Guideline

on

Submission of Application for Drug Import Permit into Thailand for Clinical Trial

International Affairs and Investigational Drug Section

Drug Control Division, Thai Food and Drug Administration

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Table of Content

Guideline on Submission of Application for Drug Import Permit into Thailand for Clinical Trial

1. **Definition: Clinical Trial Drugs** in this Guideline are included Modern Drugs or Traditional Drugs, which are indicated in the application for drug import permit into Thailand for clinical trial

2. **Procedures are as follows:**

2.1 **Screening Process**

2.1.1 Eligible applicant submits an application with attached documents as listed in the Checklist form and attached documents for the application of drug import permit into Thailand for clinical trial according to Nor Yor Mor 1 form (see Annex 3) at the One Stop Service Center(OSSC), Thai Food and Drug Administration

2.1.2 OSSC sends the application package to International Affairs and Investigational Drug Section

2.1.3 Officer of International Affairs and Investigational Drug Section screens documents/evidences as listed in the "Checklist form" and attached documents for the application of drug import permit into Thailand for clinical trial according to Nor Yor Mor 1 form (see Annex 3). Then the officer informs the eligible applicant or its attorney the screening results within 5 working days from the date, when International Affairs and Investigational Drug Section first received the application package

(1) If the screening result is "completed application package", the officer will send the application package to an assigned reviewer to proceed

(2) If the screening result is "uncompleted application package", the officer will send "Screening Result Notification form" (Annex 4) to the applicant or its attorney to correct the application package by submitting additional documents together with "Additional Documents Submission form" (see Annex 5)

If the applicant or its attorney fails to fully correct the package within 5 working days, Thai FDA will send a rejection letter and return all documents to the applicant. However, the applicant can later correct or amend the application package and re-submit it at the OSSC.

If the correction is completed, the officer will send the application package to the assigned reviewer to proceed

2.2 **Assessment Process**

Reviewer receives the application package and performs technical assessment

(1) If the reviewer finds that the package is correct and appropriate in terms of technical evidence, the reviewer will put forward this application to Thai FDA for approval of the Drug Import Permit for clinical trial

(2) If the reviewer finds that the package is inappropriate in terms of technical evidence, the reviewer will put forward this application to Thai FDA for disapproval

(3) If the reviewer considers and finds that the technical information is incomplete, the reviewer will inform the result to the applicant or its attorney to clarify and/or submit additional documents or information.

If the applicant or its attorney fails to submit additional documents or cannot amend the application package with in 5 working days, Thai FDA will issue a rejection letter and return the package to the applicant. However, the applicant can later correct or amend the application package and re-submit it at the OSSC.

If the applicant can completely correct the application package, the officer will forward the package to the assigned reviewer for re-assessment