Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA Circular
No. 2012-007-A

24 MAY 2019

SUBJECT: **Amending FDA Circular No. 2012-007: Reduction of Turn-Around-Time for the Regulatory Review of Clinical Trials and Revised Procedure for the Application of Import License for Investigational Products**

I. RATIONALE

On 7 June 2012, FDA Circular (FC) No. 2012-007 was issued which provided for the first comprehensive guideline on the regulation of clinical trials on investigational medicinal products. Under the said Circular, FDA recognized the Philippine Health Research Ethics Board (PHREB)-Accredited Institutional Reviewers (IRBs) as ethical and technical reviewers for clinical trial applications.

The process of ethical and technical review of applications for clinical trials by PHREB-Accredited IRBs, as well as the fees and turn-around-time for the reviews and application for import permit for Investigational Medicinal Products, were described in the said Circular. For the fee on the technical and ethical review by the IRB, it specifically stated that it will be standardized as Thirty Thousand Pesos and the timeline for the review from acceptance to completion should not exceed 60 days. For the access to medicines for the use in clinical trials using the import permit, the Circular stated that the procedure will be defined by FDA based on what capacity is available at its disposal.

To provide a more efficient system of issuance of permits, this Circular is promulgated to allow for the parallel submission of Clinical Trial and Import License Applications, reduction of the timeline for the regulatory review of clinical trials, and appropriate revision of fees for the FDA regulatory reviewers.

II. OBJECTIVES

The objective of this Circular is to amend FC No. 2012-007, specifically on the procedure of import license application, and turn-around-time for the regulatory review of clinical trials and its corresponding fees.

III. SCOPE

This Circular shall apply to all sponsors, contract research organizations (CROs) and investigators involved in the conduct of clinical trials.

IV. GUIDELINES

A. Submission of Application

1. A sponsor and/or CRO shall submit a clinical trial application to the FDA following the existing requirements and guidelines on the submission of application.

2. Upon receipt of the clinical trial Application, FDA shall review the completeness of the documentary submission in not more than fifteen (15) calendar days and shall assign a Regulatory Reviewer for the Clinical Trial application.

3. Applications shall be processed by the Regulatory Reviewers in not more than forty-five (45) calendar days upon receipt of application. The Regulatory Reviewers may have queries regarding the application which shall be emailed to the applicant. This shall constitute a stop clock on the processing time. The applicant is expected to respond to the query/queries within thirty (30) calendar days. If no response is received from the applicant within the required 30 calendar days, the application will be disapproved.

4. FDA shall issue a decision for all applications in not more than 15 calendar days upon receipt of recommendation from the Regulatory Reviewers (Appendix A).

5. Fees to be charged per application as fee for the Regulatory Reviewers will be Sixty Thousand Pesos (PhP 60,000.00).

B. Import License and Notification for Investigational Products:

1. Import License

1.1 Import License (IL) applications for Investigational Products (IP) shall be filed simultaneously with the clinical trial applications and shall be accepted in accordance with the FDA existing guidelines on the receipt of applications.

1.2 The following shall be the documentary requirements for IL applications:
   a. Letter of Application (Appendix B)
   b. Import License Application Form (Appendix C)
   c. Proof of payment

1.3 The Criteria for IL approval shall include the following:
   a. Complete documentary requirements
   b. Approved clinical trial application

1.4 IL shall be valid for three years and shall be issued with the Clinical Trial Approval (CTA) in accordance with FDA existing guidelines on the release of permits and certifications. Further, all on-going clinical trials shall be issued an IL valid for 3 years upon submission of requirements listed in 1.2.

1.5 Extension of validity and addition of quantity (i.e., for IP) shall be subject to FDA approval upon submission of documentary requirements listed in 1.2 and the rationale for the request and/or supporting data. Extension of validity shall be valid for two (2) years.

2. Notification

2.1 The establishment is required to notify FDA quarterly of every shipment of the Investigational Products and Ancillary Supplies entering the country.

2.2 The following shall be the documentary requirements for notification:

a. Cover Letter for Investigational Product Notification (Appendix D);
b. Proof of payment;
c. Drug Importation Report (Appendix E);
d. Ancillary Supplies Importation Report (Appendix F), if applicable; and
e. Copy of Proforma Invoice/s.

2.3 Applicants must submit two hard (2) copies of the application as well as one complete set of application files (MS Word or PDF) in soft copy. All data must be in English/translated to English.

The appropriate fees as prescribed under the existing regulation shall apply to import license applications and notifications.

V. REPEALING CLAUSE AND SEPARABILITY CLAUSE

Provisions in existing Circulars and memoranda inconsistent with this Circular are hereby withdrawn, repealed and revoked accordingly.

If any provision in this Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this Circular shall not be affected.

VI. EFFECTIVITY DATE

This Circular shall take effect 01 June 2019.

DR. ROLANDO ENRIQUE D. DOMINGO, DPBO
Officer-in-Charge, Director General

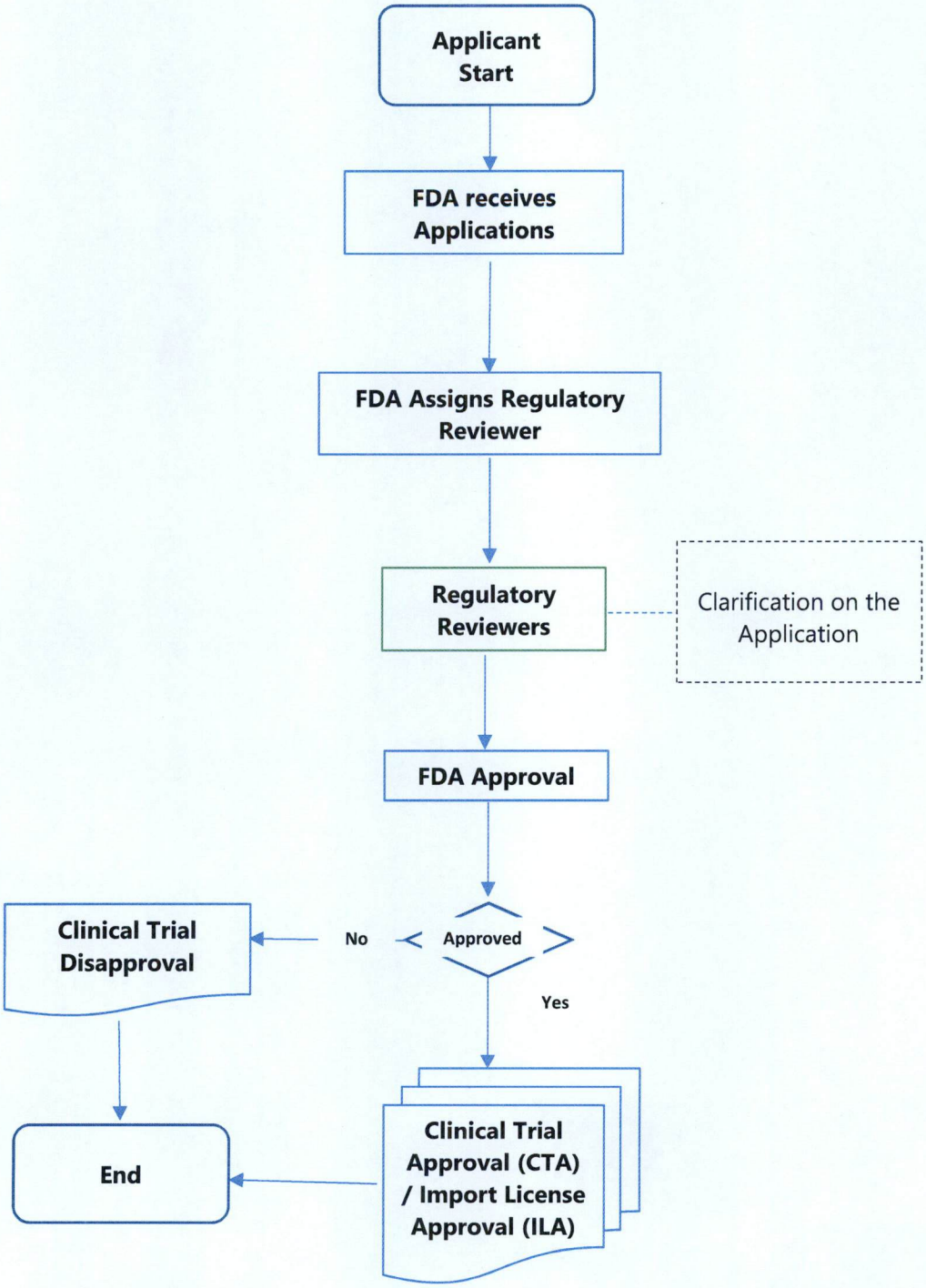
Annex 1

List of Appendices

Appendix	Title
A	Clinical Trial and Import License Approval Process
B	Cover Letter for Import License Application
C	Import License Application Form
D	Cover Letter for Investigational Product Notification
E	Drug Importation Report
F	Ancillary Supplies Importation Report

Appendix A

Clinical Trial and Import License Approval Process



Appendix B

Cover Letter for Import License Application

[Company Letterhead]

[Date]

[Director General]
Director General
Food and Drug Administration
Civic Drive, Filinvest City
1781 Alabang, Muntinlupa City

Attention: [CDRR Director]
Center for Drug Regulation and Research

Re: Import License Application
Investigational Product (IP) Code: _____

[Salutation],

[Body] Must include the following, if applicable:

- A brief description of the IP including its name, indication, and proposed formulation
- IP manufacturer's name and contact information
- Points of contact for the application

[Complimentary Close],

[Signature] *[Name of Responsible Person]* *[Sponsor]* *[Address]* *[Contact Number]*	*or*	[Signature] *[Name of Responsible Person]* *[Clinical Research Organization]* *[Address]* *[Contact Number]*

Appendix C

Import License Application Form

APPLICANT DETAILS		
1. Name of investigator/sponsor/CRO		
2. Address of sponsor		
3. Sponsor's contact information	Telephone No.:	
	Fax No.:	
	E-mail Address:	
4. Type of Submission	☐ Initial Import Permit Application ☐ Extension of Validity	
5. Full Title of the Trial		
INVESTIGATIONAL PRODUCT (IP) DETAILS *If the trial is performed with several products that require Import License, please complete this part and repeat for each IP and give each IP a sequential number in IP1, IP2, IP3 etc.*		
6. IP sequential number		
7. Use of IP	☐ IP being tested ☐ IP used as a comparator	
8. Product name		
9. Product code, where applicable		
10. Dosage strength		
11. Dosage form		
12. Route of administration		
13. Proposed shelf life		
14. Storage condition		
15. Type of IP	☐ Chemical origin ☐ Biological/Biotechnological origin ☐ Vaccine ☐ Others, *please specify*: _____	
16. Manufacturer	Name:	

	Address:	
17. Repacker	Name:	
	Address:	
18. Is this IP to be used in the trial a registered product in Philippines?	☐ Yes ☐ No	
19. Drug registration number, if registered		
20. Is the IP modified compared to the registered form?	☐ Yes. *Please specify*: _____ ☐ No	
DETAILS ON PLACEBO *If the trial is performed with several placebos that require Import License, please give each placebo a sequential number in P1, P2, P3, etc., and complete this part for each IP.*		
21. Is there a placebo involved in this trial?	☐ Yes ☐ No	
22. Placebo sequential number		
23. Specify the IP sequential number for this placebo		
24. Product name		
25. Dosage form		
26. Composition		
27. Manufacturer	Name:	
	Address:	
28. Repacker	Name:	
	Address:	
OTHER MEDICATIONS, where applicable		
29. Product name		
30. Active ingredient		
31. Dosage form		
32. Dosage strength		

33. Registration number (if applicable)		
34. Manufacturer	Name:	
	Address:	
35. Repacker	Name:	
	Address:	

QUANTITY TO BE IMPORTED	
Name	**Quantity**

ANCILLARY SUPPLIES	
Item	**Approximate Quantity**

APPLICANT STATEMENT

I/We hereby confirm that:

- The above information given is true, correct, and complete, and that all relevant information are provided.
- The Pharmaceutical and/or Quality Data of the Investigational Product included in this application is consistent with that submitted to the FDA in support of the related Clinical Trial application.

Name of applicant		
Signature		
Title/ position		
Organization		
Contact information	Telephone no.:	
	Mobile No.:	
	E-mail Address:	
Date of submission		

Appendix D

Cover Letter for Investigational Product Notification

[Company Letterhead]

[Date]

[Director General]
Director General
Food and Drug Administration
Civic Drive, Filinvest City
1781 Alabang, Muntinlupa City

Attention: [CDRR Director]
Center for Drug Regulation and Research

Re: Investigational Products Importation Notification
Investigational Product Code: _____
Clinical Trial Approval No: _____

[Salutation],

[Body] Must include the following, if applicable:

- IP details, name, manufacturer's name, and contact information
- Points of contact for the application

[Complimentary Close],

[Signature] *[Name of Responsible Person]* *[Sponsor]* *[Address]* *[Contact Number]*	*or*	[Signature] *[Name of Responsible Person]* *[Clinical Research Organization]* *[Address]* *[Contact Number]*

Appendix E

Drug Importation Report

CLINICAL TRIAL DETAILS		
Clinical trial reference no.		
Protocol title		
Protocol no.		
Product name		
Import License No.		
Total Approved Quantity		
Total number of subjects		
Trial Principal Investigators & Study Sites	Name of PI	Name of Site

No.	Date of Importation	Batch Number	Airway bill number/ Invoice number	Total Quantity Imported	Balance

SUBMISSION DETAILS	
Submitted by	
Position	
Signature	
Date of Submission	

Note:

1. The Sponsor/CRO is required to submit a Drug Importation Report for each product/item as listed in the approval letter for import license. For example, the total quantity to be imported may appear as illustrated below in the approval letter:

No.	Product name	Quantity
1.	Drug X 5mg Tablet/Placebo to Match Drug X 5mg Tablet	150 boxes*
2.	Drug X 10mg Tablet/ Placebo to Match Drug X 10mg Tablet	150 boxes*
3.	Drug X 25mg Tablet/ Placebo to Match Drug X 25mg Tablet	150 boxes*

*Each box contains 100 tablets

In the example abovementioned, Sponsor/CRO is required to submit three (3) Drug Importation Report for each item listed above.

2. Please attach a copy of invoice for each shipment.

Appendix F

Ancillary Supplies Importation Report

CLINICAL TRIAL DETAILS	
Clinical trial approval no.	
Protocol title	
Protocol no.	

No.	Date of Importation	Ancillary Supplies	Airway bill number/ Invoice number	Total Quantity Imported

SUBMISSION DETAILS	
Submitted by	
Position	
Signature	
Date of Submission	

**Please attach a copy of invoice/s for each shipment.*