HEAD OF SUPERVISORY BODY OF DRUGS AND FOOD OF THE REPUBLIC OF INDONESIA PROCEDURE FOR ISSUING RECOMMENDATION TO OBTAIN APPROVAL FOR IMPORTING MEDICINES, TRADITIONAL MEDICINES, HEALTH SUPPLEMENT, AND/OR COSMETICS AS COMPLEMENTARY GOODS

(Regulation of Head of Agency on Drugs and Food Supervison of R.I Number 27 Year 2016, dated December 23, 2016)

WITH THE BLESSING OF THE ONE ONLY GOD

Considering:

Whereas, to implement that provision in Article 9 paragraph (4) of Regulation of Minister of Health Number 14 Year 2016, concerning recommendation to obtain approval for importing complementary goods, goods for market test, and after sales service, it is necessary to stipulate Regulation of Head of Agency on Drugs and Food Supervison on procedure for issuing recommendation to obtain approval for importing Traditional Medicines, Health Supplement, and/or Cosmetics, as complementary goods.

In view of:

1. Law Number 8 Year 1999, concerning Consumer Protection (Statute Book of the Republic of Indonesia Year 1999 Number 42, Supplement to Statute Book of the Republic of Indonesia Number 3821);

2. Law Number 36 Year 2009, concerning Health (Statute Book of the Republic of Indonesia Year 2009 Number 144, Supplement to Statute Book of the Republic of Indonesia Number 5063);

3. Government Regulation Number 72 Year 1998, concerning Security on Pharmaceutical Preparation and Health appliances (Statute Book of the Republic of Indonesia Year 1998 Number 138, Supplement to Stat-

ute Book of the Republic of Indonesia Number 3781);

4. Presidential Decree Number 103 Year 2001, concerning Capacity, Duty, Function, Authority, Organizational Structure, and Work Procedure of Non-Department Government Institution as amended several times and lately by Presidential Regulation Number 145 Year 2015, concerning the Eigth Amendment to Presidential Decree Number 103 Year 2001, concerning Capacity, Duty, Function, Authority, Organizational Structure, and Work Procedure of Non-Department Government Institution (Statute Book of the Republic of Indonesia Year 2015 Number 322);

5. Presidential Decree Number 110 Year 2001, concerning Organizational Unit and Duty of Echelon I of Non-Department Governmental Institution as amended several times and lately amended by Presidential Regulation Number 4 Year 2013, concerning Eight Amendment to Presidential Decree Number 110 Year 2001, concerning Organizational Unit and Duty of Echelon I of Non-Department Governmental Institution (Statute Book of the Republic of Indonesia Year 2013 Number 11);

6. Regulation Minister of Health Number 1175/Menkes/Per/VIII/2010 Year 2010, concerning License for Cosmetics Production as amended by Regulation of Minister of Health Number 63 Year 2013, concerning Amendment to Regulation of Minister of Health Number 1175/Menkes/Per/VIII/2010 Year 2010, concerning License for Cosmetics Production (State Gazette of the Republic of Indonesia Year 2013 Number 1317);

7. Regulation of Minister of Health Number 1176/Menkes/Per/VIII/2010 Year 2010, concerning Notification on Cosmetcis (State Gazette of the Republic of Indonesia Year 2010 Number 397);

8. Regulation of Minister of Health Number 1799/Menkes/Per/XII/2010, concerning Pharmaceutical Industry (State Gazette of the Republic of Indonesia Year 2010 Number 721) as amended by Regulation Minister of Health Number 16 Year 2013, on Amendment to Regulation of the Minister of Health Number 1799/Menkes/Per/XII/2010, on Pharmaceutical Industry (State Gazette of the Republic of Indonesia Year 2013

Number 442);

9. Regulation of Minister of Health Number 006 Year 2012, concerning Industry and Business on Traditional Medicines (State Gazette of the Republic of Indonesia Year 2012 Number 225);

10. Regulation Minister of Health Number 007 Year 2012, concerning Registration of Traditional Medicines (State Gazette of the Republic of Indonesia Year 2012 Number 226);

11. Regulation of Minister of Trade Number 70/MDAG/PER/9/2015, concerning Importer Identification Number (State Gazette of the Republic of Indonesia Year 2015 Number 1516);

12. Regulation of Minister of Trade Number 87/MDAG/PER/10/2015, concerning requirements for Importing Particular Goods (State Gazette of the Republic of Indonesia Year 2015 Number 1553);

13. Regulation of Minister of Trade Number 118/MDAG/PER/12/2015, concerning requirements for Importing Complementary Goods for Market Test, and After Sales survice (State Gazette of the Republic of Indonesia Year 2015 Number 2001);

14. Regulation of Minister of Health Number 14 Year 2016, concerning recommendation to obtain approval for importing complementary goods, goods for market test, and after sales service (State Gazette of the Republic of Indonesia Year 2016 Number 475);

15. Regulatioof Head of Agency on Drugs and Food Supervison Number 14 Year 2014, concerning Organization and Work Procedure of Technical Operator (State Gazette of the Republic of Indonesia Year 2014 Number 1714);

16. Regulation of Head of Agency on Drugs and Food Supervison Number 12 Year 2015, concerning supervision on imported medicines and food to the territory of the Unitary State of the Republic of Indonesia (State Gazette of the Republic of Indonesia Year 2015 Number 1373) as amended by Regulation of Head

of Agency on Drugs and Food Supervison Number 25 Year 2016, concerning Amendment to Regulation of Head of Agency on Drugs and Food Supervison Number 12 Year 2015, on supervision on imported medicines and food into the territory of the Unitary State of the Republic of Indonesia (State Gazette of the Republic of Indonesia Year 2016 Number 1557);

17. Decision of the Head of Agency on Drugs and Food Supervison Number 02001/SK/KBPOM Year 2001, concerning Organization and work procedure of of Agency on Drugs and Food Supervison as amended by Decision of the Head of Agency on Drugs and Food Supervison Number HK.00.05.21.4231 Year 2004, on Amendment to Decision of the Head of Agency on Drugs and Food Supervison Number 02001/SK/KBPOM Year 2001, concerning Organization and work procedure of Agency on Drugs and Food Supervison;

D E C I D E S :

To stipulate:

REGULATION OF THE HEAD OF AGENCY ON DRUGS AND FOOD SUPERVISON CONCERNING PROCEDURE FOR ISSUING RECOMMENDATION TO OBTAIN APPROVAL FOR IMPORTING TRADITIONAL MEDICINES, HEALTH SUPPLEMENT, AND/OR COSMETICS AS COMPLEMENTARY GOODS.

CHAPTER I

GENERAL PROVISION

Article 1

What is meant in this Regulation of Head of Agency by:

1. Medicine shall be medicine product, including biological product constituting stuff or combined stuff used to examine and investigate physiology and patology systems to determine diagnosis for prevention, healing, recovering and improving human health and contraception.

2. Traditional medicine shall be stuff or herbs in the form of plants, animal stuff, mineral, essence preparation or mixture of the above stuff which have been utilized in descendens as medication, and applied based on the norms prevailing within the society.

3. Health supplement shall be product meant to supplement the need for nutrition to maintain, improve, and/or repair health function, is nutritious and/or improve health function, and/or effect on physiology, contain one or more stuff in the form of vitamin, mineral, amino acid and/or other non-plant stuff that may be combined with plants.

4. Cosmetics shall be stuff or preparation used for the outer part of human body (epidermic, hair, nail, lips, and outer part of genital organ) or teeth and mouth mucosa membrane to cleanse, give fragrance, modify appearance and/or drive away body odor or protect or keep physical condition well.

5. Pharmaceutical Industry shall be business entity holding License issued by Minister Minister of Health to operate business activity to manufacture Medicines or Medicinal stuff.

6. Traditional Medicine Industry, hereinafter referred to as IOT, shall be industry producing all kinds of stuff for Traditional Medicines.

7. Traditional Medicine Small Business, hereinafter referred to as UKOT, shall be business producing all kinds stuff for Traditional Medicines, except preparation for tablet and effercense.

8. Cosmetics Industry shall be industry producing Cosmetics that holds Business License for industry or Industrial Registration Certificate in line with the provisions in the statutory regulation.

9. Processed Food Producer shall be individual business and/or business entity producing, processing, changing the form of, preserving, re-packing processed food for circulation.

10. Complementary goods shall be goods imported by Company holding Producer–Importer Identification Certificate, for the purpose to support line of products originating from and produced by company in overseas that has privilege in the company possessing Producer -Importer Identification Number.

11. Privilege shall be relationship between the company possessing Producer-Importer Identification Number and the company overseas where either of the parties has capacity to control the other party or has significant effect over the other party based on the prevailing Standard Accountancy.

12. Producer-Importer Identification Number hereinafter referred to as API-P, shall be Identification Number as Producer-Importer.

13. Applicant shall be Pharmaceutical Industry in the form of IOT, UKOT, Cosmetics Industry, or Processed Food possessing API-P.

14. Import Approval shall be approval used as License to import Complementary Goods issued by the Minister of Trade.

15. Day shall be working days.

16. Head of Agency shall be Head of Agency Drugs and Food Supervison.

17. Deputy shall be Deputy on Theraphetical Product Supervsion and NAPZA or Deputy on Traditional Medicines, Cosmetics, and Complementarh Product.

Article 2

(1) Pharmaceutical Industry, IOT, UKOT, and Cosmetics Industry as holder of API-P may import Complementary Goods, as required to develop its business and investment.

(2) Complementary Goods as referred to in paragraph (1) cover Traditional Medicines, Health Supplement, and/or Cosmetics.

(3) Health Supplement as referred to in paragraph (2) includes Health Supplement imported by Producer of Processed Food.

(4) Imported Complementary Goods as referred to in paragraph (1) may be traded and/or transferred to other party.

Article 3

(1) The Complementary Goods referred to in Article 2 paragraph (2) must comply with the criteria that such Goods:

a. are not yet produced by Applicant as proven by unavailable producing facilities in the form of preparation of Complementary Goods;

b. justify with the Business License on industry or other business of the type owned by the Company possessing API-P;

c. produced by company oversease possessing Right of Privilege with the Applicant possessing API-P; and

d. holds License Identification Number for Circulating.

(2) The Privilege as referred to in paragraph (1) letter c shall be obtained by Appointment Letter as Distributor and Joint Operation.

CHAPTER II

PROCEDURE TO ISSUING RECOMMENDATION

Article 4

(1) Pharmaceutical Industry, IOT, UKOT, Cosmetic Industry, or Processed Food Producer intending to import Traditional Medicines, Health Supplement, and/or Cosmetics must recommendation from the Head of Agency.

(2) Head of Agency shall grant authority to issue recommendation to obtain approval for importing Traditional Medicines, Health Supplement, and/or Cosmetics as referred to in paragraph (1) to the Deputy based on

thee respective duty and function.

Article 5

(1) Application for recommendation to obtain approval for importing Traditional Medicines, Health Supplement, and/or Cosmetics shall be submitted to the Head of Agency.

(2) The application submitted as referred to in paragraph (1) must use the format as specified in Attachment-I constituting inseparable part of Regulation Head of Agency.

(3) The application referred to in paragraph (1), must be supported by:

a. photocopy of License Certificate on Pharmaceutical Industry, IOT, UKOT, Cosmetics production or Processed Food Producer;

b. photocopy of API-P;

c. photocopy of Obligatory Taxpayer Identification Number (NPWP);

d. Appointment Letter as Agent / Distributor issued by the company overseas and Joint Operation Agreement; and

e. list of Traditional Medicines, Health Supplement, and/or Cosmetics to be imported.

(4) List of Traditional Medicines, Health Supplement, and/or Cosmetics as referred to in paragraph (3) letter e using the format as specified in Attachment- II constituting inseparable part of Regulation Head of Agency ini.

Article 6

(1) Based on the application referred to in Article 5, the Deputy may approve or reject to issue recommendation to obtain approval for importing Traditional Medicines, Health Supplement, and/or Cosmetics.

(2) Deputy shall issue recommendation to obtain approval for importing Traditional Medicines, Health Supplement, and/or Cosmetics within ten (10) days at the latest effective as of the application referred to in Ar-

ticle 5 is declared acceptable and authentic.

(3) If the application for recommendation to obtain approval for importing Traditional Medicines, Health Supplement, and/or Cosmetics as referred to in Article 5 is rejected, Deputy shall notify rejection to issue recommendation to import Traditional Medicines, Health Supplement, and/or Cosmetics within ten (10) days at the latest supported by reason for rejection.

(4) Format of recommendation to obtain approval for importing Traditional Medicines, Health Supplement, and/or Cosmetics as referred to in paragraph (2) shall be as specified in Attachment-III constituting inseparable part of Regulation Head of Agency ini.

Article 7

Recommendation shall be issued for certain amount and the validity thereof shall comply with the recommendation of validity of License to circulate for two (2) years as of the date of issue..

CHAPTER III

REPORTING

Article 8

(1) Pharmaceutical Industry, IOT, UKOT, Cosmectics Industry, or Processed Food Producer that has obtained recommendation shall be obliged to submit Report on the implementation of Import, either it has been realized or not yet realized.

(2) The Report referred to in paragraph (1) must be submitted once in three (3) months within at the latest the 15th of the first month of the next quarter by electronic and/or in writing to the Minister in charge of Trade with copy to the Head of Agency.

CHAPTER IV

CLOSING PROVISION

Article 9

This Regulation Head of Agency takes effect one (1) month as of the date it is enacted.

For public recognition, this Regulation of the Head of Agency shall be announced by placing it in State Gazette The Republic of Indonesia.

Stipulated in Jakarta

Dated December 23, 2016

HEAD OF AGENCY ON DRUGS AND FOOD SUPERVISON

OF THE REPUBLIC OF INDONESIA,

sgd.

PENNY K. LUKITOROY A. SPARRINGA

Enacted in Jakarta

Dated December 29, 2016

DIRECTOR GENERAL OF STATUTORY REGULATION

OF THE MINISTRY OF LAW AND HUMAN RIGHTS

OF THE REPUBLIC OF INDONESIA,

sgd.

WIDODO EKATJAHJANA

STATE GAZETTE THE REPUBLIC OF INDONESIA

YEAR 2016 NUMBER 2076

ATTACHMENT- I

FORMAT OF APPLICATION FOR RECOMMENDATION

Number : ..... Jakarta, ... 20....

Attachment- : .....

Subject: Application for Recommendation for

Approval to Import in the name of PT.....

To.

Deputy of ...

Agency on Drugs and Food Supervison

in

Jakarta

Based on Regulation of the Head of Agency POM Number 27 Year 2016, concerning Procedure for granting Recommendation to obtain Approval for Importing Traditional Medicines, Health Supplement, and/or Cosmetics as Complementary Goods,, we hereby submit application for Recommendation to obtain Aproval for Importing Complementary Goods, Traditional Medicine, Health Supplement Cosmetics*) issued by the Director General of Overseas Trade.

For information, we hereby submit the data as referred to below:

1. Name of Companyh : .....
2. Address : .....
3. Producer-Imported Identification Number : ..... (API-P)
4. Obligatory Taxpayer Identification Number : .....

Attached are supporting document covering:

1. photocopy of License on Pharmaceutical Industry, Traditional Medicines, Small Business on Traditional

Medicine, Cosmetics production or Processed Food Producer*).

2. photocopy of Importer-Producer Identification Number (API-P).
3. photocopy of Obligatory Taxpayer Identification Number (NPWP).
4. Leter of Appointment as Agent / Distributor from overseas company and Joint Operation Agreement ratified by the Notary.
5. List of Medicines / Traditional Medicine, Health Supplement, Cosmetics *) to be imported (softcopy and hardcopy).

Hope this complies with the requirements.

Management of PT.....

Name .....

*): *adjust with the products to be imported.

HEAD OF AGENCY DRUGS AND FOOD SUPERVISON

OF THE REPUBLIC OF INDONESIA,

sgd.

PENNY K. LUKITO

ATTACHMENT- II

List of Medicines, Traditional Medicines, Health Supplement, Cosmetics*) to be imported

No	Name of Product	Number of License Circulation	Validity NIE	Number HS	Producer	Exporter	Total imported	Loading Ports	Destination Ports

*): adjust with the products to be imported

HEAD OF AGENCY DRUGS AND FOOD SUPERVISON

OF THE REPUBLIC OF INDONESIA,

sgd.

PENNY K. LUKITO

ATTACHMENT- III

FORMATOF RECOMMENDATION

Number : ..... Jakarta, ... 20....

Attachment- : .....

Subject : Recoomendation for Aproval for import in the name of PT.....

To.

Director General of Trade Overseas

Ministry of Trade

In

Jakarta

With regard to Letter of PT....., Number..... dated ..... concerning the above subject and based on:

1. Regulation Minister of Trade Number 118/M-DAG/PER/12/2015, concerning provisions on Complementary Goods, Goods for Market Test, and After Sale Survice;

2. Regulation of Minister of Health Number 14 Year 2016, concerning Recommendation to obtain Approval for Importing Complementary Goods, Barang Untuk Keperluan Tes Pasar, dan Pelayanan Purna Jual;

3. Regulation Head of Agency POM Number 27 Year 2016, concerning procedure to be issued Recommendation to obtain approval for importing Traditional Medicines, Health Supplement, and/or Cosmetics as Complementary Goods.

Hereby inform that:

1. Name of Company : .....
2. Address : .....
3. Importer-Producer Identification Number (API-P) : .....
4. Taxable Iden tification Number : .....

Based on the result of evaluation of the application for recommendation, has complied with requirements to obtain License for importing Medicines, Tradisional Medicines, Helath Supplement, and/or Cosmectics*) as Complementary Goods (data on imported products - attached).

This Recommendation is valid for ..... year effective as of issue so long the License Number for Circulation (NIE) of products is still valid.

This for your kind attention and cooperation, thank you.

Deputy of Supervision .....

sgd.

(Complete Name)

NIP.

Copied to:

1. Head of Agency POM
2. Management of Perusahaan PT.....
3. File

Attachment-to Letter Number....., dated .....

List of Medicines, Traditional Medicines, Health Supplement, Cosmetics*) that has obtained Recommendation

No	Name of Product	Number of License Circulation	Validity NIE	Number HS	Producer	Exporter	Total imported	Loading Ports	Destination Ports

*) : adjust with imported product

Deputy of Supervision ....

sgd.

(Complete Name)

NIP.

HEAD OF AGENCY ON DRUGS AND FOOD SUPERVISON

OF THE REPUBLIC OF INDONESIA,

sgd.

PENNY K. LUKITO

(BN)