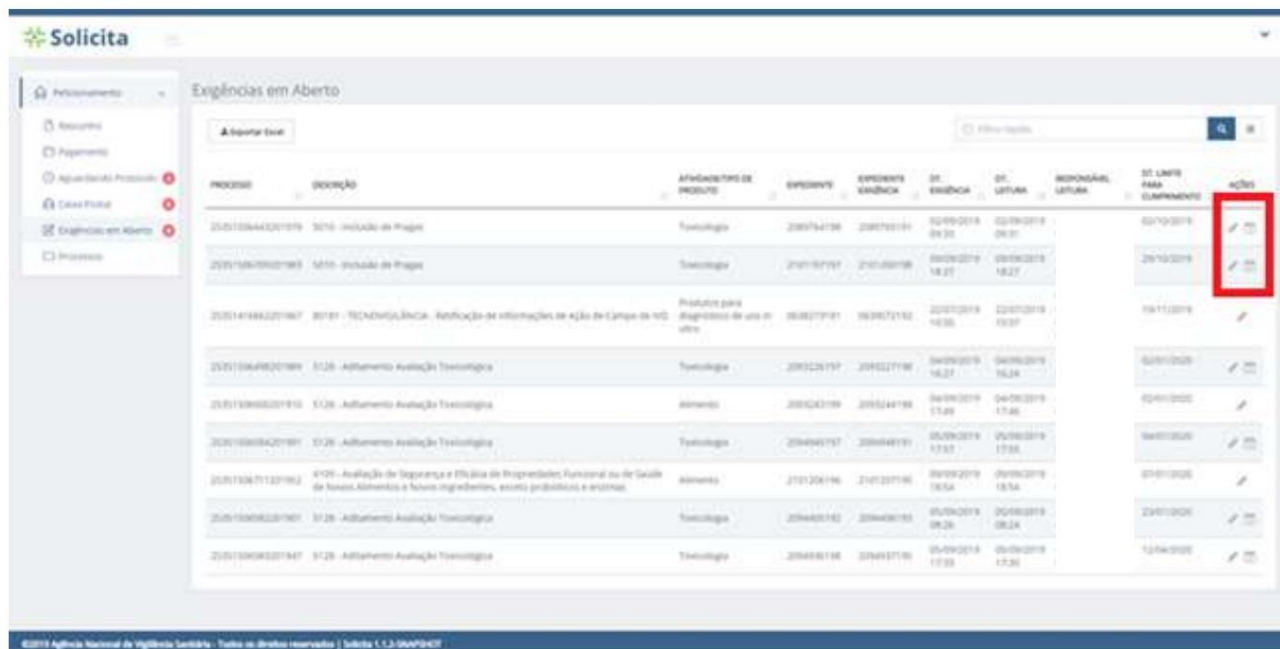
Product”, “OFFICE HOURS”, “OFFICE HOURS REQUIREMENT”, “DATE OF REQUIREMENT”, “DATE OF READING”, “READING RESPONSIBLE”, “DEADLINE FOR COMPLIANCE” and “ACTIONS”, this being the

last one where the button is located  In each process, clicking on it opens the process in a new browser tab, similar to the one presented when starting a process in the "Draft" tab, allowing the requirements to be met for each open requirement.

PROCESSO	DESCRIÇÃO	ATIVIDADE/TIPO DE PRODUTO	EXPEDIENTE	EXPEDIENTE EXIGÊNCIA	DT. EXIGÊNCIA	DT. LEITURA	RESPONSÁVEL LEITURA	DT. LIMITE PARA CUMPRIMENTO	AÇÕES
25351295477202147	12204 - MEDICAMENTO - Revisão processual	Medicamento	4655779222	4691970228	14/09/2022 16:14	14/09/2022 16:17	XXXXXXXXXX - Nome do Usuário	14/10/2022	
25351295477202147	150 - SIMILAR - Registro de Medicamento Similar	Medicamento	1327655217	4918615229	08/11/2022 16:49	09/11/2022 09:41	XXXXXXXXXX - Nome do Usuário	09/03/2023	
25351419085202341	70576 - Acompanhamento das Ações de Recolhimento	Empresas	0677289237	0677337231	03/07/2023 09:36	03/07/2023 09:37	XXXXXXXXXX - Nome do Usuário	13/07/2023	
25351295477202147	150 - SIMILAR - Registro de Medicamento Similar	Medicamento	1327655217	1034282236	28/09/2023 14:35	18/10/2023 11:09	XXXXXXXXXX - Nome do Usuário	15/02/2024	
25351295477202147	150 - SIMILAR - Registro de Medicamento Similar	Medicamento	1327655217	0509322248	20/04/2024 00:14	23/04/2024 08:17	XXXXXXXXXX - Nome do Usuário	21/08/2024	

For processes of the product type "TOXICOLOGY" – except those related to wood preservatives.

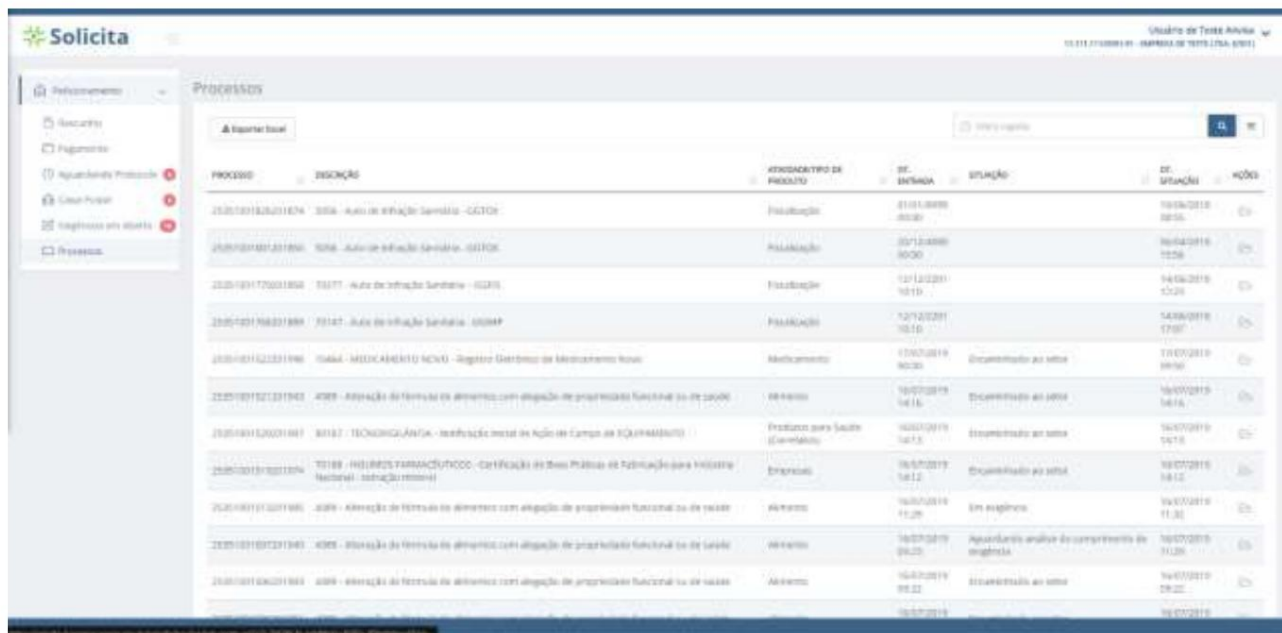
It is possible to request an extension of the deadline by clicking the button in the process or respective file, as shown below. When clicked, this button opens the process in a new browser tab, similar to the one presented when starting a process in the "Draft" tab, allowing you to request an extension of the deadline to fulfill the requirement.



The screenshot shows the 'Solicita' system interface. On the left, there is a sidebar with navigation options: 'Peticionamento', 'Recursos', 'Pagamentos', 'Agenda de Processos', 'Dados Fiscais', 'Exigências em Aberto', and 'Processos'. The main area displays a table titled 'Exigências em Aberto'. The table has the following columns: PROCESSO, DESCRIÇÃO, ATIVIDADE/TIPO DE PRODUTO, EXPEDIENTE, EXPEDIENTE EXIGÊNCIA, DT. EXIGÊNCIA, DT. LEITURA, RESPONSÁVEL LEITURA, DT. LIMITE PARA CUMPRIMENTO, and AÇÕES. The 'AÇÕES' column contains a pencil icon for each row, which is highlighted with a red box in the first row.

11. ABA PROCESSES

By selecting "Processes" in the side menu, the page displaying the list of processes will be shown. related to the company's CNPJ (Brazilian tax ID) through which access to Solicita was made and some actions:



PROCESSO	DESCRIÇÃO	TIPO DE PROCESSO	DT. INÍCIO	SITUAÇÃO	DT. SITUAÇÃO	AÇÃO
2320101152011074	3006 - Autor de Infração Sanitária - GGTOR	Infração	01/01/2019	0030	10/06/2019	0030
2320101152011080	3006 - Autor de Infração Sanitária - GGTOR	Infração	05/10/2019	0030	06/04/2019	0030
2320101170011008	3007 - Autor de Infração Sanitária - GGTOR	Infração	12/12/2019	0010	04/06/2019	0010
2320101168011009	3007 - Autor de Infração Sanitária - GGTOR	Infração	12/12/2019	0010	04/06/2019	0010
2320101152011046	0464 - MEDICAMENTO NOVO - Registro Sanitário de Medicamento Novo	Medicamento	13/07/2019	0030	13/07/2019	0030
2320101152011042	4009 - Alteração de fórmula de alimentos com alegação de propriedade funcional ou de saúde	Alimento	16/07/2019	0010	16/07/2019	0010
2320101152011047	8010 - TECNOLOGIA/NOV - Introdução inicial de Agil de Campo de Segurança	Produto para Saúde (Genérico)	16/07/2019	0010	16/07/2019	0010
2320101152011034	70109 - REGISTRO FARMACÉUTICO - Certificação de Novo Produto de Registro para Indústria Nacional - Infração (recurso)	Empresa	16/07/2019	0010	16/07/2019	0010
2320101152011040	4009 - Alteração de fórmula de alimentos com alegação de propriedade funcional ou de saúde	Alimento	16/07/2019	0010	16/07/2019	0010
2320101152011040	4009 - Alteração de fórmula de alimentos com alegação de propriedade funcional ou de saúde	Alimento	16/07/2019	0010	16/07/2019	0010
2320101152011040	4009 - Alteração de fórmula de alimentos com alegação de propriedade funcional ou de saúde	Alimento	16/07/2019	0010	16/07/2019	0010
2320101152011040	4009 - Alteração de fórmula de alimentos com alegação de propriedade funcional ou de saúde	Alimento	16/07/2019	0010	16/07/2019	0010

The processes related to Investigation Dossiers and their associated petitions or Sanitary Administrative Processes are only available for viewing once a requirement has been issued. either by Anvisa or when the process or petition is published.

A button is available on the screen.

 **Exportar Excel**

, which generates an Excel file with the processes displayed in

table, a quick filter

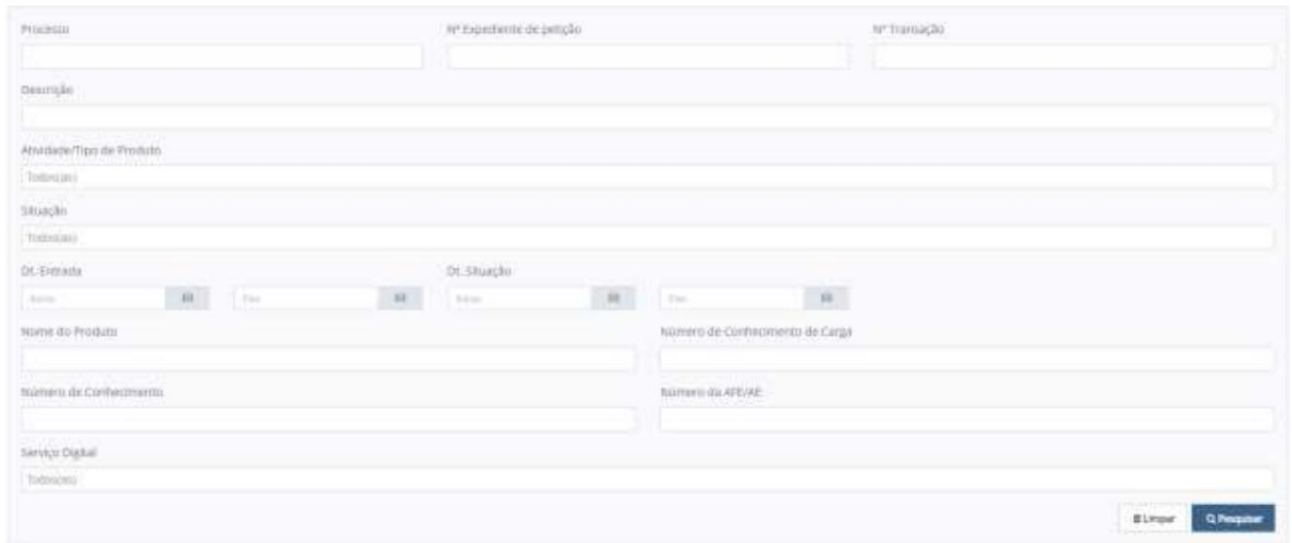
 **Filtro rápido**



and a button



To open the advanced filter:



The screenshot shows a search interface with the following fields and buttons:

- Processo**: Text input field.
- Nº Expediente de petição**: Text input field.
- Nº Transação**: Text input field.
- Descrição**: Text input field.
- Atividade/Tipo de Produto**: Text input field.
- Situação**: Text input field.
- Qt. Entrada**: Range selector with "Início" and "Fim" fields and a "SE" button.
- Qt. Situação**: Range selector with "Início" and "Fim" fields and a "SE" button.
- Nome do Produto**: Text input field.
- Número de Conhecimento**: Text input field.
- Número de Conhecimento de Carga**: Text input field.
- Número da AFE/AE**: Text input field.
- Serviço Digital**: Text input field.
- Limpar**: Button to clear filters.
- Procurar**: Button to search.

When activated, it displays the advanced filter which contains the filtering options:

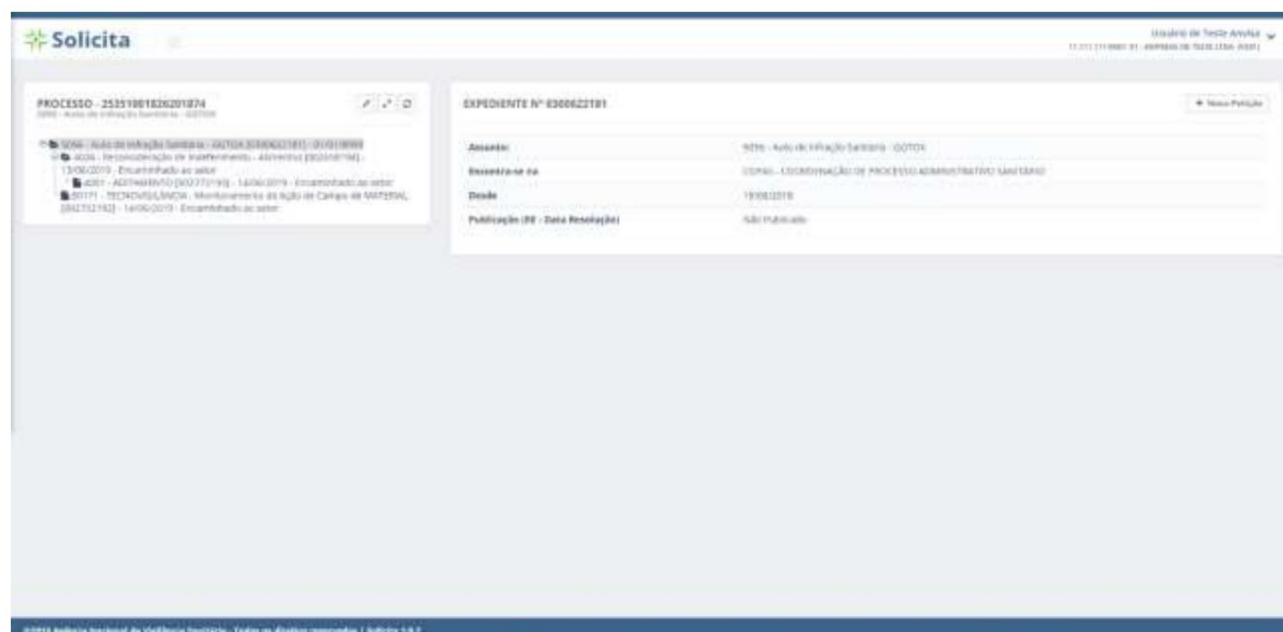
- **Process** - Displays results related to the process number.
 - **Petition File Number** - Displays results related to the petition file number.
 - **Transaction Number** – Displays results related to the transaction number.
 - **Description** - Displays results related to the process description.
 - **Activity/Product Type** - Displays results related to the activity/product type.
 - **Status** – Presents results regarding the status of the process.
 - **Entry Date** - Displays results related to the entry date within the selected period.
 - **Status Date** - Displays results relating to the status date within the selected period.
 - **Product Name** – Displays results related to the product name (if available)
 - **Bill of Lading Number** – Displays results related to the bill of lading number (also known as AWB), applicable only to petitions and processes related to import/export.
 - **Knowledge Number** – Displays results related to the knowledge number (if any); this identifier was provided for physical/manual petitions after the documentation was delivered to the Agency and before the process or file number was generated.
 - **AFE/AE Number** – Displays results related to the AFE/AE number. Applicable only to Processes and petitions related to Operating Permits or Special Permits.
 - **Digital Service** – Displays results related to the selected digital service. This filter is still under construction and will be populated as more Anvisa services are listed on the Gov portal.
- Br.

The process listing includes the columns "PROCESS", "DESCRIPTION", "ACTIVITY/PRODUCT TYPE",

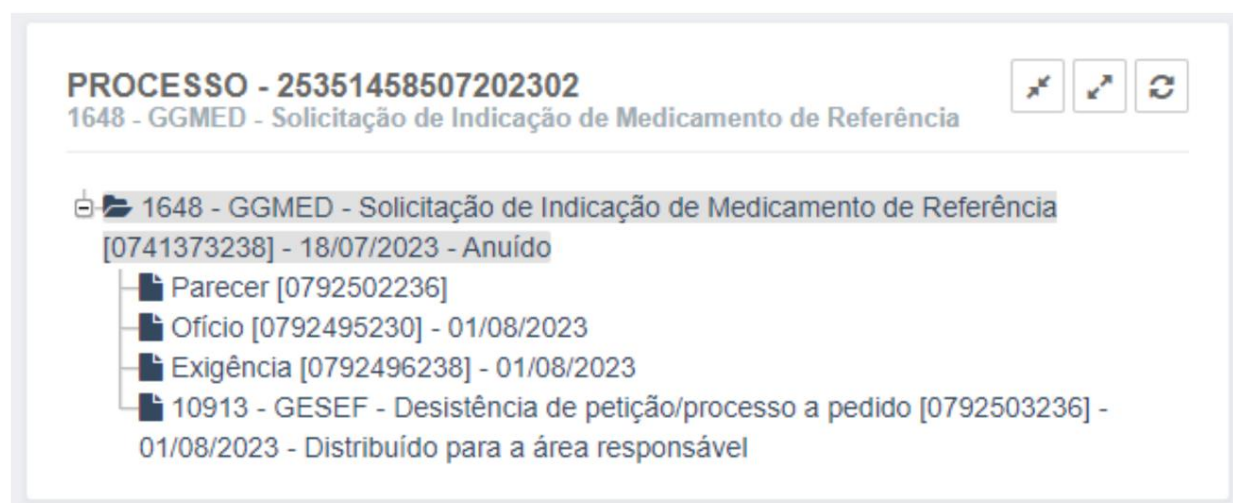
"ENTRY DATE", "STATUS", "STATUS DATE" and "ACTIONS", the last of which has a button that, when activated, opens the process information in a new tab:



that,



where it is possible to check the documents (petitions related to the process), electronic requirements, official letters. Electronic documents and opinions linked to the case and petitions can be found in the sidebar.



and on the right, a summary of the proceedings:

EXPEDIENTE Nº 0300622181 + Nova Petição

Assunto:	5056 - Auto de infração Sanitária - GGTOX
Encontra-se na	COPAS - COORDENAÇÃO DE PROCESSO ADMINISTRATIVO SANITÁRIO
Desde	19/06/2018
Publicação (RE - Data Resolução)	Não Publicado

You can add a new petition to the process by clicking the button.

+ Nova Petição

Clicking on a case or petition in the sidebar tree will display a summary on the right.
same:

EXPEDIENTE Nº 0741373238 + Nova Petição Imprimir Protocolo Imprimir Extrato Visualizar Adicionar aos favoritos

Favorecido:	11.111.111/0001-91 - EMPRESA DE TESTE LTDA. (VS01)		
Assunto:	1648 - GGMED - Solicitação de Indicação de Medicamento de Referência		
Número do Processo:	25351458507202302		
Número de Transação:	6890782023		
Número de Protocolo:	20230000000668614		
Situação	Anuído		
Encontra-se na	CGOTI - COORDENAÇÃO DE PROJETOS E GOVERNANÇA DE TI		
Desde	09/08/2023		
Publicação (RE - Data Resolução)	Não Publicado		

PAGAMENTOS

Nº	Ano	Valor	Valor Pago	2º via GRU
633339	2023	R\$ 0,00	ISENTO	

HISTÓRICO DE SITUAÇÕES

Situação	Data Inicial	Data Fim
Anuído	09/08/2023 11:41	
Distribuído para a área responsável	18/07/2023 11:17	09/08/2023 11:41

In these cases, it is possible to perform some actions by clicking on the buttons:

 Nova Petição

: Opens a new petition from the petition currently being displayed.

 Imprimir Protocolo

This opens the window for printing the online filing receipt. Printing the receipt is possible for petitions submitted in person, through the electronic filing system, or via Solicita.

 Imprimir Extrato

: Opens a window to print the extract with the petition data.

 Visualizar

This opens the petition in a new tab, with details and on a page similar to the action of opening a new petition. This button is only displayed for workflows initiated in Solicita, and only for the user who filed the petition or for users who have the Regulatory Petition User link. In cases where an amendment has been made by a third party, the field may be disabled if the third party chooses not to share the information with the applicant of the process or petition.

 Adicionar aos favoritos

: Includes the process or petition to be displayed in the favorites tab. When selecting a process, all petitions associated with it will be marked as favorites. When selecting a petition, all petitions linked "**above**" that file will also be "favorited". To delete

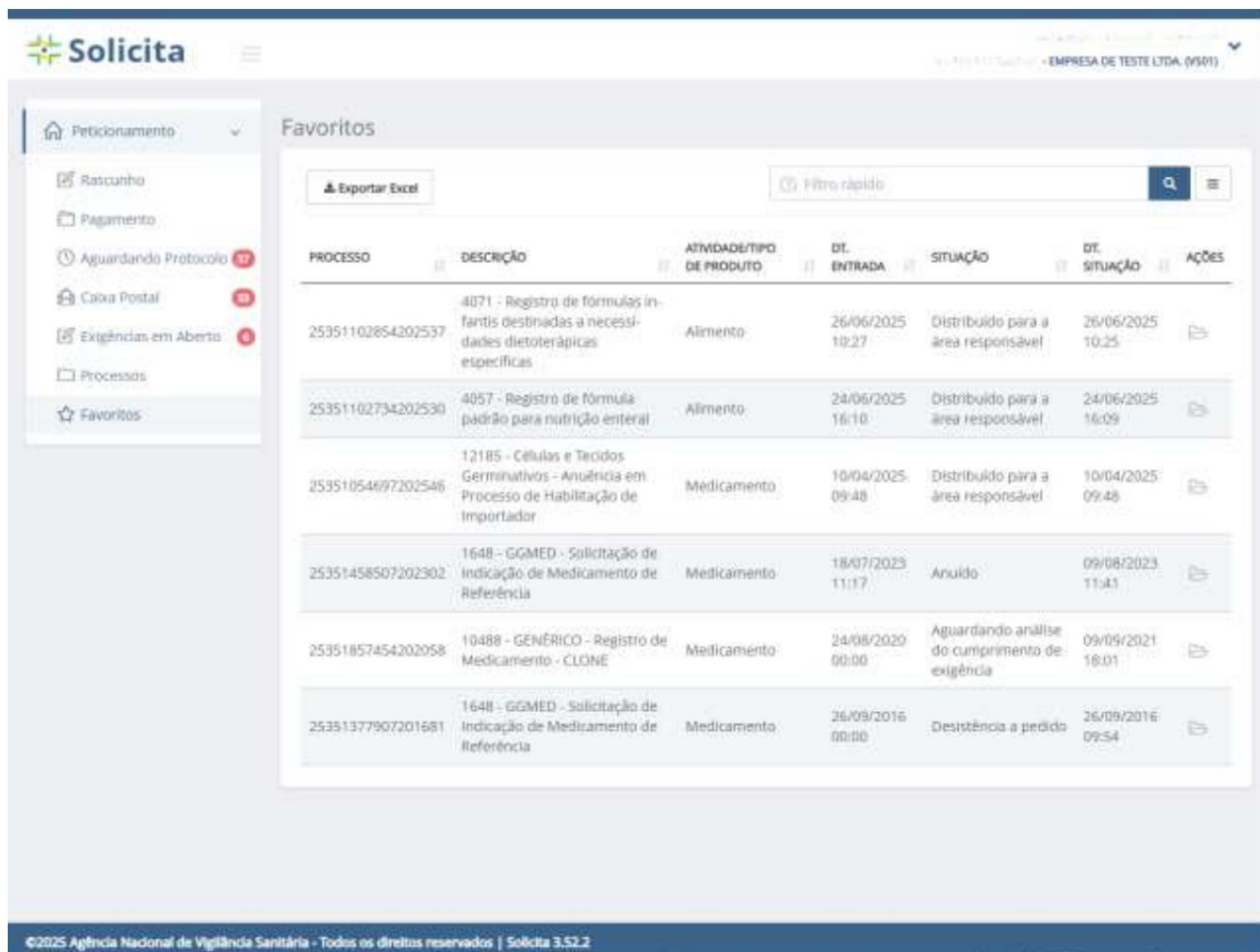
 Excluir dos favoritos

To add a case or petition from the favorites tab, simply click on it once  which is displayed the case or petition has already been selected to be displayed in the favorites tab.

Important! Petitions related to an investigation dossier do not include the information "status," "currently in," "since," "payments," and "history of situations," as these are considered confidential according to item VIII of article 23 of Law No. 12,527, of November 18, 2011.

12. ABA FAVORITES

By selecting “Favorites” in the side menu, a page will be displayed showing the list of processes “favorited” by the logged-in user, related to the company's CNPJ (Brazilian tax ID) through which access to Solicita was obtained. Done:



PROCESSO	DESCRIÇÃO	ATIVIDADE/TIPO DE PRODUTO	DT. ENTRADA	SITUAÇÃO	DT. SITUAÇÃO	AÇÕES
25351102854202537	4071 - Registro de fórmulas infantis destinadas a necessidades dietoterápicas específicas	Alimento	26/06/2025 10:27	Distribuído para a área responsável	26/06/2025 10:25	
25351102734202530	4057 - Registro de fórmula padrão para nutrição enteral	Alimento	24/06/2025 16:10	Distribuído para a área responsável	24/06/2025 16:09	
25351054697202546	12185 - Células e Tecidos Germinativos - Anuência em Processo de Habilitação de Importador	Medicamento	10/04/2025 09:48	Distribuído para a área responsável	10/04/2025 09:48	
25351458507202302	1648 - GG MED - Solicitação de Indicação de Medicamento de Referência	Medicamento	18/07/2025 11:17	Anulado	09/08/2025 11:41	
25351857454202058	10488 - GENÉRICO - Registro de Medicamento - CLONE	Medicamento	24/08/2020 00:00	Aguardando análise do cumprimento de exigência	09/09/2021 18:01	
25351377907201681	1648 - GG MED - Solicitação de Indicação de Medicamento de Referência	Medicamento	26/09/2016 00:00	Desistência a pedido	26/09/2016 09:54	

For a case to be displayed, the case or one of its petitions must have been "favorited" by the user. in the Processes tab, as described in the previous section.

In this menu, only the processes and petitions favorited for the represented CNPJ will be displayed – that is, each user will see the set of processes and petitions favorited by all representatives of that CNPJ. CNPJ.

This menu behaves very similarly to what was described in the previous section, with a few important observations:

1. When you favorite a case, all petitions linked to it are also favorited. automatically.
2. When favoriting a secondary petition, only the selected petition and the process will be favorited.

3. When favoriting a tertiary petition, only the selected petition and its secondary petition will be favorited.
and the process.
4. When you unfavorite a specific linked petition, it will no longer be displayed in the accessed view.



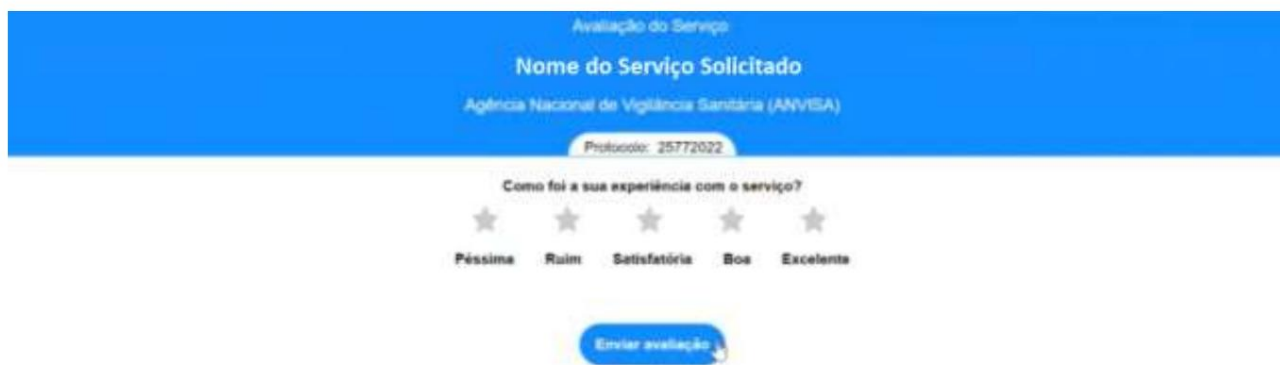
via the Favorites tab after clicking the button . but it can still be found in the tab view.
Normal processes.

5. This tab has the identifier  **Favoritos** displayed above the file tree on the left for
To signal to the user that they are accessing this specific tab and not the Processes menu.

13. SERVICE EVALUATION

In order to allow the user to evaluate the service provided, Solicita offers two options for the user to submit their opinion using the evaluation module of the Ministry of Economy.

The evaluation module is a feature being rolled out gradually, where services included in this feature will allow access to an evaluation questionnaire in the format below:



Avaliação do Serviço

Nome do Serviço Solicitado

Agência Nacional de Vigilância Sanitária (ANVISA)

Protocolo: 25772022

Como foi a sua experiência com o serviço?

★ ★ ★ ★ ★

Péssima Ruim Satisfatória Boa Excelente

Enviar avaliação

Once the service evaluation has been entered, the form will be supplemented with criteria that justify the given evaluation.



Avaliação do Serviço

Nome do Serviço Solicitado

Agência Nacional de Vigilância Sanitária (ANVISA)

Protocolo: 25772022

Como foi a sua experiência com o serviço?

★ ★ ★ ★ ★

Péssima Ruim Satisfatória Boa Excelente

Por quê?

Atendimento Usabilidade Informações

Rapidez Esforço Confiabilidade

Enviar avaliação

When you click on submit review, a screen will appear informing you that the review has been successfully registered. Only one review can be submitted per request.

Avaliação Registrada com sucesso!

Deseja registrar um elogio ou reclamação?

NÃO, OBRIGADO

SIM, REGISTRAR UM
ELOGIO

SIM, REGISTRAR UMA
RECLAMAÇÃO

The evaluation questionnaire can be accessed through the steps described below:

END OF THE PETITIONING FLOW

At the end of the petition workflow, for which the fee is waived, the "Petition successfully submitted" screen will be displayed.

The link "Rate our service" will be available in the lower corner of the screen.

Petição enviada com sucesso

Favorecido:	
Assunto:	
Número de Transação:	
Protocolo:	
Processo:	
Expediente:	
Tipo de Documento:	
Protocolizador:	

 Imprimir Comprovante

[Avalie o nosso serviço](#)

Concluir

PROOF OF FILING

After the registration is completed, the system issues a registration receipt, and for services supported by the evaluation module, this receipt will include the link "rate our service".

COMPROVANTE DE PROTOCOLIZAÇÃO ON-LINE (In: SEDOC, em 06/07/2022 11:25)

 Imprimir  Fechar


ANVISA
 AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA
COMPROVANTE DE PROTOCOLIZAÇÃO ON-LINE

Expediente:
 Número de Transação:
 Tipo de Documento:
 Número do Processo:
 Nome do Produto:
 Favorecido:
 Assunto:

Protocolizado On-Line via Petiçãoamento - Eletrônico por
 em 06/07/22 11:25:56

[Avalie o nosso serviço](#)

The proof of filing can be accessed through the mailbox or via the "print filing" button in the processes tab.

14. SPECIFIC GUIDELINES

CROSS-SECTIONAL FORMS**APPLICANT UPDATE BEFORE COMPLETION OF ANALYSIS**

On the draft screen or in the processes tab, the **succeeded** company must register a "petition linked to an existing process" to update the applicant. In the form presented, the CNPJ of the company that will be the new applicant company for the initial request must be entered.

CNPJ da empresa sucessora *

Campo obrigatório

It is important to note that, for the CNPJ (Brazilian taxpayer ID) to be included, the company that will be the new applicant needs to have a valid registration with Anvisa (Brazilian Health Regulatory Agency).

The submissions for the case will not be displayed in the petition form, as these submissions do not yet have a valid registration.

Apresentações do processo 		
Nº APRESENTAÇÃO	Nº REGISTRO	DESCRIÇÃO
1	6509000990013	TESTE 25-01

Upon completion of the petition submission, the system will automatically update the applicant's CNPJ (Brazilian tax ID), and this information will then appear in the "Processes" tab of the new applicant.



MNU - User Manual

Authorization for Amendment by a Third Party and Amendment by a Third Party

Solicita allows a company registered with Anvisa to authorize the submission of documentation to be added to a process or petition under its responsibility by another company ("third party"), of national or international origin.

The first step is to create an amendment authorization petition linked to the petition of interest, using the petition subject **"Authorization for Amendment by Third Party,"** within the product type corresponding to the selected process.

This matter is free of charge and requires the requesting company to provide the CNPJ (for national companies) or Unique Code (for international companies) of the third-party company that will send the documentation.

Dados da empresa terceira *

☒ Nacional ☐ Internacional

CNPJ da Empresa *

11.111.111/0001-91

Nome da empresa

EMPRESA DE TESTE LTDA. (VS01)

Cidade UF

VITÓRIA ES

Logradouro

SIA Trecho 5 area especial 57 tangamandapio

Dados da empresa terceira *

☐ Nacional ☒ Internacional

Código Único * ?

A.0001

Nome da empresa

3M HEALTH CARE LIMITED - A0001

País Cidade

REINO UNIDO LEICESTERSHIRE

Logradouro

DERBY ROAD, LOUGHBOROUGH, LEICESTERSHIRE, LE 11 5SF

The registration of international companies can be verified at <https://consultas.anvisa.gov.br/#/>. Select "Business Operations," then the option "Consult International Company." By clicking on the magnifying glass, you can perform an exact search or a search by part of the name.

Código Único

Upon completing the petition, the requesting company will receive a token and an access link in its mailbox, along with the petition confirmation. These must be provided to the third-party company. It is through the use of this token that the amendment can be sent by a third party through Solicita. The third-party amendment token is valid for 30 days, as shown in the image below, after which it will be necessary to restart the entire process with another petition for authorization of a third-party amendment to obtain a new valid token.

REMETENTE	ASSUNTO	DT. ENVIO
GERENCIA DE AUTORIZAÇÃO DE FUNCIONAMENTO	COMPROVANTE DE PROTOCOLIZAÇÃO ON-LINE	18/11/2019 16:57
GERENCIA DE AUTORIZAÇÃO DE FUNCIONAMENTO	TOKEN DO ADITAMENTO POR TERCEIRO	18/11/2019 16:57


ANVISA
 AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA

Aditamento por terceiro

Prezado,

Foi criado em 18/11/2019 o expediente **xxxxxxxx/xx-x** de modo a permitir que uma empresa terceira realize o aditamento a esse expediente.

Para que o terceiro realize o aditamento é necessário que o mesmo acesse o link <https://solicita.anvisa.gov.br/solicita/public/aditar> e insira o token:

14b47f58-189f-49a7-9989-5874ee1eb1da

O token em questão tem validade de 30 dias não havendo possibilidade de inabilitação antes desse prazo.

Upon accessing the link, the third-party company provides the token, and the third-party amendment form is displayed. The text on the following screens is displayed in Portuguese, English, and Spanish.

Token para aditamento/ Token for amendment/Token para añadir

Token: •

14b47f58-189f-49a7-9989-5874ee1eb1da

Enviar/Send/Enviar

Fields containing information about the petition and the company are displayed, but these are read-only. The third-party company only fills in contact information and indicates whether or not it wishes to share the documents to be amended with the company that authorized the amendment.

IMPORTANT: Once the user has authorized the sharing of information and submitted the documentation, the information will be made immediately and automatically available to the company holding the process. This option **is not reversible** after the petition has been submitted.

Nome para contato •
Contact name/Nombre de contacto

Usuário de Teste

E-mail para contato •
Contact E-mail/Email de contacto

teste@homologação.anvisa.gov.br

Telefone para contato •
Contact phone/Teléfono de contacto

55 61 5555 6161

Declaro que desejo compartilhar as informações com a empresa solicitante do registro •
I declare that I would like to share the information with the registrant company/Declaro que me gustaría compartir la información con la empresa registrada.

☐ Sim/Yes/Si ☒ Não/No/No

At the end of the submission process, the third-party company can print the receipt. The requesting company, which authorized the amendment, will receive a receipt confirming the third-party amendment in its mailbox.



ANVISA
 AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA

COMPROVANTE DE PROTOCOLIZAÇÃO ON-LINE

Protocolo:	25352001245201911
Expediente:	3673371193
Número de Transação:	164222019
Tipo de Documento:	Petição
Número do Processo:	25351026085201915
Nome do Produto:	
Favorecido:	1111111000191 - EMPRESA DE TESTE LTDA (VS01).
Assunto:	70667 - Aditamento por Terceiro

Protocolizado On- Line via Peticionamento - Eletrônico por: —
Usuário de Teste Anvisa em 18/11/19 05:17:58

If the third-party company has chosen to share the updated information with the requesting company, this information can be viewed in the "Processes" tab using the "View" button. Otherwise, the button will not be displayed.

+ Nova Petição

Imprimir Protocolo

Imprimir Extrato

Visualizar

11.111.111/0001-91 - EMPRESA DE TESTE LTDA. (VS01)
70667 - Aditamento por Terceiro
25351025901201973
161232019
25352001100201911
Encaminhado ao setor
GGFIS - GERÊNCIA-GERAL DE INSPEÇÃO E FISCALIZAÇÃO SANITÁRIA
06/11/2019
Não Publicado

TRANSFER OF OWNERSHIP**For processes of the product type Toxicology**

Follow the same step-by-step instructions described in the section "Applicant Update Before Review Completion".

For all other product types

Initially, it should be noted that only processes whose analysis has been finalized are eligible for transfer. Processes in the approval phase must follow the flow described in the item "Update the applicant before the analysis is completed".

On the draft screen or in the processes tab, the **succeeded** company must register a "Cancellation by Transfer" petition linked to an existing process in the process it wishes to transfer. The successor company's CNPJ (Brazilian tax ID) must be entered in the form provided .

CNPJ da empresa sucessora *

Campo obrigatório

It should be noted that for the CNPJ (Brazilian tax ID) to be added, the **successor** company must have a valid registration with the relevant authority. Anvisa.

The petition form will display, where applicable, submissions with active registration that will be cancelled upon publication of the "Cancellation by Transfer" notice.

Apresentações do processo		
Nº APRESENTAÇÃO	Nº REGISTRO	DESCRIÇÃO
1	6509000990017	TESTE 25-01

If there are any inconsistencies in the list of presentations, the company must request an adjustment from the relevant department through the appropriate customer service channels, since only these presentations will be available for registration by the **successor company**.

Upon completing the submission of the cancellation request for transfer, the **acquired** company will receive a message in its mailbox with the subject "OWNERSHIP TRANSFER TOKEN".

REMETENTE	ASSUNTO	DT. ENVIO	DT. LEITURA	RESPONSÁVEL LEITURA	AÇÕES
GERÊNCIA DE GESTÃO DOCUMENTAL	COMPROVANTE DE PROTOCOLIZAÇÃO ON LINE	05/02/2020 15:58	05/02/2020 17:20	Usuário de Teste Anvisa	
GERÊNCIA DE GESTÃO DOCUMENTAL	COMPROVANTE DE PROTOCOLIZAÇÃO ON LINE	05/02/2020 09:34	05/02/2020 14:02	Usuário de Teste Anvisa	
GERÊNCIA DE GESTÃO DOCUMENTAL	TOKEN DA TRANSFERÊNCIA DE TITULARIDADE	05/02/2020 09:34	05/02/2020 14:02	Usuário de Teste Anvisa	

The message will contain instructions for continuing the ownership transfer process, providing an alphanumeric code to be given to the **successor company**. Each token corresponds to the process for which the cancellation request was filed. Unlike the token for amendment by a third party, this transfer token does not have an expiration date.

 **ANVISA**
AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA

Transferência de titularidade

Prezado,

Foi criado em 05/02/2020 o expediente 0001123203 referente a uma petição de cancelamento de registro por transferência de titularidade.

De modo a permitir que a transferência seja realizada é necessário que a empresa sucessora peticione a solicitação de registro por transferência de titularidade e informe o seguinte token durante o fluxo de peticionamento:

e9f16524-1939-408b-9b8f-7472f6ca29d5

Até que o pedido de registro por transferência de titularidade seja realizado pela sucessora, esta petição de cancelamento por transferência de titularidade permanecerá na situação análise sobrestada.

Until the **successor** company submits the registration request by transfer, the cancellation request will remain in the "External analysis suspended" status, since the start of the analysis of this petition is linked to the request for registration by transfer.

To request registration through transfer of ownership, the successor company must register an "initial petition" for transfer of ownership on the draft screen.

When selecting the subject code corresponding to the request, a form will be made available with the mandatory field "Transfer Token".

Token para transferência *

Campo obrigatório

The **successor** company must enter the token provided by the **predecessor company**. If the transfer request is not being made by the company registered by the **predecessor**, the system will display the error message "The token entered is not valid for this CNPJ".

Upon entering the token, the form will be updated so that the applicant can select, where applicable, the submissions they wish to register in their application.

Selecione as apresentações que deseja migrar para seu processo. 		
☐	Nº APRESENTAÇÃO	Nº REGISTRO
☐	1	620X00290017
		TESTE 25-01

Furthermore, the petitions from the predecessor's process that are awaiting analysis or whose analysis has not yet been completed will be displayed. The successor company may select which ones it wishes to transfer. The system will automatically and mandatorily migrate the most recent registration renewal petition, as well as the most recent Product Change History (HMP) petition (if applicable), in addition to any petitions in the "Conditional Approval – No Response Within the Legal Deadline" status.

Selecione as petições que deseja migrar para seu processo. 			
Nº EXPEDIENTE	ASSUNTO	DT. ENTRADA	SITUAÇÃO

If there is any inconsistency regarding the procedures that should be available for selection, the company must request an adjustment from the relevant department through the appropriate channels.

FOOD FORMS

NOTIFICATION AND REGISTRATION OF FOODS

This feature is only available for "Alimony" type cases and petitions.

To initiate a request for registration or notification of food, you must access the drafts tab and click the "New" button, selecting the "Initial Petition" option:



In the form provided, click on the "magnifying glass" in the subject field, and on the next screen enter the name or number of the desired subject.

For registration or notification requests, the requesting company must have a food product registration. If you do not have one, you should contact the team responsible for food regulation. The absence of registration does not prevent the application process, but it may delay the notification process.

The following form will provide information that must be completed in order to characterize the product.



The "General Data" section has the following fields to be filled in.

Categoria de Produto *

Fórmula padrão para nutrição enteral

The "Product Category" field displays the categories regulated by specific legislation. Depending on the chosen subject, the "Product Category" field will be pre-filled, and the rest of the form will display, or not, the other fields according to their applicability.

Designação do Produto (Outros) *

0 / 230

The "Product Designation" field can be a drop-down list or a text field that accepts up to 230 alphanumeric characters, depending on the selected category.

The "Product Brand(s)" field allows you to enter one or more brands with up to 100 characters. alphanumeric.

+ Adicionar Marca

To register a brand, click the button.

A modal window will be displayed for inserting the desired logo.

Marca do Produto

×

Marca

0 / 100

Adicionar

Cancelar

Adicionar

After filling in the desired brand, click the button provided in the table format.

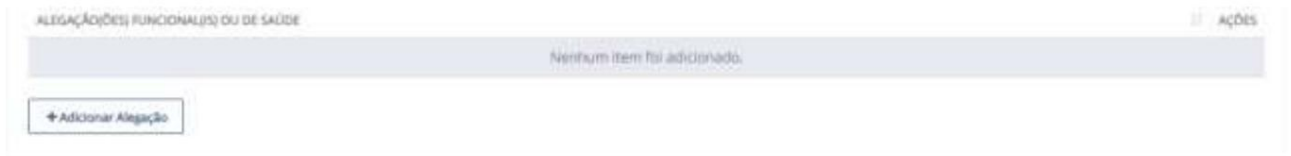
The inserted brands will be

Marca(s) do Produto *

MARCA(S) DO PRODUTO	AÇÕES
Marca 1	 
Marca 2	 

The action button  allows editing of the already inserted brand, while the button  Allows for exclusion.

For some categories, the "General Data" section also has the following fields to be filled in.



ALEGAÇÃO(S) FUNCIONAL(IS) OU DE SAÚDE

Nenhum item foi adicionado.

+ Adicionar Alegação

The "Functional or Health Claim(s)" field allows you to choose from a drop-down list of previously approved claims.

+ Adicionar Alegação

To register the claim, click the button.

A modal window will be displayed for entering the desired claim.



Alegação do Produto

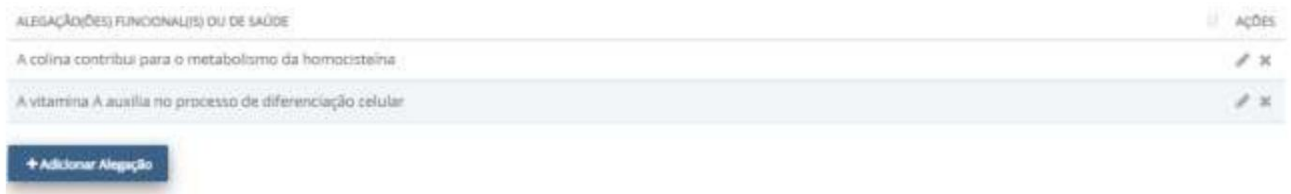
Alegação do Produto ?

Adicionar Cancelar

The "Product Claim" field is for selecting the approved claim. If the desired claim is not available, please contact the organizational unit responsible for product clearance.

Adicionar

After selecting the desired claim, click the button provided in table format. The claims entered will be



ALEGAÇÃO(S) FUNCIONAL(IS) OU DE SAÚDE

A colina contribui para o metabolismo da homocisteína	 
A vitamina A auxilia no processo de diferenciação celular	 

+ Adicionar Alegação

The delete action  allows editing of the previously entered claim, while the button allows... 

button.

Nº(s) Regularização da Resina *

Nº(S) REGULARIZAÇÃO DA RESINA

AÇÕES

Nenhum item foi adicionado.

+ Adicionar Nº Regularização da Resina

The field "Resin Regularization Number(s)" allows you to register the regularization process number. valid resin.

+ Adicionar Nº Regularização da Resina

To register the process, click the button.

A modal window will be displayed for entering the desired process number.

Nº Regularização da Resina * ?

Adicionar

Cancelar

The Resin Regularization Number field is a field to enter the process number of the resin that has been previously regularized.

Adicionar

After selecting the desired process, click on the button

The case numbers will be provided in the table format.

Nº(s) Regularização da Resina *

Nº(S) REGULARIZAÇÃO DA RESINA

AÇÕES

25351.123456/2022-00

✎ ✕

+ Adicionar Nº Regularização da Resina

The delete action  allows editing of the previously entered process, while the button allows... 

button.

Tipo(s) de Alimento(s) *

TIPOS DE ALIMENTOS	AÇÕES
Nenhum item foi adicionado.	

+ Adicionar Tipo

The "Food Type(s)" field allows you to choose from a drop-down list of food types that will be packaged in the approved containers.

To register the type of food, click the button.

+ Adicionar Tipo

A modal will be displayed for inserting the desired food item.

Tipo(s) de Alimento(s) ×

Tipo de Alimento * ?

▼

Adicionar

Cancelar

The "Food Type" field is for selecting the desired food characteristic. If the desired food type is not available, please contact the organizational unit responsible for product regulation.

After selecting the desired food, click on the button provided

Adicionar

The types of food will be

in the table format.

Tipo(s) de Alimento(s) *

TIPOS DE ALIMENTOS	AÇÕES
Aquosos ácidos	
Gordurosos	

+ Adicionar Tipo

The action button  allows editing of the type of food previously entered, while the button  allows for deletion.

Next, the "Presentation Registration" section will be available. Click the button.

+ Adicionar Apresentação

in order to access the registration screen.

This modal is used to characterize each of the product presentations and is divided into five sections:

Presentation Description

Descrição da Apresentação * ?

Apresentação 1

Sabor/Cor ?

Forma Física * ?

Via de Administração * ?

Tipo de Embalagem primária * ?

The "Presentation Description" section has five fields:

Descrição da Apresentação * ?

Apresentação 1

This field is not editable and contains a description automatically generated by the system based on the order in which the presentations were created.

Sabor/Cor ?

The "Flavor/Color" field is a text field that accepts up to 100 alphanumeric characters. In this field, the user must describe the presentation by indicating its flavor or color, if applicable.

Forma Física * ?

The "Physical Form" field is for selecting how the product will be marketed. If the desired physical form is not available, please contact the organizational unit responsible for product registration.

Important! For some products, such as transitional foods, the physical form may not be applicable, and in these cases, "not applicable" should be selected.

Via de Administração * ?

The "Route of Administration" field is for selecting how the product will be administered to the user. Due to the notification requirements, only enteral, oral, or both types of administration are permitted.

Tipo de Embalagem primária * ?

The "Primary Packaging Type" field is for selecting the type of packaging in which the food will be contained. Note that the material that makes up this packaging will only be filled in the next section.

If the desired packaging type is not available, please contact the organizational unit responsible for product regulation.

Primary Packaging Material(s)

Material(is) da Embalagem Primária *

MATERIAL(IS) DA EMBALAGEM PRIMÁRIA

AÇÕES

Nenhum item foi adicionado.

+ Adicionar Material de Embalagem Primária

Período de Validade do Produto *

Selecione

Cuidado de Conservação * ?

To register the material used in the primary packaging, click the button.

+ Adicionar Material de Embalagem Primária

A modal window will be displayed for entering the desired packaging type.

Material da Embalagem Primária ×Material • ?

Adicionar

Cancelar

The "Primary Packaging Material" field is for selecting the material used in the product packaging. If the desired packaging material is not available, please contact the organizational unit responsible for product registration.

Adicionar

After selecting the desired material, click on the button

The materials inserted will be

provided in table format.

MATERIAL(IS) DA EMBALAGEM PRIMÁRIA	AÇÕES
CELULOSICA	 
CERAMICA	 

+ Adicionar Material de Embalagem Primária

The action button  allows editing of previously inserted material, while the button allows... ×
exclusion.

Período de Validade do Produto •

Selecione

The "Product Validity Period" field is used to specify the expiration date of the product.
It consists of two fields.

The first is a numeric field for entering integers from 1 to 999.

The second field allows you to select the desired time unit for the expiration date. Note that this field only allows the expiration date to be given in days, months, or years.

If the desired value is not a whole number, the field should be filled in using a more appropriate unit of measurement; for example, "1.5 months" could be entered as "45 days".

Cuidado de Conservação * ?

0 / 500

The "Storage Instructions" field is for specifying how the product should be stored to achieve its stated shelf life. The company must enter the storage instructions as described on the label.

Target Population Group(s)

Grupo(s) Populacional(is) Indicado(s) *

GRUPO POPULACIONAL INDICADO

AÇÕES

Nenhum item foi adicionado.

+ Adicionar Grupo Populacional Indicado

To register the field "Indicated Population Group(s)", click the button.

+ Adicionar Grupo Populacional Indicado

A modal window will be displayed for entering the desired population group.

Grupo Populacional Indicado

✕

Grupo Populacional * ?

Adicionar

Cancelar

The "Population Group" field is used to specify which segment of the population the product is intended for. If the desired population group is not available, please contact the organizational unit responsible for product registration.

Adicionar

After selecting the desired population group, click the button displayed in table form.

The inserted groups will be

GRUPO POPULACIONAL INDICADO	AÇÕES
Gestantes	 
Lactantes	 

+ Adicionar Grupo Populacional Indicado

The delete action  allows editing of the previously inserted group, while the button allows...  button.

Important! Once the population group is selected, the information will be used to validate the formula and nutrients fields. Therefore, any change to the population group will result in the automatic deletion of the information entered in these fields.

Formula

Fórmula *

COMPONENTE DA FÓRMULA

QUANTIDADE CENTESIMAL

FUNÇÃO

AÇÕES

Nenhum item foi adicionado.

+ Adicionar Substância/Nutriente

Total de Quantidade Centesimal Informado (%)

Rotulagem *

☐ Contém Glúten

☐ Não Contém Glúten

☐ Contém Lactose

☐ Não Contém Lactose

ALERGÊNICOS *

Amêndoas

Amendoim

Avela

Avelãs

Castanha-de-caju

Castanha-do-brasil ou castanha-do-pará

Castanhas

Centeio

Cevada

Crustáceos

Látex natural

Leites de todas as espécies de animais mamíferos

Macadâmias

Nozes

Ovos

Pecãs

Peixes

Pinoli

Pistaches

Soja

Trigo

Lista de Ingredientes *

The formula section is used to enter the qualitative and quantitative composition of the product, as well as information that will be included on the label.

Fórmula *

COMPONENTE DA FÓRMULA	QUANTIDADE CENTESIMAL	FUNÇÃO	AÇÕES
Nenhum item foi adicionado.			
+ Adicionar Substância/Nutriente			

The "Formula" field is used to enter the components used in the product. This entry is made considering the percentage of each component in the formula, with the sum of all components necessarily equaling one hundred percent.

If the sum does not equal 100%, the message "The total of the Centesimal Quantity (%) must equal 100%" will be displayed. The system takes into account the decimal places included in each component, so attention must be paid to the sum.

The sum of the components can be seen in the "Total Percentage Quantity Reported" field.

Total de Quantidade Centesimal Informado (%)

which is updated every time a new

A component is added, removed, or changed.

To register the formula, click the button.

A modal window will be displayed for entering each of the formula's components.

Substância/Nutriente

✕

Componente da Fórmula *

Quantidade Centesimal * ?

Função * ?

Adicionar Substância/Nutriente

Cancelar

The "Substance/Nutrient" modal has three fields to be filled in.

Componente da Fórmula *

Q

This field is for specifying which component is being used. Click the button to be taken to a new modal that allows you to search by component code or name. After entering the information...

Q Pesquisar

desired click the button

The results screen will be displayed:

Selecione o componente

✕

Atenção! Caso o componente não conste na lista, clique na opção outros.

Cod

Nome

Q Pesquisar

Código	Descrição	
0	Outros	→
29467	ÁGUA	→

By clicking the button  Next to the desired component, the information will be saved on the previous screen.

Substância/Nutriente ×

Componente da Fórmula *

29.467 - ÁGUA

Q

Quantidade Centesimal * ?

Função * ?

▼

Adicionar Substância/Nutriente

Cancelar

Important! In the case of additives and some processing aids, the component description will always be preceded by its respective INS number. Therefore, this component should be selected.

If the component is unavailable, contact the organizational unit responsible for product regularization or select code “0” or the name “Other”. In this case, a new text field will be enabled that accepts up to 230 alphanumeric characters. This field should be used to indicate the missing component.

Substância/Nutriente ×

Componente da Fórmula *

0 - Outros

Q

Componente da Fórmula (Outros) *

Quantidade Centesimal * ?

Função * ?

▼

Adicionar Substância/Nutriente

Cancelar

After filling in the formula component, the other two fields must be filled in.

Quantidade Centesimal * 

The "Centennial Quantity" field is used to enter the quantity of the component being specified. It is a numeric field and, because it represents a percentage, should not exceed 100.

Função * 

The "Function" field is used to select the function that component has in the product formula.

Nutriente/Fonte de *

DESCRIÇÃO

 AÇÕES

Nenhum item foi adicionado.

[+ Adicionar item](#)

When inserting a component with the "Ingredient" function, the "Nutrient/Source of" field will be displayed.

Substância/Nutriente ×

Componente da Fórmula *

 Q

Campo obrigatório

Quantidade Centesimal * ?Função * ? ×

Nutriente/Fonte de *

DESCRIÇÃO	AÇÕES
Nenhum item foi adicionado.	

[+ Adicionar item](#)[Adicionar Substância/Nutriente](#)[Cancelar](#)[+ Adicionar item](#)

To add a new item, click the button that will appear so that the appropriate item for "nutrient / source of" can be selected.

For registered products, a modality

Adicionar Fonte de ×

Fonte de

Fonte de * ?

 ▼

Para inserir a quantidade por porção clique em editar para cada grupo populacional.

[Adicionar](#)[Cancelar](#)

For supplements, after entering the information regarding the "nutrient / source of" item, the fields "quantity per serving", "exponential" and "unit of measurement" will be displayed, with the "quantity per serving" field needing to be filled in for each selected nutrient.

Adicionar Nutriente/Fonte de

✕

Nutriente/Fonte de

Nutriente/Fonte de * ⓘ

GRUPO POPULACIONAL INDICADO

||

QUANTIDADE POR PORÇÃO

||

EXPONENCIAL

||

UNIDADE DE MEDIDA

||

AÇÕES

Nenhum item foi adicionado.

Para inserir a quantidade por porção clique em editar para cada grupo populacional.

Adicionar

Cancelar

Adicionar Nutriente/Fonte de

✕

Nutriente/Fonte de

Nutriente/Fonte de * ⓘ

ácido alfa-linolênico n-3

✕

GRUPO POPULACIONAL INDICADO

||

QUANTIDADE POR PORÇÃO

||

EXPONENCIAL

||

UNIDADE DE MEDIDA

||

AÇÕES

A partir de 12 meses

g

✎

A partir de 3 anos

g

✎

Para inserir a quantidade por porção clique em editar para cada grupo populacional.

Adicionar

Cancelar

The "indicated population group" fields will be pre-filled, reflecting the data entered in the section anterior.

You may select more than one "Nutrient/Source of". If the desired nutrient is not available, please contact the organizational unit responsible for product regulation.

For dietary supplements, if "Formula component (other)" is selected, the only options in the Function field will be: "Other (Art. 6º RDC 243/2018)" or "Flavoring Additive". Also for dietary supplements, if the function "Other (Art. 6º RDC 243/2018)" is selected, the "Specific Function" field will be displayed.

Substância/Nutriente ×

Componente da Fórmula *

Campo obrigatório

Quantidade Centesimal * ?

Função * ?

Função Específica * ?

The "Specific Function" field is a field to select the specific function, as per article 6 of RDC 243/2018, that the component has in the product formula.

After filling out as information about the desired component click no button

Adicionar Substância/Nutriente

The inserted components will be displayed in table form.

Fórmula *

COMPONENTE DA FÓRMULA	QUANTIDADE CENTESIMAL	FUNÇÃO	AÇÕES
ÁGUA	99,19	Aditivo	 
ASPARTAME - INS 951	0,81	Aditivo Aromatizante	 

The action button



allow editing of the component while the button



allows the exclusion of component.

Rotulagem *

☐ Contém Glúten ☐ Não Contém Glúten

☐ Contém Lactose ☐ Não Contém Lactose

The "Labeling" section provides a selection field to identify the presence of gluten and lactose.

ALERGÊNICOS *

Amêndoa	
Amendoim	
Aveia	
Avelãs	
Castanha-de-caju	
Castanha-do-brasil ou castanha-do-pará	
Castanhas	
Centeio	
Cevada	
Crustáceos	
Látex natural	
Leites de todas as espécies de animais mamíferos	
Macadâmias	
Nozes	
Ovos	
Pecãs	
Peixes	
Pinoli	
Pistaches	
Soja	
Trigo	

The "Allergens" field is where you should indicate whether the product contains, contains a derivative of, may contain, or does not contain an allergen.

Lista de ingredientes *

The "Ingredient List" field is a text field that accepts up to 4000 alphanumeric characters. In this field, the user must enter the list of ingredients as they will appear on the product label, according to labeling rules. Each component must be separated from the next by a semicolon (;). This list will be available later in the Product Search.

Manufacturers

Fabricantes

CNPJ	FABRICANTE	ETAPA DE FABRICAÇÃO	AÇÕES
Nenhum item foi adicionado.			
+ Adicionar Fabricante Nacional			

CÓDIGO ÚNICO	FABRICANTE	ETAPA DE FABRICAÇÃO	AÇÕES
Nenhum item foi adicionado.			
+ Adicionar Fabricante Internacional			

The section for including manufacturer data consists of two modals.

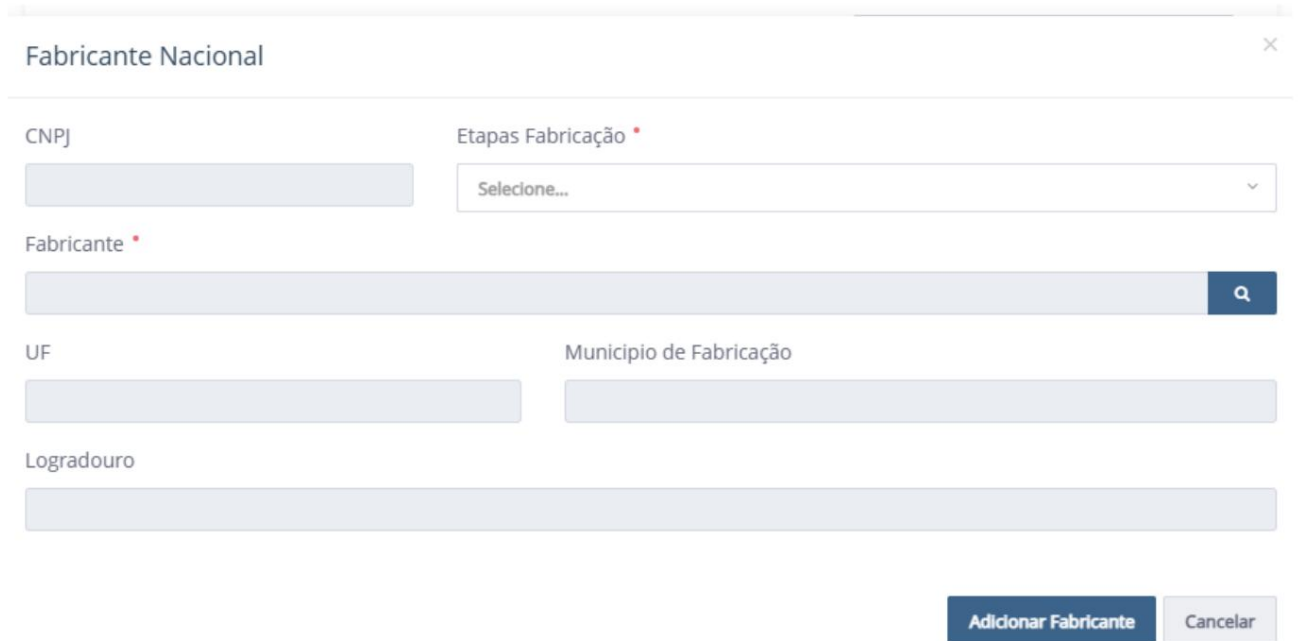
CNPJ	FABRICANTE	ETAPA DE FABRICAÇÃO	AÇÕES
Nenhum item foi adicionado.			
+ Adicionar Fabricante Nacional			

To enter data for a national manufacturer, click the button.

+ Adicionar Fabricante Nacional

to display the company selection model and the steps involved.

The manufacturing company will be responsible.



The screenshot shows a web form titled "Fabricante Nacional" with a close button (X) in the top right corner. The form contains several input fields: "CNPJ" (a text box), "Etapas Fabricação" (a dropdown menu with "Selecione..." as the placeholder), "Fabricante" (a large text box with a search icon on the right), "UF" (a text box), "Município de Fabricação" (a text box), and "Logradouro" (a text box). At the bottom right, there are two buttons: "Adicionar Fabricante" (in blue) and "Cancelar" (in light gray).

To specify the manufacturing stage(s) the company is responsible for, click on the "Manufacturing Stages" field.



The screenshot shows a dropdown menu titled "Etapas Fabricação" with a red asterisk. The menu is open, showing a placeholder text "Selecione..." and a downward arrow icon on the right.

The possible steps that can be taken will be presented, and the user can select one or more steps.

To select the company, click the button.



A new mode of transport will be opened.

Selecione a empresa nacional

✕

⚠ Atenção! Deve-se informar, pelo menos um filtro para executar a Pesquisa

CNPJ

Fabricante

Q Pesquisar

The search can be done using the company's CNPJ (Brazilian corporate tax ID) or its legal name.

CNPJ

Fabricante

Q Pesquisar

CNPJ	Fabricante	UF	Município	Logradouro	
11222333000181	EMPRESA DE TESTE	DF	BRASÍLIA	AVENIDA DE TESTE	➔
99888777000100	EMPRESA DE TESTE	DF	BRASÍLIA	RUA DE TESTE SEM FIM	➔

Once the desired company has been displayed, click the button. ➔ to select it.

The company data will be filled in the previous form.

Fabricante Nacional ×

CNPJ

11222333000181

Etapas Fabricação *

Armazenamento, Controle de qualidade

Fabricante *

EMPRESA DE TESTE Q

UF

DF

Município de Fabricação

BRASÍLIA

Logradouro

AVENIDA DE TESTE

Adicionar Fabricante

Cancelar

Click the button **Adicionar Fabricante** so that it appears in the list of manufacturers.

Fabricantes

CNPJ	FABRICANTE	ETAPA DE FABRICAÇÃO	AÇÕES
11222333000181	EMPRESA DE TESTE	Armazenamento, Controle de qualidade	 

+ Adicionar Fabricante Nacional

The action button  allow manufacturer editing while the button  Allows for exclusion.

The process for filling out the international manufacturer information is the same, with the difference being that the company search can be done by unique code or company name.

CÓDIGO ÚNICO	FABRICANTE	ETAPA DE FABRICAÇÃO	AÇÕES
Nenhum item foi adicionado.			

+ Adicionar Fabricante Internacional

If the national or international company cannot be identified, it is recommended to contact the department responsible for registration to complete the process.

New presentations can be registered using this same workflow or by copying data from an already registered presentation. This functionality is enabled once at least one presentation has been registered.

Você deseja copiar os dados de uma apresentação já cadastrada? 

☐ Sim ☒ Não

By selecting "yes", the system enables a field to select which presentation will be used as the default for the copy.

Apresentação

When the presentation is selected, the system copies the data to the form.

Apresentação

Selecione

Apresentação 1

Change to Food Notification

To initiate a request to amend a child support notification, you must access the drafts tab and click the "New" button, selecting the option "Petition Linked to an Existing Process".

When you select the notification you wish to modify, its data will be loaded onto the screen in a form identical to the one used in the initial notification so that it can be edited. It's important to note that the "Product Category" information cannot be changed.

Presentation management can be done through the "Presentation Registration" section.

Previously registered presentations will display a description of the presentation along with its "status." The presentation status will be "APPROVED" for those with no pending issues, and "NOT REVIEWED" for those requiring further verification.

from ANVISA.

 Adicionar Apresentação

New presentations can be added by clicking the button using the same registration logic as the initial request. After the presentation is added, it will be displayed without any information about its status.

Cadastro de Apresentação(ões) * 

DESCRIÇÃO DA APRESENTAÇÃO	AÇÕES
Apresentação 1 - DEFERIDA	 
Apresentação 2	 

[+ Adicionar Apresentação](#)

The presentation  allow editing of the presentation while the button  allows the exclusion of action button.

New presentations can also be added using the function to copy data from an already registered presentation. This feature is enabled once at least one presentation has been registered.

Você deseja copiar os dados de uma apresentação já cadastrada? 

☐ Sim ☒ Não

By selecting "yes", the system enables a field to select which presentation will be used as the default for the copy.

Apresentação

Selecione 

When the presentation is selected, the system copies the data to the form.

Apresentação

Selecione 

Selecione

Apresentação 1

It is important to note that deleting a previously registered presentation, identified by the presentation status information "APPROVED" or "NOT ANALYZED", will result in its cancellation. If one of these presentations is deleted, it will not be possible to undo a deletion request, and if there has been a mistake, it is recommended to delete the draft and complete a new form.

The information provided in the form will be updated in the ANVISA database **after** the petition is submitted and the protocol is confirmed.

Changes to the activities of establishments involved in the manufacture of registered food products .

MNU - User Manual

To initiate a request to change the activities of establishments involved in food manufacturing, you must access the drafts tab and click the "New" button, selecting the option "Petition Linked to an Existing Process".

When you select the process to be changed, the active presentations will be loaded on the screen.

Cadastro de Apresentação(ões)

DESCRIÇÃO DA APRESENTAÇÃO	AÇÕES
MANAUS/MA - DEFERIDA	
BRASÍLIA/DF - DEFERIDA	
GOIÂNIA/GO - DEFERIDA	

Atenção: Caso todos os Fabricantes sejam excluídos, não será possível seguir com o fluxo de peticionamento.

Select the presentation(s) that will have establishment(s) excluded by clicking the button.

Clicking will display a modal window with the manufacturers registered for that presentation.

Apresentação ✕

Descrição da Apresentação * ?

MANAUS/MA - DEFERIDA

Fabricantes

CNPJ	FABRICANTE	ETAPA DE FABRICAÇÃO	AÇÕES
11111111000191	EMPRESA DE TESTE LTDA. (V S01)	Armazenamento, Controle de qualidade, Embalagem, Processamento	

CÓDIGO ÚNICO	FABRICANTE	ETAPA DE FABRICAÇÃO	AÇÕES
Nenhum item foi adicionado.			

Atualizar **Cancelar**

To change the manufacturing steps for the desired manufacturer, click the manufacturer registration action and it will be shown button.

Fabricante Nacional ✕

CNPJ 11111111000191

Etapas Fabricação * Armazenamento, Controle de qualidade, Embalagem, Processamento

Fabricante * EMPRESA DE TESTE LTDA. (V501) Q

UF DF

Município de Fabricação BRASILIA

Logradouro SIA Trecho 5 area especial 57 - teste

Atualizar Cancelar

Etapas Fabricação * Armazenamento, Controle de qualidade, Embalagem, Processamento

Click on the Manufacturing Steps field and select the desired steps, then click update. After this action, the modal will be closed. If you do not wish to change the steps for another manufacturer, click update to close this modal. The information entered in the form will **only be updated in the ANVISA database after** the petition is submitted and the protocol is confirmed.

The system will not allow the protocol if all manufacturing steps for a manufacturer in a presentation are excluded.

EXCLUSION OF ESTABLISHMENTS INVOLVED IN THE MANUFACTURE OF REGISTERED FOODS

To initiate a request to exclude establishments involved in food manufacturing, you must access the drafts tab and click the "New" button, selecting the option "Petition Linked to an Existing Process".

When you select the process to be changed, the active presentations will be loaded on the screen.

Cadastro de Apresentação(ões)

DESCRIÇÃO DA APRESENTAÇÃO	AÇÕES
MANAUS/MA - DEFERIDA	
BRASILIA/DF - DEFERIDA	
GOIÂNIA/GO - DEFERIDA	

Atenção! Caso todos os Fabricantes sejam excluídos, não será possível seguir com o fluxo de peticionamento.

Select the presentation(s) that will have establishment(s) excluded by clicking the button.

Clicking will display a modal window with the manufacturers registered for that presentation.

Apresentação

Descrição da Apresentação * ?

GOIÂNIA/GO - DEFERIDA

Fabricantes

CNPJ	FABRICANTE	ETAPA DE FABRICAÇÃO	AÇÕES
11111111000191	EMPRESA DE TESTE LTDA. (VS01)	Armazenamento	X

CÓDIGO ÚNICO	FABRICANTE	ETAPA DE FABRICAÇÃO	AÇÕES
Nenhum item foi adicionado.			

Atualizar Cancelar

To remove the desired manufacturer, click the action button and then click update. After this action, the modal will close. The information entered in the form will only be updated in the ANVISA database **after** the petition is submitted and the protocol is confirmed.

The system will not allow the protocol if all manufacturers in a presentation have been excluded.

If, while filling out the form, the user deletes an unwanted manufacturer, it will not be possible to correct the form; in this case, it will be necessary to delete the draft and restart the request.

To initiate a request to exclude establishments involved in food manufacturing, you must access the drafts tab and click the "New" button, selecting the option "Petition Linked to an Existing Process".

When you select the process to be changed, the active presentations will be loaded on the screen.

Cadastro de Apresentação(ões)

DESCRIÇÃO DA APRESENTAÇÃO	AÇÕES
MANAUS/MA - DEFERIDA	
BRASÍLIA/DF - DEFERIDA	
GOIÂNIA/GO - DEFERIDA	

Atenção: Caso todos os Fabricantes sejam excluídos, não será possível seguir com o fluxo de peticionamento.

Select the presentation(s) that will have establishment(s) excluded by clicking the button.

Clicking will display a modal window with the manufacturers registered for that presentation.

Apresentação ✕

Descrição da Apresentação * ?

GOIÂNIA/GO - DEFERIDA

Fabricantes

CNPJ	FABRICANTE	ETAPA DE FABRICAÇÃO	AÇÕES
11111111000191	EMPRESA DE TESTE LTDA. (VS01)	Armazenamento	✕

CÓDIGO ÚNICO	FABRICANTE	ETAPA DE FABRICAÇÃO	AÇÕES
Nenhum item foi adicionado.			

Atualizar Cancelar

To remove the desired manufacturer, click the action button ✕ and then click update. After this action, the modal will close. The information entered in the form will only be updated in the ANVISA database **after** the petition is submitted and the protocol is confirmed.

The system will not allow the protocol if all manufacturers in a presentation have been excluded.

If, while filling out the form, the user deletes an unwanted manufacturer, it will not be possible to correct the form; in this case, it will be necessary to delete the draft and restart the request.

EXCLUSION OF REGISTERED FOOD BRAND

To initiate a request to remove a food brand from your trademark, you must access the drafts tab and click the "New" button, selecting the option "Petition Linked to an Existing Process".

When you select the process to be changed, the approved marks will be loaded on the screen.

Dados Gerais

Marca(s) do Produto *

MARCA(S) DO PRODUTO	Ações
DA VOVÓ	
DIANA CORUJA PAPINHA	
TESTE 2 12/12	
TESTE 12/12	

Atenção! Caso todas as Marcas do Produto sejam excluídas, não será possível seguir com o fluxo de peticionamento.

To remove the desired trademark, click the updated  The information entered in the form will be action button in the ANVISA database **only after** submitting the petition and confirming the protocol.

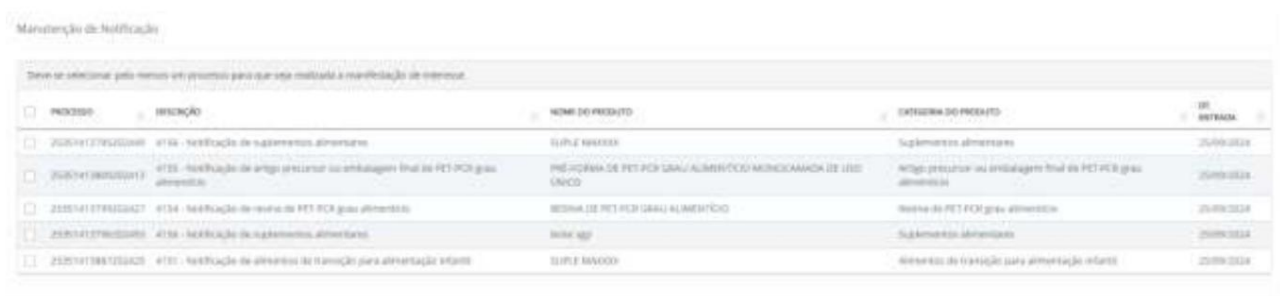
The system will not allow the protocol if all tags have been deleted. If, while filling out the form, the user deletes an unwanted tag, it will not be possible to correct the form; in this case, it will be necessary to delete the draft and restart the request.

EXPRESSION OF INTEREST AND PRODUCT REACTIVATION

Once every five years, companies must express their interest in maintaining the notified products. The frequency is defined **based on the date of publication of the regulation** and not the date of notification of the product.

During the period for expressing interest, the subject code "Notification Maintenance" will be made available, which should be accessed through the drafts tab. In this tab, click the "New" button and select the "Initial Petition" option.

The "Notification Maintenance" section will be displayed in the form.



Manutenção de Notificação

Deve-se selecionar pelo menos um produto para que seja realizada a manutenção de interesse.

☐	PROCESSO	INDICAÇÃO	NOME DO PRODUTO	CATEGORIA DO PRODUTO	DE- STACADA
☐	2020/11279/2020	4756 - Notificação de suplementos alimentares	LIPIU NUTRITION	Suplementos alimentares	25/09/2025
☐	2020/11280/2020	4755 - Notificação de artigo plástico ou embalagem final de PET PCR grau alimentar	PRÉ-PROGRAMA DE PET PCR GRAU ALIMENTÍCIO MUNDICAMON (2 - LÍQUIDO)	Artigo plástico ou embalagem final de PET PCR grau alimentar	25/09/2025
☐	2020/11279/2020	4754 - Notificação de resina de PET PCR grau alimentar	RESINA (2 PET PCR GRAU ALIMENTÍCIO)	Resina de PET PCR grau alimentar	25/09/2025
☐	2020/11279/2020	4756 - Notificação de suplementos alimentares	WOLFE 800	Suplementos alimentares	25/09/2025
☐	2020/11280/2020	4755 - Notificação de produtos de transição para alimentação infantil	LIPIU NUTRITION	Produtos de transição para alimentação infantil	25/09/2025

All notified products from the company that are **active and have not received any expression of interest for the period will be displayed**. The user must select one or more products for which they wish to express interest in maintaining notification.

The expression of interest can occur at any time during the period defined by law. If, during this period, the company identifies that it has not selected a product for which it would like to express interest, it will be possible to submit a new request including the desired product. The system allows the company to make as many requests as it wishes, provided that there are still **active products that have not yet received an expression of interest**.

If the expression of interest protocol was submitted within the regulatory deadline, the expiration date for product registration will be automatically updated, and this information can be verified in the ANVISA external search under food information.

Products for which no expression of interest has been received within the regulatory timeframe will not have their regularization deadline updated and will be automatically **deactivated** after its expiration.

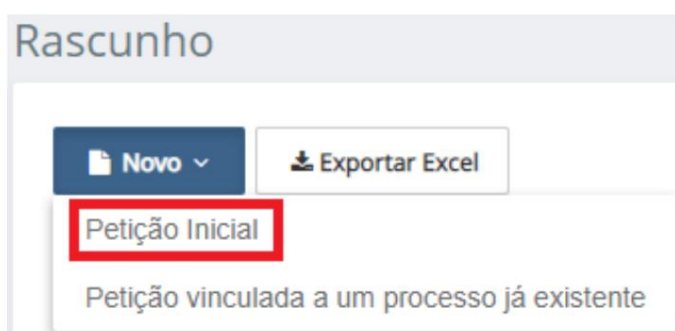
If the company wishes to reactivate products, a subject code for "Product Reactivation" will be provided, which can be accessed through the drafts tab. In this tab, click the "New" button and select the option "Petition linked to an existing process". The process number of the product for which reactivation is desired must be entered in the form. **Reactivation will only occur if the product was deactivated due to lack of response**.

OPERATING LICENSE AND FOOD REGISTRATION FORMS

GRANTING OF AFE/AE

This feature is only available for processes and petitions of the type "Companies".

To initiate a new application for an Operating Permit (AFE) or Special Permit (AE), you must access the drafts tab and click the "New" button, selecting the "Initial Petition" option.



In the form provided, click on the "magnifying glass" in the subject field, and on the next screen enter the name or code of the desired subject. Petition subjects and their relevant information are available at [\[link/website/etc.\] Inquiry of Matters](#).

Selecione o assunto ×

Atividade/Tipo de produto

Selecione ▼

Serviço

▼

Código Descrição

702

Q Pesquisar

Código	Atividade/Tipo de Produto	Descrição	
702	Empresas	AFE - CONCESSÃO - MEDICAMENTOS E INSUMOS FARMACÊUTICOS - DISTRIBUIR (SOME NTE MATRIZ)	→

The form will check if the applicant's CNPJ already has a valid AFE or AE compatible with the selected subject. If a valid AFE or AE is identified, the following information will be displayed: "The company already has a valid authorization for the type of product being requested. If the request is..."



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Once completed, the petition will be rejected. If the company wishes to expand its activities, it must submit a petition for expansion of activities as a 'Petition linked to another process'.

The following form will display the "General Company Data" section.

Dados Gerais da Empresa

Razão Social Conforme Consta na Receita Federal *

XYZ S/A

Endereço Conforme Consta na Receita Federal *

Rua sem nome, Brasília, Distrito Federal

Informação disponibilizada pela Receita Federal em 25/09/2024. Essas informações são atualizadas a cada 3 dias.

Caso existam incongruências nas informações resgatadas, favor realizar as alterações necessárias junto à Receita Federal antes de realizar o peticionamento.

This section will display the company name and address information as registered with the Brazilian Federal Revenue Service (RFB). This data cannot be modified and is updated every 3 days.

In the "Company Contact Information" section, you should enter your email address.

Informações para Contato com a Empresa

ENDEREÇO ELETRÔNICO (E-MAIL VISUALIZADO COM FREQUÊNCIA)

Nenhum item foi adicionado.

+ Adicionar

Limpar Tudo

To add, click on table.



Email addresses will be provided in the form of

Informações para Contato com a Empresa

ENDEREÇO ELETRÔNICO (E-MAIL VISUALIZADO COM FREQUÊNCIA)

xyz@gmail.com

xyz2@gmail.com

+ Adicionar

Limpar Tudo

The action button  They allow editing of the email address, while the button  allows deletion. is an email address.

Endereço Eletrônico (E-mail Visualizado Com Frequência)

✕

0 / 150

Adicionar

Cancelar

The "Intended Activity and Class" section will be used to identify which activity(ies) the applicant intends to obtain in their AFE/AE. The system will only display activities and classes related to the selected subject code. If there is a mandatory activity or class for the subject, it will already be pre-filled.

Atividade e Classe Pretendida ?

Dispensação de medicamentos não sujeitos ao controle especial *

☒ Sim ☐ Não

Comércio *

☐ Sim ☐ Não

Once the option related to that activity is selected.

☒ **Sim**

For an activity, the system will enable the classes.

Atividade e Classe Pretendida ?

Dispensação de medicamentos não sujeitos ao controle especial *

☒ Sim ☐ Não

Comércio *

☒ Sim ☐ Não

- ☐ Alimentos permitidos
- ☐ Cosméticos
- ☐ Perfumes
- ☐ Produtos de Higiene
- ☐ Produtos para saúde (dispositivos médicos)

In the "Company Representatives" section, you will need to specify who will be the legal and technical representatives associated with the authorization.

Responsáveis pela Empresa

Responsável Legal *

Responsáveis *

Para selecionar os responsáveis da empresa nesta Autorização, utilize a caixa de seleção abaixo para adicionar ou remover usuários, conforme necessário.

Os responsáveis listados abaixo serão associados a esta Autorização.

+ Adicionar Todos

123.456.789-01 - José Maria dos Santos

- Remover Todos

Associar novo responsável (CPF)

Caso o CPF não seja encontrado, acessar os sistemas de cadastro para inscrição.

Responsável Técnico *

Responsáveis *

Para selecionar os responsáveis da empresa nesta Autorização, utilize a caixa de seleção abaixo para adicionar ou remover usuários, conforme necessário.

Os responsáveis listados abaixo serão associados a esta Autorização.

+ Adicionar Todos

123.456.789-01 - José Maria dos Santos

109.876.543-21 - Maria José dos Santos

- Remover Todos

Associar novo responsável (CPF)

Caso o CPF não seja encontrado, acessar os sistemas de cadastro para inscrição.

A section of information regarding the legal or technical representative will be available, with two columns describing users with their respective names and CPF numbers (CPF numbers and surnames have been hidden in the images to protect the data of individuals registered in the system).

Responsáveis *

Aqui você pode adicionar todos os usuários atualmente associados à empresa.

Para alterar os responsáveis associados a esta Autorização, inclua ou remova usuários da caixa à direita.

+ Adicionar Todos

- Alexandre
- André
- ASD
- BETAN
- Bira
- BRUNO
- EDNEY
- Flavio
- GABRIEL

- Remover Todos

- ADENIR
- ALESSANDRA



MNU - User Manual

The column on the **right**, marked in blue, indicates the users who will be registered as the company's legal or technical representative after the request is submitted.

The column on the **left**, marked in red, indicates all users who can be registered as legal or technical representatives.

To add a user, click the arrow next to the user's name in the **left-hand table**, marked in red. The user's name will then automatically be moved to the **right-hand table**, marked in blue.

If the user was selected incorrectly, they can be removed from the user table.

To add a username, click the arrow next to it in the table on the **right**, marked in blue. The username will then automatically be moved to the table on the **left**, marked in red.

In the given example, after the request is submitted, the users ADEMIR and ALESSANDRA would be responsible.

Adding a new user to the table on the **right**, marked in blue, can also be done by entering the user's CPF (Brazilian tax identification number) in the "Associate new responsible party (CPF)" field.

Associar novo responsável (CPF)

Caso o CPF não seja encontrado, acessar os sistemas de cadastro para inserção.

If the user does not yet have registered data, the following error message will appear: "CPF not accepted, please access the registration systems to add it."

In this case, the user will need to be registered by the applicant in the ANVISA registration system.

The "Declaration" section is only available when requesting an AFE (Authorization for Operation) for a Pharmacy or Drugstore.

Declaração

A assinatura eletrônica desta declaração possibilita o andamento mais ágil do pedido e corresponde ao envio do documento previsto no art. 11, inciso III, da RDC nº 275/2019. Caso não seja assinada eletronicamente, permanece a necessidade de envio do documento solicitado no art. 11 da RDC nº 275/2019. Continue preenchendo os campos necessários para prosseguir com o posicionamento.

ANEXO I DECLARAÇÃO

Considerando o disposto na Resolução da Diretoria Colegiada - RDC nº 275, de 9 de abril de 2019, a empresa de razão social e CNPJ citados abaixo declara cumprir o disposto nas normas sanitárias vigentes para este posicionamento, conforme informações do formulário de petição.

Razão Social

Xyz S/A

CNPJ

XXXXXXXX-YY-YY-DD

Assunto da Petição

AFE - CONCESSÃO - FARMÁCIAS E DROGARIAS

A empresa declara cumprir o disposto na Lei nº 11.343 de 23 de agosto de 2006.

A empresa declara que não houve emissão de documento pela autoridade sanitária local competente quanto as atividades pleiteadas e com os dados vigentes até o momento deste posicionamento ou que o documento emitido pela autoridade sanitária contempla as atividades peticionadas e dados vigentes, conforme formulário de petição.

A empresa declara estar ciente que a autorização de funcionamento ou autorização especial, isoladamente, não assegura o início das suas atividades de farmácia.

A empresa se responsabiliza pela veracidade e fidedignidade das informações aqui prestadas e declara que está ciente de que é responsável pela qualidade dos serviços a serem prestados, bem como assegura que estes estão adequados aos fins a que se destinam e cumprem os requisitos legais e sanitários.

Declaro estar ciente que o descumprimento das disposições contidas nesta Resolução constitui infração sanitária, nos termos da Lei nº. 6.437, de 20 de agosto de 1977, sem prejuízo das responsabilidades civil, administrativa e penal cabíveis.

☐ Declaro que sou o responsável técnico e/ou legal e li e concordo com os termos e condições

By clicking the checkbox

☐ Declaro que sou o responsável técnico e/ou legal e li e concordo com os termos e condições

The user declares that they comply with the provisions of RDC No. 275, of April 9, 2019, and this allows for a faster analysis of the request by Anvisa than if the same self-declaration were sent as an attachment.

Important! If the person filing the petition is not the legal or technical representative, but wishes to file using the electronic self-declaration, we suggest that the petition be saved as a Draft and completed later by the company's technical or legal representative.



GENERATION OF FOOD REGISTRATION

This feature is only available for "Alimony" type cases and petitions.

To initiate a new request for Food Registration Generation, you must access the drafts tab and click the "New" button, selecting the "Initial Petition" option.



In the form provided, click on the "magnifying glass" in the subject field, and on the next screen enter the name or code of the desired subject. Petition subjects and their relevant information are available at [\[link/website/etc.\]](#).

[Inquiry of Subjects:](#)

Selecione o assunto

Atividade/Tipo de produto

Selecione

Serviço

Código

4192

Descrição

Q. Pesquisar

Código	Atividade/Tipo de Produto	Descrição
4192	Alimento	Gerar cadastro de alimentos

The form will check if the applicant's CNPJ (Brazilian tax ID) already has a Food product registration. If a valid registration is identified, the following information will be displayed: "The company already has a valid authorization for the type of product being requested. If the request is completed, the petition will be rejected."

The following form will display the "General Company Data" section.



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Dados Gerais da Empresa

Razão Social Conforme Consta na Receita Federal *

XYZ S/A

Endereço Conforme Consta na Receita Federal *

Rua sem nome, Brasília, Distrito Federal

Informação disponibilizada pela Receita Federal em 25/09/2024. Essas informações são atualizadas a cada 3 dias.

Caso existam incongruências nas informações resgatadas, favor realizar as alterações necessárias junto à Receita Federal antes de realizar o peticionamento.

This section will display the company name and address information as registered with the Brazilian Federal Revenue Service (RFB). This data cannot be modified and is updated every 3 days.

In the "Company Contact Information" section, you should enter your email address.

Informações para Contato com a Empresa

ENDEREÇO ELETRÔNICO (E-MAIL VISUALIZADO COM FREQUÊNCIA)

AÇÕES

Nenhum item foi adicionado.

+ Adicionar

Limpar Tudo

+ Adicionar

To add, click on table. Email addresses will be provided in the form of

Informações para Contato com a Empresa

ENDEREÇO ELETRÔNICO (E-MAIL VISUALIZADO COM FREQUÊNCIA)

AÇÕES

xyz@gmail.com

xyz2@gmail.com

+ Adicionar

Limpar Tudo

The action button  They allow editing of the email address, while the button allows deletion  is an email address.

Endereço Eletrônico (E-mail Visualizado Com Frequência)



0 / 150

Adicionar

Cancelar

The "Desired Activity and Class" section will be used to identify which activity(ies) the applicant intends to obtain in their registration. The system will only display activities and classes related to the Food registration. If there is a mandatory activity or class for the subject, it will already be pre-filled.

Atividade e Classe Pretendida

Armazenar *

☐ Sim ☐ Não

BENEFICIAR *

☐ Sim ☐ Não

Comércio *

☐ Sim ☐ Não

Dispensar *

☐ Sim ☐ Não

Embalar *

☐ Sim ☐ Não

Once the option related to that activity is selected.

☒ Sim

For an activity, the system will enable the classes.

Atividade e Classe Pretendida 

Armazenar *

☒ Sim ☐ Não

☐ Alimento

BENEFICIAR *

☒ Sim ☐ Não

☐ Alimento

Comércio *

☐ Sim ☐ Não

Dispensar *

☐ Sim ☐ Não

In the "Company Representatives" section, you will need to specify who will be the legal and technical representatives.
linked to the registration.

Responsáveis pela Empresa

Responsável Legal *

Responsáveis *

Para selecionar os responsáveis da empresa nesta Autorização, utilize a caixa de seleção abaixo para adicionar ou remover usuários, conforme necessário.

Os responsáveis listados abaixo serão associados a esta Autorização.

+ Adicionar Todos

123.456.789-01 - José Maria dos Santos

- Remover Todos

Associar novo responsável (CPF)

Caso o CPF não seja encontrado, acessar os sistemas de cadastro para inscrição.

Responsável Técnico *

Responsáveis *

Para selecionar os responsáveis da empresa nesta Autorização, utilize a caixa de seleção abaixo para adicionar ou remover usuários, conforme necessário.

Os responsáveis listados abaixo serão associados a esta Autorização.

+ Adicionar Todos

123.456.789-01 - José Maria dos Santos

109.876.543-21 - Maria José dos Santos

- Remover Todos

Associar novo responsável (CPF)

Caso o CPF não seja encontrado, acessar os sistemas de cadastro para inscrição.

A section of information regarding the legal or technical representative will be available, with two columns describing users with their respective names and CPF numbers (CPF numbers and surnames have been hidden in the images to protect the data of individuals registered in the system).

Responsáveis *

Para selecionar os responsáveis da empresa nesta Autorização, utilize a caixa de seleção abaixo para adicionar ou remover usuários, conforme necessário.

Os responsáveis listados abaixo serão associados a esta Autorização.

+ Adicionar Todos

- Alexandre

- André

- ASD

- BETAN

- Bira

- BRUNO

- EDNEY

- Flavio

- GABRIEL

- Remover Todos

- ADENIR

- ALESSANDRA



MNU - User Manual

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If the user was selected incorrectly, they can be removed from the user table.

To add a username, click the arrow next to it in the table on the **right**, marked in blue. The username will then automatically be moved to the table on the **left**, marked in red.

In the given example, after the request is submitted, the users ADEMIR and ALESSANDRA would be responsible.

Adding a new user to the table on the **right**, marked in blue, can also be done by entering the user's CPF (Brazilian tax identification number) in the "Associate new responsible party (CPF)" field.

Associar novo responsável (CPF)

Caso o CPF não seja encontrado, acessar os sistemas de cadastro para inserção.

If the user does not yet have registered data, the following error message will appear: "CPF not accepted, please access the registration systems to add it."

In this case, the user will need to be registered by the applicant in the ANVISA registration system.

CHANGE OF ADDRESS FOR AFE/AE

This feature is only available for petitions of the type "Companies".

Initiate a petition linked to the AFE (Authorization for Operation) process you wish to modify, following the steps described in this manual. If you do not know the process number linked to the AFE you wish to modify, this information can be obtained through the Company Operation query, "Consult National Company," available at <https://consultas.anvisa.gov.br/#/empresas/empresas/>



Select the subject corresponding to the change you wish to make: address change or company name change. The list of subject codes is available for consultation at the following link: <https://consultas.anvisa.gov.br/#/consultadeassuntos/>

The information block will provide both the address as it currently appears in the Anvisa (Brazilian Health Regulatory Agency) registry and the address as it appears in the Federal Revenue Service database.



The information from the Federal Revenue Service is updated every 3 days, and this information is available on the form. from the date of the last update. Ex: **Informação disponibilizada pela Receita Federal em 10/11/2022.**

If there is a discrepancy between the information displayed on the form and the Federal Revenue Service database, check the date of the last update. If there is still a discrepancy between the data, contact the responsible department so that the reason for the problem can be investigated.

Active AFEs/AEs Field: This will be displayed if the selected company has other processes with AFEs/AEs active.

AFEs/AEs Ativas

Por força legal, a alteração de razão social precisa ser peticionada em todas as AFEs/AEs ativas da empresa. Deseja peticionar para todos os processos? *

☐ Sim ☐ Não

Initially, the user will be asked if they want to make the same change for all active authorizations.

If the user selects the "No" option, a checkbox will be displayed for the user to declare that they are aware that failure to submit to all processes may result in the rejection of the request.

☐ Declaro que estou ciente que a não submissão para todos os processos poderá ensejar o indeferimento da solicitação. *

In this workflow, checking the checkbox is mandatory, and failure to check it will prevent the request from being submitted.

If the user selects the "Yes" option, an interface will be made available where all valid authorizations for the company will be displayed, as well as the process related to that authorization.

If an active authorization is not displayed or an inactive authorization is displayed, please contact the area responsible for authorization so that the Anvisa team can assess the situation.

☒ Sim ☐ Não

Nº	AUTORIZAÇÃO	PROCESSO	ASSUNTO	FATOR GERADOR	VALOR	AÇÕES
1	A000085	253510163030206				
2	1152671	25351003370201968				
3	1152685	25351025383201998				
4	1367254	9999999999999999999				
5	2000193	25351002851202090				
6	4085825	25351001487202041				
7	7050902	25351000426202066				
8	8999999	9999999999999999999				
9	9074901	25351213221201601				

Click the edit option in the actions column.

Nº	AUTORIZAÇÃO	PROCESSO	ASSUNTO	FATOR GERADOR	VALOR	AÇÕES
1	A000085	253510163030206				

A new modal will be displayed for selecting the subject; clicking on the magnifying glass  which will be used for will allow you to file a petition of the same type of request selected at the beginning of the workflow.

AFEs ou AEs Ativas

Autorização

A000085

Processo

253510163030206

Assunto *

Q

Fato Gerador

Porte da Empresa

Valor da Taxa

Nº

ITEM

OBRIGATÓRIO

ARQUIVOS

AÇÕES

Nenhum item foi adicionado.

Confirmar

Cancelar

If an address change subject was selected at the beginning of the form, the system will only display address change subjects. Similarly, if a company name change subject was selected, the system will only display company name change subjects in the modal.

Selecione o assunto

Atividade/Tipo de produto

Selecione

Serviço

Código

Descrição

Q Pesquisar

Código	Atividade/Tipo de Produto	Descrição	
7003	Empresas	MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de EXPORTADORA do produto sujeito a Controle Especial - ENDEREÇO DA SEDE	→

When you select a subject, the modal will display the fee associated with that request and the *checklist* items for attaching the requested documents.

AFEs ou AEs Ativas

Autorização		Processo	
A000085		253510163030206	
Assunto			
INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança do ENDEREÇO DA SEDE			
Fato Gerador	Porte da Empresa	Valor da Taxa	
38601	MEDIA - GRUPO IV	R\$ 1.600,00	

Nº	ITEM	OBRIGATÓRIO	ARQUIVOS	AÇÕES
1	Formulário de Petição devidamente assinado e preenchido	Sim		
2	Comprovante de pagamento, ou de isenção, da Taxa de Fiscalização de Vigilância Sanitária (TFVS), mediante Guia de Recolhimento da União (GRU) específica	Não		
3	Relatório de inspeção ou documento equivalente que ateste o cumprimento dos requisitos técnicos para as atividades e classes pleiteadas, emitidos pela autoridade sanitária local competente ou licença sanitária vigente com os dados atualizados	Não		



After attaching the requested documents, click confirm.

The interface will be updated to display the selected subject, its generating event, and the associated rate.

Nº	AUTORIZAÇÃO	PROCESSO	ASSUNTO	FATOR GERADOR	VALOR	AÇÕES
1	A000085	253510163030206	INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança do ENDEREÇO DA SEDE	38601	R\$ 1.600,00	

If you wish to change the selected subject or the attached documents, simply click on the edit icon.

Continue filling in the subjects for each of the processes, always keeping in mind the need to choose the most appropriate subject for each type of authorization that will be updated.

After filling in the information regarding all processes related to active AFEs or AEs, the user must check the box indicating that the “attached documentation is valid and that all information is legitimate”. In addition, the user will also acknowledge that “there may be a difference of up to 3 hours between the main protocol and the remaining AFEs/AEs”.

☒ Declaro que visualizei a documentação anexada e que todas as informações são legítimas. Estou ciente de que pode haver uma diferença de até 3 horas entre o protocolo principal e o restante das AFEs/AEs. *

After completing the Active AFEs/AEs section, the user must insert the documents related to the subject selected at the beginning of the form.

Documentação

Nº	ITEM	OBRIGATORIO	ARQUIVOS	AÇÕES
1	Formulário de Petição devidamente assinado e preenchido	Sim		
2	Comprovante de pagamento, ou de isenção, da Taxa de Fiscalização de Vigilância Sanitária (TFVS), mediante Guia de Recolhimento da União (GRU) específica	Não		
3	Relatório de inspeção ou documento equivalente que ateste o cumprimento dos requisitos técnicos para as atividades e classes pleiteadas, emitidos pela autoridade sanitária local competente ou licença sanitária vigente com os dados atualizados	Não		
4	ATENÇÃO: A licença sanitária, o relatório de inspeção ou o documento equivalente devem informar explicitamente que o estabelecimento cumpre os requisitos de controle especial constantes da Portaria SVS/MS nº 344, de 1998 e da Portaria SVS/MS nº 6, de 1999, ou atos normativos posteriores que vierem a substituí-las.	Não		

Fechar

Validar

Salvar

Enviar

By clicking submit



The user should view the documents related to the request that...

This gave rise to the form.

Confirmação de envio



⚠ Atenção! Antes de confirmar o envio é necessário visualizar todos os anexos.
Ao confirmar o envio a petição será protocolada e não será possível realizar a alteração das informações.

Nº	Item	Anexos	Visualizado
1	Formulário de Petição devidamente assinado e preenchido	1.pdf	Não
2	Comprovante de pagamento, ou de isenção, da Taxa de Fiscalização de Vigilância Sanitária (TFVS), mediante Guia de Recolhimento da União (GRU) específica		
3	Cadastro Nacional de Pessoa Jurídica (CNPJ) com dados atualizados		

Cancelar

Confirmar Envio

After viewing all the files, the user must click the "Confirm Submission" button.

If the total amount of the requests results in an exempt value, the requests will be registered, generating the documents and their respective registration receipts.

If the total of the requests results in a value that does not qualify for exemption, the payment selection screen will be displayed.

Petição aguardando pagamento



Favorecido:	11.111.111/0001-91 - UHIEQKX WHNHIWD NH FIXKHUUWPHMVX NH NWNXU (UHIFIX)
Assunto:	7006 - INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança na RAZÃO SOCIAL
Número de Transação:	43792022
 Selecionar Pagamento	

Concluir

By clicking on "select payment," you will be able to generate the GRU (payment slip) or activate PagTesouro (a payment processing system).

The generated payment slip will have a different format, referring to a "multiple guide" that will include the fee for all requested changes.

The payment slip details will be displayed on the first page.

 Agência Nacional de Vigilância Sanitária Taxa de Fiscalização de Vigilância Sanitária Guia de Recolhimento da União - GRU Cobrança		Vencimento	11/12/2022
		Número da Guia	4056/2022
		Nº Guia Referência	-
		Valor da Taxa	R\$ 24.800,00
Nome ou Razão Social/Endereço/Fone		Taxa Complementar	-
UHIEQXK WNNHWD NH FINKHUWPHMVK NH NWNXU (UHIFIX)		Valor Multa	-
		Acréscimo Multa	-
CNPJ/CPE: 11.111.111.0001-01		Descontos Multa	-
Tipo da Guia: Normal		Total da Guia	R\$ 24.800,00
Instruções Esta guia é pessoal e intransferível. O uso irregular pode causar, dentre outras implicações, a não identificação do recolhimento. Os valores emitidos por este boleto não são passíveis de descontos. Caso o valor apresentado não corresponda ao enquadramento do porte da empresa, providencie a atualização dos dados conforme a RDC 225/2006.			
Porte: MEDIA - GRUPO IV	Classe:		
Nº Endossatário:	Modalidade:	Número:	Qt. Itens:
Fato(s) Gerador(es): 3034 (2), 38601 (8)			
Nome Endossatário:		Assinatura:	
Número da Transação: 43792022		00190.00009 02941.055002 43792.022170 1 91960002480000	
Válido somente com autenticação bancária.			

BANCO DO BRASIL		001-9	00190.00009 02941.055002 43792.022170 1 91960002480000		
Local de Pagamento					Vencimento
Pagável em qualquer banco até o vencimento					11/12/2022
Cedente					Agência/Unid. Cliente
ANVISA - Agência Nacional de Vigilância Sanitária					1667-1.0335030-1
Data do Documento	Nº do Documento	Espécie Documento	Acerto	Data Process.	Nosso Número
11/11/2022	4056/2022			11/11/2022	43792022
Use do Boleto	Carteira	Espécie	Quantidade	Valor	(=) Valor do Documento
	18	Real		R\$ 24.800,00	R\$ 24.800,00
Instruções					(-) Desconto/Abatimento
NÃO RECEBER ESTE TÍTULO APÓS A DATA DE VENCIMENTO					(-) Outras Deduções
ATENÇÃO:					(-) Multa Multa
ESTA GUIA É PESSOAL E INTRANSFERÍVEL. O USO IRREGULAR PODE CAUSAR A NÃO IDENTIFICAÇÃO DO SEU PAGAMENTO					(-) Outros Acréscimos
Número da Transação: 43792022					(=) Valor Cobrado
 Governo Federal - Guia de Recolhimento da União - GRU - Cobrança.					R\$ 24.800,00
Sacado UHIEQXK WNNHWD NH FINKHUWPHMVK NH NWNXU (UHIFIX) VITÓRIA - ES - 75012200 Sacador/Avalista					
Cod. Baixa					



Autenticação Mecânica - Ficha de Conservação

In the generated payment slip, the "Generating Event(s)" field displays the generating events and a counter that indicates...

How many petitions were created for each triggering event. Ex: **Fato(s) Gerador(es): 3034 (2), 38601 (8)**

The payment slip will display a second page where you can see the data related to the multiple guide (red box), the request related to the process for which the request form was initiated (green box), and the requests for processes related to other active AFEs/AEs (blue box).

Guia Múltipla: 4056
Data: 11/11/2022 15:05:10

Guia Pai						
Ordem	Transação	Processo	Assunto	Guia	Fato Gerador	Valor
1	43792022	25351000035201916	7006-INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança na RAZÃO SOCIAL	4056	3034	R\$ 6000.00

Guias Filhas						
Ordem	Autorização	Processo	Assunto	Guia	Fato Gerador	Valor
1	A000085	253510163030206	7006-INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança na RAZÃO SOCIAL	4057	3034	R\$ 6.000,00
2	1152671	25351003370201968	7013-MEDICAMENTOS - (Alteração na AE) de TRANSPORTADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4058	38601	R\$ 1.600,00
3	1152685	25351025383201998	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4059	38601	R\$ 1.600,00
4	1367254	99999999999999995	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4060	38601	R\$ 1.600,00
5	2009193	25351002851202090	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4061	38601	R\$ 1.600,00
6	4085825	25351001487202041	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4062	38601	R\$ 1.600,00
7	7050902	25351000426202066	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4063	38601	R\$ 1.600,00
8	8999999	99999999999999995	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4064	38601	R\$ 1.600,00
9	9074901	25351213221201601	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4065	38601	R\$ 1.600,00

The payment slip covers all requests, and if the amount paid is less than the amount specified on the slip, **no request will be processed.**

Due to differences in the processing of the forms, it is expected that there will be **an interval of up to 3 hours between the registration of the parent form and the registration of the child form(s).**

After the protocol is submitted, a petition will be created for each process listed in the multiple tab. A protocol receipt will also be made available in the mailbox for each petition created.

The petition extract, available in the processes tab (see previous sections to understand how to access this feature), may show the company name or address that was registered with Anvisa and the company name or address that was registered with the Federal Revenue Service at the time of the user's request, as well as the date the information was updated with the Federal Revenue Service.

Example of the information contained in the address change request statement.

Endereço Conforme Consta na Anvisa:	VITÓRIA-ES, SIA TRECHO 4 AREA ESPECIAL 57 TANGAMANDAPIO 75012200
Data Atualização Receita Federal:	Informação disponibilizada pela Receita Federal em 11/11/2022. Essas informações são atualizadas a cada 3 dias.
Endereço Conforme Consta na Receita Federal:	ASA NORTE-DF, 70836900, BRASIL

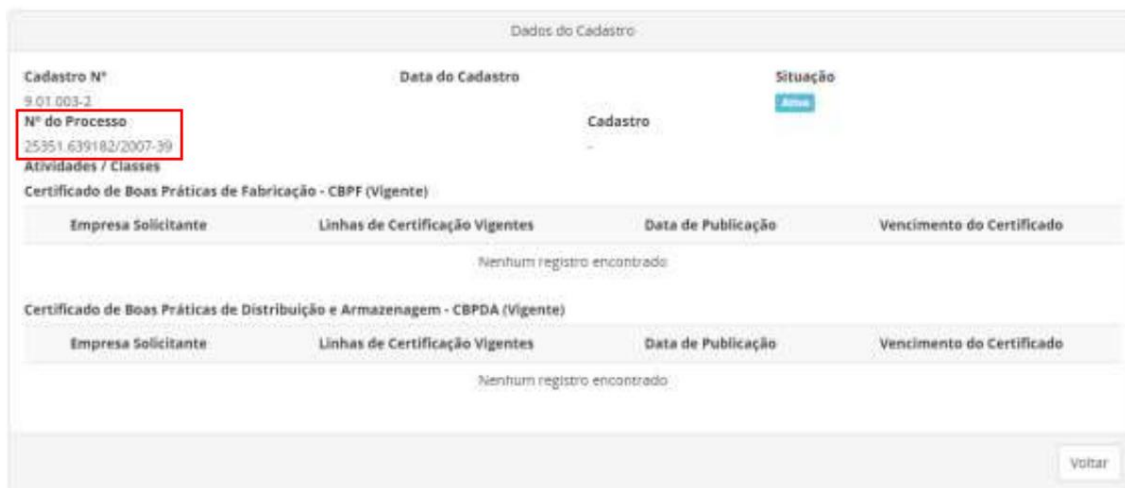
Example of the information contained in the statement of requests for change of company name.

Razão Social Conforme Consta na Anvisa:	UHIEQKX WHNHIWD NH FIXKHUUWPHMVX NH NWNXU (UHIFIX)
Data Atualização Receita Federal:	Informação disponibilizada pela Receita Federal em 11/11/2022. Essas informações são atualizadas a cada 3 dias.
Razão Social Conforme Consta na Receita Federal:	UHIEQKX WHNHIWD NH FIXKHUUWPHMVX NH NWNXU (UHIFIX)

Change of company name to AFE/AE

This feature is only available for petitions of the type "Companies".

Initiate a petition linked to the AFE (Authorization for Operation) process you wish to modify, following the steps described in this manual. If you do not know the process number linked to the AFE you wish to modify, this information can be obtained through the Company Operation query, "Consult National Company," available at <https://consultas.anvisa.gov.br/#/empresas/empresas/>



Select the subject corresponding to the change you wish to make: address change or company name change. The list of subject codes is available for consultation at the following link: <https://consultas.anvisa.gov.br/#/consultadeassuntos/>

The information block will include the company name as it currently appears in the Anvisa registry and the company name as it appears in the Federal Revenue database.



The information from the Federal Revenue Service is updated every 3 days, and this information is available on the form.

from the date of the last update. Ex:

Informação disponibilizada pela Receita Federal em 10/11/2022.

If there is a discrepancy between the information displayed on the form and the Federal Revenue Service database, check the date of the last update. If there is still a discrepancy between the data, contact the responsible department so that the reason for the problem can be investigated.

Active AFEs/AEs Field: This will be displayed if the selected company has other processes with AFEs/AEs active.

AFEs/AEs Ativas

Por força legal, a alteração de razão social precisa ser peticionada em todas as AFEs/AEs ativas da empresa. Deseja peticionar para todos os processos? *

☐ Sim ☐ Não

Initially, the user will be asked if they want to make the same change for all active authorizations.

If the user selects the "No" option, a checkbox will be displayed for the user to declare that they are aware that failure to submit to all processes may result in the rejection of the request.

☐ Declaro que estou ciente que a não submissão para todos os processos poderá ensejar o indeferimento da solicitação. *

In this workflow, checking the checkbox is mandatory, and failure to check it will prevent the request from being submitted.

If the user selects the "Yes" option, an interface will be made available where all valid authorizations for the company will be displayed, as well as the process related to that authorization.

If an active authorization is not displayed or an inactive authorization is displayed, please contact the area responsible for authorization so that the Anvisa team can assess the situation.

☒ Sim ☐ Não

Nº	AUTORIZAÇÃO	PROCESSO	ASSUNTO	FATOR GERADOR	VALOR	AÇÕES
1	A000085	253510163030206				
2	1152671	25351003370201968				
3	1152685	25351025383201998				
4	1367254	9999999999999999999				
5	2000193	25351002851202090				
6	4085825	25351001487202041				
7	7050902	25351000426202066				
8	8999999	9999999999999999999				
9	9074901	25351213221201601				

Click the edit option in the actions column.

Nº	AUTORIZAÇÃO	PROCESSO	ASSUNTO	FATOR GERADOR	VALOR	AÇÕES
1	A000085	253510163030206				

A new modal will be displayed for selecting the subject; clicking on the magnifying glass  which will be used for will allow you to file a petition of the same type of request selected at the beginning of the workflow.

AFEs ou AEs Ativas

Autorização

Processo

Assunto *

Q

Fato Gerador

Porte da Empresa

Valor da Taxa

Nº	ITEM	OBRIGATÓRIO	ARQUIVOS	AÇÕES
Nenhum item foi adicionado.				

Confirmar

Cancelar

If an address change subject was selected at the beginning of the form, the system will only display address change subjects. Similarly, if a company name change subject was selected, the system will only display company name change subjects in the modal.

Selecione o assunto

Atividade/Tipo de produto

▼

Serviço

▼

Código

Descrição

Q Pesquisar

Código	Atividade/Tipo de Produto	Descrição	
7003	Empresas	MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de EXPORTADORA do produto sujeito a Controle Especial - ENDEREÇO DA SEDE	→

When you select a subject, the modal will display the fee associated with that request and the *checklist* items for attaching the requested documents.

AFEs ou AEs Ativas

Autorização		Processo	
A000085		253510163030206	
Assunto			
INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança do ENDEREÇO DA SEDE			
Fato Gerador	Porte da Empresa	Valor da Taxa	
38601	MEDIA - GRUPO IV	R\$ 1.600,00	

Nº	ITEM	OBRIGATÓRIO	ARQUIVOS	AÇÕES
1	Formulário de Petição devidamente assinado e preenchido	Sim		
2	Comprovante de pagamento, ou de isenção, da Taxa de Fiscalização de Vigilância Sanitária (TFVS), mediante Guia de Recolhimento da União (GRU) específica	Não		
3	Relatório de inspeção ou documento equivalente que ateste o cumprimento dos requisitos técnicos para as atividades e classes pleiteadas, emitidos pela autoridade sanitária local competente ou licença sanitária vigente com os dados atualizados	Não		



After attaching the requested documents, click confirm.

The interface will be updated to display the selected subject, its generating event, and the associated rate.

Nº	AUTORIZAÇÃO	PROCESSO	ASSUNTO	FATOR GERADOR	VALOR	AÇÕES
1	A000085	253510163030206	INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança do ENDEREÇO DA SEDE	38601	R\$ 1.600,00	

If you wish to change the selected subject or the attached documents, simply click on the edit icon.

Continue filling in the subjects for each of the processes, always keeping in mind the need to choose the most appropriate subject for each type of authorization that will be updated.

After filling in the information regarding all processes related to active AFEs or AEs, the user must check the box indicating that the “attached documentation is valid and that all information is legitimate”. In addition, the user will also acknowledge that “there may be a difference of up to 3 hours between the main protocol and the remaining AFEs/AEs”.

☒ Declaro que visualizei a documentação anexada e que todas as informações são legítimas. Estou ciente de que pode haver uma diferença de até 3 horas entre o protocolo principal e o restante das AFEs/AEs. *

After completing the Active AFEs/AEs section, the user must insert the documents related to the subject selected at the beginning of the form.

Documentação

Nº	ITEM	OBRIGATORIO	ARQUIVOS	AÇÕES
1	Formulário de Petição devidamente assinado e preenchido	Sim		
2	Comprovante de pagamento, ou de isenção, da Taxa de Fiscalização de Vigilância Sanitária (TFVS), mediante Guia de Recolhimento da União (GRU) específica	Não		
3	Relatório de inspeção ou documento equivalente que ateste o cumprimento dos requisitos técnicos para as atividades e classes pleiteadas, emitidos pela autoridade sanitária local competente ou licença sanitária vigente com os dados atualizados	Não		
4	ATENÇÃO: A licença sanitária, o relatório de inspeção ou o documento equivalente devem informar explicitamente que o estabelecimento cumpre os requisitos de controle especial constantes da Portaria SVS/MS nº 344, de 1998 e da Portaria SVS/MS nº 6, de 1999, ou atos normativos posteriores que vierem a substituí-las.	Não		

Fechar

Validar

Salvar

Enviar

By clicking submit

Enviar

The user should view the documents related to the request that...

This gave rise to the form.

Confirmação de envio



⚠ Atenção! Antes de confirmar o envio é necessário visualizar todos os anexos.
Ao confirmar o envio a petição será protocolada e não será possível realizar a alteração das informações.

Nº	Item	Anexos	Visualizado
1	Formulário de Petição devidamente assinado e preenchido	1.pdf	Não
2	Comprovante de pagamento, ou de isenção, da Taxa de Fiscalização de Vigilância Sanitária (TFVS), mediante Guia de Recolhimento da União (GRU) específica		
3	Cadastro Nacional de Pessoa Jurídica (CNPJ) com dados atualizados		

Cancelar

Confirmar Envio

After viewing all the files, the user must click the "Confirm Submission" button.

If the total amount of the requests results in an exempt value, the requests will be registered, generating the documents and their respective registration receipts.

If the total of the requests results in a value that does not qualify for exemption, the payment selection screen will be displayed.

Petição aguardando pagamento



Favorecido:	11.111.111/0001-91 - UHIEQKX WHNHIWD NH FIXKHUUWPHMVX NH NWNXU (UHIFIX)
Assunto:	7006 - INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança na RAZÃO SOCIAL
Número de Transação:	43792022
 Selecionar Pagamento	

Concluir

By clicking on "select payment," you will be able to generate the GRU (payment slip) or activate PagTeseuro (a payment processing system).

The generated payment slip will have a different format, referring to a "multiple guide" that will include the fee for all requested changes.

The payment slip details will be displayed on the first page.

 Agência Nacional de Vigilância Sanitária Taxa de Fiscalização de Vigilância Sanitária Guia de Recolhimento da União - GRU Cobrança		Vencimento	11/12/2022
		Número da Guia	4056/2022
		Nº Guia Referência	-
		Valor da Taxa	R\$ 24.800,00
Nome ou Razão Social/Endereço/Fone		Taxa Complementar	-
UNIEQXK WNNHWD NH FINKHUWPHMVK NH NWNXU (UNIFIX)		Valor Multa	-
		Acréscimo Multa	-
CNPJ/CPE: 11.111.111.0001-01		Descontos Multa	-
Tipo da Guia: Normal		Total da Guia	R\$ 24.800,00
Instruções Esta guia é pessoal e intransferível. O uso irregular pode causar, dentre outras implicações, a não identificação do recolhimento. Os valores emitidos por este boleto não são passíveis de descontos. Caso o valor apresentado não corresponda ao enquadramento do porte da empresa, providencie a atualização dos dados conforme a RDC 225/2006.			
Porte: MEDIA - GRUPO IV	Classe:		
Nº Endossatário:	Modalidade:	Número:	Qt. Itens:
Fato(s) Gerador(es): 3034 (2), 38601 (8)			
Nome Endossatário:		Razão Social:	
Número da Transação: 43792022		00190.00009 02941.055002 43792.022170 1 91960002480000	
Válido somente com autenticação bancária.			

BANCO DO BRASIL		001-9	00190.00009 02941.055002 43792.022170 1 91960002480000		
Local de Pagamento					Vencimento
Pagável em qualquer banco até o vencimento					11/12/2022
Cedente					Agência/Unid. Cliente
ANVISA - Agência Nacional de Vigilância Sanitária					1607-1.0335030-1
Data do Documento	Nº do Documento	Espécie Documento	Aceite	Data Process.	Nosso Número
11/11/2022	4056/2022			11/11/2022	43792022
Use do Boleto	Carteira	Espécie	Quantidade	Valor	(=) Valor do Documento
	18	Real		R\$ 24.800,00	R\$ 24.800,00
Instruções					(-) Desconto/Abatimento
NÃO RECEBER ESTE TÍTULO APÓS A DATA DE VENCIMENTO					(-) Outras Deduções
ATENÇÃO:					(-) Multa Multa
ESTA GUIA É PESSOAL E INTRANSFERÍVEL. O USO IRREGULAR PODE CAUSAR A NÃO IDENTIFICAÇÃO DO SEU PAGAMENTO					(-) Outros Acréscimos
Número da Transação: 43792022					(-) Valor Cobrado
 Governo Federal - Guia de Recolhimento da União - GRU - Cobrança.					R\$ 24.800,00
Sacado UNIEQXK WNNHWD NH FINKHUWPHMVK NH NWNXU (UNIFIX) VITÓRIA - ES - 75012200 Sacador/Avalista					
Cód. Baixa					



Autenticação Mecânica - Ficha de Conservação

In the generated payment slip, the "Generating Event(s)" field displays the generating events and a counter that indicates...

How many petitions were created for each triggering event. Ex: **Fato(s) Gerador(es): 3034 (2), 38601 (8)**

The payment slip will display a second page where you can see the data related to the multiple guide (red box), the request related to the process for which the request form was initiated (green box), and the requests for processes related to other active AFEs/AEs (blue box).

Guia Múltipla: 4056
Data: 11/11/2022 15:05:10

Guia Pai						
Ordem	Transação	Processo	Assunto	Guia	Fato Gerador	Valor
1	43792022	25351000035201916	7006-INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança na RAZÃO SOCIAL	4056	3034	R\$ 6000.00

Guias Filhas						
Ordem	Autorização	Processo	Assunto	Guia	Fato Gerador	Valor
1	A000085	253510163030206	7006-INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança na RAZÃO SOCIAL	4057	3034	R\$ 6.000,00
2	1152671	25351003370201968	7013-MEDICAMENTOS - (Alteração na AE) de TRANSPORTADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4058	38601	R\$ 1.600,00
3	1152685	25351025383201998	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4059	38601	R\$ 1.600,00
4	1367254	99999999999999995	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4060	38601	R\$ 1.600,00
5	2009193	25351002851202090	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4061	38601	R\$ 1.600,00
6	4085825	25351001487202041	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4062	38601	R\$ 1.600,00
7	7050902	25351000426202066	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4063	38601	R\$ 1.600,00
8	8999999	99999999999999995	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4064	38601	R\$ 1.600,00
9	9074901	25351213221201601	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4065	38601	R\$ 1.600,00

The payment slip covers all requests, and if the amount paid is less than the amount specified on the slip, **no request will be processed.**

Due to differences in the processing of the forms, it is expected that there will be **an interval of up to 3 hours between the registration of the parent form and the registration of the child form(s).**

After the protocol is submitted, a petition will be created for each process listed in the multiple tab. A protocol receipt will also be made available in the mailbox for each petition created.

The petition extract, available in the processes tab (see previous sections to understand how to access this feature), may show the company name or address that was registered with Anvisa and the company name or address that was registered with the Federal Revenue Service at the time of the user's request, as well as the date the information was updated with the Federal Revenue Service.

Example of the information contained in the address change request statement.

Endereço Conforme Consta na Anvisa:	VITÓRIA-ES, SIA TRECHO 4 AREA ESPECIAL 57 TANGAMANDAPIO 75012200
Data Atualização Receita Federal:	Informação disponibilizada pela Receita Federal em 11/11/2022. Essas informações são atualizadas a cada 3 dias.
Endereço Conforme Consta na Receita Federal:	ASA NORTE-DF, 70836900, BRASIL

Example of the information contained in the statement of requests for change of company name.

Razão Social Conforme Consta na Anvisa:	UHIEQKX WHNHIWD NH FIXKHUUWPHMVX NH NWNXU (UHIFIX)
Data Atualização Receita Federal:	Informação disponibilizada pela Receita Federal em 11/11/2022. Essas informações são atualizadas a cada 3 dias.
Razão Social Conforme Consta na Receita Federal:	UHIEQKX WHNHIWD NH FIXKHUUWPHMVX NH NWNXU (UHIFIX)

Change of Legal Representative and Technical Representative for AFE/AE

This feature is only available for petitions of the type "Companies".

Initiate a petition linked to the AFE (Authorization for Operation) process you wish to modify, following the steps described in this manual. If you do not know the process number linked to the AFE you wish to modify, this information can be obtained through the Company Operation query, "Consult National Company," available at <https://consultas.anvisa.gov.br/#/empresas/empresas/>

Dados da Empresa Nacional		
Razão Social EMPRESA DE TESTE LTDA. (V501)	CNPJ 11.111.111/0001-91	
Nome Fantasia EMPRESA DE TESTE LTDA. (V501)		
Endereço na Internet www.anvisa.gov.br	SAC 1212121212	
Endereço Completo SIA Trecho 5 área especial 57 - Asa Norte CEP: 75.012-200	Cidade/UF VITÓRIA/ES	
Responsável Técnico CAFURA RA	Responsável Legal (sem dados cadastrados)	

Dados do Cadastro		
Cadastro Nº 1.36725-4	Data do Cadastro 19/10/2004	Situação Ativa
Nº do Processo 99999.999999/9999-95	Cadastro 1 - Medicamento	
Atividades / Classes		
Dispensar • Insumos Farmacêuticos • Medicamento		
Manipular • Insumos Farmacêuticos		

Voltar

Select the subject corresponding to the change you wish to make: change of legal representative or change of technical representative.

After the selection, a block of information regarding the legal or technical representative will be made available, depending on the chosen subject.

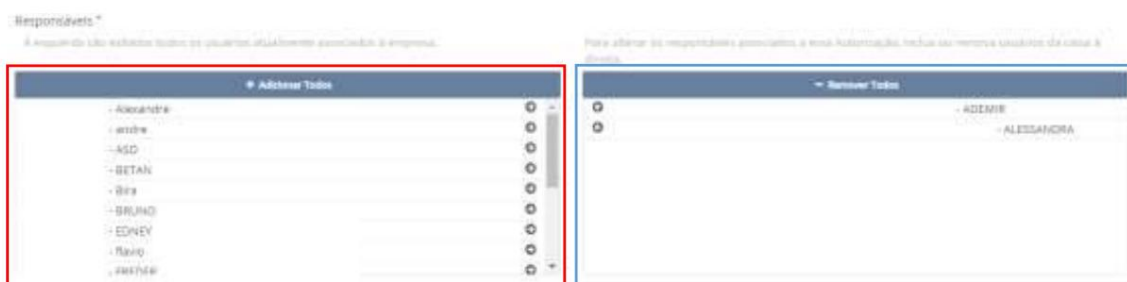


In the first field, the system will indicate which AFE (Authorization for Operation) the request will change the information of the legal representative or technical representative. In the example case, it would be AFE 6074603:

Identificação da Autorização

6074603 - AFE

In the second field, we have two columns, where users are listed with their respective names and CPF numbers (the CPF data and surnames have been hidden in the images to protect the data of the people registered in the system).



The right-hand column, marked in blue, indicates the users who will be updated as legal or technical representatives (depending on the chosen subject) of the company after the request is submitted. When the subject is selected, the right-hand column will contain the users who are currently registered as technical or legal representatives (depending on the chosen subject) for the selected AFE (Authorization for Operation). This information can also be verified in the Company Operation query, as previously mentioned.

The left-hand column, marked in red, indicates all users who can be registered as legal or technical representatives (depending on the chosen subject).

To add a user, click the arrow next to the user's name in the left-hand table, marked in red. The user's name will then automatically be moved to the right-hand table, marked in blue.

To delete a user, click the arrow next to the user's name in the right-hand table, marked in blue. The user's name will then automatically be moved to the left-hand table, marked in red.

If the user was selected incorrectly, they can be removed from the user table.

Included by clicking the arrow next to the user's name in the **right-hand table**, marked in blue. The user's name will automatically be transferred to the **left-hand table**, marked in red.

In the given example, after the request is submitted, users ADEMIR and ALESSANDRA would become the new responsible parties.

Adding a new user to the table on the **right**, marked in blue, is done by entering the user's CPF (Brazilian tax identification number) in the "Associate new responsible party (CPF)" field.

Associar novo responsável (CPF)

Caso o CPF não seja encontrado, acessar os sistemas de cadastro para inserção.

If the user does not yet have registered data, the following error message will appear: "CPF not accepted, please access the registration systems to add it."

In this case, the user will need to be registered by the applicant in the ANVISA registration system.

After completing this step, the user must follow the rest of the workflow, as detailed in previous sections of this manual, until the protocol is finalized.

After the protocol is completed, a message will be sent to your mailbox informing you who will be the company representative(s) after the petition has been filed:



ALTERAÇÃO DE RESPONSÁVEL LEGAL De: GEDOC em 20/05/2020 09:51

Imprimir Fechar

ANVISA
AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA

Petitionamento Eletrônico
Comunicamos a alteração do Responsável Legal da empresa para:

NOME	CPF
ADEMIR	
ALESSANDRA	

Atenciosamente,
Sistema de Petitionamento Eletrônico da ANVISA

The petition extract, available in the processes tab (see previous sections to understand how to access this feature), shows information about the representatives before and after the request was finalized.

Responsáveis Anteriores	
CPF	Nome
Responsáveis Atualizados	
CPF	Nome
	ADEMIR
	ALESSANDRA

Expansion of Business Authorization Activity

This feature is only available for petitions of the type "Companies".

Initiate a petition linked to the AFE (Authorization for Operation) process you wish to modify, following the steps described in this manual. If you do not know the process number linked to the AFE you wish to modify, this information can be obtained through the Company Operation query, "Consult National Company", available at <https://consultas.anvisa.gov.br/#/empresas/empresas/>

Dados da Empresa Nacional

Razão Social
EMPRESA DE TESTE LTDA. (V501)

CNPJ
11.111.111/0001-91

Nome Fantasia
EMPRESA DE TESTE LTDA (V501).

SAC
1212121212

Endereço na Internet
www.anvisa.gov.br

Cidade/UF
VITÓRIA/ES

Endereço Completo
SIA Trecho 5 area especial 57 - Asa Norte CEP: 75.012-200

Responsável Legal
(sem dados cadastrados)

Responsável Técnico
CAFURA RA.

Dados do Cadastro

Cadastro Nº
1.36725-4

Data do Cadastro
19/10/2004

Situação
Ativa

Nº do Processo
99999.999999/9999-95

Cadastro
1 - Medicamento

Atividades / Classes

Dispensar

- Insumos Farmacêuticos
- Medicamento

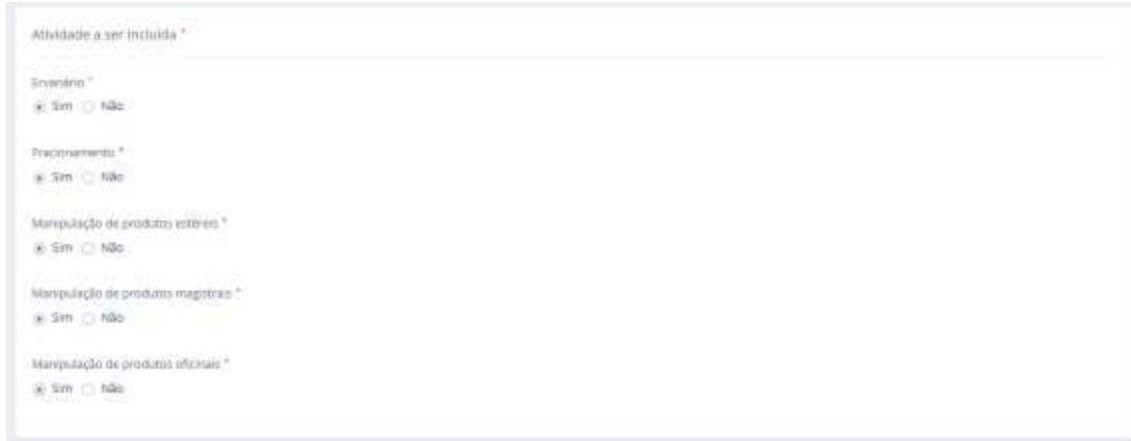
Manipular

- Insumos Farmacêuticos

Voltar

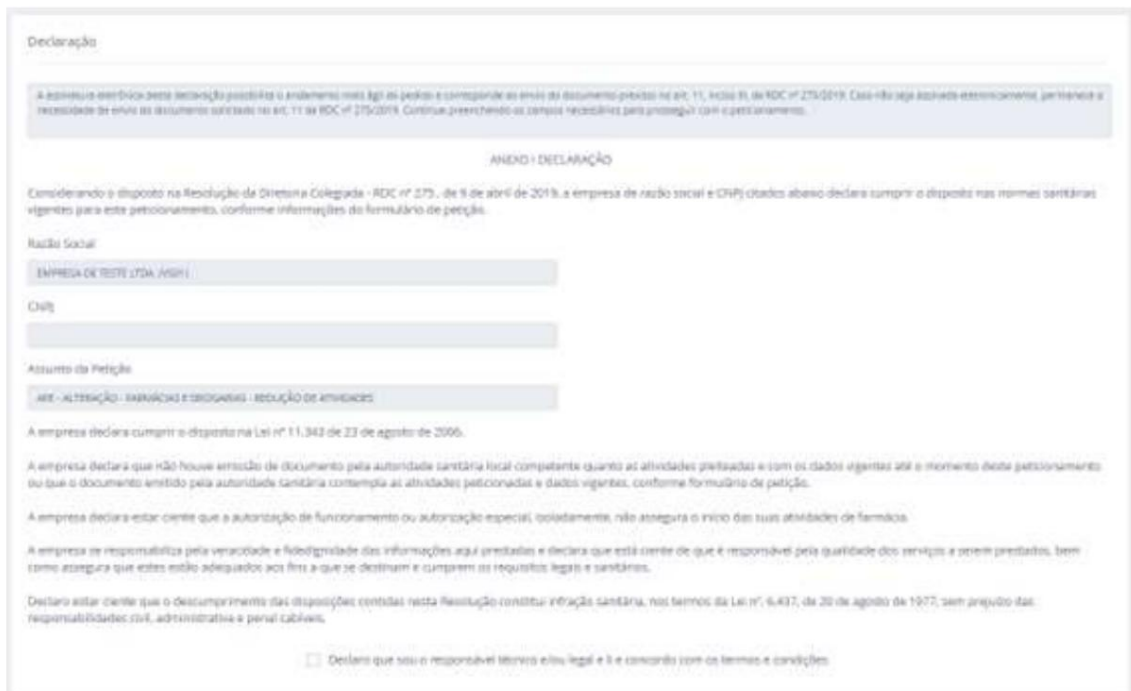
Select the topic that corresponds to the activity expansion.

After the selection, an information block regarding the "Activity to be included" will be available. The form will display which eligible activities can be requested according to the AFE (Authorization for Economic Activity) granted in the chosen process.



Please note that it will not be possible to request an expansion of activity for an authorization if all classes possible ones are already authorized.

The "Declaration" section is only available in cases of changes to a Pharmacy or Drugstore AFE (Authorization for Operation).



By clicking the checkbox:

☐ Declaro que sou o responsável técnico e/ou legal e li e concordo com os termos e condições

The user declares that they comply with the provisions of RDC No. 275, of April 9, 2019, and this allows for a faster analysis of the request by Anvisa than if the same self-declaration were sent as an attachment.

Important! If the person filing the petition is not the legal or technical representative, but wishes to file using the electronic self-declaration, we suggest that the petition be saved as a Draft and completed later by the company's technical or legal representative.

After completing this step, the user must follow the rest of the workflow, as detailed in previous sections of this manual, until the protocol is finalized.

Expansion of Company Authorization Class

This feature is only available for petitions of the type "Companies".

Initiate a petition linked to the AFE (Authorization for Operation) process you wish to modify, following the steps described in this manual. If you do not know the process number linked to the AFE you wish to modify, this information can be obtained through the Company Operation query, "Consult National Company," available at <https://consultas.anvisa.gov.br/#/empresas/empresas/>

Dados da Empresa Nacional		
Razão Social EMPRESA DE TESTE LTDA. (V501)	CNPJ 11.111.111/0001-91	
Nome Fantasia EMPRESA DE TESTE LTDA (V501)		
Endereço na Internet www.anvisa.gov.br	SAC 1212121212	
Endereço Completo SIA Trecho 5 área especial 57 - Asa Norte CEP: 75.012-200	Cidade/UF VITÓRIA/ES	
Responsável Técnico CAFLURA RA	Responsável Legal (sem dados cadastrados)	

Dados do Cadastro		
Cadastro Nº 1.36725-4	Data do Cadastro 19/10/2004	Situação Ativa
Nº do Processo 99999.999999/9999.95	Cadastro 1 - Medicamento	
Atividades / Classes		
Dispensar		
• Insumos Farmacêuticos • Medicamento		
Manipular		
• Insumos Farmacêuticos		

Voltar

Select the topic that corresponds to the class extension.

After the selection, a block of information regarding "Class to be Included" will be made available.

The form will display which classes can be requested according to the AFE granted in the process.
chosen.

Classe a ser Incluída *

Armazenar

☐ Insumos Farmacêuticos

Distribuir

☐ Insumos Farmacêuticos

Expedir

☐ Insumos Farmacêuticos

Please note that it will not be possible to request the expansion of classes for an authorization if all classes
Possible ones are already authorized.

Important! If the person filing the petition is not the legal or technical representative, but wishes to file using the electronic self-declaration, we suggest that the petition be saved as a Draft and completed later by the company's technical or legal representative.

After completing this step, the user must follow the rest of the workflow, as detailed in previous sections of this manual, until the protocol is finalized.

REDUCTION OF BUSINESS AUTHORIZATION ACTIVITY

This feature is only available for petitions of the type "Companies".

Initiate a petition linked to the AFE (Authorization for Operation) process you wish to modify, following the steps described in this manual. If you do not know the process number linked to the AFE you wish to modify, this information can be obtained through the Company Operation query, "Consult National Company," available at <https://consultas.anvisa.gov.br/#!/empresas/empresas/>

Dados da Empresa Nacional		
Razão Social EMPRESA DE TESTE LTDA. (V501)	CNPJ 11.111.111/0001-91	
Nome Fantasia EMPRESA DE TESTE LTDA (V501)		
Endereço na Internet www.anvisa.gov.br	SAC 1212121212	
Endereço Completo SIA Trecho 5 area especial 57 - Asa Norte CEP: 75.012-200	Cidade/UF VITÓRIA/ES	
Responsável Técnico CAFURA RA	Responsável Legal (sem dados cadastrados)	

Dados do Cadastro		
Cadastro Nº 1.36725-4	Data do Cadastro 19/10/2004	Situação Ativa
Nº do Processo 99999.999999/9999-95	Cadastro 1 - Medicamento	
Atividades / Classes		
Dispensar		
• Insumos Farmacêuticos • Medicamento		
Manipular		
• Insumos Farmacêuticos		

[Voltar](#)

Select the topic that corresponds to the reduction in activity.

After the selection, a block of information regarding "Activity to be Excluded" will be available. The form will display which activities are eligible for exclusion according to the AFE (Authorization for Economic Activity) granted in the chosen process.

Atividade a ser Excluída (7)

Comércio *

☐ Sim ☐ Não

Dispensação de medicamentos contendo substâncias sujeitas ao controle especial *

☐ Sim ☐ Não

Dispensação de medicamentos não sujeitos ao controle especial

☒ Sim ☐ Não

Ervariano *

☐ Sim ☐ Não

Fracimentos *

☐ Sim ☐ Não

Manipulação de produtos antineoplásicos *

☐ Sim ☐ Não

Manipulação de produtos magistrais *

☐ Sim ☐ Não

Manipulação de produtos oftálmicos *

☐ Sim ☐ Não

Prestação de Serviços Farmacêuticos *

☐ Sim ☐ Não

In this section, mandatory activities are pre-filled with the option "no," and it is not possible to change them to "yes." Note that deleting an Activity will delete all related Classes automatically.

The "Declaration" section is only available in cases of changes to a Pharmacy or Drugstore AFE (Authorization for Operation).

Declaração

A aquisição eletrônica desta declaração possibilita o andamento mais ágil do pedido e correspondente ao envio do documento previsto no art. 11, inciso II, da RDC nº 275/2018. Caso não seja assinado eletronicamente, permanece a necessidade de envio do documento assinado no art. 11 da RDC nº 275/2018. Continue preenchendo os campos necessários para prosseguir com o posicionamento.

ANEXO I - DECLARAÇÃO

Considerando o disposto na Resolução da Diretoria Colegiada - RDC nº 275, de 9 de abril de 2018, a empresa de razão social e CNPJ citados abaixo declara cumprir o disposto nas normas sanitárias vigentes para este posicionamento, conforme informações do formulário de petição.

Razão Social:

EMPRESA DE TESTE LTDA /VISHI

CNPJ:

Assunto da Petição:

AFE - Alteração - Expansão e reorganização - redução de funcionários

A empresa declara cumprir o disposto na Lei nº 11.343 de 23 de agosto de 2006.

A empresa declara que não houve emissão de documento pela autoridade sanitária local competente quanto às atividades prestadas e com os dados vigentes até o momento deste posicionamento ou que o documento emitido pela autoridade sanitária contempla as atividades solicitadas e dados vigentes, conforme formulário de petição.

A empresa declara estar ciente que a autorização de funcionamento ou autorização especial, isoladamente, não assegura o início das suas atividades de farmácia.

A empresa se responsabiliza pela veracidade e fidelidade das informações aqui prestadas e declara que está ciente de que é responsável pela qualidade dos serviços e produtos prestados, bem como assegura que estes estão adequados aos fins a que se destinam e cumprem os requisitos legais e sanitários.

Declaro estar ciente que o descumprimento das disposições contidas nesta Resolução constitui infração sanitária, nos termos da Lei nº 6.437, de 20 de agosto de 1977, sem prejuízo das responsabilidades civil, administrativa e penal cabíveis.

☐ Declaro que sou o responsável técnico e sou legal e li e concordo com os termos e condições.

By clicking the checkbox



MNU - User Manual

☐ Declaro que sou o responsável técnico e/ou legal e li e concordo com os termos e condições

The user declares that they will comply with the provisions of RDC No. . dated April 9, 2019, and makes a more thorough analysis possible. 275, which expedites the processing of the request by Anvisa, rather than submitting the same self-declaration as an attachment.

Important! If the person filing the petition is not the legal or technical representative, but wishes to file using the electronic self-declaration, we suggest that the petition be saved as a Draft and completed later by the company's technical or legal representative.

After completing this step, the user must follow the rest of the workflow, as detailed in previous sections of this manual, until the protocol is finalized.

Reduction in Company Authorization Class

This feature is only available for petitions of the type "Companies".

Initiate a petition linked to the AFE (Authorization for Operation) process you wish to modify, following the steps described in this manual. If you do not know the process number linked to the AFE you wish to modify, this information can be obtained through the Company Operation query, "Consult National Company," available at <https://consultas.anvisa.gov.br/#/empresas/empresas/>

Dados da Empresa Nacional		
Razão Social EMPRESA DE TESTE LTDA. (V501)	CNPJ 11.111.111/0001-91	
Nome Fantasia EMPRESA DE TESTE LTDA (V501)		
Endereço na Internet www.anvisa.gov.br	SAC 1212121212	
Endereço Completo SIA Trecho 5 area especial 57 - Asa Norte CEP: 75.012-200	Cidade/UF VITÓRIA/ES	
Responsável Técnico CAFURA RA	Responsável Legal (sem dados cadastrados)	

Dados do Cadastro		
Cadastro Nº 1.36725-4	Data do Cadastro 19/10/2004	Situação Ativa
Nº do Processo 99999.999999/9999-95	Cadastro 1 - Medicamento	
Atividades / Classes		
Dispensar		
• Insumos Farmacêuticos • Medicamento		
Manipular		
• Insumos Farmacêuticos		

[Voltar](#)

Select the subject corresponding to the Class reduction.

After the selection, a block of information regarding "Class to be Excluded" will be made available. The form will display which classes are eligible for exclusion according to the AFE granted in the chosen process.

Classe a ser Excluída

Exportar

- ☒ Cosmético
- ☒ Perfume
- ☐ Prod. de Higiene

Fabricar

- ☐ Cosmético
- ☐ Perfume
- ☐ Prod. de Higiene

Importar

- ☐ Cosmético
- ☐ Perfume
- ☐ Prod. de Higiene

Produzir

- ☐ Cosmético
- ☐ Perfume
- ☐ Prod. de Higiene

In this section, the required activities are pre-filled with the option "no," and it is not possible to change them to "yes."

Please note that it is not possible to delete all classes from an Activity. **If you really want to delete all Classes, please submit a petition to reduce the Activity.**

Important! If the person filing the petition is not the legal or technical representative, but wishes to file using the electronic self-declaration, we suggest that the petition be saved as a Draft and completed later by the company's technical or legal representative.

After completing this step, the user must follow the rest of the workflow, as detailed in previous sections of this manual, until the protocol is finalized.

CHANGE OF ADDRESS FOR FOOD REGISTRATION

This feature is only available for petitions of the type "Food/Alimony".

Initiate a petition linked to the Food Registration process that you wish to modify, following the steps described in this manual. If you do not know the process number linked to the registration that...

If you wish to make changes, the information can be obtained through the Business Operations query, "Consult National Company", available at <https://consultas.anvisa.gov.br/#/empresas/empresas/>



Select the subject corresponding to the change you wish to make: address change or company name change. The list of subject codes is available for consultation at the following link: <https://consultas.anvisa.gov.br/#/consultadeassuntos/>

The information block will provide both the address as it currently appears in the Anvisa (Brazilian Health Regulatory Agency) registry and the address as it appears in the Federal Revenue Service database.



The information from the Federal Revenue Service is updated every 3 days, and this information is available on the form. from the date of the last update. Ex: **Informação disponibilizada pela Receita Federal em 10/11/2022.**

If there is a discrepancy between the information displayed on the form and the Federal Revenue Service database, check the date of the last update. If there is still a discrepancy between the data, contact the responsible department so that the reason for the problem can be investigated.

Active AFEs/AEs field: This will be displayed if the selected company has processes with active AFEs/AEs.

AFEs/AEs Ativas

Por força legal, a alteração de razão social precisa ser peticionada em todas as AFEs/AEs ativas da empresa. Deseja peticionar para todos os processos? *

☐ Sim ☐ Não

Initially, the user will be asked if they want to make the same change for all active authorizations.

If the user selects the "No" option, a checkbox will be displayed for the user to declare that they are aware that failure to submit to all processes may result in the rejection of the request.

☐ Declaro que estou ciente que a não submissão para todos os processos poderá ensejar o indeferimento da solicitação. *

In this workflow, checking the checkbox is mandatory, and failure to check it will prevent the request from being submitted.

If the user selects the "Yes" option, an interface will be made available where all valid authorizations for the company will be displayed, as well as the process related to that authorization.

If an active authorization is not displayed or an inactive authorization is displayed, please contact the area responsible for authorization so that the Anvisa team can assess the situation.

☒ Sim ☐ Não

Nº	AUTORIZAÇÃO	PROCESSO	ASSUNTO	FATOR GERADOR	VALOR	AÇÕES
1	A000085	253510163030206				
2	1152671	25351003370201968				
3	1152685	25351025383201998				
4	1367254	9999999999999995				
5	2009193	25351002851202090				
6	4085825	25351001487202041				
7	7050902	25351000426202066				
8	8999999	9999999999999995				
9	9074901	25351213221201601				

Click the edit option in the actions column.

Nº	AUTORIZAÇÃO	PROCESSO	ASSUNTO	FATOR GERADOR	VALOR	AÇÕES
1	A000085	253510163030206				

A new modal will be displayed for selecting the subject; clicking on the magnifying glass  which will be used for will allow you to file a petition of the same type of request selected at the beginning of the workflow.

AFEs ou AEs Ativas

Autorização

A000085

Processo

253510163030206

Assunto *

Q

Fato Gerador

Porte da Empresa

Valor da Taxa

Nº

ITEM

OBRIGATÓRIO

ARQUIVOS

AÇÕES

Nenhum item foi adicionado.

Confirmar

Cancelar

If an address change subject was selected at the beginning of the form, the system will only display address change subjects. Similarly, if a company name change subject was selected, the system will only display company name change subjects in the modal.

Selecione o assunto

Atividade/Tipo de produto

Selecione

Serviço

Código

Descrição

Q Pesquisar

Código	Atividade/Tipo de Produto	Descrição	
7003	Empresas	MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de EXPORTADORA do produto sujeito a Controle Especial - ENDEREÇO DA SEDE	→

When you select a subject, the modal will display the fee associated with that request and the *checklist* items for attaching the requested documents.

AFEs ou AEs Ativas

Autorização		Processo	
A000085		253510163030206	
Assunto			
INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança do ENDEREÇO DA SEDE			
Fato Gerador	Porte da Empresa	Valor da Taxa	
38601	MEDIA - GRUPO IV	R\$ 1.600,00	

Nº	ITEM	OBRIGATÓRIO	ARQUIVOS	AÇÕES
1	Formulário de Petição devidamente assinado e preenchido	Sim		
2	Comprovante de pagamento, ou de isenção, da Taxa de Fiscalização de Vigilância Sanitária (TFVS), mediante Guia de Recolhimento da União (GRU) específica	Não		
3	Relatório de inspeção ou documento equivalente que ateste o cumprimento dos requisitos técnicos para as atividades e classes pleiteadas, emitidos pela autoridade sanitária local competente ou licença sanitária vigente com os dados atualizados	Não		



After attaching the requested documents, click confirm.

The interface will be updated to display the selected subject, its generating event, and the associated rate.

Nº	AUTORIZAÇÃO	PROCESSO	ASSUNTO	FATOR GERADOR	VALOR	AÇÕES
1	A000085	253510163030206	INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança do ENDEREÇO DA SEDE	38601	R\$ 1.600,00	

If you wish to change the selected subject or the attached documents, simply click on the edit icon.

Continue filling in the subjects for each of the processes, always keeping in mind the need to choose the most appropriate subject for each type of authorization that will be updated.

After filling in the information regarding all processes related to the registration of active food products or AFEs (Authorization for Operation) or AEs (Authorization for Establishment), the user must check the box indicating that the "attached documentation is valid and that all information is legitimate". In addition, the user will also acknowledge that "there may be a difference of up to 3 hours between the main protocol and the remaining AFEs/AEs".

☒ Declaro que visualizei a documentação anexada e que todas as informações são legítimas. Estou ciente de que pode haver uma diferença de até 3 horas entre o protocolo principal e o restante das AFEs/AEs. *

After completing the Active AFEs/AEs section, the user must insert the documents related to the subject selected at the beginning of the form.

Documentação

Nº	ITEM	OBRIGATORIO	ARQUIVOS	AÇÕES
1	Formulário de Petição devidamente assinado e preenchido	Sim		
2	Comprovante de pagamento, ou de isenção, da Taxa de Fiscalização de Vigilância Sanitária (TFVS), mediante Guia de Recolhimento da União (GRU) específica	Não		
3	Relatório de inspeção ou documento equivalente que ateste o cumprimento dos requisitos técnicos para as atividades e classes pleiteadas, emitidos pela autoridade sanitária local competente ou licença sanitária vigente com os dados atualizados	Não		
4	ATENÇÃO: A licença sanitária, o relatório de inspeção ou o documento equivalente devem informar explicitamente que o estabelecimento cumpre os requisitos de controle especial constantes da Portaria SVS/MS nº 344, de 1998 e da Portaria SVS/MS nº 6, de 1999, ou atos normativos posteriores que vierem a substituí-las.	Não		

Fechar

Validar

Salvar

Enviar

By clicking submit

Enviar

The user should view the documents related to the request that...

This gave rise to the form.

Confirmação de envio



⚠ Atenção! Antes de confirmar o envio é necessário visualizar todos os anexos.
Ao confirmar o envio a petição será protocolada e não será possível realizar a alteração das informações.

Nº	Item	Anexos	Visualizado
1	Formulário de Petição devidamente assinado e preenchido	1.pdf	Não
2	Comprovante de pagamento, ou de isenção, da Taxa de Fiscalização de Vigilância Sanitária (TFVS), mediante Guia de Recolhimento da União (GRU) específica		
3	Cadastro Nacional de Pessoa Jurídica (CNPJ) com dados atualizados		

Cancelar

Confirmar Envio

After viewing all the files, the user must click the "Confirm Submission" button.

If the total amount of the requests results in an exempt value, the requests will be registered, generating the documents and their respective registration receipts.

If the total of the requests results in a value that does not qualify for exemption, the payment selection screen will be displayed.

Petição aguardando pagamento



Favorecido:	11.111.111/0001-91 - UHIEQKX WHNHIWD NH FIXKHUUWPHMVX NH NWNXU (UHIFIX)
Assunto:	7006 - INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança na RAZÃO SOCIAL
Número de Transação:	43792022
 Selecionar Pagamento	

Concluir

By clicking on "select payment," you will be able to generate the GRU (payment slip) or activate PagTeseuro (a payment processing system).

The generated payment slip will have a different format, referring to a "multiple guide" that will include the fee for all requested changes.

The payment slip details will be displayed on the first page.

 Agência Nacional de Vigilância Sanitária Taxa de Fiscalização de Vigilância Sanitária Guia de Recolhimento da União - GRU Cobrança		Vencimento	11/12/2022
		Número da Guia	4056/2022
		Nº Guia Referência	-
		Valor da Taxa	R\$ 24.800,00
Nome ou Razão Social/Endereço/Fone: UHE QXK WNNHWD NH FINKHUWPHMVK NH NWNXU (UHIFIX)		Taxa Complementar	-
		Valor Multa	-
		Acréscimo Multa	-
CNPJ/CPE: 11.111.111.0001-01		Descontos Multa	-
Tipo da Guia: Normal		Total da Guia	R\$ 24.800,00
Instruções Esta guia é pessoal e intransferível. O uso irregular pode causar, dentre outras implicações, a não identificação do recolhimento. Os valores emitidos por este boleto não são passíveis de descontos. Caso o valor apresentado não corresponda ao enquadramento do porte da empresa, providencie a atualização dos dados conforme a RDC 225/2006.			
Porte: MEDIA - GRUPO IV		Classe:	
Nº Embrascos:		Modalidade:	Número:
Fato(s) Gerador(es): 3034 (2), 38601 (8)			Qt. Itens:
Nome Embrascos:		Bandeira:	
Número da Transação: 43792022		00190.00009 02941.055002 43792.022170 1 91960002480000	
Válido somente com autenticação bancária.			

BANCO DO BRASIL		001-9	00190.00009 02941.055002 43792.022170 1 91960002480000		
Local de Pagamento					Vencimento
Pagável em qualquer banco até o vencimento					11/12/2022
Cedente					Agência/Unid. Cliente
ANVISA - Agência Nacional de Vigilância Sanitária					1607-1.0335030-1
Data do Documento	Nº do Documento	Espécie Documento	Acerto	Data Process.	Nosso Número
11/11/2022	4056/2022			11/11/2022	43792022
Use do Boleto	Carteira	Espécie	Quantidade	Valor	(=) Valor do Documento
	18	Real		R\$ 24.800,00	R\$ 24.800,00
Instruções					(-) Desconto/Abatimento
NÃO RECEBER ESTE TÍTULO APÓS A DATA DE VENCIMENTO					(-) Outras Deduções
ATENÇÃO:					(-) Multa Multa
ESTA GUIA É PESSOAL E INTRANSFERÍVEL. O USO IRREGULAR PODE CAUSAR A NÃO IDENTIFICAÇÃO DO SEU PAGAMENTO					(-) Outros Acréscimos
Número da Transação: 43792022					(-) Valor Cobrado
 Governo Federal - Guia de Recolhimento da União - GRU - Cobrança.					R\$ 24.800,00
Sacado: UHE QXK WNNHWD NH FINKHUWPHMVK NH NWNXU (UHIFIX) VITÓRIA - ES - 75012200 Sacador/Avalista:					
Cod. Baixa					



Autenticação Mecânica - Ficha de Conservação

In the generated payment slip, the "Generating Event(s)" field displays the generating events and a counter that indicates...

How many petitions were created for each triggering event. Ex: **Fato(s) Gerador(es): 3034 (2), 38601 (8)**

The payment slip will display a second page where you can see the data related to the multiple guide (red box), the request related to the process for which the request form was initiated (green box), and the requests for processes related to other active AFEs/AEs (blue box).

Guia Múltipla: 4056
Data: 11/11/2022 15:05:10

Guia Pai						
Ordem	Transação	Processo	Assunto	Guia	Fato Gerador	Valor
1	43792022	25351000035201916	7006-INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança na RAZÃO SOCIAL	4056	3034	R\$ 6000.00

Guias Filhas						
Ordem	Autorização	Processo	Assunto	Guia	Fato Gerador	Valor
1	A000085	253510163030206	7006-INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança na RAZÃO SOCIAL	4057	3034	R\$ 6.000,00
2	1152671	25351003370201968	7013-MEDICAMENTOS - (Alteração na AE) de TRANSPORTADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4058	38601	R\$ 1.600,00
3	1152685	25351025383201998	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4059	38601	R\$ 1.600,00
4	1367254	99999999999999995	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4060	38601	R\$ 1.600,00
5	2009193	25351002851202090	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4061	38601	R\$ 1.600,00
6	4085825	25351001487202041	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4062	38601	R\$ 1.600,00
7	7050902	25351000426202066	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4063	38601	R\$ 1.600,00
8	8999999	99999999999999995	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4064	38601	R\$ 1.600,00
9	9074901	25351213221201601	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4065	38601	R\$ 1.600,00

The payment slip covers all requests, and if the amount paid is less than the amount specified on the slip, **no request will be processed.**

Due to differences in the processing of the forms, it is expected that there will be **an interval of up to 3 hours between the registration of the parent form and the registration of the child form(s).**

After the protocol is submitted, a petition will be created for each process listed in the multiple tab. A protocol receipt will also be made available in the mailbox for each petition created.

The petition extract, available in the processes tab (see previous sections to understand how to access this feature), may show the company name or address that was registered with Anvisa and the company name or address that was registered with the Federal Revenue Service at the time of the user's request, as well as the date the information was updated with the Federal Revenue Service.

Example of the information contained in the address change request statement.

Endereço Conforme Consta na Anvisa:	VITÓRIA-ES, SIA TRECHO 4 AREA ESPECIAL 57 TANGAMANDAPIO 75012200
Data Atualização Receita Federal:	Informação disponibilizada pela Receita Federal em 11/11/2022. Essas informações são atualizadas a cada 3 dias.
Endereço Conforme Consta na Receita Federal:	ASA NORTE-DF, 70836900, BRASIL

Example of the information contained in the statement of requests for change of company name.

Razão Social Conforme Consta na Anvisa:	UHIEQKX WHNHIWD NH FIXKHUUWPHMVX NH NWNXU (UHIFIX)
Data Atualização Receita Federal:	Informação disponibilizada pela Receita Federal em 11/11/2022. Essas informações são atualizadas a cada 3 dias.
Razão Social Conforme Consta na Receita Federal:	UHIEQKX WHNHIWD NH FIXKHUUWPHMVX NH NWNXU (UHIFIX)

Change of company name for food registration.

This feature is only available for petitions of the type "Food/Alimony".

Initiate a petition linked to the Alimony registration process that you wish to modify, following the steps described in this manual. If you do not know the process number linked to the Alimony registration that...

If you wish to make changes, the information can be obtained through the Business Operations query, "Consult National Company", available at <https://consultas.anvisa.gov.br/#/empresas/empresas/>



Select the subject corresponding to the change you wish to make: address change or company name change. The list of subject codes is available for consultation at the following link: <https://consultas.anvisa.gov.br/#/consultadeassuntos/>

The information block will include the company name as it currently appears in the Anvisa registry and the company name as it appears in the Federal Revenue database.



The information from the Federal Revenue Service is updated every 3 days, and this information is available on the form.

from the date of the last update. Ex: **Informação disponibilizada pela Receita Federal em 10/11/2022.**

If there is a discrepancy between the information displayed on the form and the Federal Revenue Service database, check the date of the last update. If there is still a discrepancy between the data, contact the responsible department so that the reason for the problem can be investigated.

Active AFEs/AEs field: This will be displayed if the selected company has processes with active AFEs/AEs.

AFEs/AEs Ativas

Por força legal, a alteração de razão social precisa ser peticionada em todas as AFEs/AEs ativas da empresa. Deseja peticionar para todos os processos? *

☐ Sim ☐ Não

Initially, the user will be asked if they want to make the same change for all active authorizations.

If the user selects the "No" option, a checkbox will be displayed for the user to declare that they are aware that failure to submit to all processes may result in the rejection of the request.

☐ Declaro que estou ciente que a não submissão para todos os processos poderá ensejar o indeferimento da solicitação. *

In this workflow, checking the checkbox is mandatory, and failure to check it will prevent the request from being submitted.

If the user selects the "Yes" option, an interface will be made available where all valid authorizations for the company will be displayed, as well as the process related to that authorization.

If an active authorization is not displayed or an inactive authorization is displayed, please contact the area responsible for authorization so that the Anvisa team can assess the situation.

☒ Sim ☐ Não

Nº	AUTORIZAÇÃO	PROCESSO	ASSUNTO	FATOR GERADOR	VALOR	AÇÕES
1	A000085	253510163030206				
2	1152671	25351003370201968				
3	1152685	25351025383201998				
4	1367254	9999999999999995				
5	2009193	25351002851202090				
6	4085825	25351001487202041				
7	7050902	25351000426202066				
8	8999999	9999999999999995				
9	9074901	25351213221201601				

Click the edit option in the actions column.

Nº	AUTORIZAÇÃO	PROCESSO	ASSUNTO	FATOR GERADOR	VALOR	AÇÕES
1	A000085	253510163030206				

A new modal will be displayed for selecting the subject; clicking on the magnifying glass  which will be used for will allow you to file a petition of the same type of request selected at the beginning of the workflow.

AFEs ou AEs Ativas

Autorização

A000085

Processo

253510163030206

Assunto *

Q

Fato Gerador

Porte da Empresa

Valor da Taxa

Nº

ITEM

OBRIGATÓRIO

ARQUIVOS

AÇÕES

Nenhum item foi adicionado.

Confirmar

Cancelar

If an address change subject was selected at the beginning of the form, the system will only display address change subjects. Similarly, if a company name change subject was selected, the system will only display company name change subjects in the modal.

Selecione o assunto

Atividade/Tipo de produto

Selecione

Serviço

Código

Descrição

Q Pesquisar

Código	Atividade/Tipo de Produto	Descrição	
7003	Empresas	MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de EXPORTADORA do produto sujeito a Controle Especial - ENDEREÇO DA SEDE	→

When you select a subject, the modal will display the fee associated with that request and the *checklist* items for attaching the requested documents.

AFEs ou AEs Ativas

Autorização		Processo	
A000085		253510163030206	
Assunto			
INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança do ENDEREÇO DA SEDE			
Fato Gerador	Porte da Empresa	Valor da Taxa	
38601	MEDIA - GRUPO IV	R\$ 1.600,00	

Nº	ITEM	OBRIGATÓRIO	ARQUIVOS	AÇÕES
1	Formulário de Petição devidamente assinado e preenchido	Sim		
2	Comprovante de pagamento, ou de isenção, da Taxa de Fiscalização de Vigilância Sanitária (TFVS), mediante Guia de Recolhimento da União (GRU) específica	Não		
3	Relatório de inspeção ou documento equivalente que ateste o cumprimento dos requisitos técnicos para as atividades e classes pleiteadas, emitidos pela autoridade sanitária local competente ou licença sanitária vigente com os dados atualizados	Não		



After attaching the requested documents, click confirm.

The interface will be updated to display the selected subject, its generating event, and the associated rate.

Nº	AUTORIZAÇÃO	PROCESSO	ASSUNTO	FATOR GERADOR	VALOR	AÇÕES
1	A000085	253510163030206	INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança do ENDEREÇO DA SEDE	38601	R\$ 1.600,00	

If you wish to change the selected subject or the attached documents, simply click on the edit icon.

Continue filling in the subjects for each of the processes, always keeping in mind the need to choose the most appropriate subject for each type of authorization that will be updated.

After filling in the information regarding all processes related to the registration of active food products or AFEs (Authorization for Operation) or AEs (Authorization for Establishment), the user must check the box indicating that the "attached documentation is valid and that all information is legitimate". In addition, the user will also acknowledge that "there may be a difference of up to 3 hours between the main protocol and the remaining AFEs/AEs".

☒ Declaro que visualizei a documentação anexada e que todas as informações são legítimas. Estou ciente de que pode haver uma diferença de até 3 horas entre o protocolo principal e o restante das AFEs/AEs. *

After completing the Active AFEs/AEs section, the user must insert the documents related to the subject selected at the beginning of the form.

Documentação

Nº	ITEM	OBRIGATORIO	ARQUIVOS	AÇÕES
1	Formulário de Petição devidamente assinado e preenchido	Sim		
2	Comprovante de pagamento, ou de isenção, da Taxa de Fiscalização de Vigilância Sanitária (TFVS), mediante Guia de Recolhimento da União (GRU) específica	Não		
3	Relatório de inspeção ou documento equivalente que ateste o cumprimento dos requisitos técnicos para as atividades e classes pleiteadas, emitidos pela autoridade sanitária local competente ou licença sanitária vigente com os dados atualizados	Não		
4	ATENÇÃO: A licença sanitária, o relatório de inspeção ou o documento equivalente devem informar explicitamente que o estabelecimento cumpre os requisitos de controle especial constantes da Portaria SVS/MS nº 344, de 1998 e da Portaria SVS/MS nº 6, de 1999, ou atos normativos posteriores que vierem a substituí-las.	Não		

By clicking submit



The user should view the documents related to the request that...

This gave rise to the form.

Confirmação de envio



⚠ Atenção! Antes de confirmar o envio é necessário visualizar todos os anexos.
Ao confirmar o envio a petição será protocolada e não será possível realizar a alteração das informações.

Nº	Item	Anexos	Visualizado
1	Formulário de Petição devidamente assinado e preenchido	1.pdf	Não
2	Comprovante de pagamento, ou de isenção, da Taxa de Fiscalização de Vigilância Sanitária (TFVS), mediante Guia de Recolhimento da União (GRU) específica		
3	Cadastro Nacional de Pessoa Jurídica (CNPJ) com dados atualizados		

After viewing all the files, the user must click the "Confirm Submission" button.

If the total amount of the requests results in an exempt value, the requests will be registered, generating the documents and their respective registration receipts.

If the total of the requests results in a value that does not qualify for exemption, the payment selection screen will be displayed.

Petição aguardando pagamento



Favorecido:	11.111.111/0001-91 - UHIEQKX WHNHIWD NH FIXKHUUWPHMVX NH NWNXU (UHIFIX)
Assunto:	7006 - INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança na RAZÃO SOCIAL
Número de Transação:	43792022
 Selecionar Pagamento	

Concluir

By clicking on "select payment," you will be able to generate the GRU (payment slip) or activate PagTesouro (a payment processing system).

The generated payment slip will have a different format, referring to a "multiple guide" that will include the fee for all requested changes.

The payment slip details will be displayed on the first page.

 Agência Nacional de Vigilância Sanitária Taxa de Fiscalização de Vigilância Sanitária Guia de Recolhimento da União - GRU Cobrança		Vencimento	11/12/2022
		Número da Guia	4056/2022
		Nº Guia Referência	-
		Valor da Taxa	R\$ 24.800,00
Nome ou Razão Social/Endereço/Fone: UNIEQXK WNNHWD NH FINKHUWPHMVK NH NWNXU (UNIFIX)		Taxa Complementar	-
		Valor Multa	-
		Acréscimo Multa	-
CNPJ/CPE: 11.111.111.0001-01		Descontos Multa	-
Tipo da Guia: Normal		Total da Guia	R\$ 24.800,00
Instruções Esta guia é pessoal e intransferível. O uso irregular pode causar, dentre outras implicações, a não identificação do recolhimento. Os valores emitidos por este boleto não são passíveis de descontos. Caso o valor apresentado não corresponda ao enquadramento do porte da empresa, providencie a atualização dos dados conforme a RDC 225/2006.			
Porte: MEDIA - GRUPO IV		Classe:	
Nº Endossatário:		Modalidade:	Número:
Fato(s) Gerador(es): 3034 (2), 38601 (8)			Qt. Itens:
Nome Endossatário:		Razão Social:	
Número da Transação: 43792022		00190.00009 02941.055002 43792.022170 1 91960002480000	
Válido somente com autenticação bancária.			

BANCO DO BRASIL		001-9	00190.00009 02941.055002 43792.022170 1 91960002480000		
Local de Pagamento					Vencimento
Pagável em qualquer banco até o vencimento					11/12/2022
Cedente					Agência/Unid. Cliente
ANVISA - Agência Nacional de Vigilância Sanitária					1607-1.0335030-1
Data do Documento	Nº do Documento	Espécie Documento	Acerto	Data Process.	Nosso Número
11/11/2022	4056/2022			11/11/2022	43792022
Use do Boleto	Carteira	Espécie	Quantidade	Valor	(=) Valor do Documento
	18	Real		R\$ 24.800,00	R\$ 24.800,00
Instruções					(-) Desconto/Abatimento
NÃO RECEBER ESTE TÍTULO APÓS A DATA DE VENCIMENTO					(-) Outras Deduções
ATENÇÃO:					(-) Multa Multa
ESTA GUIA É PESSOAL E INTRANSFERÍVEL. O USO IRREGULAR PODE CAUSAR A NÃO IDENTIFICAÇÃO DO SEU PAGAMENTO					(-) Outros Acréscimos
Número da Transação: 43792022					(=) Valor Cobrado
 Governo Federal - Guia de Recolhimento da União - GRU - Cobrança.					R\$ 24.800,00
Sacado: UNIEQXK WNNHWD NH FINKHUWPHMVK NH NWNXU (UNIFIX) VITÓRIA - ES - 75012200 Sacador/Avalista:					
Cód. Barra:					



Autenticação Mecânica - Tíxua de Conservação

In the generated payment slip, the "Generating Event(s)" field displays the generating events and a counter that indicates...

How many petitions were created for each triggering event. Ex: **Fato(s) Gerador(es): 3034 (2), 38601 (8)**

The payment slip will display a second page where you can see the data related to the multiple guide (red box), the request related to the process for which the request form was initiated (green box), and the requests for processes related to other active AFEs/AEs (blue box).

Guia Múltipla: 4056
Data: 11/11/2022 15:05:10

Guia Pai						
Ordem	Transação	Processo	Assunto	Guia	Fato Gerador	Valor
1	43792022	25351000035201916	7006-INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança na RAZÃO SOCIAL	4056	3034	R\$ 6000.00

Guias Filhas						
Ordem	Autorização	Processo	Assunto	Guia	Fato Gerador	Valor
1	A000085	253510163030206	7006-INSUMOS FARMACÊUTICOS - (Alteração na AE) de FRACIONADORA do produto sujeito a Controle Especial por mudança na RAZÃO SOCIAL	4057	3034	R\$ 6.000,00
2	1152671	25351003370201968	7013-MEDICAMENTOS - (Alteração na AE) de TRANSPORTADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4058	38601	R\$ 1.600,00
3	1152685	25351025383201998	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4059	38601	R\$ 1.600,00
4	1367254	99999999999999995	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4060	38601	R\$ 1.600,00
5	2009193	25351002851202090	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4061	38601	R\$ 1.600,00
6	4085825	25351001487202041	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4062	38601	R\$ 1.600,00
7	7050902	25351000426202066	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4063	38601	R\$ 1.600,00
8	8999999	99999999999999995	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4064	38601	R\$ 1.600,00
9	9074901	25351213221201601	7017-MEDICAMENTOS e INSUMOS FARMACÊUTICOS - (Alteração na AE) de ARMAZENADORA do produto sujeito a Controle Especial - RAZÃO SOCIAL	4065	38601	R\$ 1.600,00

The payment slip covers all requests, and if the amount paid is less than the amount specified on the slip, **no request will be processed.**

Due to differences in the processing of the forms, it is expected that there will be **an interval of up to 3 hours between the registration of the parent form and the registration of the child form(s).**

After the protocol is submitted, a petition will be created for each process listed in the multiple tab. A protocol receipt will also be made available in the mailbox for each petition created.

The petition extract, available in the processes tab (see previous sections to understand how to access this feature), may show the company name or address that was registered with Anvisa and the company name or address that was registered with the Federal Revenue Service at the time of the user's request, as well as the date the information was updated with the Federal Revenue Service.

Example of the information contained in the address change request statement.

Endereço Conforme Consta na Anvisa:	VITÓRIA-ES, SIA TRECHO 4 AREA ESPECIAL 57 TANGAMANDAPIO 75012200
Data Atualização Receita Federal:	Informação disponibilizada pela Receita Federal em 11/11/2022. Essas informações são atualizadas a cada 3 dias.
Endereço Conforme Consta na Receita Federal:	ASA NORTE-DF, 70836900, BRASIL

Example of the information contained in the statement of requests for change of company name.

Razão Social Conforme Consta na Anvisa:	UHIEQKX WHNHIWD NH FIXKHUUWPHMVX NH NWNXU (UHIFIX)
Data Atualização Receita Federal:	Informação disponibilizada pela Receita Federal em 11/11/2022. Essas informações são atualizadas a cada 3 dias.
Razão Social Conforme Consta na Receita Federal:	UHIEQKX WHNHIWD NH FIXKHUUWPHMVX NH NWNXU (UHIFIX)

Change of Legal Representative and Technical Representative for Food Registration

This feature is only available for petitions of the type "Food/Alimony".

Initiate a petition linked to the food registration process you wish to modify, following the steps described in this manual. If you do not know the process number linked to the food registration you wish to modify, this information can be obtained through the Business Operations query.

"Consultar Empresa Nacional", available at <https://consultas.anvisa.gov.br/#/empresas/empresas/>

Dados da Empresa Nacional		
Razão Social EMPRESA DE TESTE LTDA. (V501)	CNPJ 11.111.111/0001-91	
Nome Fantasia EMPRESA DE TESTE LTDA. (V501)		
Endereço na Internet www.anvisa.gov.br	SAC 1212121212	
Endereço Completo SIA Trecho 5 área especial 57 - Asa Norte CEP: 75.012-200	Cidade/UF VITÓRIA/ES	
Responsável Técnico CAFURA RA	Responsável Legal (sem dados cadastrados)	

Dados do Cadastro		
Cadastro Nº 1.36725-4	Data do Cadastro 19/10/2004	Situação Ativa
Nº do Processo 99999.999999/9999-95	Cadastro 1 - Medicamento	
Atividades / Classes		
Dispensar • Insumos Farmacêuticos • Medicamento		
Manipular • Insumos Farmacêuticos		

[Voltar](#)

Select the subject corresponding to the change you wish to make: change of legal representative or change of technical representative.

After the selection, a block of information regarding the legal or technical representative will be made available, depending on the chosen subject.

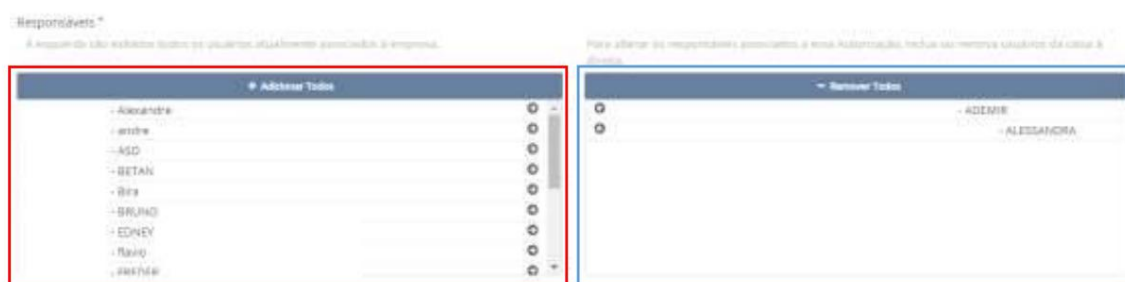


In the first field, the system will indicate for which food product registration the request will change the information regarding the legal representative or technical representative. In the example case, it would be the food product registration. XYZ:

Identificação da Autorização

6074603 - AFE

In the second field, we have two columns, where users are listed with their respective names and CPF numbers (the CPF data and surnames have been hidden in the images to protect the data of the people registered in the system).



The right-hand column, marked in blue, indicates the users who will be updated as legal or technical representatives (depending on the chosen subject) of the company after the request is submitted. When the subject is selected, the right-hand column will contain the users who are currently registered as technical or legal representatives (depending on the chosen subject) for the selected AFE (Authorization for Operation). This information can also be verified in the Company Operation query, as previously mentioned.

The **left-hand column**, marked in red, indicates all users who can be registered as legal or technical representatives (depending on the chosen subject).

To add a user, click the arrow next to the user's name in the **left-hand table**, marked in red. The user's name will then automatically be moved to the **right-hand table**, marked in blue.

To delete a user, click the arrow next to the user's name in the **right-hand table**, marked in blue. The user's name will automatically be moved to the **left-hand table**, marked in red.

If the user was selected incorrectly, they can be removed from the user table.

Included by clicking the arrow next to the user's name in the **right-hand table**, marked in blue. The user's name will automatically be transferred to the **left-hand table**, marked in red.

In the given example, after the request is submitted, users ADEMIR and ALESSANDRA would become the new responsible parties.

Adding a new user to the table on the **right**, marked in blue, is done by entering the user's CPF (Brazilian tax identification number) in the "Associate new responsible party (CPF)" field.

Associar novo responsável (CPF)

Caso o CPF não seja encontrado, acessar os sistemas de cadastro para inserção.

If the user does not yet have registered data, the following error message will appear: "CPF not accepted, please access the registration systems to add it."

In this case, the user will need to be registered by the applicant in the ANVISA registration system.

After completing this step, the user must follow the rest of the workflow, as detailed in previous sections of this manual, until the protocol is finalized.

After the protocol is completed, a message will be sent to your mailbox informing you who will be the company representative(s) after the petition has been filed:



ALTERAÇÃO DE RESPONSÁVEL LEGAL De: GEDOC em 20/05/2020 09:51

ANVISA
AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA

Petitionamento Eletrônico
Comunicamos a alteração do Responsável Legal da empresa para:

NOME	CPF
ADEMIR	
ALESSANDRA	

Atenciosamente,
Sistema de Petitionamento Eletrônico da ANVISA

Imprimir Fechar

The petition extract, available in the processes tab (see previous sections to understand how to access this feature), shows information about the representatives before and after the request was finalized.

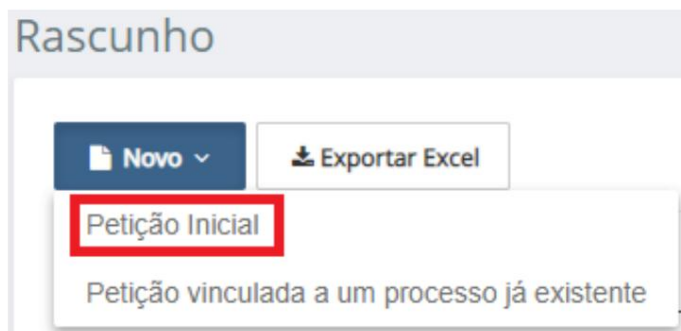
Responsáveis Anteriores	
CPF	Nome
Responsáveis Atualizados	
CPF	Nome
	ADEMIR
	ALESSANDRA

COSMETIC FORMULAS

Notification and Registration of Cosmetics

This feature is only available for "Cosmetics" type processes and petitions.

To initiate a request for notification or registration of cosmetics, you must access the drafts tab and click the "New" button, selecting the "Initial Petition" option.



In the form provided, click on the "magnifying glass" in the subject field, and on the next screen enter the name or number of the desired subject.



Seleção o assunto

Atividade/Tipo de produto

Selecione

Código

2871

Descrição

Registro de Produto Grau 2 - Importado

Pesquisar

Código	Atividade/Tipo de Produto	Descrição
2871	Cosmético	Registro de Produto Grau 2 - Importado

For notification or registration requests for domestic products, the applicant company must have an AFE (Authorization for Operation) to manufacture cosmetics.

For requests for notification or registration of international products, the applicant company must have an AFE (Authorization for Operation) to import cosmetics.

The following form will provide information that must be completed in order to characterize the product.

Important! The "Product Classification" section is used to characterize products according to sanitary regulations. The information entered is used to perform various validations in the form fields, and any changes made during form completion will result in the **deletion of all data entered up to that point.**

The "Product Classification" section has the following fields to be filled in.

Classe de Produto * 

The "Product Class" field displays the operating authorization classes for the "Cosmetics" product type. The options are enabled according to the Operating Authorization (AFE) of the logged-in company. The product class options are "Cosmetics", "Perfumes", and "Hygiene Products".

Destinação *

The "Intended Use" field indicates the area of the body where the product will be used.

Destinação Específica *

Depending on the chosen destination, a specific destination field will be available, detailing the area in which the product will be used.

Grupo de Produto *

The "Product Group" field will enable selection options based on the items selected in the "Product Class", "Purpose", and "Specific Purpose" fields, when applicable.

Ensure that the final product group designation complies with applicable legislation. An incorrect product group designation may lead to the rejection or cancellation of the product registration.

Questionnaire

1. O produto exige instrução para o público-alvo?

Selecione

2. O produto exige instrução para gestores ou técnicos?

Selecione

3. O produto exige instrução para regimes de prestação de cuidados?

Selecione

4. O produto exige uso com ou sem energia? (Para produtos que exigem uso em ambientes fechados, deve-se associar a opção "sem energia" para a resposta)

Selecione

5. O produto exige uso para aplicação em local específico do corpo?

Selecione

6. O produto exige instrução para pele sensível? (Necessário estudo de segurança antes efetivar)

Selecione

7. O produto exige ação preventiva da pele? (Necessário estudo de segurança antes efetivar)

Selecione

8. O produto exige ação antiodor? (Necessário estudo de segurança antes efetivar)

Selecione

9. O produto exige ação hidratante (como ação secundária ou como ação multifuncional)? (Ação hidratante primária caracteriza o produto como produto pele - que é sujeito de regime. Necessário estudo de segurança antes efetivar)

Selecione

10. O produto exige instrução para pessoas com pele normal? (Necessário estudo de segurança antes efetivar)

Selecione

11. O produto exige ação esfoliante? (Necessário estudo de segurança antes efetivar)

Selecione

12. O produto exige ação anti-aging? (Necessário estudo de segurança antes efetivar)

Selecione

13. O produto exige instrução de uso como CPD - Equipamento de Proteção Individual?

Selecione

The "Questionnaire" field is enabled for a better characterization of the product claims that will be submitted. **Changing the answer to any question after the questionnaire has been fully completed will result in the deletion of the registered presentations/formulas/shades.**

Grau de Risco Produto

Grau 2

The "Product Risk Level" field is automatically defined according to the information entered in the "Questionnaire" fields.

The "General Data" section is used to provide broad product information.

Dados Gerais

Nome do Produto (incluindo Marca ou nome da Linha) * ?

Tipo de Formulação * ?

The "Product Classification" section has the following fields to be filled in.

Nome do Produto (incluindo Marca ou nome da Linha) * ?

0 / 230

In the "Product Name (including Brand or Line name)" field, you can enter names with up to 230 alphanumeric characters.

Tipo de Formulação * ?

In the "Formulation Type" field, you must select the physical form of the product. If the desired physical form is not available, please contact the team at the responsible organizational unit.

The "Manufacturers" section allows the inclusion of national or international manufacturers, with at least one manufacturer being registered. The section is composed of two modes: one for entering data for national manufacturers and another for entering data for international manufacturers.

CNPJ

FABRICANTE

ETAPA DE FABRICAÇÃO

AÇÕES

Nenhum item foi adicionado.

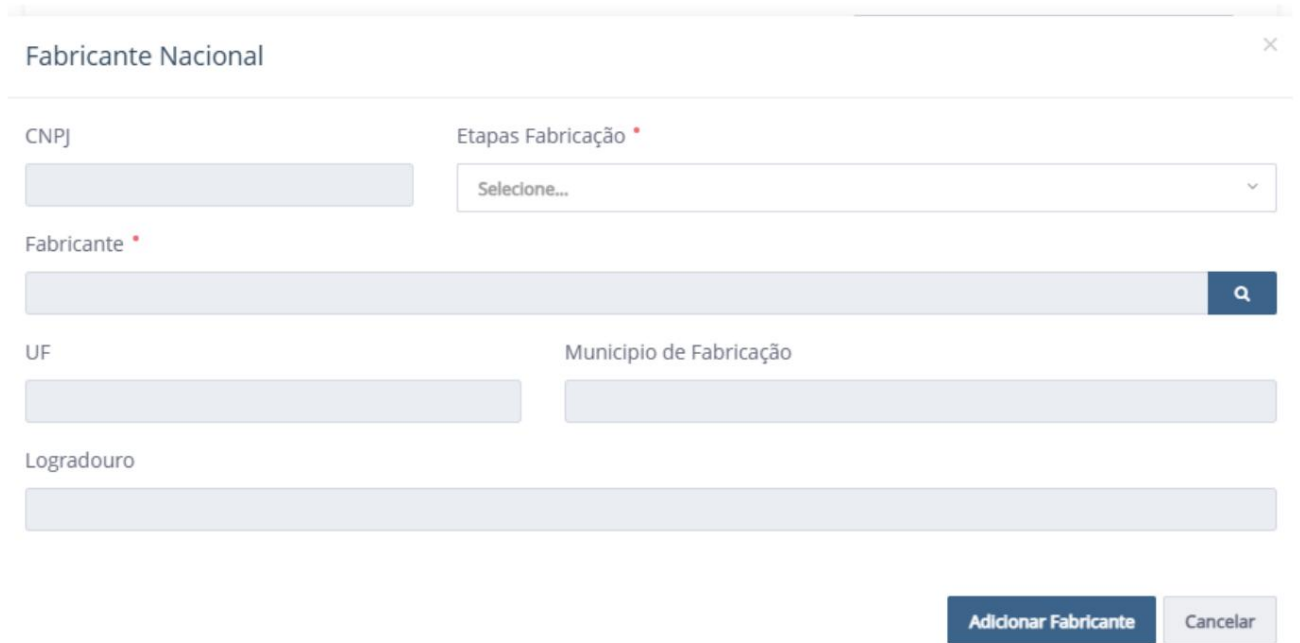
+ Adicionar Fabricante Nacional

To enter data for a national manufacturer, click the button.

+ Adicionar Fabricante Nacional

to display the company selection model and the steps involved.

The manufacturing company will be responsible.



The screenshot shows a form titled "Fabricante Nacional" with a close button (X) in the top right corner. The form contains several input fields: "CNPJ" (a text box), "Etapas Fabricação" (a dropdown menu with "Selecione..." as the placeholder), "Fabricante" (a large text box with a search icon on the right), "UF" (a text box), "Município de Fabricação" (a text box), and "Logradouro" (a text box). At the bottom right, there are two buttons: "Adicionar Fabricante" (in blue) and "Cancelar" (in light gray).

To specify the manufacturing stage(s) the company is responsible for, click on the "Manufacturing Stages" field.



The screenshot shows a dropdown menu titled "Etapas Fabricação" with a red asterisk. The placeholder text "Selecione..." is visible, and a small downward arrow is on the right side of the menu.

The possible steps that can be taken will be presented, and the user can select one or more steps.

To select the company, click the button.



A new mode of transport will be opened.

Selecione a empresa nacional

✕

⚠ Atenção! Deve-se informar, pelo menos um filtro para executar a Pesquisa

CNPJ

Fabricante

The search can be done using the company's CNPJ (Brazilian corporate tax ID) or its legal name.

CNPJ

Fabricante

CNPJ	Fabricante	UF	Município	Logradouro	
11222333000181	EMPRESA DE TESTE	DF	BRASÍLIA	AVENIDA DE TESTE	→
99888777000100	EMPRESA DE TESTE	DF	BRASÍLIA	RUA DE TESTE SEM FIM	→

Once the desired company has been displayed, click the button.  to select it.

The company data will be filled in the previous form. If the national company does not have an Operating Authorization compatible with the selected product class, warning messages will be displayed indicating that "The CNPJ (Brazilian tax ID) provided or its parent company is not authorized to Package, Manufacture, Fractionate or Repackage Cosmetics" and that "If this form is submitted, the registration request may be rejected, as the manufacturing company does not have an AFE (Operating Authorization) to manufacture the selected product class, thus violating sanitary legislation."

Fabricante Nacional ×

CNPJ

11222333000181

Etapas Fabricação *

Armazenamento, Controle de qualidade

Fabricante *

EMPRESA DE TESTE Q

UF

DF

Município de Fabricação

BRASÍLIA

Logradouro

AVENIDA DE TESTE

Adicionar Fabricante

Cancelar

Adicionar Fabricante

Click the button so that it appears in the list of manufacturers.

Fabricantes

CNPJ	FABRICANTE	ETAPA DE FABRICAÇÃO	AÇÕES
11222333000181	EMPRESA DE TESTE	Armazenamento, Controle de qualidade	 

+ Adicionar Fabricante Nacional

The action button  allow editing of the component while the button  allows the exclusion of component.

The process for filling out the international manufacturer information is the same, with the difference being that the company search can be done by unique code or company name.

CÓDIGO ÚNICO	FABRICANTE	ETAPA DE FABRICAÇÃO	AÇÕES
Nenhum item foi adicionado.			

+ Adicionar Fabricante Internacional

If the desired manufacturer is not registered, please contact the team at the responsible organizational unit.

The "Product Technical Data" section allows the inclusion of data relating to presentation details, as well as the product formula.

Apresentações *

DESTINAÇÃO DO PRODUTO	PERÍODO DE VALIDADE DO PRODUTO	TIPO DO PERÍODO	APRESENTAÇÃO DO PRODUTO (EMB. PRIMÁRIA + EMB. SECUNDÁRIA)	AÇÕES
Nenhum item foi adicionado.				

[+ Adicionar Apresentação](#)

Fórmula * ?

COMPONENTE DA FÓRMULA	QUANTIDADE (G/100G DE PRODUTO ACABADO)	FUNÇÃO	INSCRIÇÃO (REFERÊNCIA)	AÇÕES
Nenhum item foi adicionado.				

[+ Adicionar Substância](#)

To enter presentation data, click the button to display the presentation registration modal.

[+ Adicionar Apresentação](#)

Apresentações

Destinação do Produto *

Período de Validade do Produto *

Tipo do Período *

Embalagem Primária * ?

Embalagem Secundária * ?

Apresentação do Produto (Emb. primária + Emb. secundária)

[Adicionar Apresentação](#)

[Cancelar](#)

A modal offers several fields to characterize a presentation.

Destinação do Produto *

In the "Product Destination" field, you must select the intended use of the product.

Período de Validade do Produto *

Tipo do Período *

In the "Product Validity Period" field, enter an integer and then choose the time period corresponding to the product's validity period.

Embalagem Primária * ?

In the "Primary Packaging" field, specify the packaging to be used.

Embalagem Secundária * ?

In the "Secondary Packaging" field, specify the packaging to be used. If secondary packaging is not used, enter the information "Product contains only primary packaging".

If the desired primary or secondary packaging is not listed, please contact the team at the responsible organizational unit.

Adicionar Apresentação

After completing the form, click the button displayed in the table format.

The inserted groups will be

Apresentações *				
DESTINAÇÃO DO PRODUTO	PERÍODO DE VALIDADE DO PRODUTO	TIPO DO PERÍODO	APRESENTAÇÃO DO PRODUTO (EMB. PRIMÁRIA + EMB. SECUNDÁRIA)	AÇÕES
COMERCIAL	30	DIAS	REFIL DE POLIETILENO + PRODUTO SOMENTE CONTEM EMBALAGEM PRIMARIA	 

[+ Adicionar Apresentação](#)

The presentation  allows editing of the presentation, while the button  allows the exclusion of action button.

New presentations can be registered using this same workflow or by copying data from an already registered presentation. This functionality is enabled once at least one presentation has been registered.

Você deseja copiar os dados de uma apresentação já cadastrada? 

☐ Sim ☒ Não

By selecting “yes”, the system enables a field to select which presentation will be used as the default for the copy.

Apresentação

Selecione 

When the presentation is selected, the system copies the data to the form.

Apresentação

Selecione 

Selecione

REFIL DE POLIETILENO + PRODUTO SOMENTE CONTEM EMBALAGEM PRIMARIA

Selecione  | Seleciona 

Apresentações

Você deseja copiar os dados de uma apresentação já cadastrada? 

☒ Sim ☐ Não

Apresentação

REFIL DE POLIETILENO + PRODUTO SOMENTE CONTEM EMBALAGEM PRIMARIA 

Destinação do Produto *

COMERCIAL 

Período de Validade do Produto *

30

Tipo do Período *

DIAS 

Embalagem Primária * 

REFIL DE POLIETILENO 

Embalagem Secundária * 

PRODUTO SOMENTE CONTEM EMBALAGEM PRIMARIA 

Apresentação do Produto (Emb. primária + Emb. secundária)

REFIL DE POLIETILENO + PRODUTO SOMENTE CONTEM EMBALAGEM PRIMARIA - Cópia - 20/09/2024 18:56:24

The next section concerns the product's "Formula". This section will only be enabled once the presentation field has been filled in.

Dados Técnicos do Produto

Fórmula *

COMPONENTE DA FÓRMULA	QUANTIDADE (g/100g DE PRODUTO ACABADO)	FUNÇÃO	INSCRIÇÃO (REFERÊNCIA)	AÇÕES
Nenhum item foi adicionado				

+ Adicionar Substância

The formula registration is done substance by substance. To do so, click the button.

+ Adicionar Substância

A new screen will be available.

Substância

Componente da Fórmula * ?

Quantidade (g/100g de produto acabado) *

Inscrição (Referência)

Função * ?

Selecione

Adicionar Substância Cancelar

Click on the magnifying glass and choose the substance by entering the "substance name" or the "inscription (reference)". In both cases, the search allows for exact or partial searches. Note that depending on the characteristics of the product and the selected substance, warning messages may be displayed indicating that the selected substance cannot be used, "The selected formula component is not permitted for personal hygiene products, perfumes and cosmetics" or that the quantity entered is not compatible with the product being registered "The substance does not allow the use of the informed purposes or does not allow the chosen concentration. Adjust the substance or its concentration or choose another purpose. ". If the desired substance is not registered, please contact the team of the responsible organizational unit.

Selecione a substância desejada

Nome da Substância	Inscrição (Referência)	
ACACIA DECURRENS DEALBATA FLOWER EXTRACT	93685-96-2	+
ACACIA DECURRENS EXTRACT	98903-76-5	+
ACACIA DECURRENS FLOWER CERA	98903-76-5	+
ACACIA DECURRENS FLOWER EXTRACT	98903-76-5	+
ACACIA DECURRENS/JOJOBA/SUNFLOWER SEED CERA/POLYGLYCERYL-3 ESTERS	-	+
CALOCEDRUS DECURRENS LEAF/STEM EXTRACT	-	+
CALOCEDRUS DECURRENS LEAF/STEM OIL	-	+
DECURSINOL	23458-02-8	+

After selecting the substance, enter the quantity of the substance in g/100g. If the user enters a value greater than 100, or if the sum of the substances exceeds 100, an error message will be displayed stating that **"The value of the substance exceeds the maximum permitted concentration limit of 100."**

After entering the quantity, please specify the function associated with that product. If the desired function is not registered, please contact the team at the responsible organizational unit.

With each entry, the list of substances used in the product formula can be viewed on the form's main screen.

Dados Técnicos do Produto

Fórmula *

COMPONENTE DA FÓRMULA	QUANTIDADE (g/100g DE PRODUTO ACABADO)	FUNÇÃO	INSCRIÇÃO (REFERÊNCIA)	AÇÃO
DECURSINOL	10,00	Aromatizante	23458-02-8	 
ACTINOPTERIS DICHOTOMA EXTRACT	90,00	Aromatizante	-	 

Using the button



It is possible to change the data of an entered substance by using the button.



It is possible to exclude an inserted substance.

Important! Post-registration applications do not include fields for "Manufacturers," "Substances," or "Presentations" in their form.

Finally, the user must complete the section related to "Microbiological Specification of Finished Product".

Especificação Microbiológica de Produto Acabado

☐ Produto não suscetível a contaminação microbiológica, conforme justificativa técnica anexa ao processo

MICROORGANISMO TESTADO	LIMITE MÁXIMO	UNIDADE DE MEDIDA (CONTAGEM DE MICROORGANISMO)	AUSÊNCIA EM (TAMANHO DA AMOSTRA)	UNIDADE DE MEDIDA (TAMANHO DA AMOSTRA)	AÇÕES
Nenhum item foi adicionado.					
+ Adicionar Microorganismo					

If the product is not susceptible to microbiological contamination, the user should check the box:

☐ Produto não suscetível a contaminação microbiológica, conforme justificativa técnica anexa ao processo

In this situation, it will not be possible to include information regarding the microorganisms tested.

In situations where there is a possibility of contamination, the user should click the button.

Clicking this button will enable the modal for inserting the Information regarding each microorganism tested.



Especificação Microbiológica de Produto Acabado

Microrganismo Testado ^{*} [?]

☐ Microrganismo Ausente

Limite Máximo ^{*}

Unidade de Medida (Contagem de microrganismo) ^{*} [?]

Perform the search using the microorganism's name or part of its name in the "Tested Microorganism" menu and, depending on the result, check the box to indicate that the microorganism was absent.

☐ **Microorganismo Ausente**

or report the "Maximum Limit" found. If the desired microorganism

If you are not registered, please contact the team at the responsible organizational unit.

If the option indicating that the microorganism is absent is selected, the size of the sample tested and the sample size/quantity must be provided.

Microorganismo Testado * ?

MESÓFILOS TOTAIS AERÓBIOS

☒ **Microorganismo Ausente****Limite Máximo** *

0

Ausência em (Tamanho da amostra) * ?

150

Unidade de Medida (Tamanho da amostra) *

GRAMA



If the microorganism has been identified, the value for the "Maximum Limit" and the "Unit" must be entered.
"Measurement" associated with the entered value.

Limite Máximo *

10

Unidade de Medida (Contagem de microorganismo) * ?

UNIDADE FORMADORA DE COLÔNIAS/GRAMA



With each entry, the list of tested microorganisms will be updated and can be viewed on the main screen.
of the form.

MICROORGANISMO TESTADO	LIMITE MÁXIMO	UNIDADE DE MEDIDA (CONTAGEM DE MICROORGANISMO)	ALUSÊNCIA EM (TAMANHO DA AMOSTRA)	UNIDADE DE MEDIDA (TAMANHO DA AMOSTRA)	AÇÕES
COLIFORMES TOTAIS E FECALIS	10	UNIDADE FORMADORA DE COLÔNIAS/GRAMA			 
MESÓFILOS TOTAIS AERÓBIOS	0		150	GRAMA	 

Using the button



It is possible to change the data of a microorganism, and by using the button  it is possible to do so. to eliminate a microorganism.

Notification and registration of tinted cosmetics

Requests for "Cosmetics," "Perfumes," and "Hygiene Products" that can be differentiated by product shades require a form modification to allow for the insertion of data from the "Product Technical Data" section, grouped for each shade.

Tonalidade *

NOME DA TONALIDADE	FÓRMULA	AÇÕES
Nenhum item foi adicionado.		

+ Adicionar Tonalidade

+ Adicionar Tonalidade

To enter data for a "Shade," click the button to display the shade registration modal.

to

Tonalidade

Nome da Tonalidade *
0 / 100

Apresentações *

DESTINAÇÃO DO PRODUTO	PERÍODO DE VALIDADE DO PRODUTO	TIPO DO PERÍODO	APRESENTAÇÃO DO PRODUTO (EMB. PRIMÁRIA + EMB. SECUNDÁRIA)	AÇÕES
Nenhum item foi adicionado.				

+ Adicionar Apresentação

Fórmula * ?

COMPONENTE DA FÓRMULA	QUANTIDADE (G/100G DE PRODUTO ACABADO)	FUNÇÃO	INSCRIÇÃO (REFERÊNCIA)	AÇÕES
Nenhum item foi adicionado.				

+ Adicionar Substância

Adicionar Tonalidade

Cancelar

In the "Key" field, enter the name of the key, and then enter the data relating to "Presentations" and "Formula" as instructed in the previous item.

Tonalidade ✕

Nome da Tonalidade *

Apresentações *

DESTINAÇÃO DO PRODUTO	PERÍODO DE VALIDADE DO PRODUTO	TIPO DO PERÍODO	APRESENTAÇÃO DO PRODUTO (EMB. PRIMÁRIA + EMB. SECUNDÁRIA)	AÇÕES
COMERCIAL	12	DIAS	REFIL DE POLIETILENO + PRODUTO SOMENTE COM EMBALAGEM PRIMÁRIA	

+ Adicionar Apresentação

Fórmula * ?

COMPONENTE DA FÓRMULA	QUANTIDADE (G/100G DE PRODUTO ACABADO)	FUNÇÃO	INSCRIÇÃO (REFERÊNCIA)	AÇÕES
HYDROGENATED CASTOR OIL/ADIPIC ACID COPOLYMER	100	Abrasivo	----	 

+ Adicionar Substância

Atualizar Cancelar

After completing the form, click the button.

Atualizar

The inserted shades will be displayed in

table format.

Tonalidade *

NOME DA TONALIDADE	FÓRMULA	AÇÕES
Azul	HYDROGENATED CASTOR OIL/ADIPIC ACID COPOLYMER	 

+ Adicionar Tonalidade

The action button



allow editing of the tone while the button



allows the exclusion of

tone.

Change to Cosmetics Notification

To initiate a request to change a cosmetics notification, you must access the drafts tab and click the "New" button, selecting the option "Petition Linked to an Existing Process".

When selecting the notification to be modified, its data will be loaded onto the screen in a form identical to that used in the initial notification so that it can be edited. It should be noted that the information in the "Product Classification" section and the "Product Name (including Brand or Line name)" field cannot be modified.

Presentation management can be done through the "Product Technical Data" section.



New submissions can be added by clicking the button using the same registration logic as the initial request.

Apresentações *

DESTINAÇÃO DO PRODUTO	PERÍODO DE VALIDADE DO PRODUTO	TIPO DO PERÍODO	APRESENTAÇÃO DO PRODUTO (EMB. PRIMÁRIA + EMB. SECUNDÁRIA)	AÇÕES
COMERCIAL	24	MESES	BISNAGA DE PLÁSTICO + CARTUCHO DE CARTOLINA	 
COMERCIAL	24	MESES	BISNAGA DE PLÁSTICO + CARTOLINA DE ACETADO	 



The presentation  allow editing of the presentation while the button  allows the exclusion of action button.

New presentations can also be added using the function to copy data from an already registered presentation. This feature is enabled once at least one presentation has been registered.

Você deseja copiar os dados de uma apresentação já cadastrada? 

☐ Sim ☒ Não

By selecting "yes", the system enables a field to select which presentation will be used as the default for the copy.

Apresentação

Selecione

When the presentation is selected, the system copies the data to the form.

Apresentação



The screenshot shows a web interface with a label 'Apresentação' above a dropdown menu. The dropdown menu is open, displaying two options: 'Seleção' (highlighted in grey) and 'Apresentação 1'.

It is important to note that deleting a previously registered presentation will result in its cancellation. If one of these presentations is deleted, it will not be possible to undo the deletion request, and if there has been a mistake, it is recommended to delete the draft and complete a new form.

The information provided in the form will be updated in the ANVISA database **after** the petition is submitted and the protocol is confirmed.

EXPRESSION OF INTEREST IN CONTINUING THE COMMERCIALIZATION OF THE NOTIFICATION

Once every five years, companies must express their interest in maintaining the notified products. The frequency is determined **from the date of the product notification**.

To initiate a request for a declaration of interest in continuing the marketing of a product exempt from registration, it is necessary to access the drafts tab and click the "New" button, selecting the option "Petition Linked to an Existing Process".

When selecting the notification process, the subject must be selected to inform the manifestation of the interest.

The expression of interest can occur at any time during the period defined by law.

If the expression of interest protocol was submitted within the regulatory deadline, the expiration date for product registration will be automatically updated, and this information can be verified in the ANVISA external search under cosmetics.

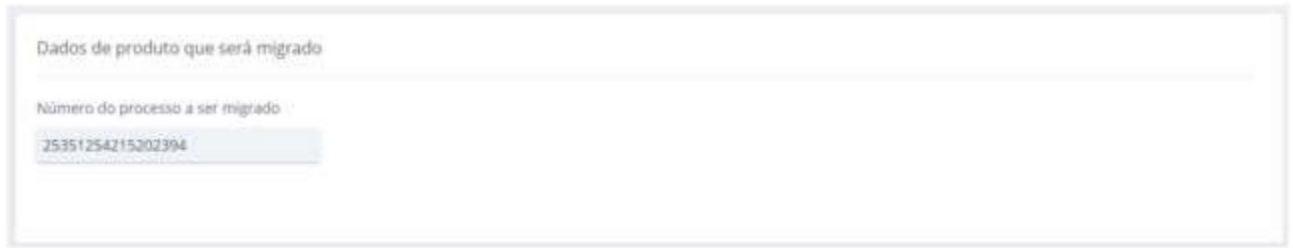
Cosmetic products exempt from registration that have not received an expression of interest within the regulatory deadline will not have their registration expiration date updated and will be automatically **deactivated** after its expiration. After the deactivation of a cosmetic product exempt from registration due to lack of expression of interest, **reactivation will not be possible**.

COSMETICS NOTIFICATION MIGRATION

To initiate a request to migrate a cosmetics notification made in the SGAS system, you need to access the drafts tab and click the "New" button, selecting the "Initial Petition" option.

When selecting the subject "Migration of Product Exempt from Registration," a form identical to that described in the Cosmetics Notification and Registration section will be displayed.

The section "Product data to be migrated" has been added to this basic structure.



Dados de produto que será migrado

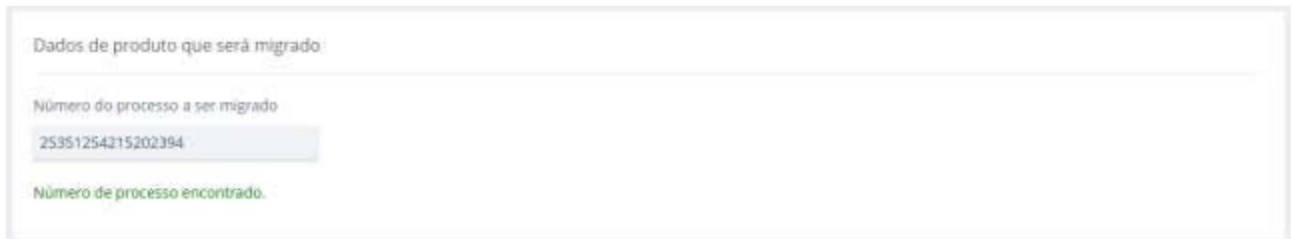
Número do processo a ser migrado

25351254215202394

When entering a process number, the system will validate whether:

- The user represents the company that requested the process in SGAS;
- The product is valid;
- This process has not yet been migrated to the Solicita system.

If these criteria are met, the system will display a message stating that the "Process number was found".



Dados de produto que será migrado

Número do processo a ser migrado

25351254215202394

Número de processo encontrado.

Upon successful validation, the system will pre-populate the information in the "Data" section.

General information is not possible; this information cannot be changed.

TOBACCO PRODUCT FORMS**REGISTRATION OF TOBACCO -DERIVED PRODUCT**

This feature is only available for processes and petitions of the type "Tobacco Derivatives".

To begin the process of registering a tobacco product, you must access the drafts tab and click the "New" button, selecting the "Initial Petition" option.



In the form provided, click on the "magnifying glass" icon in the "Subject" field to bring up the subject selection screen.



The subject can be searched by selecting "Tobacco Derivatives" in the "Activity/Product Type" field, or by selecting the corresponding service, or by entering the name or number of the desired subject.

Click the button  **Pesquisar** and select the subject.



The following form will provide the information that must be completed in order to characterize the product being requested and all presentations (describing the primary and secondary presentations) that will be marketed.

General Information (Product Characteristics)

The "General Data" section contains fields intended to characterize the requested product.

Dados Gerais (Características do Produto)

Nome do Produto * ⓘ

Produto *

Selecione

Caso o Produto seja alterado, todos os dados do formulário serão excluídos e deverão ser preenchidos novamente.

Product Name: This field can hold up to 100 characters and accepts accented characters, but only the following special characters can be used: ";" ":" "." "-" "ç" "&" "o" "(" ")"

Product: This field displays the categories regulated by specific legislation. The rest of the form will have fields that are dynamic depending on the selected "Product".

Warning: If the product type is changed, all previously entered information will be deleted, and the user will need to fill in the data again.

Length and Circumference: For **cigar**, **cigarillo**, **filtered cigarette**, **kretek cigarette**, and **unfiltered cigarette** products, the fields "Length" and "Circumference" are displayed. The user must fill in the values in millimeters, and can enter a value with up to five digits and two decimal places.

Comprimento (mm) *

12345,67

Circunferência (mm) *

1234,56

Filter and Wrapper: In the case of products with a filter (**filtered cigarettes and kretek cigarettes**), the section is enabled. "Specifications and Physical Characteristics of the Filter and Enclosure":

Especificações e Características Físicas do Filtro e Envolório *

Tipo do Filtro *

Selecione

Características Físicas do Filtro * ⓘ

Características	Média	Desvio Padrão
Ventilação total (L/100%)		
Queda de Pressão com fluxo de ventilação aberto (mm H ₂ O)		
Queda de Pressão com fluxo de ventilação fechado (mm H ₂ O)		

Características Físicas do Papel Envolvente do Filtro *		Características Físicas do Papel da Ponteira *		Características Físicas do Papel Envolvente do Produto *		
Características	Média	Desvio Padrão	Média	Desvio Padrão	Média	Desvio Padrão
Gramatura (g/m ²)						
Permeabilidade com vapor d'água (15%)						
Resistência (mg/cm)						

The "Filter Type" field is a drop-down menu. If it becomes necessary to add new options to the field, the user must submit **a primary petition for the Inclusion of Controlled Tobacco Vocabulary**.

In the "Filter Physical Characteristics" field, you must enter the values for "Total Ventilation" (0 - 100%), "Pressure Drop with Vent Holes Open (mm H2O)", "Pressure Drop with Vent Holes Closed (mm H2O)", as well as fill in the data regarding the characteristics of the filter wrapping paper, the tip paper, and the product wrapping paper.

If the wrapping paper is not permeable, enter the value 0.00.

Tobacco Blend: This section indicates the types of tobacco used in the product. Click the button.




Mistura de Tabaco *

Nome do item a ser adicionado:

+ Incluir

A data field will be enabled to select the type of tobacco and enter the quantity in grams, allowing the value to be entered with up to two digits and two decimal places:



Mistura de Tabaco *

TIPO DE TABACO * QUANTIDADE(G) *

VIRGÍNIA (Fue-Curado) 0.55

Quantidade Total de Tabaco por Produto(g/unidade) * 0.55

+ Incluir

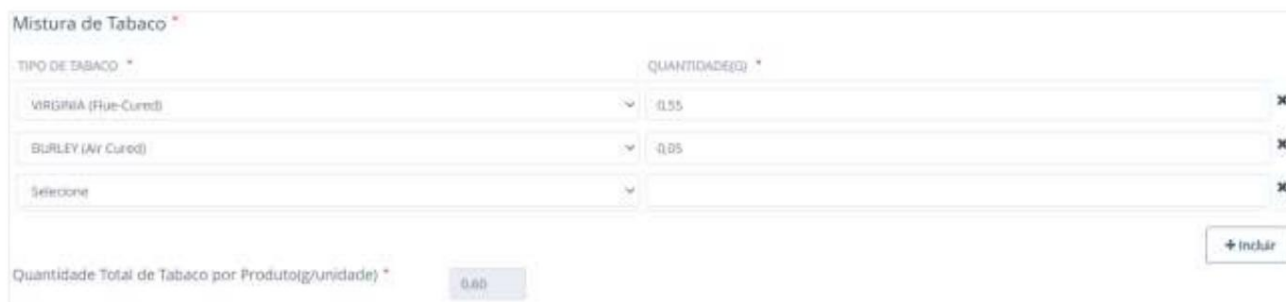
The "Tobacco Type" field is a drop-down menu. If it becomes necessary to add new options to the field, the user must submit a **primary petition for the Inclusion of Controlled Tobacco Vocabulary**.

To include more than one type of tobacco, click the button again.



For each line included, the field

The "Total Amount of Tobacco per Product (g/unit)" will be updated to display the total amount of tobacco entered in the form:



Mistura de Tabaco *

TIPO DE TABACO * QUANTIDADE(G) *

VIRGÍNIA (Fue-Curado) 0.55

BURLEY (Air Cured) 0.05

Selecione

Quantidade Total de Tabaco por Produto(g/unidade) * 0.60

+ Incluir

If you need to delete a row of data, click the icon to allow deletion and confirm.



delete by clicking the button



which will be displayed in the window.



Excluir o item selecionado:

Confirme a exclusão?

Cancelar Excluir

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In the case of the **cigar** product, the user must indicate the quantity, in grams, present in the **wrapper, binder, and filler**, and may enter the value with up to two digits and two decimal places.

Mistura de Tabaco *

TIPO DE TABACO *	QUANTIDADE(g) CAPA *	QUANTIDADE(g) CAPOTE *	QUANTIDADE(g) MILO *
CONNECTICUT SUNGROWN	0,05	0	0
CONNECTICUT SHADE	0	0,05	0
TABACO NEGRO HABANO NICARAQUA	0	0	8,50

Quantidade Total de Tabaco por Produto(g/unidade) * **8,60**

+ Incluir

The procedure for adding and removing new data rows is the same as described previously.

List of Additives Used: This section is intended to inform you of the additives present in the product:

Relação de Aditivos Utilizados

☐ Declara-se que não é utilizado qualquer aditivo desde o beneficiamento do(s) tabaco(s) até a obtenção do produto acabado. *

Nenhum item foi adicionado.

+ Incluir

If no additives are used, select the checkbox: *"It is declared that no additives are used from the processing of the tobacco(s) to obtaining the finished product"*. This action will disable the field for entering additive information.

☒ Declara-se que não é utilizado qualquer aditivo desde o beneficiamento do(s) tabaco(s) até a obtenção do produto acabado. *

If the product contains additives, click the button.



to display a line of data for each additive.

Relação de Aditivos Utilizados

☐ Declara-se que não é utilizado qualquer aditivo desde o beneficiamento do(s) tabaco(s) até a obtenção do produto acabado. *

ADITIVO(S) / CAS *	CATEGORIA *	ADICIONADO A *	QUANTIDADE ADICIONADA *	UNIDADE *
	Selecione	Selecione		Selecione

+ Incluir

The "Additive" field allows you to search by additive name or its CAS code.

The fields "Additives/CAS", "Category", "Added to", and "Unit" are drop-down menus. If it is necessary to include new options for the field, the user must submit a **primary petition for the Inclusion of Controlled Tobacco Vocabulary**.

If you need to add more additives, click the button.



If you need to delete a row of data, click the icon to allow deletion and confirm. 

delete by clicking the button



which will be displayed in the window:



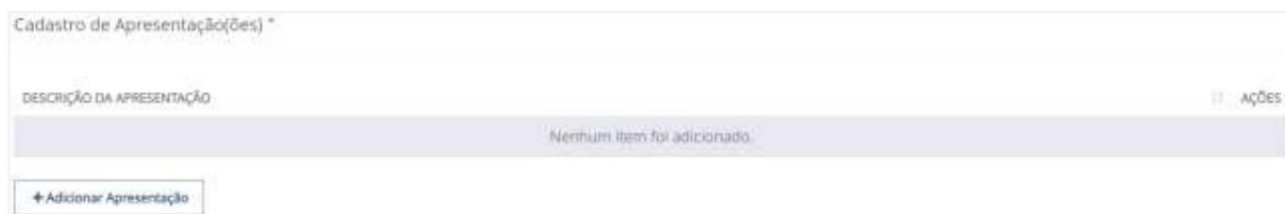
Excluir o item selecionado

Confirma a exclusão?

Presentation Registration(s)

Next, the **"Presentation Registration(s)" section will be available**, intended for registering Presentations that have primary packaging(s) and, where applicable, secondary packaging(s).



Cadastro de Apresentação(ões) *

DESCRIÇÃO DA APRESENTAÇÃO

Nenhum item foi adicionado.



AÇÕES

For each package that will be used in the marketing of the product, the user must click the button.



The screen will display the information for registering each product presentation, separately showing the data for each primary packaging and then, if applicable, the data for each secondary packaging.

Presentation Description: This field is not editable, and the description is automatically generated by the system based on the information entered in the fields that make up this section.

To register primary packaging: The fields **"Primary Packaging"**, **"Quantity"** and **"Unit"** are intended to characterize the packaging(s) that contain the product.



Dados da Embalagem

Embalagem Primária * Seleção

Quantidade *

Unidade * Seleção

Embalagem Secundária * 

Quantidade

Complemento 

APRESENTAÇÃO SOMENTE CONTEM EMBALAGEM

The "Primary Packaging" field is a drop-down menu. If it becomes necessary to add new options to the field, the user must submit **a primary petition for the Inclusion of Controlled Tobacco Vocabulary**.

The "Quantity" field refers to the quantity of product in the primary packaging, in product units or in grams (in this case, you can enter a value with up to six digits and two decimal places). In the case of

For filtered cigarettes and kretek cigarettes, the system automatically fills in the quantity and unit fields.

The "Secondary Packaging" field, which is the product's outer packaging and contains more than one primary package, should have the **"Presentation with primary packaging only" option selected when registering Presentations that have only primary packaging(s).**

The "Additional Information" field should be used if there is more than one layout for the same type of packaging. This field can contain information that will allow consumers to differentiate between packages, such as shape, packaging material, opening system, or other information, which will be included in the description to be published in the Official Gazette.

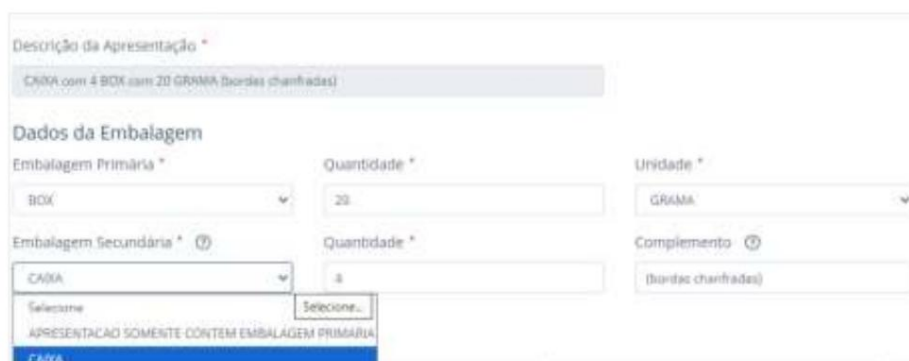
Below is an example of how fields are used to structure the description of a primary presentation:



To register secondary packaging: The fields "Primary Packaging", "Quantity" and "Unit" must be filled with the data of the primary packaging that will be contained within the secondary packaging.

The fields "Secondary Packaging" and "Quantity" are intended to describe the secondary packaging, used to contain more than one primary package.

The "Quantity" field on the secondary packaging refers to the number of primary packages contained within the secondary packaging.



The "Secondary Packaging" field is a drop-down menu. If it becomes necessary to include new options for the field, the user must submit **a primary petition for the Inclusion of Controlled Vocabulary.**

Tobacco.

Below are two examples of how fields are used to structure the description of a presentation:

Descrição da Apresentação *

PACOTE com 30 SACO (tipo POUCH) com 10 GRAMA Pacote transparente

Dados da Embalagem

Embalagem Primária *	Quantidade *	Unidade *
SACO (tipo POUCH)	10	GRAMA
Embalagem Secundária *	Quantidade *	Complemento
PACOTE	30	Pacote transparente

The **"Companies"** field should be used to list **all companies involved in the manufacturing of the product, from tobacco processing to the finished product and final packaging.**

Empresas ⓘ

CNPJ	EMPRESA	ETAPA DE FABRICAÇÃO	AÇÕES
Nenhum item foi adicionado.			
+ Adicionar Empresa Nacional			
EMPRESA	ETAPA DE FABRICAÇÃO	AÇÕES	
Nenhum item foi adicionado.			
+ Adicionar Empresa Internacional			

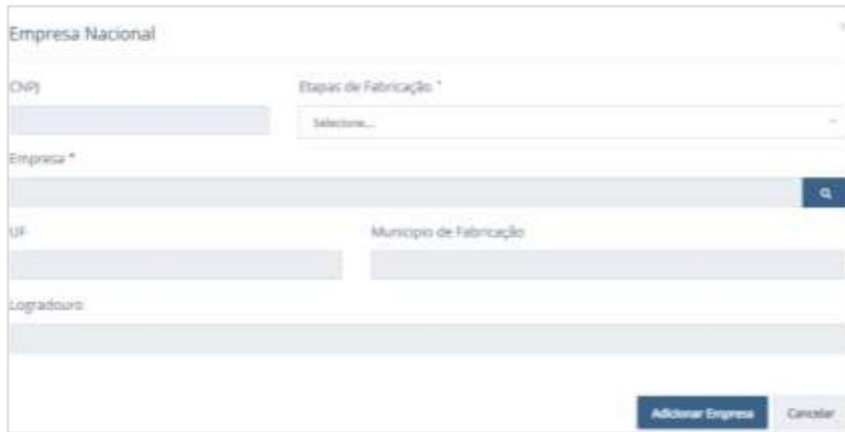
The section for including company data consists of two windows.

To enter the data for a national company, click the button.

+ Adicionar Empresa Nacional

CNPJ	EMPRESA	ETAPA DE FABRICAÇÃO	AÇÕES
Nenhum item foi adicionado.			
+ Adicionar Empresa Nacional			

The system displays a window to select the steps involved in manufacturing and to indicate the national company responsible for each step:



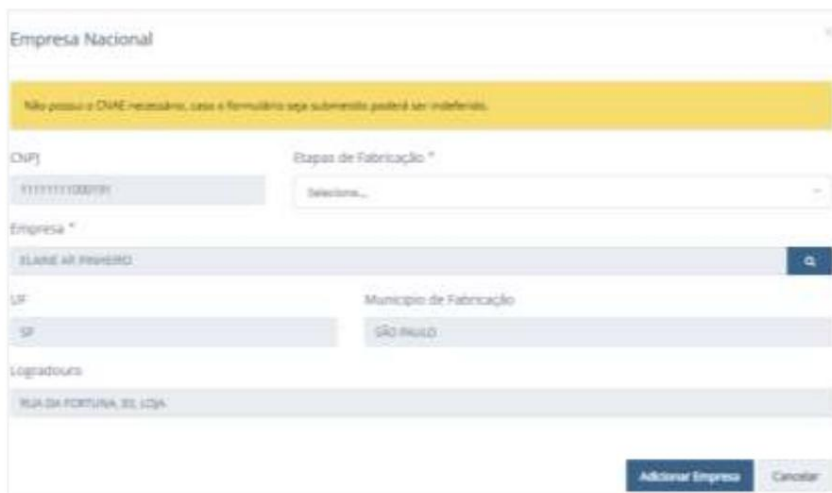
The **"Manufacturing Steps"** field is a drop-down menu that displays the possible steps that can be performed, allowing the user to select one or more steps. If it becomes necessary to add new options to the field, the user must submit a **primary petition for the Inclusion of Controlled Tobacco Vocabulary**.

To select the company responsible for the stage(s) involved in manufacturing, click the button; a new window . One will open to enter the CNPJ of the national company.



Enter the CNPJ and click the button.  to search for the company's data. Once the desired company is found.

Once the information has been displayed, click the button to select it. After it's selected, the system will close this window and load the company data into the previous window.





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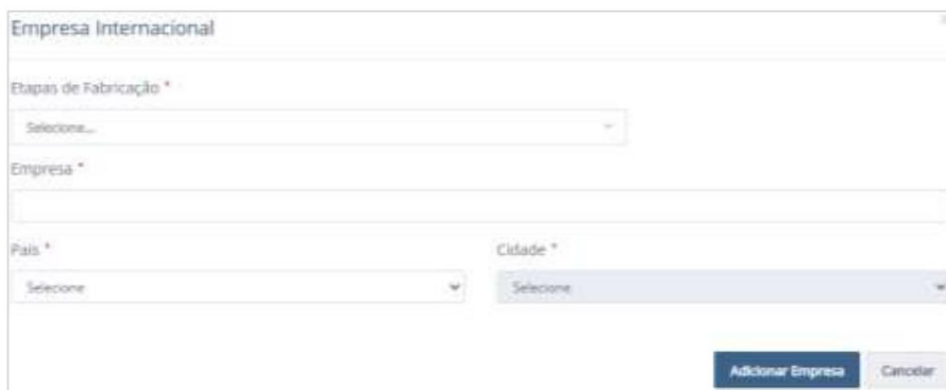
Click on the button  so that the company data entered is displayed for the Presentation (packaging) that is being registered.

The system validates whether the company has a CNAE (National Classification of Economic Activities) code that qualifies it to carry out the stated activity.

If an application is submitted that includes companies that do not have the appropriate CNAE codes, the application may be rejected after review.

The action button  allows you to edit the company, while the button  allows you to delete it.

The process for filling out the international company information is the same, with the difference being that the "Company" field is filled in manually by the user, who then selects the "Country" and "City," which are dropdown fields.



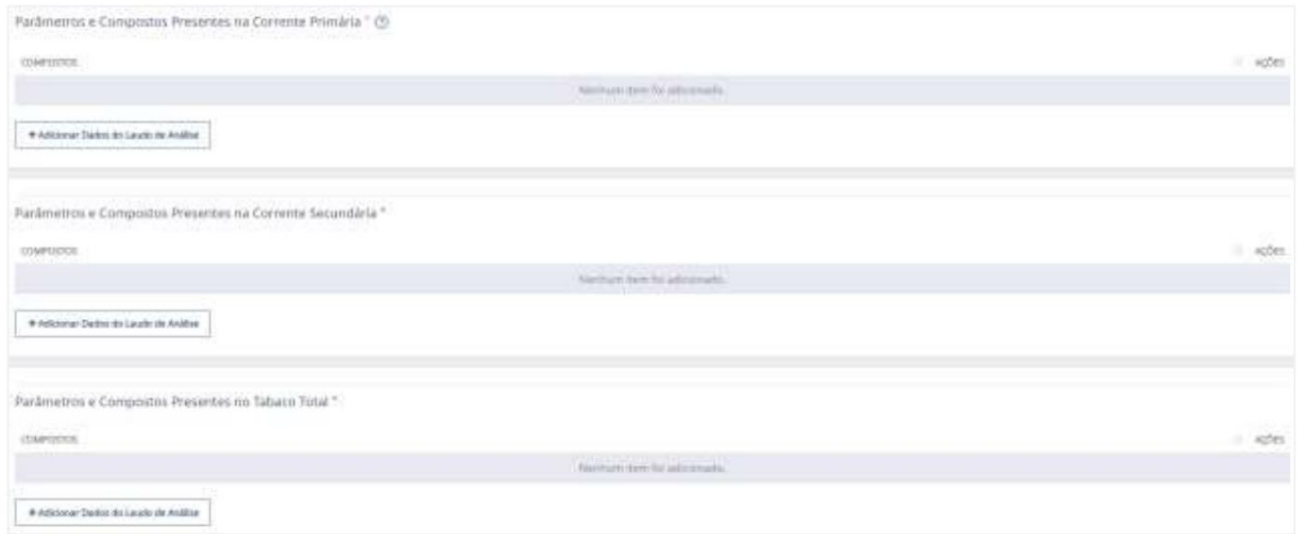
If the country or city is not available, the user must submit **a primary petition for the inclusion of controlled tobacco vocabulary.**

Parameters and Compounds Present in Primary Stream, Secondary Stream, and Total Tobacco

This section is intended to provide information from the product **analysis report** regarding "Parameters and Compounds Present in the Primary Stream," "Parameters and Compounds Present in the Secondary Stream," and "Parameters and Compounds Present in Total Tobacco," **according to the type of product being requested.**

By clicking the button  A window will appear for filling in the "Content" fields.

"Average" and "Standard Deviation" of each mandatory information component, with the results of the report:



The user must fill in the values, paying attention to the unit of each field, and can enter values with up to eight digits and four decimal places.



If the substance being evaluated is **below the Detection Limit or the Quantification Limit** of the method, the **Average Content** field should be filled with the information “<LOD/LOQ” and the Standard Deviation field with the information “N/A”. In this case, it is possible to leave the fields blank and select the checkbox “**Automatically fill in the fields with results below the detection/quantification limit with the information <LOD/LOQ.**”

Once all the values have been filled in, click the button.



Documentation

In this section, **all requested documents** for the chosen subject must be attached. The system indicates the mandatory documents without which the product petition will not be processed.

File attachments of the following types are allowed: jpg, jpeg, bmp, png, pdf, doc, docx, xls, and xlsx. **Limited to 50MB.** The file name, including the file type, must be limited to 149 characters.

Attention: **The files for each packaging (Presentation) declared in the Presentation Registration section** must be attached.

Once all the data has been entered and all the files have been attached and viewed, you can complete and submit the petition by clicking the button.



Since registration/renewal of registration petitions are subject to an inspection fee, they will remain in the "Awaiting Protocol" status on the homepage until the system identifies the... collection of the fee.

More details can be found in the topic "4. CREATING A DRAFT OF A PRIMARY PETITION" of this document. manual.

Renewal of the registration of a tobacco- derived product .

To initiate a **registration renewal request**, one of the following paths can be followed:

Option 1 – Start with the **"Processes" tab**:

Access the "Processes" tab. The system will display the company's list of processes. The desired process can be filtered by entering its number and clicking on the magnifying glass at the top of the screen.



PROCESSO	DESCRIÇÃO	ATIVIDADE/TIPO DE PRODUTO	DT. ENTRADA	SITUAÇÃO	DT. SITUAÇÃO	AÇÕES
25351124249202006	0001 - Registro de Produto Fumigante - Dado Cadastro	Derivados do Tabaco	15/07/2025 08:00	Publicado deferimento	15/07/2025 15:18	[Ações]

Click the "Actions" button to view process details. The system will open a screen with the process data.

To start a Registration Renewal petition, click on the Registration process line on the left side of the screen and then click the **"New Petition" button**:



PROCESSO - 25351124249202006
0001 - Registro de Produto Fumigante - Dado Cadastro

0001 - Registro de Produto Fumigante - Dado Cadastro [0001/000001] 15/07/2025 - Publicado deferimento

EXPEDIENTE Nº 0007169205

+ Nova Petição | **00 - Ignorar Protocolo** | **0 - Adicionar aos favoritos**

Nome do Produto: TESTE

Favorabilidade: 11.111.111/0001-01 - EMPRESA DE TESTE LTDA. (V501)

Assunto: 0001 - Registro de Produto Fumigante - Dado Cadastro

Número do Processo: 25351124249202006

Número de Transação: 9291872226

Número de Protocolo: 20200000000023983

Situação: Publicado deferimento

Encontro-se na: GGTAB - GERENCIA GERAL DE REGISTRO E FISCALIZAÇÃO DE PRODUTOS FUMIGANTES, DERIVADOS OU NÃO DO TABACO

Desde: 15/07/2025

Publicação (RE - Data Resolução): 01 - 15/10/2025

The system will open the form to initiate the new petition linked to the Registration process, and select the Subject of the petition.

Option 2 – Start from the “**Drafts**” tab:

In the “Drafts” tab, click the “**New**” button and select the option “**Petition linked to an existing process**”:



In the form provided, click on the “magnifying glass” in the “Original Petition” field to display the screen for selecting the Registration process to be renewed.

After selecting the process, click on the “magnifying glass” in the “Subject” field to display the screen for selecting the Subject of the Renewal petition.

Next, the fields in the **Product Characteristics** section will be made available with the **information declared in the previous** Registration or Renewal application and approved in the technical analysis.

The fields “**Product Name**” and “**Product**” are not editable, as they cannot be changed.

The “**Filter Type**” field, in the case of products with filters, is not editable, as stipulated in the regulations for the registration of tobacco-derived products.

The remaining fields in the Product Features section are editable.

The section “**Parameters and Compounds Present in Primary Stream, Secondary Stream, and Total Tobacco**” will display **empty fields** available for the insertion of new laboratory report results.

The **Presentation Registration** section will display the Presentations that have been previously registered and Approved in the analysis. And they will be available for deletion and editing of companies and manufacturing stages. And it will be possible to include new Presentations in the petition.

NOTIFICATION OF TOBACCO DERIVED PRODUCT

This feature is only available for processes and petitions of the type “Tobacco Derivatives”.

To initiate a request for a **Tobacco Derivative Product Notification**, you must access the drafts tab and click the “New” button, selecting the “Initial Petition” option.

Rascunho

Novo Exportar Excel

Petição Inicial

Petição vinculada a um processo já existente

In the form provided, click on the "magnifying glass" icon in the "Subject" field to bring up the subject selection screen.

Dados gerais da petição

Assunto *

Fato Gerador Porte da Empresa Valor da Taxa

The subject can be searched by selecting "Tobacco Derivatives" in the "Activity/Product Type" field, or by selecting the corresponding service, or by entering the name or number of the desired subject.

Click the button Pesquisar and select the subject.

Selecione o assunto

Atividade/Tipo de produto

Selecione

Serviço

Código Descrição

Pesquisar

The following form will provide the information that must be completed in order to characterize the product being requested and all presentations that have primary packaging(s) and, where applicable, secondary packaging(s).

General Data (Product Characteristics Exclusive for Export)

The "General Data" section contains fields intended to characterize the requested product.

Dados Gerais (Características do Produto)

Nome do Produto * ?

Produto *

Selecione

Caso o Produto seja alterado, todos os dados do formulário serão excluídos e deverão ser preenchidos novamente.

Product Name: The "Product Name" field can hold up to 100 characters and accepts accents, but only the following special characters can be used: ";" ":" "." "-" "ç" "&" "°" "(" ")"

Product: The "Product" field displays the categories regulated by specific legislation. The rest of the form will have fields that are dynamic depending on the selected "Product".

Warning: If the product type is changed, all previously entered information will be deleted, and the user will need to fill in the data again.

For the products CIGAR, CIGARILLO, FILTERED CIGARETTE, KRETEK CIGARETTE, and UNFILTERED CIGARETTE, the fields **"Length"** and **"Circumference"** are displayed. The user must fill in the values, in millimeters, and can enter a value with up to five digits and two decimal places:

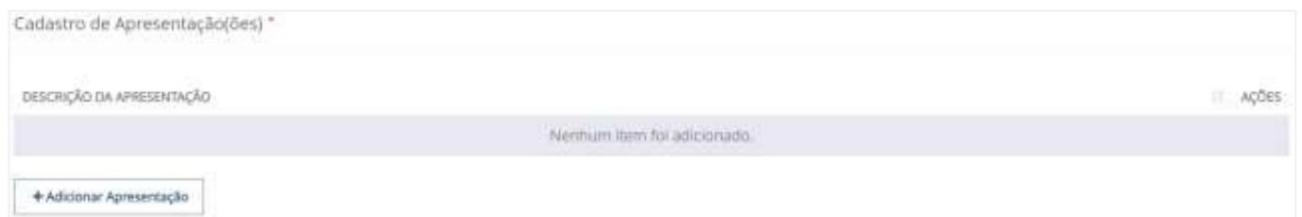


Comprimento (mm) * Circunferência (mm) *

12345,12 12345,12

Registration of Product Presentation(s) Exclusive for Export

Next, the "Presentation Registration(s)" section will be available, intended for registering Presentations that have primary packaging(s) and, where applicable, secondary packaging(s).



Cadastro de Apresentação(ões) *

DESCRIÇÃO DA APRESENTAÇÃO AÇÕES

Nenhum item foi adicionado.

+ Adicionar Apresentação

For each package that will be used in **exporting the product**, the user must click the button.



+ Adicionar Apresentação

The screen will display the information for registering each product presentation, separately showing the data for each primary packaging and then, if applicable, the data for each secondary packaging.

Presentation Description: This field is not editable, and the description is automatically generated by the system based on the information entered in the fields that make up this section.

To register primary packaging: The fields **"Primary Packaging"**, "Quantity" and "Unit" are intended to characterize the packaging(s) that contain the product.



Dados da Embalagem

Embalagem Primária * Quantidade * Unidade *

Selecione Selecione

Embalagem Secundária * ⓘ Quantidade Complemento ⓘ

APRESENTAÇÃO SOMENTE CONTEM EMBALAGEM

The "Primary Packaging" field is a drop-down menu. If it becomes necessary to add new options to the field, the user must submit a **primary petition for the Inclusion of Controlled Tobacco Vocabulary**.

The "Quantity" field refers to the amount of product in the primary packaging, in product units or in grams (in this case, you can enter a value with up to six digits and two decimal places). In the case of **filtered cigarettes and kretek cigarettes**, the system automatically fills in the quantity and unit fields.

The "Secondary Packaging" field, which is the product's outer packaging and contains more than one primary package, should have the "Presentation with primary packaging only" option selected when registering Presentations that have only primary packaging(s).

The "Additional Information" field should be used if there is more than one layout for the same type of packaging. This field can contain information that will allow consumers to differentiate between packages, such as shape, packaging material, opening system, or other information, which will be included in the description to be published in the Official Gazette.

Below is an example of how fields are used to structure the description of a primary presentation:



To register secondary packaging: The fields "Primary Packaging", "Quantity" and "Unit" must be filled with the data of the primary packaging that will be contained within the secondary packaging.

The fields "Secondary Packaging" and "Quantity" are intended to describe the secondary packaging, used to contain more than one primary package.

The "Quantity" field on the secondary packaging refers to the number of primary packages contained within the secondary packaging.



The "Secondary Packaging" field is a drop-down menu. If it becomes necessary to add new options to the field, the user must submit a **primary petition for the Inclusion of Controlled Tobacco Vocabulary**.

Below are two examples of how fields are used to structure the description of a presentation:



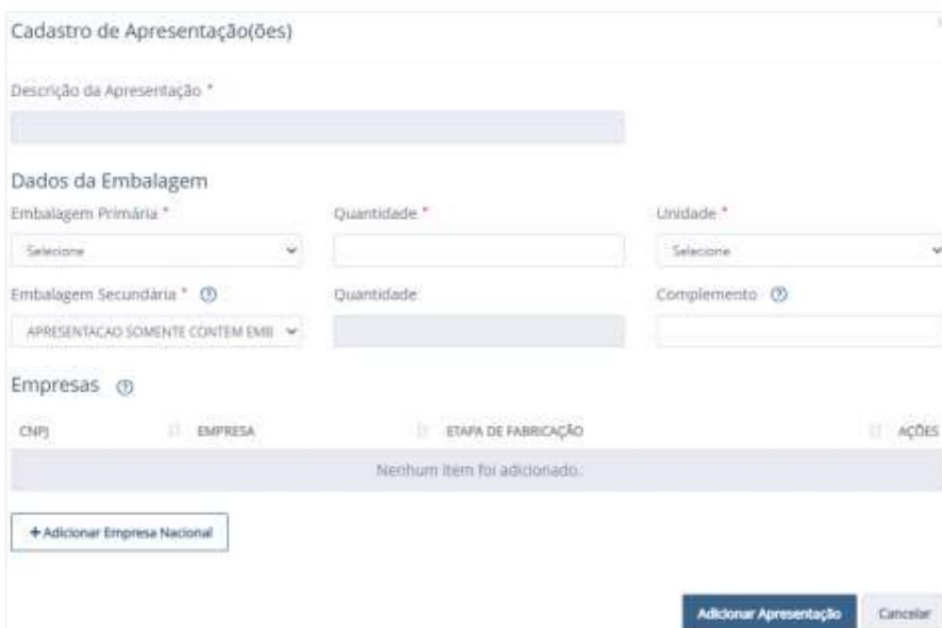
Descrição da Apresentação *

PACOTE com 30 SACO (tipo POUCH) com 10 GRAMA Pacote transparente

Dados da Embalagem

Embalagem Primária *	Quantidade *	Unidade *
SACO (tipo POUCH)	10	GRAMA
Embalagem Secundária * ⓘ	Quantidade *	Complemento ⓘ
PACOTE	30	Pacote transparente

The "**Companies**" field should be used to list **all companies involved in the manufacturing of the product, from tobacco processing to the finished product and final packaging**.



Cadastro de Apresentação(ões)

Descrição da Apresentação *

Dados da Embalagem

Embalagem Primária *	Quantidade *	Unidade *
Selecione		Selecione
Embalagem Secundária * ⓘ	Quantidade	Complemento ⓘ
APRESENTACAO SOMENTE CONTEM EMII		

Empresas ⓘ

CNPJ	EMPRESA	ETAPA DE FABRICAÇÃO	AÇÕES
Nenhum item foi adicionado.			

[+ Adicionar Empresa Nacional](#)

[Adicionar Apresentação](#) [Cancelar](#)

The section for including company data consists of two windows.

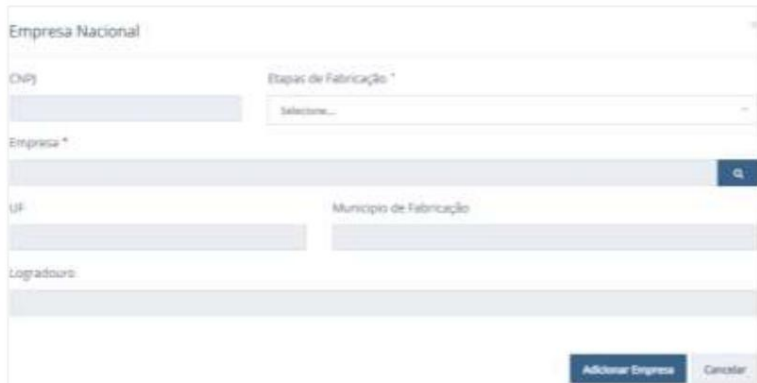
To enter the data for a national company, click the button.



CNPJ	EMPRESA	ETAPA DE FABRICAÇÃO	AÇÕES
Nenhum item foi adicionado.			

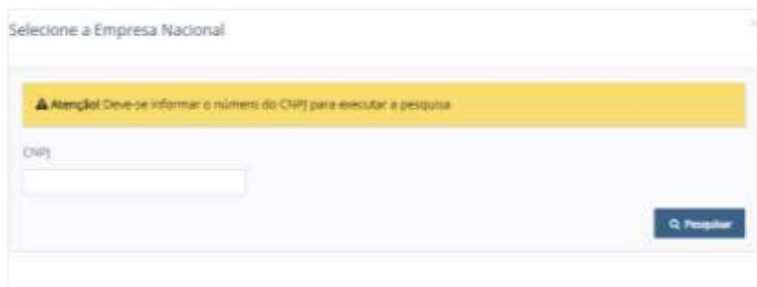
[+ Adicionar Empresa Nacional](#)

The system displays a window to select the steps involved in manufacturing and to indicate the national company responsible for each step:

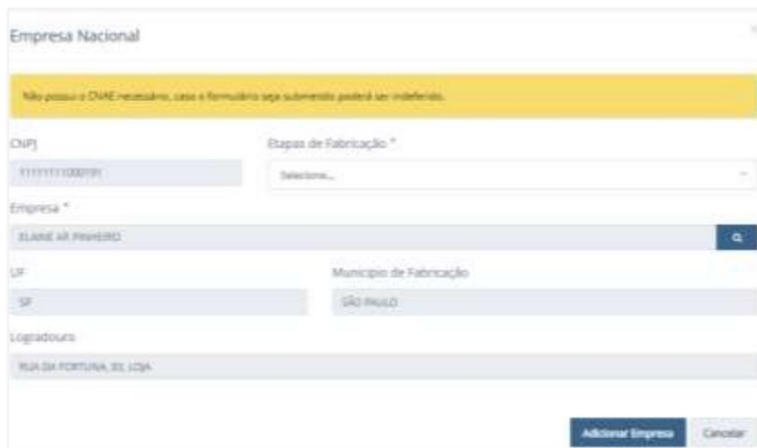


The **"Manufacturing Steps"** field is a drop-down menu that displays the possible steps that can be performed, allowing the user to select one or more steps. If it becomes necessary to add new options to the field, the user must submit a **primary petition for the Inclusion of Controlled Tobacco Vocabulary**.

To select the company responsible for the stage(s) involved in manufacturing, click the button; a new . One window will open to enter the CNPJ of the national company.



Enter the CNPJ (Brazilian company tax ID) and click the button to search for the company's data. Once the desired company is displayed, click the button to select it. Once selected, the system will close this window, loading the company's data into the previous window.





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Click on the button  so that the company data entered is displayed for the Presentation (packaging) that is being registered.

The system validates whether the company has a CNAE (National Classification of Economic Activities) code that qualifies it to carry out the stated activity.

If an application is submitted that includes companies that do not have the appropriate CNAE codes, the application may be rejected after review.

The action button allows you to edit the company, while the button allows you to delete it.

Documentation

In this section, **all requested documents** for the chosen subject must be attached. The system indicates the mandatory documents without which the product petition will not be processed.

File attachments of the following types are allowed: jpg, jpeg, bmp, png, pdf, doc, docx, xls, and.xlsx. **Limited to 50MB.** The file name, including the file type, must be limited to 149 characters.

Attention: **The files for each packaging (Presentation) declared in the Presentation Registration section** must be attached.

More details can be found in the section "4. CREATING A DRAFT OF A PRIMARY PETITION" in this manual.

Once all the data has been entered and all the files have been attached and viewed, you can complete and submit the petition by clicking the button.



Since registration/renewal of registration petitions are subject to an inspection fee, they will remain in the "Awaiting Protocol" status on the homepage until the system identifies the... collection of the fee.

Renewal of Notification for Tobacco -Derived Product

To initiate a request for **Renewal of Notification of Tobacco-Derived Product**, one of the following paths can be followed:

Option 1 – Start with the **“Processes” tab**:

Access the “Processes” tab. The system will display the company's list of processes. The desired process can be filtered by entering its number and clicking on the magnifying glass at the top of the screen.

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PROCESSO	SITUAÇÃO	ATIVIDADE DO PRODUTO	DT. ENTRADA	SITUAÇÃO	DT. SITUAÇÃO	AÇÃO
263060000130040	0073 - Inutilização de Produto Fungicida Derivado do Tabaco Exclusivo para Exportação	Derivado do Tabaco	25/08/2024 11:24	Ativo	25/08/2024 11:24	
263060000370081	0071 - Registro de Produto Fungicida Derivado do Tabaco	Derivado do Tabaco	14/07/2024 14:34	Em análise	24/07/2024 15:09	
263060000400028	0071 - Registro de Produto Fungicida Derivado do Tabaco	Derivado do Tabaco	18/07/2024 11:27	Em análise	23/07/2024 17:08	
253011240400086	0007 - Registro de Produto Fungicida - Zinco Cadifenos	Derivado do Tabaco	16/09/2024 09:09	Publicado deferimento	16/09/2024 10:19	
063060000130043	0073 - Inutilização de Produto Fungicida Derivado do Tabaco Exclusivo para Exportação	Derivado do Tabaco	03/09/2024 15:40	Ativo	18/09/2024 11:58	

Click the “Actions” button to view process details. The system will open a screen with the process data.

To initiate a **Notification Renewal** petition, click on the Notification process line on the left side of the screen and then click the **“New Petition”** button:

[illegible]

The system will open the form to initiate the new petition linked to the Notification process, and selection of the petition's Subject.

The form will include fields **containing the information declared in the previous Notification/Renewal of Exclusive Export Product petition**, relating to Product Characteristics and Presentations.

Option 2 – Start from the “**Drafts**” tab:

In the "Drafts" tab, click the "New" button and select the option "Petition linked to an existing process":

Petição vinculada a um processo já existente

In the form provided, click on the "magnifying glass" in the "Original Petition" field to display the screen for selecting the desired case.



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Next, click on the "magnifying glass" in the "Subject" field to bring up the screen for selecting the petition's subject.

After selecting the Subject, the form will display fields containing the information declared in the previous petition, Notification/Renewal of Exclusive Export Product, relating to Product Characteristics and Presentations.

The fields "Product Name" and "Product" are not editable, as they cannot be changed.

For **cigars, cigarillos, filtered cigarettes, kretek cigarettes, and unfiltered cigarettes**, the "Length" and "Circumference" fields are displayed with information from the last Notification/Renewal of Notification petition. These fields are editable.

The **Presentation Registration** section will display the Presentations that have been previously registered in the Notification and Notification Renewal petitions. These will be available for deletion and for editing companies and manufacturing stages. It will also be possible to add new Presentations to the petition.

REGISTRATION OF PROCESSED TOBACCO

This feature is only available for processes and petitions of the type "Tobacco Derivatives".

To begin the process of requesting an **Annual Registration of Processed Tobacco**, you must access the drafts tab and click the "New" button, selecting the "Initial Petition" option .



In the form provided, click on the "magnifying glass" icon in the "Subject" field to bring up the subject selection screen.

The subject can be searched by selecting "Tobacco Derivatives" in the "Activity/Product Type" field, or by selecting the corresponding service, or by entering the name or number of the desired subject.

Click the button  and select the subject.



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After selecting the desired subject, the fields in the "General Petition Data" section will be automatically completed, and up to 3 blocks will appear: "Form Templates," "Legal Basis," and "Documentation."

Click on the **"Processed Tobacco"** form template , fill in the information regarding the origin of the types of tobacco processed in the previous year , and save the document.

It will be mandatory to attach this document to the respective checklist item in the "Documentation" section.



Public Health Laboratory Forms

Authorization and Accreditation of Public Health Laboratories - REBLAS

To submit an initial application for authorization or accreditation, start a new petition and select the subject corresponding to the desired request.

Initial Qualification and Initial Accreditation

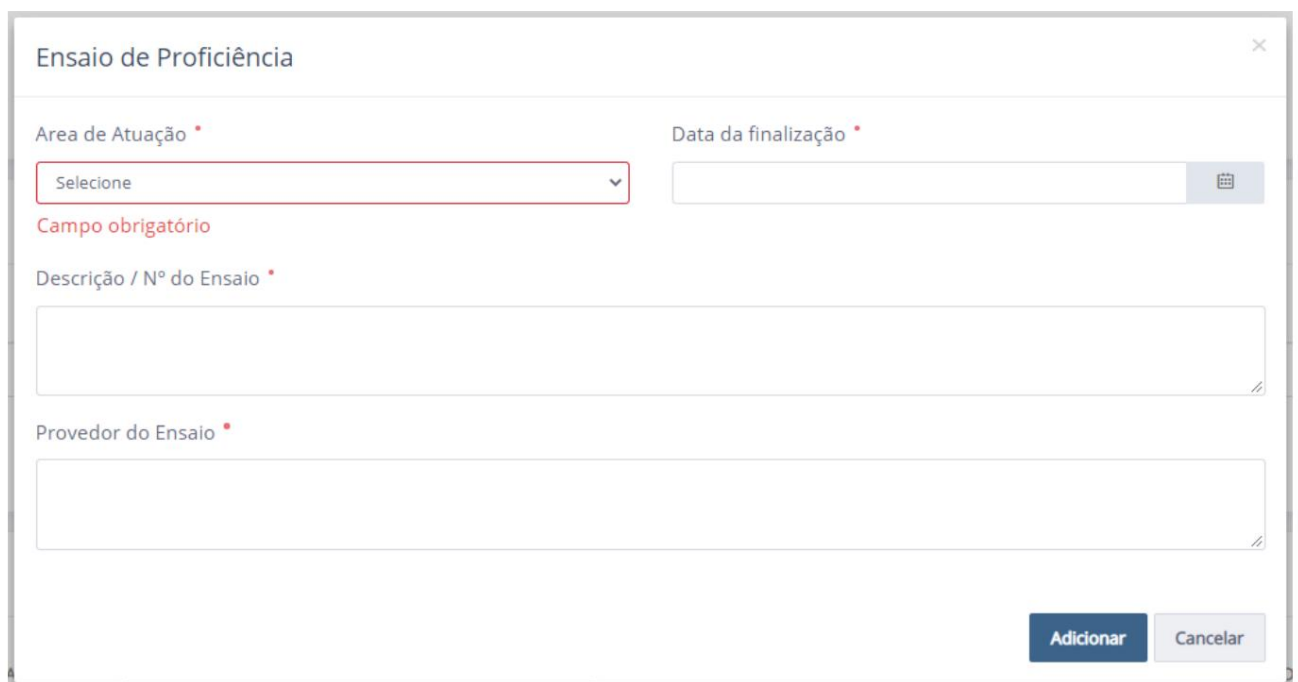
For these types of matters, a field will be displayed regarding the health license or operating permit issued by a Health Surveillance agency. This document is mandatory, and is only exempt from presentation for laboratories that are part of the Public Administration or established by it.



Next, the information block relating to the requested scope will be presented, where the areas of expertise and products should be filled in as desired.



In the next section, information regarding proficiency testing will be required. Completing this information is mandatory only for applications involving laboratory accreditation.



The following section contains fields related to accreditations. This field is optional.



Finally, the evaluation information block must be completed. In this block, the fields are dynamic according to the selected answers. For example, when selecting the option “no” for the question “Does the laboratory meet all the evaluation criteria of the Good Laboratory Practices Compliance Assessment Roadmap (Appendix to Annex I)?”, a set of information will be presented to indicate which categories had an evaluation criterion that was not met or is not applicable. When a category is selected, the criteria will be displayed afterwards.



After completing this step, the user must follow the rest of the process, as detailed in previous sections of this manual, until the protocol is completed and the protocol receipt is received.

Initial Accreditation

The application form for designation as an official accrediting laboratory does not have open fields for completion; only the requested attachments need to be included. The user must follow the rest of the process, as detailed in previous sections of this manual, until the protocol is completed and proof of protocol is received.

The request for designation as an official accrediting laboratory applies only to laboratories of Ministry of Health or equivalent body of the Union, States, Municipalities and the Federal District legally established and responsible for carrying out fiscal, control and guidance analyses, among others, on food, medicines, pharmaceutical inputs, personal hygiene products, cosmetics, perfumes, health products, sanitizers and other products subject to sanitary surveillance;

Renewal of Qualification, Accreditation and Scope Change

To submit a request for renewal or change of scope of qualification in Reblas or accreditation of an analytical laboratory, start a petition linked to an existing process, locate the desired initial process, and then select the petition subject of interest.

Next, the system will automatically load the existing information for the Sanitary License, Requested Scope, Proficiency Testing, and Accreditations blocks, if applicable. The company can then make any necessary changes to the information presented.

For the evaluation information section, the company must complete the form again, as previously instructed.

Cancellation of Accreditation

The accreditation cancellation form does not have open fields for completion; only the requested attachments need to be included. The user must follow the rest of the process, as detailed in previous sections of this manual, until the protocol is completed and proof of protocol is received.

MEDICINE AND BIOLOGICAL PRODUCT FORMS

Prioritization and Rare Disease

This feature is only available for processes and petitions of the type "Medicine".

When starting drafts of matters that are eligible for prioritization, according to [RDC 1001/2025 and its updates](#), or rare diseases, as defined by [RDC 205/2017 and its updates](#), The user will be asked to fill in the "Prioritization Information" field:



Informações de Priorização

Informações de Priorização *

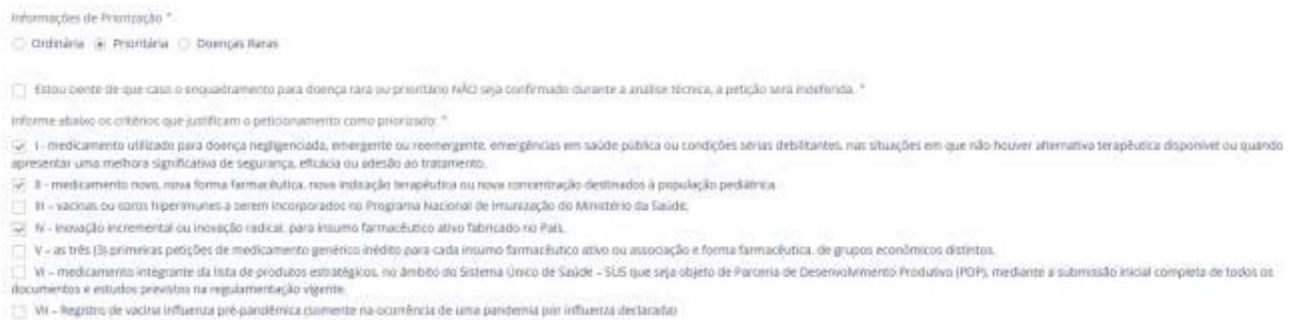
☐ Ordinária ☒ Prioritária ☐ Doenças Raras

Important! The options displayed here will depend on the specific subject matter of each petition. For example, if a subject allows priority selection but does not allow the option for rare diseases, that option will be displayed.

The last one will not be shown.

The "Ordinary" option indicates that the petition in question will not be subject to prioritization or rare disease review, and will follow the same path as a regular petition, being displayed in the corresponding queue and analyzed according to the area's standard workflow.

The "Priority" option indicates that the company is requesting classification in accordance with the provisions of RDC 1001/2025 and its updates. Selecting this option will display the selectable sections according to the category of the selected subject (registration, post-registration, clinical research):



Informações de Priorização *

☐ Ordinária ☒ Prioritária ☐ Doenças Raras

☐ Estou ciente de que caso o enquadramento para doença rara ou prioritário NÃO seja confirmado durante a análise técnica, a petição será indeferida. *

Informe abaixo os critérios que justificam o posicionamento como priorizado: *

☒ I - medicamento utilizado para doença negligenciada, emergente ou reemergente, emergências em saúde pública ou condições sérias debilitantes, nas situações em que não houver alternativa terapêutica disponível ou quando apresentar uma melhoria significativa de segurança, eficácia ou adesão ao tratamento.

☒ II - medicamento novo, nova forma farmacêutica, nova indicação terapêutica ou nova concentração destinados à população pediátrica

☐ III - vacinas ou soros hiperimunes a serem incorporados no Programa Nacional de Imunização do Ministério da Saúde;

☒ IV - inovação incremental ou inovação radical, para insumo farmacêutico ativo fabricado no País.

☐ V - as três (3) primeiras petições de medicamento genérico inédito para cada insumo farmacêutico ativo ou associação e forma farmacêutica, de grupos econômicos distintos.

☐ VI - medicamento integrante da lista de produtos estratégicos, no âmbito do Sistema Único de Saúde - SUS que seja objeto de Parceria de Desenvolvimento Produtivo (POP), mediante a submissão inicial completa de todos os documentos e estudos previstos na regulamentação vigente.

☐ VII - registro de vacina influenza pré-pandêmica (sujeito na ocorrência de uma pandemia por influenza declarada)

The option "Rare Diseases" indicates that the company is requesting classification in accordance with the provisions of RDC 205/2017 and its updates. In this option, there are no specific sections to be selected.

Informações de Priorização *

☐ Ordinária ☐ Prioritária ☒ Doenças Raras☐ Estou ciente de que caso o enquadramento para doença rara ou prioritário NÃO seja confirmado durante a análise técnica, a petição será indeferida. *

In both cases, the company must indicate in the displayed checkbox that, if the requested classification is not confirmed during the technical analysis, the petition will be rejected in accordance with applicable laws. Furthermore, the company must attach supporting documentation proving the selection made using the [method/tool - context needed].

icon  in the "Files" line of this section, and also check the checkbox declaring that the information They are legitimate and have been verified by the company before shipping:

ARQUIVOS

AÇÕES

documentação comprobatória.pdf

☒ Declaro que visualizei a documentação anexada e que todas as informações são legítimas. *

NOTIFICATION OF MEDICINES – MEDICINAL GASES

Functionality available only for processes of the "Medicine" type and for the regulatory category. "Medical Gases".

To initiate a request for notification of medical gases, you must access the drafts tab and click the "New" button, selecting the "Initial Petition" option:



In the form provided, click on the "magnifying glass" in the subject field, and on the next screen enter the name or code of the desired subject.



Código	Atividade/Tipo de Produto	Descrição
12293	Medicamento	Gás Medicinal - Notificação de medicamento

By selecting the appropriate subject, the drug notification form will be displayed to the user, where the information must be filled in to characterize the product.

IMPORTANT! The **applicant for the notification** must have active Good Manufacturing Practices (GMP) or Good Distribution and Storage Practices (GDSP) certification for medicines in order for the notification to be activated. Otherwise, an alert message will be displayed:

Dados gerais da petição

Assunto *

Em caso de submissão deste formulário, a notificação não será ativada, pois a empresa notificadora não possui CBPF/CBPDV válido, infringindo a legislação sanitária

Dados Gerais

Nome do Medicamento *

Categoria *

Descrição *

Forma Farmacêutica *

Linha de Produção *

The first block of information relates to general product data, with all fields being mandatory.

The drug name is a free text field. The "category" field will only allow the selection of the Medical Gases option. After this selection, the "Description" field will display the options for medical gases or cryogenic liquids subject to regulation through notification; to include a new description, the user must request it from the responsible area via a specific petition in the Solicita system and await a response from Anvisa regarding this request. The "Pharmaceutical Form" field will allow the selection of options related to the selected description. The "Production Line" field is read-only and will be automatically filled in according to the previous selections.

Next, the "Presentation Registration(s)" section must be completed:

Cadastro de Apresentação(ões) * ?

DESCRIÇÃO DA APRESENTAÇÃO

⌵ AÇÕES

Nenhum item foi adicionado.

+ Adicionar apresentação

+ Adicionar apresentação

By clicking the button about the product: . A modal window will open for inserting presentations.

Apresentações

Descrição da Apresentação * ?

Embalagem Primária * ?

Embalagem Secundária * ?

PRODUTO SOMENTE CONTEM EMBALAGEM PRIMARIA

Prazo de Validade *

Unidade de Tempo *

Selecione

Volume/Quantidade *

Unidade de Medida *

The "Presentation Description" field is free-text, but must follow the [Controlled Vocabulary of Pharmaceutical Forms, Routes of Administration and Packaging of Medicines](#).

The Primary Packaging and Secondary Packaging fields will display the available options for the user to select. By default, the second field will automatically load the option "PRODUCT ONLY CONTAINS PRIMARY PACKAGING," but this can be changed by the user as needed.

If the desired option is not displayed, the user should contact the responsible department. The Expiry Date field should be filled with numbers only, and the Time Unit selected in the following field. The Volume/Quantity field should also be filled with numbers only, and the Unit of Measurement selected in the following field.

Fórmula

COMPONENTE DA FÓRMULA	QUANTIDADE	UNIDADE DE MEDIDA	FUNÇÃO	AÇÕES
HÉLIO	100	%	Princípio Ativo	

The information in the Formula block will be pre-loaded according to the description of the selected product and, therefore, cannot be changed.

In the next section, the user will enter information about national and international manufacturers. **It is mandatory to register at least one manufacturer, whether national or international.**

IMPORTANT! The manufacturer must have active Good Manufacturing Practices (GMP) or Good Distribution and Storage Practices (GDSP) certification for the medical gas line for the notification to be activated; otherwise, an alert message will be displayed.

Em caso de submissão deste formulário, a notificação não será ativada, pois uma ou mais das empresas fabricantes selecionadas não possui CBPF/CBPA válido, infringindo a legislação sanitária.

Fabricantes

CNPJ	FABRICANTE	ETAPA DE FABRICAÇÃO	AÇÕES
Nenhum item foi adicionado.			
+ Adicionar Fabricante Nacional			

CÓDIGO ÚNICO	FABRICANTE	ETAPA DE FABRICAÇÃO	AÇÕES
Nenhum item foi adicionado.			
+ Adicionar Fabricante Internacional			

By pressing the button

[+ Adicionar Fabricante Nacional](#)

A modal will load for selecting the national manufacturer to be added. The user must add one manufacturer at a time and, in the case of multiple manufacturers, press the same button to add the others sequentially.

Fabricante Nacional
 ×

CNPJ

Etapas Fabricação *

Fabricante *

UF

Município de Fabricação

Logradouro

In the modal, the user must select which manufacturing step is the responsibility of the manufacturer to be...

inserted. By clicking the button



You can search for the manufacturer using their CNPJ (Brazilian tax ID) or company name.

By pressing the button



A modal window will load for selecting the international manufacturer to be added. The user must add one manufacturer at a time and, in the case of multiple manufacturers, use the same button to add the others sequentially.

Fabricante Internacional

×

Código Unico

Etapas de Fabricação *

Selecione...

▼

Fabricante *

Q

Município de Fabricação

País

Logradouro

Adicionar Fabricante

Cancelar

In the modal, the user must select which manufacturing step is the responsibility of the manufacturer to be...

inserted. By clicking the button



You can search for the manufacturer by unique code, name, or country. If the desired international company is not registered, please contact the team at the responsible organizational unit.

After adding the manufacturer(s), their data will be available on the presentation screen, being

It is possible to add one or more manufacturers. Using the button



It is possible to change the company data.

The inserted manufacturer can be deleted using the button.



After the first presentation is added, if the user wishes to add more presentations, subsequent presentations will display an option to copy from an already registered one, in order to optimize the user's data entry process.

Você deseja copiar os dados de uma apresentação já cadastrada? 

☐ Sim ☒ Não

Apresentação

Selecione

Selecione

Apresentação 1

Apresentação 2

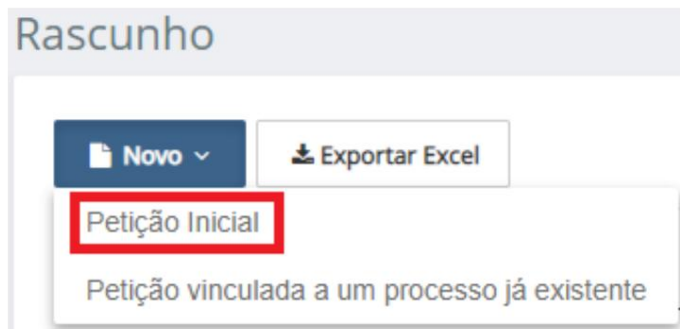
CLINICAL RESEARCH FORMS

Clinical Drug Research Forms

Drug Clinical Development Dossier (DDCM) Form

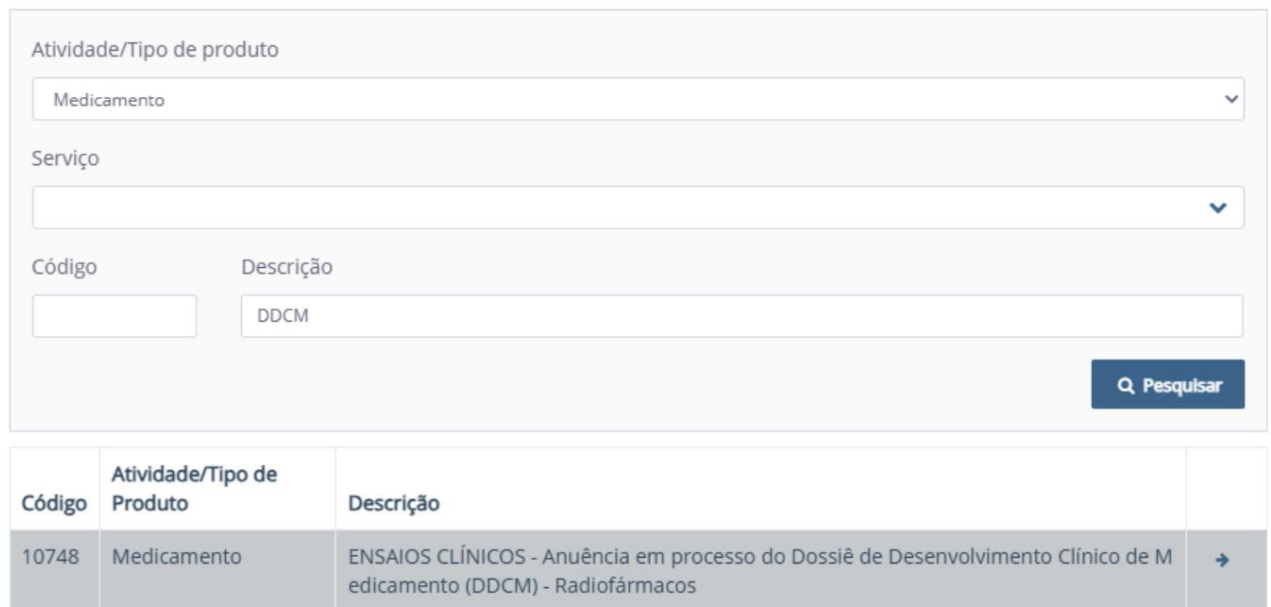
This feature is only available for processes of the "Medicines" type.

To initiate a request related to a Clinical Drug Development Dossier (DDCM), it is necessary to access the "Drafts" tab and click the "New" button, selecting the "Petition" option. "Initial".



In the form provided, click on the "magnifying glass" in the subject field, and on the next screen enter the name or number of the desired subject.

Selecione o assunto



Código	Atividade/Tipo de Produto	Descrição	
10748	Medicamento	ENSAIOS CLÍNICOS - Anuência em processo do Dossiê de Desenvolvimento Clínico de M edicamento (DDCM) - Radiofármacos	→

The following form will provide information that must be completed in order to characterize the clinical research.

The "General Data" section has the following fields to be filled in.

Dados das Empresas Envolvidas

A Empresa Solicitante se enquadra como: *

☐ Patrocinador ☐ ORPC

In this section, the company must indicate whether it is the sponsor of the DDCM itself, or whether it is a Clinical Research Organization (CRO) representing the sponsor. For pharmaceuticals, the applicant should only indicate CRO in cases where the sponsor does not have a headquarters or branch in Brazil. In this case, a field will open to provide the corporate name of the foreign sponsor:

Razão Social do Patrocinador Estrangeiro: * ?

Next, the "Experimental Product Data" section is intended to describe the experimental drug.

Tipo de Medicamento * ?

The "drug type" field presents a drop-down menu with options for selection. The company must select the appropriate investigational drug type.

Classe Terapêutica (Categoria do Produto) * ?

The "therapeutic class (product category)" field is intended to classify the product according to the *Anatomical Therapeutic Chemical* (ATC) categories available in the dropdown list. Note that there are options available when the product is innovative and does not yet have an appropriate category registered, such as "other" and "all other therapeutic products". To add new categories to the dropdown list, please contact the responsible area.

É um produto sob investigação complexo? *

☐ Sim ☐ Não

Next, the question is presented as to whether the product under investigation is "complex" in terms of current legislation. By selecting "yes," other options will be displayed for selection, and it is mandatory to select at least one category in this case:

É um produto sob investigação complexo? *

☒ Sim ☐ Não

Ele se enquadra na(s) seguinte(s) categoria(s): *

☐ Substâncias ativas ou insumos farmacêuticos ativos complexos, incluindo anticorpos monoclonais (mAbs), anticorpos ou frações de anticorpos conjugados, hormônios, substâncias derivadas de tecnologia de DNA recombinante (rDNA), mRNAs, fatores de coagulação sanguínea, produtos originados de tecidos humanos, compostos poliméricos, misturas complexas de origem natural (fitoterápicos), nucleotídeos sintéticos, peptídeos ou oligopeptídeos, substâncias sintéticas de alto peso molecular, produtos enzimáticos.

☐ Formas farmacêuticas complexas, incluindo lipossomos, microesferas, nanocristais, partículas poliméricas, nano-suspensões e nano-emulsões, implantes injetáveis.

☐ Combinação de medicamentos com dispositivos médicos, como canetas injetoras, seringas preenchidas e outros dispositivos.

É obrigatória a seleção de pelo menos uma categoria

É um produto sob investigação complexo? *

☒ Sim ☐ Não

Ele se enquadra na(s) seguinte(s) categoria(s): *

☐ Substâncias ativas ou insumos farmacêuticos ativos complexos, incluindo anticorpos monoclonais (mAbs), anticorpos ou frações de anticorpos conjugados, hormônios, substâncias derivadas de tecnologia de DNA recombinante (rDNA), mRNAs, fatores de coagulação sanguínea, produtos originados de tecidos humanos, compostos poliméricos, misturas complexas de origem natural (fitoterápicos), nucleotídeos sintéticos, peptídeos ou oligopeptídeos, substâncias sintéticas de alto peso molecular, produtos enzimáticos.

☐ Formas farmacêuticas complexas, incluindo lipossomos, microesferas, nanocristais, partículas poliméricas, nano-suspensões e nano-emulsões, implantes injetáveis.

☐ Combinação de medicamentos com dispositivos médicos, como canetas injetoras, seringas preenchidas e outros dispositivos.

É obrigatória a seleção de pelo menos uma categoria

Next, the fields related to product registration in Brazil and abroad are presented:

O produto possui registro no Brasil? *

☐ Sim ☐ Não

O Produto possui registro no Exterior? *

☐ Sim ☐ Não

By selecting "yes" for the first question, a field will open to enter the 9-digit product registration number, and the system will automatically load the trade name and list of active ingredients as registered.

O produto possui registro no Brasil? *

☒ Sim ☐ Não

Número do Registro: (*)

18000000

Nome Comercial

Algoritmo de Inteligência

Princípio(s) Ativo(s)

Salicina, Sulfato de Hidrocortisona

If the "no" option is selected, the system will display open text fields to enter the product code (assigned by the manufacturer/sponsor) and the active ingredients:

O produto possui registro no Brasil *

☐ Sim ☒ Não

Código do Produto *

Princípio Ativo *

Important! The active ingredient field does not accept special characters, so the company must use the full text and normal characters to describe the ingredients. For example, ^{99m}Tc should be described as **technetium-99m**; and γ -tocopherol should be described as **alpha-tocopherol**. For combinations, the active ingredients should be separated by a semicolon (;).

Next, the company must indicate whether the product is registered abroad. Selecting "yes" will display a table where the company must provide the trade name and the countries where the product is registered under that name.

Produtos Registrados no Exterior

Nome Comercial	Países onde o produto está registrado
Nenhum item foi adicionado.	

+ Adicionar

Adding to the table can be done using the button, which will load the modal below. In it, the business name is entered in the text field, and the dropdown menu allows multiple selection of applicable countries. This procedure must be repeated for each distinct trade name the product may have abroad.

Produto(s) Registrado(s) no Exterior

Nome Comercial *

TESTE 01

Países onde o produto está registrado *

AÇORES, ALAND, ILHAS, ANDORRA

>>> NÃO INFORMADO (CARGA SISPAFRA)

AÇORES ✓

AFEGANISTÃO

ÁFRICA DO SUL, REPÚBLICA DA

ALAND, ILHAS ✓

ALBÂNIA

ALEMANHA

ANDORRA ✓

ANGOLA

Produtos Registrados no Exterior

NOME COMERCIAL	PAÍSES ONDE O PRODUTO ESTÁ REGISTRADO	AÇÕES
TESTE 01	AÇORES, ALAND, ILHAS, ANDORRA	 
+ Adicionar		

The action button  allows editing, while the button  allows the deletion of that line.

The "Manufacturers" section allows the inclusion of national or international manufacturers, with at least one manufacturer being registered. The section is composed of two modes: one for entering data for national manufacturers and another for entering data for international manufacturers.

Fabricantes

A petição deve possuir pelo menos uma empresa Fabricante Nacional ou Internacional.

CNPJ	FABRICANTE	AÇÕES
Nenhum item foi adicionado.		
+ Adicionar Fabricante Nacional		

FABRICANTE	PAÍS	CIDADE	AÇÕES
Nenhum item foi adicionado.			
+ Adicionar Fabricante Internacional			

To enter data for a national manufacturer, click the button.

+ Adicionar Fabricante Nacional

to display the selection option for the responsible company.



MNU - User Manual

Fabricante Nacional

CNPJ

Fabricante *

UF

Município de Fabricação

Logradouro

Adicionar Fabricante

Cancelar



To select the company, click the button.

A new mode of transport will be opened.

Selecione a empresa nacional

⚠ **Atenção!** Deve-se informar, pelo menos um filtro para executar a Pesquisa

CNPJ

Fabricante

Pesquisar

The search can be done using the company's CNPJ (Brazilian corporate tax ID) or its legal name.

CNPJ

Fabricante

 Pesquisar

CNPJ	Fabricante	UF	Município	Logradouro	
11222333000181	EMPRESA DE TESTE	DF	BRASÍLIA	AVENIDA DE TESTE	
99888777000100	EMPRESA DE TESTE	DF	BRASÍLIA	RUA DE TESTE SEM FIM	

Once the desired company has been displayed, click the button.



to select it.

The company data will be filled in the previous form.

Important! The data entered here is retrieved from the Federal Revenue Service database. To include a national manufacturer, the CNPJ (Brazilian taxpayer ID) must be active with the Revenue Service, otherwise an error message will be displayed, preventing the insertion of the selected company.

O CNPJ informado não está ativo.

Adicionar Fabricante

Click the button

so that it appears in the list of manufacturers.

The action button



allows editing, while the button



Allows the line to be deleted.

For international manufacturers, the shipping method will be charged as follows:

Fabricante Internacional ×

Fabricante *

Campo obrigatório

País *

 ▼

Cidade *

 ▼

Adicionar Fabricante

Cancelar

In this case, the company manually fills in the international manufacturer's company name and then selects the country where the company is located. Once the country is selected, the list of cities will be loaded for selection.

Fabricante Internacional

Fabricante *

empresa de teste

País *

PARAGUAI

Cidade *

CIUDAD DEL ESTE

Selecione

ASSUNCAO

CAPIATÁ

CIUDAD DEL ESTE

FERNANDO DE LA MORA

HERNANDARIAS

ITAUGUA

LUQUE

MINGA GUAZÚ

PEDRO JUAN CABALLERO

PRESIDENTE FRANCO

SAN JUAN BAUTISTA

SAN LORENZO

Adicionar Fabricante

Click the button so that it appears in the list of manufacturers.

The action button  allows editing, while the button  Allows the line to be deleted.

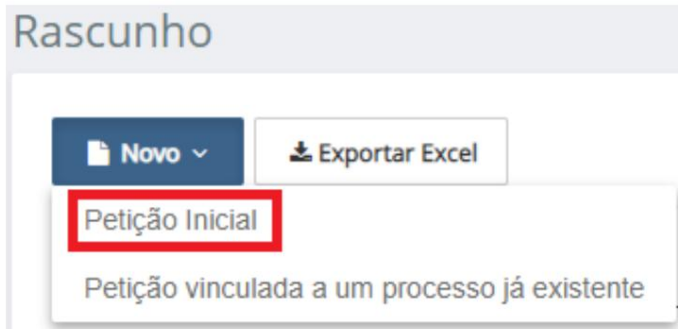
For information on prioritizing analysis, [see the appropriate section of this manual.](#)

Clinical Trial Specific Dossier Form (DEEC)

This feature is only available for processes of the "Medicines" type.

To initiate a request for a Clinical Trial Specific Dossier (DEEC), you must access the drafts tab and click the "New" button, selecting the "Initial Petition" option.

Important! In order to request a DEEC, the DDCM to which it will be linked must already have been registered with Anvisa.



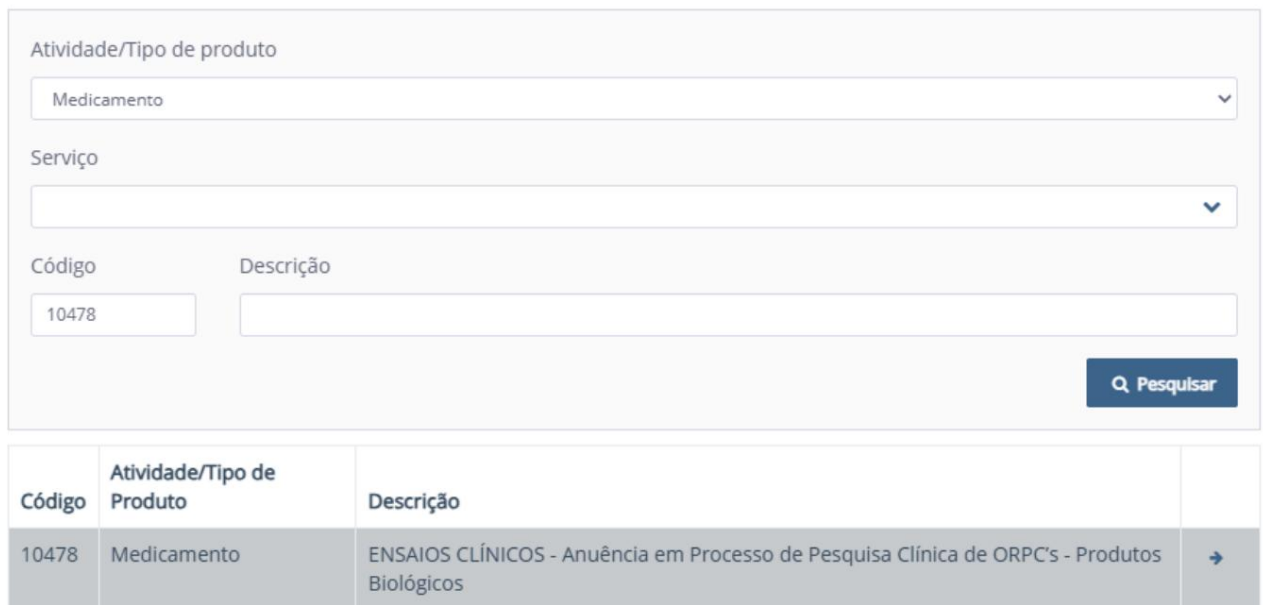
Rascunho

Novo ▾ Exportar Excel

Petição Inicial

Petição vinculada a um processo já existente

In the form provided, click on the "magnifying glass" in the subject field, and on the next screen enter the name or number of the desired subject.



Atividade/Tipo de produto

Medicamento ▾

Serviço

▾

Código Descrição

10478

Pesquisar

Código	Atividade/Tipo de Produto	Descrição	
10478	Medicamento	ENSAIOS CLÍNICOS - Anuência em Processo de Pesquisa Clínica de ORPC's - Produtos Biológicos	→

The following form will provide information that must be completed in order to characterize the clinical trial.

The first block of information is "DDCM Data," where the company must provide the DDCM process number to which the DEEC on screen will be linked.

Dados do DDCM

Número do processo de DDCM ao qual esse DEEC será vinculado * ?

By entering a valid DDCM process number, the rest of the form will be loaded on the screen.

Since the company requesting the DEEC may be different from the company requesting the DDCM (as in the case of a CRO, for example), the "Experimental Product Data" block will be displayed first, exactly as it was filled in by the company requesting the DDCM. Most of this section is locked for editing (read-only), serving only for verification by the company requesting the DEEC; the only editable fields are "Therapeutic Class (Product Category)" and "Is the Product Registered Abroad?", where the company requesting the DEEC must update the information as applicable.

Dados do DDCM

Número do processo de DDCM ao qual esse DEEC será vinculado * ?

25351.000012/2026-22

Dados das Empresas Envolvidas

A Empresa Solicitante se enquadra como: *

☒ Patrocinador ☐ ORPC

Dados do Produto Experimental

Tipo de Medicamento * ?

Gás medicinal

Classe Terapêutica (Categoria do Produto) * ?

ABARELIX



É um produto sob investigação complexo? *

☒ Sim ☐ Não

Ele se enquadra na(s) seguinte(s) categoria(s): *

- ☐ Substâncias ativas ou insumos farmacêuticos ativos complexos, incluindo anticorpos monoclonais (mAbs), anticorpos ou frações de anticorpos conjugados, hormônios, substâncias derivadas de tecnologia de DNA recombinante (rDNA), mRNAs, fatores de coagulação sanguínea, produtos originados de tecidos humanos, compostos poliméricos, misturas com plexas de origem natural (fitoterápicos), nucleotídeos sintéticos, peptídeos ou oligopeptídeos, substâncias sintéticas de alto peso molecular, produtos enzimáticos.
- ☒ Formas farmacêuticas complexas, incluindo lipossomos, microesferas, nanocristais, partículas poliméricas, nano-suspensões e nano-emulsões, implantes injetáveis.
- ☒ Combinação de medicamentos com dispositivos médicos, como canetas injetoras, seringas preenchidas e outros dispositivos.

O produto possui registro no Brasil? *

☒ Sim ☐ Não

Número de Registro * ?

118190230

Nome Comercial

MULTIGRIP

Princípio(s) Ativo(s)

CLORIDRATO DE FENILEFRINA, MALEATO DE CLORFENIRAMINA, PARACETAMOL

O Produto possui registro no Exterior? *

☒ Sim ☐ Não

Produtos Registrados no Exterior

NOME COMERCIAL	PAÍSES ONDE O PRODUTO ESTÁ REGISTRADO	AÇÕES
NOMECOMERCIAL1	CANADÁ, ESTADOS UNIDOS DA AMÉRICA	 
NOMECOMERCIAL2	BRASIL, ALEMANHA, INGLATERRA (REINO UNIDO)	 
+ Adicionar		

Next, the "Clinical Trial Data" section will be displayed, where the company must describe the clinical trial.

Estudo Estritamente Nacional ou Há Cooperação Internacional? *

☐ Estritamente Nacional ☐ Cooperação Internacional

In this section, the company must indicate whether it is a strictly national study (i.e., conducted ONLY in Brazil), or whether it is a study with international cooperation (i.e., conducted in Brazil and other countries).

If the “International Cooperation” option is selected, an additional section will be displayed where the company must provide a list of the countries where the clinical trial is planned to be conducted:

Países onde está sendo planejada a condução do Ensaio Clínico Proposto *

Nenhum item foi adicionado.

+ Incluir

+ Incluir

By pressing the button . An editable line will be provided for selecting the country from a drop-down list, followed by the answer as to whether or not the study has already begun in that country. This procedure should be repeated for all countries where the study is planned to be conducted.

Países onde está sendo planejada a condução do Ensaio Clínico Proposto *

PAÍS *	ESTUDO JÁ INICIADO? *	
ARGÉLIA	Sim	✕
CUBA	Sim	✕
MÉXICO	Não	✕

+ Incluir

To delete a row, use the button. 

The following sections are intended for identifying the clinical protocol and include the fields “Title of Protocol”, “Clinical Protocol Number/Code”, “Clinical Protocol Version”, “Version Date
Clinical Protocol:

Título do Protocolo *

Número/Código do Protocolo clínico *

Versão do Protocolo clínico *

Data da versão do Protocolo clínico *



In the clinical protocol version, include the version number and the respective date. Example: Version 2.1 of March 30, 2025.

The field "Trial Registration in Database" is intended for providing information on the registration of the clinical protocol in international public databases, such as CTIS, ClinicalTrials.gov, and ICTRP. In this field, include the registration number and the respective database.

Registro do Ensaio em Base de Dados *

☐ Será apresentado posteriormente *

If this information is not available at the time of the request, the company can check the "Will be displayed later" checkbox.

Registro do Ensaio em Base de Dados

☒ Será apresentado posteriormente *

Next, the company must answer whether there was a prior meeting with Anvisa regarding the trial in question. If the option "Yes" is selected, the company must attach the meeting minutes to the respective checklist item at the end of the form, and fill in the dates and hearing numbers in the fields that will be displayed:

Houve previamente reunião com a ANVISA sobre esse Ensaio? *

☒ Sim ☐ Não

Datas (Anexar a ata da reunião no processo) *

1) 01/01/2025 2) 10/12/2025

Número da audiência *

1) 12345 2) 6789

The "Clinical Trial Characteristics" information block will be filled with information to characterize the trial.

The first question to be answered is "Does it have a comparator?". If the answer is "Yes", a multi-select drop-down menu will be displayed to select the types of comparators to be used: active comparator, placebo, placebo-only use, and/or other. This last option opens a free text field for detailing the comparator. The "placebo-only use" option should only be selected if there is no other therapy being administered concomitantly (Example: baseline therapy).

If another therapy is planned along with the placebo, select the "placebo" option.

Possui Comparador? *

☒ Sim ☐ Não

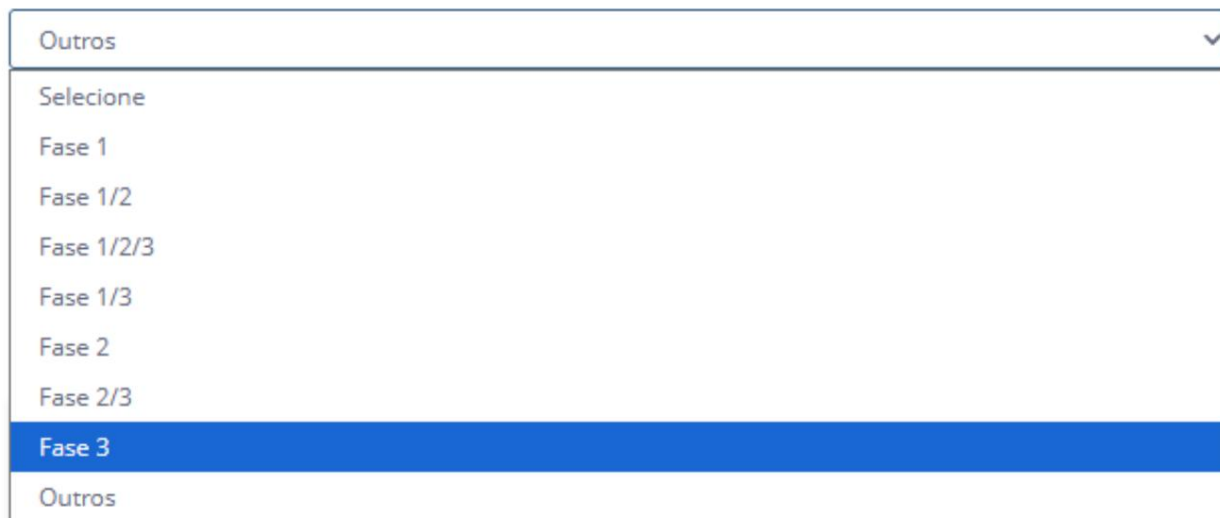
Tipo(s) de Comparador(es) * ?

Comparador Ativo, Outros, Placebo, Uso Exclusivo de Placebo	
Comparador Ativo	✓
Outros	✓
Placebo	✓
Uso Exclusivo de Placebo	✓

Outros *

The "Clinical trial phase" field should be selected according to the trial phase.

Fase do ensaio clínico *



If the predefined options are not sufficient, the company should select the "Other" option, which enables a text field for entering the information:

Fase do ensaio clínico *

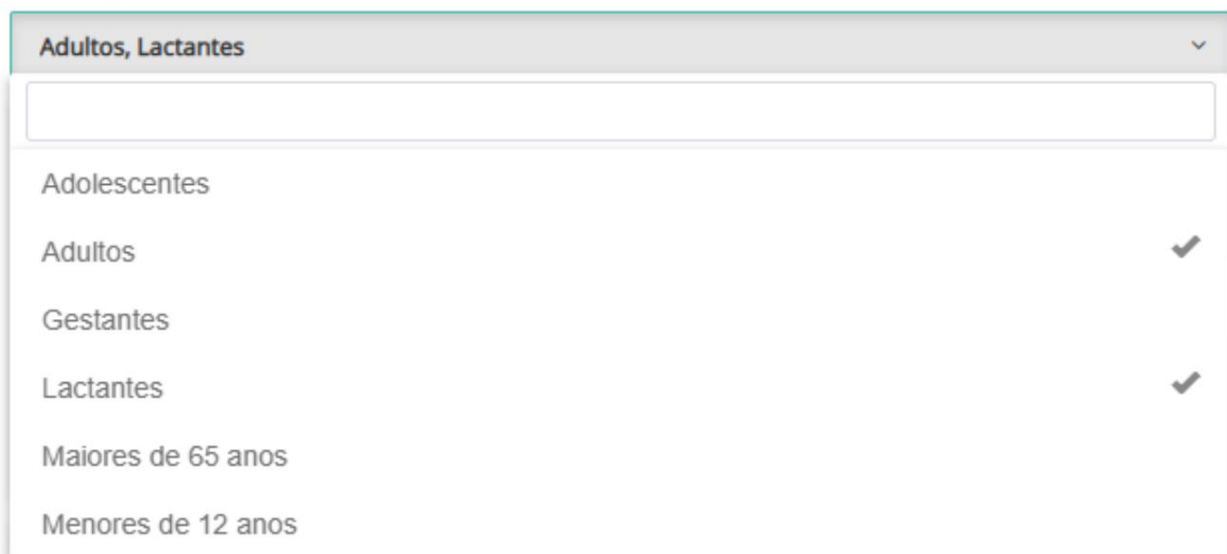


Outros *



The "Clinical trial populations" field allows for multiple selections and should be filled in according to the characteristics of the population to be studied in the trial.

População do ensaio clínico *



In the following section, the company must specify which diseases/conditions are under investigation, the clinical indication to be researched, and the treatments or therapies already available.

DOENÇA OU AGRAVO EM INVESTIGAÇÃO	INDICAÇÃO CLÍNICA A SER PESQUISADA	TRATAMENTO OU TERAPIA JÁ DISPONÍVEL	AÇÕES
Nenhum item foi adicionado.			

[+ Adicionar](#)
[+ Adicionar](#)

To add a record, the company must click the button. capital:

which will open the following

Agravo

Doença ou agravo em investigação (CID) *

Indicação clínica a ser pesquisada *

Tratamento ou terapia já disponível *

Selecione

Adicionar

Cancelar

The disease or condition under investigation must be identified according to its International Classification of Diseases.

Diseases (ICD). Using the disease description button:



The search can be done using the ICD code or part of it.

Selecione o registro ×

Código CID

Descrição do Agravado

Código CID	Descrição do Agravado	
A90	Dengue [dengue clássico]	→
A91	Febre hemorrágica devida ao vírus do dengue	→

Once the desired issue has been found, click the button.

→ to select it.

The clinical indication to be researched is a text field for providing information, and the "treatment or therapy already available" is a "yes"/"no" selection – this information should be described in the protocol or other documents. DEEC documents..

Agravado ×

Doença ou agravado em investigação (CID) *

A90 - Dengue [dengue clássico]



Indicação clínica a ser pesquisada *

dengue grave

Tratamento ou terapia já disponível *

Sim



Adicionar

Cancelar

Adicionar

By clicking on . The record will be included in the listing. The procedure must be repeated for... all diseases/conditions applicable to the trial.

DOENÇA OU AGRAVO EM INVESTIGAÇÃO	INDICAÇÃO CLÍNICA A SER PESQUISADA	TRATAMENTO OU TERAPIA JÁ DISPONÍVEL	AÇÕES
A90 - Dengue [dengue clássico]	dengue grave	Não	 

+ Adicionar

The action button  allows editing, while the button  allows the deletion of that line.

The following question is intended to determine whether the test is complex according to applicable legislation. If the answer is "Yes," multiple-choice options will be displayed for the company to select all applicable options:

É um ensaio clínico complexo (conforme VIII do Art. 3º da IN 338/2024 e Art 1º da IN 345/2025)? *

☒ Sim ☐ Não

Marque o(s) Tipo(s) de Ensaio(s) Clínico(s): *

- ☐ Ensaios que estudam múltiplas terapias ou múltiplas indicações em um único ensaio clínico, chamados de protocolos mestres ou master protocols (em inglês, Basket trials, Umbrella trials, Platform trials).
- ☒ Novos desenhos de ensaios adaptativos que permitem que alterações planejadas no protocolo do estudo ocorram em momentos pré-especificados durante o ciclo de vida de um ensaio.
- ☒ Ensaios clínicos Fase 1, cujo medicamento experimental está sendo usado pela primeira vez em humanos (em inglês, First In Human - FIH).
- ☒ Ensaios clínicos Fase 1, 2 e 3 integrados em um único protocolo.
- ☐ Ensaios clínicos pragmáticos ou contendo dados de mundo real (RWD).
- ☐ Ensaios clínicos contendo população vulnerável como a pediátrica, gestante e lactantes.

The next section is "Clinical Trial Risk Category". This field offers three higher risk levels: "Low risk", "moderate risk", and "high risk". For each selected item, the company must also indicate the applicable subcategories. Finally, for the "low risk" subcategory and the first "moderate risk" category, the company must also indicate whether it wishes to request the application of the optimized analysis procedure in accordance with applicable legislation.

☒ Baixo Risco

Subcategoria(s): *

Subcategoria(s):

☒ a. Medicamento utilizado tal como registrado no Brasil ou por AREE, sem modificações substanciais.

☒ Solicitamos a aplicação do procedimento otimizado de análise, nos termos do Art. 8º da IN nº 338/2024. ⓘ

☐ b. Nova indicação terapêutica e/ou população-alvo e/ou regime posológico, apoiados por evidências robustas de literatura científica baseadas em meta-análises, revisões sistemáticas de artigos científicos publicados em revista indexada contendo informações quanto a segurança e eficácia do medicamento ou do IFA.

☐ Solicitamos a aplicação do procedimento otimizado de análise, nos termos do Art. 8º da IN nº 338/2024. ⓘ

☐ c. Associações em dose fixa (ADF) com insumos farmacêuticos ativos (IFAs) registrados e já utilizados concomitantemente na prática médica, na mesma indicação pleiteada, população-alvo e regime posológico (sem interação farmacocinética e/ou farmacodinâmica clinicamente significativa).

☐ Solicitamos a aplicação do procedimento otimizado de análise, nos termos do Art. 8º da IN nº 338/2024. ⓘ

The next section is "Information about the Clinical Trial Center(s)".

Informações sobre o(s) Centro(s) de Ensaio(s) Clínico(s) *

CNES	RAZÃO SOCIAL	NOME FANTASIA	CIDADE/UF	CPF	EMAIL DO INVESTIGADOR	NÚMERO DE PARTICIPANTES	AÇÕES
Nenhum item foi adicionado.							

+ Adicionar Centro Clínico

+ Adicionar Centro Clínico

By clicking on . A modal window will be displayed for filling in the information:

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Informações sobre o Centro Clínico



Informações sobre o Centro de Ensaio Clínico

CNES *

Campo obrigatório

Razão Social *

Nome Fantasia *

UF *

Cidade *

CPF *

Email do Investigador *

Número de Participantes *

Adicionar Centro

Cancelar

The company name, trade name, state, and city information will be automatically retrieved from the Ministry of Health's database when the National Health Establishment Registry (CNES) number is provided.
For information:

CNES *

0010510

Razão Social *

FUNDACAO UNIVERSIDADE DE BRASILIA

Nome Fantasia *

HOSPITAL UNIVERSITARIO DE BRASILIA

UF *

DF

Cidade *

BRASILIA

The "CPF" field is a numeric field and will validate the CPF number provided with the Federal Revenue Service, so only valid CPF numbers can be entered.

The "Researcher Email" field requires an email address in a valid format, and the "Number of Participants" field only accepts numbers.

This form must be completed repeatedly for all research centers planned for the trial.

CNES	RAZÃO SOCIAL	NOME FANTASIA	CIDADE/UF	CPF	EMAIL DO INVESTIGADOR	NÚMERO DE PARTICIPANTES	AÇÕES
0010510	FUNDACAO UNIV ERSIDADE DE BRASILIA	HOSPITAL UNIVE RSITARIO DE BRA SILIA	BRASILIA/DF	021.462. 921-05	teste@hotmail.co m	24	 

The action button  allows editing, while the button  allows the deletion of that line.

The "Activity(ies) delegated to ORPC(s)" section is intended for information on activities delegated to other ORPCs, such as import and export activities, among others. The information entered in this field will be reflected in the Import Document issued to the DDCM.

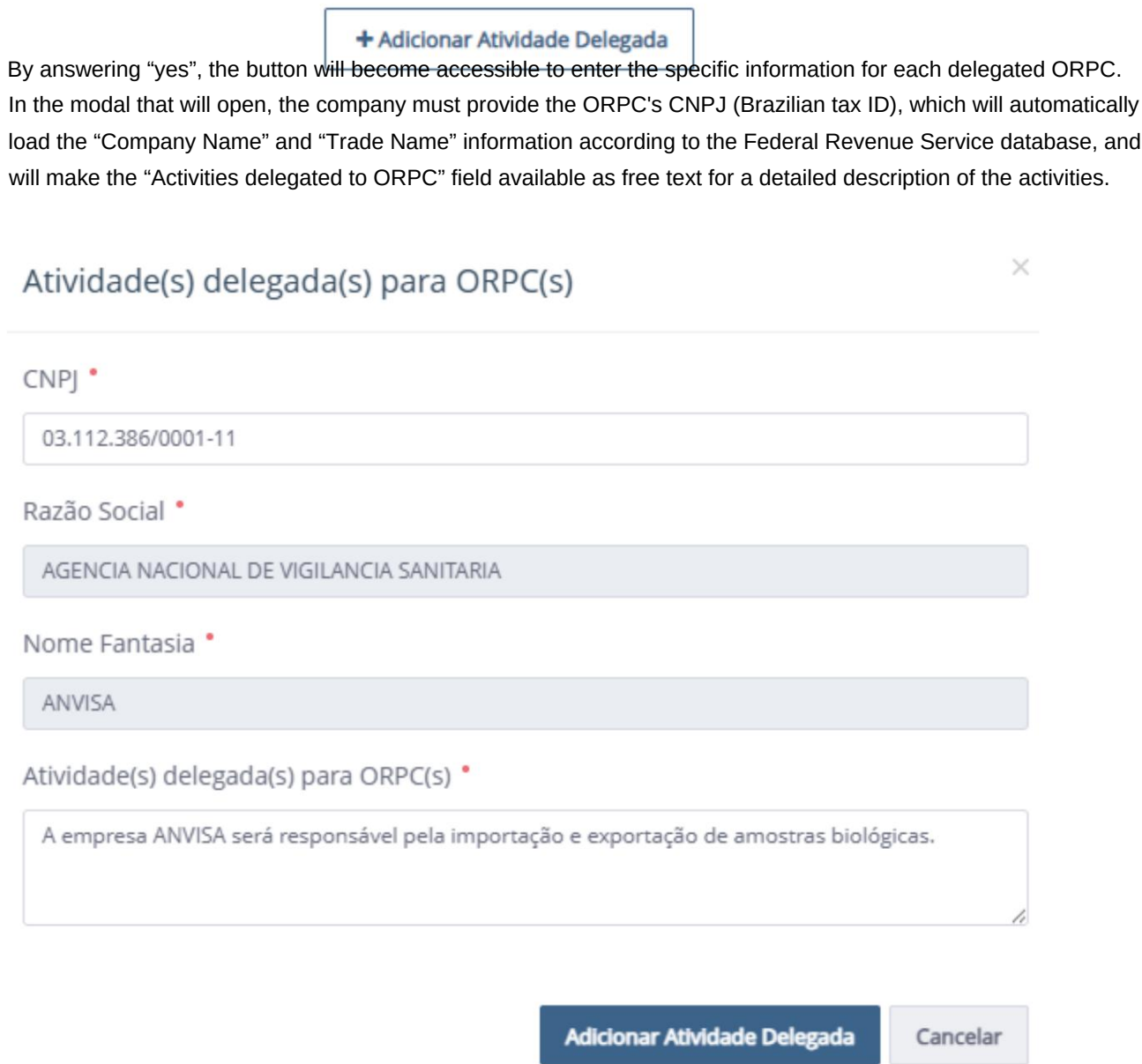
Atividade(s) delegada(s) para ORPC(s)

Existem atividades do ensaio clínico delegadas para ORPC? *

☒ Sim ☐ Não

CNPJ	RAZÃO SOCIAL	NOME FANTASIA	ATIVIDADE(S) DELEGADA(S) PARA ORPC(S)	AÇÕES
Nenhum item foi adicionado.				

[+ Adicionar Atividade Delegada](#)


 + Adicionar Atividade Delegada

By answering “yes”, the button will become accessible to enter the specific information for each delegated ORPC. In the modal that will open, the company must provide the ORPC’s CNPJ (Brazilian tax ID), which will automatically load the “Company Name” and “Trade Name” information according to the Federal Revenue Service database, and will make the “Activities delegated to ORPC” field available as free text for a detailed description of the activities.

Atividade(s) delegada(s) para ORPC(s)

CNPJ *

03.112.386/0001-11

Razão Social *

AGENCIA NACIONAL DE VIGILANCIA SANITARIA

Nome Fantasia *

ANVISA

Atividade(s) delegada(s) para ORPC(s) *

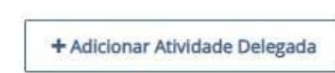
A empresa ANVISA será responsável pela importação e exportação de amostras biológicas.

Adicionar Atividade Delegada

Cancelar

This form must be completed repeatedly for all ORPCs that have delegated activities.

CNPJ	RAZÃO SOCIAL	NOME FANTASIA	ATIVIDADE(S) DELEGADA(S) PARA ORPC(S)	AÇÕES
03.112.386/001-11	AGENCIA NACIONAL DE VIGILANCIA SANITARIA	ANVISA	A empresa ANVISA será responsável pela importação e exportação de amostras biológicas.	 


 + Adicionar Atividade Delegada

The action button  allows editing, while the button  allows the deletion of that line.

The last section of the form relates to "Information about the product(s) to be imported/exported".

Informações sobre o(s) produto(s) a ser(em) importado(s)/exportado(s)

Existem produtos a serem importados/exportados? *

☒ Sim ☐ Não

TIPO DE PRODUTO	DESCRIÇÃO DO PRODUTO	CONDIÇÃO DE ARMAZENAMENTO	PRAZO DE VALIDADE	FORMA FARMACÊUTICA	VIA DE ADMINISTRAÇÃO	MEDICAMENTO CONTROLADO
Nenhum item foi adicionado.						





If "Yes" is selected for the question "Are there products to be imported/exported?", the



The company must activate the button.

For displaying the modal for completion:

Informações sobre o produto a ser importado/exportado ×

Tipo de Produto * ?

Descrição do Produto *

Condição de Armazenamento *

Prazo de Validade *

Forma Farmacêutica *

Via de Administração * ?

Medicamento Controlado *

☐ Sim ☐ Não

Adicionar

Cancelar

The "Product Type" is a drop-down menu with the options: medical devices, medication, and supplies. The option "medicine" should be selected to describe all medicines to be imported, such as experimental medicines, comparators, rescue medicines, concomitant therapies, etc. The option "medical device" should be selected when the product fits the definition of a device according to specific regulations. The option "supplies" should be used when the product does not fit into the other options, such as laboratory kits, electrocardiograms, refrigerators, needles, tablets and cell phones, infusion pumps, etc. The fields "product description", "storage conditions" and "expiration date" are free text fields. For medicines, in "product description" include the name of the medicine and its respective presentation (Example: ABC/placebo 100 mg/mL injectable solution in glass vial, 4 per box). The fields "form"

The fields “pharmaceutical” and “route of administration” are drop-down menus for selection, and are only mandatory when the selected product type is “medication”. The “Controlled Medication” field is a simple “yes” / “no” selection, according to current legislation.

Informações sobre o(s) produto(s) a ser(em) importado(s)/exportado(s)

Existem produtos a serem importados/exportados? *

☒ Sim ☐ Não

TIPO DE PRODUTO	DESCRIÇÃO DO PRODUTO	CONDIÇÃO DE ARMAZENAMENTO	PRAZO DE VALIDADE	FORMA FARMACÊUTICA	VIA DE ADMINISTRAÇÃO	MEDICAMENTO CONTROLADO	AÇÕES
Medicamento	Medicamento Experimental	Conservar entre 15 e 30°C	12 meses/	Comprimido de Liberação Prolongada	ORAL	Sim	 

[+ Adicionar Produto](#)

This form must be filled out repeatedly for all products to be imported/exported.

The action button  allows editing, while the button  allows the deletion of that line.

FORMS FOR PORTS, AIRPORTS AND CUSTOMS AREAS**Certificate of Free Practice and Vessel Health Certificate**

The petitioning process has been adapted to allow for requests for Certificates of Free Practice (CLP) and Vessel Health Certificates (CSE)

Four fields were included for these requests:

1 – Net Tonnage – Field to indicate the vessel's class.

Arqueação Líquida *

 ▼

2 – Ship's Flag – Name of the country of origin of the vessel

Bandeira da Embarcação *

 ▼

3 - Vessel Number - Vessel identification number

Número da Embarcação *

4 – Vessel Name - Name that identifies the vessel

Nome da Embarcação *

To submit, you must provide the "Request Location" information.

Local de Solicitação *



To select a location, click the magnifying glass in the upper right corner of the field. A modal window will appear where you can search for request locations by state (UF) or by location description.

Selecione o Local de Solicitação ×

UF	Descrição do Local de Solicitação
Selecione	
Q Pesquisar	

Select the desired state or location description and click search.

Selecione o Local de Solicitação ×

UF	Descrição do Local de Solicitação
Pernambuco - PE	
Q Pesquisar	

Estado (UF)	Local de Solicitação	Local de Atendimento	
PE	Pernambuco	COORDENAÇÃO DE VIGILÂNCIA SANITÁRIA DE PORTOS, AEROPORTOS, FRONTEIRAS E RECINTOS ALFANDEGADOS NO ESTADO DE PERNAMBUCO	→

The results will show all results that match the information entered in the filters. In addition to the information regarding the state and the description of the request location, the results will show the "Service Location" information, which corresponds to the Anvisa organizational unit that will be responsible for analyzing the request.

In general terms, the Request Location corresponds to the location where the documentation was routinely delivered in paper form, while the Service Location indicates the Anvisa unit that will handle the request. The Service Location will also be the unit displayed as "Located at" both in the Processes tab and on the Anvisa Consultation Portal (<http://consultas.anvisa.gov.br>).

ARRIVAL NOTIFICATION

In order to ensure the correct routing of requests for evaluation by Anvisa units, in some cases the applicant may be required to include the location of the request. In these specific situations, the "Request Location" field will be available.

Local de Solicitação *

To select a location, click the magnifying glass in the upper right corner of the field. A modal window will appear where you can search for request locations by state (UF) or by location description.

Selecione o Local de Solicitação

UF

Descrição do Local de Solicitação

Select the desired state or location description and click search.

Selecione o Local de Solicitação

UF

Descrição do Local de Solicitação

Estado (UF)	Local de Solicitação	Local de Atendimento	
PE	Pernambuco	COORDENAÇÃO DE VIGILÂNCIA SANITÁRIA DE PORTOS, AEROPORTOS, FRONTEIRAS E RECINTOS ALFANDEGADOS NO ESTADO DE PERNAMBUCO	→

The results will show all results that match the information entered in the filters. In addition to the information regarding the state and the description of the request location, the results will show the "Service Location" information, which corresponds to the Anvisa organizational unit that will be responsible for analyzing the request. It should be noted that the list of destination locations may vary depending on the selected subject code.

In general terms, the Request Location corresponds to the location where the documentation was routinely delivered in paper form, while the Service Location indicates the Anvisa unit that will handle the process.



MNU - User Manual

Meeting the demand. The Service Location will also be the unit that will be displayed as "Located at" both in the Processes tab and on the Anvisa Consultation Portal (<http://consultas.anvisa.gov.br>).

EXPORT BY LPCO

To submit an export request for Licenses, Permits, Certificates, and Other Documents

(LPCO), an information block called "Petitions linked to the Single Portal of

"Foreign Trade," where the company must provide the LPCO number and indicate whether the holder of the product registration with Anvisa is the applicant or a third party:

Peticionamento vinculado ao Portal Único de Comércio Exterior

Número da LPCO *

100000000008

O detentor da regularização do produto junto a Anvisa é um terceiro? *

☒ Sim ☐ Não

If the option is for a petition linked to an initial LPCO petition, the form will display the LPCO information for viewing purposes only.

For all requests of this type, it is necessary to apply for an Import License in Siscomex and an LPCO (License for Import and Control) in the Single Window for Foreign Trade. For more details, consult the LI Web Guide, available at <http://siscomex.gov.br/wp-content/uploads/2019/09/CARTILHA-LI-WEB.pdf>, and the Manual for completing the TA/LPCO module, importer view, available at <http://siscomex.gov.br/wp-content/uploads/2021/02/Manual-de-Preenchimento-LPCO-Importador.pdf>.



IMPORT/EXPORT BY EXPRESS SHIPPING

The petitioning process for matters related to import/export (PAF) has been adapted in Solicita to encompass the situation of Express Shipment by an individual and Express Shipment by a legal entity.

For these requests, the following fields must be completed:

1 – “Knowledge Number”

Field for entering the bill of lading/cargo number.

Número de Conhecimento

If the bill of lading/cargo number information is also provided, the request will be registered and available for analysis by ANVISA.

However, the company may choose to provide the bill of lading/cargo number.

subsequent to the initial filing. In this case, to insert this data, the subject 90172 - Ports, Airports and Borders - Amendment - Express Shipment should be used as a petition linked to the initial Express Shipment petition. When accessing the petitioning form, the field for the waybill number will be mandatory. After the petitioning protocol is completed, the document status of the Express Shipment petition will be updated and available for review.

ANVISA.

2 – “Are you performing the protocol for a third party?”

This field is used to identify whether the export/import is being carried out on behalf of the requesting company or a third party. This field is only available when the beneficiary is a legal entity.

Você está realizando protocolo para um terceiro? *

☒ Sim ☐ Não

If the "No" option is selected, the fee to be collected will take into account the applicant's CNPJ (Brazilian tax ID) data.

If the "Yes" option is selected, the field for entering the third party's CNPJ will be made available.

Você está realizando protocolo para um terceiro? *

☒ Sim ☐ Não

CNPJ *

Razão Social

Fato Gerador

Porte da Empresa

Valor da Taxa

After entering the CNPJ number, the fields related to the company name, taxable event, and company size will be filled in by the system, and the fee amount will be updated according to the size of the beneficiary company.

It is important to note that, for the third party's CNPJ to be included, it is necessary that they are registered in ANVISA's petitioning system. Without this prior step, it will not be possible to continue the process, as the fee will not be updated and the payment slip or payment via PagTesouro will not be issued.

3 – Beneficiary's CPF (Brazilian Individual Taxpayer Registry) number

To complete the process on behalf of an individual beneficiary, the field for entering the CPF (Brazilian taxpayer ID) will be displayed.

CPF do beneficiário *

In these cases, the CPF (Brazilian taxpayer ID) will be validated against the Federal Revenue Service database.

4 – Imported quantity

In the "Quantity Imported" field, you should enter the number of units to be imported.

Quantidade Importada *

The field can be filled with up to 3 digits, and for subjects that have a minimum and maximum number of units, the system validates the quantity entered.

Quantidade Importada *

A quantidade escolhida deve estar entre 0 e 20 unidades. Ajuste a quantidade ou selecione um código de assunto diferente

If the quantity entered is incompatible with the desired number of units, the user should search for a suitable topic for the desired quantity.

EXPRESS SHIPPING OF CANNABIS -DERIVED PRODUCTS

To arrange express shipping of *cannabis-derived products*, the user must fill in the following fields:

Remessa Expressa

Número de Conhecimento

Número da Autorização de Importação *

A atualização das informações referentes à autorização de importação é feita diariamente às 00:00 horas. A última atualização foi feita em 16/09/2024.

CPF do Paciente *

Nome Comercial do(s) Produto(s) Importado(s) *

Selecione...

Quantidade Total Importada *

Para invoice/fatura com mais de um produto, informar a quantidade total importada.

5 - Import Authorization Number

This field, containing 17 characters, is for entering the import authorization number granted through the service ["Request authorization to import Cannabis-derived products"](#).

The system will perform the validation against the information present in the system used to request authorization to import *Cannabis-derived products*. For the authorization numbers entered that are valid in the Anvisa system, the patient's CPF field will be enabled for completion. The data relating to the authorizations, for this validation, are updated daily at 00:00.

6 - Patient's CPF (Brazilian Taxpayer Identification Number)

An 11-digit number that will be validated against the Federal Revenue Service database.

The system will validate the information against the data in the system used to request authorization to import *cannabis-derived products*. If the entered CPF (Brazilian taxpayer ID) matches the one requested for the authorization number, the "Commercial Name of the Imported Product" field will be enabled. If the CPF number does not match the one linked to the Import Authorization, is incorrect, or is nonexistent, the system will display an error message.

7 - Trade Name of the Imported Product

Dropdown field for choosing the name of the product to be imported.

The system will validate the information against the data in the system used to request authorization to import *cannabis-derived products*. If the entered CPF (Brazilian taxpayer ID) matches the authorization number provided, the "Commercial Name of the Imported Product" field will be enabled, displaying the selection of items from the import request among the products listed in the authorization granted by Anvisa (Brazilian Health Regulatory Agency).

Important! If the authorization was issued without associated products, it will not be possible to continue the flow in Solicita. In these cases, the user must:

1. Start a new request through the portal;
2. In the "confirm data" step, take a screenshot showing the selected product;
3. Choose the product, fill in the required information, and complete the request.
4. If the Authorization is issued with the same problem, the user should send an email to med.controlados@anvisa.gov.br. Please provide a screenshot and the protocol number. This will allow the responsible department to analyze the new request and forward the issue to technical support.

8 – Total quantity imported

Report the total quantity of units imported. For invoices with more than one product, report the total quantity imported. Example: Invoice with 10 units of product A and 5 units of product B, fill in with the number 15.

9 - Recipient's Address

A field with 100 characters for entering the recipient's address.

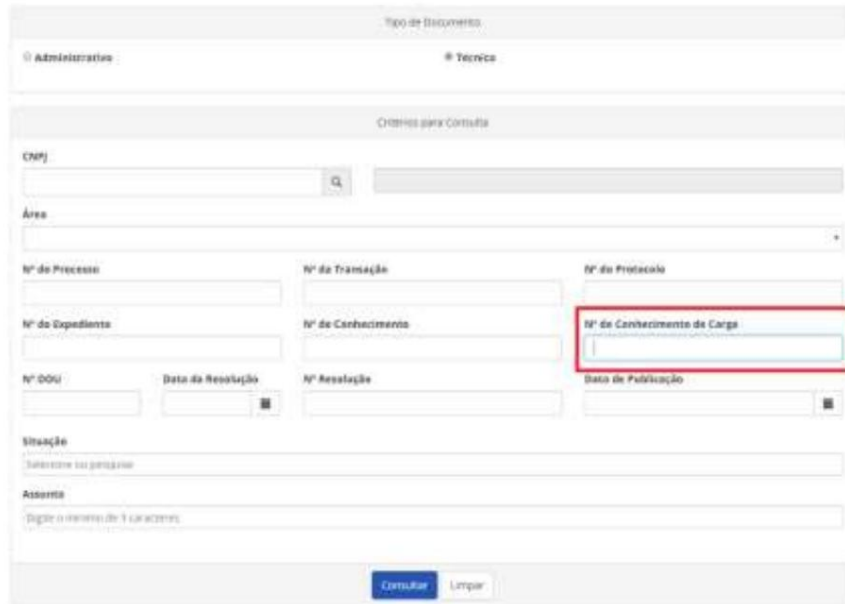
10 – Exporter's Name

A field with 100 characters for entering the name of the exporter who will import the product.

11 – Exporting Country

Field to select the country from which the product will be shipped.

It is possible to check the status of express shipping requests by providing the bill of lading number. Access is available at <https://consultas.anvisa.gov.br/#/>, Select **"Document Status"**, then **"Technical"**. The filter allows you to search for the exact document number or part of it.



The image shows a web form for consulting document status. At the top, there are two tabs: "Administrativo" and "Técnico", with "Técnico" selected. Below the tabs is a section titled "Critérios para Consulta". It contains several input fields for search criteria: "CNPJ" with a search icon, "Área" with a dropdown arrow, "Nº do Processo", "Nº da Transação", "Nº do Protocolo", "Nº do Expediente", "Nº de Conhecimento", "Nº de Conhecimento de Carga" (highlighted with a red box), "Nº DOU", "Data da Resolução", "Nº Resolução", and "Data de Publicação". There are also fields for "Situação" (with a dropdown arrow) and "Assunto" (with a character count "Digite o máximo de 1 caractere"). At the bottom, there are two buttons: "Consultar" and "Limpar".

IMPORTATION BY LPCO WITH LI

To submit an import request using Licenses, Permits, Certificates, and Other Documents (LPCO) with an Import License (LI), start a new petition for initial petitions and select the subject corresponding to the desired request. For the filing of replacement LIs, start a petition linked to an existing process and select the subject corresponding to the desired request.

For all requests of this type, it is necessary to apply for an Import License in Siscomex and an LPCO (License for Import and Control) in the Single Window for Foreign Trade. For more details, consult the LI Web Guide, available at <http://siscomex.gov.br/wp-content/uploads/2019/09/CARTILHA-LI-WEB.pdf>, and the Manual for completing the TA/LPCO module, importer view, available at <http://siscomex.gov.br/wp-content/uploads/2021/02/Manual-de-Preenchimento-LPCO-Importador.pdf>.

Initial Petition

For this type of matter, an information block called "Petitioning linked to the Single Window for Foreign Trade" will be displayed, where the company must provide the LPCO number, the related LI number, and whether the holder of the product's registration with Anvisa is the applicant or a third party.



After completing this step, the user must follow the rest of the process, as detailed in previous sections of this manual, until the protocol is completed and the protocol receipt is received.

Linked Petition

If the option is for a petition linked to an initial LPCO petition with LI, the form will display the LPCO information for viewing only, but will allow editing of the field relating to the LI number when the subject matter is a petition for a substitute LI.



After completing this step, the user must follow the rest of the process, as detailed in previous sections of this manual, until the protocol is completed and the protocol receipt is received.



SEMI-ANNUAL PLATFORM INSPECTION

In order to ensure the correct routing of requests for evaluation by Anvisa units, in some cases the applicant may be required to include the location of the request. In these specific situations, the "Request Location" field will be available.

Local de Solicitação *



To select a location, click the magnifying glass in the upper right corner of the field. A modal window will appear where you can search for request locations by state (UF) or by location description.

Selecione o Local de Solicitação

UF	Descrição do Local de Solicitação	
Selecione		Pesquisar

Select the desired state or location description and click search.

Selecione o Local de Solicitação

UF	Descrição do Local de Solicitação	
Pernambuco - PE		Pesquisar

Estado (UF)	Local de Solicitação	Local de Atendimento	
PE	Pernambuco	COORDENAÇÃO DE VIGILÂNCIA SANITÁRIA DE PORTOS, AEROPORTOS, FRONTEIRAS E RECINTOS ALFANDEGADOS NO ESTADO DE PERNAMBUCO	→

The results will show all results that match the information entered in the filters. In addition to the information regarding the state and the description of the request location, the results will show the "Service Location" information, which corresponds to the Anvisa organizational unit that will be responsible for analyzing the request. It should be noted that the list of destination locations may vary depending on the selected subject code.

In general terms, the Request Location corresponds to the location where the documentation was routinely delivered in paper form, while the Service Location indicates the Anvisa unit that will handle the request. The Service Location will also be the unit displayed as "Located at" both in the Processes tab and on the Anvisa Consultation Portal (<http://consultas.anvisa.gov.br>).

MEDICAL DEVICE FORMS

Notification and registration of medical devices

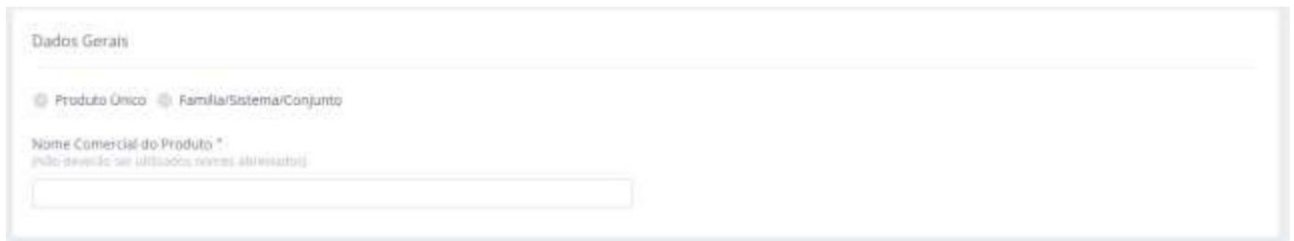
This functionality is only available for processes classified as "Health Products (Related Products)" or " *In Vitro* Diagnostic Products ," also defined as "Medical Devices" or " *In Vitro* Diagnostic Medical Devices ."

To initiate a request for registration or notification of medical devices, you must access the drafts tab and click the "New" button, selecting the "Initial Petition" option.



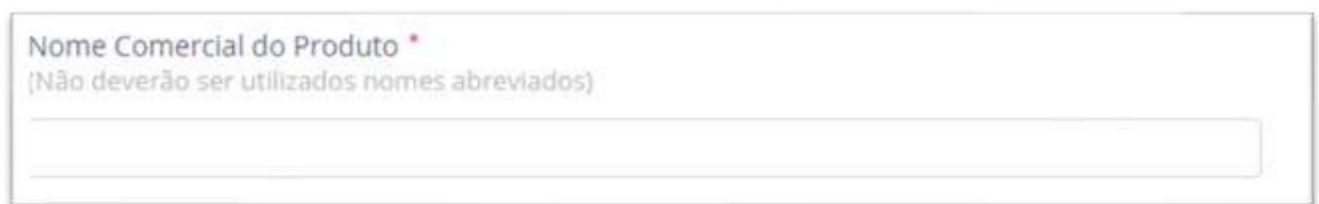
In the form provided, click on the "magnifying glass" in the subject field, and on the next screen enter the name or number of the desired subject.

The following form will provide information that must be completed in order to characterize the product.



When dealing with product notification matters, the user can choose whether it refers to a single product or a family/system/set of products.

If a "single product" material, equipment, or IVD subject is selected, the field below should be filled with the product's trade name.



If a "family/system/assembly" material, equipment, or IVD subject is selected, the field below should be filled with the product family name.

Nome da Família de Produtos *
(Não deverão ser utilizados nomes abreviados)

When dealing with matters relating to product registration, the "single product" or "family/system/set" field will be pre-filled according to the selected subject code.

Depending on the type of product selected, the next section will be called "Single Product" or "Family of Products" or "IVD Product Family".

Produto Único

O sistema organiza automaticamente a relação de apresentações ou modelos em ordem alfabética.

APRESENTAÇÃO OU MODELO

Nenhum item foi adicionado.

+ Adicionar

Limpar Tudo

Anexar Lista de Apresentações ou Modelos

Clique aqui para anexar a lista de apresentações ou modelos por meio de arquivo Excel (.xlsx) conforme padrão disponibilizado na seção Materiais de Formulários.

Enviar

In both cases, the structure presented will be the same. Clicking the button will bring up a modal for inserting product presentations or templates.

+ Adicionar

it will be opened

When dealing with a "single product" or "product family," the following option will be available:

Apresentação ou Modelo

When dealing with an "IVD product family," the following option will be available:

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Each time the presentation or template is added, it will appear in a list:



By clicking on  It will be possible to edit the registered presentation or template.

By clicking on it,  you will be able to delete the registered presentation or template.

The button  This process deletes all registered presentations or templates.

Since it may be necessary to include multiple presentations or templates, the option to include them by uploading an Excel spreadsheet has been made available.



In order to ensure that no errors occur during the upload process, a spreadsheet template will be available in the "Form Templates" section. There will be one standardized spreadsheet for inserting the "List of Presentations or Templates" and another for the "List of Family Components (IVD)".



We request that you always use this provided template, otherwise errors may occur in the process of filling out the registration or notification request forms.

The next section concerns the product's "nomenclature" and "risk classification".



Initially, the user must click on the icon.



to access a modal to select the name

Product technician.

The search for the technical name can be done using the code or the technical name:



Clicking on search will provide a list of technical names related to the product type of the selected subject code and the associated risk class (if any):



Código	Nome Técnico	Classe de Risco Vinculada	Descrição
2501191	Cateter Urinario Externo de Uso Masculino		

By clicking on the icon



The chosen technical name will be selected:

Nomenclatura e Classificação de Risco

Nome Técnico do Produto *

Casaca Unihair Externa de Uso Masculino

Regra de Classificação de Risco de Produto *

Selecione

Classe de Risco *

Selecione

If the chosen technical name is already associated with a risk class, the field will be automatically filled in. Otherwise, the user must fill in the risk classification from the menu:

Classe de Risco *

Selecione

In any context, the user must fill out the menu:

Regra de Classificação de Risco de Produto *

Selecione

If the desired risk classification rule is not available, the user should contact the area responsible for product registration or notification.

After filling in this information, it is necessary to identify if there are presentations or templates that They will be sold sterile.

Esterilização *

☐ Todos os modelos/apresentações são comercializados estéreis.

☐ Alguns modelos/apresentações são comercializados estéreis.

☐ Nenhum modelo/apresentação é comercializado estéril.

MÉTODO DE ESTERILIZAÇÃO UTILIZADO

Nenhum item foi adicionado.

+ Adicionar Método de Esterilização

AÇÕES

+ Adicionar Método de Esterilização

If one or more models are sold as sterile, a button will be provided to indicate the sterilization method(s) used.



By clicking the button
information:

A modal will be enabled for insertion and



Metódo de Esterilização

Adicionar Método de Esterilização Cancelar

With each insertion, the selected sterilization method will appear in a list:

MÉTODO DE ESTERILIZAÇÃO UTILIZADO	Ações
Calor seco	 
Filtração	 

By clicking on 

It will be possible to edit the registered sterilization method.

By clicking on 

you will be able to delete the registered sterilization method.

If the desired sterilization method is not available, the user should contact the area responsible for product registration or notification.

The next section concerns data related to Artificial Intelligence.

Answer the question "Does the medical device use artificial intelligence (AI) to achieve its medical purpose or to assist it in achieving that purpose?" using the radio button.



Inteligência Artificial *

O dispositivo médico utiliza inteligência artificial (IA) para atingir seu propósito médico ou para auxiliá-lo a atingir esse propósito? *

☐ Sim ☐ Não

The next section concerns the product's expiration date.

If the *checkbox* for "Indefinite Expiration Date / Not applicable (equipment and instruments)" is checked, the expiration date field will not be necessary.



The screenshot shows a form section titled "Prazo de Validade *". It contains a checkbox labeled "Prazo de Validade Indeterminado / Não aplicável (equipamentos e instrumentos) *". Below this, there are two input fields: "Prazo de Validade *" and "Unidade de Tempo *". The "Unidade de Tempo *" field is a dropdown menu with "Selecione" as the selected option.

The field

Prazo de Validade *



A text input field for "Prazo de Validade".

it must be

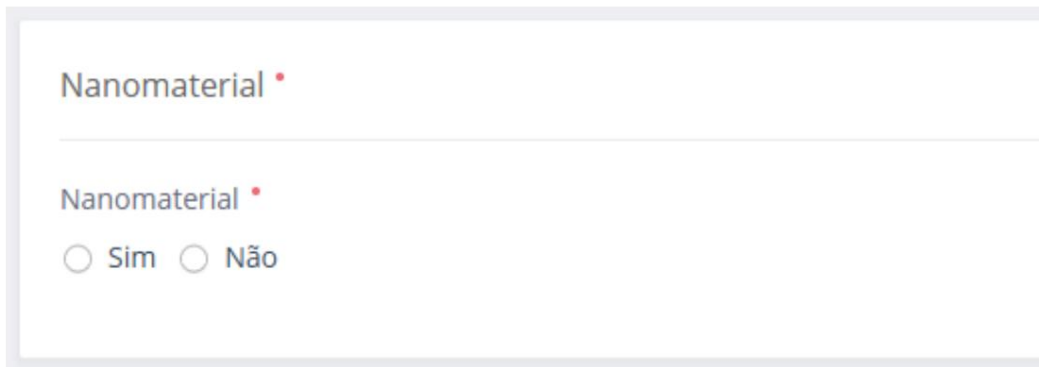
Pre-filled with numbers only, with the time unit being filled in via the *dropdown menu*.

Unidade de Tempo *



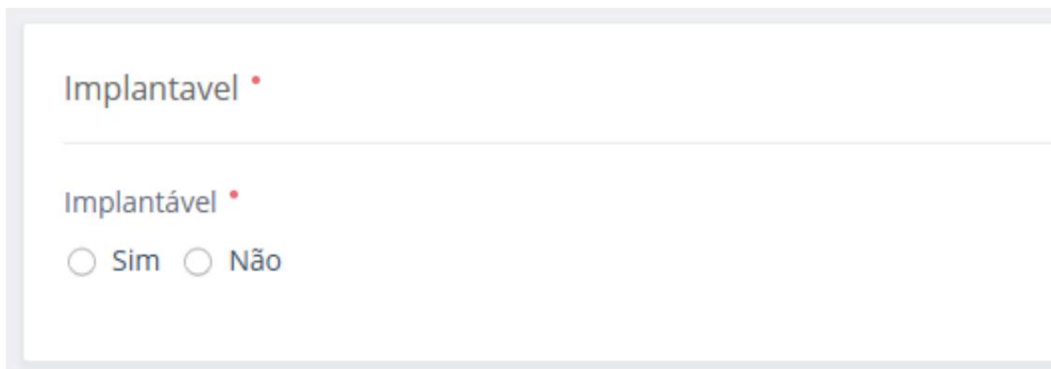
A dropdown menu for "Unidade de Tempo" with "Selecione" as the selected option.

The next section concerns identifying whether it is a nanomaterial or not:



The form section is titled "Nanomaterial *". It contains a sub-section also titled "Nanomaterial *" with two radio button options: "Sim" and "Não".

Next, it must be indicated whether it is implantable or not:



The form section is titled "Implantável *". It contains a sub-section also titled "Implantável *" with two radio button options: "Sim" and "Não".

The next section requests information regarding the need for approval by ANATEL:

Homologação Anatel *

O dispositivo médico se aplica a homologação da ANATEL? *

☐ Sim ☐ Não

After filling in this information, it is necessary to provide the data regarding the expiration date of the Inmetro certificate.

Vencimento Certificado Inmetro *

☐ Não aplicável
☐ Data de Validade
☐ Indeterminado

Data de Validade

If the "Expiration Date" option is selected, the "Expiration Date" field will be enabled for completion.

Vencimento Certificado Inmetro *

☐ Não aplicável
☒ Data de Validade
☐ Indeterminado

Data de Validade *

If the selected topic is an IVD (Initial Diagnostic and Propagation System), the sections relating to Methodology and Biological Samples and Storage Conditions will be available.

The section concerning methodology and biological samples is presented as follows:



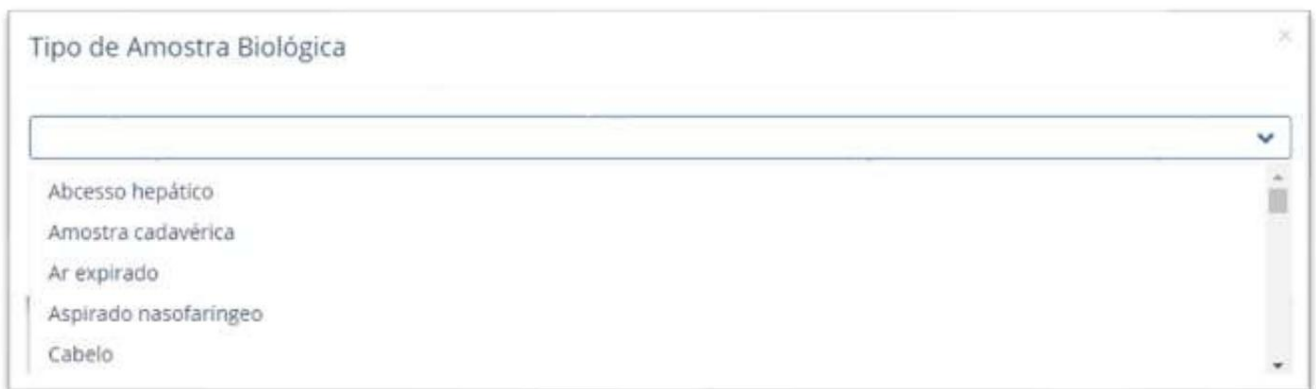
By clicking on the *dropdown*



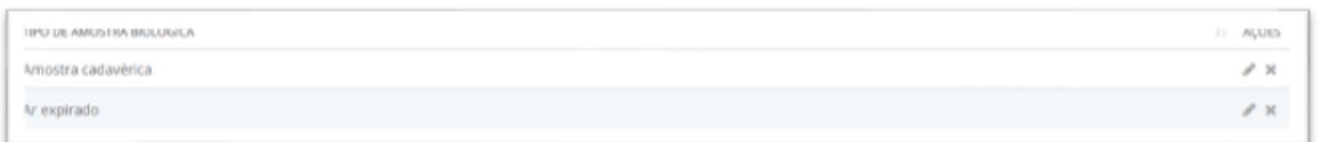
the user should



Select the methodology used and then click to include one or more biological samples used for that specific methodology. The modal will display a group of predefined biological samples.



With each addition, the biological sample will be displayed in a list:



By clicking on  It will be possible to edit the registered sample.

By clicking on it,  you will be able to delete the registered sample.

If the desired sample is not available, the user should contact the area responsible for product registration or notification.

The section regarding storage conditions is presented as follows:



By clicking on



A modal will be made available for choosing the condition of

storage.



Clicking on



The storage condition will be displayed in a list:



By clicking on



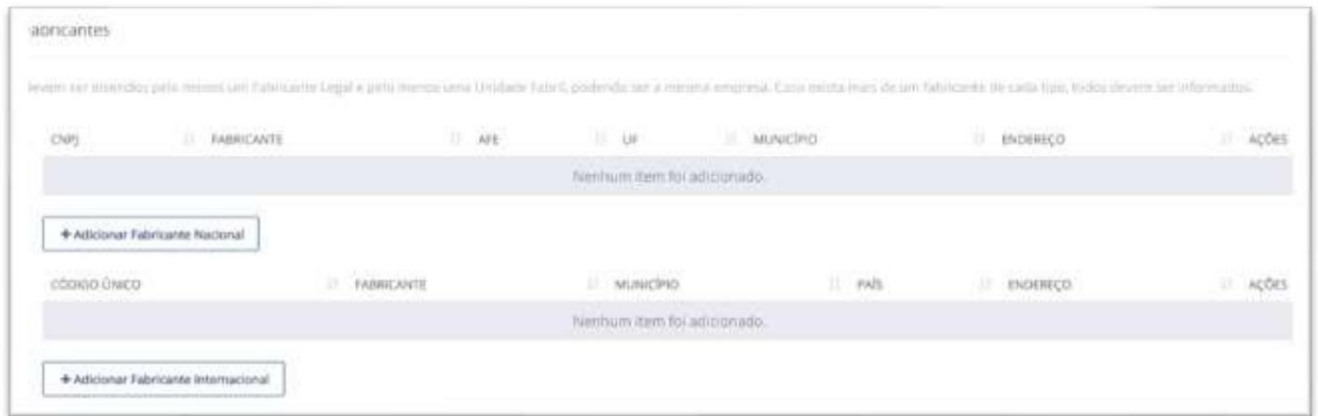
It will be possible to edit the registered storage condition.

By clicking on it, you will be able to delete the registered storage condition.



If the desired storage conditions are not available, the user should contact the department responsible for product registration or notification.

Finally, a field will be provided for entering the product manufacturer(s) data:



+ Adicionar Fabricante Nacional

To add the national manufacturer, click the button; a modal will appear for including the manufacturer's information.

and it will be



It must be indicated whether the manufacturer is a "Manufacturing Unit" and/or "Legal Manufacturer" by clicking on the icon.



A new feature where it will be possible to search for the manufacturer by CNPJ (Brazilian company tax ID), company name, or number. operating permit.





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+ Adicionar Fabricante Internacional

To add the international manufacturer, click the button; a modal will appear for including the manufacturer's information.

and it will be

Fabricante Internacional

Tipo Fabricante *

☐ Unidade Fabril

☐ Fabricante Legal

Fabricante *

Q

Adicionar Fabricante

Cancelar

It must be indicated whether the manufacturer is a "Manufacturing Unit" and/or "Legal Manufacturer" by clicking on the icon.



A new modal where it will be possible to search for the manufacturer by unique code, company name, or name.

of the country.

Código Unico

0 / 50

Fabricante

País

It is mandatory to register at least one "Manufacturing Unit" and at least one "Legal Manufacturer".

After adding the manufacturer, their data will be displayed on the main screen, allowing you to add one or more manufacturers.

Código Unico	Fabricante	Município	País	Endereço	Ações
3000308	ANHUI BIOCHEM UNITED PHARMACEUTICAL CO., LT D. - 80008	HEFEI	CHINA, REPÚBLICA POP ULAR	ZONE B, INNOVATION AVENUE, TAIHE INDUSTRIAL PARK, ANH UI PROVINCE	

Using the button  It is possible to change the data of the company entered, and by using the button  Delete the inserted manufacturer.

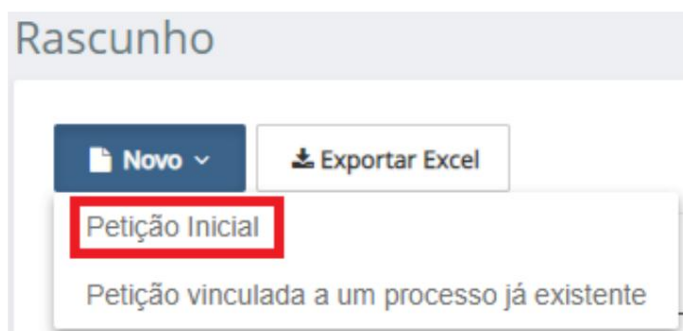
Requests for the creation and deactivation of Unique Codes for international manufacturers and manufacturing units (exclusively for Medical Devices and IVDs of Risk Classes I and II) must be made electronically through the Solicita system on the Anvisa Portal, via primary petition under subject 80326. To see the complete step-by-step instructions, the list of required documents, and the analysis deadlines, please access the service page on the Gov.Br portal, [available at this link.](#)

SANITIZING PRODUCTS FORMS

Notification and registration of sanitizing products.

This feature is only available for "Sanitizing" type processes.

To initiate a request for registration or notification of sanitizing products, you must access the drafts tab and click the "New" button, selecting the "Initial Petition" option.



In the form provided, click on the "magnifying glass" in the subject field, and on the next screen enter the name or number of the desired subject.

For applications for registration or notification of domestic products, the applicant company must have an AFE (Authorization for Operation) to manufacture sanitizing products.

For registration or notification requests for international products, the applicant company must have an AFE (Authorization for Operation) to import sanitizing products.

The following form will provide information that must be completed in order to characterize the product.



If the desired formulation type is not available, please contact the team at the responsible organizational unit.

Depending on the selected category, the Sales/Employment field will be automatically filled in.

The information blocks "Physico-Chemical Characteristics" and "Toxicological Characteristics" are mandatory.

The fields "Alkalinity (Free Expressed as Na₂O)", "Pests and Vectors", "Skin Irritation", "Eye Irritation", and "Skin Sensitization" will be displayed depending on the selected product category.

Next, a field will be provided for entering the product manufacturer(s) data. **The requesting company must have an AFE (Authorization for Operation) for sanitizing products with the activity of importing in order for the registration of international manufacturers to be available. At least one of the national manufacturers must have an AFE for sanitizing products with the activity of manufacturing.**

To add the manufacturer, click the button, at which point a new screen will appear for entering the manufacturer's unique code. Once the code is entered, the other fields will be automatically filled in. If the desired company is not registered, please contact the team at the responsible organizational unit.

Fabricante Internacional
×

Código Único * ?

E.p001

Fabricante

EMPRESA ALEMÃ - NOME 2

Município de Fabricação

SANTA CRUZ DE LAS SIERRA

País

BOLÍVIA

Logradouro

ENDEREÇO NA ALEMANHA PARA TESTES

Adicionar Fabricante

Cancelar

If the product is made in Brazil, the process for adding manufacturers is the same; however, when clicking on...

button + Adicionar Fabricante The screen will display the CNPJ field.

Fabricante

✕

CNPJ *

Campo obrigatório

Fabricante

Nº Autorização/Cadastro

UF

Município de Fabricação

Código do Município

Adicionar Fabricante

Cancelar

After adding the manufacturer, their data will be available on the main screen, making it possible to...
Insert one or more manufacturers.

Fabricantes Internacionais *

CODIGO UNICO	FABRICANTE	MUNICIPIO DE FABRICAÇÃO	PAIS	LOCALIZACAO	AÇÕES
E.0001	EMPRESA ALEMÃ - NOME 2	SANTA CRUZ DE LAS SIERRA	BOLÍVIA	ENCOSTEÇO NA ALEMANHIA PARA TESTES	 
E.0002	TESTE	FRANKFURT	ALEMANHA	TESTES	 

Using the button



It is possible to change the entered company, and by using the button  it is possible to delete it.
Manufacturer inserted.

The next section of information concerns version registration. This section is only available for specific product categories.
For categories that do not include versioning, the product's technical data is presented directly in the form.

Cadastro de Versão *

NOME DA VERSÃO	FÓRMULA	AÇÕES
Nenhum item foi adicionado.		

Adicionar Versão

+ Adicionar Versão

To register the version, click the button.

A new screen will be available.

After entering the desired version name, you will need to fill in the data for the measure type, formula, and presentations:

Versão

Nome da Versão *

Versão 1

Tipo de Medida *

g/100g

Fórmula *

COMPONENTE DA FÓRMULA	QUANTIDADE CENTESIMAL	FUNÇÃO	INSCRIÇÃO (REFERÊNCIA)	AÇÕES
Nenhum item foi adicionado.				

+ Adicionar Substância

Apresentações *

APRESENTAÇÃO	AÇÕES
Nenhum item foi adicionado.	

+ Adicionar Apresentação

Adicionar Versão

Cancelar

The formula registration is done substance by substance, and to do so, click the button.

+ Adicionar Substância

A new screen will be available.

Substância

Componente da Fórmula * ?

Quantidade (g/100g de produto acabado) *

Inscrição (Referência)

Função * ?

Selecione

Adicionar Substância

Cancelar

Click on the magnifying glass and select the substance by entering the "substance name" or the "inscription (reference)". In both cases, the search allows for exact or partial searches, and the inscription should be filled in with only the numbers and without the dashes.

Selecione a substância desejada

Nome da Substância	Inscrição (Referência)	
ACACIA DECURRENS DEALBATA FLOWER EXTRACT	93685-96-2	+
ACACIA DECURRENS EXTRACT	98903-76-5	+
ACACIA DECURRENS FLOWER CERA	98903-76-5	+
ACACIA DECURRENS FLOWER EXTRACT	98903-76-5	+
ACACIA DECURRENS/JOJOBA/SUNFLOWER SEED CERA/POLYGLYCERYL-3 ESTERS	-	+
CALOCEDRUS DECURRENS LEAF/STEM EXTRACT	-	+
CALOCEDRUS DECURRENS LEAF/STEM OIL	-	+
DECURSINOL	23458-02-8	+

After selecting the substance, enter the quantity of the substance according to the selected measurement type and indicate its function in that product. If the desired function is not registered, please contact the team of the responsible organizational unit. Certain substances have maximum limits when used as preservatives, according to Collegiate Board Resolution – RDC No. 30, of July 4, 2011, or its updates.

With each entry, the list of substances used in the product formula can be viewed on the form's main screen.

Fórmula

COMPONENTE DA FÓRMULA	QUANTIDADE CENTESIMAL	FUNÇÃO	INSCRIÇÃO (REFERÊNCIA)	AÇÕES
ACARBOSE	50,00	Abrasivo	56180940	
ÓXIDO DE ZINCO	50,00	Agente formador de filme	1314132	

Adicionar Substância

Using the button



It is possible to change the data of an entered substance by using the button.



It is possible to exclude an inserted substance.

The sum of the substances must equal 100%, regardless of the measurement type selected. If the sum of the substances does not equal 100%, the system will display an error message.

O Total da quantidade (%) está em 101,00% e deve ser fechado em 100%

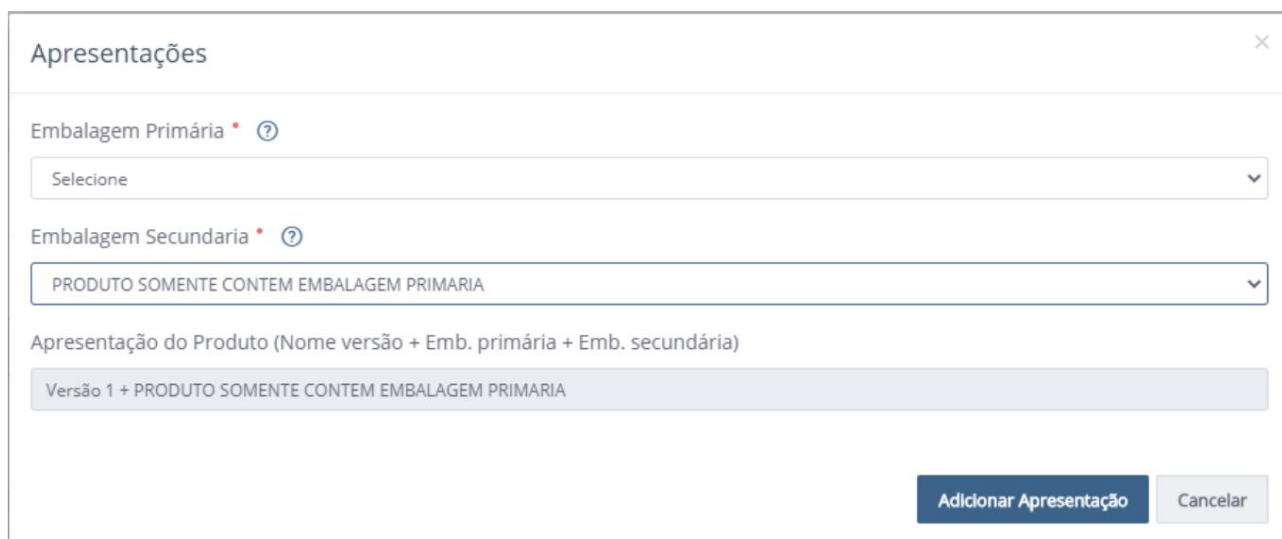
Finally, the applicant must include the information regarding the presentation(s) in the presentations field.



To add presentation information, click the button, which will display a new screen for entering the presentation details.

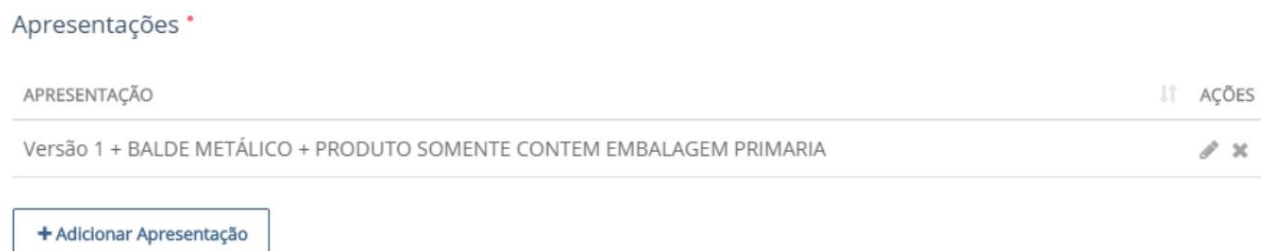
+ Adicionar Apresentação

not at the moment



All fields are required, and if the product does not have secondary packaging, the option "PRODUCT ONLY CONTAINS PRIMARY PACKAGING" should be selected. If the desired packaging types are not registered, please contact the team of the responsible organizational unit.

With each entry, the list of product presentations can be viewed on the form's main screen.





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Using the button  It is possible to change the data of an entered substance by using the button. 
It is possible to exclude an inserted substance.

The data for the registered version(s) will be available on the main screen.

Using the button  It is possible to change the data of an inserted version, and by using the button it is possible to... 
delete an inserted version.

After uploading the necessary files, the user must click the submit button to proceed to the completion of the petitioning workflow.

Important: Post-registration petitions do not include fields related to "Manufacturers," "Version," or "Presentations" in their form.



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Change to the notification of sanitizing products.

This feature is only available for processes of the type "Sanitizing Products".

To initiate a request to change a sanitation product notification, you must access the drafts tab and click the "New" button, selecting the option "Petition Linked to an Existing Process".

When you select the notification you want to change, its data will be loaded onto the screen in a form identical to the one used in the initial notification.

Due to the migration to the Solicita system, information regarding "pH Standard Deviation," "Corrosivity," "LD50," "Substance," and "Measurement Type" from notifications prior to August 2020 may be loaded incompletely. The company must complete the required fields to enable this petition. Once this update is completed, future changes to these notifications will have their forms loaded correctly.

EXPRESSION OF INTEREST IN CONTINUING THE COMMERCIALIZATION

This feature is only available for "Sanitizing" type processes.

To express interest in continuing commercialization, the system will automatically update the product's expiration date at the end of the petitioning process. This update will only occur if the petition is filed within the regulatory deadline defined for this request.

BLOOD, TISSUE AND ORGAN FORMS**EMBRYO PRODUCTION REGISTRATION**

Start an initial petition or a petition linked to an existing case. If you don't know the case number you want, you can search for it in the "cases" tab of the application. Select the subject corresponding to the request you wish to make.

After the selection, a block of information relating to the reference year of the information being provided will be made available. It should be noted that this field is mandatory and it is only possible to fill in data relating to previous years.



After completing the "Petition Reference Data" section, the following information blocks will be available for completion:

- Intrauterine insemination procedures;
- Oocyte retrieval procedures for IVF;
- Egg reception procedures;
- Oocyte collection procedures intended exclusively for cryopreservation;
- Oocyte thawing procedures for personal use;
- Embryo thawing procedures;
- Embryo donation procedures;
- Semen collection procedures for donation

For all blocks, a question will be provided regarding the performance of procedures related to that specific block. If the user answers that the procedures related to the block in question were performed by the Assisted Human Reproduction Center (CRHA), a questionnaire related to the procedure will be provided. For example: the questionnaire will be presented similarly to the information block regarding intrauterine insemination procedures, as shown in the following figure:





MNU - User Manual

After completing this step, the user must follow the rest of the workflow, as detailed in previous sections of this manual, until the protocol is finalized.

TOXICOLOGY FORMS

Registration for Pesticide Residue Studies

Start a petition linked to an existing case. If you don't know the case number you're looking for, you can search for it in the "Cases" tab of the application.

Select the subject that corresponds to the request you wish to make.

After the selection, the system will evaluate whether the registration of the product to which the study will be associated is complete. If the registration is incomplete, the following error message will be displayed.

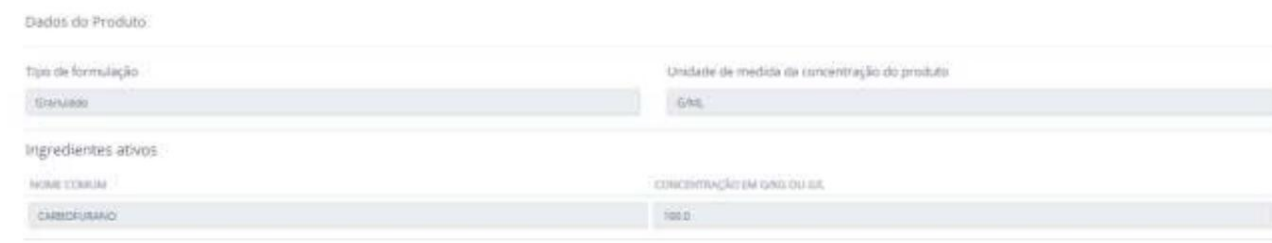


To complete your registration, please contact the ANVISA organizational unit responsible for evaluating pesticides.

After a valid process is entered, the system will display, if any exist, all pesticide residue studies associated with the selected process.



The product details will be available below this block.



Next, the information block regarding the waste study registration will be made available.



After completing the information section related to the residue study registration, the section related to the product's label information must be completed.

Dados da bula do Produto Formulado

SEQUÊNCIA DE APLICAÇÃO	MODALIDADE DE EMPREGO	UNIDADE DE MEDIDA (P.C.)	DOSE MÁXIMA POR APLICAÇÃO (P.C.)	VOLUME DE CALDA MÁXIMO POR HECTARE (LITROS)	Nº MÁXIMO DE APLICAÇÕES	É APLICADO COM ADJUVANTE?	AÇÕES
Nenhum item foi adicionado.							

[+ Adicionar item](#)

Intervalo de segurança (em dias) *

Não determinado devido a modalidade de emprego *

☐ Sim ☐ Não

Clicking the "add item" button will display a screen for filling in information from the product's leaflet.

Adicionar Dados da Bula

Sequência de aplicação: 1*

Modalidade de emprego:

Unidade de medida (p.c.):

Dose máxima por aplicação (p.c.):

Volume de calda máximo por hectare (Litros):

Nº máximo de aplicações:

É aplicado com adjuvante? *

☐ Sim ☐ Não

[Adicionar Dados da Bula](#) [Cancelar](#)

After filling in the information, click the "Add package insert data" button. If you do not wish to save the information and want to abandon the process, click "Cancel".

After the data is entered, it will be available in the data block of the product's package insert.

It is possible to edit by clicking on the icon.



or deleting the data by clicking the icon.



Dados da bula do Produto Formulado

SEQUÊNCIA DE APLICAÇÃO	MODALIDADE DE EMPREGO	UNIDADE DE MEDIDA (P.C.)	DOSE MÁXIMA POR APLICAÇÃO (P.C.)	VOLUME DE CALDA MÁXIMO POR HECTARE (LITROS)	Nº MÁXIMO DE APLICAÇÕES	É APLICADO COM ADJUVANTE?	AÇÕES
1*	Aplicação no tronco	kg p.c./conv	10,00	1,00	7	Sim	 

[+ Adicionar item](#)

If you wish to include more than one application sequence, simply click on the icon.

[+ Adicionar item](#)

After entering the desired data, enter the information regarding the safety interval (in days) or if this interval was not determined due to the employment modality.

Intervalo de segurança (em dias) *

Não determinado devido a modalidade de emprego *

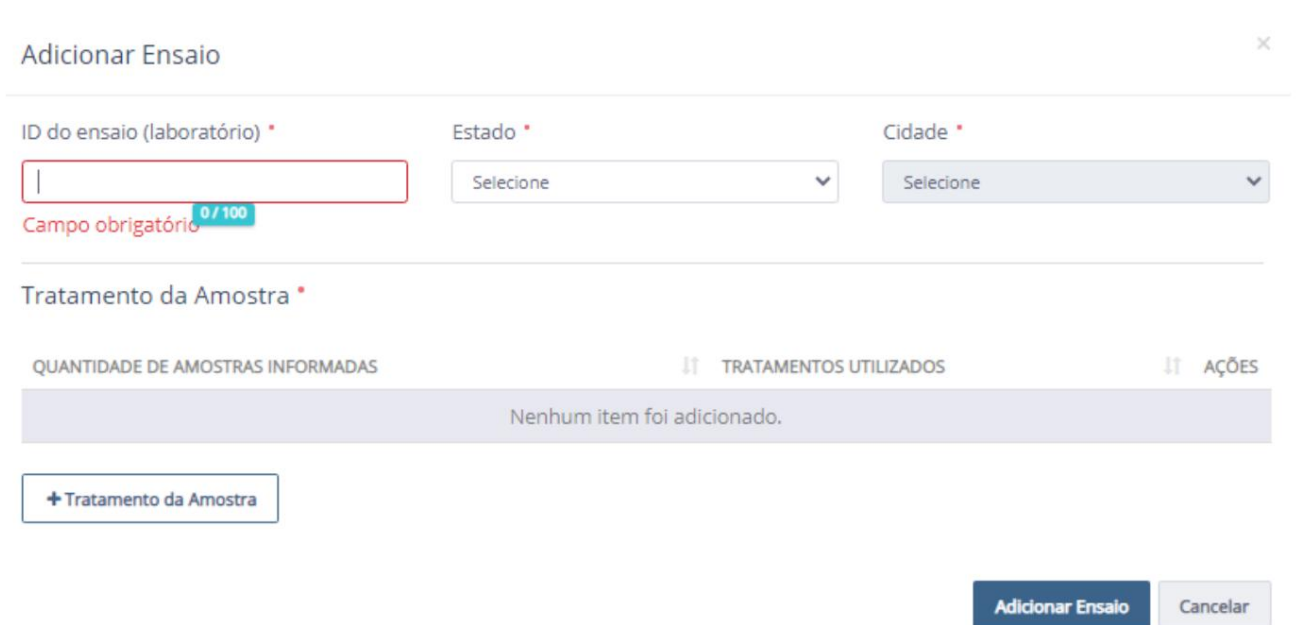
☐ Sim ☒ Não

If the interval has not been determined due to the type of employment, the safety interval field (in days) will be disabled.

The next data set concerns the trials.



Clicking the "add item" button will display a screen for filling in information about tests performed.



For each batch of tests, the test ID, the state, and the city where the test was performed must be provided. After entering this information, the sample treatment data must be filled in. To access them, you...

you must click on the icon

+ Tratamento da Amostra

Clicking will display the following:

Adicionar Tratamento da Amostra ×

Tratamento da Amostra *

MODALIDADE DE EMPREGO *	UNIDADE DE MEDIDA (P.C.) * ?	VOLUME DE CALDA POR HECTARE *	É APLICADO COM ADJUVANTE? *
Selecione ▼	Selecione ▼		☐ Sim ☐ Não ×

+ Tratamento da Amostra

Amostra * ?

AMOSTRA	MODALIDADE DE EMPREGO - DOSE	DAT (DIAS)	DATA DE COLHEITA	DATA DE ANÁLISE	AÇÕES
Nenhum item foi adicionado.					

+ Amostra

Adicionar

Cancelar

First, you must fill in the data relating to the treatment(s) given to the sample; it is possible to enter one or more treatments. If you wish to delete the data for a sample treatment type, click [button name/icon].

in the icon. ×

After entering the data, you will need to enter the information regarding the sample(s) used. For

+ Amostra

You must click on the icon.

A new screen will then be made available.

This screen is composed of two groups of information. In the first, you should enter the information regarding the DAT (in days), the Harvest Date, and the Analysis Date. It is important to note that the analysis date cannot be earlier than the harvest date;

Adicionar Amostra ×

Amostra 1		
DAT (dias) *	Data de colheita *	Data de análise * ?
		

The second group should contain the results data for the active ingredient(s) and metabolite(s).

Resultados

INGREDIENTE ATIVO	LOQ (MG/KG)	RESÍDUOS MENOR QUE O LOQ	RESÍDUO	METABÓLITOS	AÇÕES
CARBOFURANO					

To enter the data, click on the icon to fill in the data related to the selected . A screen will be enabled for the active ingredient.

Atualizar Resultados

Ingrediente Ativo CARBOFURANO	LoQ (mg/Kg) *
Quantidade de resíduos menor que o LoQ * ☐ Sim ☐ Não	Possui Metabólitos * ☐ Sim ☐ Não

If the answer is that the active ingredient has metabolites, a new field will be enabled for filling in information regarding the metabolite. One or more metabolites can be entered, but it should be noted that only metabolites related to the searched active ingredient are available.

Metabólitos *

METABÓLITO *	LOQ *	QUANTIDADE DE RESÍDUOS MENOR QUE O LOQ	RESÍDUO * 
Selecione		☐ Sim ☐ Não	

Finally, a last section refers to any observations from the study.

Observações

Informar como o resíduo está sendo expresso (metabólito, parenteral, outros) nesse campo.

If necessary, you can use the bottom right border of the observation field to view the box.

To write in a larger area, click on the shaded area and select the  and drag so that the box takes over the desired dimensions.

After completing this step, the user must follow the rest of the workflow, as detailed in previous sections of this manual, until the protocol is finalized.

15. PROBLEM SOLVING

I CANNOT ACCESS THE REQUEST

- The user must be previously registered with Anvisa to access Solicita. See registration information on the page <https://www.gov.br/anvisa/pt-br/sistemas/cadastrados/cadastro-de-companies>
- Only users registered with the company as security manager, legal representative, or Regulatory petition users can access Solicita.

I CANNOT FIND A DRAFT OF A "PETITION LINKED TO AN EXISTING PROCESS"

Because the system cannot find the process or petition that I entered in the "Original Petition" field.

- To make a request in an existing process, you must access the request through the
The CNPJ (Brazilian taxpayer ID) to which the process is associated.

I CANNOT VIEW DOCUMENTS FROM REQUESTS MADE BY OTHER USERS OF SAME COMPANY.

- To view documents associated with requests made by any company user in Solicita, the security manager and/or legal representative must be registered with the regulatory petition user link. Note: only users already associated as security manager and/or legal representative can be associated as a regulatory petition user.

I CANNOT FIND A SUBJECT CODE IN THE "INITIAL PETITION" OPTION.

- Verify that the desired subject code corresponds to an initial petition (primary petition), meaning it is a petition that will result in the opening of a new case. Note: amendments, alterations, withdrawals, appeals, or corrections will not appear under "initial petition," as these are petitions linked to an already existing case (secondary petitions).

This verification can be done by consulting the desired petition subject in the Subject [Search](#). The [result will](#) indicate in which menu of Solicita the subject can be found:

Resultado da Consulta de Assunto					
Código de Assunto	Assunto	Tipo de Solicitação	Atividade/Tipo de Produto	Sistema de Peticionamento	Fato Gerador
287	REG. COSMETICOS - Registro de Produto - Nacional	Primária / Novo Processo	Cosmético	SOLICITA	2011

- Verify that the subject code matches the "activity/product type" selected in the tab.
choice of topics.
- Verify that the subject code matches the "service" type of the initial petition you are applying to.
to file a related petition.
- If in doubt, clear all filters and enter only the desired subject code or part of it.
description.

I CANNOT FIND A SUBJECT CODE IN THE "PETITION LINKED TO AN EXISTING PROCESS" OPTION.

- Verify that the desired subject code corresponds to a linked petition (secondary petition), meaning it is a petition that will be included in a previously filed case.

This verification can be done by consulting the desired petition subject in the Subject [Search](#). The [result](#) will indicate in which menu of Solicita the subject can be found:

Resultado da Consulta de Assunto					
Código de Assunto	Assunto	Tipo de Solicitação	Atividade/Tipo de Produto	Sistema de Peticionamento	Fato Gerador
230	REG. COSMÉTICOS - Modificação de Fórmula de Produto Registrado - Nacional	Secundária / Petição vinculada a Processo já existente	Cosmético	SOLICITA	2020

- If you are attempting to complete the protocol associated with an initial petition:

Check if the subject code matches the "activity/product type" of the initial petition to which you want to file a linked petition. If the initial petition does not have a service...

Additionally, the "activity/product type" filter will be pre-filled with the same option as the initial petition.

Check if the subject code corresponds to a "service" (visible in the image marked in red) associated with the "service" of the initial petition to which you want to file a linked petition (access to services can be done via the button marked in the image in blue). This verification can be done by consulting the desired petition subject in the [Consultation section](#).

[Matters.](#)

Detalhes do Assunto	
Assunto	230 - REG. COSMÉTICOS - Modificação de Fórmula de Produto Registrado - Nacional
Atividade/Tipo de Produto	Cosmético
Serviço	Alterar Registro de Cosméticos
Serviços Associados	

Serviços Associados



[Solicitar Registro de Cosméticos](#)

[Solicitar transferência de titularidade de cosméticos](#)

Fechar

If in doubt, clear all filters and enter only the desired subject code. • If you are trying to perform the protocol associated with a petition linked to an initial petition:

In this situation, the system only accepts petitions for amendments, withdrawals, appeals, or corrections. This information is displayed in the yellow bar when selecting the petition subject.



I CANNOT FIND MY PENDING REQUEST IN THE "PAYMENT" TAB.

- Since the validity of payment transactions is up to 30 calendar days, only transactions for which the payment slip (GRU) was issued up to 30 calendar days before the date the query is made in Solicita are available for payment.

My request was not registered.

- Check if the request is in the "awaiting payment" tab. If the petition is in this tab, it means that the payment has not yet been processed. You need to make the payment and wait for the processing.
- Check if the request is in the "awaiting protocol" tab. If the petition is in this tab, it means that the transaction is waiting for the protocol system to process (internalize) the request. If the request has been in this situation for more than 24 hours, please contact Anvisa informing them of the transaction number.

I CANNOT MEET A REQUIREMENT IN THE "REQUIREMENTS" TAB.

- Check if the request received was made electronically.

I CANNOT ACCESS A CASE OR PETITION IN THE "CASES" TAB

- To access a process in the "processes" tab, access the request using the CNPJ (Brazilian company tax ID) to which the process is associated.

I DO NOT HAVE ACCESS TO THE "PRINT PROTOCOL" BUTTON IN THE "PROCESSES" TAB .

- This option is only displayed for petitions filed through the Solicita system.

I DO NOT HAVE ACCESS TO THE "PRINT STATEMENT" BUTTON IN THE "PROCESSES" TAB .

- This option is only displayed for petitions filed through the Solicita system.

I DO NOT HAVE ACCESS TO THE "VIEW" BUTTON IN THE "PROCESSES" TAB .

- This option is only displayed for petitions filed through the Solicita system.
- Verify that you were the petitioner for the petition you wish to view, or verify that you are associated with the petition. to this company as a regulatory petition user.

I CANNOT FIND A SPECIFIC PETITION IN THE PROCESS TREE

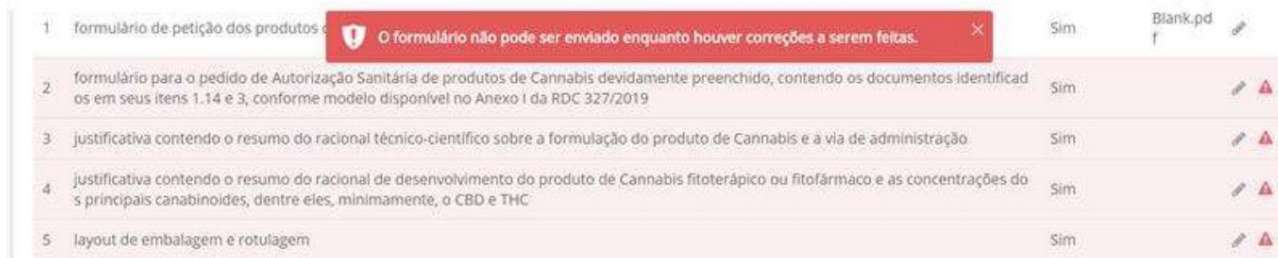
- Make sure you are accessing via the "Processes" tab to have access to the complete tree of The process. Access via the "Favorites" tab will only display previously favorited petitions.

I CANNOT FIND A PROCESS IN THE "FAVORITES" TAB

- Make sure you are accessing with the correct CNPJ (Brazilian company tax ID).
- Make sure the desired process has been previously favorited in the "Processes" tab.

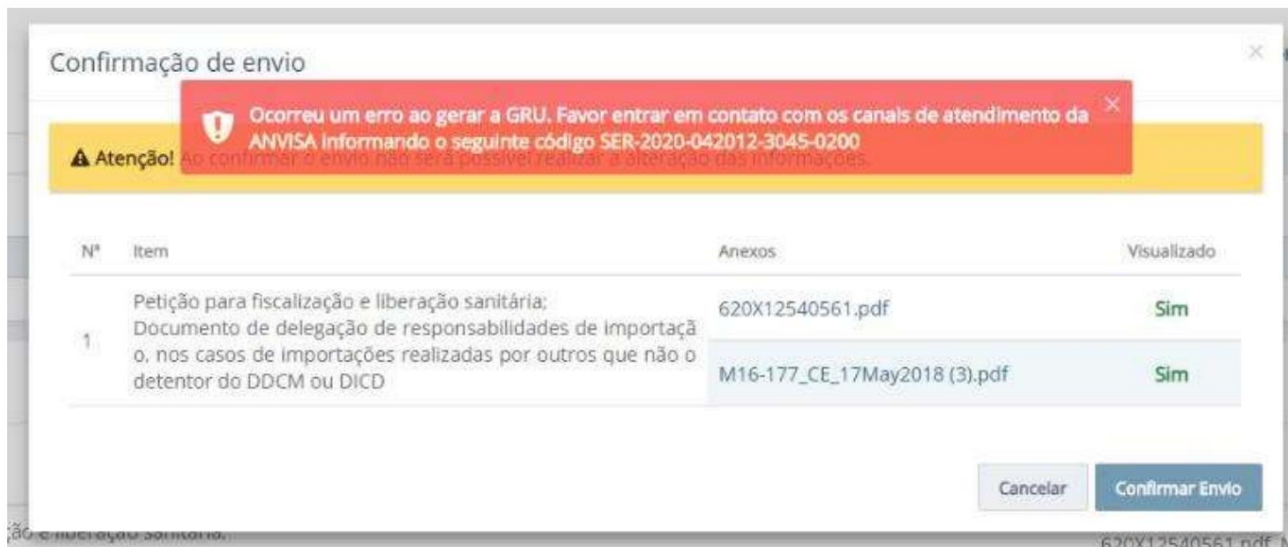
MOST COMMON ERROR SCREENS

- Error related to the user incorrectly filling out the form. By filling it out correctly, the error will be corrected and the user can proceed normally. Errors like this are accompanied by the symbol  , which shows the user what action is needed when positioning the .
hover your mouse cursor over it.

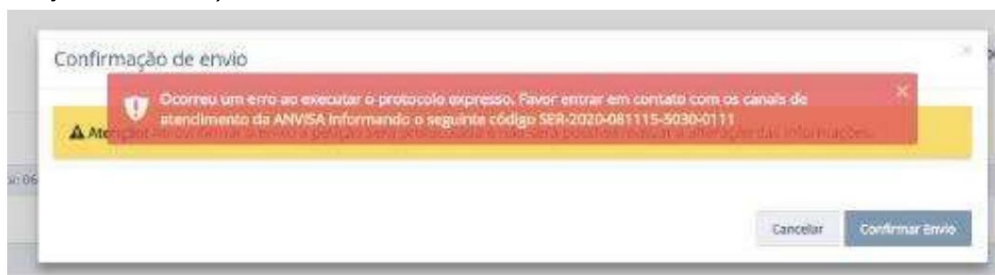


1	formulário de petição dos produtos	 O formulário não pode ser enviado enquanto houver correções a serem feitas.	Sim	Blank.pdf
2	formulário para o pedido de Autorização Sanitária de produtos de Cannabis devidamente preenchido, contendo os documentos identificados em seus itens 1.14 e 3, conforme modelo disponível no Anexo I da RDC 327/2019		Sim	
3	justificativa contendo o resumo do racional técnico-científico sobre a formulação do produto de Cannabis e a via de administração.		Sim	
4	justificativa contendo o resumo do racional de desenvolvimento do produto de Cannabis fitoterápico ou fitofármaco e as concentrações dos principais canabinoides, dentre eles, minimamente, o CBD e THC		Sim	
5	layout de embalagem e rotulagem		Sim	

- Error related to GRU generation, usually linked to momentary instabilities and resolved by trying again within a few moments. If the error persists, please contact Anvisa with as much detail as possible about the error (screenshots, approximate date and time of the error, subject of petition used, etc.).



- Error related to petition submission. Please check if the petition has been moved to the “Awaiting Protocol” tab, which indicates that the protocol system will continue trying to register it. Otherwise, or if it remains in this tab for more than 24 hours, please contact Anvisa informing them of the transaction number and details related to the error (screenshots, approximate date and time of the error, petition subject used, etc.).



- Example of a generic Solicita error. When this error occurs, please contact Anvisa informing them of the transaction number and details related to the error (screenshots, approximate date and time of the error, petition subject used, etc.).

