



กองผลิตภัณฑ์สุขภาพนวัตกรรมและบริการ  
Division of Innovative Health Products  
and Services

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## Guidelines for submitting a product license application by electronic means

### Guidelines for submitting a product license application by electronic means

There is now a widespread problem of the coronavirus disease 2019 ( COVID - 19 ) outbreak . As a guideline for preventing the spread of Covid - 19, the Division of Innovative Health Products and Services ( STP ) has a guideline for applying for permission to bring or order medicines into the kingdom that are exempt. Request for drug formula registration and sample drug license request for registration of drug formula by electronic means as following steps

#### **1. Submitting an application for permission to bring or order drugs into the Kingdom that are exempt from the need to register for drug formulas (NorMor.1,NorMor.2,NorMor.3 and NorMor.4) contain details episode as follows**

1. Submit an application for permission to bring or order drugs into the Kingdom that are exempt from the need to apply for registration of drug formulas in the form of N.Yor.M. 1, N.M. 2, N.M. 3, or Nov. 4 (in the case of government hospitals) and supporting evidence for permission By allowing you to prepare the document in PDF format ( version 1 . 4 and above) and contain the document according to the specified folder structure (details in the attachment) by sending the Folder Structure containing the said document to the electronic mail [hpi2017@fda.moph.go.th](mailto:hpi2017@fda.moph.go.th)

2. Officers of the Office of the Police receive the matter, proceeding to issue the receiving number in the system. Send a fee payment order to the licensee via electronic mail and consider the request for permission

3. The licensee pays the fee through the e - payment system and sends the payment document to the electronic mail by Reply to the original letter.

4. Employees of the Office of the Registrar Record the request in the database and the result of approval in the information system linked to the License Per Invoice ( LPI ) system.

5. Office of the Office of the Registrar to submit the results of consideration to the licensee via electronic mail

6. Licensee Able to apply for permission to import at the Food and Drug Administration By referring to the electronic mail item 5. and does not require a document authorizing the importation or ordering of

drugs into the Kingdom that is exempt from the need to apply for registration, the original version.

7. In the event that the licensee requires the original license document It can be performed according to the following options:

**Option 1.** Licensee The aforementioned documents can be sent to the Office of the Registrar of Police by post, the original signed documents will be sent back by mail or coordinated with the messenger to deliver the documents to the recipient. allow according to the location that you have informed the appointment by the licensee will be responsible for the cost of document delivery

**Option 2.** Licensee or an attorney including messenger staff You can submit the original form of the NCC at Counter e - CTD OSSC, Floor 5, Building 6, by making an appointment in advance with the Office of the President (details in Note No. 1). You can wait to receive the signed original document. allowed to return

## **2. Submission of an application for a license for a sample drug for registration of a drug formula by electronic means (Phor.Por.8/ Nor.**

1. Submission of an application for a license for a sample drug for registration of a drug formula by electronic means in the form of Nor.Jor.8, Chor.8 and Nor.Jor.8, together with supporting evidence. By allowing you to prepare the document in PDF format ( version 1 . 4 and up) by packing such documents according to the specified folder structure (details in the attachment) by sending the Folder Structure containing such documents to the electronic mail [hpi2017@fda . moph . go . th](mailto:hpi2017@fda.moph.go.th)

2. Officers of the Office of the Police receive the matter, proceeding to issue the receiving number in the system. Send a fee payment order to the licensee via electronic mail and consider the said request

3. The licensee pays the fee through the e - payment system and sends the payment document to the electronic mail by Reply to the original letter.

4. Employees of the Office of the Registrar of Police record the request in the database and the results of the approval in the information system. In the case of bringing or ordering drugs into the kingdom, the system will be linked to the Licen se Per Invoice ( LPI ) system.

5. The officers of the Office of the Medical Education Commission submit the form to report the results of the sample drug license for registration of the drug formula by electronic means to the licensee. via electronic mail

6. Licensee Able to apply for permission to import at the Food and Drug Administration By referring to the electronic mail item 5. and does not require the original document of permission to bring or order a sample drug .

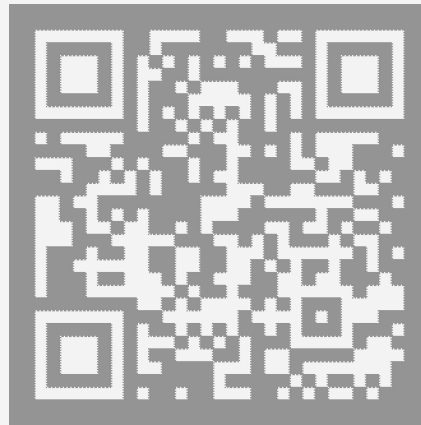
7. In the event that the licensee needs the original license document, they can proceed according to the following options:

**Option 1.** Licensee The aforementioned documents for permission can be sent to the Office of the Registrar of Police by post, whereby the officers of the Office of the Registrar will send the original signed documents back by post or coordinate with the messenger to deliver the documents to the licensee. according to the location that you have informed the appointment by the licensee will be responsible for the cost of document delivery

**Option 2.** Licensee or an attorney including messenger staff You can submit the original form of the NCC at Counter e - CTD OSSC, Floor 5, Building 6, by making an appointment in advance with the Office of the President (details in Note No. 1). You can wait to receive the signed original document. allowed to return

**note**

1. In case of appointment to submit documents in advance, you can make an appointment at 02 590 7614 or shorturl . at / pwAL0 or QR CODE.



2. Address for sending original documents by post

Division of Innovative Health Products and Services  
88/24 Moo 4, Talat Khwan Subdistrict, Mueang District, Nonthaburi  
Province 11000

If you have any questions, you can ask for more information at 02 590 7614, 086 - 3109302, 065 - 9240100 by contacting the Assessment Management Group staff.

## **attachment**

**convenience book Electronic filing**

**Documents to submit documents supporting COVID-19**

**V4**

**Folder structure**

Tiwanon Road, Nonthaburi 1100



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