REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 27 OF 2022
ON
IMPORTATION CONTROL OF FOOD AND DRUGS
INTO THE TERRITORY OF INDONESIA

BY THE BLESSINGS OF ALMIGHTY GOD

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

Considering : a. that the public is needed to be protected from the importation of food and drugs which do not meet the requirements of safety, efficacy/benefit and quality into the territory of Indonesia;

b. that based on the provisions of Article 3 section (1) point d of Presidential Regulation Number 80 of 2017 on Indonesian Food and Drug Authority, the Indonesian Food and Drug Authority has a controlling function prior to the circulation and during circulation;

c. that the administration of importation control of food and drugs as regulated in Regulation of the Indonesian Food and Drug Authority Number 30 of 2017 on Importation Control of Food and Drugs into the Territory of Indonesia as amended by Regulation of the Indonesian Food and Drug Authority Number 15 of 2020 on Amendment to Regulation of the Indonesian Food and Drug Authority Number 30 of 2017 on Importation Control of Food and Drugs into the Territory of Indonesia is no longer in line with the legal requirements, so it is necessary to be replaced;

d. that based on the consideration as referred to in point a, point b, and point c, it is necessary to issue Regulation of the Indonesian Food and Drug Authority on Importation Control of Food and Drugs into the Territory of Indonesia;

Observing : 1. Law Number 10 of 1995 on Customs (State Gazette of the Republic of Indonesia of 1995 Number 75, Supplement to the State Gazette of the Republic of Indonesia Number 3612) as amended by Law Number 17 of 2006 on Amendment to Law Number 10 of 1995 on Customs (State Gazette of the Republic of Indonesia of 2006 Number 93, Supplement to the State Gazette of the Republic of Indonesia Number 4661);

2. Presidential Regulation Number 80 of 2017 on Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia of 2017 Number 180);

3. Regulation of the Indonesian Food and Drug Authority Number 21 of 2020 on Organization and Work Procedures of Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2020 Number 1002) as amended by Regulation of the Indonesian Food and Drug Authority Number 13 of 2022 on Amendment to Regulation of the Indonesian Food and Drug Authority Number 21 of 2020 on Organization and Work Procedures of Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2022 Number 629);
4. Regulation of the Indonesian Food and Drug Authority Number 22 of 2020 on Organization and Work Procedures of Technical Implementation Units within Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2020 Number 1003) as amended several times and last by Regulation of the Indonesian Food and Drug Authority Number 24 of 2022 on Second Amendment to Regulation of the Indonesian Food and Drug Authority Number 22 of 2020 on Organization and Work Procedures of Technical Implementation Units within Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2022 Number 1111);
5. Regulation of the Indonesian Food and Drug Authority Number 23 of 2020 on Organization and Work Procedures of Technical Implementation Units within National Food and Drug Testing Development Center of Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2021 Number 1004);
6. Regulation of the Indonesian Food and Drug Authority Number 10 of 2021 on Standards for Business Activities and Products on Implementation of Risk-Based Business Licensing for Food and Drug Sector (State Bulletin of the Republic of Indonesia of 2021 Number 292);

HAS DECIDED:

To issue : REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON IMPORTATION CONTROL OF FOOD AND DRUGS INTO THE TERRITORY OF INDONESIA.

CHAPTER I
GENERAL PROVISIONS

Article 1

In this Authority Regulation:

1. Food and Drugs mean Drugs, Traditional Medicines, Quasi Medicines, Cosmetics, Health Supplements, and Processed Food.
2. Importation of Food and Drugs means importation of Food and Drugs into the territory of Indonesia.
3. Border Import Certificate (*Surat Keterangan Impor* Border), hereinafter referred to as SKI Border, means an approval of letter of importation of goods into the territory of Indonesia which is fulfilled before the goods are

released from the customs area in the framework of controlling the circulation of Food and Drugs.

4. Post Border Import Certificate (*Surat Keterangan Impor* Post Border), hereinafter referred to as SKI Post Border, means an approval letter of importation of goods into the territory of Indonesia which is fulfilled before or after the goods are released from the customs area in the framework of controlling the circulation of Food and Drugs.
5. Marketing Authorization means a registration approval for Traditional Medicines, Quasi Medicines, Health Supplements, and Processed Food or an approval in the form of notice that the Cosmetics has been notified, commitment compliance of processed food and an approval of processed food to be circulated in the territory of Indonesia.
6. Emergency Use Authorization, hereinafter abbreviated as EUA, means an approval for Drug use during the public health emergency for Drugs that have not obtained the Marketing Authorization or Drugs that have obtained a Marketing Authorization with different indications for use/new indications.
7. SKI Border Applicant means the Marketing Authorization holder, or a government institution and an importer authorized by the Marketing Authorization holder, to apply for the importation of Drugs and Traditional Medicines into the territory of Indonesia.
8. SKI Post Border Applicant means the company holding the Marketing Authorization or an importer authorized by the company holding the Marketing Authorization, to apply for the importation of Quasi Medicines, Health Supplements, Cosmetics, and Processed Food into the territory of Indonesia.
9. Drug means a finished medicine including Biological Products, which is an ingredient or combination of ingredients used to influence or investigate the physiological system or state of pathology in order to establish diagnosis, prevention, healing, recovery, and improvement of health, and contraception for humans.
10. Biological Product means a product containing biological materials derived from a human, animal, or microorganism prepared in a conventional way, including extraction, fractionation, reproduction, cultivation, or through biotechnology methods, among others fermentation genetic engineering, cloning, including but not limited to enzymes, monoclonal antibodies, hormones, stem cells, gene therapy, vaccines, blood products, DNA recombinant products, and immunosuppressants.
11. Traditional Medicine means materials or ingredients in the form of vegetable materials, animal materials, mineral materials, dosage from extracts (galenic), or a mixture of those materials which have been used hereditarily for medication purposes, and which can be administered in accordance with norms prevailing in society.

12. Quasi Medicine means dosage with active ingredients with pharmacological effect that has non-systemic or local characteristics for minor complaints.
13. Health Supplement means a product designed to supplement nutrient intake, to maintain, to increase, and/or to improve health functions, to have nutritional value and/or a physiological effect, to contain one or more materials in the form of vitamins, minerals, amino acids and/or other non-plant materials combinable with plants.
14. Cosmetic means a material or dosage form designed for topical use on the human body, e.g., epidermis, hair, nails, lips, and external genital organs, or teeth and the oral mucosa mainly to clean, to perfume, to alter the appearance, and/or to improve body odor or to protect or to maintain the body in good condition.
15. Processed Food means food or beverage that is processed in a certain way or method with or without food additives.
16. Bulk Product means an ingredient having been processed and only requiring packaging to become finished products.
17. Business Identification Number (*Nomor Induk Berusaha*), hereinafter abbreviated as NIB, means the identity of a business actor issued by the Online Single Submission Institution after the business actor submits a registration.
18. Aju Number means a number given by the system for every application of SKI Border or SKI Post Border.
19. Expiration means information on the ending of period of time of Food and Drugs are edible for consumption in the form of date, month, and year, or month and year.
20. Indonesia National Single Window System (*Sistem* Indonesia National Single Window), hereinafter abbreviated as SINSW, means an electronic system that integrates systems and/or information relating to the process of handling customs documents, quarantine, licensing documents, port/airport documents, and other documents, related to exports, imports, national logistics documents, and/or the transportation of certain goods, which ensures data and information security and integrates the flow and process of information between internal systems automatically.
21. Technical Implementation Unit (*Unit Pelaksana Teknis*) within the Indonesian Food and Drug Authority, hereinafter abbreviated as UPT of the Indonesian FDA, means an independent work unit that carries out certain operational technical duties and/or certain supporting technical duties in the field of Food and Drug control.
22. Chairperson of the Authority means the Chairperson of the Indonesian Food and Drug Authority.
23. Deputy means the Deputy within the Indonesian Food and Drug Authority.
24. Day means a calendar day.
25. Hour means a work hour.

Article 2

(1) Food and Drugs that are imported into the territory of Indonesia for distribution are required to obtain a Marketing Authorization.
(2) In addition to being required to obtain a Marketing Authorization as referred to in section (1), Food and Drugs that are imported into the territory of Indonesia must also comply with the provisions of legislation.

Article 3

(1) In addition to fulfilling the provisions as referred to in Article 2, the Importation of Food and Drugs is also required to obtain an approval from Chairperson of the Authority.
(2) The approval from Chairperson of the Authority as referred to in section (1) is in the form of:
    a. SKI Border, for the importation of Drugs and Traditional Medicines into the territory of Indonesia; or
    b. SKI Post Border, for the importation of Quasi Medicines, Health Supplements, Cosmetics, and Processed Food into the territory of Indonesia.
(3) The SKI Border or the SKI Post Border as referred to in section (2) is only valid for 1 (one)-time importation.
(4) Drugs and/or Traditional Medicines that are imported into the territory of Indonesia must obtain the SKI Border when applying for the import notification issued by the authorized institution.
(5) Quasi Medicines, Health Supplements, Cosmetics, and/or Processed Food that are imported into the territory of Indonesia are required to obtain an SKI Post Border not later than 7 (seven) Days as of the issuance date of goods release letter issued by the authorized institution.
(6) The SKI Border Applicant can apply for the SKI Post Border before getting a registration number and date of import notification of goods.
(7) Exempted from the provisions as referred to in section (1), the importation of Drugs in the form of narcotics, psychotropics or pharmaceutical precursors must meet the following requirements:
    a. control analysis; and
    b. import authorization,
    in accordance with the provisions of legislation.
(8) The SKI Border or the SKI Post Border as referred to in section (2) uses a format of import certificate as set out in Annex I as an integral part of this Authority Regulation.

Article 4

(1) To obtain the SKI Border or the SKI Post Border as referred to in Article 3 section (2), Food and Drugs imported into the territory of Indonesia at the time of submitting the application for SKI Border or SKI Post Border must have the shelf life of at least:

a. 9 (nine) months before the Expiration, for Drugs in the form of Biological Products;
b. 2/3 (two thirds) of the shelf life, for Drugs other than Biological Products, Traditional Medicines, Quasi Medicines, Health Supplements, and/or Processed Food;
c. 1/3 (one third) of the shelf life for Cosmetics; or
d. 2 (two) years before the Expiration, for Drugs intended for donation purposes.

(2) Exempted from the provisions as referred to in section (1), are Food and Drugs in the form of:
a. Drugs that have EUA in accordance with the provisions of legislation; and
b. Processed Food that has no Expiration in accordance with the provisions of legislation.

(3) Exempted from the provisions as referred to in section (1) point d, for donation Drugs with Expiration period of 2 (two) years must have the remaining shelf life of at least 2/3 (two thirds) of the expiration period.

Article 5

The SKI Border or the SKI Post Border as referred to in Article 3 section (2) also applies for the Importation of Food and Drugs into the free trade zones and free ports, special economic zones and bonded storage.

Article 6

(1) The importation of Food and Drugs can only be conducted by the Marketing Authorization holder or its proxy.

(2) The Marketing Authorization holder can give an authorization to other pharmaceutical industries, pharmaceutical wholesaler importers, or government institutions as executors of Drug import.

(3) The government institutions as referred to in section (2) can conduct the importation of Drugs on the recommendation of the minister administering government affairs in the field of health.

(4) In the event that the importation is conducted by the proxy as referred to in section (1), then:
a. the proxy must have a license in accordance with the provisions of legislation;
b. the product importation and distribution are the responsibility of the Marketing Authorization holder;
c. the power of attorney must clearly include the address and the status of the warehouse where the product is stored; and
d. the drug quality approval prior to the circulation is still conducted by the Marketing Authorization holder.

(5) In the event of the drug quality release prior to the circulation as referred to in section (4) point d, the Drug storage prior to release must be conducted at the warehouse location of the Marketing Authorization holder in accordance with the provisions of legislation.

Article 7

(1) The list of Food and Drugs of which importation is limited into the territory of Indonesia is issued by Chairperson of the Authority.
(2) In the event that the HS Code listed in the SKI Border or the SKI Border as referred to in Article 3 section (2) is different from the HS Code stipulated by the authorized institution in customs, the eligible HS Code is the one stipulated by the authorized institution in accordance with the provisions of legislation.

CHAPTER II
APPLICATION PROCEDURES

Part One
Applicant Registration of SKI Border or SKI Post Border

Article 8

(1) The SKI Border Applicant or the SKI Post Border Applicant must obtain an NIB through Online Single Submission in order to receive the SKI Border or the SKI Post Border service.
(2) The SKI Border submitted by the government institution is exempted from the provisions as referred to in section (1).
(3) The SKI Border Applicant or the SKI Post Border Applicant as referred to in section (1) must submit a registration in order to get a user name and a password with single sign on mechanism on the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or through SINSW.
(4) The registration through single sign on mechanism as referred to in section (3) is carried out in order to obtain the login access at in-house Indonesian Food and Drug Authority, including UPT of the Indonesian FDA and SINSW.
(5) In the event that the application is submitted by the proxy, then the proxy must obtain the power of attorney certified by a notary.

Article 9

(1) The SKI Border Applicant or the SKI Post Border Applicant submits a registration through data entry electronically and uploads the supporting documents to the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW.
(2) The supporting documents as referred to in section (1) consist of the scanning of:
    a. original application letter signed by the director or the proxy of board of director;
    b. duly stamped, original statement letter of the responsible person;
    c. original import power of attorney in the form of a general deed by a notary if the SKI Border Applicant

or the SKI Post Border Applicant is the recipient of the power of attorney in importation;

d. list of HS Code of commodities which will be imported;
e. original of Resident Identity Card (KTP) of the Responsible person; and
f. front view and back view photos of the warehouse and office.

(3) In the event that there are differences in determining HS Code between the SKI Border Applicant or the SKI Post Border Applicant and the Indonesian Food and Drug Authority for the commodity to be imported, then the Indonesian Food and Drug Authority may request the SKI Border Applicant or the SKI Post Border Applicant to attach a Pre-Import Classification Settlement (*Penetapan Klasifikasi Sebelum Impor*, PKSI) from the authorized institution in the field of customs in accordance with the provisions of legislation.

(4) In addition to fulfilling the requirements as referred to in section (2), the SKI Border Applicant or the SKI Post Border Applicant must clearly state the address of the warehouse where the Food and Drugs are stored;

(5) In the event of warehouses as referred to in section (4) are more than 1 (one), the SKI Border Applicant or the SKI Post Border Applicant must include all addresses of warehouses where Food and Drugs are stored, including the temporary/rental/contract warehouses.

(6) In addition to fulfilling the requirements as referred to in section (2), SKI Border applications in the form of Drugs, must also be completed with the scanning of original documents of:

a. pharmaceutical industry business license or pharmaceutical wholesaler business license in accordance with the provisions of legislation; and
b. certificate of Good Distribution Practice (*Cara Distribusi Obat yang Baik*, CDOB) for pharmaceutical wholesalers.

(7) The SKI Border proposed by government institutions is exempted from the provisions as referred to in section (2) point f and section (4).

Article 10

(1) In addition to meeting the requirements as referred to in Article 9 section (2), the application for the SKI Post Border for Processed Food must also be completed with the scanning of original document of Processed Food Safety Management System Certificate at the circulation facility.

(2) In the event of an emergency condition in the form of scarcity and/or shortage of Drugs and/or Traditional Medicines, exempted from the provisions as referred to in Article 8 section (5) and Article 9 section (2) point c, the power of attorney for the SKI Border Applicant in the form of government institutions can be in the form of an appointment letter of import executor from the Marketing Authorization Holder.

(3) The registration application as referred to in Article 9 section (1) to section (6) is verified electronically or if necessary, the verification can be carried out non-electronically.

(4) In the event that the verification results are declared complete and correct, the SKI Border Applicant or the Post Border Applicant receives the registration approval in the form of a user name and password in order to log into the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW.

Article 11

(1) The registration of the SKI Border Applicant or the SKI Post Border Applicant as referred to in Article 8 can only be conducted 1 (one) time.

(2) The SKI Border Applicant or the SKI Post Border Applicant may change the registration data that has been approved..

(3) In the event of data changes as referred to in section (2), the SKI Border Applicant or the SKI Post Order Applicant is required to change the data through the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW by attaching the supporting data related to the data being changed.

(4) To the data changes as referred to in section (3), verification is carried out by the Indonesian Food and Drug Authority.

(5) Based on the verification results as referred to in section (4), the Indonesian Food and Drug Authority gives an approval or rejection to the data changes submitted by the SKI Border Applicant or the SKI Post Border Applicant.

(6) Based on the verification results as referred to in section (4), the Indonesian Food and Drug Authority gives an approval or rejection to the data changes submitted by the SKI Border Applicant or the SKI Post Border Applicant not later than 2 (two) work days since the SKI Border Applicant or the SKI Post Border Applicant submits the data changes.

(7) The issuance of the approval or rejection of data changes as referred to in section (5) is conducted with time to respond mechanism.

(8) The time to respond mechanism as referred to in section (6) is conducted in accordance with the following provisions:

a. the calculation of the evaluation period in order to give an approval or rejection as referred to in section (5) is stopped if additional data is required based on the evaluation results; and

b. the calculation of the evaluation period in order to give an approval or rejection as referred to in section (5) restarts from the beginning after the SKI Border Applicant or the SKI Post Border Applicant submits additional data.

Article 12

(1) In the event that the SKI Border Applicant or the SKI Post Border Applicant fails to log into the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW, the 'forget password' facility can be applied.
(2) In the event that the SKI Border Applicant or the SKI Post Border Applicant fails to use the 'forget password' facility, the SKI Border Applicant or SKI Post Border Applicant may submit application letter of identity updates to the Indonesian Food and Drug Authority manually with the following requirements:
    a. the SKI Border Applicant or the SKI Post Border Applicant shows the original power of attorney from the company director;
    b. the original of application letter uses the company letterhead, is duly stamped, and signed by the company director;
    c. the copy of NIB and shows the original document; and
    d. the copy of company director's Resident Identity Card.
(3) The approval of changes will be issued not later than 2 (two) work days as of the receipt of the application letter as referred to in section (2) is declared complete and correct.

Article 13

The registration procedures of the SKI Border Applicant or the SKI Post Border Applicant and data changes of the SKI Border Applicant or the SKI Post Border Applicant are included in the usage instructions online on the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW.

Article 14

The application for import certificates is carried out in accordance with the provisions of Regulation of the Indonesian Food and Drug Authority which regulates electronically integrated business licensing services in Food and Drugs sector.

Part Two

Application Submission of SKI Border or SKI Post Border

Article 15

The application of SKI Border or SKI Post Border is carried out online.

Article 16

(1) The application of SKI Border or SKI Post Border as referred to in Article 15 must be completed with the following electronic documents of:
    a. a Marketing Authorization approval;
    b. a certificate of analysis or a Certificate of Indonesian National Standard Marking on Product/SNI Marking

on Product (*Sertifikat Produk Penggunaan Tanda Standar Nasional Indonesia* - SPPT SNI) for Compulsory SNI Food (*Pangan Standar Nasional* Indonesia) ; and

c. invoice.

(2) In the event that the validity period of the Marketing Authorization is less than 3 (three) months, the SKI Border or the SKI Post Border applications must also be supported by the re-registration receipt.

(3) The importation of Food and Drugs in the form of Bulk Products must attach the Marketing Authorization approval of Food and Drugs in accordance with the provisions of legislation.

(4) The certificate of analysis as referred to in section (1) point b is issued by the manufacturer.

(5) In the event that certificate of analysis is not issued by the manufacturer, then the certificate of analysis as referred to in section (1) point b for the importation of Traditional Medicines, Quasi Medicines, Health Supplements, Cosmetics, and Processed Food can only be issued by an accredited laboratory.

(6) Further provisions regarding the testing by an accredited laboratory as referred to in section (5) for the importation of Traditional Medicines, Quasi Medicines, Health Supplements, and Cosmetics use testing parameters according to the technical instructions issued by Chairperson of the Authority.

Article 17

(1) Exempted from the provisions as referred to in Article 16 section (5), in the event that the certificate of analysis for Drug importation is not issued by the manufacturer, then the certificate of analysis as referred to in Article 16 section (1) point b can only be issued by other pharmaceutical industries or laboratories that carry out testing for and on behalf of the manufacturer.

(2) The certificate of analysis as referred to in Article 16 section (1) point b must at least contain the following information:

a. name and address of the manufacturer;
b. name of products;
c. testing parameter based on the provisions;
d. test results;
e. analysis method;
f. batch number/lot number/production code;
g. production date; and
h. expiration date.

(3) The Indonesian Food and Drug Authority may carry out sampling and testing at an accredited laboratory in order to ensure the validity and legality of the certificate of analysis as referred to in section (2).

(4) The financing for the testing as referred to in section (3) is borne by the SKI Border Applicant or the SKI Post Border Applicant.

(5) In the event that it is necessary to ensure compliance with the safety, quality and data integrity aspects, the Indonesian Food and Drug Authority may request the SKI Border Applicant or the SKI Post Border Applicant to attach supporting documents other than those as referred to in Article 16 and as referred to in section (1) and section (2) in accordance with the provisions of legislation.

Part Three
Application Submission of Vaccine and Sera

Article 18

(1) In addition to fulfilling the provisions as referred to in Article 16 and Article 17, the SKI application in the form of vaccine must also be completed with the following documents:
   a. Vaccine batch/lot release certificate from the authorized agency in the country of origin where the vaccine is released for every importation; and
   b. summary batch/lot protocol issued by the manufacturer.

(2) In the event that the requirements as referred to in section (1) point a cannot be fulfilled, the SKI Border approval can still be given as long as it meets the condition of batch/lot release in accordance with the provisions of legislation.

(3) In addition to fulfilling the provisions as referred to in Article 16 and Article 17, the SKI application in the form of sera must also be completed with certificate of analysis stating the source of active substances.

Article 19

(1) The vaccine that has obtained the SKI Border can only be circulated after the sampling, testing, and evaluation by the Indonesian Food and Drug Authority.

(2) The sampling, testing, and evaluation as referred to in section (1) are conducted in order to obtain a vaccine batch/lot release certificate from the Indonesian Food and Drug Authority.

(3) All fees of the sampling, testing, and evaluation are the responsibility of the SKI Border Applicant.

Article 20

The provisions as referred to in Article 18 section (1) can be exempted for SKI Border application in the form of vaccine that has EUA and has met the following requirements:

a. has been used in the management of public health emergency in Indonesia; and

b. has obtained an emergency use approval from World Health Organization for the management of public health emergency and/or an emergency use approval from the country with an outstanding evaluation system/a reference country in accordance with the provisions of legislation.

Article 21

(1) The vaccine that has obtained a vaccine batch/lot release certificate from the authorized agency in the country of origin where the vaccine is released receives the following activities:
   a. an evaluation against the summary batch/lot protocol, certificate of analysis and label; and
   b. an appearance test.
(2) The evaluation and testing results as referred to in section (1) are in the form of a release certificate.

Article 22

(1) The vaccine that has not obtained a vaccine batch/lot release certificate from the authorized agency in the country of origin where the vaccine is released, receives the following activities:
   a. an evaluation against the summary batch/lot protocol, certificate of analysis, and label;
   b. a descriptive testing; and
   c. a potential testing and/or another testing that has been determined.
(2) The evaluation and testing results as referred to in section (1) are in the form of a certificate of release and a testing certificate.

Article 23

Further provisions regarding the vaccine batch/lot release certificate as referred to in Article 18 to Article 22 are conducted in accordance with the provisions of legislation.

Article 24

Exempted from the provisions as referred to in Article 19, Article 21, Article 22, and Article 23, the issuance of a certificate of release for vaccine that has EUA is conducted in accordance with the provisions of legislation.

Part Four

Application Submission of Traditional Medicines, Quasi Medicines, Cosmetics and Health Supplements

Article 25

In addition to fulfilling the provisions as referred to in Article 15, Article 16, and Article 17, the application submission for the SKI Border for Traditional Medicines or the SKI Post Border for Quasi Medicines, Health Supplements, and Cosmetics must also be completed with the following documents:

a. product name, packaging, and packaging size listed on the invoice must match the product name, packaging, and packaging size listed on the Marketing Authorization;
b. in the event that the product name as referred to in point a does not match the name listed in the Marketing Authorization, the application must be supported with the reference letter from the manufacturer; and/or

c. other required certificates/reference letters in accordance with the provisions of legislation.

Part Five
Application Submission of Processed Food

Article 26

In the importation of Processed Food, in addition to fulfilling the provisions as referred to in Article 15, Article 16, and Article 17, the Applicant must also upload:

a. approved label at the time of application;
b. certificate from the manufacturer of the country of origin, if the exporter is different from the manufacturer;
c. an agreement document authorized by a notary, if the importation is conducted by a different importer from the importer holding the registration approval;
d. for Processed Food name in the import document that is not the same as the one stated in the Marketing Authorization, the application needs to be completed with a reference letter from the manufacturer; and/or
e. other required certificates/reference letters in accordance with the provisions of legislation.

Part Six
Responsibilities of Applicant

Article 27

(1) The SKI Border Applicant or the SKI Post Border Applicant is obligated to complete the application documents correctly and legally which are uploaded on the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW.
(2) The SKI Border Applicant or the SKI Post Border Applicant is obligated to ensure that the Food and Drugs imported into the territory of Indonesia are in accordance with the approval of the SKI Border or the SKI Post Border.
(3) The SKI Border Applicant or the SKI Post Border Applicant is prohibited from importing the Food and Drugs other than those stated in the approval of the SKI Border or the SKI Post Border.
(4) The SKI Border Applicant or the SKI Post Border Applicant is prohibited from circulating, transferring, and/or using Food and Drugs prior to the issuance of the SKI Border or the SKI Post Border.

CHAPTER III
IMPORTATION APPROVAL

Article 28

(1) Within a maximum period of 6 (six) Hours after the documents are received in full according to the requirements and after the payment of non-tax state revenue, the application documents as referred to in

Article 16 to Article 26 are evaluated to determine fulfillment of the administrative requirements and requirements for safety, efficacy/benefit, and quality to issue an approval or rejection.

(2) The Indonesian Food and Drug Authority conducts an evaluation using a clock-on and clock-off mechanism for the fulfillment of the requirements as referred to in section (1).

(3) In the event that the evaluation result is in the form of revision to the fulfillment of the requirements as referred to in section (1), then the calculation of the period as referred to in section (1) is clocked off until the SKI Border Applicant or the SKI Post Border Applicant submits additional data.

(4) The SKI Border Applicant or the SKI Post Border Applicant submits additional data for a maximum of 3 (three) times within a time limit of not later than 30 (thirty) Days from the date of the Aju Number is issued.

(5) The calculation of the evaluation period will be clocked on after the SKI Border Applicant or the SKI Post Border Applicant submits additional data completely and correctly within the time limit as referred to in section (4).

(6) In the event that the SKI Border Applicant or the SKI Post Border Applicant fails to submit additional data within the time limit as referred to in section (4) or receives a rejection, then:
   a. the application is considered invalid and the fees paid are non-refundable; and
   b. the SKI Border Applicant or the SKI Post Border Applicant must submit a new application by paying a non-tax state revenue.

Article 29

(1) The application approval of the SKI Border or the SKI Post Border as referred to in Article 28 section (1) is issued electronically, and does not require stamp and signature.

(2) The SKI Border or the SKI Post Border as referred to in section (1) is issued for a maximum of 6 (six) Hours after the application has been completely received and has fulfilled the requirements.

(3) In the event that the application of SKI Border or SKI Post Border as referred to in Article 28 section (1) is rejected, then the rejection is announced online through the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW.

(4) The SKI Border or the SKI Post Border may be printed by the SKI Border Applicant or the SKI Post Border Applicant or other corresponding institutions through SINSW.

Article 30

(1) The issuance of the SKI Border or the SKI Post Border can be provided with an accelerated service for the

purposes of overcoming outbreaks/pandemic and/or public health emergency in accordance with the provisions of legislation.

(2) The accelerated service as referred to in section (1) is stipulated by Chairperson of the Authority.

Article 31

(1) The SKI Border Applicant is obligated to submit importation data in the form of an import notification on the official website of SKI Border service of the Indonesian Food and Drug Authority through SINSW.

(2) The importation data as referred to in section (1) can be used as an importation report that has been conducted by the SKI Border Applicant.

Article 32

The SKI Post Border Applicant is obligated to submit an approval of SKI Post Border through the official website of SKI Post Border service of the Indonesian Food and Drug Authority which is integrated with SINSW within a maximum period of 7 (seven) Days after the release of goods.

CHAPTER IV
DOCUMENTATION

Article 33

(1) The Importation document of Food and Drugs must be properly documented at least for 3 (three) years by the Marketing Authorization holder, and the government institution or an importer granted a proxy by the Marketing Authorization holder.

(2) The Indonesian Food and Drug Authority, during the issuance process of the SKI Border and the SKI Post Border, may conduct a random checking on the validity and legality of the SKI Border and the SKI Post Border documents at the premises of the SKI Border Applicant and the SKI Post Border Applicant.

CHAPTER V
FEES

Article 34

(1) The SKI Border Applicant or the SKI Post Border Applicant is subject to fees for every importation as non-tax state revenue in accordance with the provisions of legislation.

(2) The non-tax state revenue as referred to in section (1) is conducted with online payment mechanism.

(3) In case of emergencies, the payment of non-tax state revenue can be settled manually.

(4) In the event that such application as referred to in section (1) is rejected, then such fees already paid are non-refundable.

Article 35

(1) The payment of non-tax state revenue is settled not later than 3 (three) work days after the SKI Border Applicant or the SKI Post Border Applicant sends the application through the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW.
(2) The Aju Number is issued since the document was firstly created on the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW as the starting point for calculating the submission number.
(3) The service level arrangement is calculated since the payment has been updated to the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority or SINSW.
(4) The service level arrangement as referred to in section (3) is the service level of issuance of an approval or rejection of the SKI Border or the SKI Post Border of Importation of Food and Drugs.
(5) Each 1 (one) Aju Number can contain a maximum of 20 (twenty) product items.

CHAPTER VI
RE-IMPORTATION

Article 36

(1) The business actor with the intention of conducting a re-importation of Food and Drugs into the territory of Indonesia must submit a re-importation application to Chairperson of the Authority.
(2) The re-importation of Food and Drugs into the territory of Indonesia as referred to in section (1) must attach the following documents:
    a. export documents, and/or other documents from corresponding institutions confirming that the Food and Drugs are originally from the territory of Indonesia;
    b. an export certificate issued by the Indonesian Food and Drug Authority, if any;
    c. a re-importation reasoning letter, if necessary can be completed with chronological details of release and re-importation of products; and
    d. a follow-up action plan for products being re-imported.
(3) The procedures of re-importation of Food and Drugs as referred to in section (1) are in accordance with the provisions of application procedures of the SKI Border or the SKI Post Border as referred to in Article 8 to Article 26, for the re-importation of Food and Drugs.

CHAPTER VII
IMPORTATION OF FOOD AND DRUGS FOR SPECIFIC PURPOSES

Article 37

(1) Food and Drugs that have not obtained the Marketing Authorization can be imported into the territory of Indonesia for specific purposes.
(2) The specific purposes as referred to in section (1) include:
   a. a personal/individual use;
   b. a research;
   c. a product development and/or science;
   d. a donation;
   e. a sample for registration/application of Marketing Authorization;
   f. a clinical trial for registration requirement, product development, and/or science;
   g. a government program;
   h. emergency national interests;
   i. a special use for health service which cannot be produced domestically; and
   j. an exhibition.

Article 38

(1) The research, product development, and exhibition as referred to in Article 37 section (2) point b, point c and point j are not intended for market testing.
(2) The donation as referred to in Article 37 section (2) point d only applies to Drugs, Traditional Medicines, Health Supplements, Quasi Medicines and Processed Food.
(3) The clinical trials for registration requirement, product development, and/or science as referred to in Article 37 section (2) point f, emergency national interests as referred to in Article 37 section (2) point h, and special use for health service which cannot be produced domestically as referred to in Article 37 section (2) point i only apply for Drugs, Traditional Medicines, Health Supplements, Quasi Medicines and Processed Food with disease risk reduction claims.
(4) The clinical trials as referred to in Article 37 section (2) point f include test drugs with the expanded access program approval.
(5) Further provisions regarding the expanded access program as referred to in section (4) are determined by the Chairperson of the Authority.
(6) The government program as referred to in Article 37 section (2) point g only applies for Drugs.
(7) The exhibition as referred to in Article 37 section (2) point j only applies for Traditional Medicines, Quasi Medicines, Health Supplements, Cosmetics, and/or Processed Food.

Article 39

(1) The Importation of Food and Drugs into the territory of Indonesia as referred to in Article 37 section (2) is conducted through a special access scheme.

(2) The Importation of Drugs through the special access scheme as referred to in section (1) for the purposes as referred to in Article 37 section (2) point d, point g, point h, and point i may only be conducted as long as the Drugs have obtained the Marketing Authorization or the emergency use authorization from the authorities in the country of origin or other countries.

(3) The Importation of Drugs through the special access scheme as referred to in section (1) for the purpose as referred to in Article 37 section (2) point i which can be produced domestically can only be conducted as long as there has been no similar Drug available or in extremely low quantity.

(4) The Importation through the special access scheme as referred to in section (1) must obtain an approval from the Chairperson of the Authority.

(5) Exempted from the provisions as referred to in section (4), the importation of Drug other than Biological products as referred to in Article 37 section (2) point d, point g, point h, and point i must obtain an approval from the minister administering government affairs in the field of health in accordance with the provisions of legislation.

(6) Exempted from the provision as referred to in section (4), the importation through the special access scheme for purposes as referred to in Article 37 section (2) point a can only be conducted in limited quantity based on the needs using the notification form of Importation of Food and Drug for personal use as set out in Annex II as an integral part of this Authority Regulation.

(7) The form as referred to in section (6) can be in a printed or electronic form.

Article 40

(1) The Importation of Food and Drug into the territory of Indonesia as referred to in Article 37 section (2) point a can be conducted through the following methods:
   a. delivery/cargo/postal services;
   b. passenger belongings;
   c. crew of cargo; or
   d. cross border.

(2) The Importation of Food and Drug for personal use through cross border as referred to in section (1) point d is conducted in accordance with the provisions of legislation.

Article 41

(1) The Importation of Drug for the purposes as referred to in Article 37 section (2) point a can only be conducted based on a prescription and/or a recommendation from the hospital.

(2) The hospital prescription and/or recommendation as referred to in section (2) must meet the following requirements of:

a. using the language which is essentially comprehensible; and
b. being signed/authorized by a doctor or a dentist that prescribes it in the country of origin.

(3) Exempted from the provisions as referred to in section (1) is for the importation of Drug that can be released without a prescription in accordance with the provisions of legislation under the following requirements of:
a. being imported into the territory of Indonesia through passenger belongings, crew of cargo and cross border; and
b. in limited quantity for maximum of 3 (three) Days.

Article 42

(1) The Importation of Food and Drugs into the territory of Indonesia as referred to in Article 37 section (2) must meet the following requirements:
a. not for sale; and
b. in limited quantities as needed.

(2) The quantity limit of Food and Drugs imported for the purpose as referred to in Article 37 section (2) point a, point e, and point j is in accordance with the provision of quantity limit of imported products without Marketing Authorization through the Special Access Scheme as set out in Annex III as an integral part of this Authority Regulation.

(3) Further provisions regarding the requirements, application procedures, and control of the Importation of Food and Drugs through the special access scheme are implemented in accordance with the provisions of legislation regulating the Importation of Food and Drugs through the special access scheme.

Article 43

(1) The Importation Control of Food and Drugs into the territory of Indonesia for the purpose as referred to in Article 37 section (2) point a is implemented by the Directorate General of Customs and Excise in accordance with the provisions of legislation.

(2) The control as referred to in section (1) is conducted using the form as referred to in Article 39 section (6).

(3) In the event that the result as referred to in section (1) found suspected Food and Drugs not in accordance with the provisions of laws and regulations, the Directorate General of Customs and Excise can coordinate with the Indonesian Food and Drug Authority.

(4) In the event that based on the control as referred to in section (1), the Importation of Food and Drugs is found not in compliance with the provisions as referred to in Article 41 and/or Article 42 section (1), the Food and Drugs can be eradicated or returned/re-exported in accordance with the provisions of legislation.

(5) Further provisions regarding control coordination as referred to in section (3) are determined by the Chairperson of the Authority.

CHAPTER VIII
CONTROL

Article 44

(1) The Importation Control of Food and Drugs is conducted through the product and facility inspection in accordance with the provisions of legislation.
(2) The control as referred to in section (1) is conducted to ensure:
    a. the compatibility of Food and Drugs imported into the territory of Indonesia with the data listed in the import documents; and
    b. the compliance with the legislation.
(3) The Importation Control of Food and Drugs is conducted based on risk analysis.
(4) The risk analysis as referred to in section (3) may be conducted in accordance with importation realization data of the Importation of Food and Drugs sent through the SINSW.
(5) The Importation Control of Food and Drugs is conducted in coordination with corresponding Ministries/Institutions.

CHAPTER IX
SANCTIONS

Article 45

(1) The SKI Border Applicant and/or the SKI Post Border Applicant that violates the provisions in Article 2, Article 3 section (1), Article 3 section (4), Article 3 section (5), Article 6 section (1), Article 11 section (3), Article 19 section (1), Article 27, Article 31 section (1), Article 32, Article 39 section (2), Article 39 section (3), Article 39 section (6), and/or Article 41 section (1) is subject to administrative sanctions.
(2) Administrative sanctions as referred to in section (1) are in the form of:
    a. a written warning;
    b. a temporary discontinuation of importation and/or circulation activity;
    c. an online access blocking to submit applications for the SKI Border and the SKI Post Border for the corresponding product for a maximum of 1 (one) year;
    d. a recall of Food and Drugs products from circulation;
    e. a destruction or re-delivery/re-export;
    f. a suspension of Marketing Authorization; and/or
    g. a revocation of Marketing Authorization.
(3) Administrative sanctions as referred to in section (1) can be copied to the corresponding Ministries/Institutions.
(4) Administrative sanctions as referred to in section (1) to section (2) are imposed by the Chairperson of the Authority.

Article 46

The procedures for imposing administrative sanctions as referred to in Article 45 are carried out in accordance with

Regulations of the Indonesian Food and Drug Authority which regulate follow-up of the monitoring results.

CHAPTER X
TRANSITIONAL PROVISIONS

Article 47

(1) Applications for the SKI Border or the SKI Post Border that have been submitted prior to the enforcement of this Authority Regulation, will still be processed based on Regulation of the Indonesian Food and Drug Authority Number 30 of 2017 on Importation Control of Food and Drugs into the Territory of Indonesia (State Bulletin of the Republic of Indonesia of 2017 Number 1843) as amended by Regulation of the Indonesian Food and Drug Authority Number 15 of 2020 on Importation Control of Food and Drugs into the Territory of Indonesia (State Bulletin of the Republic of Indonesia of 2020 Number 754).
(2) The approval for the SKI Border or the SKI Post Border that has been issued based on Regulation of the Indonesian Food and Drug Authority Number 30 of 2017 on Importation Control of Food and Drug into the Territory of Indonesia (State Bulletin of the Republic of Indonesia of 2017 Number 1843) as amended by Regulation of the Indonesian Food and Drug Authority Number 15 of 2020 on Importation Control of Food and Drugs into the Territory of Indonesia (State Bulletin of the Republic of Indonesia of 2020 Number 754), is declared valid until the Food and Drugs have been imported into the territory of Indonesia.
(3) The Food and Drug imported into the territory of Indonesia as referred to in section (1) and section (2), are still eligible for circulation as long as they meet the standards and/or requirements of safety, efficacy/benefit, and quality.

CHAPTER XI
CLOSING PROVISIONS

Article 48

At the time this Authority Regulation comes into force:
a. Regulation of the Indonesian Food and Drug Authority Number HK.00.05.42.2996 of 2008 on Importation Control of Traditional Medicines; and
b. Regulation of the Indonesian Food and Drug Authority Number 30 of 2017 on Importation Control of Food and Drugs into the Territory of Indonesia (State Bulletin of the Republic of Indonesia of 2017 Number 1843) as amended by Regulation of the Indonesian Food and Drug Authority Number 15 of 2020 on Amendment to Regulation of the Indonesian Food and Drug Authority Number 30 of 2017 on Importation Control of Food and Drugs into the Territory of Indonesia (State Bulletin of the Republic of Indonesia of 2020 Number 754),

are repealed and declared ineffective.

Article 49

This Authority Regulation comes into force after 30 (thirty) Days as of the date of its promulgation.

In order that every person may know thereof, it is ordered to promulgate this Authority Regulation by its placement in the State Bulletin of the Republic of Indonesia.

Issued in Jakarta
on 14 November 2022

CHAIRPERSON OF THE INDONESIAN
FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

Promulgated in Jakarta
on 14 November 2022

MINISTER OF LAW AND HUMAN RIGHTS
OF THE REPUBLIC OF INDONESIA,

signed

YASONNA H. LAOLY

STATE BULLETIN OF THE REPUBLIC OF INDONESIA OF 2022 NUMBER 1154

Jakarta, 10 July 2023
Has been translated as an Official Translation
on behalf of Minister of Law and Human Rights
of the Republic of Indonesia
DIRECTOR GENERAL OF LEGISLATION,

DIREKTUR JENDERAL PERATURAN PERUNDANG-UNDANGAN KEMENTERIAN HUKUM DAN HAK ASASI MANUSIA R.I.

ASEP N. MULYANA

ANNEX I TO
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 27 OF 2022
ON
IMPORTATION CONTROL OF FOOD AND DRUGS
INTO THE TERRITORY OF INDONESIA

IMPORT CERTIFICATE FORMAT

IMPORT CERTIFICATE
FOOD AND DRUG COMMODITIES
Number: ST .....

Chairperson of the Indonesian Food and Drug Authority of the Republic of Indonesia has granted the approval to:

Importer's Name	:	
Office Address	:	
NPWP (Taxpayer Identification Number)	:	
API/NIB	:	
Exporter's Name	:	
Exporter's Country of Origin	:	

To receive:

No.	Product Name	Packaging	MA Number	Quantity	Lot/Batch Number	HS Code
	Manufacturer					
	Manufacturer's Country of Origin					

No. and Date of Invoice :
Through : Office of Customs and Excise Service

With the provisions:
1. The above product must meet the provisions of legislation in the field of Food and Drugs.
2. This Import Certificate can be directly accessed through the official website of SKI Border or SKI Post Border of the Indonesian Food and Drug Authority or SINSW.

Thus, we truly make this Import Certificate in order to be used accordingly.

Jakarta, ...
On behalf of Chairperson of the Indonesian Food and Drug Authority of the Republic of Indonesia
Director of ......

signed

(Full Name)
NIP

This document is official, and issued electronically through the official website of SKI Border or SKI Post Border service of the Indonesian Food and Drug Authority; thus, it does not require stamp and signature.

CHAIRPERSON OF THE INDONESIAN
FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

ANNEX II TO
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 27 OF 2022
ON
IMPORTATION CONTROL OF FOOD AND DRUGS
INTO THE TERRITORY OF INDONESIA

A. IMPORT FORM OF FOOD AND DRUGS THROUGH TRANSPORT SERVICES FOR PERSONAL USE

IMPORT FORM OF FOOD AND DRUGS
THROUGH TRANSPORT SERVICES FOR PERSONAL USE

Name	:	
Phone Number and E-mail	:	
Date of Birth (DD/MM/YYYY)	:	.../.../...
Address	:	
ID number/passport number	:	
Receipt	:	
Shipping Receipt Number	:	
Shipper Name and Address	:	
Country of Origin	:	

Product Description

No.	Product Name and Brand	Package Size	Product Quantity (pcs)	Remarks*

*For Drugs: please attach Doctor's prescription/Hospital recommendation for prescription drug

Note:
1. On the Remarks column, state the amount of use per day. For prescription drug, please state the amount according to Doctor's prescription/Hospital recommendation;
2. The above-mentioned product(s) is solely for personal use and not for sale;
3. Directorate General of Customs and Excise is not responsible for the risks of using the above-mentioned product;
4. If a violation occurs, it will be subject to sanctions in accordance with the provisions of legislation.

Jakarta, (dd/mm/yyyy)

Applicant, Officer,

(name and signature) (signature and stamp)

Technical Documents:
1. Recommendation and data support form the doctor*
2. Justification of the number of needs

B. IMPORT FORM OF FOOD AND DRUGS THROUGH PASSANGERS BELONGINGS, CREW OF CARGO AND CROSS BORDER FOR PERSONAL USE

IMPORT FORM OF FOOD AND DRUGS THROUGH PASSANGERS BELONGINGS, CREW OF CARGO AND CROSS BORDER FOR PERSONAL USE

Name	:	
Phone Number and E-mail	:	
Date of Birth (DD/MM/YYYY)	:	.../.../...
Address	:	
ID Number/Passport Number	:	
Country of Origin	:	
Flight/Voyage Number	:	
Date of Arrival	:	

Product Description:

No.	Product Name and Brand	Package Size	Product Quantity (pcs)	Remarks*

*For Drugs: please attach Doctor's prescription/Hospital recommendation for prescription drug

Note:

1. On the Remarks column, state the amount of use per day. For prescription drug, please state the amount according to Doctor's prescription/Hospital recommendation;
2. The above-mentioned product(s) is solely for personal use and not for sale;
3. Directorate General of Customs and Excise is not responsible for the risks of using the above-mentioned product;
4. If a violation occurs, it will be subject to sanctions in accordance with the provisions of legislation.

Jakarta, (dd/mm/yyyy)

Applicant,

(name and signature)

C. INSTRUCTIONS FOR FILLING THE FORM OF THE IMPORT OF GOODS FOR PERSONAL USE

Column on the Form		**Filling Instructions**
Name	:	Filled with full name according to ID Card/ Passport of the passenger or consignee
Phone Number and E-mail	:	Filled with contactable telephone number and email
Date of Birth (DD/MM/YYYY)	:	Filled with place and date of birth with the format (Day/Month/Year) of the passenger or consignee
Address	:	Filled with domicile address of the passenger or consignee
ID Number/ Passport Number	:	Filled with identification number of the passenger or consignee based on the ID Card/Passport
Flight/Voyage Number	:	Filled with airline name/flight number used by the passenger
Date of Arrival	:	Filled with date of arrival of the passenger
Receipt	:	Filled with number and date of receipt
Shipping Receipt Number	:	Filled with shipping receipt number
Shipper Name and Address	:	Filled with shipper name and address
Country of Origin	:	Filled with country of origin of the goods
Product Description		
Product Name and Brand	:	1. Filled with brand name and product type, e.g.,: a. "SUPER LEZAT" instant noodles (Product type: instant noodles, brand: SUPER LEZAT) b. Health Supplement "Energi Oke" c. Traditional Medicine "Tolak Pegel Linu" d. Cosmetics "BMZ Lipstick Shine 0" 2. For Drugs, filled with the name of active ingredients followed by the brand (if generics, filled with active ingredients only), for example:

		Paracetamol Drug "Pasemol".
Package Size	:	Filled with individual size of product package, e.g.,: a. 100 grams (a net weight / product net) b. Box, bottle @ 60 capsules @ 500 mg c. Box, 6 sachets @ 4 grams d. Box, 10 strips @ 10 capsules @ 500 mg e. Tube Box, 3.5 grams
The Amount of Products (pcs)	:	1. Filled with the amount of products sent per product type, for example: 5 pieces (amount of products is subject to each primary package) 2. Specifically for Drug, it is filled with the smallest unit of use (e.g.,: 30 tablets/capsules, 250 milliliters of syrup, 100 grams of cream, 10 units of single dose)
Remarks*	:	Filled with the information regarding the doctor's prescription attached (amount of usage per day, for example: 3 tablets per day, 15 milliliters of syrup per day, 1 single dose per day)
Applicant, **Name and Signature**	:	Filled with the name and signature of the passenger or consignee
Officer, **Signature and Stamp,** **Name**	:	Filled with the name, signature and stamp of local Customs and Excise officer

CHAIRPERSON OF THE INDONESIAN
FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

ANNEX III TO
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 27 OF 2022
ON
IMPORTATION CONTROL OF FOOD AND DRUGS
INTO THE TERRITORY OF INDONESIA

QUANTITY LIMIT OF IMPORTED GOODS WITHOUT MARKETING AUTHORIZATION
THROUGH SPECIAL CHANNELS

Commodity	**Quantity Limit of Importation of Goods**		
	Personal/Individual Use Purpose	**Sample Purpose for Registration/Application**	**Display Purpose**
Drugs: a. Prescription Drugs (drugs with prescription requirement)	According to the doctor's prescription for the requirement of maximum 90-day treatment.	-	-
b. OTC Drugs and Limited OTC Drugs (drugs without prescription requirement)	1. personal goods of passengers/ personal goods of crew of cargo/ personal goods of border crossers: for medication needs are maximum 3 (three) days. 2. goods of carrier/ transportation/postal service: according to the doctor's prescription for the requirement of maximum 90-day treatment.		
Traditional Medicines	Maximum 5pcs* per passenger/ recipient for each product	Maximum 2 pcs/items of Traditional Medicine	Maximum 10 pcs/items of products for each package.

	type/item. *) Notes:	products for each package or according to sample requirements for testing.	
Health Supplements	For tablet/capsule dosage forms in strips/blisters/bottles and packaged in small boxes, the permitted quantity is 5 small boxes.	Maximum 2 pcs/items of Health Supplement products for each package or according to sample requirements for testing.	Maximum 10 pcs/items of products for each package.
Cosmetics	Maximum 20 pcs per passenger/recipient.	Maximum 2 pcs/items of Cosmetic products for each package or according to sample requirements for testing.	Maximum 10 pcs/items of products for each package.
Food: a. Food for Special Nutritional Needs	According to the doctor's prescription.	-	-
b. Other Processed Food, excluding Alcoholic Beverages	5 Kilograms per passenger/ recipient.	-	-

CHAIRPERSON OF THE INDONESIAN
FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO