REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
OF THE REPUBLIC OF INDONESIA
NUMBER 10 OF 2024
ON
LABELING OF HERBAL MEDICINE, QUASI-DRUGS,
AND HEALTH SUPPLEMENTS

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 use of herbal medicine, quasi drugs, and health supplements that are improper, inappropriate, and irrational, thereby posing a health risk, it is necessary to regulate the inclusion of objective, complete, and non-misleading information on labeling;

b. that the inclusion of objective, complete, and non-misleading information as referred to in point a is one of the criteria for the herbal medicine, quasi drugs, and health supplements to meet safety, efficacy/benefit, and quality standards and/or requirements;

c. that based on the consideration as referred to in point a and point b, and in order to implement Article 17 of Regulation of the Indonesian Food and Drug Authority Number 32 of 2022 on Criteria and Procedures for Health Supplement Registration, Article 23 of Regulation of the Indonesian Food and Drug Authority Number 7 of 2023 on Criteria and Procedures for Quasi Drug Registration, and Article 15 of Regulation of the Indonesian Food and Drug Authority Number 25 of 2023 on Criteria and Procedures for Herbal Medicine Registration, it is necessary to issue the Regulation of the Indonesian Food and Drug Authority on Labeling of Herbal Medicine, Quasi Drugs, and Health Supplements;

Observing : 1. Presidential Regulation Number 80 of 2017 on the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia of 2017 of 180);
2. Regulation of the Indonesian Food and Drug Authority Number 21 of 2020 on Organization and Working 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 Working 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 32 of 2022 on Criteria and Procedures for Health Supplement Registration (State Bulletin of the Republic of Indonesia of 2022 Number 1320);
4. Regulation of the Indonesian Food and Drug Authority Number 7 of 2023 on Criteria and Procedures for Quasi Drug Registration (State Bulletin of the Republic of Indonesia of 2023 Number 214);
6. Regulation of the Indonesian Food and Drug Authority Number 19 of 2023 on Organization and Working Procedures of Technical Implementation Unit within the Indonesian Food and Drug Authority (State Bulletin of the Republic of Indonesia of 2023 Number 611);
7. Regulation of the Indonesian Food and Drug Authority Number 25 of 2023 on Criteria and Procedures for Herbal Medicine Registration (State Bulletin of the Republic of Indonesia of 2023 Number 785);

HAS DECIDED:

To issue : REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON LABELING OF HERBAL MEDICINE, QUASI DRUGS, AND HEALTH SUPPLEMENTS.

CHAPTER I
GENERAL PROVISIONS

Pasal 1

In this Agency Regulation, hereinafter referred to:
1. Herbal Medicine means any materials or ingredients, concoctions of ingredients, or products derived from natural resources in the form of plants, animals, minerals, galenic, or other ingredients from natural resources, or a mixture of those ingredients which has been used for generations, or has been proven to be efficacious, safe, and of good quality, used for health care, health improvement, disease prevention, treatment, and/or health recovery based on empirical and/or scientific evidence.

2. Quasi Drugs mean medicines with active ingredients with pharmacological effect that has non-systemic or local characteristics for minor complaints.
3. Health Supplement means a product designed to supplement nutrient intake, to maintain, to increase, and/or to improve health functions, to have nutritional value and/or a physiological effect, to contain one or more materials in the form of vitamins, minerals, amino acids, and/or other non-plant materials combinable with plants.
4. Labeling means complete information concerning the safety, efficacy/benefit, and usage instruction, as well as other information related to the product, which is affixed to the label and/or brochure included in the packaging of Herbal Medicine, Quasi Drugs, or Health Supplements.
5. Brochure means a sheet made of paper or other materials containing labeling information about Herbal Medicine, Quasi Drugs, or Health Supplements, which is included in the product packaging.
6. Packaging means any materials that either directly or indirectly have contact with the content of Herbal Medicine, Quasi Drugs, or Health Supplements.
7. Primary Packaging means any materials that directly come into contact with the content of Herbal Medicine, Quasi Drugs, and Health Supplements.
8. Secondary Packaging means any materials that do not have direct contact with the content of Herbal Medicine, Quasi Drugs, and Health Supplements.
9. Marketing Authorization means a form of registration approval for Herbal Medicine, Quasi Drugs, and Health Supplements to be distributed in the territory of Indonesia.
10. Business Actor means an individual or business enterprise, operating either as a legal entity or otherwise, that has been established and is domiciled or performs activities in the jurisdiction of the Republic of Indonesia, either individually or collectively, under an agreement to perform business activities in the field of Herbal Medicine, Quasi Drugs, and Heath Supplements.
11. Generic name means the name used for Herbal Medicine, Quasi Drugs, or Health Supplements, which may be in the form of a generic name or a name based on the empirical composition formula, empirical efficacy, a name of the main active ingredient, and/or a name designated in the national health program.
12. Trade Name means the brand name used for Herbal Medicine, Quasi Drugs, or Health Supplements that are traded by an individual or a group of individuals, or a legal entity, to distinguish them from other Herbal Medicine, Quasi Drugs, and Health Supplements.
13. Main Supporting Composition for Efficacy means the primary active ingredient that supports the claimed indication for Herbal Medicinal products.
14. Irradiated Product means any product that is deliberately subjected to ionizing radiation, regardless of the source or period of irradiation or the nature of the energy used.

15. Genetically Engineered Product means an organism, living organism, its parts, and/or its derivative that has a new genetic composition that results from the application of modern biotechnology.
16. Nano Product means a product fabricated through nanotechnology processes, with particle sizes ranging from 1 nanometer to less than 1,000 nanometers.
17. Chairperson of the Authority means the Chairperson of the Indonesian Food and Drug Authority.

Article 2

(1) Business Actors that manufacture Herbal Medicine, Quasi Drugs, and/or Health Supplements to be distributed in the territory of Indonesia shall include the Labeling.
(2) The Herbal Medicine as referred to in section (1) shall include:
    a. traditional herbal medicine/jamu;
    b. standardized herbal medicine;
    c. phytopharmaceuticals; and
    d. other Herbal Medicine,
    in accordance with the laws and regulations.
(3) The labeling as referred to in section (1) shall be in the form of writing, pictures, a combination of both, or other forms according to the innovation and advancement of science and technology in Labeling.
(4) In the case of Herbal Medicine, Quasi-Drug, and/or Health Supplements as referred to in section (2) are imported products, the Business Actors, as the Importer, shall affix the labeling information at the time the Herbal Medicine, Quasi-Drugs, and/or Health Supplements enter the territory of Indonesia.
(5) The Labeling as referred to in sections (1) and (3) shall comply with the Marketing Authorization from the Indonesian Food and Drug Authority.
(6) The fulfillment of the Marketing Authorization as referred to in section (4) shall be implemented in accordance with the regulations of the Indonesian Food and Drug Authority concerning the criteria and procedures for registration of Herbal Medicine, Quasi Drugs, and Health Supplements.

Article 3

The labeling inclusion, as referred to in Article 2, shall be affixed to:
a. Primary Packaging;
b. Secondary Packaging; and
c. Brochure/leaflet.

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CHAPTER II
LABELING CRITERIA

Part One
General

Article 4

The labeling as referred to in Article 3 shall be:

a. directly printed or firmly attached to the container and/or Packaging;
b. not easily worn off; and
c. resistant to water, abrasion, and sunlight.

Article 5

(1) The labeling referred to in Article 4 shall contain information that meets the criteria of objectivity, completeness, and non-misleading.
(2) The criteria of objectivity, completeness, and non-misleading as referred to in section (1) are as follows:
    a. objective, meaning it provides information in accordance with existing facts and does not deviate from the characteristics of efficacy/benefit, usage, and safety of Herbal Medicine, Quasi Drugs, and/or Health Supplements;
    b. non-misleading, meaning it provides honest, accurate, and reliable information and does not exploit public concerns about health issues; and/or
    c. complete, meaning it includes information on the use of Herbal Medicine, Quasi Drugs, and/or Health Supplements, warnings, and other important considerations for consumers.

Article 6

(1) Labeling as referred to in Article 2 shall at least contain the following information:
    a. product name and dosage form;
    b. name and address of the industry and/or Business Actor;
    c. name and address of contract provider and/or contract receiver for contracted products;
    d. name and address of licensor and/or licensee for licensed products;
    e. net content, net weight, and/or quantity;
    f. composition;
    g. food additives;
    h. efficacy/benefit claims;
    i. Usage instruction/directions for use;
    j. contraindications, side effects, interactions, warnings, and/or precautions
    k. Marketing Authorization number;
    l. 1production code;
    m. expiration date;
    n. storage condition;
    o. 2D Barcode;

p. logo and text for Herbal Medicine or text for Health Supplements; and
q. other information, subject to compliance with applicable safety and quality standards and/or requirements.

(2) Other information as referred to in section (1) point q can be in the form of:
a. halal label;
b. alcohol content; and
c. information on the origin of specific ingredients.

(3) The inclusion of other information on Labeling as referred to in section (2) shall be regulated by the Indonesian Food and Drug Authority.

(4) In the case of Herbal Medicine and/or Health Supplements containing nutrients, the Labeling may include the percentage of the Recommended Dietary Allowance (RDA/AKG) per day, in accordance with the applicable laws and regulations.

(5) The Recommended Dietary Allowance (RDA/AKG) as referred to in section (4) represents the average daily nutrient requirements for all individuals, based on age group, sex, body size, and physical activity, to achieve optimal health.

(6) The inclusion of information as referred to in section (1) point a, point b, point c, point d, point e, point j, point k, point l, point m, point n, point o, point p, and/or point q shall be placed on the most visible and readable part of the label.

(7) Information other than that referred to in section (1) that may be included in the Labeling is set out in Annex I as an integral part of this Agency Regulation.

(8) The inclusion of information other than that contained in Annex I as referred to in section (1) shall be supported by evidence and relevant studies on the safety and efficacy/benefit.

Article 7

(1) In cases where the label area on the Primary Packaging, based on the evaluation by the Indonesian Food and Drug Authority, does not allow the inclusion of the information as referred to in Article 6 section (1), the labeling shall include:
a. product name;
b. name and address of Business Actor; at least city and country;
c. Marketing Authorization number;
d. production code; and
e. expiration date.

(2) In cases where the label area on the Primary Packaging, as referred to in section (1), is 10 cm2 (ten square centimeters) or less, the inclusion of the name and address of the Business Actor, as referred to in section (1), point b, can be included on the Secondary Packaging.

(3) In cases where Herbal Medicine, Quasi Drugs, and/or Health Supplements are packaged in Primary Packaging with limited dimensions and design, supplementary information in the form of data and/or information other than that referred to in section (1) shall be provided on a separate labeling medium, such as a hangtag, brochure, display panel, shrink wrap, or other attached labeling material.

Article 8

(1) The information referred to in Article 6 section (1) shall be written and printed in the Indonesian language, Arabic numerals, and Latin characters, except for the product name.
(2) The product name as referred to in section (1) can be written in a language other than Indonesian.
(3) The text referred to in section (2) shall be printed in Arabic numerals and Latin characters.
(4) In cases where the information referred to in section (1) is printed in a language other than Indonesian, Arabic numerals, and Latin characters, the inclusion of information shall be accompanied by an equivalent translation in Indonesian, obtained from a sworn translator in Indonesia
(5) In cases where the information referred to in section (2) does not have an equivalent translation in Indonesian, the information may be included in a language other than Indonesian and/or foreign terms.
(6) The foreign terms as referred to in section (5) may include:
    a. words, sentences, numbers, or characters other than Indonesian; and/or
    b. technical or scientific terms to describe a specific ingredient in the list of ingredients.

Article 9

Images, colors, and/or other designs may be used as background, provided that they do not compromise the legibility of the text included in the Labeling.

Article 10

Information in the form of text shall be presented in a regular, clear, visible, readable, and proportional manner to the surface area of the Labeling.

Part Two
Information on Labeling

Paragraph 1
Product Name and Dosage Form

Article 11

(1) The product name as referred to in Article 6, section (1), point a can be in the form of:

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a. Generic Name; and/or
b. Trade Name.

(2) The product name as referred to in section (1) shall meet the following criteria:
a. shall be transparent and reflective of a single product name unity;
b. not in conflict with the provisions of laws and regulations, religious moral principles, cultural values, ethics, and/or public decency;
c. does not use promotional or misleading language, codes, symbols, or images;
d. does not use a name that is similar in essence or entirely, including spelling and pronunciation, to a product name that has already been granted a Marketing Authorization;
e. does not use the same Trade Name for different compositions;
f. does not use the name of a disease that requires clinical diagnosis by a doctor;
g. does not use part of or the entire names of Herbal Medicine, Quasi Drugs, and/or Health Supplements that have been revoked, with the following conditions:
1. contain isolated or synthetic chemical substances with medicinal properties; or
2. contain unauthorized ingredients.
h. does not use the same name for different groups of Herbal Medicine, except for the registration of products that were previously registered in the same group of Herbal Medicine with varying forms of dosage or packaging.

(3) The group of Herbal Medicine, as referred to in section (2), point h, shall be in accordance with the provisions of laws and regulations.

(4) The Trade name of Herbal Medicine, quasi-drugs, or Health Supplements may use an umbrella name derived from:
a. product name with similar efficacy/benefit; or
b. trademark or company name.

(5) The trademark or company name as referred to in section (4) point b may be used as long as it does not conflict with aspects of safety, efficacy/benefit, and/or quality.

Article 12

(1) The addition of information to a product name shall be in the form of information that indicates a difference in content, strength, or efficacy/benefit of the product.

(2) The addition of information as referred to in section (1) may use terms such as “plus”, “forte”, or other similar terms.

(3) The addition of information as referred to in section (2) shall meet the following criteria:
a. originates from a product with the same primary composition;
b. originates from a product with a Generic Name; or
c. has evidence of greater benefits compared to the product without the added term.

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Article 13

The inclusion of dosage forms as referred to in Article 6, section (1), point a shall accurately reflect the product that is manufactured and distributed pursuant to a Marketing Authorization issued by the Indonesian Food and Drug Authority.

Paragraph 2
Name and Address of Industry and/or Business Actor, Contract Provider/Contract Recipient, and/or Licensor/Licensee

Article 14

The inclusion of the address as referred to in Article 6 section (1) point b, point c, and point d on the Labeling shall at least include the names of the city and the country.

Article 15

(1) The name and address of the Business Actor as an Importer who has obtained an appointment from the manufacturer in the country of origin shall be included on the labeling, along with the name and address of the manufacturer in the country of origin.
(2) The inclusion of the name of the Business Actor as an Importer as referred to in section (1) shall begin with the statement "imported by ..." or use a similar phrase.
(3) The information included in the address of the Business Actor as an Importer as referred to in Article 14 shall at least include the city name and Indonesia.

Article 16

The inclusion of the name of the contract provider and/or contract recipient as referred to in Article 6, section (1), point c shall be accompanied by the information "Manufactured by... for ...” or a similar phrase.

Article 17

The inclusion of the name and address of licensor and/or licensee as referred to in Article 6 section (1) point d shall be accompanied by the information “Manufactured by ... under license of ...” or a similar phrase.

Paragraph 3
Net Content, Net Weight, and/or Quantity

Article 18

(1) The net content and net weight as referred to in Article 6, section (1), point e are information regarding the content or weight of Herbal Medicine, Quasi Drugs, and Health Supplements contained in a single packaging unit or container, expressed in metric units.
(2) The inclusion of metric units as referred to in section (1) includes:

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a. Net content for liquid formulations of Herbal Medicine, Quasi Drugs, and Health Supplements.
b. Net weight for solid formulations of Herbal Medicine, Quasi Drugs, and Health Supplements.
c. Net content or net weight for semi-solid or liquid formulations of Herbal Medicine, Quasi Drugs, and Health Supplements.

(3) The inclusion and inscription of the net content or net weight as referred to in section (2) shall include:
a. weight measurements expressed in miligrams (mg), grams (g), or kilograms (kg); or
b. volume measurements expressed in milliliters (mL), liters (L).

(4) In cases of Herbal Medicine, Quasi Drugs, and Health Supplements as referred to in section (1) that are in the form of solid or liquid preparations, in addition to inclusion of the net content or net weight as referred to in section (3), the labeling shall also include the quantity as referred to in Article 6 section (1) point e for each packaging unit.

(5) The provision as referred to in section (4) shall not apply to Herbal Medicine, Quasi Drugs, and Health Supplements in the form of patches, film strips, or other forms, which only require the inclusion of quantity.

(6) Other dosage forms as referred to in section (5) shall be in accordance with the innovation and advancement of science and technology in the field of Herbal Medicine, Quasi Drugs, and Health Supplements.

(7) Net content, net weight, and/or quantity as referred in sections (1) through (6) shall be prominently displayed in a location that is readily visible and/or legible to consumers.

Paragraph 4
Composition

Article 19

(1) The composition as referred to in Article 6, section (1), point f consists of the qualitative and quantitative formulation of the active ingredients of Herbal Medicine, Quasi Drugs, and Health Supplements.

(2) The inclusion of active ingredients as referred to in section (1) shall be preceded by the inclusion of the following text:
a. “Composition:”;
b. “Ingredients used:”;
c. “Ingredients:” or
d. other equivalent phrases.

Article 20

(1) In the case that the active ingredients as referred to in Article 19 section (1) are the Main Supporting Composition for Efficacy, the active ingredients shall be listed on the labeling in both qualitative and quantitative terms.

(2) In the case that the active ingredients as referred to in Article 19 section (1) do not include the Main Supporting Composition for Efficacy as referred to in section (1), the

active ingredients shall be listed on the labeling in qualitative terms.

(3) In the case that the active ingredients as referred to in section (2) consist of more than one type of active ingredient, the inclusion of the quantitative composition shall be done cumulatively based on the total weight.

(4) Active ingredients as referred to in section (1) that are derived from animals, plants, animal extracts, or plant extracts shall be listed according to their Latin/scientific name, including the genus and species, along with the part used.

(5) In addition to the inclusion as referred to in section (4), active ingredients as referred to in section (1) that are derived from animals, plants, animal extracts, or plant extracts may also be accompanied by their Common Name.

(6) In the case of active ingredients as referred to in section (1) that are derived from non-marine animals, in addition to complying with the provisions as referred to in section (4), the Common Name shall also be listed.

Article 21

(1) Active ingredients in the composition as referred to in Article 19 section (2) point a used in the manufacture of Quasi Drugs or Health Supplements shall be included qualitatively and quantitatively.

(2) The active ingredients as referred to in section (1) shall be included using the active ingredient name according to the generic name or international generic name designated by the World Health Organization.

(3) Active ingredients or food additives, as referred to in Article 19 section (2), that do not have an international generic name may use another name according to internationally recognized references.

(4) In cases where the active ingredients used in Quasi Drugs or Health Supplements are derived from plants and/or animals, the listing of active ingredients shall comply with the provisions as referred to in Article 20, section (4).

(5) In cases where the active ingredients used in Health Supplements contain probiotics, they must be listed according to the genus name, species name, and strain.

Article 22

In cases where the Labeling includes the content of a group/compound of active ingredients in the composition as referred to in Article 19, the labeling shall be accompanied by supporting data from quantitative testing.

Paragraph 5
Food Additives

Article 23

(1) Food additives used in the manufacture of Herbal Medicine, Quasi Drugs, and/or Health Supplements, as referred to in Article 6, section (1), point g, shall be qualitatively included in the composition.
(2) Food additives as referred to in section (1) can be in the form of:
    a. sweeteners;
    b. preservatives;
    c. coloring agents; and/or
    d. flavorings.

Paragraph 6
Efficacy/Benefit Claim

Article 24

(1) Business Actors are required to include efficacy/benefit claims as referred to in Article 6, section (1), point h, in accordance with the approval issued by the Chairperson of the Indonesian FDA.
(2) The inclusion and approval of efficacy/benefit claims as referred to in section (1) shall be implemented in accordance with the provisions of laws and regulations.

Paragraph 7
Usage Instruction/Direction of Use

Article 25

(1) The inclusion of information regarding usage instructions/methods of use as referred to in Article 6, section (1), point i shall be in the form of:
    a. information on preparation instruction with clear and easily comprehensible language; and/or
    b. usage instruction accompanied by images.
(2) In cases where the Labeling includes information on preparation instructions for Herbal Medicine, Quasi Drugs, and Health Supplements, the Labeling must comply with the preparation instructions that the Indonesian Food and Drug Authority has approved.

Paragraph 8
Contraindications, Side Effects, Interactions, Warnings, and/or Precautions

Pasal 26

(1) Contraindications, side effects, interactions, warnings, and/or precautions as referred to in Article 6 section (1) point j shall be included in the Labeling in accordance with the results of the registration evaluation by the Indonesian Food and Drug Authority.
(2) The inclusion of information regarding contraindications, side effects, interactions, warnings, and/or precautions as referred to in section (1) is contained in Annex II, as an integral part of this Agency Regulation.

Paragraph 9
Marketing Authorization Number

Article 27

(1) The inclusion of Marketing Authorization Number as referred to in Article 6 section (1) point k on the Labeling shall begin with the text “POM”, followed by 2 (two) letters and a 9-digit number.
(2) The inclusion of 2 (two) letters and 9 (nine)-digit number as referred to in section (1) shall be implemented in accordance with the letters and digits listed in the Marketing Authorization.
(3) In addition to including 2 (two) letters and a 9 (nine)-digit number, the Labeling for export Packaging shall also add the letter “E” after the inclusion of the 9 (nine)-digit number.
(4) The Marketing Authorization Number, as referred to in section (1), shall be included in the most visible and readable part of the Labeling.

Paragraph 10
Production Code

Article 28

(1) The production code as referred to in Article 6, section (1), point I is the Labeling that consists of numbers, letters, or a combination of both.
(2) The production code as referred to in section (1) serves as an identifier for a specific batch, enabling traceability and a comprehensive review of the batch’s production history, including all stages of production, supervision, and distribution.
(3) The production code as referred to in section (1) may be separately included from other information on Labeling.

Paragraph 11
Expiration Date

Article 29

(1) The expiration date as referred to in Article 6, section (1), point m serves as information provided on each product container stating the date until which the product is expected to remain within its specifications, provided it is stored properly.
(2) The inclusion of the expiration date as referred to in Article 6 section (1) point m on the Labeling includes the following information:
    a. date, month, and year; or
    b. month and year.
(3) The expiration date information as referred to in section (1) may be separately included from the Labeling attached to the packaging, accompanied by instructions on where to find the expiration date, such as:

a. ”expiry date, see bottom of bottle”, or
b. ”expiry date, see bottle cap”.

(4) The labeling as referred to in section (2) shall include additional information on the maximum usage period after the packaging is opened.
(5) The inclusion of information as referred to in section (4) is implemented based on the risk assessment.

Paragraph 12
Storage Condition

Article 30

(1) The information regarding storage conditions as referred in Article 6, section (1), point n shall be in accordance with the quality documents submitted during registration.
(2) In cases where Herbal Medicine, Quasi Drugs, and Health Supplements are used more than once, the Labeling may include information on storage conditions after the packaging is opened.

Paragraph 13
2D Barcode

Article 31

(1) The 2D Barcode as referred to in Article 6 section (1) point o serves as a graphical representation of digital data in a two-dimensional format with high decoding capacity that can be read by optical devices used for identification, tracking, and tracing.
(2) The inclusion procedures of 2D Barcode, as referred to in section (1), are implemented in accordance with the provisions of laws and regulations.

Paragraph 14
Logo and Text for Herbal Medicine or
Text for Health Supplements

Article 32

(1) The logo and text for Herbal Medicine or Health Supplements, as referred to in Article 6, section (1), point p, shall be included in Primary Packaging, Secondary Packaging, and/or Brochures in proportion to the packaging size.
(2) The text for Health Supplements, as referred to in section (2), shall be included in vivid/contrasting colors.
(3) The provision as specified in section (1) shall not apply to Primary Packaging in the form of strips and blisters.

Article 33

(1) The logo and text of Herbal Medicine as referred to in Article 32 section (1) are only designated for Herbal

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Medicine that are manufactured and distributed in the territory of Indonesia.

(2) The provisions as referred to in section (1) are exempted for Herbal Medicine under a domestic manufacturing license.

(3) The procedures for writing and inclusion of logo and text for Herbal Medicine as referred to in section (1) are contained in Annex III as an integral part of this Agency Regulation.

Paragraph 15
Information on the Origin of Ingredients
with Specific Technology or Process

Article 34

(1) In the case of Herbal Medicine, Quasi Drugs, and Health Supplements that use ingredients produced with specific technology and process, the Labeling shall include information in the form of:
   a. Genetically Engineered Product;
   b. Irradiated Product;
   c. Organic product;
   d. Nano Product.

(2) The organic product as referred to in section (1), point c, is a product that is manufactured in accordance with the organic production standard and certified by an official certification institution.

(3) The information regarding the product as referred to in section (1) shall be included in the Labeling based on approval from the Indonesian Food and Drug Authority.

Article 35

(1) In the case of Herbal Medicine, Quasi-Drugs, and/or Health Supplements that are included in Genetically Engineered Products as referred to in Article 34 section (1) point a, the raw materials shall meet safety requirements, and the labeling shall include a statement indicating that the product is a Genetically Engineered Product.

(2) Genetically engineered materials that have been approved as safe for use as genetically engineered food can be used as raw materials for Herbal Medicine, quasi-drugs, and/or Health Supplements.

(3) In addition to fulfilling the requirements as referred to in section (2), genetically engineered materials that have not yet been approved as safe for use as genetically engineered food can only be used as raw materials for Herbal Medicine, Quasi Drugs, and/or Health Supplements after a safety and quality assessment has been conducted by the Indonesian Food and Drug Authority.

(4) The requirement to include a statement about Genetically Engineered Products as referred to in section (1) applies to products that contain one or more genetically engineered materials with a minimum content of 5% (five percent)

deoxyribonucleic acid (DNA) of the Genetically Engineered Product.

(5) In the case of Herbal Medicine, Quasi Drugs, and/or Health Supplements that contain more than one genetically engineered material, the percentage of deoxyribonucleic acid (DNA) of the Genetically Engineered Product, as referred to in section (4), is calculated for each genetically engineered material.

(6) The content of deoxyribonucleic acid (DNA) of the Genetically Engineered Product is evidenced by the results of testing conducted on the genetically engineered material by an accredited laboratory.

(7) The inclusion of information on the Genetically Engineered Product as referred to in section (1) is contained in Annex IV as an integral part of this Agency Regulation.

Article 36

(1) In the case of Herbal Medicine, Quasi Drugs, and/or Health Supplements that are included in Irradiated Products as referred to in Article 34 section (1) point b, the Labeling shall include a statement indicating that the product has been irradiated ('irradiated' text).

(2) In addition to the provisions as referred to in section (1), in the case of Herbal Medicine, Quasi Drugs, and/or Health Supplements that are produced using irradiation technology, the labeling shall include information indicating that the product has been irradiated ('irradiated" text).

(3) The inclusion of irradiation information on the labeling as referred to in section (1) shall be accompanied by an irradiation certificate issued by an irradiation facility that has obtained a permit for the utilization of nuclear energy from the government institution responsible for research, development, and utilization of nuclear science and technology, in accordance with applicable laws and regulations.

(4) In the case of imported Herbal Medicine, Quasi Drugs, and Health Supplements as referred to in section (1), the inclusion of a statement indicating irradiation ('irradiated' text) on the Labeling shall be accompanied by an irradiation certificate issued by an irradiation facility that has obtained a permit for the utilization of nuclear energy from the authorized institution in the country of origin.

(5) The inclusion of information on the Irradiated Product as referred to in section (1) is contained in Annex IV as an integral part of this Agency Regulation.

Article 37

(1) In the case of Herbal Medicine, Quasi Drugs, and/or Health Supplements that are manufactured using ingredients produced through organic processes and are

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included in organic products as referred to in Article 34 section (1) point c, the Labeling may include information on organic logos and text.

(2) The products as referred to in section (1) shall be supported by an organic certificate issued and certified by an organic certification institution in accordance with the provisions of laws and regulations.

(3) The inclusion of organic information on the Labeling as referred to in section (1) for Herbal Medicine, Quasi Drugs, and/or Health Supplements that contain at least 95% (ninety-five percent) organic materials by total weight of the product excludes food additives.

(4) In the case of Herbal Medicine, Quasi Drugs, and/or Health Supplements as referred to in section (3) with an organic composition of less than 95% (ninety-five percent), the organic text may only be listed in the composition after the name of the organic material.

(5) The inclusion of organic logo on the Labeling of imported products may only be carried out after re-certification by an authorized organic certification institution in accordance with the provisions of laws and regulations.

(6) The inclusion of information on organic logos and text as referred to in section (1) is contained in Annex IV, as an integral part of this Agency Regulation.

Article 38

(1) In the case of Herbal Medicine, Quasi Drugs, and/or Health Supplements that are included in Nano Products as referred to in Article 34 section (1) point d, the Labeling shall include information in the form of "nano" text.

(2) In addition to the provisions as referred to in section (1), in the case of Herbal Medicine, Quasi Drugs, and/or Health Supplements that are produced using nanotechnology, the Labeling must include information in the form of "nano" text.

(3) The inclusion of information on "nano" text as referred to in section (1) is contained in Annex IV, as an integral part of this Agency Regulation.

CHAPTER III
GUIDANCE

Articlel 39

(1) In the event that, based on the monitoring results, it is found that the Labeling is not in accordance with the Marketing Authorization, the Indonesian Food and Drug Authority may provide technical guidance to the Business Actor.

(2) The technical guidance as referred to in section (1) shall be in corrective actions to the inclusion of Labeling.

(3) Business Actors shall submit a report to the Indonesian Food and Drug Authority as part of the implementation of

the technical guidance as referred to in section (1), which include:

a. the quantity of old Packaging stock;
b. production code;
c. expiration date; and
d. Packaging samples that have been affixed with sticker.

(4) Based on the report as referred to in section (3), the Indonesian Food and Drug Authority shall conduct an evaluation to determine the type of correction action that must be taken by Business Actors.

(5) The corrective actions as referred to in section (4) shall include:

a. corrective actions using the stickers; or
b. re-printing the packaging of Herbal Medicine, Quasi Drugs, and Health Supplements, ,

in accordance with the Marketing Authorization granted by the Indonesian Food and Drug Authority.

CHAPTER IV
PROHIBITION

Article 40

Business Actors are prohibited from including information on the Labeling that contain the following information:

a. claims of being free from certain ingredients when the product actually contains those ingredients, whether intentionally or unintentionally, or as a carry-over substance;
b. images or descriptions related to healthcare professionals, religious figures, or public officials, or portrays them as healthcare professionals, religious figures, or public officials;
c. information, text, or images that offend or discriminate against certain ethnic groups, religions, races, or social classes;
d. information about contests, sweepstakes, or prizes;
e. information, text, or images that are prohibited or contradictory to the provisions of laws and regulations;
f. information that creates a perception or image that contradicts moral norms, ethics, or public order;
g. excessive or unrelated visualizations or information about Herbal Medicine, Quasi Drugs, or Health Supplements; and/or
h. additional information that creates a misleading perception regarding the safety/efficacy/benefits, and quality of the product.

CHAPTER V
ADMINISTRATIVE SANCTIONS

Article 41

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(1) Business Actors that violate the provisions in Article 2 section (1), Article 2 section (4), Article 4, Article 5 section (1), Article 6 section (1), Article 7 section (3), Article 10, Article 13, Article 15 section (1), Article 20 section (1), Article 20 section (2), Article 20 section (3), Article 20 section (4), Article 20 section (6), Article 21 section (1), Article 21 section (5), Article 24 section (1), Article 25 section (2), Article 26 section (1), Article 32 section (1), Article 32 section (2), Article 34 section (3), Article 35 section (1), Article 36 section (1), Article 36 section (2), Article 38 section (1), Article 38 section (2), Article 39 section (4), and/or Article 40 shall be subject to administrative sanctions.

(2) Administrative sanctions as referred to in section (1) shall be in the form of:
   a. warning;
   b. product recall;
   c. eradication;
   d. temporary suspension of activities;
   e. revocation of certificate of Good Manufacturing Practice (GMP) for Herbal Medicine or certificate of compliance with Good Manufacturing Practice (GMP) for Herbal Medicine or certificate of Good Manufacturing Practice (GMP) for Cosmetics or certificate of compliance with Good Manufacturing Practice (GMP) for Cosmetics, and the approval letter of joint facility;
   f. cancellation/revocation of Marketing Authorization numbers; and/or
   g. public announcement.

(3) The administrative sanctions as referred to in section (1) shall be imposed by the Chairperson of the Authority.

Article 42

The procedures for imposing administrative sanctions as referred to in Article 41 shall be carried out in accordance with the provisions in Regulation of the Indonesian Food and Drug Authority governing the follow-up actions on the monitoring results of Herbal Medicine, Quasi Drugs, Health Supplements, and cosmetics.

CHAPTER VI
TRANSITIONAL PROVISIONS

Article 43

Herbal Medicine, Quasi Drugs, and Health Supplements that have obtained Marketing Authorization prior to the enactment of this Agency Regulation, shall comply with the provisions in this Agency Regulation no later than 24 (twenty-four) months from the date of promulgation of this Agency Regulation.

CHAPTER VII
CLOSING PROVISIONS

Article 44

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

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

Issued in Jakarta
on 3 June 2024

Int. CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY

(electronically signed)

LUCIA RIZKA ANDALUSIA

Promulgated in Jakarta
on 7 June 2024

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

ASEP N. MULYANA

STATE BULLETIN OF THE REPUBLIC OF INDONESIA OF 2024 NUMBER 309

ANNEX I
REGULATION OF INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 10 OF 2024
ON
LABELING OF HERBAL MEDICINE, QUASI DRUGS, AND HEALTH SUPPLEMENTS

THE INCLUSION OF ADDITIONAL INFORMATION ON THE LABELING OF HERBAL MEDICINE, QUASI DRUGS, AND HEALTH SUPPLEMENTS

The inclusion of additional information on the labeling of Herbal Medicine, Quasi Drugs, and Health Supplements, shall be presented as follows:

No.	Additional information	Requirements
1.	Nutritional Content	a. Information on the nutritional content may be included on the Labeling of Herbal Medicine or Health Supplements in the form of 'Nutrition Facts'. b. Information in the form of Nutrition Facts shall be based on the testing results from an Indonesian industrial laboratory that holds CPOB/CPOTB certificates or an accredited laboratory. c. The requirements and procedures for including Nutrition Facts shall be implemented in accordance with the provisions of laws and regulations.
2.	Quality Assurance Documents	a. Information on the implementation of Quality Assurance may be in the form of Good Manufacturing Practice (GMP) or a Quality Management System. b. This information shall be supported by the attachment of valid supporing data.
3.	Customer Care Information	a. The Labeling of Herbal Medicine, Quasi Drugs, and Health Supplements shall include information on Customer Care. b. Customer Care may include telephone number, website, email, or social media, name of the unit, or department that can be contacted by consumers.
4.	Information on Images, Logos, and/or Text	a. Images of plants or animals may be included on the labeling of Herbal Medicine, Quasi Drugs, and Health Supplements only if the product contains the respective active or main ingredient. b. Herbal Medicine, Quasi Drugs, and/or Health Supplements that contain fruit flavourings shall only display animated fruit images.

No.	Additional information	Requirements
		c. The inclusion of vegan logo and/or the text 'vegan' on the labeling is permitted as long as the Herbal Medicine, Quasi Drugs, and Health Supplements do not contain animal-derived ingredients and their by-products, including honey. The requirements for the inclusion of vegan logo shall be accompanied by: 1) a vegan certificate from a domestic or overseas vegan organization; and/or 2) the results of animal deoxyribonucleic acid (DNA) testing from an accredited laboratory.
5.	Information on Gluten-Free, Alcohol-Free, and No Added Ingredients	a. Claims on 'gluten-free', 'alcohol-free', and 'no added ingredients' shall be supported by evidence. b. The inclusion of claims on 'gluten-free', 'alcohol-free', and 'no added ingredients' shall comply with the provisions of laws and regulations.
6	Low Lactose and Lactose-Free Claims	a. Only applicable to products that typically contain lactose. b. In addition to the word "free", equivalent words such as "without", "does not contain" can be used. c. Lactose-Free Requirements: Not more than 10 mg/100 kcal and Low Lactose: Not more than 2 g/100 g.
7	Information on 'Clinically Tested' or 'Clinically Proven'	Information on 'Clinically Tested' or 'Clinically Proven' shall be accompanied by valid and qualified clinical trial data on the finished product, conducted in accordance with good clinical practice.
8	Information on marketing achievements or awards	Claims of marketing achievements or awards shall be accompanied by the year of achievement and supported by a certificate issued within the last 2 years.

Int. CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY

signed

LUCIA RIZKA ANDALUSIA

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ANNEX II
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 10 OF 2024
ON
LABELING OF HERBAL MEDICINE, QUASI DRUGS, AND HEALTH SUPPLEMENTS

THE INCLUSION OF INFORMATION ON CONTRAINDICATIONS, SIDE EFFECTS, INTERACTIONS, WARNINGS, AND/OR PRECAUTIONS ON HERBAL MEDICINE, QUASI DRUGS, AND HEALTH SUPPLEMENTS

Information on contraindications, side effects, interactions, warnings, and/or precautions shall be included in the Labeling using a clear and readable font type and size, as well as color.

The inclusion of information on contraindications, side effects, interactions, warnings, and precautions on Herbal Medicine, Quasi Drugs, and Health Supplements with specific ingredients and/or claims displayed on the Labeling, shall refer to the table of sample inclusion of contraindications, side effects, interactions, and warnings, and/or precautions as follows:

A. Active Ingredients

No.	Active Ingredients	Contraindications, Side Effects, Interactions, Warnings, and/or Pracautions
1.	Allium sativum Bulbus	<u>Contraindications</u> Not recommended for patients with stomach ulcers. <u>Warning and Precautions</u> ● Consume with caution when using this product in conjuction with anticoagulants, consult your doctor before undergoing surgery. ● Discontinue use immediately if allergic reactions occur (topical products). Warnings and Precautions shall be included on the following products: 1) Products containing Allium sativum in a single dose. 2) Products containing Allium sativum in combination with other ingredients, with the following compositions requirements: - Powder : more than 300 mg per single use and/or more than 900 mg/day. - Liquid extract: more than 110 mg per single use and/or more than 440 mg/day.

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No.	Active Ingredients	Contraindications, Side Effects, Interactions, Warnings, and/or Pracautions
		- Dry extract: more than 100 mg per single use and/or more than 100 mg/day.
2.	Aloe vera	<u>Warnings and Precautions</u> ● Consume with caution when taking this product in conjunction with diabetes medications. ● Not recommended for pregnant women, breastfeeding mothers, and children under 10 years of age.
3.	Alpha lipoic acid	<u>Side Effects</u> May cause headache, dizziness, and fatique. <u>Warnings and Precautions</u> ● Avoid use in pregnant women or breastfeeding mothers. ● Consume with caution when taking this product in conjunction with diabetes medications. ● Consult a doctor periodically during use.
4.	Andrographis paniculata herb	Indicated for single-composition products with claims to help maintain immune system function. <u>Warning and Precautions</u> ● Consume with caution when taking this product in conjunction with diabetes medications. ● Not recommended for pregnant women or breastfeeding mothers.
5.	Angelica sinensis	<u>Warnings and Precautions</u> ● Not recommended for patients before and after surgery, or those undergoing anticoagulant and anti-thrombotic therapy, such as warfarin and aspirin ● Not recommended for pregnant women.
6.	Azadirachta indica	<u>Warnings and Precautions</u> ● Do not use this product for more than 3 weeks. ● This product may cause liver and kidney damage. ● Not recommended for children, pregnant women, or breastfeeding mothers

No.	Active Ingredients	Contraindications, Side Effects, Interactions, Warnings, and/or Pracautions
		● Use with caution in patients with diabetes, or those undergoing insulin or oral hypoglycemic therapy. (To be included only for products with diabetes-related claims).
7.	Raw materials derived from marine sources Warnings and Precautions	<u>Warnings and Precautions</u> May cause allergic reactions in patients with seafood allergies.
8.	Iron (>15 mg/serving)	<u>Side Effects</u> ● May cause black stools. Do not use in patients with frequent blood transfusions or anemia not caused by iron deficiency.
9.	Oral Liquid contains free sugars, minimum 6 grams per 100 mL	<u>Warnings and Precautions:</u> Use with caution in patients with diabetes or hypertension.
10.	Camphora	Camphora (for external use only) <u>Warnings and Precautions</u> ● Not recommended for children under 2 years of age. ● Do not apply directly under the nostrils.
11.	Cassia senna/ Cassia angustifolia	<u>Contraindications</u> Contraindicated in patients with kidney disease, heart disease, intestinal obstruction, intestinal inflammation, appendicitis, abdominal pain of unknown cause, dehydration, and electrolyte disturbances. <u>Side Effects</u> May cause stomach cramps, abdominal pain, and diarrhea. <u>Warnings and Precautions</u> ● Consult a doctor before using this product with other medications. ● Not recommended for patients with gastrointestinal disorders, such as stomach pain, nausea, and vomiting.

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No.	Active Ingredients	Contraindications, Side Effects, Interactions, Warnings, and/or Pracautions
		● Avoid use in children under 12 years of age, pregnant women or breastfeeding mothers. ● May cause urine discoloration (yellow or red). ● Consult a doctor if constipation persists (for laxative and hemorrhoid claims).
12.	Centella asiatica	Products containing single or combination extracts of Centella Asiatica with a daily dose exceeding 200 mg (equivalent to 2 grams of Centella Asiatica herb) shall include warnings, precautions, and contraindications. Contraindications Not recommended for use with aspirin/anticoagulants. Warnings and Precautions ● Not recommended for children under 2 years of age and pregnant women. ● Do not use continuously for more than 6 weeks, but may be reused after a 2-week discontinuation period. ● For topical use, do not apply directly to open wounds.
13.	Chitosan	Side Effects: Gastrointestinal disorders such as nausea, diarrhea, or constipation may occasionally occur. Warnings and Precautions ● May cause allergic reactions in patients with seafood allergies. ● May affect the absorption of other substances, including vitamins A, D, E, and K. It is recommended to have a 2-3 hour interval between administrations. ● Avoid use in children under 12 years of age, pregnant women or breastfeeding mothers. ● Avoid using this product with anticoagulants such as warfarin, heparin, and aspirin.
14.	Single Citicholine	Warnings and Precautions Use under medical supervision.

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No.	Active Ingredients	Contraindications, Side Effects, Interactions, Warnings, and/or Pracautions
15.	Co Enzyme Q10 combination	Warnings and Precautions ● Avoid use in pregnant women or breastfeeding mothers. ● Use with caution in patients using warfarin. ● Consult a doctor before using this product with other medications.
16.	Single Coenzyme Q10	Warnings and Precautions ● Use under medical supervision. ● Avoid use in pregnant women or breastfeeding mothers. ● Use with caution in patients taking warfarin and statin. ● Consult a doctor before using this product with other medications.
17.	Conjugated linoleic acid	Side Effects May cause gastrointestinal disturbances. Warnings and Precautions ● Avoid use in children, pregnant women, or breastfeeding mothers. ● Discontinue use immediately if allergic reactions occur.
18.	Creatine	Contraindications Patients with impaired renal function. Warnings and Precautions ● Avoid use in children, pregnant women, or breastfeeding mothers. ● Recommended to be taken with at least 8 glasses of water per day.
19.	Echinacea sp	Contraindications Patients with multiple sclerosis, collagen disease, leukemia, tuberculosis, AIDS, and autoimmune disorders.. Interactions Should not be used in conjunction with immunosuppressive products. Warnings and Precautions ● Discontinue use immediately if allergic reactions occur. ● Not recommended for use exceeding 8 weeks.

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No.	Active Ingredients	Contraindications, Side Effects, Interactions, Warnings, and/or Pracautions
		● Avoid use in pregnant women or breastfeeding mothers. ● Consult a doctor before using this product with other medications.
20.	Evening Primrose Oil (EPO)	<u>Warnings and Precautions</u> ● Not recommended for pregnant women or breastfeeding mothers. ● Avoid using this product with anticoagulants such as warfarin, heparin, and aspirin. ● Discontinue use 2 weeks prior to surgery due to increased risk of bleeding. ● Exceeding the recommended dosage may cause gastrointestinal disturbances, skin allergies, headaches, and bleeding such as nosebleeds and subcutaneous hemorrhages. For topical use or in the form of a mixture for oral use with a small dose (less than 100 mg/day), warnings/precautions are not required unless combined with substances that intensify the risk of bleeding.
21.	Ganoderma lucidum	<u>Warnings and Precautions</u> ● If adverse reactions occur, discontinue use of this product immediately and consult a doctor. ● Consult a doctor before using this product with other medications. ● Not recommended for children, pregnant women, or breastfeeding mothers.
22.	Gingko biloba	<u>Warnings and Precautions</u> ● Not recommended for use exceeding 4 weeks. ● Avoid use in children under 12 years of age, pregnant women, or breastfeeding mothers. ● Avoid using this product with anticoagulants such as warfarin, heparin, and aspirin. ● Discontinue use 2 weeks prior to surgery due to increased risk of bleeding. ● Consult a doctor before using this product with other medications.

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No.	Active Ingredients	Contraindications, Side Effects, Interactions, Warnings, and/or Pracautions
		● Exceeding the recommended dosage may cause gastrointestinal disturbances, skin allergies, headaches, and bleeding such as nosebleeds and subcutaneous hemorrhages.
23.	Glychirhiza glabra, Glychirhiza uralensis	Contraindications Patients with hypertension, hypokalemia, kidney disease, and edema. Interactions ● Interacts with corticosteroid medications such as prednisolone. ● Interacts with thiazides, potent diuretics, cardiac glycosides, spironolactone, or amiloride. Warnings and precautions should be included if the product contains more than 2g/day of Glycyrrhizae Radix. Warnings and Precautions ● Not recommended for pregnant women or breastfeeding mothers. ● Use for more than 4 weeks should be under medical supervision.
24.	Herbal products containing Caffeine such as Coffea sp, Cola acuminata, Cola nitida, Ilix paraguariensis, Paulinia cupana combined with Panax ginseng; Panax notoginseng; Panax pseudoginseng; Panax quinquefolius Caffeine and Herbal products containing Caffeine such as Coffea sp, Cola acuminata, Cola Nitida, Ilix paraguariensis, Paulinia cupana	Warnings and Precautions ● Not recommended for children, pregnant women, or breastfeeding mothers. ● Use with caution in patients with hypertension or diabetes ● Do not exceed the recommended dosage.

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No.	Active Ingredients	Contraindications, Side Effects, Interactions, Warnings, and/or Pracautions
	combined with Panax ginseng; Panax notoginseng; Panax pseudoginseng; Panax quinquefolius	
25.	Caffeine and Herbal products containing Caffeine such as Coffea sp, Cola acuminata, Cola Nitida, Ilix paraguariensis, Paulinia cupana	Warnings and Precautions: ● Not recommended for children, pregnant women, or breastfeeding mothers. ● Do not exceed the recommended dosage.
26.	Colostrum	Contraindications Hypersensitivity or allergy to lactose or cow's milk. Warnings and Precautions ● Use with caution in individuals with lactose intolerance. ● Avoid use in children under 1 year of age.
27.	Chromium	Warnings and Precautions ● Consult a doctor before using this product for more than 6 months or if you have kidney or liver disease. ● Use in patients with diabetes and obesity shall be under medical supervision. ● Do not use this product during pregnancy or breastfeeding, unless recommended by a doctor.
28.	Honey	Warnings and Precautions ● Not recommended for children under 1 year of age. ● Use with caution in individuals with history of allergy to bee products and their derivatives.
29.	Honey derivatives e.g. royal jelly, propolis, bee pollen	Warnings and Precautions Use with caution in individuals with history of allergy to bee products and their derivatives.

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No.	Active Ingredients	Contraindications, Side Effects, Interactions, Warnings, and/or Pracautions
30.	Methyl sulfonyl methane (MSM)	Side Effects Prolonged or excessive use, particularly in elderly individuals, may lead to adverse effects such as nausea, vomiting, diarrhea, and headache Warnings and Precautions Avoid use in pregnant women or breastfeeding mothers.
31.	Monascus purpureus	Warnings and Precautions ● Not recommended for patients with liver and kidney disorders, children under 18 years of age, adults over 70 years of age, pregnant women or breastfeeding mothers. ● Consult a doctor periodically during use. ● Use with caution when in conjunction with other medications, particularly cholesterol-lowering agents (such as atorvastatin, simvastatin, lovastatin). ● The maximum recommended duration of use is 3 months/do not exceed 3 months of continuous use.
32.	Octacosanol	Side Effects May cause headache, insomnia, and skin redness. Warnings and Precautions ● Avoid use in children, pregnant women, or breastfeeding mothers. ● Avoid using this product with anticoagulants such as warfarin. ● Discontinue use 2 weeks prior to surgery. ● Discontinue use immediately if allergic reactions occur.
33.	Panax ginseng; Panax notoginseng; Panax pseudoginseng; Panax quinquefolius	The following warnings and precautions apply only to: - Single-ingredient compositions. - Combinations with other herbal ingredients intended for male stamina, female health, and blood circulation. Warnings and Precautions ● Use with caution in patients with hypertension or diabetes.

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No.	Active Ingredients	Contraindications, Side Effects, Interactions, Warnings, and/or Pracautions
		● Avoid use in pregnant women or breastfeeding mothers.
34.	Phsyllium husk	<u>Side Effects</u> May cause bloating. <u>Warnings and Precautions</u> ● Adequate hydration of minimum 8 glasses of water per day and a low-fat diet are essential during use. ● Do not use without water. ● Do not consume in powder form. ● If used in conjunction with other medications, administer with a 2-3 hour interval between oral administration of other medications and this product to minimize potential effects on drug absorption. ● Not recommended in patients with pancreatic enzyme disorders, as it may inhibit lipase enzyme activity. ● Discontinue use immediately if allergic reactions occur. ● Use with caution when in conjunction with antidiabetic medications.
35.	Psyllium husk and Cassia senna combination	<u>Warnings and Precautions</u> May cause nausea.
36.	Policosanol	<u>Side Effects</u> May cause headache, insomnia, and skin redness. <u>Warnings and Precautions</u> ● Avoid use in children, pregnant women, or breastfeeding mothers. ● Avoid using this product with anticoagulants such as warfarin. ● Discontinue use 2 weeks prior to surgery. ● Discontinue use immediately if allergic reactions occur.
37.	Product with higher EPA content than DHA	<u>Warnings and Precautions</u> ● Use with caution when consuming products with higher EPA content than DHA in combination with anticoagulants, as it may intensify the risk of bleeding..

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No.	Active Ingredients	Contraindications, Side Effects, Interactions, Warnings, and/or Pracautions
		● If undergoing surgery, inform your doctor about the use of this supplement.
38.	Rutin	<u>Contraindications</u> Patients with hypersensitivity to products containing rutin. <u>Interactions</u> May inhibit the effectiveness of quinolone antibiotics. <u>Warnings and Precautions</u> ● Avoid use in pregnant women or breastfeeding mothers. ● Discontinue use immediately if allergic reactions occur.
39.	Valeriana Officinalis	<u>Contraindicatioins</u> Not recommended for patients with liver function disorders. <u>Warnings and Precautions</u> ● Do not drive or operate heavy machinery that requires high concentration. ● Avoid use in conjuction with alcohol or other sedative substances. ● Avoid use in children under 12 years of age, pregnant women, or breastfeeding mothers. ● If sleep disturbances persist or worsen after 2 weeks of use, consult a doctor. (These warnings are specifically applicable to Valerian products with sleep disorder claims) ● Do not use for more than 2 weeks continuously and do not exceed the recommended dose. (This warning applies when the Valerian extract dose is 300-600 mg, equivalent to 2-3 g of dried Valerian root, taken 1-5 times per day.)
40.	Vitamin D single dose, more than 800 IU up to 1000 IU	<u>Warnings and Precautions</u> ● Check blood Vitamin D levels periodically, after 6 months or more of continuous use; ● Consult a doctor before using this product, for pregnant women or breastfeeding mothers;

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No.	Active Ingredients	Contraindications, Side Effects, Interactions, Warnings, and/or Pracautions
		● Discontinue use immediately if allergic reactions occur; and ● Consume calcium within the recommended dietary allowance to avoid hypercalcemia.
41.	High-dose Vitamin E 400 IU = 240 mg	Warnings and Precautions Do not exceed the recommended dose, as it may induce adverse effects, including depletion of vitamin A reserves, inhibition of vitamin K absorption or activity, gastrointestinal disturbances such as diarrhea and stomach pain and fatigue.
42.	Vitamin K1 / Vitamin K2	Warnings and Precautions This product should not be administered to individuals undergoing treatment with warfarin (anticoagualant) or similar medications.
43.	Whey	Warnings and Precautions ● Not recommended for individuals with liver or kidney dysfunction. ● Long-term use exceeding recommended dosage may impair liver and kidney function. ● Patients with hypersensitivity to milk proteins. ● Not suitable for pregnant women and children under 15 years of age.

B. Inactive Ingredients (Excipients)

No.	Inactive Ingredients	Warnings and Precautions
1.	Aspartame	● Contains artificial sweetener aspartame. ● This product contains phenylalanine, not recommended for individuals with phenylketonuria.
2.	Artificial sweetener (example: acesulfame, sucralose, neotame, sodium cyclamate, saccharin)	● Containes artificial sweetener ..... (name of artificial sweetener). ● This product is not recommended for infants under 1 year of age.

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C. Herbal Medicine Claims

No.	Claims	Warnings and Precautions
1.	UR/Urinating	• If symptoms do not improve, consult a doctor immediately. • Drink plenty of water, at least 2 liters per day.
2.	Fever	• If fever persists for more than 3 days after using this medication, seek medical attention immediately from a doctor or healthcare facility. • Fever-reducing medication only alleviates symptoms, but does not eliminate the underlying cause of the illness.
3.	Diarrhea	• If used in conjunction with other medications, it is recommended to administer this product with a 2-3 hour interval between oral administration of other medications and this product, as it may affect the absorption of other medications. (Particularly for anti-diarrheal medications containing activated charcoal and other adsorbent materials). • Not recommended for children under 5 years old and patients should also consume oral rehydration therapy. • If symptoms do not improve within 3 days of use, consult a doctor immediately.
4.	Kidney/Oxalate Stone Claims	• If symptoms do not improve, consult a doctor immediately. • Drink at least 2 liters (8 cups) of water per day. • Avoid prolonged or continuous use of this product.
5.	Diabetes Claims	• For use only in patients with diabetes (diabetics) as prescribed by a doctor. • Consult a doctor periodically during use.
6.	Helps Maintain Health Condition in Cancer Patients	• Consult a doctor before taking this medication. • This product is intended for use as a complementary therapy in cancer treatment.
7.	Supports Vaginal Health and Reduces Excess Discharge	Consult a doctor if discharge does not decrease, or if it has a strong odor, yellow color, or contains blood.

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No.	Claims	Warnings and Precautions
8.	Helps Reduce Body Fat (Weight Loss)	The use of this product should be accompanied by regular exercise and a low-calorie and low-fat diet.
9.	Relieves Cold, Sinus, and Flu Symptoms	Consult a doctor if symptoms recur or persist.
10.	Supports Prostate Health	Consult a doctor before taking this medication.
11.	Helps Lower High Blood Pressure	● For use only in patients with hypertension (high blood pressure) as prescribed by a doctor. ● Consult a doctor periodically during use.
12.	Soothes Digestive Issues and Relieves Stomach Discomfort	Consult a doctor if symptoms recur or persist.

D. Health Supplement Claims

No.	Claims	Warnings and Precautions
1.	Dietary supplement to help support health in people with diabetes	● For use only in patients with diabetes (diabetics) as prescribed by a doctor. ● Consult a doctor periodically during use.
2.	Helps reduce body fat	The use of this product should be accompanied by regular exercise and a low-calorie and low-fat diet.

Int. CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed

LUCIA RIZKA ANDALUSIA

ANNEX III
REGULATION OF INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 10 OF 2024
ON
LABELING OF HERBAL MEDICINE, QUASI DRUGS, AND HEALTH SUPPLEMENTS

PROCEDURES FOR INSCRIPTION AND INCLUSION OF LOGOS AND TEXTS ON HERBAL MEDICINE PRODUCTS

No.	Herbal Medicine	Procedures for Inscription and Inclusion of Logos
1.	Jamu	a. The jamu logo features a "leafy branch within a circle" design, placed at the top left corner of the Primary Packaging, Secondary Packaging, and/or Brochure. The logo is printed in green on a white or contrasting background. b. The text “JAMU” must be clear and easily readable, printed in black on a white or contrasting background with the text “JAMU”. c. Jamu Logo  JAMU
2.	Standardized Herbal Medicine	a. The logo features "three pairs of leaf fingers within a circle" and is placed at the top left corner of the Primary Packaging, Secondary Packaging, and/or Brochure. The logo is printed in green on a white or contrasting background with the logo color. b. The text "STANDARDIZED HERBAL MEDICINE" must be clear and easily readable, printed in black on a white or contrasting background with the text “STANDARDIZED HERBAL MEDICINE”.

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SWORN TRANSLATOR
Indonesian Into English

No.	Herbal Medicine	Procedures for Inscription and Inclusion of Logos
		c. Standardized Herbal Medicine Logo 
3.	Phytopharmaceuticals	a. The logo features "leaf fingers forming a star within a circle" and is placed at the top left corner of the Primary Packaging, Secondary Packaging, and/or Brochure. The logo is printed in green on a white or contrasting background with logo color. b. The text "PHYTOPHARMACEUTICALS" must be clear and easily readable, printed in black on a white or contrasting background with the text “PHYTOPHARMACEUTICALS”. c. Phytopharmaceuticals Logo 

Int. CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed

LUCIA RIZKA ANDALUSIA

ANNEX IV
REGULATION OF INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 10 OF 2024
ON
LABELING OF HERBAL MEDICINE, QUASI DRUGS, AND HEALTH SUPPLEMENTS

THE INCLUSION OF INFORMATION ON GENETICALLY ENGINEERED PRODUCTS, IRRADIATED PRODUCTS, ORGANIC PRODUCTS, AND NANO PRODUCTS ON HERBAL MEDICINE, QUASI DRUGS, AND HEALTH SUPPLEMENTS

No.	Inclusion of Information	Requirements
1.	Genetically Engineered Products	• Herbal Medicine, Quasi Drugs and/or Health Supplements that utilize genetic engineering technology shall display Genetically Engineering Product Information in the form of the text "GENETICALLY ENGINEERED PRODUCT". • The text "GENETICALLY ENGINEERED PRODUCT" shall be displayed in the composition section, immediately following the name of the genetically engineered ingredient.
2.	Irradiated Products	Information on Herbal Medicine, Quasi Drugs, and Health Supplements that have undergone Irradiation of the final product shall include: a. the text “IRRADIATED” shall be included after the Irradiation logo; b. the text “DO NOT IRRADIATE AGAIN” c. the date, month, and year of irradiation. d. the name of country where the irradiation was completed; and e. irradiation logo:
3.	Organic Products	The Organic Indonesia Logo is a circular symbol consisting of two parts, inscribed with "Organic Indonesia" accompanied by a single leaf image attached to the letter "G" in the shape of a root bud

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No.	Inclusion of Information	Requirements
		ORGANIK INDONESIA
4.	Nano Products	The term "nano" may be added after the name of the ingredient in the composition, in accordance with the provisions of laws and regulations.

Int. CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

signed.

LUCIA RIZKA ANDALUSIA

MOCH HIKMAT GUMILAR
SWORN TRANSLATOR
Indonesian Into English

TRANSLATOR'S AFFIDAVIT

I, Moch Hikmat Gumilar, a Sworn Translator in the Republic of Indonesia under the rules and regulations applicable in the Republic of Indonesia, certify and declare under the oath of office that this document is an accurate, faithful, and complete translation from the source document provided to me—appointment by Decree of the Minister of Law and Human Rights of the Republic of Indonesia No. AHU-11 AH.03.07.2023. Verify the authenticity of this translation at https://penerjemah-id.com/verify by entering the unique code **tHLtn**, scanning the QR code with an internet-connected mobile phone, or sending an email to penerjemah@penerjemah-id.com, WhatsApp to +6281289908544 (working hours) or +62811174361 (outside working hours). Printed and signed in Tangerang Selatan on 11 November 2024. ATA (American Translators Association) Associate Member No. 252219.

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