



Ministry of Health - MS

National Health Surveillance Agency - ANVISA

RESOLUTION OF THE COLLEGIATE BOARD OF DIRECTORS - RDC No. 102, OF AUGUST 24, 2016

(Published in DOU No. 164, of August 25, 2016)

Provides for procedures for transferring ownership of registration of products subject to sanitary surveillance, global transfer of responsibility for clinical trials and updating registration data related to the operation and certification of companies, as a result of corporate operations or commercial operations.

The Collegiate Board of the National Health Surveillance Agency, in the use of the attribution conferred by art. 15, III and IV allied to art. 7, III, and IV, of Law nº 9.782, of January 26, 1999, art. 53, V, §§ 1 and 3 of the Internal Regulations approved pursuant to Annex I of the Resolution of the Collegiate Board - RDC No. 61, of February 3, 2016, resolves to adopt the following Resolution of the Collegiate Board, as resolved at a meeting held in July 12, 2016, and I, CEO, determine its publication.

CHAPTER I

GENERAL PROVISIONS

Art. 1 This Resolution applies to corporate operations and commercial operations between companies that carry out activities provided for in the federal health legislation and that result in the need to update registration data related to the operation and certification of companies, global transfer of responsibility for clinical trials and transfer ownership of registration of products subject to sanitary surveillance.

Single paragraph. This Resolution also covers cases of operations carried out abroad that imply the need for updating within the scope of ANVISA.

Art. 2nd The procedures established by this Resolution apply exclusively to cases in which the technical and sanitary conditions and characteristics of companies, products and clinical trials are maintained.

Art. 3rd The procedures established by this Resolution do not apply to changes of corporate name not related to the operations mentioned in art. 1 of this Resolution, which are subject to the specific rules in force.



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Art. 4 For the purposes set forth in this Resolution, the following definitions are adopted:

I - technical-sanitary characteristics: regular conditions, with ANVISA, of the product, company, or clinical trial, immediately prior to the corporate or commercial transaction;

II - split: corporate operation by which a legal entity transfers portions of its assets to one or more legal entities, constituted for this purpose or already existing, extinguishing the split company, if there is a transfer of all its assets, or dividing it whether its capital, whether partial version;

III - successor company: legal entity that assigns to the successor company the rights and obligations over the product object of transfer of registration ownership, over the establishment, or over the responsibility for a clinical trial, as a result of corporate or commercial operations;

IV - successor company: legal entity that acquires rights and obligations over the product subject to the transfer of registration ownership, over the establishment, or over the responsibility for a clinical trial, as a result of corporate or commercial operations;

V - merger: corporate operation by which two or more legal entities come together to form a third, who will succeed them in all rights and obligations;

VI - incorporation: corporate operation by which one or more legal entities they are absorbed by another, which succeeds them in all rights and obligations;

~~VII - commercial operation: operation between companies that results in the sale of assets or a set of assets, without the occurrence of any corporate transaction between them;~~

VII - commercial operation: operation between companies that results in the transfer of assets or a set of assets, without the occurrence of any corporate transaction between them;
(Wording provided by Resolution - RDC No. 233, of June 20, 2018)

VIII - corporate transaction: business act involving spin-off, merger or incorporation pursuant to Law No. 10,406, of January 10, 2002 and, in a subsidiary way, Law No. 6,404, of December 15, 1976;

IX - Mercosur representative: company located in the receiving State Party (EPR), hired to represent a company holding a product registration in the State Producer Party (EPP) and which assumes legal and technical responsibility in the EPR;

X - global transfer of responsibility for a clinical trial: change characterized by a change in the applicant for clinical trial dossiers, clinical trial notification, clinical drug development dossiers (DDCM),



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clinical investigation dossiers on medical devices (DICD), expanded access programs, compassionate use programs and post-study drug supply, in cases of corporate operations or commercial operations, without any change in the technical-sanitary characteristics being checked constant in Specific Special Notice (CEE), Document for Product Importation under Investigation or Special Notice (CE), object of the change;

XI - transfer of ownership of registration: change characterized by the change of registration holder of products subject to sanitary surveillance, in the cases of corporate operations or commercial operations, without any change being made to the technical-sanitary characteristics in the registration of the product object of the transfer .

Art. 5 The companies must, as a result of corporate or commercial operations, file a request to update registration data related to the operation and certification of companies, global transfer of responsibility for clinical trials and transfer of ownership of registration of products subject to health surveillance, in the terms of this Resolution.

Single paragraph. In the case of successive corporate or commercial operations, it is necessary to file a petition for each operation carried out.

Art. 6 From the completion of the corporate or commercial operation, the successor company is subrogated as to the rights and obligations of the successor company, including with regard to compliance with deadlines and rules for compliance with health legislation and any restrictive measures imposed on product circulation.

CHAPTER II

UPDATE OF REGISTRATION DATA

Art. 7 Companies must file with ANVISA, requests for alteration, granting and or cancellation of Company Operating Authorization (AFE) and Special Authorization (AE), for updating the Certificate of Good Manufacturing Practices (CBPF) or Certificate of Good Practices for Distribution and Storage (CBPDA), and updating the Certificate of Good Practices for Bioavailability/Bioequivalence of Medicines (CBPBD/BE), whenever a corporate or commercial operation takes place.

Section I

Company Operating Authorization (AFE) and Special Authorization (AE)



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Art. 8 The companies must request the update of AFE and AE by means of a petition for alteration, cancellation, or concession, whenever the corporate transaction takes place.

Art. 9 When the corporate transaction results in a new legal entity, or an existing legal entity that has not been regularized with the sanitary surveillance, the regularization will take place through an application for the initial grant of AFE and AE.

Art. 10 The request for cancellation of the AFE and AE must be filed by the succeeding company within 30 (thirty) days after the publication of the Resolution of cancellation and transfer of ownership of records, when applicable.

Single paragraph. Only after the transfer of ownership of all records of the successor company to one or more successor companies will the AFE and AE of the successor company be cancelled.

Art. 11 The petition to update data in the AFE or AE must be accompanied by the following documents:

I – application form duly completed and signed; It is

II - statement of the corporate transaction carried out, as provided in Annex I.

Section II

Certification in Good Practices

Subsection I

Certification in Good Manufacturing Practices and Certification in Good

Distribution and Storage Practices

Art. 12 The successor company must request updating of the registration data referring to the establishments involved in the CBPF, or in the CBPDA, provided that the previously examined technical-sanitary characteristics remain unchanged, whenever the corporate or commercial operation takes place.

§1 The update referred to in the caption of this article does not imply a new certification, and the validity period of the certificate published prior to the operation remains unchanged.

§2 The data update in the CBPF will be carried out by production line and will only be applicable in cases where the corporate or commercial operations involve the entirety of this production line.

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§3 In the case of corporate operations that take place exclusively abroad, the update referred to in the caput of this article must be requested by the current company requesting the current certification.

Art. 13 The request to update data in the CBPF or CBPDA must be accompanied by the following documents:

I – application form duly completed and signed;

II – copy of the current CBPF or CBPDA, in case it has been published prior to the transaction;

III – statement of the corporate or commercial transaction carried out, as provided in the Attachments;

IV – copy of the updated publication in the DOU of the AFE or AE, in the event that the corporate operation results in alteration or granting of AFE or AE; It is

V – copy of the CBPF in force on behalf of the successor company, issued by the health authority of the country where the production establishment is located or a statement from this authority attesting the operation, in the case of a corporate operation carried out abroad.

Art. 14 Updating data in the CBPF or CBPDA does not apply to initial certification requests that are awaiting analysis or whose analysis has not yet been completed.

§1 For the cases provided for in the caput, the successful company must promote the addition of the petition to update the documentation, with a view to the instruction and the continuation of the analysis of the petition in progress.

§2 The successful company must submit the documents provided for in art. 13 of this Resolution.

Subsection II

Certification in Good Practices of Bioavailability/Bioequivalence of Medicines

Art. 15 The successor company must request an update of the registration data regarding the establishments involved in the CBPBD/BE, provided that the previously examined technical-sanitary characteristics remain unchanged, whenever the corporate transaction takes place.



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§1 The update referred to in the caption of this article does not imply a new certification, and the validity period of the certificate published prior to the operation remains unchanged.

Paragraph 2 In the case of corporate operations occurring exclusively abroad, the update referred to in the caption of this article must be requested by the current company requesting the current certification.

Art. 16 The petition to update data in the CBPBD/BE must be accompanied by the following documents:

I – application form duly completed and signed;

II – copy of the current CBPBD/BE; It is

III - statement of the corporate transaction carried out, as provided in Annex I.

Art. 17 The CBPBD/BE update request does not apply to initial certification requests, which are awaiting analysis or whose analysis has not yet been completed.

§1 For the cases provided for in the caption, the successful company must promote the addition of the petition to update the documentation, with a view to the instruction and the continuation of the analysis of the petition in progress.

§2 The successful company must submit the documents provided for in art. 16 of this Resolution.

CHAPTER III

TRANSFER OF OWNERSHIP

Section I

Pesticides, their Components and the like

Art. 18 The successor company must communicate to ANVISA the transfer of ownership of the registration of pesticides, their components and the like, at the registering federal agency, in accordance with the provisions of Decree No. 4,074, of January 4, 2002, within 60 (sixty) days, by means of a request for notification of change of ownership, whenever a corporate or commercial transaction takes place.

Art. 19 The petition for notification of change of ownership must be filed with the following documents:



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I – application form duly completed and signed; It is

II – copy of the DOU proving the transfer of ownership at the registering federal agency.

Section II

Of Smoking Products Derived or Not from Tobacco

Art. 20 Companies must update the data related to the registration of smoking products with ANVISA, through a petition for transfer of ownership and cancellation of registration, whenever a corporate or commercial operation occurs that implies a change in ownership of the registrations.

Art. 21 Petitions for transfer of ownership and cancellation of registration must be concurrently filed with ANVISA, respectively by the successor and successor companies, within a period of up to 60 (sixty) days.

§1 Petitions filed after the deadline set forth in the caption of this article will be rejected by ANVISA.

Paragraph 2 The term referred to in the caput of this article shall start from the date of filing of the corporate act registered with the competent commercial board, or the signing of the contractual instrument for the transfer of assets or a set of assets, as the case may be.

§3 In the case of a Mercosur representative, the period provided for in the caput of this article will be counted from the date on which the contractual relationship between the Mercosur representative company domiciled and registration holder in Brazil and the represented company, registration holder in another Member State of Mercosur.

Art. 22 The transfer of ownership of smoking products implies simultaneous publication, in the DOU, of the new registration and the cancellation of the old registration, keeping unchanged the technical-sanitary characteristics of the product and the period of validity of the registration object of transfer.

Art. 23 The registration ownership transfer petition must be accompanied by the following documents:

I – application form duly completed and signed;

II – statement of the corporate or commercial transaction carried out, as provided in Annex I;

III - proof of Enrollment and Registration Status with the Secretariat of Federal Revenue Service of Brazil - National Registry of Legal Entities (CNPJ); It is

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IV – copy of the Executive Declaratory Act (ADE) granting registration Manufacturer or Importer Special, in the case of a cigarette or cigarillo type product, issued by the Federal Revenue Service of Brazil, already referring to the company successor.

Art. 24 Corporate or commercial operations involving the transfer of rights and obligations relating to registration requests that are awaiting analysis or whose analysis has not yet been completed, do not characterize transfer of ownership.

§1 For the cases provided for in the caput, the successful company must promote the addition of the petition to update the documentation, with a view to the instruction and the continuation of the analysis of the petition in progress.

§2 The successful company must submit the documents provided for in art. 23 of this Resolution.

Section III

Medicines, Active Pharmaceutical Inputs, Cosmetics, Sanitizing, Health Products and Food

Art. 25 Companies must update the data related to the registration of products subject to sanitary surveillance, through a petition for transfer of ownership and cancellation of registration, whenever a corporate or commercial transaction occurs that implies changing the ownership of the registration of products.

Art. 26 Petitions for transfer of ownership and cancellation of registration must be concurrently filed with ANVISA, respectively by the successor and successor companies, within a period of up to 180 (one hundred and eighty) days.

§1 Petitions filed after the deadline set forth in the *caption* of this article will be rejected by ANVISA.

Paragraph 2 The term referred to in the caput of this article shall start from the date of filing of the corporate act registered with the competent commercial board, or the signing of the contractual instrument for the transfer of assets or a set of assets, as the case may be.

§3 In the case of a Mercosur representative, the period provided for in the *caput* of this article will be counted from the date on which the contractual relationship between the Mercosur representative company domiciled and registration holder in Brazil and the represented company, registration holder in another Member State of Mercosur.

Art. 27 Products subject to registration are equivalent to those subject to registration for the purpose of transferring ownership of registrations.

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Art. 28 Products subject to notification and exempt from registration are not subject to transfer of ownership, and the successor company must carry out a new notification or new regularization procedure, as the case may be.

Art. 29 The transfer of registration ownership implies the simultaneous publication, in the DOU, of the new registration number and the cancellation of the old number, keeping the characteristics of the product and the validity period of the registration subject to transfer unchanged.

Art. 30 The registration ownership transfer petition must be accompanied by the following documents:

I – application form duly completed and signed;

II – proof of payment or exemption from the Inspection Fee for Sanitary Surveillance (TFVS), through Union Collection Guide (GRU);

III – statement of the corporate or commercial transaction carried out, as provided in Annex I; It is

IV – copy of the operating license or health permit issued by the competent body, duly updated after the corporate or commercial transaction.

Art. 31 Corporate or commercial operations involving the transfer of rights and obligations relating to registration requests that are awaiting analysis, or whose analysis has not yet been concluded, do not characterize a transfer of ownership.

§1 For the cases provided for in the caput, the successful company must promote the addition of the petition to update the documentation, with a view to the instruction and the continuation of the analysis of the petition in progress.

§2 The successful company must submit the documents provided for in art. 30 of this Resolution.

Art. 32 Post-registration petitions already filed by the succeeding company and which are awaiting analysis or whose analysis has not yet been completed may be transferred to the successor company, upon presentation of the declaration of interest set out in Annex I.

Single paragraph. Post-registration petitions that are not included in the declaration set out in Annex I will characterize withdrawal by the successor company and will be closed by ANVISA.

Art. 33 Adjustments in the texts of instructions for use, package inserts and labels, arising from the transfer of ownership, may be implemented after approval of the petition for transfer of ownership by ANVISA.

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§1 The adjustments in the texts of instructions for use, package inserts and labels that deal with the *caput* of this article are restricted to updating the registration holder's data.

Paragraph 2 In the case of medicines, the successor company will have a period of up to 30 (thirty) days, after the entry into force of the Resolutions on cancellation and transfer of ownership of registrations, to petition for the Notification of alteration of the text of the leaflet and Notification of alteration of labeling related to the characteristics of the new company holding the registration.

Art. 34 As a result of the transfer of ownership, the maintenance of different or distinct names for drugs with the same active ingredient(s) will be allowed.

CHAPTER IV

**GLOBAL TRANSFER OF RESPONSIBILITY FOR TEST
CLINICAL**

Art. 35 The successful company must update the data relating to the clinical trial by means of a petition for the global transfer of responsibility for the clinical trial, whenever a corporate or commercial operation takes place.

Art. 36 The petition for the global transfer of responsibility for a clinical trial must be accompanied by the following documents:

I – application form duly completed and signed; It is

II – statement of the corporate or commercial transaction carried out, as provided in Annex I.

Art. 37 For requests for the global transfer of responsibility for a clinical trial, even those under the responsibility of a Representative Organization for Clinical Research (ORPC), a Special Communiqué, Specific Special Communiqué or Document for Importation of Product under Investigation will be issued in the name of the new person responsible for the respective process.

CHAPTER V

OF THE FINAL AND TRANSITIONAL PROVISIONS

Art. 38 Imports by the successor company, based on the AFE of the successor company, will be allowed until ANVISA decides on the regularization



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of the company, provided that the deadlines for the protocol established by this Resolution are obeyed.

Single paragraph. The importing company must submit a certified copy of the declaration of the operation carried out to the health authority of the place of clearance, as a document proving the corporate or commercial operation, as provided in Annex I.

Art. 39 Responsibility for the product and any remaining stock of finished products will fall on the successor company, including for import purposes, in cases of transfer of registration ownership.

§1 Until the transfer of ownership of product registrations with ANVISA occurs, imports carried out by the successor company must be accompanied by a declaration from the successor company, signatory of the product regularization petition with ANVISA, authorizing the import.

Paragraph 2 The provisions of the *caput* of this article do not exclude the joint and several liability of the successful company before the health surveillance bodies and entities for acts performed prior to the corporate or commercial operation.

Art. 40 The remaining stock of finished products subject to the transfer of ownership may be regularly imported or sold by the new registration holder, provided that it was produced before the entry into force of the Resolutions on cancellation and transfer of ownership of registrations.

Single paragraph. Companies will have a maximum period of 180 (one hundred and eighty) days, after the entry into force of the Resolutions on cancellation and transfer of ownership of registrations, to deplete the remaining stock of finished products.

Art. 41 The use and depletion of any remaining stock of packaging with outdated wording or labeling information for new batches produced after the entry into force of the Resolutions on cancellation and transfer of ownership of registrations will not be allowed.

Art. 42 The provisions contained in Articles 39, 40 and 41 do not apply to agrochemical products, their components and the like, as they are subject to the rules established by the registering federal agency.

Art. 43 Petitions for the transfer of ownership of product registration as a result of corporate transactions, filed before the effective date of this Resolution will be analyzed in accordance with the Resolution in force at the time of the protocol.



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Art. 44 The deadlines for filing established by this Resolution will not affect requests for the transfer of ownership of product registration as a result of commercial operations carried out prior to the effectiveness of this Resolution.

Single paragraph. In the cases included in the *caput*, companies may file with ANVISA, within a period of up to 180 (one hundred and eighty) days from the effectiveness of this Resolution, concomitant requests for transfer of ownership and cancellation of product registration, as the case may be. .

Art. 45 Companies involved in corporate and commercial operations must provide information and present additional documents, whenever requested by ANVISA.

Art. 46 ANVISA may, at any time, request a copy of the filing certificate of the registered corporate act, in the case of a corporate transaction, or of the contractual instrument for the transfer of assets or a set of assets, in the case of a commercial transaction.

Art. 47 Unless otherwise stated, the Resolutions on cancellation and transfer of ownership of registration of products subject to sanitary surveillance dealt with in this Resolution begin to take effect 90 (ninety) days after their publication.

Art. 48 Delay, omission or provision of false or misleading information, in disagreement with the provisions of this Resolution, constitutes a health infraction, subjecting the offender to the penalties provided for in Law No. 6,437, of August 20, 1977, without prejudice to civil and penalty provided for in the applicable rules in force.

Art. 49 The Resolution of the Collegiate Board - RDC No. 22, of June 17, 2010, Normative Instruction No. 03, of May 3, 2012, and item 4, Chapter III of the Annex to RDC No. 323, of 10 November 2003.

Art. 50 This Resolution enters into force within 120 (one hundred and twenty) days, counted from the date of its publication.

JARBAS BARBOSA DA SILVA JR.



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ANNEX I

DECLARATION OF UPDATE OF REGISTRATION DATA RELATED TO THE
OPERATION AND CERTIFICATION OF COMPANIES, TRANSFER
GLOBAL RESPONSIBILITY ON CLINICAL TRIAL AND
TRANSFER OF OWNERSHIP OF PRODUCT REGISTRATION
SUBJECT TO HEALTH SURVEILLANCE.

For the purposes of updating registration data relating to the operation and certification of
companies, responsibility for a clinical trial, and transfer of ownership of
registration of products subject to health surveillance, the **SUCCEEDED COMPANY**

_____, registered with the CNPJ under No.
_____, headquartered at _____
_____, city _____,
State _____, legally represented by _____
_____, identity No.
_____, issued by the _____ body, CPF No.
_____, **COMPANY**

SUCCESSOR _____, enrolled in the
CNPJ under O _____, with site To
_____, city
_____, state _____, represented
legally by _____,
identity No. _____, issued by the body
_____, CPF No. _____,

DECLARE UNDER PENALTIES OF THE LAW, before ANVISA, for the purposes of the provisions of
RDC Resolution No. 102, of August 24, 2016, which carried out the



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operation _____ (corporate OR commercial) called _____
 _____ (merger, spin-off or incorporation, in case of
 corporate transaction, or sale of assets or a set of assets, in case of
 commercial operation), as stated _____ (of
 certificate of filing of the registered corporate act, in case of corporate transaction,
 or the contractual instrument for the transfer of assets or a group of assets, in
 case of operation commercial), issued for the
 _____ (identification of the board of trade, in
 case of corporate transaction, or by the company succeeded to conclude the transfer,
 in case of commercial operation) in _____ by _____ by _____.

(FILL IN CASE OF UPDATING AFE AND AE DATA):

The successor company DECLARES that the petition is related to the establishments
 Branches of the successful company listed below:

CNPJ	Corporate Name	Address

(FILL IN CASE OF UPDATE OF GOOD GOOD CERTIFICATE
 MANUFACTURING PRACTICES (CBPF) OR DISTRIBUTION AND
 STORAGE (CBPDA)):

The successor and successor companies DECLARED that the petition is related to the
 production line informed below:

Production line (according to current legislation)	Products manufactured on the production line

The successor company DECLARES that it maintains interest in analyzing the petitions for
 certifications filed by the successful company and which have not yet been analyzed
 completed by ANVISA according to the list below:

Protocol date Number	Office hour	do	Subject	Products manufactured on the production line



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(FILL IN CASE OF UPDATE OF GOOD GOOD CERTIFICATE
PRACTICES OF BIOAVAILABILITY/BIOEQUIVALENCE OF
MEDICINES (CBPBD/BE)):

The successor company DECLARES that it maintains interest in analyzing the petitions for certifications filed by the successful company and which have not yet been analyzed completed by ANVISA according to the list below:

Protocol date	File number	Subject

(FILL IN CASE OF GLOBAL TRANSFER OF
RESPONSIBILITY FOR CLINICAL TRIAL):

The successful company DECLARES that, in the event of a global transfer of responsibility for DDCM or DICD processes, transfers the responsibility of following clinical trial specific dossier processes for the successor company:

Protocol date	File number	Subject

The successful company DECLARES that clinical trial processes not mentioned above will be kept under the responsibility of the person responsible for the initial submission to the ANVISA.

This table does not apply to situations involving specific test dossiers clinical trials, clinical trial reporting, expanded access programs, compassionate use and provision of post-study medication.

(FILL IN CASE OF TRANSFER OF OWNERSHIP OF
PRODUCT REGISTRATION):

The successor company DECLARES that it maintains an interest in the analysis of the petitions after registration filed by the successful company and which have not yet been analyzed completed by ANVISA according to the list below:

Protocol date	File number	Subject



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The successor company DECLARES that it withdraws from post-registration petitions that are not included from the list above, and is aware that these petitions will be closed by ANVISA, as provided in the sole paragraph of art. 32 of Resolution RDC No. 102, of 24th of August 2016.

The aforementioned companies DECLARED under the penalties of the Law, through their legal and technical representatives, that there was no change in the technical characteristics previously approved by ANVISA and DECLARED that no change in the technical-sanitary characteristics will be carried out until there is authorization, approval or certification of the activity, in accordance with the respective formal acts issued by the ANVISA.

The mentioned companies DECLARED UNDER PENALTIES OF THE LAW, through their legal and technical representatives, that the information provided above is the expression of true and both assume joint responsibility for its accuracy.

Technical Manager of the successful company
Signature _____
CPF: _____
_____, of _____ of _____

Technical Manager of the company
successor
Signature _____
CPF: _____
_____, of _____ of _____

Legal representative of the successful company
Signature _____
CPF: _____
_____, of _____ of _____

Legal representative of the successor company
Signature _____
CPF: _____
_____, of _____ of _____

(Rectified in DOU No. 165, of August 26, 2016)

Technical Manager of the successful company
Signature _____
CPF: _____
_____, of _____ of _____

Technical Manager of the company
successor
Signature _____
CPF: _____
_____, of _____ of _____



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ANNEX II

DECLARATION OF CORPORATE OPERATIONS PRACTICED ABROAD

For the purpose of updating registration data relating to the operation of companies, the

APPLICANT COMPANY

_____ ,
registered with the CNPJ under No. _____ , thirsty at
_____ , city
_____ , state _____ , represented
legally by _____ ,
identity No. _____ , issued by _____ organ
_____ , CPF No. _____ , DECLARES

before ANVISA, for the purposes of the provisions of Resolution RDC No. 102, of August 24,

2016, _____ what _____ a _____ **COMPANY** _____ **SUCCESSFUL**
_____ , with _____ site _____ To
_____ , city
_____ , state _____ Country _____ It is,

the **SUCCESSOR COMPANY**

_____ ,
thirsty at _____ , city
_____ , state _____ , Country _____ ,
carried out the corporate transaction abroad in _____ by _____ by _____ .

The requesting company DECLARES under the penalties of the Law, through its representative legal, that there was no change in the technical-sanitary characteristics previously approved by ANVISA and DECLARES that no change in the characteristics technical-sanitary tests will be carried out until there is authorization, approval or certification of the activity, in accordance with the respective formal acts issued by ANVISA.

The requesting company DECLARES UNDER PENALTIES BY LAW, through its legal representative, that the information provided above is the expression of the truth and assumes responsibility for its accuracy.

Legal representative of the applicant company
Signature _____
CPF: _____
_____ , _____ of _____ of _____