THE INDONESIAN FOOD AND DRUG AUTHORITY
OF THE REPUBLIC OF INDONESIA

DISCLAIMER:
The Original document is written in Bahasa Indonesia, and subsequently translated into English. In the event of a discrepancy between the two versions, Bahasa Indonesia version shall take precedence.

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY NUMBER 7 OF 2019

ON

ASSESSMENT OF COMPLIANCE WITH THE REQUIREMENTS FOR PROPER MANUFACTURING METHODS FOR IMPORTED DRUG MANUFACTURING FACILITIES

BY THE GRACE OF GOD ALMIGHTY

THE INDONESIAN FOOD AND DRUG AUTHORITY,

Considering :

a. whereas in order to protect the public from the circulation of imported drugs that do not meet the quality requirements, it is necessary to evaluate pharmaceutical industry of the imported drugs in order to ensure the requirements for proper methods of drug manufacturing;

b. whereas the proper methods of drug manufacturing as referred to in letter a is a requirement that must be fulfilled in the application for registration of imported drugs;

c. whereas based on the considerations as referred to in letter a and b, it is necessary to stipulate the Regulation of the Indonesian Food and Drug Authority on the Assessment of Compliance with the Requirements for Proper Manufacturing Methods for Imported Drug Manufacturing Facilities;

Bearing in mind :

1. The Government Regulation Number 32 of 2017 on the Types and Rates of Type of Non-Tax State Revenue

Applicable to the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia Year 2017 Number 198, Supplement to the State Gazette of the Republic of Indonesia Number 6116);

2. Presidential Regulation Number 80 of 2017 on the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia Year 2017 Number 180);
3. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 24 of 2017 on the Criteria and Procedures for Drug Registration (State Gazette of the Republic of Indonesia Year 2017 Number 1692);
4. Regulation of the Indonesian Food and Drug Authority Number 26 of 2017 on the Organization and Administration of the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia Year 2017 Number 1745);
5. Regulation of the Indonesian Food and Drug Authority Number 12 of 2018 on the Organization and Work Procedure of Technical Implementing Units within the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia Year 2018 Number 784);

HAS DECIDED:

Stipulate : REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON THE ASSESSMENT OF COMPLIANCE WITH THE REQUIREMENTS FOR PROPER MANUFACTURING METHODS FOR IMPORTED DRUG MANUFACTURING FACILITIES.

CHAPTER I
GENERAL PROVISIONS

Article 1

In this Agency Regulation, the meaning of:

1. Drug is a substance or combination of substance including biological products, which are used to influence or investigate physiological systems or pathological conditions in the framework of determining diagnosis, prevention, cure, recovery and improvement of health, and contraception for humans.

2. Imported Drug is drug made by Manufacturer in the form of finished products or bulk products in primary packages to be circulated in Indonesia.
3. Registrant is a domestic pharmaceutical industry that has obtained a

pharmaceutical industry permit in accordance with the provisions of legislation applying for the Registration of Imported Drug.

4. Manufacturer is a foreign pharmaceutical industry carrying out part or all of the activities to manufacture imported drugs.
5. Manufacturing Facility is facility used in a series of activities to produce an Imported Drug, including production and quality control, starting from the procurement of starting materials and packaging materials, processing, packaging to finished Drugs for distribution.
6. Registration is a procedure for registration and evaluation of Drugs to obtain approval.
7. Pharmaceutical Industry is a business entity having a license to carry out activities for manufacturing Drugs or Drug substances in accordance with the provisions of the legislation.
8. Pre-Inspection Documents are quality documents owned by Manufacturers submitted by Registrants in the framework of Desktop Inspection or before the implementation of Inspection of Imported Medicine Manufacturing Facilities.
9. Desktop Inspection is an assessment of the implementation and fulfillment of CPOB requirements for Imported Drug Manufacturing Facilities that is carried out through the evaluation of Pre-Inspection Documents.
10. The Master Document of Pharmaceutical Industry, hereinafter abbreviated as DIIF, is a document containing specific information regarding the policy of quality management and production activities and/or quality control of the Drug manufacturing activities, Drug substances, which are carried out at that location and related activities in the surrounding buildings.
11. Corrective Action and Preventive Action, hereinafter abbreviated as CAPA, is the inspection result document submitted by the Registrant in order to follow up the result of the Inspection.
12. Proper Methods of Drug Manufacturing, hereinafter abbreviated as CPOB, is a method of making Drugs with the aim of ensuring that the quality of the produced Drugs is in accordance with the requirements and the intended use
13. Inspection is a comprehensive or partial examination of the fulfillment of CPOB requirements for the Imported Drug Manufacturing Facility.
14. Distribution Permit is a form of approval for Drug Registration to be circulated in the territory of Indonesia.
15. Days are working days.
16. The Head of Indonesian FDA is the Chairperson of the Indonesian Food and Drug Authority.

CHAPTER II

PROCEDURES FOR ASSESSING THE FULFILLMENT OF CPOB

REQUIREMENTS FOR IMPORTED DRUG MANUFACTURING FACILITIES

Part One
General

Article 2

(1) Imported Drug Manufacturing Facility must meet CPOB requirements.

(2) Fulfillment of the CPOB requirements as referred to in clause (1) for the Imported Drug Manufacturing Facility is a requirement and part of the Imported Drug Registration process that is the responsibility of the Registrant.

(3) Imported Drug Registration is carried out by Registrants who have obtained written approval from Manufacturers.

(4) Criteria and procedures for Imported Drug Registration as referred to in clause (3) shall be implemented in accordance with the provisions of legislation.

Article 3

(1) Assessment of the fulfillment of CPOB requirements for the Imported Drug Manufacturing Facility as referred to in Article 2 clause (2) must be carried out before the Imported Drug obtains the approval for the distribution permit.

(2) Assessment of the fulfillment of CPOB requirements for Imported Drug Manufacturing Facilities as referred to in clause (1) includes:

a. assessment of the documents of Imported Drug Registration related to the compliance with CPOB requirements;
b. Desktop Inspection;
c. Inspection of Imported Drug Manufacturing Facility; and/or
d. CAPA evaluation as the results of the Inspection of Imported Drug Manufacturing Facilities.

Part Two
Assessment of the Documents of Imported Drug Regstration related to the Fulfillment of CPOB Requirements

Article 4

Applications for assessing the documents of Imported Drug Registration related to the fulfillment of CPOB requirements can only be made by the Registrants who have applied for Imported Drug Registration to obtain a Distribution Permit.

Article 5

(1) Application for evaluation of the documents of Imported Drug Registration related to the fulfillment of CPOB requirements shall be submitted to the

Chairperson of the Indonesian FDA.

(2) The application as referred to in clause (1) is completed with documents in the form of:

a. proof of submission of application for the Registration of Imported Drugs at the Registration stage and

b. the documents of Imported Drug Registration related to the fulfillment of CPOB requirements from Manufacturers.

(3) The documents of Imported Drug Registration related to the fulfillment of CPOB requirements from Manufacturers as referred to in clause (2) letter b include:

a. Pharmaceutical Industry permit from the local state authority;

b. a valid CPOB certificate or other equivalent document issued by the local Drug control authority and/or Drug control authority of other countries;

c. the report on the results of the final Inspection and changes related to production facilities of the registered product within a maximum period of 2 (two) years issued by the local drug control authority and/or drug control authorities of other countries; and

d. DIIF terkini yang diterbitkan dalam 2 (dua) tahun terakhir.

(4) The documents as referred to in clause (2) that have been completed will be evaluated.

Article 6

(1) A decision on the evaluation results as referred to in Article 5 clause (4) can be in the form of a statement that:

a. Imported Drug Manufacturing Facilities meet CPOB requirements;

b. Desktop Inspection is required;

c. The inspection of Imported Drug Manufacturing Facilities is required; or

d. The Imported Drug Manufacturing Facilities do not meet CPOB requirements.

(2) The decision on the evaluation results as referred to in clause (1) shall be submitted to the Registrant within 15 (fifteen) Days after the receipt of the complete documents.

(3) The decision on the evaluation results as referred to in clause (1) shall be issued by the Chairperson of the Indonesian FDA.

Part Three

Desktop Inspection

Article 7

Application for Desktop Inspection can only be submitted by Registrants who have received evaluation results in the form of a statement that the Desktop Inspection is required to do as referred to in Article 6 clause (1) letter b.

Article 8

(1) Application for Desktop Inspection as referred to in Article 7 is submitted to the Chairperson of the Indonesian FDA.

(2) Application for Desktop Inspection as referred to in clause (1) shall be submitted no later than 80 (eighty) days after the publication of the evaluation result as referred to in Article 6 clause (1) letter b.

(3) Application for Desktop Inspection as referred to in clause (1) is completed with Pre-Inspection Documents in electronic form.

(4) The type of Pre-Inspection Documents as referred to in clause (3) is listed in Attachment I that is an integral part of this Agency Regulation.

(5) The Pre-Inspection Documents as referred to in clause (3) must use Indonesian and/or English.

(6) The Pre-Inspection Documents as referred to in clause (3) are confidential documents that are used only for evaluation and supervision purposes by authorized officers.

(7) In the event the Registrant fails to comply with the provisions as referred to in clause (2), the Imported Drug manufacturing facility will be subject to an Inspection.

(8) The application for Desktop Inspection that has been declared complete are carried out.

Article 9

(1) The decision on the results of Desktop Inspection as referred to in Article 8 clause (8) shall be in the form of a statement that:
   a. The Imported Drug Manufacturing Facilities meet CPOB requirements;
   b. The inspection of Imported Drug Manufacturing Facilities is required; or
   c. The Imported Drug Manufacturing Facilities do not meet CPOB requirements.

(2) The decision on the Desktop Inspection results as referred to in clause (1) shall be submitted to the Registrant within 20 (twenty) Days after the application for Desktop Inspection has been received completely.

(3) The decision on the Desktop Inspection results as referred to in clause (1) shall be issued by the Chairperson of the Indonesian FDA.

Part Four

Inspection of the Imported Drug Manufacturing Facilities

Article 10

Applications for the Inspection of Imported Drug Manufacturing Facilities can only be submitted by Registrant who has obtained:

a. the evaluation results in the form of a statement describing the requirement of an Inspection of Imported Drug Manufacturing Facilities as referred to in Article 6 clause (1) letter c;
b. notification that the Registrant is unable to comply with the provisions as referred to in Article 8 clause (2); or
c. the Desktop Inspection results in the form of a statement describing the requirements of an Inspection of Imported Drug Manufacturing Facilities as referred to in Article 9 clause (1) letter b.

Article 11

(1) Application for Inspection as referred to in Article 10 is submitted to the Chairperson of the Indonesian FDA.

(2) Application for Inspection as referred to in the clause is in the form of invitation letter for carrying out Inspection from Manufacturer that is submitted within the maximum period of:
   a. 80 (eighty) days after the issuance of the evaluation results in the form of a statement that the Inspection of Imported Drug Manufacturing Facilities is required as referred to in Article 6 clause (1) letter c;
   b. 30 (thirty) days after notification that the Registrant does not fulfill the provisions as referred to in Article 8 clause (2); or
   c. 10 (ten) days after the issuancce of the Desktop Inspection results in the form of a statement that the Inspection of Imported Drug Manufacturing Facilities is required as referred to in Article 9 clause (1) letter b.

(3) In the event that the application for Inspection is submitted based on the provisions as referred to in Article 10 letter a and letter b, the Registrant must complete the Pre-Inspection Document in electronic form.

(4) The type of Pre-Inspection Documents as referred to in clause (3) is listed in Attachment I that is an integral part of this Agency Regulation.

(5) In the event the Registrant fails to comply with the provisions as referred to in clause (2), the Imported Drug Manufacturing Facility is declared not fulfilling CPOB requirements.

(6) Inspection is carried out no later than 60 (sixty) Days after receiving the application for Inspection as referred to in clause (1).

Article 12

Inspection as referred to in Article 6 clause (1) letter c, Article 8 clause (7), and Article 9 clause (1) letter b can be carried out on all facilities involved in each stage of the process of making Imported Drugs.

Article 13

(1) The inspection as referred to in Article 12 is carried out by the Inspection team of the Indonesian Food and Drug Authority.

(2) There are at least 2 (two) people and a maximum of 4 (four) people of the members of the Inspection team of the Indonesian Food and Drug Authority as referred to in clause (1).

(3) The inspection as referred to in the clause is carried out within the maximum period of:

a. 3 (three) days for non-sterile products; and
b. 4 (four) days for sterile products.

(4) The Inspection Team of the Indonesian Food and Drug Authority must be accompanied by the quality assurance department of the Registrant during the inspection.

Article 14

(1) The decision on the Inspection result as referred to in Article 12 contains a statement in the form of:

a. The Imported Drug Manufacturing Facilities are declared to meet CPOB requirements;
b. Request for CAPA; or
c. The Imported Drug Manufacturing Facilities are declared not meeting CPOB requirements without CAPA request.

(2) The decision on the Inspection result as referred to in clause (1) shall be submitted to the Registrant within a maximum period of 22 (twenty two) Days from the date of the Inspection.

(3) The decision on the Inspection results as referred to in clause (1) is issued by the Chairperson of the Indonesian FDA.

Part Five

CAPA Evaluation of the Inspection Result of the Imported Drug Manufacturing Facilities

Article 15

Application for CAPA evaluation of the Inspection results of the Imported Drug Manufacturing Facilities can only be submitted by Registrant who has obtained

the decision of the Inspection result in the form of CAPA requests as referred to in Article 14 clause (1) letter b.

Article 16

(1) The Registrant must submit a request for CAPA evaluation to the Chairperson of the Indonesian FDA.

(2) Application for CAPA evaluation as referred to in clause (1) must be completed with CAPA document from the Manufacturer.

(3) Application for CAPA evaluation as referred to in clause (1) shall be submitted within a maximum period of 80 (eighty) Days after the issuance of the decision of the Inspection result in the form of CAPA request as referred to in Article 14 clause (1) letter b.

(4) CAPA documents as referred to in clause (2) must use Indonesian and/or English.

(5) CAPA documents as referred to in clause (2) must be submitted in electronic form.

(6) CAPA documents as referred to in clause (2) are listed in Attachment II that is an integral part of this Agency Regulation.

(7) Regarding the application for CAPA evaluation as referred to in clause (1), CAPA evaluation shall be carried out.

Article 17

(1) The decision on the results of CAPA evaluation as referred to in Article 16 clause (7) shall be in the form of a statement that:
   a. Imported Drug Manufacturing Facilities meet CPOB requirements;
   b. revision of CAPA documents is required; or
   c. Imported Drug Manufacturing Facilities do not meet CPOB requirements.

(2) The decision on the results of the CAPA evaluation as referred to in clause (1) shall be submitted to the Registrant within a maximum period of 30 (thirty) Days since the application for CAPA evaluation is received.

(3) The decision on the results of CAPA evaluation as referred to in clause (1) shall be issued by the Chairperson of the Indonesian FDA.

Article 18

(1) In the event that the results of CAPA evaluation are in the form of a statement as referred to in Article 17 clause (1) letter b, the Registrant must submit the revised CAPA documents from the Manufacaturer within a period of 30 (thirty) Days from the issuance of the request for revising CAPA.

(2) The Chairperson of the Indonesian FDA shall deliver notification of the evaluation results of the revision of CAPA documents as referred to in

clause (1) within a period of 30 (thirty) Days from the receipt of the revised CAPA document.

(3) Notification of the evaluation results of the revision of CAPA document as referred to in paragraph (2) in the form of a statement that:

a. Imported Drug Manufacturing Facilities meet CPOB requirements;

b. revision of the CAPA document is required; or

c. Imported Drug Manufacturing Facilities do not meet CPOB requirements.

Article 19

The Imported Drug Manufacturing Facilities are declared not meeting CPOB requirements if:

a. Manufacturers cannot fulfill the provisions as referred to in Article 16 clause (3) or Article 18 clause (1); or

b. Manufacturers have submitted 2 (two) revisions to CAPA document and have not met the CPOB requirements.

Part Six

Reassessment of Compliance with CPOB Requirements during Circulation

Article 20

(1) In the event that the decision in the form of a statement that the Imported Drug Manufacturing Facilities are declared to meet the CPOB requirements as referred to in Article 6 clause (1) letter a, Article 9 clause (1) letter a, Article 14 clause (1) letter a, Article 17 clause (1) letter a, and Article 18 clause (3) letter a, Imported Drug Producers in circulation may be re-evaluated through the Inspection of Imported Drug Manufacturing Facilities.

(2) The re-evaluation as referred to in clause (1) is based on the following considerations:

a. surveillance based on risk assessment; and/or

b. there are allegations of cases of quality, safety and efficacy of Imported Drugs.

(3) The Inspection of Imported Drug Manufacturing Facilities as referred to in clause (1) is carried out in accordance with the provisions as referred to in Article 10 to Article 19.

(4) In the event that the Inspection results of Imported Drug Manufacturing Facilities during circulation as referred to in clause (1), are in the form of CAPA requests for critical findings, the Registrant must submit CAPA documents from the Manufacturer to the Chairperson of the Indonesian FDA within a maximum period of 22 (twenty two) Days since the issuance of the decision of Inspection results.

Part Seven

Responsibilities of the Registrant

Article 21

(1) The Registrant is responsible for the completeness, correctness, and validity of documents submitted at the time of submitting an application for assessing the fulfillment of CPOB requirements, Desktop Inspection, Inspection of Imported Drug Manufacturing Facilities, and CAPA evaluation as the Inspection result.

(2) Tanggung jawab Pendaftar sebagaimana dimaksud pada ayat (1) harus dinyatakan secara tertulis dalam surat pernyataan sesuai dengan format tercantum dalam Lampiran III yang merupakan bagian tidak terpisahkan dari Peraturan Badan ini. The responsibility of the Registrant as referred to in clause (1) must be stated in writing in the statement letter according to the format contained in Attachment III that is an integral part of this Agency Regulation.

CHAPTER III

EXPENSES

Article 22

(1) The application for Desktop Inspection as referred to in Article 7, application for Inspection of Imported Drug Manufacturing Facilities as referred to in Article 10 and application for CAPA evaluation as referred to in Article 15 are subject to fees that constitute non-tax state revenue in accordance with the provisions of legislation.

(2) Application fee for Inspection of Imported Drug Manufacturing Facility as intended in paragraph (1) does not include transportation and accommodation costs for the implementation of the Inspection.dan akomodasi pelaksanaan Inspeksi. Application fee for Inspection of Imported Drug Manufacturing Facilities as referred to in clause (1) does not include transportation and accommodation costs for the implementation of the Inspection.

(3) The transportation and accommodation costs as referred to in clause (2) shall be borne by the Registrant in accordance with the provisions of legislation.

(4) The components and amount of payment for transportation and accommodation costs as referred to in clause (2) are listed in Attachment IV that is an integral part of this Agency Regulation.

(5) Transportation and accommodation costs are paid directly by the Registrant to the transportation and accommodation service providers.

(6) Registrants are prohibited from providing transportation and

accommodation costs to the Inspection team of the Indonesian Food and Drug Authority as referred to in Article 13 clause (1).

Article 23

All costs paid by the Registrant for the purpose of carrying out the Inspection of the Imported Drug Manufacturing Facilities cannot be withdrawn.

Article 24

(1) The Registrant is required to submit reports on transportation and accommodation costs that he/she has paid as referred to in Article 22 clause (5).

(2) The report as referred to in clause (1) shall contain at least:
   a. identity of the Inspection Team of the Indonesian Food and Drug Authority;
   b. the time of Inspection;
   c. Registrant's identity;
   d. financing background; and
   e. type and amount of cost.

(3) The report as referred to in clause (2) shall be submitted to the Chairperson of the Indonesian FDA within 5 (five) Days after carrying out the Inspection.

(4) If the Registrant does not submit the report as referred to in clause (3), the issuance of the decision on the Inspection result as referred to in Article 14 clause (2) shall be postponed until the Registrant fulfills the obligation on the report as referred to in paragraph (1).

CHAPTER V

CLOSING PROVISIONS

Article 25

This Agency Regulation comes into force on the date of promulgation.

For public cognizance, this Agency Regulation shall be promulgated by placing it in the State Gazette of the Republic of Indonesia.

Stipulated in Jakarta
on 24 April 2019

THE CHAIRPERSON OF INDONESIAN FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

Promulgated in Jakarta

on 30 April 2019

DIRECTOR GENERAL
LEGISLATION
THE MINISTRY OF LAW AND HUMAN RIGHTS
THE REPUBLIC OF INDONESIA,

signed

WIDODO EKATJAHJANA

STATE GAZETTE OF THE REPUBLIC OF INDONESIA YEAR 2019 NUMBER 478

ATTACHMENT I
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY NUMBER 7 OF 2019
ON
ASSESSMENT OF COMPLIANCE WITH THE REQUIREMENTS FOR PROPER MANUFACTURING METHODS FOR IMPORTED DRUG MANUFACTURING FACILITIES

PRE-INSPECTION DOCUMENTS

The submitted Pre-Inspection Documents are the most recent documents, which include, among others, the following documents:

No	Type of Document	Bentuk Sediaan		
		Non-sterile Product	Sterile Product with Final Sterilization	Sterile Product with Aseptic Sterilization
1	Quality Assessment of Products registered for the last 2 years	□	□	□
2	Validation Master Plan and last year's RIV realization	□	□	□
3	Protocol and Summary Report of Media Filling Validation for the last 1 year	-	-	□
4	Trend Analysis in Environmental Monitoring and Water Testing Results for the last 1 year	□	□	□
5	Release Procedures of Final Product	□	□	□
6	History of recall, sanctions and quality defects of the last 3 years	□	□	□

THE CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

ttd.

PENNY K. LUKITO

ATTACHMENT II
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 7 OF 2019
ON
ASSESSMENT OF COMPLIANCE WITH THE REQUIREMENTS FOR PROPER MANUFACTURING METHODS FOR IMPORTED DRUG MANUFACTURING FACILITIES

CAPA DOCUMENT

Name of Pharmaceutical Industry :.....
Address :.....
Scope of Inspection :.....
Inspection Date :.....

No.	Finding[1]	Requirement[2]	Current Condition[3]	Gap Analysis 4	Analysis of Root of Problem	CAPA[6]	Completion Time – Status[7]	Person in charge[8]	Proof of Improvement[9]

Information:

1. Filled in with findings in accordance with the Inspection Report.
2. Filled in with CPOB requirements and other requirements including internal requirements, for example the company's quality policy, regular procedures.

3. Filled in with a description of the availability of procedures/documents (core documents and supporting documents).
4. Filled in with shortcomings compared to the current terms and conditions.
5. Filled in with causes of the existing shortcomings in the column of Gap Analysis.
6. CAPA needs to describe in detail regarding corrective actions (CA) and preventive actions (PA). If there are no precautions, explain the justification.
7. If it is in process, the time limit for completion is filled with a rational time limit and it is filled in for each step. The status is filled with completed or in process.
8. Filled in with the person in charge for the implementation of CAPA.
9. Filled in with the document number that is the proof of improvement, including the document related to the change control, if the improvement needs the change control. The proof of improvement must be attached.

THE CHAIRPERSON OF THE INDONESIAN FOOD
AND DRUG AUTHORITY,

ttd.

PENNY K. LUKITO

ATTACHMENT III
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY NUMBER 7 OF 2019
ON
ASSESSMENT OF COMPLIANCE WITH THE REQUIREMENTS FOR PROPER MANUFACTURING METHODS FOR IMPORTED DRUG MANUFACTURING FACILITIES

STATEMENT LETTER OF THE REGISTRANT

I, the undersigned below:

Name : .....
Position : Person in Charge of Quality Assurance
Phone Number : .....
E-mail Address : .....

states that all information in the documents of Imported Drug Registration related to Fulfillment of CPOB Requirements/Pre-Inspection Documents/CAPA documents* in the context of Imported Drug Registration are as follows:

Name of Drug : .....
Active Substance : .....
Form of the Dosage : .....
Type and Size of Packaging : .....
Registrant : .....
Manufacturer : .....
Manufacturer's Address : .....

is complete and true. I certify that I have checked and I am responsible for:

1. The completeness of the submitted documents
2. The correctness of all information stated in the document
3. The correctness and validity of the attached documents

* cross out the unnecessary options

If the provided statement is not in accordance with the fact, we are willing to cancel the process of Imported Drug Registration.

....., date .....

Person in Charge of Quality Assurance

Stamp duty

signed

(Clear name)

THE CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

ttd.

PENNY K. LUKITO

ATTACHMENT II
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY NUMBER 7 OF 2019
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ASSESSMENT OF COMPLIANCE WITH THE REQUIREMENTS FOR PROPER MANUFACTURING METHODS FOR IMPORTED DRUG MANUFACTURING FACILITIES

COMPONENTS AND AMOUNT OF TRANSPORTATION AND ACCOMMODATION COSTS IN THE CONTEXT OF INSPECTION OF IMPORTED DRUG MANUFACTURING FACILITIES

1. Transportation

   The components of transportation include:

   a. The cost of round-trip airfare, travel insurance, taxi from the domicile to the airport (round-trip), and taxi from the airport to the destination (round-trip) refers to the Input Cost Standard for the current year stipulated by the Minister of Finance;
   b. The flight used has the closest distance without transit and preferably uses state-owned airlines unless there is no other flight option;
   c. The flight class is economy class and/or adjusted to the Input Cost Standard for the current year.

2. Accommodation

   The total amount of accommodation costs refers to the amount of daily costs for foreign official travel as stated in the Input Cost Standard for the current year stipulated by the Minister of Finance.

   The components of accomodation include:

   a. Meals
   b. Local transportation
   c. Hotel accomodation
      1) 4 (four) stars hotel shall be provided.
      2) The location of the hotel is relatively close to the Manufacturer's location.

3) The Registrant shall submite the estimated travel time from the hotel to the Manufacturer's location.

THE CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO