REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 32 OF 2022
ON
CRITERIA AND PROCEDURES FOR HEALTH SUPPLEMENT REGISTRATION

BY THE BLESSINGS OF ALMIGHTY GOD

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

Considering : a. that in order to protect the public from the distribution of health supplements that do not meet the requirements of safety, efficacy, and quality, it is necessary to issue a regulation on health supplement registration;

b. that based on the provisions of Article 3 section (1) point d of Presidential Regulation Number 80 of 2017 on the 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 provisions of the health supplement registration as regulated in Regulation of the Indonesian Food and Drug Authority Number 11 of 2020 on Criteria and Procedures for Health Supplement Registration are no longer valid with the legal needs and development of science and technology in the field of health supplements, so it is necessary to be replaced;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 a Regulation of the Indonesian Food and Drug Authority on Criteria and Procedures for Health Supplement Registration;

Observing : 1. Presidential Regulation Number 80 of 2017 on the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia of 2017 Number 180);

2. Regulation of the Indonesian Food and Drug Authority Number 21 of 2020 on Organization and Work Procedures of the 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 the Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2022 Number 629);

3. Regulation of the Indonesian Food and Drug Authority Number 22 of 2020 on Organization and Work Procedures of Technical Implementation Units within the 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 Amendment to Regulation of the Indonesian Food and Drug Authority Number 22 of 2020 on Organization and Work Procedures of Technical Implementation Units within the Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2022 Number 1111);

HAS DECIDED:

To issue: REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON CRITERIA AND PROCEDURES FOR HEALTH SUPPLEMENT REGISTRATION.

CHAPTER I
GENERAL PROVISIONS

Article 1

In this Authority Regulation:

1. Health Supplement Registration, hereinafter referred to as Registration, means the procedure for registration and evaluation of Health Supplements electronically in order to obtain a Marketing Authorization approval.
2. Health Supplement means a product intended to complete nutritional needs, maintain, enhance, and improve the healthy function, having nutritional values and/or physiological effects, containing one or more substances in the form of vitamins, minerals, amino acids and/or other non-plant substances that can be combined with plants.
3. Marketing Authorization means a form of Registration approval for Health Supplements for marketing in territory of Indonesia.
4. Pharmaceutical Industry means a business entity holding a license from a government institution that administers government affairs in the field of health to engage in the activities of manufacturing drugs or drug substances.
5. Traditional Medicine Industry (*Industri Obat Tradisional*), hereinafter abbreviated as IOT, means an industry which can manufacture all dosage forms of traditional medicines.
6. Traditional Medicine Small Enterprise (*Usaha Kecil Obat Tradisional*), hereinafter abbreviated as UKOT, means an enterprise which can manufacture all dosage forms of traditional medicines, excluding tablet, effervescent, suppository, soft capsule, and aerosol for external use.
7. Food Industry means a company that manufactures processed food.
8. Importer means a business entity in the form of a legal entity or non-legal entity that imports Health Supplements into the territory of Indonesia.
9. Good Manufacturing Practice means all manufacturing aspects that aim to ensure the product produced meet the stipulated quality requirements are in accordance with the purposes of use.
10. Good Manufacturing Practice for Pharmaceutical Products

(*Cara Pembuatan Obat yang Baik*), hereinafter abbreviated as CPOB means a method of Drugs manufacturing that aims to ensure that the quality of drugs produced is in accordance with the requirements and purposes of use.

11. Good Manufacturing Practices for Traditional Medicines (*Cara Pembuatan Obat Tradisional yang Baik*), hereinafter abbreviated as CPOTB, means all aspects of manufacturing Traditional Medicines which aim to ensure the product produced meet the stipulated quality requirements are in accordance with the purposes of use.
12. Good Manufacturing Practices for Processed Food (*Cara Produksi Pangan Olahan yang Baik*), hereinafter abbreviated as CPPOB, means guidelines describing how to manufacture Processed Food so that it is safe, of good quality and suitable for consumption.
13. CPOB Certificate means a legal document which acts as an evidence that the Pharmaceutical Industry has complied with all the CPOB requirements in the manufacture of one type of pharmaceutical dosage form.
14. CPOTB Certificate means a legal document which acts as an evidence that the Traditional Medicine industry and enterprise have complied with all the technical requirements of CPOTB in the manufacture of one type of Traditional Medicine dosage form.
15. CPPOB implementation permit means evidence that the manufacturing facility of certain processed food has complied with the CPPOB requirements and standards in the manufacturing activities of processed food.
16. Bulk Product means an ingredient that has been processed and only requires packaging to become the finished product.
17. Contract Health Supplement means Health Supplement with all or some manufacturing stages delegated based on the contract.
18. License means a permit granted by a licensor for a licensee based on a written agreement to use research and development result which relate to safety, efficacy, quality, and technology transfer in the manufacture and/or use of trade names and marketing of a Health Supplement.
19. New Registration means a Registration for Health Supplements that have not obtained Marketing Authorization in Indonesia.
20. Variation Registration means the Health Supplement Registration of changes in aspects of administration, safety, efficacy, quality, and/or labels for Health Supplement that have already obtained a Marketing Authorization in Indonesia.
21. Minor Variation Registration with Notification means a Variation Registration for a particular aspect that does not affect on aspects of safety, efficacy, and/or quality of Health Supplements, and does not change the information on the Marketing Authorization.
22. Minor Variation Registration with Approval means a Variation Registration which is not included in the categories of Minor Variation Registration with Notification

or Major Variation Registration.

23. Major Variation Registration means a Variation Registration that affects on the aspects of administration, safety, efficacy, and/or quality of Health Supplements.
24. Renewal Registration means Health Supplement Registration for extension of the Marketing Authorization validity period.
25. Labeling means complete information concerning the efficacy, safety, and instruction of use as well as other information related to the product which is affixed to the label and/or brochure inserted in the Health Supplement packaging.
26. Composition means list of qualitative and quantitative of active ingredients.
27. Formula means list of qualitative and quantitative of active and inactive ingredients.
28. Health Supplement Advertisement, hereinafter referred to as Advertisement, means any information or statement regarding Health Supplements in the form of images, texts, or other forms which are delivered through various means for the purposes of marketing and/or trade of Health Supplements.
29. Principal means a business entity in the form of a legal entity or non-legal entity, domestic or overseas, that appoints a domestic Distributor or Agent to sell the Products manufactured, possessed or controlled by the Principal.
30. Officer means an employee of the Indonesian Food and Drug Authority who is given an assignment by authorized officials to conduct an inspection based on an assignment letter.
31. Business Actor means a business entity, operating either as a legal entity or otherwise, that has been established and is domiciled in the jurisdiction of the Unitary State of the Republic of Indonesia, either individually or collectively, to perform business activities in the field of Health Supplement.
32. Marketing Authorization Holder means a Business Actor who has obtained a Marketing Authorization.
33. Contract Giver means the Business Actor who delegates the activity of manufacturing Health Supplement based on a contract.
34. Contract Acceptor means the Pharmaceutical Industry, IOT, UKOT or Food Industry that accepts Health Supplement manufacturing activity based on a contract.
35. Indonesian Food and Drug Authority, hereinafter referred to as the Indonesian FDA, means a non-ministerial government Institution administering government affairs in the field of Drug and Food control.
36. Chairperson of the Authority means the Chairperson of the Indonesian Food and Drug Authority.
37. Day means a work day.

CHAPTER II
CRITERIA

Part One
General

Article 2

The Business Actor is obligated to ensure that manufactured or imported Health Supplements to be marketed in the territory of Indonesia meet the following criteria:

a. safety, efficacy, and quality; and
b. Labeling.

Part Two
Safety, Efficacy, and Quality

Article 3

(1) The safety, efficacy, and quality criteria as referred to in Article 2 include:
   a. use of raw materials in accordance with the provisions of the Indonesian pharmacopoeia, Indonesian herbal pharmacopoeia, pharmacopoeia of other countries or recognized scientific references;
   b. safety and efficacy substantiation through empirical and/or scientific evidence; and
   c. Good Manufacturing Practice is implemented in accordance with the provisions of legislation.

(2) Good Manufacturing Practices as referred to in section (1) point c include:
   a. CPOB;
   b. CPOTB; and/or
   c. CPPOB.

Article 4

Safety and efficacy substantiation through empirical and/or scientific evidence as referred to in Article 3 section (1) point b is carried out based on scientific references, non-clinical and/or clinical data in accordance with the latest developments in science and technology in the field of Health Supplements.

Article 5

(1) Health Supplements may contain active and inactive ingredients.
(2) In the event that the active ingredients as referred to in section (1) are from plants, they must meet the requirements as follows:
   a. they have been equipped with information regarding the origin of the plant, parts used, and preparation method; and
   b. the standardization, qualitative testing, and/or quantitative testing of active compounds in raw materials and finished products have been conducted.
(3) In the event that the Health Supplement packaging stating active compounds as referred to in section (2), a quantitative testing must be carried out.

Article 6

(1) The inactive ingredients as referred to in Article 5 section (1) may be in the following forms:
   a. preservatives;
   b. colourants;
   c. sweeteners;
   d. flavourings;
   e. anti-caking agents;
   f. emulsifiers;
   g. glazing agents;
   h. stabilizers;
   i. solvents; and/or
   j. other inactive ingredients.

(2) The inactive ingredients as referred to in section (1) are the inactive ingredients allowed to be used in the manufacture of Health Supplements in accordance with the provisions of legislation.

Article 7

(1) The active ingredients as referred to in Article 5 section (2) and the inactive ingredients as referred to in Article 6 originating from the source other than plants, must attach a document explaining which the material origin.

(2) The document explaining the material origin as referred to in section (1) is evaluated in accordance with the provisions of legislation.

Article 8

(1) The stability testing to fulfill the quality criteria as referred to in Article 2 is carried out at the temperature and humidity of zone IVb in accordance with the guidelines regarding stability testing that apply internationally.

(2) In the event that the product is unstable based on zone IVb as referred to in section (1), the Business Actor must provide a justification and conduct a stability testing at the appropriate temperature and humidity.

Part Three
Labeling

Article 9

The labeling as referred to in Article 2 point b is require to meet the criteria of complete, objective and not misleading.

Article 10

(1) The labeling as referred to in Article 9 must meet the following criteria:
   a. it is printed or sticks tightly to the container and/or packaging;
   b. it is not easily detachable; and
   c. it cannot be damaged by water, friction, or the sunlight exposure.

(2) In addition to complying with the Labeling criteria as referred to in Article 9, the Business Actor must meet the technical requirements of Labeling.

(3) The technical requirements of Labeling as referred to in section (2) must meet the information on the Labeling.
(4) In the event that the Health Supplements are packed in strips or blisters, Labeling must be printed on the packaging.

Article 11

(1) The details on the Label as referred to in Article 10 section (3) at least include the following information:
   a. product name in the form of generic and/or trade name;
   b. the words “Suplemen Kesehatan”;
   c. dosage form;
   d. name and address of the industry and/or the Business Actor;
   e. name and address of the Contract Giver and/or Contract Acceptor;
   f. name and address of Licensor and/or Licensee;
   g. size, content, and net weight;
   h. Composition in qualitative and quantitative;
   i. qualitative inactive ingredients;
   j. benefit claim;
   k. instruction/direction of use;
   l. contraindication, side effect, and warning if any;
   m. Marketing Authorization number;
   n. batch number/production code;
   o. expiry date;
   p. storage condition;
   q. 2D barcode in accordance with the provisions of legislation; and
   r. other information in compliance with the standards and/or requirements of safety, quality, and/or origin of certain substances in accordance with the provisions of legislation.
(2) The information as referred to in section (1) point i includes sweeteners, colourants, preservatives and/or flavourings.
(3) The product details and/or information as referred to in section (1) are in accordance with the documents approved by the Indonesian FDA.
(4) The inclusion of product details and/or information as referred to in section (1) is set out in Annex I as an integral part of this Authority Regulation.

Article 12

The 1 (one) product name as referred to in Article 11 section (1) point a with the same trade name may only be registered by 1 (one) Business Actor.

Article 13

(1) The details and/or information as referred to in Article 11 must use Indonesian language, Arabic numerals and Latin alphabets.
(2) In the event that the details and/or information as referred to in section (1) uses a language other than Indonesian language, the Business Actor must include the equivalent

details and/or information into Indonesian language written by a sworn translator in Indonesia.

(3) Exempted from the provisions as referred to in section (2) are the details and/or information already written in English, the translation from a sworn translator is not necessary.

(4) If the Business Actor is unable to implement the provisions as referred to in section (2), the details and/or information included must:
   a. be translated into English in the country of origin; and
   b. be verified by local notary.

Article 14

(1) In the event that there is a change in the Composition of a Health Supplement so that it impacts the efficacy aspect, the product name as referred to in Article 11 section (1) point a must be changed.

(2) Exempted from the provisions as referred to in section (1) are Health Supplements with product names that do not explain or describe the benefit of the product.

Article 15

The nutritional value information which is stated on the Label must be in accordance with test results from accredited laboratories in Indonesia or industrial laboratories in Indonesia that have obtained a CPOB/CPOTB Certificate.

Article 16

(1) The Business Actor may include the benefit claim on the Health Supplement Labeling when submitting a Registration application.

(2) The benefit claim as referred to in section (1) is in the form of:
   a. general or nutritional claim;
   b. functional claim; and/or
   c. isease risk reduction claim.

(3) Health Supplements are not intended to make claims for prevention or treatment of any disease.

(4) Further provisions regarding the benefit claim as referred to in section (2) are implemented in accordance with Regulation of the Indonesian Food and Drug Authority that regulates Health Supplement claims.

Article 17

Further provisions on the Labeling as referred to in Article 9 to Article 15 are regulated by Regulation of the Indonesian Food and Drug Authority.

CHAPTER III
HEALTH SUPPLEMENT REGISTRATION

Part One
General

Article 18

(1) Health Supplements that are marketed in territory of Indonesia are required to meet the criteria as referred to in Article 2.
(2) In order to ensure that Health Supplements marketed in territory of Indonesia have met the criteria as referred to in section (1), the Health Supplements marketed by the Business Actor are required to obtain a Marketing Authorization.
(3) The Marketing Authorization as referred to in section (2) is obtained by submitting a Registration application.
(4) The Registration application as referred to in section (3) is submitted by the Business Actor to the Chairperson of Authority.

Article 19

(1) The Marketing Authorization as referred to in Article 18 section (2) is exempted for Health Supplements imported into the territory of Indonesia for particular purposes.
(2) The importation of Health Supplements for particular purposes as referred to in section (1) is conducted in accordance with the provisions of legislation.

Article 20

(1) The Business Actors as referred to in Article 18 section (4) include:
    a. Pharmaceutical Industry;
    b. IOT or UKOT;
    c. Food Industry;
    d. Importer; or
    e. business entity in the field of Health Supplement marketing.
(2) The Business Actors as referred to in section (1) must obtain a business registration number in accordance with the provisions of legislation.

Part Two
Requirements

Article 21

The Registration application as referred to in Article 18 section (3) includes:
a. local Registration;
b. export Registration; and
c. import Registration.

Paragraph 1
Local Registration

Article 22

The local Registration as referred to in Article 21 point a includes:

a. Registration for Health Supplements self-manufactured by the Business Actors;
b. contract-based Registration ; and/or
c. License-based Registration.

Article 23

(1) Registration for Health Supplements self-manufactured by the Business Actors as referred to in Article 22 point a is submitted by the Business Actors.
(2) The Business Actors as referred to in section (1) are in the form of Pharmaceutical Industry, IOT, UKOT, or Food Industry.
(3) The Business Actors as referred to in section (2) submitting for Registration application must complete the following required documents:
    a. Taxpayer Identification Number (NPWP);
    b. Good Manufacturing Practice certificate/Good Manufacturing Practice application permit in accordance with the dosage type and form being stated in the Registration form which includes:
        1. CPOB Certificate;
        2. CPOTB Certificate; or
        3. CPPOB Application Permit and an approval to manufacture Health Supplements in the food manufacturing facility.
    c. power of attorney for the person in charge of the account from the company director; and
    d. notarial deed of company establishment.
(4) Pharmaceutical Industry that manufacture Health Supplements with the Composition of non-drug class substances, apart from having to fulfill the provisions as referred to in section (3) point b point 1, must also have an approval for sharing drug manufacturing facilities with Health Supplements in accordance with the dosage type and form for which Registration will be submitted.
(5) In addition to the requirement to submit the documents as referred to in section (3), in the event that data verification is required, the Business Actors must also show the original documents.
(6) The approval to manufacture Health Supplements in food manufacturing facilities as referred to in section (3) point b point 3 is a legal document indicating that the food manufacturing facility has implemented aspects of Good Manufacturing Practice for Traditional Medicines.
(7) In the event that the Registration application is submitted by a Business Actor who has a trademark certificate, apart from having to fulfill the requirements as referred to in section (3) and section (4), the Business Actor must also attach a copy of the trademark certificate.

(8) In the event that the Registration application is submitted by a Business Actor who is appointed as the acceptor of a trademark License, the Business Actor must, in addition to attaching the documents as referred to in section (7), also attach a copy of the License agreement between the trademark owner and the Registration applicant.
(9) If necessary, the Officer may require the Business Actor to show the original documents of the trademark certificate as referred to in section (7) and the License agreement as referred to in section (8).
(10) The Registration Application as referred to in section (7) and section (8) is submitted by attaching a statement letter stating that the Business Actor is willing to have his or her Marketing Authorization number canceled if there is another party who has rights to the brand and/or product name being registered in accordance with the provisions of legislation.

Article 24

(1) Contract-based Registration as referred to in Article 22 point b is submitted by the Business Actors.
(2) The Business Actors as referred to in section (1) are in the form of Pharmaceutical Industry, IOT, UKOT, or Food Industry.
(3) The Business Actor as referred to in section (2) acts as the Contract Giver.
(4) The Contract Giver as referred to in section (3) acts as the Marketing Authorization Holder of the Health Supplements.
(5) The contract-based manufactured Health Supplements as referred to in Article 22 point b include:
    a. partial manufacturing stages; and
    b. all manufacturing stages.
(6) The Business Actor as referred to in section (2) submitting Registration application must complete the following required documents:
    a. Taxpayer Identification Number (NPWP);
    b. Good Manufacturing Practice certificate/Good Manufacturing Practice application permit in accordance with the dosage type and form being stated in the Registration form which includes:
        1. CPOB Certificate;
        2. CPOTB Certificate; or
        3. CPPOB Application Permit and an approval to manufacture Health Supplements in the food manufacturing facility.
    c. Valid manufacturing contract agreement documents with the following conditions:
        1. Pharmaceutical Industry, IOT, or UKOT have obtained Good Manufacturing Practice certificates; or
        2. Food Industry has obtained CPPOB Application Permit in accordance with the dosage form for which Registration will be submitted and the approval document to manufacture Health Supplements in the food manufacturing facility.

(7) Good Manufacturing Practice certificate as referred to in section (6) point b is exempted for business entity in the field of Health Supplement marketing.

(8) In addition to fulfilling the requirements as referred to in section (6) point a and point c, the Business Actor in the form of business entity in the field of Health Supplement marketing r must obtain the business entity recommendation in the field of marketing which has a contract for the manufacture of Health Supplements as the evidence that the marketing business entity has fulfilled the standards and/or requirements as the Contract Giver and the Marketing Authorization Holder for Health Supplements.

(9) In order to obtain the business entity recommendation in the field of marketing which has a contract for the manufacture of Health Supplements as referred to in section (8), the business entity in the field of marketing must meet the following requirements:
   a. has a pharmacist in charge, proven by a duly-stamped statement letter.
   b. has storage facilities in accordance with the legislation; and
   c. has a quality testing laboratory in accordance with Regulation of the Indonesian Food and Drug Authority that regulates CPOTB.

Article 25

(1) In the event of manufacturing contract-based Health Supplements, if certain stages as referred to in Article 24 section (5) point a are self-manufactured by Pharmaceutical Industry, IOT, UKOT, or Food Industry, then the documents as referred to in Article 25 section (6) point b must comply with the dosage type and form for which Registration will be submitted.

(2) Pharmaceutical Industry that manufacture Health Supplements with the Composition of non-drug class substances with partial manufacturing stage contract, apart from having to fulfill the provisions as referred to in section (1), must also have an approval for sharing drug manufacturing facilities with Health Supplements in accordance with the dosage type and form for which Registration will be submitted.

(3) The approval for sharing drug manufacturing facilities with Health Supplements as referred to in section (2) is carried out in accordance with the provisions of legislation.

Article 26

(1) The Officer conducts an audit of storage facilities and quality testing laboratory as referred to in Article 24 section (9) point b and point c.

(2) The audit as referred to in section (1) is conducted before the Contract Giver submits the account registration application documents and Registration documents.

(3) In the event that the Registration application is submitted by a Business Actor who has a trademark certificate, apart

from having to fulfill the requirements as referred to in Article 24 section (6) and section (8), the Business Actors must also attach a copy of the trademark certificate by showing the original documents.

(4) In the event that the Registration application is submitted by a Business Actor who is appointed as the acceptor of a trademark License, the Business Actors must, in addition to attaching the documents as referred to in Article 24 section (6) and section (8), also attach a copy of the License agreement between the trademark owner and the Registration applicant by showing the original documents.

(5) The Registration application as referred to in section (3) and section (4) is submitted by attaching a statement letter stating that the Business Actor is willing to have his or her Marketing Authorization number canceled if there is another party who has rights to the brand and/or product name being registered in accordance with the provisions of legislation.

Article 27

(1) The contract agreement document as referred to in Article 24 section (6) point c must at least contain an agreement concerning:
   a. validity period of the contract;
   b. names and formulas of the contract-based Health Supplements;
   c. partial or all manufacturing stages conducted by the Contract Acceptor; and
   d. assignment of obligations and responsibilities of the parties by considering aspects of Good Manufacturing Practice as regulated in CPOB, CPOTB or CPPOB.

(2) The contract agreement document as referred to in section (1) must be endorsed by a notary.

Article 28

(1) The Contract Acceptor for the manufacture of Health Supplements must obtain a Good Manufacturing Practice certificate/Good Manufacturing Practice application permit in accordance with the dosage type and form for which Registration will be submitted.

(2) Good Manufacturing Practice certificate/Good Manufacturing Practice application permit as referred to in section (1) includes:
   a. CPOB Certificate;
   b. CPOTB Certificate; or
   c. CPPOB Application Permit and an approval to manufacture Health Supplements in the food manufacturing facility.

(3) Pharmaceutical Industry that manufacture contract-based Health Supplements with the Composition of non-drug class substances, apart from having to fulfill the provisions as referred to in section (2), must also have an approval for sharing drug manufacturing facilities with Health Supplements in accordance with the dosage type and form being contracted.

(4) The Contract Acceptor may not delegate the manufacture of contract-based Health Supplements to the third party.

Article 29

(1) The Contract Giver and the Contract Acceptor are required to be responsible for the safety, efficacy and quality of contract-based manufacture Health Supplements with the Contract Giver as the leading person in charge.
(2) The Contract Giver may propose additions and/or changes to the alternative site to anticipate force majeure as stated in the contractual agreement.
(3) The Contract Giver is obligated to register additions and/or changes to the alternative site as referred to in section (2) as a Variation Registration.
(4) The business entity in the field of Health Supplement marketing is obligated to report any additions and/or changes to storage facilities and quality testing laboratories.

Article 30

(1) License-based Registration Application as referred to in Article 22 point c is submitted by the Business Actors.
(2) The Business Actors as referred to in section (1) are in the form of Pharmaceutical Industry, IOT, UKOT, and Food Industry.
(3) Pharmaceutical Industry, IOT, UKOT, and Food Industry as referred to in section (2) act as the Licensee.
(4) The submission of the Registration application as referred to in section (1) is carried out by the Licensee based on the Licenses given by the following institutions:
    a. overseas industry; or
    b. domestic or overseas research agency holding the formula and technology.
(5) The Licensee as referred to in section (3) must have the following documents:
    a. Good Manufacturing Practice certificate/Good Manufacturing Practice application permit in accordance with the dosage type and form that will be conducted by the License includes:
        1. CPOB Certificate;
        2. CPOTB Certificate; or
        3. CPPOB Application Permit and the approval to manufacture Health Supplements in the processed food manufacturing facilities.
    b. License agreement documents; and
    c. Certificate of Free Sale (CFS) or Certificate of Pharmaceutical Product (CPP), or other equivalent documents issued by the government authority in the country of origin or other institutions appointed by the government of the country of origin proven by the attachment of appointment letter.
(6) In the event that the Certificate of Free Sale (CFS) or Certificate of Pharmaceutical Product (CPP), or other equivalent documents as referred to in section (5) point c originates from a country that is bound to the convention of legalization requirement elimination for foreign public

documents, Certificate of Free Sale (CFS) or Certificate of Pharmaceutical Product (CPP), or other equivalent documents must be legalized with apostille by the authorized official in the country of origin.

(7) In the event that the Certificate of Free Sale (CFS) or Certificate of Pharmaceutical Product (CPP), or other equivalent documents as referred to in section (5) point c originates from a country that is not bound to the convention of legalization requirement elimination for foreign public documents, Certificate of Free Sale (CFS) or Certificate of Pharmaceutical Product (CPP), or other equivalent documents must be legalized by the Indonesian Embassy/Consulate General of the Republic of Indonesia in that country.

(8) Pharmaceutical Industry that manufactures License-based Health Supplements with the Composition of non-drug class substances, apart from having to fulfill the provisions as referred to in section (5), must also have an approval for sharing drug manufacturing facilities with Health Supplements in accordance with the dosage type and form for which Registration will be submitted.

(9) The License agreement document as referred to in section (5) point b must at least contain the following information:
   a. validity period of the License; and
   b. product name, packaging unit, and License-based manufactured Health Supplement Formula.

(10) The requirements as referred to in section (5) point c are exempted for the Licensor originating from local research agency holding the formula and technology.

(11) The Licensee is obligated to be responsible for the safety, efficacy, and quality of License-based manufactured Health Supplements.

Paragraph 2
Export Registration

Article 31

(1) Export Registration application as referred to in Article 21 point b is submitted by the Business Actors.

(2) The Business Actors as referred to in section (1) are in the form of Pharmaceutical Industry, IOT, UKOT, Food Industry, or business entity in the field of Health Supplement marketing.

(3) Pharmaceutical Industry, IOT, UKOT, or Food Industry as referred to in section (2) must have Good Manufacturing Practice certificate/Good Manufacturing Practice application permit in accordance with the dosage type and form that will be exported, which includes:
   a. CPOB Certificate;
   b. CPOTB Certificate; or
   c. CPPOB Application Permit and the approval to manufacture Health Supplements in the food manufacturing facilities.

(4) Pharmaceutical Industry that manufactures exported

Health Supplements with the Composition of non-drug class substances, apart from having to fulfill the provisions as referred to in section (3), must also have an approval for sharing drug manufacturing facilities with Health Supplements in accordance with the dosage type and form for which Registration will be submitted.

Article 32

(1) Health Supplements submitted through export Registration as referred to in Article 31 must meet the following provisions of:
   a. safety, efficacy, and quality aspects; and
   b. being manufactured with the implementation of Good Manufacturing Practice proven by a certificate/an application permit.
(2) In the event that the provisions as referred to in section (1) point a has differences with safety, efficacy, and quality aspects applied in Indonesia, the Business Actor must attach a document in the form of a certificate stating that the exported Health Supplements have fulfilled the safety, efficacy, and quality aspects from the export destination country.

Article 33

The business entity in the field of Health Supplement marketing as referred to in Article 31 section (2) must meet the following requirements:
a. Taxpayer Identification Number (NPWP);
b. manufacturing contract agreement documents with the following conditions:
   1. Pharmaceutical Industry, IOT, or UKOT have obtained Good Manufacturing Practice certificates in accordance with the dosage type and form for which Registration will be submitted; or
   2. Food Industry has obtained CPPOB Application Permit in accordance with the dosage form for which Registration will be submitted and the approval document to manufacture Health Supplements in the processed food manufacturing facility.
c. has business entity recommendation in the field of marketing which has a contract for the manufacture of the Health Supplements as the Marketing Authorization Holder of Health Supplements, with the following requirements:
   1. has a pharmacist in charge, proven by a duly-stamped statement letter.
   2. has storage facilities in accordance with the provisions of legislation; and
   3. has a quality testing laboratory in accordance with Regulation of Indonesian Food and Drug Authority that regulates CPOTB.

Article 34

Exported Health Supplements are prohibited to be marketed in the territory of Indonesia.

Paragraph 3
Import Registration

Article 35

(1) Import Registration application as referred to in Article 21 point c is submitted by the Business Actor.
(2) The Business Actor as referred to in section (1) is an Importer.

Article 36

(1) The Importer as referred to in Article 35 section (2) must meet the following required documents:
    a. Taxpayer Identification Number (NPWP);
    b. an appointment letter of agency and rights to submit a Registration from the manufacturer/Principal of country of origin which remains valid for a minimum period of 3 (three) years at the Registration date, written in Indonesian language and/or English, and at least includes the following information:
        1. name and address of manufacturer/Principal of the country of origin;
        2. name of Importer;
        3. brand and/or name and packaging size of the product;
        4. publication date;
        5. validity period of the agency appointment;
        6. the right to carry out a Registration, importation, and distribution from the manufacturer/Principal of the country of origin; and
        7. name and signature of the director/manufacturing head/Principal of the country of origin.
    c. Certificate of Free Sale (CFS) or Certificate of Pharmaceutical Product (CPP), or other equivalent documents issued by the government authority in the country of origin or other institutions appointed by the government of the country of origin proven by the attachment of appointment letter;
    d. Good Manufacturing Practice certificate or other documents equivalent with Good Manufacturing Practice certificate applicable in Indonesia, with the following conditions:
        1. in accordance with the imported dosage form;
        2. has a validity period of at least 1 (one) year before the certificate expires; and
        3. issued by the government authority in the country of origin, or issued by other institutions appointed by the government of the country of origin proven by appointment letter from the government authority in the country of origin.
(2) In the event that the Certificate of Free Sale (CFS) or Certificate of Pharmaceutical Product (CPP), or other equivalent documents as referred to in section (1) point c, and/or Good Manufacturing Practice certificate or

equivalent documents as referred to in section (1) point d point 3 originates from a country that is bound to the convention of legalization requirement elimination for foreign public documents, Certificate of Free Sale (CFS) or Certificate of Pharmaceutical Product (CPP), or other equivalent documents, and/or Good Manufacturing Practice certificate or equivalent documents must be legalized with apostille by the authorized official in the country of origin.

(3) In the event that the Certificate of Free Sale (CFS) or Certificate of Pharmaceutical Product (CPP), or other equivalent documents as referred to in section (1) point c, and/or Good Manufacturing Practice certificate or equivalent documents as referred to in section (1) point d point 3 originates from a country that is not bound to the convention of legalization requirement elimination for foreign public documents, Certificate of Free Sale (CFS) or Certificate of Pharmaceutical Product (CPP), or other equivalent documents must be legalized by the Indonesian Embassy/Consulate General of the Republic of Indonesia in that country.

(4) In the event that the Good Manufacturing Practice certificate as referred to in section (1) point d does not include a validity period, the Importer must attach the following documents:
   a. inspection result documents for the last 2 (two) years and/or documents proving the implementation of Good Manufacturing Practice issued by the government authority in the country of origin; or
   b. Good Manufacturing Practice certificate issued not later than 2 (two) years before the Registration date.

(5) The Officer may carry out a local inspection regarding compliance with the requirements and/or provisions of Good Manufacturing Practice as referred to in section (1) point d.

(6) In the event that the Good Manufacturing Practice certificate as referred to in section (1) point d is in the form of Good Manufacturing Practice in Processed Food sector, the importer must attach the following documents:
   a. Site Master File (SMF) from the manufacturer in the country of origin; and
   b. equivalence assessment application for Good Manufacturing Practice to be evaluated by the Indonesian FDA.

(7) In accordance with the evaluation as referred to in section (6) point b, the Indonesian FDA issues a decision in the form of:
   a. approval; or
   b. rejection.

(8) The decision in the form of rejection as referred to in section (7) point b is issued if the following findings exist during the evaluation:
   a. documents submitted for the purpose of equivalence assessment application for Good Manufacturing Practice are proven to be falsified or legally invalid; and/or

b. non-compliance with Good Manufacturing Practice applicable in Indonesia.

(9) The import registration as referred to in section (1) may be submitted in the form of:
a. Bulk Products; or
b. finished products.

Article 37

(1) The Importer that conducts an import Registration in the form of Bulk Products as referred to in Article 36 section (9) point a must meet the following provisions:
a. the Pharmaceutical Industry must have a CPOB Certificate;
b. the IOT and/or the UKOT must have a CPOTB Certificate;
c. the Food Industry must have a CPPOB Application Permit and an approval to manufacture the Health Supplements in food production facilities; and
d. the business entity in the marketing sector that has obtained a recommendation of business entity in the field of marketing with the manufacturing contract Health Supplements.

(2) Good Manufacturing Practice certificate/CPPOB Application Permit as referred to in section (1) is in accordance with dosage type and form for which Registration will be submitted.

(3) In the event that the import Registration in the form of Bulk Products as referred to in section (1) is submitted by a business entity in the field of marketing, it must attach a copy of the cooperation agreement document with an industry that has a Good Manufacturing Practice certificate in accordance with the imported dosage form.

(4) Good Manufacturing Practice certificate as referred to in section (3) includes:
a. CPOB Certificate;
b. CPOTB Certificate; or
c. CPPOB Application Permit and an approval to manufacture Health Supplements in food manufacturing facilities.

(5) Pharmaceutical Industry as referred to in section (1) point a or Pharmaceutical Industry that receives the cooperation regarding imported Health Supplement packaging with the Composition of non-drug class substances from the business entity in the field of marketing as referred to in section (3) must have an approval for sharing drug manufacturing facilities with Health Supplements in accordance with the dosage type and form for which Registration will be submitted.

(6) In order to obtain a business entity recommendation in the field of marketing which has a contract for the manufacture of Health Supplements as referred to in section (1) point d, the business entity in the field of marketing must meet the following requirements of:
a. having a pharmacist in charge, proven by a duly-stamped statement letter.

b. having storage facilities in accordance with the provisions of legislation; and
c. having a quality testing laboratory in accordance with Regulation of the Indonesian Food and Drug Authority that regulates CPOTB.

Article 38

In the event that the importation of Health Supplements in the form of finished products as referred to in Article 36 section (9) point b into the territory of Indonesia is carried out by the manufacturing Importer, it is only allowed in the dosage form outside his or her manufacturing facilities in accordance with Good Manufacturing Practice certificate/Good Manufacturing Practice application permit and the approval to manufacture Health Supplements in processed food production facilities.

Article 39

(1) In the event that imported Health Supplements are imported into the territory of Indonesia in the form of finished products, the Labeling must be included when entering the territory of Indonesia.
(2) The Labeling as referred to in section (1) must be in accordance with the information and/or description in the statement letter of Registration approval that has been approved by the Indonesian FDA.

Article 40

(1) In addition to fulfilling the requirements as referred to in Article 36 section (1), the Importer must also submit the following technical documents:
a. methods and results of quality testing of raw materials and finished products;
b. results of quality testing of finished products from accredited laboratories in Indonesia or industrial laboratories in Indonesia that have a Good Manufacturing Practice certificate with a maximum validity period of 1 (one) year after being issued by the laboratory;
c. results of toxicity tests, pharmacodynamic tests, and/or clinical trials;
d. samples of original products, packaging and Labeling marketed in the country of origin;
e. Importer recommendations for the fulfillment of requirements for distribution facilities for imported Health Supplements as proof that the Importer's distribution facilities have implemented good storage and dispatch methods in accordance with the provisions of legislation;
f. list and addresses of all product storage facilities used; and
g. duly stamped statement letter confirming the existence of the pharmacist in charge.
(2) If the safety profile verification of the Health Supplements is required at the time of Registration, the Importer must attach a toxicity test as referred to in section (1) point c.
(3) If the efficacy profile verification of the Health Supplements is required at the time of Registration, the Importer must attach the results of the pharmacodynamic test as referred

to in section (1) point c.

(4) If the efficacy and/or safety profile verification of the Health Supplements are required at the time of Registration, the Importer must attach a clinical trial as referred to in section (1) point c to the Indonesian population.

(5) The distribution facilities as referred to in section (1) point e is audited by the Indonesian FDA based on the application submitted by the Importer.

(6) Requests for facility audits as referred to in section (5) are submitted by requesting distribution facility inspections to the Indonesian FDA.

(7) The Inspection of distribution facilities as referred to in section (6) is carried out to obtain a recommendation as an Importer.

(8) Recommendation as an Importer as referred to in section (7) is the requirement that must be fulfilled by the Importer when submitting an account registration application and product Registration.

(9) The Importer as referred to in Article 35 section (2) is obligated to submit any changes and additions to distribution facilities to the Indonesian FDA.

Article 41

(1) The Officer may carry out an audit of storage facilities as referred to in Article 40 section (1) point f.

(2) The audit as referred to in section (1) is carried out before the Business Actors submit the account registration application documents and product Registration documents.

Article 42

The appointment of an agent and the right to submit a Registration as referred to in Article 36 section (1) point b with the same product name and Formula and same efficacy from the same overseas manufacturer, can only be given to 1 (one) Importer in the field of Health Supplement.

Article 43

(1) In the event that the agency appointment letter for imported Health Supplements is terminated before the expiration of the validity period of the agency appointment letter, the Registration applicant appointed by the manufacturer or Principal of the country of origin must attach the following documents:
   a. a copy of the agency appointment document between the Registration applicant and the manufacturer or Principal of the country of origin by showing the original document; and
   b. agency clean break letter between the previous Importer and the manufacturer or Principal of the country of origin is endorsed before a notary.

(2) The Indonesian FDA may ask for a clarification to the previous Importer and/or manufacturer or Principal of the country of origin regarding the documents as referred to in section (1).

(3) The clarification as referred to in section (2) must be provided by the previous Importer within a maximum period of 3 (three) months from the sent date of the letter.
(4) If within the time period as referred to in section (3) the clarification from the Importer as referred to in section (2) is not received by the Indonesian FDA, then the Indonesian FDA may proceed the Registration application and revoke the Marketing Authorization previously held by the Importer.
(5) In the event that there is an objection from the previous Importer regarding the validity of the documents in section (1), the Indonesian FDA may postpone the granting of the Marketing Authorization to the Registration applicant until a complete settlement has been made by the parties.
(6) In the event that it is notified that the agency appointment period of the previous Importer has ended, the Indonesian FDA may follow up on the Registration application from the Registration applicant and revoke the Marketing Authorization obtained by the previous Importer.

Article 44

The Importer is obligated to be responsible for the safety, efficacy and quality of imported Health Supplements.

Article 45

(1) The imported Health Supplements submitted for Registration and manufactured under overseas contract must meet the following conditions:
    a. the technology and manufacturing facilities applied have not been obtained by an industry in Indonesia; or
    b. Health Supplements that are centrally manufactured overseas by multinational industries that have industries in Indonesia with a balance of export and import activities.
(2) The imported Health Supplements as referred to in section (1) must meet the following requirements of:
    a. having obtained a justification document that Health Supplements cannot be manufactured in Indonesia; and
    b. using raw materials or combination of raw materials with well-known safety and efficacy profiles and which have already had similar products registered in Indonesia.

Article 46

(1) The Registration of Health Supplements as referred to in Article 45 is carried out by the Business Actors in the form of Pharmaceutical Industry and IOT.
(2) The Contract Giver of Health Supplement manufacturing as referred to in Article 45 must have:
    a. CPOB Certificate or CPOTB Certificate; and
    b. contract manufacturing agreement document.
(3) The Contract Acceptor of Health Supplement manufacturing as referred to in Article 45 must have:

a. Good Manufacturing Practice certificate in accordance with dosage form of which the Registration will be submitted; and
b. inspection result document for the last 2 (two) years.

(4) The contract manufacturing agreement document as referred to in section (2) point b must at least contain the following data and/or information:
a. validity period of the contract manufacturing agreement;
b. product name and Formula of Health Supplements being contracted;
c. part of or whole of the manufacturing stages carried out by the Contract Acceptor; and
d. assignment of obligations and responsibilities of the parties by considering the Good Manufacturing Practice aspects as regulated in CPOB or CPOTB.

(5) Good Manufacturing Practice certificate as referred to in section (3) point a must meet the following provisions of:
a. having a validity period of at least 1 (one) year before the certificate expires; and
b. being issued by the government authority in the country of origin, or issued by another institution appointed by the government of the country of origin and proven by a certificate from the government authority in the country of origin.

(6) In the event that the Good Manufacturing Practice certificate as referred to in section (5) point b originates from a country that is bound to the convention of legalization requirement elimination for foreign public documents, the Good Manufacturing Practice certificate must be legalized with apostille by the authorized official in the country of origin.

(7) In the event that the Good Manufacturing Practice certificate as referred to in section (5) point b originates from a country that is not bound to the convention of legalization requirement elimination for foreign public documents, Good Manufacturing Practice certificate must be legalized by the Indonesian Embassy/Consulate General of the Republic of Indonesia in that country.

Article 47

(1) The imported Health Supplements as referred to in Article 45 section (1) must be gradually subjected to technology transfer to be manufactured locally.

(2) Technology transfer as referred to in section (1) can be in the form of transfer of knowledge/ability in the field of:
a. product development;
b. procedures and methods/processes of manufacturing; and/or
c. quality control.

(3) The technology transfer as referred to in section (1) may be given to representative of the overseas pharmaceutical industry in Indonesia or other Pharmaceutical Industries in Indonesia based on an agreement between the holder and recipient of the technology.

Paragraph 4
New Registration, Variation Registration, and Renewal Registration

Article 48

The Registration as referred to in Article 21 may be carried out through:

a. new Registration;
b. variation Registration; and
c. renewal Registration.

Article 49

The New Registration as referred to in Article 48 point a consists of:

a. local New Registration, which consists of:
    1. category 1 (one) for single active ingredient in the form of vitamins or minerals which is well-known safety and efficacy profiles;
    2. category 2 (two) for single active ingredient other than vitamins and minerals or combinations which is well-known safety and efficacy profiles;
    3. category 3 (three) for:
        a. new single active ingredient or combinations;
        b. new posology;
        c. new claim;
        d. new dosage form; or
        e. unknown safety and efficacy profiles.
b. Import New Registration, category 4.

Article 50

(1) The Variation Registration as referred to in Article 48 point b consists of:
    a. Minor Variation Registration with Notification;
    b. Minor Variation Registration with Approval; and
    c. Major Variation Registration.
(2) The Minor Variation Registration with Notification as referred to in section (1) point a is carried out through a do and tell mechanism and then submits a report not later than 6 (six) months after the change.
(3) The Minor Variation Registration with Notification as referred to in section (1) point a is the Variation Registration for certain aspects that do not affect the safety, efficacy and/or quality of Health Supplements and do not change the information on the Labeling and Marketing Authorization.
(4) In the event that the reported changes to the Minor Variation Registration with Notification as referred to in section (2) do not meet the provisions as referred to in section (3), the Minor Variation Registration with Notification is canceled and the Business Actors must submit a Registration in accordance with the specified Variation Registration category.

(5) The Variation Registration as referred to in section (1) is set out in Annex II as an integral part of this Authority Regulation.

Article 51

(1) Renewal Registration as referred to in Article 48 point c is a Renewal Registration that may be carried out:
   a. without changes; and
   b. with changes.
(2) The changes as referred to in section (1) point b which can be submitted simultaneously with Renewal Registration are minor changes except for changes to bundle packaging or special packaging.
(3) Minor changes as referred to in section (2) are set out in Annex II as an integral part of this Authority Regulation.

Part Three
Registration Procedures

Paragraph 1
Account Registration

Article 52

(1) The Business Actor must submit a registration of company account before submitting a Registration application.
(2) The company account registration as referred to in section (1) aims to obtain a username and password.
(3) The account registration as referred to in section (1) is carried out through the official website of the Indonesian FDA Registration service.

Article 53

(1) The account registration as referred to in Article 52 section (1) is carried out by filling in the data through the official website of the Indonesian FDA Registration service.
(2) The Indonesian FDA verifies the account registration as referred to in section (1) using a time to respond mechanism which is carried out within a maximum period of 10 (ten) Days from the time the Indonesian FDA receives a copy of the supporting documents for account registration.
(3) In the event that verification of the validity of the supporting documents for account registration as referred to in section (2) is required, the Business Actor must show the original documents and submit copies of the supporting documents for account registration to the Officer.
(4) In the event that based on the verification results as referred to in section (2) the supporting documents for account registration are declared complete and correct, the Business Actor receives a username and password.

Article 54

(1) The username and password as referred to in Article 53 section (4) are confidential data of the company.
(2) The company is responsible for the inappropriate use of username and password as referred to in section (1).

Article 55

(1) The account registration as referred to in Article 52 and Article 53 is only carried out 1 (one) time as long as there is no change in the Business Actor's data.
(2) In the event that there are changes in the data as referred to in section (1), the Business Actor must:
    a. submit a notification of data changes; or
    b. apply for a new account registration.

Paragraph 2
Registration Document

Article 56

The Registration documents are confidential documents that are restricted to be used only for evaluation purposes by authorized Officers.

Article 57

(1) Registration documents as referred to in Article 56 include the following documents:
    a. administrative documents;
    b. safety, efficacy, and quality documents; and
    c. Labeling documents.
(2) Registration documents as referred to in section (1) may use Indonesian language and/or English.
(3) Labeling documents as referred to in section (1) point c must be supported by a packaging design that will be marketed.
(4) The minimum information that must be included by the Business Actor in the packaging design as referred to in section (3) is in accordance with the details and/or information as referred to in Article 11 section (4).

Paragraph 3
Application Submission of New Registration

Article 58

(1) New Registration Stages as referred to in Article 49 consist of:
    a. pre-Registration; and
    b. Registration.
(2) Pre-Registration Stages as referred to in section (1) point a includes:
    a. administrative document checking and assessment;
    b. Formula data checking;
    c. category establishment; and
    d. Registration fee establishment.
(3) Registration Stages as referred to in section (1) point b include checking and assessment activities of administrative safety, efficacy, quality, and Labeling documents.

Article 59

(1) The Officer carries out an evaluation at the pre-Registration

stages as referred to in Article 58 section (1) point a.

(2) The evaluation of the pre-Registration stages as referred to in section (1) is carried out not later than 15 (fifteen) Days from the time the pre-Registration application is received by the Indonesian FDA.

(3) Exempted from the provisions as referred to in section (2), the evaluation of the Category I pre-Registration stage is carried out not later than 10 (ten) Days from the time the pre-Registration application is received by the Indonesian FDA.

Article 60

The decision upon the evaluation during pre-Registration stages as referred to in Article 59 is in the form of:

a. an approval; or
b. a rejection.

Article 61

(1) The approval at the pre-Registration stages as referred to in Article 60 point a is valid not later than 20 (twenty) Days from the issuance date.

(2) The decision as referred to in section (1) becomes the basis for the Registration stage as referred to in Article 58 section (1) point b.

(3) In the event that an application at the pre-Registration stages is accepted, the Business Actor must submit the complete and correct Registration documents in accordance with the period as referred to in section (1).

(4) In the event that the Business Actor is unable to submit the Registration documents in accordance with the period as referred to in section (1), the pre-Registration application is deemed to be canceled and the fees paid cannot be refunded.

Article 62

(1) Administrative, safety, efficacy, quality, and Labeling documents for Registration stages as referred to in Article 58 section (1) point b include:
   a. a decision letter on the pre-Registration evaluation results as referred to in Article 60 point a; and
   b. Registration documents as set out in Annex III as an integral part of this Authority Regulation.

(2) Administrative, safety, efficacy, quality, and Labeling documents as referred to in section (1) are Registration documents that must be prepared to be uploaded and/or saved by the Business Actors.

(3) The Officer may verify the Registration documents as referred to in section (2).

Article 63

A Registration payment order is issued after the Business Actor completes the Registration documents as referred to in Article 62.

Paragraph 4
Application Submission of Variation Registration

Article 64

(1) Application submission of Variation Registration is conducted by the Business Actor by attaching Variation Registration documents in accordance with the submitted changes.
(2) The Variation Registration Documents as referred to in section (1) are set out in Annex IV as an integral part of this Authority Regulation.

Paragraph 5
Application Submission of Renewal Registration

Article 65

(1) In the event that the validity period of the Marketing Authorization will expire and Health Supplement will still be marketed, the Business Actor is obligated to submit an application for Renewal Registration to extend the validity period of the Marketing Authorization.
(2) The Business Actor who applies for the Renewal Registration as referred to in section (1) must apply with the following conditions:
    a. no sooner than 180 (one hundred and eighty) calendar days before the validity period of the Marketing Authorization expires; and
    b. not later than 1 (one) calendar day before the validity period of the Marketing Authorization expires.

Article 66

(1) The Business Actor applying for Renewal Registration without changes as referred to in Article 51 section (1) point a, must attach the following documents:
    a. an approval of the Marketing Authorization and Labeling which has been approved by the Indonesian FDA.
    b. product Formula;
    c. a statement letter that the product is still being manufactured and marketed by stating the last batch number manufactured;
    d. last import certificate for imported Health Supplements;
    e. agency appointment letter and right to submit a Registration from the industry in the country of origin which is still valid for imported Health Supplements.
    f. long-term stability test results (real time)/post-marketing stability test results up to the proposed shelf life.
    g. a Good Manufacturing Practice certificate which is still valid or a Good Manufacturing Practice certificate which is issued not later than 2 (two) years before the Registration date and/or documents resulting from inspections for the last 2 (two) years and/or documents as the evidence of the implementation of

Good Manufacturing Practice issued by the government authority in the country of origin; and

h. a cooperation agreement which is still valid, for products manufactured based on the contract.

(2) The agency appointment letter as referred to in section (1) point e must at least contain:
   a. name and address of manufacturer/Principal of the country of origin;
   b. name of Importer;
   c. brand and/or name and packaging size of the product;
   d. issuance date;
   e. validity period of agency appointment;
   f. the right to submit a Registration, an importation, and a distribution from the manufacturer/Principal of the country of origin; and
   g. name and signature of the director/leading manufacturer/Principal of the country of origin.

(3) In the event that the Good Manufacturing Practice certificate as referred to in section (1) point g is a CPOB Certificate, the Pharmaceutical Industry which manufactures Health Supplements with the composition of non-drug class ingredients, must also have approval for sharing drug manufacturing facilities with Health Supplements in accordance with the dosage type and form for which the Registration will be submitted.

(4) In the event that the Good Manufacturing Practice certificate as referred to in section (1) point g is in the form of a CPPOB Application Permit, the Food Industry must attach the approval to manufacture Health Supplements in food facilities.

(5) In addition to having to attach the documents as referred to in section (1), the Business Actor must also attach the approval letter of variation and the latest Labeling that has been approved by the Indonesian FDA if they have obtained an approval in the previous Variation Registration.

(6) In the event that an application for Renewal Registration is submitted by an Importer, apart from having to attach the documents as referred to in section (1), it must also be supported by the latest recommendation of Health Supplements Importer.

(7) In the event that the application for Renewal Registration is submitted by a business entity in the field of marketing, in addition to having to attach the documents as referred to in section (1), it must also be supported by a the latest recommendation of the business entity in the field of marketing which has a manufacturing contract of Health Supplements as Marketing Authorization Holder.

Article 67

The Business Actor in applying for Renewal Registration accompanied by changes as referred to in Article 51 section (1) point b must attach the following documents:

a. documents as referred to in Article 66; and

b. Variation Registration documents in accordance with the type of changes submitted as set out in Annex IV as an integral part of this Authority Regulation.

Article 68

(1) The Marketing Authorization Number is not valid if the Business Actors does not submit a Renewal Registration in accordance with the provisions as referred to in Article 65 to Article 67 for Health Supplements with expired Marketing Authorization.

(2) In the event that the Marketing Authorization has expired and the Business Actor does not submit a Renewal Registration in accordance with the provisions as referred to in Article 65 to Article 67, the Marketing Authorization Number becomes invalid and the Business Actor must submit an application for a New Registration in accordance with the provisions as referred to in Article 49.

Paragraph 6
Priority Service

Article 69

(1) The Business Actor who submits a Registration can be provided priority services in the form of the issuance acceleration of Marketing Authorization.

(2) The Priority Service as referred to in section (1) is provided to the Business Actors that meets the following criteria:
   a. The Business Actors in the field of Health Supplement who have been registered with the Indonesian FDA and have already obtained a Marketing Authorization Number;
   b. Priority service registration only applies to local new product registration;
   c. they have never been involved in criminal acts in the field of food and drugs;
   d. they have complete administrative documents without any falsified documents, and have extended the Good Manufacturing Practice certificate;
   e. they do not use a service agent in applying for the Marketing Authorization;
   f. they have never been received a warning letter related to violations and/or listed in a public warning regarding cases of illegal Health Supplement chemical substances for the last 2 (two) years;
   g. they have never been received a stern warning letter other than the warning letter as referred to in point f for the last 2 (two) years; and
   h. the priority is provided to companies that have already had a side effect reporting system.

(3) Procedures for priority services as referred to in section (1) are set out in Annex V as an integral part of this Authority Regulation.

Part Four
Responsibilities

Paragraph 1
Responsibilities of Business Actors

Article 70

(1) The Business Actor is obligated to be responsible for:
   a. completeness of the submitted registration documents;
   b. the correctness and validity of all information contained in the Registration documents;
   c. guarantee for the safety, efficacy, and quality of products submitted for Registration, manufactured and marketed;
   d. guarantee that there are no medicinal chemicals and/or prohibited substances in Health Supplement products which are manufactured and/or marketed;
   e. data correction and submission, and product information required during the Registration process or when the product is already in market;
   f. changes in product data and information that are in the process of submitting a Registration application or have already obtained a Marketing Authorization number; and
   g. provision of reference standards in accordance with the needs in the supervision context.

(2) The Business Actor is obligated to manufacture or import Health Supplements that have already obtained a Marketing Authorization within a time limit of not later than 1 (one) year from the approval date of the Marketing Authorization.

(3) The responsibilities of the Business Actor as referred to in section (1) must be stated in writing in a statement letter using the format as set out in Annex VI as an integral part of this Authority Regulation.

(4) Company commissioners, directors and/or principals of the Business Actor must never be legally proven and/or not be involved in criminal acts in the field of food and drugs.

Paragraph 2
Responsibilities of Marketing Authorization Holder of Health Supplements

Article 71

(1) The Marketing Authorization Holder of Health Supplements is obligated to monitor the safety, efficacy and quality of marketed products.

(2) The provisions as referred to in section (1) can be implemented by monitoring the storage of retention samples for each batch and conducting supervision on marketed products.

(3) Storage of retention samples as referred to in section (2) is carried out in sufficient quantities and stored for a minimum of 1 (one) year after the expiry date.

(4) In the event of a nonconformity regarding the safety, efficacy and quality of the product, the Marketing

Authorization number Holder is obligated to recall the marketed product and report it to the Chairperson of the Authority.

(5) Further provisions regarding monitoring, recall of marketed product, and reporting as referred to in section (1) and section (4) are regulated by Regulation of the Indonesian Food and Drug Authority.

Article 72

(1) Monitoring of the safety as referred to in Article 71 section (1) is in the form of complaints regarding cases of adverse events of Health Supplements as well as other safety aspects of Health Supplements during the circulation.

(2) The Monitoring as referred to in section (1) is carried out by the Marketing Authorization Holder in the form of an obligation to implement a mechanism for monitoring adverse events of Health Supplements, as well as monitoring other safety aspects of Health Supplements during circulation to ensure the safety of products in circulation.

(3) The monitoring results of adverse events of Health Supplements as referred to in section (1) as well as the monitoring results of other security aspects of Health Supplements during circulation is required be reported by the Marketing Authorization Holder to the Chairperson of the Authority through an adverse event monitoring mechanism of Health Supplements.

(4) The implementation of the monitoring mechanism for adverse events of Health Supplements as referred to in section (2) is conducted in accordance with the Regulation of the Indonesian Food and Drug Authority which regulates the implementation of the monitoring mechanism for adverse events for traditional medicines, quasi-drugs, and Health Supplements.

Part Five
Evaluation and Issuance of Decisions

Paragraph 1
General

Article 73

(1) The Indonesian FDA conducts an evaluation on every Registration application that has been received completely.

(2) The evaluation as referred to in section (1) is conducted through a checking and assessment of the suitability of the Registration documents towards fulfillment of standards and/or requirements for safety, efficacy, and quality.

Paragraph 2
Evaluation

Article 74

(1) The evaluation as referred to in Article 73 is conducted after the following conditions:

a. the receipt of complete Registration documents; and
b. the Business Actor has settled the payment according to the value as stated in the payment order notification letter not later than 7 calendar days from the date of the notification letter.

(2) The evaluation as referred in section (1) is conducted using a time to respond mechanism.

(3) The decision on the evaluation results as referred to in section (1) is issued with the following conditions:
a. Category 1 (one) maximum 15 (fifteen) Days;
b. Category 2 (two) maximum 30 (thirty) Days;
c. Category 3 (three) maximum 50 (fifty) Days;
d. Category 4 (four) maximum 50 (fifty) Days;
e. Minor Variation Registration with Notification is issued for a maximum period of 5 (five) Days;
f. Minor Variation Registration with Approval is issued with a maximum period of 7 (seven) Days;
g. Major Variation Registration is issued for a maximum period of 30 (thirty) Days;
h. Renewal Registration without changes is issued for a maximum period of 10 (ten) Days;
i. Renewal Registration with changes is issued for a maximum period of 30 (thirty) Days; and
j. Export Registration is issued for a maximum period of 3 (three) Days.

Article 75

(1) In the event that the evaluation results as referred to in Article 74 of Health Supplements do not meet the provisions and/or requirements for Registration, the Indonesian FDA may issue requests for corrections and/or additional data to the Business Actor.

(2) Requests for additional data as referred to in section (1) are issued through the official website of the Indonesian FDA Registration service.

(3) The time to respond evaluation mechanism as referred to in Article 74 section (2) is implemented with the following provisions:
a. the calculation of the evaluation period as referred to in Article 74 section (3) is clocked off if based on the evaluation results, corrections and/or additional data are required; and
b. The calculation of the evaluation period as referred to in Article 74 section (3) is clocked on from the beginning after the Business Actor submits corrections and/or additional data.

(4) The Business Actor must submit corrections and/or additional data as referred to in section (1) not later than 60 (sixty) calendar days from the date of the letter requesting corrections and/or additional data.

(5) If corrections and/or additional data are required, the Business Actor must submit the corrections and/or additional data to the Indonesian FDA not later than 40 (forty) calendar days from date of the letter requesting corrections and/or additional data.

Article 76

In the event that the Business Actor fails to submit corrections and/or additional data in accordance with the time period as referred to in Article 75 section (4) and section (5), the Registration application is declared canceled and the fee paid will not be refunded.

Paragraph 3

Evaluation Team and National Health Supplement Evaluation Committee

Article 77

(1) The evaluation as referred to in Article 74 is conducted by the Evaluation Team on the Safety, Efficacy, and Quality of Health Supplements.
(2) In conducting the evaluation as referred to in section (1), the Evaluation Team of Safety, Efficacy, and Quality of Health Supplements may include the National Health Supplement Evaluation Committee.
(3) The National Health Supplement Evaluation Committee as referred to in section (2) provides recommendations, suggestions, responses and input on criteria, safety, efficacy, and quality for:
    a. New Registration category 3 as referred to in Article 49 point a point 3 and New Registration category 4 as referred to in Article 49 point b; and
    b. Major Variation Registration as referred to in Article 50 section (1) point c.

Article 78

(1) The Evaluation Team as referred to in Article 77 section (1) consists of Officers.
(2) The National Health Supplement Evaluation Committee as referred to in Article 77 section (2) consists of:
    a. academician;
    b. researchers;
    c. practitioners; and/or
    d. representatives of related Ministries/Institutions.
(3) The Evaluation Team and the National Health Supplement Evaluation Committee as referred to in Article 77 are regulated by a Decision of Chairperson of Authority.

Paragraph 4

Hearing

Article 79

(1) In the event that a detailed technical clarification and/or explanation is needed regarding the safety, efficacy, and quality aspects of the Registration documents, the Chairperson of the Authority can request clarification from the Applicant through a written hearing mechanism.
(2) The hearing as referred to in section (1) is conducted before the issuance of a decision of approval or rejection.

Article 80

(1) The Business Actor may submit requests for hearings through a written application submitted to the Indonesian FDA.
(2) The hearing mechanism as referred to in section (1) is conducted 1 (one) time.

Paragraph 5
Issuance of Decisions

Article 81

(1) The Chairperson of Authority issues a decision on the evaluation results of Health Supplements submitted by the Business Actor through the submission of a Registration application.
(2) The decision as referred to in section (1) is in the form of:
    a. an approval; or
    b. a rejection.

Article 82

(1) The Chairperson of Authority issues a decision in the form of an Approval as referred to in Article 81 section (2) point a if based on the evaluation results the provisions and/or requirements of the Registration are fulfilled.
(2) The Chairperson of Authority issues a decision in the form of a Rejection as referred to in Article 81 section (2) point b if based on the evaluation results the provisions and/or requirements of the Registration are not fulfilled.

Article 83

Issuance of decisions in the form of an approval or a rejection of registration as referred to in Article 81 section (2) is conducted electronically.

Article 84

(1) In the event that based on the evaluation results the Indonesian FDA issues a decision in the form of Approval for Variation Registration as referred to in Article 64 and Approval for Renewal Registration as referred to in Article 65, the Business Actor is obligated to fulfill the provisions as follows:
    a. implement the decision not later than 6 (six) months from the date the approval is issued; and
    b. report the quantity, batch number and expiry date of the last batch marketed prior to the implementation of the new agreement to the Chairperson of the Authority.
(2) Products with previous approval as referred to in section (1) can still be manufactured or imported not later than 6 (six) months since the date of the new approval is issued and if the new approval has not been implemented.

Article 85

Health Supplements with previous packaging that were manufactured or imported before the implementation of the new

approval can be marketed if the products still meet the quality requirements, unless the Formula change variations submitted in the Registration as referred to in Article 64 affect the safety aspect.

Article 86

(1) In the event that 6 (six) months after the issuance of the new approval there is remaining stock of the previous packaging, the Business Actor may submit a request to dispose this previous packaging stock.
(2) Requests for the disposal of remaining stock of previous packaging as referred to in section (1) are submitted in writing to the Indonesian FDA and supported by a justification.
(3) Concerning the application as referred to in section (1), the Indonesian FDA conducts a risk analysis based on the supervision results of products while in circulation.

Paragraph 6
Application for Appeal

Article 87

(1) In the event that the Business Actor has an objection to a decision in the form of a rejection as referred to in Article 81 section (2) point b issued by the Indonesian FDA, the Business Actor may submit an application for an appeal.
(2) The application for appeal as referred to in section (1) may be submitted by the Business Actor supported by complete new data or data that has already been submitted during Registration along with justification.
(3) The application for appeal as referred to in section (1) can only be submitted if the Registration evaluation process requires supporting evidence in the form of pre-clinical data and/or clinical data.
(4) The application for appeal as referred to in section (1) is submitted in writing by the Business Actor to the Chairperson of the Authority not later than 30 (thirty) Days from the issuance date of rejection letter .

Article 88

(1) The Business Actor may submit an application for appeal as referred to in Article 87 section (1) for 1 (one) time.
(2) The Chairperson of the Authority issues a decision regarding the application for appeal as referred to in section (1) within a maximum period of 100 (one hundred) Days after the letter of application for appeal is received.
(3) The decision as referred to in section (2) is in the form of:
    a. an approval; or
    b. a rejection.

Article 89

(1) The Business Actor can submit a new Registration application if based on the evaluation, the Chairperson of the Authority issues a decision in the form of:
    a. a rejection of the Registration application as referred to

in Article 81 section (2) point b submitted by the Business Actor; or

b. a rejection of the application for appeal as referred to in Article 88 section (3) point b submitted by the Business Actor.

(2) The new Registration application as referred to in section (1) must be submitted by the Business Actor and be supported with new supporting data.

Part Six
Health Supplements that Cannot Be Registered

Article 90

(1) Health Supplements which are manufactured, imported and/or marketed in territory of Indonesia are prohibited from the following conditions:
   a. being presented in injection, eye drop and topical dosage forms;
   b. containing vitamins, minerals, amino acids and/or other substances exceeding the maximum limits as set out in Annex VII as an integral part of this Authority Regulation;
   c. containing substances which are harmful to health based on health considerations and/or based on research as set out in Annex VIII as an integral part of this Authority Regulation;
   d. containing ethyl alcohol at a level greater than 1% (one percent) and is in the form of an oral liquid dosage form;
   e. containing drugs, medicinal chemicals, narcotics, or psychotropic substances;
   f. containing protected animals or plants in accordance with the provisions of legislation; and
   g. containing materials which do not meet standards and/or requirements for safety, efficacy and quality based on the supervision results and/or risk assessment of the Indonesian FDA.

(2) Health Supplements as referred in section (1) cannot be submitted for a Registration.

CHAPTER IV
MARKETING AUTHORIZATION VALIDATION PERIOD

Article 91

(1) Marketing Authorization is valid for a maximum of 5 (five) years insofar not contrary to the provisions of legislation.

(2) The Marketing Authorization as referred to in section (1) may be renewed through a Renewal Registration mechanism.

(3) Exempted from the provisions as referred to in section (1) are for Health Supplements submitted through import Registration based on the agency appointment letter with a validity period of less than 5 (five) years.

(4) The validity period of the Marketing Authorization as referred to in section (3) is in accordance with the validity period of the agency appointment letter.

Article 92

Health Supplements with expired Marketing Authorization and without renewal, are declared as Health Supplements without Marketing Authorization.

CHAPTER V
FEES

Article 93

(1) Business Actor who applies for Registration for the pre-Registration and Registration stages are subject to a fee as a non-tax state revenue in accordance with the provisions of legislation.
(2) In the event that the application for Registration as referred to in section (1) is deemed to be canceled or rejected, the fees paid by the Business Actor cannot be refunded.

CHAPTER VI
RE-ASSESSMENT/RE-EVALUATION

Article 94

(1) The Chairperson of the Authority may conduct a re-assessment/re-evaluation on the marketed Health Supplements.
(2) The re-assessment/re-evaluation as referred to in section (1) is conducted if based on the monitoring results, new developments regarding the safety, efficacy, and quality of the Health Supplements which affect public health and safety are discovered.
(3) Data and/or information regarding the safety criteria which affect public health and safety as referred to in section (2) can be obtained through the supervision mechanism and monitoring mechanism for adverse events of Health Supplements, and data on Health Supplement testing results.
(4) Based on the re-assessment/re-evaluation as referred to in section (1), the Chairperson of the Authority issues a decision in the form of:
    a. Labeling changes;
    b. Composition/Formula improvements; and/or
    c. the provision of usage restrictions;
(5) Apart from being able to issue a decision based on re-assessment/re-evaluation as referred to in section (4), based on the risk assessment, the Indonesian FDA may also issue a decision in the form of:
    a. recall of Health Supplements from market;
    b. Marketing Authorization suspension; and/or
    c. Marketing Authorization cancellation.
(6) The decision as referred to in section (4) and/or section (5) is submitted in writing to the Business Actor for follow-up.

Article 95

(1) The Marketing Authorization Holder of Health Supplements may apply for the return of the Marketing Authorization number to the Chairperson of the Authority accompanied by justification for the return of the Marketing Authorization number.
(2) Regarding the application for the restoration of the Marketing Authorization number as referred to in section (1), the Chairperson of the Authority issues a decision to cancel the Marketing Authorization number.

CHAPTER VII
FORCE MAJEURE

Article 96

(1) In the event that a force majeure occurs during the Registration process, the submission of the application and/or issuance of the Registration decision can be performed manually.
(2) The force majeure as referred to in section (1) can be in the form of a malfunctioning electronic system, riots, fire, and/or natural disasters.
(3) In the event that the force majeure occurs as referred to in section (2), the calculation of the period as referred to in Article 74 section (3) is clocked off.

CHAPTER VIII
ADVERTISEMENT

Article 97

(1) Health Supplements that have obtained a Marketing Authorization and an Advertisement approval from the Chairperson of the Authority can be promoted through Advertisements.
(2) Provisions regarding Advertisements for Health Supplements as referred to in section (1) are conducted in accordance with the Regulations of the Indonesian Food and Drug Authority that regulate advertising supervision of traditional medicines, quasi-drugs and Health Supplements.

CHAPTER IX
SANCTIONS

Article 98

(1) The Business Actor and/or Marketing Authorization Holder that violates the provisions in Article 2, Article 9, Article 18 section (1), Article 18 section (2), Article 29 section (1), Article 29 section (3), Article 29 section (4), Article 30 section (11), Article 34, Article 40 section (7), Article 44, Article 65 section (1), Article 70 section (1), Article 70 section (2), Article 71 section (1), Article 71 section (4), Article 72 section (3), Article 84 section (1), and/or Article 90 are subject to administrative sanctions.

(2) Administrative sanctions as referred to in section (1) are in the form of:
   a. cancellation/revocation of Marketing Authorization number;
   b. suspension of Marketing Authorization number; and/or
   c. closure of online access for registration applications for a maximum of 1 (one) year.

(3) Administrative sanctions as referred to in section (1) are imposed by the Chairperson of the Authority.

Article 99

(1) Administrative sanctions in the form of cancellation/revocation of the Marketing Authorization number as referred to in Article 98 section (2) point a, are imposed in the following cases:
   a. The Business Actor did not manufacture or import Health Supplements for 2 (two) consecutive years;
   b. The Business Actor did not manufacture or import Health Supplements not later than 1 (one) year from the issuance of the Marketing Authorization; and/or
   c. Good Manufacturing Practice certificate is revoked.

(2) Apart from being imposed based on the provisions as referred to in section (1), administrative sanctions in the form of cancellation/revocation of the Marketing Authorization number as referred to in Article 98 section (2) point a may also be imposed based on the recommendations from supervision results by the Indonesian FDA and/or other related agencies/institutions.

Article 100

The procedures for imposing administrative sanctions as referred to in Article 98 are conducted in accordance with Regulations of the Indonesian Food and Drug Authority which regulate follow-up to monitoring results of traditional medicines, quasi-drugs, Health Supplements, and cosmetics.

CHAPTER X
TRANSITIONAL PROVISIONS

Article 101

(1) The Business Actor that submitted applications for Registration prior to the enforcement of this Authority Regulation is still being processed based on the Regulation of of the Indonesian Food and Drug Authority Number 11 of 2020 on Criteria and Procedures for Health Supplement Registration.

(2) The Marketing Authorization that is still valid and does not meet the standards and/or requirements for safety, efficacy, and quality as regulated in this Authority Regulation, is obligated to adapt to this Authority Regulation not later than 2 (two) years from the promulgation of this Authority Regulation.

CHAPTER XI
CLOSING PROVISIONS

Article 102

At the time this Authority Regulation comes into force, Regulation of the Indonesian Food and Drug Authority Number 11 of 2020 on Criteria and Procedures for Health Supplement Registration (State Bulletin of the Republic of Indonesia of 2020 Number 610), is repealed and declared ineffective.

Article 103

At the time this Authority Regulation comes into force:

a. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.05.12.3428 of 2012 on Prohibition on Production and Marketing of Traditional Medicines and Food Supplements Containing *Pausinystalia* Yohimbe Plants (State Bulletin of the Republic of Indonesia of 2012 Number 623); and
b. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 10 of 2014 on Prohibition on Production and Marketing of Traditional Medicines and Food Supplements Containing *Coptis* sp., Berberis sp., Mahonia sp., Chelidonium majus sp., *Phellodendron* sp., *Arcangelica flava*, *Tinosporae* radix, and *Cataranthus* roseus Plants (State Bulletin of the Republic of Indonesia of 2014 Number 1070),

insofar they regulate Health Supplements, are repealed and declared ineffective.

Article 104

This Authority Regulation comes into force on the date of its promulgation.

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

Issued in Jakarta
on 22 December 2022

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

Promulgated in Jakarta
on 26 December 2022

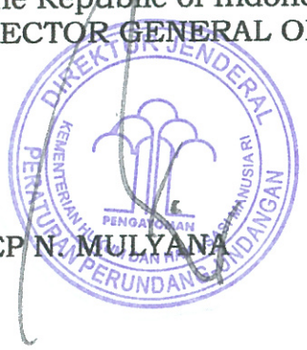
MINISTER OF LAW AND HUMAN RIGHTS
OF THE REPUBLIC OF INDONESIA,

signed

YASONNA H. LAOLY

STATE BULLETIN OF THE REPUBLIC OF INDONESIA OF 2022 NUMBER 1320

Jakarta, 6 June 2024
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,



ASEP N. MULYANA

ANNEX I TO
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 32 OF 2022 ON
CRITERIA AND PROCEDURES FOR
HEALTH SUPPLEMENT REGISTRATION

LABELING DOCUMENT

MINIMUM INFORMATION THAT MUST BE CONTAINED ON THE DESIGNS OF SECONDARY PACKAGE, ETIQUETTE/LABEL/SACHET. STRIP/BLISTER, AND BROCHURE

Information		Secondary Package	Etiquette/ Label/ Sachet	Strip/ Blister	Brochure
1.	Product name	√	√	√	√
2.	Health Supplement	√	√	-	√
3.	Dosage form	√	√	-	√
4.	Packaging size	√	√	-	√
5.	Composition in qualitative and quantitative	√	√	-	√
6.	Name and address of manufacturer (Name of city and country) *	√	√	√	√
7.	Name and address of importer (Name of city and country) *	√	√	-	√
8.	Name and address of licensor/licensee (Name of city and country) *	√	√	-	√
9.	Name and address of contract giver/ acceptor(Name of city and country) *	√	√	-	√
10.	Marketing authorization	√	√	√	√

Information		Secondary Package	Etiquette/ Label/ Sachet	Strip/ Blister	Brochure
	number				
11.	Batch number/ production code	√	√	-	-
12.	Expiry date	√	√	-	-
13.	Benefit claims	√	√	-	√
14.	Instructions of use	√	√	-	√
15.	Side effects, Warnings-Precautions, Contraindications, Drug interaction (if any)	±	±	-	√
16.	Storage conditions	√	√	-	√
17.	Specific information (e.g. related to origin of particular ingredients, alcohol content, radiation use, ingredients from GMO (Genetically Modified Organism)	√	√	-	√
18.	Information on sweeteners, colourants, preservatives, and flavourings	√	±	-	√

Notes:
√ : Information must be included
± : Information can be included or can state 'See Brochure' if the packaging cannot contain this information. If no brochure is available, this information must be included.
- : Information does not need to be included
* : Based on product status

CHAIRPERSON OF
THE INDONESIAN FOOD AND DRUG AUTHORITY

signed

PENNY K. LUKITO

ANNEX II TO
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 32 OF 2022 ON
CRITERIA AND PROCEDURES FOR
HEALTH SUPPLEMENT REGISTRATION

VARIATION REGISTRATION

A. Minor Variation Registration with Notification

Minor Variation Registration with Notification can be conducted, initially through do and tell mechanism without attaching documents and then reporting not later than 6 (six) months after the changes. Types of changes to the Minor Variation Registration with Notification are as listed in the following table:

No.	Types of Changes
1.	Changes to batch numbering system
2.	Changes to or additions of imprint bossing or other marking on tablet or changes to or addition of printing and ink on capsules
3.	Changes to the raw material analysis method that do not change quality of raw materials and finished products, in accordance with Pharmacopoeia monograph or as relevant
4.	Reduction of manufacturing sites of raw materials (active and inactive ingredients) of which have been approved
5.	Changes to manufacturer's name or address of raw materials which do not change the manufacturer's location.
6.	Changes to the raw material specifications to meet the latest Pharmacopoeia requirements, that do not change the finished product specifications
7.	Narrowing of limits of raw material/ finished product specifications
8.	Changes to secondary packaging materials that do not change the information on the label
9.	Inclusion extension of halal logo
10.	Changes to industrial permit status without changes to manufacturing location

B. Minor Variation Registration with Approval

No.	Types of Changes
1.	Changes to packaging design that do not affect safety, efficacy, and/or quality aspects of Health Supplements as well as do not change information stated in the Marketing Authorization approval include: - changes to colour of packaging design, - changes to graphic layout or product information, - changes to font types or sizes, - inclusion of or changes to company logo, - inclusion of or changes to halal logo - removal of foreign language from the label, - changes to packaging shapes and/or dimensions changes to specifications of primary packaging materials
2.	Changes to product names
3.	Changes to images
4.	Inclusion of logo/trademark
5.	Inclusion of award logo or other logos
6.	Addition of product information in English or other languages
7.	Changes to tag lines that do not affect the product efficacy
8.	Inclusion of distributors
9.	Changes to information on packaging design
10.	Changes to or addition of brochures/leaflets
11.	Changes to or addition of secondary packaging
12.	Changes to or addition of packaging size
13.	Changes to name of and/or Applicant, licensor and/or ,manufacturer without change in location (without change in ownership status)
14.	Changes to name and/or address of the Business Actor applying for Registration (office)/ licensor/ importer with change in location (without change in ownership status)
15.	Change to or addition of secondary packaging site
16.	Request for bundle packaging or specific packaging
17.	Changes to colour of capsule shells
18.	Changes to specifications of finished products to comply with compendial or the prevailing legislation
19.	Changes in analysis method of raw materials (non-compendial) that do not change specifications of raw materials and finished products
20.	Reduction or removal of active ingredients overages
21.	Scaling up/down the product batch size up to ten folds, which does not affect the reproducibility and specifications of the finished products

No.	Types of Changes
22.	Changes to/ Addition of capsule shell manufacturer that do not change specifications of capsule shells
23.	Changes to quick-release capsule shell size that do not affect the Formula, product specifications and stability
24.	Changes to the shapes or dimensions of quick-release tablets that do not change the Formula, average weight and product specifications (except dimension)
25.	Changes to analysis method of finished products that do not change the specifications of the finished product
26.	Changes to storage conditions of the product
27.	Changes to and/or additions of active ingredients manufacturer that do not change specifications of both raw materials and finished products
28.	Changes to or addition of export destination countries
29.	Changes to and/or addition of manufacturers of inactive ingredients that do not change specifications of raw materials or finished products

C. Major Variation Registration

No.	Types of Changes
1.	Changes in specifications of finished products
2.	Changes in product Formula that do not affect the safety and efficacy of the product
3.	Changes in benefit claims, tagline, and/or instruction of use
4.	Changes in type or specifications of primary packaging materials
5.	Changes in stability data
6.	Changes to or additions of manufacturing site and/or primary packaging site
7.	Changes in specifications of raw materials
8.	Increase in product batch size by more than tenfold that does not affect the reproducibility and specifications of finished product
9.	Changes in product manufacturing process that do not affect the Formulas and specifications of finished product

CHAIRPERSON OF
THE INDONESIAN FOOD AND DRUG AUTHORITY

signed

PENNY K. LUKITO

ANNEX III TO
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 32 OF 2022 ON
CRITERIA AND PROCEDURES FOR
HEALTH SUPPLEMENT REGISTRATION

COMPLETENESS OF NEW REGISTRATION DOCUMENTS OF HEALTH SUPPLEMENTS

A. PRE-REGISTRATION RESULTS (HPR/ *HASIL PRA REGISTRASI*)

B. ADMINISTRATIVE DOCUMENTS

1. Registration of Local Self-Manufacturing Health Supplements

a. Taxpayer Identification Number;

b. CPOB Certificate; CPOTB Certificate; CPPOB Application Permit and the approval to manufacture Health Supplements based on dosage forms submitted in the Registration;

c. In addition to CPOB Certificate, the Pharmaceutical Industry that manufacture Health Supplements with the Composition of non-drug class substances must also have an approval for sharing drug manufacturing facilities with Health Supplements in accordance with the dosage type and form for which Registration will be submitted.

d. Statement letter from the pharmacist as the technical person in charge.

2. Registration of Local Contract Manufacturing Health Supplements

a. Contract Giver

1) Taxpayer Identification Number;

2) CPOB Certificate, CPOTB Certificate; or CPPOB Application Permit, and the approval to manufacture Health Supplements; or has business entity recommendation in the field of marketing which

has a contract for the manufacture of Health Supplements as Marketing Authorization Holder of Health Supplements;

3) Statement letter from the pharmacist as the technical person in charge.

b. Contract Acceptor

CPOB Certificate; CPOTB Certificate; CPPOB Application Permit and the approval to manufacture Health Supplements based on dosage forms submitted being contracted;

c. Contract agreement document.

d. Pharmaceutical Industry receiving the contract, or conduct certain parts of self-manufacturing for contract-based Health Supplements with the Composition of non-drug class substances, must also have an approval for sharing drug manufacturing facilities with Health Supplements in accordance with the dosage type and form being contracted.

3. Registration of Local License-based Health Supplements

a. Proof of status as an industry in the Health Supplements sector for overseas licensors;

b. Profile of the research agency owning the Formula and technology for local or overseas licensors;

c. CPOB Certificate; CPOTB Certificate; CPPOB Application Permit and the Approval to Manufacture Health Supplements based on dosage forms for which Registration will be submitted by the Licensee;

d. In addition to CPOB Certificate, the Pharmaceutical Industry that manufacture License-based Health Supplements with the Composition of non-drug class substances must also have an approval for sharing drug manufacturing facilities with Health Supplements in accordance with the dosage type and form for which Registration will be submitted by the Licensee.

e. Statement letter from the pharmacist as the technical person in charge;

f. License agreement document;

g. Certificate of Free Sale (CFS) or Certificate of Pharmaceutical Product (CFP), or other equivalent documents which are still valid and in accordance with the provisions as referred to in Article 30.

4. Registration of Imported Health Supplements in Finished Product

a. Recommendation of Health Supplement Importer;

b. Statement letter from the pharmacist as the technical person in charge in Importer;

c. Agency appointment letter and rights to submit a Registration from the manufacturer of country of origin which is still valid for a minimum period of 3 (three) years at the Registration date;

d. Certificate of Free Sale (CFS) or Certificate of Pharmaceutical Product (CFP), or other equivalent documents which are still valid and in accordance with the provisions as referred to in Article 36;

e. Good Manufacturing Practice certificate in accordance with the dosage form imported from the government authority in the country of origin, or other documents equivalent with Good Manufacturing Practice certificate applicable in Indonesia;

f. Inspection result documents for the last 2 (two) years issued by the government authority in the country of origin for Good Manufacturing Practice certificate that does not include a validity period;

g. Contract agreement document if imported Health Supplement products are manufactured based on a contract.

5. Registration of Imported Health Supplements in Bulk

a. CPOB Certificate; CPOTB Certificate; CPPOB Application Permit and the approval to manufacture Health Supplements based on dosage forms for which Registration will be submitted;

b. In addition to CPOB Certificate, the Pharmaceutical Industry that submits imported Health Supplement Registration in the form of Bulk Products or the Pharmaceutical Industry that collaborates the packaging of imported Health Supplements with the Composition of non-drug class substances with business entity in the field of marketing must also have an approval for sharing use of drug manufacturing facilities with Health Supplements in accordance with the dosage type and form for which Registration will be submitted;

c. The recommendation of business entity in the marketing sector which has a contract for the manufacture of Health Supplements as Marketing Authorization Holder of Contract Health Supplements;

d. Cooperation agreement, if necessary;

e. Good Manufacturing Practice Certificate owned by the Manufacturer in the imported dosage form, or other documents equivalent with Good Manufacturing Practice certificate applicable in Indonesia;

f. Statement letter from the pharmacist in charge;

g. Agency appointment letter and rights to submit a registration from the industry of country of origin which is still valid for a minimum period of 3 (three) years at the registration date;

h. Certificate of Free Sale (CFS) or Certificate of Pharmaceutical Product (CFP), or other equivalent documents which are still valid and in accordance with the provisions as referred to in Article 36;

i. Inspection result documents for the last 2 (two) years issued by the government authority in the country of origin for Good Manufacturing Practice certificate that does not include a validity period;

6. Registration of Exported Products

a. CPOB Certificate; CPOTB Certificate; CPPOB Application Permit and the approval to manufacture Health Supplements based on dosage forms;;

b. In addition to CPOB Certificate, the Pharmaceutical Industry that manufacture exported Health Supplements with the Composition of non-drug class substances must also have an approval for sharing use of drug manufacturing facilities with Health Supplements in accordance with the dosage type and form for which Registration will be submitted;

c. The recommendation of business entity in the field of marketing which has a contract for the manufacture of Health Supplements, for business entity in the field of Health Supplements marketing as Marketing Authorization Holder based on contract;

d. Contract agreement document if exported Health Supplement products are manufactured based on a contract.

7. Other Requirements

a. Sample of finished products with the packaging design and label for local Health Supplements;

b. Sample of finished products with original packaging and labeling marketed in the country of origin for imported Health Supplements.

C. QUALITY DOCUMENTS

1. Formula

a. The formula for each dosage form/serving size includes the name and amount of each ingredient used, both active and inactive ingredients, along with the function of each ingredient.

b. The origins of each component of the active ingredients in the Composition.

2. Manufacturing Procedures

a. The planned quantity for one manufacturing, for example:

Capsules: 1,000,000 capsules @ 300 mg;

b. The quantity of each ingredient used for one manufacturing is expressed in units of weight or volume (kg or liters) of each ingredient;

c. Include every activity conducted from preparing raw materials to obtaining the finished product, according to the Standard Operating Procedures (SOP). All working stages conducted must be explained clearly and in details, especially for some work that require further attention;

d. Tools or machines used.

3. Source of Raw Materials

a. Write down the source of each raw material (raw material manufacturer).

b. Write down the origin of raw materials derived from animals.

c. Write down the manufacturing method of raw materials derived from animals.

4. Quality Assessment Method of Raw Materials

a. Specifications of raw materials and references used; and/or

b. Quality testing results of raw materials.

5. Packaging Specification

6. Quality Assessment Method of Finished Products

a. Specifications of finished products and reference used;

b. Testing method of finished products;

c. Quality testing results of finished products;

d. Quality testing results of finished products from accredited laboratories in Indonesia for imported Health Supplements.

7. Stability Establishment Method of Finished Products

a. The stability protocol contains, among other things: testing sample batch number, storage conditions, testing frequency, testing type, estimated quantity of testing samples.

b. Stability testing results of at least 2 batches at a temperature of 30 ± 2ºC RH 75 ± 5% until the proposed shelf life or stability testing results at a temperature of 30 ± 2ºC RH 75 ± 5% for a minimum of 6 months, accompanied by accelerated stability at a temperature of 40 ± 2º C RH 75 ± 5 % minimum 6 months and stability commitment.

The testing is conducted periodically (0, 3, 6, 9, 12, 18, 24 months, etc.). The testing type should be in accordance with the quality testing of finished products. The testing results are given in tabular form.

c. The stability conclusion based on the aforementioned observation and testing results must be notified to the person in charge of manufacturing or authorized official.

8. Acquisition Origin of Particular Ingredients

Attaching the acquisition origin of particular ingredients in accordance with applicable regulations, for example:

a. source of gelatin capsule used;

b. halal certificate of the capsules used;

c. BSE free certificate for gelatin capsules derived from cows.

D. SAFETY AND EFFICACY DOCUMENTS

1. Results of toxicity tests for products with unknown safety profile;
2. Results of pharmacodynamic tests and/or clinical trials for products with unknown efficacy profile.

E. LABELING DOCUMENTS

Attaching a Labeling design that includes information as set out in Annex I.

CHAIRPERSON OF
THE INDONESIAN FOOD AND DRUG AUTHORITY

signed

PENNY K. LUKITO

ANNEX IV TO
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 32 OF 2022 ON
CRITERIA AND PROCEDURES FOR
HEALTH SUPPLEMENT REGISTRATION

COMPLETENESS OF VARIATION REGISTRATION DOCUMENTS

A. Minor Variation Registration with Notification

No.	Types of Changes	Conditions	Required Documents
1.	Changes to the batch numbering system	-	1. Cover letter stating justification from the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Matching matrix 5. New batch numbering system
2.	Changes to or additions of imprint bossing or other marking on tablet or changes to or addition of printing and ink on capsules	1. Specifications of finished products remain unchanged (except for descriptions) 2. The ink used must meet the requirements of pharmaceutical regulations 3. New descriptions do not cause an ambiguity in the registered products.	1. Cover letter stating the submitted changes 2. Decision letter for Approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. comparison matrix 5. Design or Imprint bossing graphics or other marking on printing tablet and/or ink used on capsules

No.	Types of Changes	Conditions	Required Documents
			6. Specifications and Certificate of Analysis of the new finished products (previous and new)
3.	Changes to the raw material analysis method that do not change specifications and quality of raw materials and finished products, in accordance with Pharmacopoeia monograph or as relevant	1. Raw material specifications remain unchanged. 2. Product specifications remain unchanged.	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. comparison matrix 5. Analysis method of Raw Materials and/or finished products (previous and new)
4.	Reduction of manufacturing sites of raw materials (active Ingredients, or inactive ingredients) of which have been approved	1. The approved manufacturing sites with the same function/designation still exist. 2. The reduction of manufacturing sites is not caused by critical factors related to the manufacturing process.	1. Cover letter stating justification from the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Certificate of analysis of Raw Materials (previous and new)
5.	Changes to manufacturer's name or address of raw materials that do not change the	1. The location of the manufacturer of raw materials remains unchanged. 2. Specifications of raw	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved

No.	Types of Changes	Conditions	Required Documents
	manufacturer's location	materials remain unchanged.	packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Justification of submitted changes 6. Certificate of analysis of Raw Materials (previous and new)
6.	Changes to the raw material specifications to meet the latest Pharmacopoeia requirements, that do not change the finished product specifications	1. The product specifications remain unchanged. 2. Impurity and Active ingredient Specification remains unchanged (particle size profile, polymorphism form)	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Justification of submitted changes 6. Specifications of Raw materials (previous and new). 7. Certificate of analysis of raw materials 8. Internal analysis testing results of raw materials from the previous and new specifications 9. Pharmacopoeia references used as guideline.
7.	Narrowing of limits of raw material/ finished product	1. Changes are within the approved range of specification limits	1. Cover letter stating the submitted changes 2. Decision letter for

No.	Types of Changes	Conditions	Required Documents
	specifications	2. The testing procedure remains unchanged or only minor changes made to its procedures	approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Justification of submitted changes 6. Specification of finished product released (previous & new) 7. Certificate of analysis of new finished product
8.	Changes to secondary packaging materials that do not change the included information	Labeling remains unchanged	1. Cover letter stating justification from the submitted changes 2. Decision letters for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Justification of submitted changes 6. Specifications of secondary packaging (previous and new)
9.	Inclusion extension of halal logo	Labeling remains unchanged	1. Cover letter stating justification from the submitted changes 2. Decision letter for approval of marketing authorization & approved

No.	Types of Changes	Conditions	Required Documents
			packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Valid Halal certification issued by BPJPH
10.	Changes to industrial permit status without changes to manufacturing location	1. The location of the manufacturer site remains unchanged 2. The production line used remains unchanged 3. The company name remains unchanged 4. Labeling remains unchanged	1. Cover letter stating justification from the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Manufacturing certificate 6. Valid Good Manufacturing Practice certificate 7. Proof of renewal of Industrial permit status on the company account in e-registration system

B. Minor Variation Registration with Approval

No.	Types of Changes	Required Documents
1.	Changes to Colour of packaging design	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Latest packaging design
2.	Changes to the graphic Layout or product information	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved

No.	Types of Changes	Required Documents
		packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Latest packaging design
3.	Changes to font Types or sizes	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Latest packaging design
4.	Inclusion or Changes to company Logo	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Latest packaging design
5.	Inclusion or Changes to halal Logo	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Latest packaging design 6. Valid halal certificate issued by BPJPH
6.	Removal of foreign language from the label	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Latest packaging design
7.	Changes to package Shapes and/or dimensions without change to specifications of primary packaging materials	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Latest packaging design 6. Specifications of shapes and/or dimensions of previous and new packaging
8.	Changes to the product	1. Cover letter stating the submitted

No.	Types of Changes	Required Documents
	names	changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Statement letter regarding the product's name changes from the manufacturer 6. Latest packaging design
9.	Changes to the images	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Cooperation agreement letter/ statement of no objection to the inclusion of images (if using the model/image that has a copyright) 6. Latest packaging design
10.	Inclusion of logo/trademark	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Valid Certificate of trademark/logo from an authorized institution 6. Latest packaging design
11.	Inclusion of Award Logo or other logos	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Certificate of award logo/other logos from an authorized institution 6. Latest packaging design
12.	Addition of product information in English or other languages	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix. 5. Translation result from a sworn translators for foreign languages

No.	Types of Changes	Required Documents
		other than English 6. Latest packaging design
13.	Changes to tag lines that do not affect the product efficacy	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Latest packaging design
14.	Inclusion of distributors	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Distribution cooperation agreement and SIUP in OT and SK Sector 6. Latest packaging design
15.	Changes to information on the package design	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Latest packaging design 6. Supporting data (if any)
16.	Changes to brochures/leaflets	1. Cover letter stating the submitted changes 2. Decision for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Latest packaging design (including the submitted brochure design)
17.	Changes to secondary packaging	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Specifications of secondary packaging 6. Latest packaging design
18.	Addition of secondary package	1. Cover letter stating the submitted changes 2. Decision letter for approval of

No.	Types of Changes	Required Documents
		marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Specifications of secondary packaging 6. Latest packaging design
19.	Addition to packaging size	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Statement Letter for the additions to/ changes to package size from the manufacturer 6. Specifications and/or Certificate of analysis of previous and new primary packaging 7. Latest packaging design
20.	Changes to packaging size	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Statement letter for the additions to/ changes to packaging size from the manufacturer 6. Specifications and/or Certificate of analysis of previous and new primary packaging 7. Latest packaging design
21.	Changes to the name of and/or Applicant, licensor and/or manufacturer without change in location (without change in ownership status)	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Administrative documents regarding changes to the name and/or address from an authorized institution (NIBSIUP/ Manufacturing Certificate/GMP) 6. Notification letter of address change from an authorized Institution 7. List of product's data (Product name, Dosage form, packaging Size, NIE) that change

No.	Types of Changes	Required Documents
		8. Latest packaging design
22.	Changes to the name and/or address of the Business Actor applying for Registration (office)/ licensor/ importer with change in location (without change in ownership status)	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Administrative documents regarding changes to the name and/or address from an authorized institution (NIB/ SIUP/ Manufacturing Certificate) 6. List of product's data (Product name, Dosage form, packaging Size, NIE) that change 7. Minutes of inspection of facilities for importer (if there is a change of warehouse address) 8. Latest packaging design
23.	Change or Addition of secondary packaging manufacturer	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix of changes 5. Justification for the addition to packaging manufacturer 6. Cooperation agreement with secondary packaging manufacturer 7. Industrial permit of secondary packaging manufacturer 8. good manufacturing practice Certificate from secondary packaging manufacturer in accordance with dosage form that will be packaged 9. Latest packaging design
24.	Request for bundle packaging or special packaging	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations (if any) & approved packaging design (if any) 4. Comparison matrix of changes 5. Justification for the request for bundle packaging or special packaging 6. Latest packaging design
25.	Changes of colour of capsule shell	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization 3. Approval of variations (if any)

No.	Types of Changes	Required Documents
		4. Comparison g matrix of changes 5. Justification for colour changes of capsule shells 6. Certificate of analysis of capsule shells, BSE-Free certificate, halal certificate and duly stamped statement letter for BSE-Free capsule shell 7. Certificate of Analysis of Finished Products 8. Specifications of finished products 9. Protocols and stability data for 2 batches with a minimum of 6 months (real time and accelerated) accompanied by a commitment to conducted stability up to the proposed shelf life 10. Other supporting data (e.g. calculation of inactive ingredients in the capsule shell limited based on the provisions of legislation
26.	Changes to specifications of finished products to comply with compendial or the prevailing of legislation	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization 3. Approval of variations (if any) 4. Comparison matrix 5. Specifications of finished products (previous & new) 6. Certificate of analysis of finished products (previous & new) 7. Protocols and stability data of new finished product specifications with a minimum of 6 months for 2 batches (real time and accelerated) 8. Compendial or regulations used as change references
27.	Changes in analysis method of raw materials (non compendial) that do not change specifications of raw materials and finished products	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization 3. Approval of variations (if any) 4. Comparison matrix 5. Justification from proposed changes 6. Analysis methods (previous & new) 7. Certificate of analysis of raw materials (previous & new) 8. Certificate of analysis of finished products (previous & new) 9. References or supporting Data that support changes related to the analysis method as referred
28.	Reduction or removal of active ingredients overages	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved

No.	Types of Changes	Required Documents
		packaging design 3. Approval of variations & approved packaging design (if any) 4. Justification for submitted changes 5. Comparison matrix of submitted Formula and approved Formula 6. Formula per dosage and per batch 7. Specifications of finished products 8. Certificate of analysis of finished products 9. Protocols and stability data for 2 batches with a minimum of 6 months (real time and accelerated) accompanied by a commitment to conducted stability up to the proposed shelf life
29.	Increase/decrease in product batch size up to ten folds that does not affect the reproducibility and specifications of finished product	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization 3. Approval of variations (if any) 4. Comparison matrix 5. Justification for submitted changes 6. Formula (per dosage and per batch) 7. Manufacturing method 8. Specifications of finished products 9. Certificate of analysis of finished products (previous & new)
30.	Changes to/ Addition to capsule shell manufacturer that do not change specifications of capsule shells and products	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization 3. Approval of variations (if any) 4. Comparison matrix 5. Justification of submitted changes 6. Specifications and Certificate of analysis of capsule shells (previous & new) 7. BSE-Free certificate, halal certificate and duly stamped statement letter for BSE-Free capsule shell from the new manufacturer 8. Specifications and certificate of analysis of finished products 9. Protocols and stability data with a minimum of 6 months for 2 batches (real time and accelerated) accompanied by a commitment to conducted stability up to the proposed shelf life 10. Other supporting data (e.g. calculation of inactive ingredients in the capsule shell limited based on the provisions of legislation
31.	Changes to quick-release capsule shell size that do not	1. Cover letter stating the submitted changes

No.	Types of Changes	Required Documents
	affect the Formula, product specifications and stability	2. Decision Letter for approval of marketing authorization 3. Approval of variations (if any) 4. Comparison matrix 5. Justification of submitted changes 6. Formula per capsule 7. Specifications and Certificate of analysis of capsule shells previous & new) 8. BSE-Free certificate, halal certificate and duly stamped statement letter for BSE-Free capsule shell from the new manufacturer 9. Specifications and certificate of analysis of finished products (previous and new) 10. Other supporting data (e.g. calculation of inactive ingredients in the capsule shell limited based on the provisions of legislation)
32.	Changes to the shapes or dimensions of quick-release tablets that do not change the Formula, average weight and product specifications (except dimension)	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization 3. Approval of variations (if any) 4. Comparison matrix 5. Justification of submitted changes 6. Formula per tablet 7. Specifications and Certificate of Analysis of Finished Products (previous and new)
33.	Changes to analysis method of finished products that do not change the specifications	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization 3. Approval of variations (if any) 4. Comparison matrix 5. Analysis method (previous & new) 6. Certificate of analysis of finished products (previous & new) 7. References or supporting data the supported changes related to the analysis method as referred
34.	Changes to storage conditions of the product	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Justification of submitted changes 6. Specifications of Finished Products 7. Protocols and stability data with a minimum of 6 months for 2 batches (real time based on new submitted

No.	Types of Changes	Required Documents
		storage condition and accelerated) accompanied by a commitment to stability up to the proposed shelf life 8. New packaging design
35.	Changes to and/or additions to active ingredients manufacturer that do not change specifications of raw materials and finished products	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization 3. Approval of variations (if any) 4. Comparison matrix 5. Justification from submitted changes 6. Specifications and Certification of analysis of raw materials (previous & new) 7. Specifications and Certification of analysis of finished products (previous & new) 8. Other supporting documents (if any)
36.	Changes to or addition to export destination countries	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Statement letter for changes to or addition of export destination countries 6. Packaging design for new export destination countries
37.	Changes to and/or addition to manufacturers of inactive ingredients that do not change specifications of raw materials or finished products 1. Inactive ingredients specifications remain unchanged 2. Product specifications remain unchanged 3. Requirements for capsule Shell materials: only designated for capsules with the size and composition of the capsule shell the same as the approved materials	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Justification of submitted changes 6. Specifications and Certificate of analysis of raw materials (previous & new) 7. Specifications and Certificate of analysis of finished products (previous & new) 8. Other supporting documents (if any)

C. Major Variation Registration

No.	Types of Changes	Required Documents
1.	Changes in specifications of finished products	1. Cover letter stating the submitted changes 2. Decision letter for approval of

No.	Types of Changes	Required Documents
		marketing authorization & approved packaging design 3. Approval of variations (if any) 4. Comparison matrix 5. Justification of submitted changes 6. Specifications and Certificate of analysis of finished products (previous & new) 7. Testing methods of finished products 8. Protocols and stability data accelerated & long term, each of which 2 batches for a minimum of 6 months accompanied by a commitment to stability tests up to the proposed shelf life 9. References/data supporting the proposed changes (if necessary)
2.	Changes in product Formula that do not affect the safety and efficacy of the product	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Justification of changes 6. New packaging design 7. Formula per dosage and per batch 8. Manufacturing method 9. Certificate of analysis of raw materials 10. Certificate of analysis of new finished products 11. Specifications and Testing Methods of finished products 12. Protocols and stability data accelerated & long term, each of which 2 batches for a minimum of 6 months accompanied by a commitment to carry out stability tests up to the proposed shelf life 13. References/data supporting the proposed changes (if necessary) 14. Results of quality testing of finished products from an accredited laboratory in Indonesia for imported Health Supplements
3.	Changes in usage claims, tagline, and/or instruction of use	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Justification of proposed changes

No.	Types of Changes	Required Documents
		6. New packaging design 7. Scientific data or other references supporting the proposed changes
4.	Changes in type or specifications of primary packaging	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Justification of submitted changes 6. New packaging design 7. Certificate of analysis of finished products with new packaging 8. Protocols and stability data accelerated & long term, each of which 2 batches for a minimum of 6 months accompanied by a commitment to stability tests up to the proposed shelf life 9. Specifications and/or certificate of analysis of finished products (previous & new)
5.	Changes in stability data	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization 3. Approval of variations (if any) 4. Comparison matrix 5. Justification of submitted changes 6. Protocols and stability data accelerated & long term, until proposed stability period 7. Specifications of Finished Products
6.	Changes or additions of manufacturing site and/or primary packaging	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations & approved packaging design (if any) 4. Comparison matrix 5. Justification of changes 6. New packaging design 7. manufacturing Certificate of new manufacturer 8. Valid Good Manufacturing Practice certificate of new manufacturer 9. Formula per dosage and per batch 10. Manufacturing method 11. Certificate of analysis of finished products 12. Specifications and testing Methods of finished products 13. Protocols and stability data

No.	Types of Changes	Required Documents
		accelerated & long term, each of which 2 batches for a minimum of 6 months accompanied by a commitment to stability tests up to the proposed shelf life 14. Product/batch code supported by the code definition 15. Administrative documents supporting the submitted changes (e.g.: valid manufacturing joint agreement)
7.	Changes in specifications of raw materials	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations (if any) 4. Comparison matrix 5. Justification of proposed changes 6. Specifications and changed Certificate of analysis of raw materials (previous & new) 7. Specifications and Certificate of analysis of finished products (previous & new) 8. Protocols and stability data accelerated & long term, each of which 2 batches for a minimum of 6 months accompanied by a commitment to stability tests up to the proposed shelf life 9. References/data supporting the changes (if necessary)
8.	Increase in product batch size more than ten folds that does not affect the reproducibility and specifications of finished product	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & approved packaging design 3. Approval of variations (if any) 4. Comparison matrix 5. Justification of changes 6. Formula per dosage and per batch 7. Manufacturing method 8. Specifications and Certificate of analysis of finished products (previous & new) 9. Protocols and stability data accelerated & long term, each of which 2 batches for a minimum of 6 months accompanied by a commitment to stability tests up to the proposed shelf life
9.	Changes in the product manufacturing process that do not affect the Formulas and specifications of finished product	1. Cover letter stating the submitted changes 2. Decision letter for approval of marketing authorization & last approved packaging design

No.	Types of Changes	Required Documents
		3. Approval of variations (if any) 4. Comparison matrix 5. Justification of changes 6. Formula per dosage and per batch 7. Manufacturing method (previous & new) 8. Specifications and Certificate of analysis of finished products (previous & new) 9. Protocols and stability data accelerated & long term, each of which 2 batches for a minimum of 6 months accompanied by a commitment to stability tests up to the proposed shelf life 10. References/data supporting the changes (if necessary)

CHAIRPERSON OF
THE INDONESIAN FOOD AND DRUG AUTHORITY

signed

PENNY K. LUKITO

ANNEX V TO
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 32 OF 2022 ON
CRITERIA AND PROCEDURES FOR
HEALTH SUPPLEMENT REGISTRATION

PROCEDURESFOR PRIORITY SERVICES

I. **PRODUCT CRITERIA**

Criteria for local Health Supplement products that can be registered through Priority Services:

1. Single vitamin or mineral composed by raw materials with well-known safety and efficacy;
2. A combination of vitamins and/or minerals composed by raw materials with well-known safety and efficacy, with general or functional claims.

II. **REQUIREMENTS**

1. The company registration can be done by attaching the following required documents:
   a. valid Industrial License/Manufacturing Certificate;
   b. valid Good Manufacturing Practice for Pharmaceutical Products (*CPOB*) certificate, Good Production Practice for Processed Food (*CPPOB*) certificate, Good Manufacturing Practice for Traditional Medicine (*CPPOB*) certificate, or Good Manufacturing Practice for Pharmaceutical Products (*CPOTB*) in stages of at least stage 2;
   c. a statement letter from the pharmacist or pharmaceutical technical personnel as responsible parties for registration;
   d. a stamped statement letter stating that the company has never been involved in criminal acts in the field of food and drugs;

e. a stamped statement letter regarding the originality and validity of the registration documents; and

f. a stamped statement letter of not using a service agency in applying for the marketing authorization.

2. After the selection stage, the chosen companies will be declared through an announcement letter from the Deputy for Supervision of Traditional Medicines, Health Supplements and Cosmetics.

3. For selected companies that have obtained priority services, the clustering menu on the company account in the asrot system will be activated.

4. Product registration can be done through the clustering menu.

III. **PRIORITY SERVICE FORMAT**

Service Level Agreement (SLA) or product evaluation time is 50% (fifty percent) of the registration route in accordance with the provisions of legislation.

CHAIRPERSON OF
THE INDONESIAN FOOD AND DRUG AUTHORITY

signed

PENNY K. LUKITO

ANNEX VI TO
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 32 OF 2022
ON
CRITERIA AND PROCEDURES FOR
HEALTH SUPPLEMENT REGISTRATION

STATEMENT LETTER OF THE BUSINESS ACTOR'S RESPONSIBILITIES

STATEMENT LETTER

I hereby,
Name : ……
Identification Number : ……
Address : ……

As Director/ Pharmacist in Charge of the Pharmaceutical Industry/ IOT/ UKOT/ Food Industry/ Business Entity in the field of Health Supplements Marketing / Importer in the field of Health Supplements of:
Company Name : ……
Company Address : ……

Hereby declare full responsibility for the validity of the documents and the correctness of the product information in the Health Supplement registration documents of:
Product Name : ……
Dosage Form/Packaging : ……
Product Category :……

In addition to the aforementioned, we also declare that we will comply with the provisions of the legislation applied in Indonesia.

Thus, this statement letter is made truthfully.

……., ……..

Duly Stamp 10000
(Full Name and Signature)

CHAIRPERSON OF
THE INDONESIAN FOOD AND DRUG AUTHORITY
signed
PENNY K. LUKITO

ANNEX VII TO
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 32 OF 2022
ON
CRITERIA AND PROCEDURES FOR
HEALTH SUPPLEMENT REGISTRATION

LIST OF VITAMINS, MINERALS, AMINO ACIDS, AND OTHER SUBSTANCES PERMISSIBLE FOR USE IN HEALTH SUPPLEMENTS WITH LIMITATION

I. VITAMINS AND MINERALS

NO	NAME(S)	MAXIMUM LIMIT / DAY	NOTES
1.	Vitamin A	5000 UI (1500 mcg)	
2.	Beta Carotene	15 mg = 25,000 UI	
3.	Vitamin B1	100 mg	
4.	Vitamin B2	40 mg	
5.	Nicotinic Acid	15 mg	
6.	Nicotinamide	450 mg	
7.	Pantothenic Acid	200 mg	
8.	Vitamin B6	100 mg	
9.	Vitamin B12	0.6 mg	
10.	Biotin	0.9 mg	
11.	Folic Acid	0.9 mg	For pregnant women, maximum 100 mcg/day
12.	Vitamin D	1000 IU	- In the form of Vitamin D3 (cholecalciferol) - Can be combined with other substances with a maximum dose of 800 IU/day - The dosage from 800 IU/day to 1000 IU/day is only permitted in single form
13.	Vitamin E	400 IU	

NO	NAME(S)	MAXIMUM LIMIT / DAY	NOTES
14.	Vitamin C	1000 mg	
15.	Vitamin K	0.12 mg	- Only Vitamin K1 and/or Vitamin K2 - For use in the form of multivitamin/multimineral for adults and not as a single Composition - Consult with health practitioners before using Vitamin K while receiving anticoagulant therapy or warfarin at the same time
16.	Iron	30 mg	
17.	Boron	3 mg	
18.	Phosphor	800 mg	
19.	Potassium	200 mg	
20.	Calcium	1200	
21.	Chromium	0.2 mg	
22.	Magnesium	350 mg	
23.	Manganese	3.5 mg	
24.	Molybdenum	75 µg	
25.	Selenium	0.2 mg	- For Pregnant Women and lactating mothers, a maximum dose is 60 mcg/day - Selenium in the form of Elemental
26.	Copper	2 mg	
27.	Vanadium	20 µg	
28.	Iodine	0.15 mg	
29.	Zinc	30 mg	For use in combination form, and not as a single Composition

II. AMINO ACIDS

NO	NAME(S)	MAXIMUM LIMIT / DAY	NOTES
1.	Glutamine	2000 mg	
2.	Glutathione	600 mg	
3.	Inositol	200 mg	
4.	Carnitine	2000 mg	
5.	Co Enzyme Q	100 mg	
6.	Choline	3000 mg	
7.	l-Arginine	1000 mg	
8.	Leucine	500 mg	
9.	Lysine	10000 mg	
10.	Methyl cysteine	200 mg	
11.	Cysteine	1500 mg	
12.	Taurine	3000 mg	
13.	Tyrosine	500 mg	

III. OTHER SUBSTANCES

NO	NAME(S)	MAXIMUM LIMIT / DAY	NOTES
1.	Flavonoids	200 mg	Equivalent with Quercetin
2.	Chitosan	1500 mg	
3.	Fluorine	0.4 mg	For infants
		0.9 mg	For toddlers
		2.7 mg	For teenagers
		3 mg	For adults, pregnant women, and lactating mothers
4.	Glucosamine	1500 mg	
5.	Caffeine	150 mg	Divided into minimal 3 (three) doses
6.	Chondroitin sulfate	1200 mg	
7.	Methylsulfonylmethane	3000 mg	

CHAIRPERSON OF
THE INDONESIAN FOOD AND DRUG AUTHORITY

signed

PENNY K. LUKITO

ANNEX VIII TO
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 32 OF 2022
ON
CRITERIA AND PROCEDURES FOR
HEALTH SUPPLEMENT REGISTRATION

I. PROHIBITED SUBSTANCES FOR HEALTH SUPPLEMENTS

A. Plants

No.	Plant Name (Species)	Common Name(s)	Harmful Parts	Simplicia Name(s)
1.	*Abrus precatorius L.*	Saga	Seed	Abri Precatorius Semen
2.	*Aconitum spp.*	Aconite	Whole plant	Aconiti Herba and Aconiti Radix
3.	*Actaea racemosa L. Syn. Cimicifuga racemosa (L) Nutt.*	Black *Cohosh*	Rhizome and root	Actaeae Racemosae Rhizoma and Actaeae Racemosae Radix (Syn. Cimicifugae Racemosae Rhizoma and Cimicifugae Racemosae Radix)
4.	*Adonis vernalis L.*	Adonis	Whole plant	Adonis Vernalidis Herba and Adonis Vernalidis Radix
5.	*Antiaris toxicaria Lesch.*	Upas tree	Latex	Antiaris Toxicariae Latex
6.	*Arcangelisia flava (L.) Merr.*	Yellow fruit moonseed	Wood	Arcangelisiae Flavae Caulis
7.	*Aristolochia spp.*	Aristolochia/ Birthwort	Whole plant	Aristolochiae Herba and Arstolochiae Radix

No.	Plant Name (Species)	Common Name(s)	Harmful Parts	Simplicia Name(s)
8.	*Artemisia spp.*	Artemisia/ Wormwood	Leaf	Artemesiae Folium
9.	*Aspidosperma quebracho- blanco Schtdl.*	Bracho, quebracho	Bark	Aspidospermae Quebracho-blancoi Cortex
10.	*Atropa belladonna L.*	Belladona/ Deadly nightshade	Whole plant	Atropae Belladonnae Herba and Atropae Belladonnae Radix
11.	*Azadirachta indica A. Juss.*	Nimba, Neem	Seeds	Azadirachtae Indicae Semen
12.	*Barnadia japonica (Thunb.) Schult. & Schult.f.* *Syn. Scilla sinensis (Lour.) Merr.*	-	Bulb	Barnadiae Japonicae Bulbus Syn. Scillae Sinensidis Bulbus
13.	*Berberis spp*	Barberry	Root, Bark, Rhizome	Berberis Caulis
14.	*Brucea javanica (L.) Merr.* *Syn. Brucea amarissima Desv. Ex Gomes, B. sumatrana Roxb*	Macassar kernels	Dried fruits & Seed	Bruceae Javanicae Fructus and Bruceae Javanicae Semen
15.	*Calotropis gigantea (L) Dryand* *Syn. Asclepias gigantea L.*	Giant milkweed	Whole plant	Calotropis Giganteae Herba and Calotropis Giganteae Radix Syn. Asclepias Giganteae Herba and Asclepias Giganteae Radix
16.	*Calotropis procera (Aiton) Dryand*	Small crown flower	Whole plant	Calotropis Procerae Herba and Calotropis Procerae

No.	Plant Name (Species)	Common Name(s)	Harmful Parts	Simplicia Name(s)
				Radix
17.	*Cannabis sativa L.*	Marijuana	Whole plant	Cannabis Sativae Herba and Cannabis Sativae Radix
18.	*Cannabis indica Lam.*	Marijuana	Whole plant	Cannabis Indica Herba and Cannacis Indica Radix
19.	*Catharanthus roseus (L.) G.Don Syn. Vinca rosea L.*	Rosy periwinkle	Whole plant	Catharanthi Rosei Herba and Catharanthi Rosei Radix Syn. Vincae Roseae Herba and Vincae Roseae Radix
20.	*Cerbera manghas L. Syn. Cerbera odollam Gaertn*	Dog bane	Seed	Cerberae Manghasae Semen Syn. Cerberae Odollamae Semen
21.	*Chelidonium majus L.*	Celandine	Whole plant	Chelidonii Majusi Herba and Chelidonii Majusi Radix
22.	*Chondrodendron tomentosum Ruiz & Pav.*	Curare	Stems	Chondrodendronis Tomentosum Caulis
23.	*Chincona spp.*	Quine	Bark	Cinchonae Cortex
24.	*Citrullus colocynthis (L.) Schrader*	Bitter apple	Fruit, Seed	Citrulli Colocynthidis Fructus and Citrulli Colocynthidis

No.	Plant Name (Species)	Common Name(s)	Harmful Parts	Simplicia Name(s)
				Semen
25.	*Claviceps purpurea (Fr.) Tul*	Ergot	Sclerotium	Clavicepsis Purpureae Thallus
26.	*Colchicum autumnale L.*	Meadow saffron	Seed	Colchici Autumnalis Semen
27.	*Conium maculatum L.*	Hemlock	Whole plant	Conii Maculati Herba and Conii Maculati Radix
28.	*Coptis spp.*	Coptidis	Rhizome	Coptis Rhizoma
29.	*Croton tiglium L.*	Purging croton	Whole plant	Croton Tiglii Semen and Croton Tiglii Oleum
30.	*Datura spp.*	Jimson weed	Whole plant	Daturae Herba and Daturae Radix
31.	*Delphinium staphisagria L.*	-	Seeds	Delphinii Staphisagriae Semen
32.	*Digitalis spp.*	Digitalis	Whole plant	Digitalis Herba and Digitalis Radix
33.	*Drimia maritima (L.) Stearn* *Syn. Urginea maritima, Urginea pancration, Urginea scilla, Scilla maritima*	Squill	Bulb	Drimiae Maritimae Bulbus Syn. Urgineae Maritimae Bulbus, Urgineae Pancrationis Bulbus
34.	*Dryobalanops sumatrensis (J.F.Gmel)-Kosterm.* *Syn. D. aromatica D.F. Gaertn.;* *D. lanceolata Burck;* *D. camphora Colebr.*	Borneo camphor	Whole plant	Dryobalanopsis Sumatrensis Radix, Dryobalanopsis Sumatrensis Caulis, Dryobalanopsis Sumatrensis Folium, Dryobalanopsis Sumatrensis Flos,

No.	Plant Name (Species)	Common Name(s)	Harmful Parts	Simplicia Name(s)
				Dryobalanopsis Sumatrensis Semen Syn. Dryobalanopsis Aromaticae Radix, Dryobalanopsis Aromaticae Caulis, Dryobalanopsis Aromaticae Folium, Dryobalanopsis Aromaticae Flos, Dryobalanopsis Aromaticae Fructus, Dryobalanopsis Aromaticae Semen, Dryobalanopsis Lanceolatae Radix, Dryobalanopsis Lanceolatae Caulis, Dryobalanopsis Lanceolatae Folium, Dryobalanopsis Lanceolatae Flos, Dryobalanopsis Lanceolatae Fructus, Dryobalanopsis Lanceolatae Semen, Dryobalanopsis Champorae Radix, Dryobalanopsis Champorae Caulis,

No.	Plant Name (Species)	Common Name(s)	Harmful Parts	Simplicia Name(s)
				Dryobalanopsis Champorae Folium, Dryobalanopsis Champorae Flos, Dryobalanopsis Champorae Fructus, Dryobalanopsis Champorae Semen
35.	*Dryopteris filix-max (L.) Schott*	Male fern	Whole plant	Dryopteridis Filisis Herba and Dryopteridis Filisis Radix
36.	*Ephedra spp.*	Ephedra/ Joint-pine	Whole plant	Ephedrae Herba and Ephedrae Radix
37.	*Euphorbia tirucalli L.*	Indian tree spurge	Herb	Euphorbiae Tirucallii Herba
38.	*Euphorbia antiquorum L.*	Triangular spurge	Whole plant	Euphorbiae Antiquori Herba and Euphorbiae Antiquori Radix
39.	*Euphorbia trigona Mill.*	-	Whole plant	Euphorbiae Trigonae Herbae and Euphorbiae Trigonae Radix
40.	*Excoecaria agallocha L.*	Blinding tree	Whole plant	Excoecariae Agallochae Radix, Excoecariae Agallochae
41.	*Fritillatia spp.*	-	Dried bulb	Fritillarie Bulbus
42.	*Garnicia hanburyi Hook. F.* *Syn. Garcinia morella*	Gamboge	Whole plant	Garniciae Hanburyii Radix, Garniciae Hanburyii Caulis,

No.	Plant Name (Species)	Common Name(s)	Harmful Parts	Simplicia Name(s)
	Gaertn.			Garniciae Hanburyii Folium, Garniciae Hanburyii Flos, Garniciae Hanburyii Fructus, Garniciae Hanburyii Semen Syn. Garniciae Morellae Radix, Garniciae Morellae Caulis, Folium, Garniciae Morellae Flos, Garniciae Morellae Fructus, Garniciae Morellae Semen
43.	*Garcinia elliptica Wall.ex.Wight*	Gamboge	Whole plant	Garciniae Ellipticae Radix, Garciniae Ellipticae Caulis, Garciniae Ellipticae Folium, Garciniae Ellipticae Flos, Garciniae Ellipticae Fructus, Garciniae Ellipticae Semen
44.	*Gelsemium sempervirens (L.) J.St.Hil.*	Yellow jessamine	Root, Leaf, Rhizome	Gelsemii Sempervirensis Herba, Gelsemii Sempervirensis Rhizoma, Gelsemii Sempervirensis Radix
45.	*Gelsemium elegans (Gardn. Et Champ.) Benth*	Heartbreak grass	Root, Leaf, Rhizome	Gelsemii Elegansis Herba, Gelsemii Elegansis Rhizoma, Gelsemii Elegansis Radix

No.	Plant Name (Species)	Common Name(s)	Harmful Parts	Simplicia Name(s)
46.	*Gluta usitata (Wall.) Ding Hou* *Syn. Melanorrhoea usitata Wall.*	Vanish tree	Latex	Glutae Usitatae Latex Syn. Melanorrhoeae Usitatae Latex
47.	*Hydrastis canadensis L.*	Golden seal	Root and Bulb	Hydrastis Canadensidis Radix, Hydrastis Canadensidis Rhizoma
48.	*Hypericum perforatum L.*	St. John's wort	Herb	Hyperici Perforati Herba
49.	*Hyoscyamus niger L.*	Hyoscyamine, Bisson tobacco, Black henbane	Whole plant	Hyoscyami Nigeris Herba, Hyoscyami Nigeris Radix
50.	*Hyoscyamus muticus L.*	Henbane	Whole plant	Hyoscyami Mutici Herba, Hyoscyami Radix
51.	*Jatropha multifida L.* *Syn. Jatropha janipha Blanco*	Coral bush	Fruit, Seed	Jatrophae Multifidae Fructus, Jatrophae Multifidae Semen Syn. Jatrophae Janiphae Fructus, Jatrophae Janiphae Semen
52.	*Juniperus sabina L.*	Savin	Whole plant	Juniperi Sabinae Radix, Juniperi Sabinae Caulis, Juniperi Sabinae Folium, Juniperi Sabinae Flos, Juniperi Sabinae Fructus, Juniperi

No.	Plant Name (Species)	Common Name(s)	Harmful Parts	Simplicia Name(s)
				Sabinae Semen
53.	*Lantana camara L.*	Tembelekan	Whole plant	Lantanae Camarae Radix, Lantanae Camarae Herba
54.	*Larrea tridentata (Sesse & Moc. Ex DC.) Coville*	Chaparral, greasewood	Whole plant	Larreae Tridentatae Herba, Larreae Tridentatae Radix
55.	*Larrea mexicana Moric*	Chaparral	Whole plant	Larreae Mexicanae Herba, Larreae Mexicanae Radix
56.	*Lobelia chinensis Lour.*	Chinese lobelia	Whole plant	Lobeliae Chinensidis Herba, Lobeliae Chinensidis Radix
57.	*Lobelia nicotianifolia Roth ex Schult*	Wild tobacco	Whole plant	Lobeliae Nicotianifoliae Herba, Lobeliae Nicotianifoliae Radix
58.	*Lobelia inflata L.*	Indian tobacco	Whole plant	Lobeliae Inflatae Herba, Lobeliae Inflatae Radix
59.	*Lobelia tupa L. Syn. Lobelia turgida E. Wimm.,*	Devils tobacco	Whole plant	Lobeliae Tupae Herba, Lobeliae Tupae Radix
60.	*Magnolia officinalis Rehder & E.H. Wilson*	Magnolia – bark, hou po	Whole plant	Magnoliae Officinalis Radix, Magnoliae Officinalis Caulis, Magnoliae Officinalis Folium, Magnoliae Officinalis Flos, Magnoliae Officinalis Fructus,

No.	Plant Name (Species)	Common Name(s)	Harmful Parts	Simplicia Name(s)
				Magnoliae Officinalis Semen
61.	*Mahonia spp.*	Oregon grape	Root, Bark, Rhizome	Mahoniae Radix Mahoniae Cortex Mahoniae Rhizoma
62.	*Melaleuca alternifolia (Maiden & Betche) Cheel*	Tea Tree Oil	Leaf, from whole plant (prohibited for oral)	Melaleucae Alternifoliae Oleum
63.	*Mitragyna speciosa (Korth.) Havil. Syn. Mitragyna stivulosa (DC.) Kuntze.*	Kratom	Whole plant	Mitragynae Speciosae Herba, Mitragynae Speciosae Radix
64.	*Mucuna pruriens (L.) DC.*	Cowhage, Cowage	Seed	Mucunae Pruriensis Semen
65.	*Nerium oleander L. Syn. Nerium indicum Mill*	Oleander	Whole plant	Nerii Oleanderis Herba, Nerii Oleanderis Radix Syn. Nerii Indici Herba, Nerii Indici Radix
66.	*Nicotiana tabacum L.*	Tobacco	Leaf	Nicotianae Tabacum Folium
67.	*Papaver spp.*	Opium, Poppy	Whole plant	Papaveris Herba and Papaveris Radix
68.	*Pausinystalia johimbe (K.Schum) Pierre ex Beille*	Yohimbe	Bark	Pausinystaliae Johimbe Cortex
69.	*Physostigma venenosum*	Calabar bean	Seed	Physostigmae Venenosum Semen
70.	*Phellodendron spp.*	Amur cork tree	Bark	Phellodendronis Cortex
71.	*Pilocarpus spp.*	-	Whole plant	Pilocarpi Folium

No.	Plant Name (Species)	Common Name(s)	Harmful Parts	Simplicia Name(s)
				and Pilocarpi Cortex
72.	*Piper methysticum G. Forst.*	Kava kava	Whole plant	Piperis Methystici Herba
73.	*Podophyllum emodi Wall.ex. Hook.f. & Thomson*	Mandrake	Root and Leaf	Podophylli Emodii Folium and Podophylli Emodii Radix
74.	*Podophyllum peltatum L.*	Mayapple	Root and Leaf	Podophylli Peltati Folium and Podophylli Peltati Radix
75.	*Psilocybe cubensis (Earle) Singer*	-	Whole plant	Psilocybis Cubensis Thallus
76.	*Plumbago zeylanica L.*	Ceylon leadwort	Root	Plumbaginis Zeylanicae Radix
77.	*Plumbago indica L.*	Indian leadwort	Root and Root bark	Plumbaginis Indicae Radix and Plumbaginis Indicae Radicis Cortex
78.	*Punica granatum L.*	Pomegranate	Stem bark and Root bark	Punicae Granati Cortex and Punicae Granati Radicis Cortex
79.	*Rauvolfia spp.*	Rauwolfia, Indian snakeroot, Snakeroot	Whole plant	Rauvolfiae Herbadan, Rauvolfiae Radix
80.	*Sanguinaria canadensis L.*	Bloodroot, Indian paint	Rhizome and Root	Sanguinariae Canadensis Radix
81.	*Schoenocaulon officinale (Schltdl. & Cham.) A. Gray ex*	Sabadilla	Seed	Schoenocaulonis Officinalis Semen

No.	Plant Name (Species)	Common Name(s)	Harmful Parts	Simplicia Name(s)
	Benth			
82.	*Senecio spp.*	-	Whole plant	Senecioi Herbadan Senecioi Radix
83.	*Sophora tomentosa L.*	Sea coast, Laburnum, Silver bush	Seed	Sophorae Tomentosae Semen
84.	*Solanum dulcamara L.*	Bittersweet	Whole plant	Solani Dulcamaris Herba and Solani Dulcamaris Radix
85.	*Solanum americanum Mill.* *Syn. Solanum nigrum L*	Black nightshade	Leaf and Flowering Tops	Solani Americani Herba and Solani Americani Radix Syn. Solani Nigris Herba and Solani Nigris
86.	*Spigelia marilandica L.*	Pinkroot	Whole plant	Spigeliae Marilandicae Herba and Spigeliae Marilandicae Radix
87.	*Stephania tetrandra S. Moore*	Fang ji Fen fang ji Han fang ji Stephania root	Whole plant	Stephaniae Tetrandrae Herba and Stephaniae Tetrandrae Radix
88.	*Strophanthus spp.*	Kombe, Gardenia oleander, Climbing oleander	Whole plant	Strophanthi Herba and Strophanthi Radix
89.	*Strychnos spp.*	Nux vomica, Ignatius bean, Phayaa mue lek	Seed and Fruit	Strycni Semen and Strycni Radix
90.	*Symphytum spp.*	Comfrey	Whole plant	Symphyti Herba and Symphyti

No.	Plant Name (Species)	Common Name(s)	Harmful Parts	Simplicia Name(s)
				Radix
91.	*Tinospora crispa (L.) Miers ex Hook.f. & Thoms*	Bitter grape/ Brotowali	Root	Tinosporae Crispae Radix
92.	*Valerian spp.*	Valerian	Root	Valerianae Radix
93.	*Veratrum spp.*	False Hellebore	Whole plant	Veratri Herba and Veratri Radix
94.	*Vinca minor L.*	Lesser periwinkle	Whole plant	Vincae Minoris Herba and Vincae Minoris Radix

B. Animals

1. Bufo *gargarizans* Cantor, Bufo *melanostictus* Schneider, *Bufo vulgaris* Lour (*Samsu, Kodok Kerok*).
2. Glandula parathyreoidea, Glandula suprarenalis, Glandula pinealis (Pituitary gland), Glandula thyreoidea (Thymus gland), hypophysis posterior, hypophysis anterior, ovaries, pancreas, testes, placenta, hormones.
3. *Lytta vesicatoria* (Cantharis)
4. *Mylabris phalerata* Pall
5. *Mylabris cichorii* Linnaeus
6. Animals that are protected in accordance with Indonesian Government regulations.

C. Minerals

1. Copper Compounds: Chalcanthite/blue Stone/blue vitriol/Copper Sulfate/Copper (II) sulfate pentahydrate*

2. Lead Compounds:
    a. Litharge/Lead oxide
    b. Minium/Lead tetraoxide
3. Arsenic Compounds:
    a. Arsenic trioxide
    b. Arsenic trichloride
    c. Orpiment (Arsenic Trisulfide)
    d. Realgar
4. Mercury Compounds:
    a. Calomel/Mercuro chloride
    b. Sublimate/Mercury chloride
    c. Cinnabaris/Cinnabar/Mercury sulfide
5. Sulphur, except for external medicine.

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