Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY
San Lazaro Compound, Rizal Avenue, Manila
Telephone No: 743-83-01 to 23 loc. 1125-1126

28 December 2004

ADMINISTRATIVE ORDER
No. 184 s. 2004

SUBJECT: Guidelines on the Registration of Traditionally-Used Herbal Products

I. RATIONALE/ BACKGROUND

Pursuant to the provision of Sections 3(a) and (b) and 26 (a) of R.A. 3720 known as the "Food, Drug and Cosmetic Act", amended by Sections 4 and 19 of E.O. 175 (An Act To Ensure The Safety And Purity Of Foods And Cosmetics, And The Purity, Safety, Efficacy And Quality Of Drugs And Devices Being Made Available To The Public, Vesting The Bureau Of Food And Drugs With Authority To Administer And Enforce The Laws Pertaining Thereto, And For Other Purposes), the following regulations are hereby promulgated governing the registration of drugs herein defined as traditionally-used herbal products.

II. SCOPE/ COVERAGE

The Department of Health through its Bureau of Food and Drugs (BFAD) shall ensure the safety, good quality, and claimed application of Traditionally-Used Herbal Products.

This Order shall be applicable to all traditionally-used herbal products except as provided herein:

1. Medicines/drugs that do not fall within the definition of traditionally-used herbal products cited in this regulation shall be governed by other regulations promulgated for other herbal products in general.

2. Herbal preparations, which are fresh plant material or which have not undergone any process or treatment other than what is essential to their proper drying, packaging, and storage.

III. DEFINITION OF TERMS

For the purpose of this Order, the terms:

Plant Material means fresh or dried aerial or underground part(s) of a plant such as leaves, flowers, fruits, seeds, stems, wood, bark, roots, rhizomes or other plant parts, which maybe entire, fragmented or powdered, including juices, gums, fatty oils, essential oils, and any other substance derived from the plant to be used as is or for further processing such as for galenicals or pharmaceutical dosage forms.

Traditionally-Used Herbal Products refer to preparations from plant materials whose claimed application/s is/are based only on traditional experience of long usage which should be at least five (5) or more decades as documented in medical, historical and ethnological literature.

For products originating from other countries, authentication of the documents shall be done by the Philippine Consulate.

Common Name refers to the generally accepted local name of the plant as recognized in ethno-botanical or other relevant literature.

Scientific Name refers to the binomial nomenclature consisting of the genus and the species to which the specific plant belongs and the name of the author, based on a systematic classification indicating genetic relationships, in which both terms are underlined or italicized and the first letter of the genus is capitalized.

Official Name refers to the scientific name, common/local name and the part of the active plant material used in the preparation of the traditionally-used herbal product.

IV. POLICIES AND GUIDELINES

1. Only establishments for traditionally-used herbal products with a valid license to operate can apply for registration of such products. These establishments can be the manufacturer, trader, importer or distributor of the product.

2. No person shall manufacture, import, export, distribute, sell, offer for sale, advertise, or transfer any traditionally-used herbal products which are not registered with the BFAD.

V. REGISTRATION REQUIREMENTS

1. Notarized letter of application and duly accomplished Form No. 8

2. Certificate of Brand Name Clearance (when applicable)

Every proposed brand name for a Traditionally-Used Herbal Product shall be submitted for name clearance prior to the filing of an application for registration. This will prevent similarity in brand names with other previously registered products whether Food, Drugs and Devices, Cosmetics or Household Hazardous Substances.

No imported Traditionally-Used Herbal Product even if it is patented and/or registered in other countries, shall be issued certificate of brand name clearance if the proposed brand name is identical or similar to any brand name registered with the BFAD.

Application, processing and approval of brand names shall be in accordance with the provisions of Bureau Circular No.21 series of 1999 (Guidelines for the Evaluation of Brand Names for Products to be Registered with the Bureau of Food and Drugs) and Bureau Circular No.8 series of 2003 (Clarification of Guidelines on the Use of BFAD Registered Brand Names).

3. A duly notarized certificate of agreement executed between the manufacturer, trader, importer and/or distributor

4. List of all active plant material(s) and inactive ingredients

4.1 A complete list of ingredient(s) whether active or inactive with the corresponding amount per unit dose, expressed in the metric system

4.2 Statement of the active ingredient/s (plant material/s) using scientific name with the common/local name printed below the scientific name. Specific plant part(s) used shall be stated after the common name.

4.3 Ingredient(s) which are used in the manufacture but which may not be present in the finished product shall be included in the list (e.g. alcohol). Alcohol, if present, in the formulation shall be expressed in percentage (%).

5. Requirements for Raw Materials of Traditionally-Used Herbal Products

5.1 A certification as to the authenticity of the plant specimen shall be obtained from the Philippine National Museum or any BFAD-recognized taxonomist. In case of imported products, the certificate of authenticity of the plant shall be obtained from the authorized government agency in the country of origin and the Philippine Consulate shall duly authenticate such document.

6. Physical description and tests/quality standards of the finished product

6.1 Organoleptic and macroscopic description of the finished product
A description of the appearance, texture, color, odor and taste of the finished product

6.2 Moisture Content

6.3 pH (if applicable)

6.4 Alcohol content (if applicable)

Standards and limits for specific tests are presented in Annex A.

7. Certificate of analysis of the submitted samples

   An analytical report of the tests carried out to establish the identity, quality and safety of the submitted batch sample/s

8. Full report of methods used, the facilities and quality control procedures in the manufacture, processing and packaging of the finished product

   A complete and detailed description of the manufacturing procedure, including all in-process quality control procedures and the facilities and equipment used in each stage of the manufacturing process

   Full description of the packaging materials used (Refer to Annex C for the Packaging Requirements)

9. Complete quality control procedure(s) for the finished product

   The manufacturer shall conduct quality control tests and procedures. The manufacturer shall establish specifications or limits for such tests where no standard has been set by the BFAD.

   All quality control test procedures for the finished product shall be given in detail including the preparation of test samples for analysis to provide information on how the quality and batch-to-batch uniformity of the product is ensured.

   Data obtained from these tests shall also provide information on the absence of synthetic substances and microbial contaminants.

   A method of identification, and where possible, the quantification of the plant material in the finished product should be defined. If the identification of an active principle is not possible, it should be sufficient to identify a characteristic substance or mixture of substances (e.g. "chromatographic fingerprint") to ensure consistent quality of the product. The finished product should comply with general requirements for the particular dosage form.

10. Stability studies to support claimed shelf-life of the finished product

    Stability studies conducted under the following recommended conditions shall be done to determine the most appropriate conditions of storage and to support claimed shelf life:

Room temperature:	$30^0C \pm 2^0C$, 75% RH ± 5% RH
Elevated Temperature:	$40^0C \pm 2^0C$, 75% RH ± 5% RH
Cool temperature:	$8\text{-}15^0C$

11. Labels and other labeling materials

The labeling materials for traditionally-used herbal products shall conform to the following requirements:

11.1 General Requirements

All information required to appear on the label shall be:

11.1.1 Written in English or in both English and Filipino

11.1.2 Clearly and prominently printed

11.1.3 Sufficiently legible as to distinguish the color contrast, position and spacing of information.

11.1.4 The minimum mandatory information in the labeling materials are:

11.1.4.1 Official name and brand name (if any)

11.1.4.2 Dosage form and dosage strength

11.1.4.3 Claimed application/ folkloric use

11.1.4.4 Complete name and address of the manufacturer, trader and/or distributor/importer

11.1.4.5 Net content

11.1.4.6 Formulation

11.1.4.7 Contraindication(s), precaution(s), warning, wherever applicable

11.1.4.8 Mode of administration / direction for use

11.1.4.9 Batch and/or Lot number

11.1.4.10 Date of manufacture and expiry/expiration date

11.1.4.11 Registration number

11.1.4.12 Storage conditions

11.1.5 The principal display panel shall:

11.1.5.1 Contain the particulars required in 11.1.4.1 to 11.1.4.5

11.1.5.2 Conform to the presentation as illustrated in the sample label in Annex B

11.1.6 The following information shall appear outside of the principal display panel:

11.1.6.1 Contain the particulars required in 11.1.4.6 to 11.1.4.12

11.1.6.2 Relevant graphics or illustrations to the identification of the plant material used shall be allowed on the labels as long as it does not obscure or cover pertinent information.

11.1.7 Other information and additional details shall appear on other labeling materials such as inserts/leaflets or secondary packaging.

11.1.8 Formulation

11.1.8.1 The active ingredient stated in its scientific name with the common/local name and part used printed below the scientific name

11.1.8.2 The plant part(s) used stated after the common name

11.1.8.3 The corresponding amount or potency of active ingredient(s) expressed in the metric system

11.1.8.4 Alcohol content expressed in percentage (%).

11.2 Specific Requirements

11.2.1 Official name of the product shall be printed inside an outlined box as illustrated in the sample label in Annex B.

11.2.2 No claim shall be made for principal treatment of any medical condition or therapeutic indication that needs supervision by a physician.

11.2.3 The traditional/ folkloric claim shall be presented in layman's term stated as:

"Traditionally/ folklorically used to relieve pain/ for relief of pain."

11.2.4 The statement below shall be in an outlined box parallel to the base of the label located in the information panel:

"The traditional application/use of this product has not been evaluated by the Bureau of Food and Drugs."

11.2.5 The following phrases shall be printed on all labeling materials:

11.2.5.1 "If symptoms persist, consult your doctor."

11.2.5.2 "Not allowed for use in pregnant, lactating mothers, and children below 18 years."

12. Sufficient samples (in market or commercial presentation) for laboratory analysis

Samples of the traditionally-used herbal product in commercial presentation with batch and lot no. the same as that on the submitted Certificate of Analysis shall be submitted for the BFAD analysis.

13. Evidence of safety and claimed application

13.1 The evidence of safety shall be based on:

13.1.1 Documentation of prolonged and apparently uneventful use of the traditionally-used herbal product, and

13.1.2 The absence of unsuspected potential for systematic toxicity, carcinogenicity and teratogenicity

13.2 Evidence for claimed application shall be based on medical/ pharmaceutical literature or similar sources or a documentation of the knowledge on the application of such product through medical, historical, and ethnological documents.

13.3 No product shall be registered as Traditionally-Used Herbal Product if:

13.3.1 There is a valid report of adverse drug reaction on the use of the plant material as determined by the BFAD.

13.3.2 There is a valid report of abuse or dependence potential on the use of the plant material.

13.3.3 It contains chemically defined therapeutically active substance(s), including chemically defined isolated constituent(s) of plants used in conventional/western medicine.

13.4 Additional Requirements for Imported Traditionally-Used Herbal Products

Certificate of Traditionally-Used Herbal Product (or its equivalent) issued by the Government Health Agency or any other appropriate agency from the country of origin and duly authenticated by the Philippine Consulate.

No traditionally-used herbal product from other countries may be registered unless they are freely sold in the country of origin. In case where the product is not freely sold in the country of manufacture, two separate Certificates of Traditionally-Used Herbal Product (or its equivalent) shall be submitted: the Certificate of Traditionally-Used Herbal Product (or its equivalent) from the country of manufacture and the Certificate of Traditionally-Used Herbal Product (or its equivalent) from a country where the product is freely sold.

13.5 Requirements for Renewal Registration of Traditionally-Used Herbal Product (Refer to Annex D)

VI. PROCEDURES FOR REGISTRATION

1. Filing of application for registration of Traditionally-Used Herbal Products

A duly licensed traditionally-used herbal product establishment files a formal application for registration of traditionally-used herbal products. Such establishment can be the manufacturer, trader, or importer-distributor of the product.

The applicant shall submit data and representative samples of the product in support of its request for registration. All information regarding the product shall be fully disclosed.

1.1 Evaluation of submitted documents and samples

The Product Services Division of the BFAD shall evaluate the documents. The quality conformance of the sample products with BFAD-set standards shall be verified at the Laboratory Services Division or any laboratory accredited by the BFAD.

1.2 Final recommendation/action on the application for registration

Final action of approval or denial on the application for registration shall be issued by the BFAD based on the results of the evaluation conducted pursuant to Section 1.1 hereof.

2. Payment of Registration Fees and Costs of Laboratory Analysis

Upon application for registration of traditionally-used herbal products, the following non-refundable fees shall be charged for each application:

2.1 Traditionally-Used Herbal Products

2.1.1 Initial registration [for one (1) year]

2.1.1.1 Generic: Php 2,000.00

2.1.1.2 Branded: Php 3,000.00

2.1.2 Renewal registration [for five (5) years]

2.1.2.1 Generic: Php 7,500.00

2.1.2.2 Branded: Php 10,000.00

Note:

1. Initial registration may be valid for 2, 3, 4, or 5 years with payment of corresponding fees.
2. Renewal registration is for five-year duration for traditionally-used herbal products starting on the date of expiration of the CPR.

2.2. Cost of laboratory analysis - to be computed based on the test requirements of a specific product

VII. PROHIBITED ACTS AND SANCTIONS

The prohibited acts and sanctions embodied in R.A. 3720 as amended by E.O. 175 as far as applicable are hereby adopted.

VIII. REPEALING CLAUSE

All orders, circulars, rules and regulations, or portions thereof, inconsistent with this Order are hereby repealed or modified accordingly.

IX. EFFECTIVITY

This regulation shall take effect fifteen (15) days after its publication in two newspapers of general circulation.

MANUEL M. DAYRIT, M.D., MSc.
Secretary of Health

ANNEX A

Standards for the Determination of the Identity, Purity and Quality of Traditionally-Used Herbal Products

1. To establish the identity of the plant material, an herbarium specimen of the medicinal plant shall be prepared from each of the different sources where such plant material has been obtained. Such herbarium specimens shall be submitted for authentication to the National Museum or any BFAD-recognized taxonomist.

2. All traditionally-used herbal products shall be free from extraneous matters such as soil, excreta, helminths or parasitic ova, stones, other plants and/or other part(s) of the same plant to be used.

3. Tests and standards shall be in full compliance with the pharmocopeial requirements. For plant materials, which are not included in any official pharmacopeia, the following tests and standards shall be followed:

   3.1 Organoleptic and macroscopic description and illustration of the plant material

   3.2 Ash content
   - 3.2.1 Total Ash
   - 3.2.2 Acid-Insoluble Ash
   - 3.2.3 Water-Soluble Ash

   3.3 Extractable Matter
   - 3.3.1 Ethanol-Soluble Extractive
   - 3.3.2 Water-Soluble Extractive

   3.4 Moisture Content (Loss on Drying/Water Content)

   3.5 Heavy Metals:

   For dried plants, limits for adults are as follows:

Lead	- 10 mcg/g (ppm)
Cadmium	- 0.3 mcg/g (ppm)
Mercury	- 0.5 mcg/g (ppm)
Arsenic	- 0.3 mcg/g (ppm)

   3.6 Volatile oil (if applicable)

   3.7 Pesticide residue - shall conform to the limits as defined in FAO/WHO Codex Alimentarius

   3.8 Foreign Matter
   All plant materials shall be free from extraneous matter such as soil, excreta, helminths or parasitic ova, stones, other plants and/or plant part(s) other than the specific part(s) used.

3.9 Microbial limits

Test to detect and quantify the following microbial contaminants shall be conducted: aerobic bacteria, Sacchromycetes and Hypomycetes

3.9.1 For untreated plant material harvested under acceptable hygienic conditions intended for further processing:

Organisms	Unit	Limits
Escherichia coli	cfu/ g	Negative
Moulds propagules	cfu/ g	Maximum 10^5
Staphylococcus	cfu/ g	Negative

3.9.2 Plant materials that will undergo pre-treatment (e.g. with boiling water as used for herbal teas and infusions) or if the material is to be used for topical dosage form:

Organisms	Unit	Limits
Aerobic bacteria	cfu/ g	Maximum 10^7
Yeasts and moulds	cfu/ g	Maximum 10^4
Escherichia coli	cfu/ g	Negative
Salmonellae	cfu/ g	Negative
Staphylococcus	cfu/ g	Negative
Other *Enterobacteria*	cfu/ g	Maximum 10^4

3.9.3 Plant materials to be used in drugs for internal use:

Organisms	Unit	Limits
Aerobic bacteria	cfu/ g	Maximum 10^5
Yeasts and moulds	cfu/ g	Maximum 10^3
Escherichia coli	cfu/ g	Negative
Salmonellae	cfu/ g	Negative
Staphylococcus	cfu/ g	Negative
Other *Enterobacteria*	cfu/ g	Maximum 10^3

3.10 Aflatoxin limits

Total aflatoxin shall conform with the prescribed specification of 20 mcg/kg and aflatoxin B1 of 10 mcg/kg by ELISA Method or Liquid Chromatography.

3.11 Identification Tests

3.11.1 Chemical Tests

Determine the active constituent/s present in the plant(s)

3.11.2 Thin Layer Chromatography (TLC) Profile

The TLC Profile of the plant material shall be established and used as basis in determining the identity, purity and batch-to-

batch uniformity of the chemical components present in the plant.

3.11.3 Other chromatographic procedures such as HPLC, GC-Mass Spectroscopy and NMR

4. The following tests and standards shall be utilized in determining the quality of the finished product:

4.1 Moisture Content –not more than 10%

4.2 pH

4.3 Microbial Limits

4.3.1 For Solid Products

Organisms	Unit	Limits
Aerobic bacteria	cfu/ g	Maximum 10^4
Yeasts and moulds	cfu / g	Maximum 10^3
Escherichia coli	cfu/ g	Negative
Salmonellae	cfu/ g	Negative
Staphylococcus	cfu/ g	Negative
Other *Enterobacteria*	cfu/ g	Maximum 10^2

4.3.2 For Liquid Products

Organisms	Unit	Limits
Aerobic bacteria	cfu/ g	Maximum 10^2
Yeasts and moulds	cfu/ g	Maximum 10^2
Escherichia coli	cfu/ g	Negative
Salmonellae	cfu/ g	Negative
Staphylococcus	cfu/ g	Negative
Other *Enterobacteria*	cfu/ g	Maximum 10^2

4.4 Identification Tests

4.4.1 Chemical

4.4.2 Thin Layer Chromatography

4.4.3 Other chromatographic procedures

4.5 Test for synthetic substance(s) as appropriate for the claimed application such as:

4.5.1 Aspirin

4.5.2 Paracetamol

4.5.3 Dipyrone

4.5.4 Phenylbutazone

4.5.5 Pyrazolone

4.5.6 Corticosteroids

4.5.7 Anabolic steroids

4.5.8 Gonadal Hormones

4.5.9 Ephedrine

4.5.10 Sildenafil and other related substances

4.5.11 Indomethacin

4.5.12 Chlorpheniramine

4.5.13 Aminopyrine
4.5.14 Caffeine
4.5.15 any other synthetic substance

5. Specific Tests Required for Different Dosage Forms

5.1 Tablet
- Weight variation
- Content uniformity
- Disintegration test
- Hardness test
- Friability
- Microbial test

5.2 Capsule
- Weight variation
- Content uniformity
- Microbial test

5.3 Syrup / Liquid
- Viscosity
- pH
- Microbial test

5.4 Suspension
- Suspendability
- Homogeneity
- Viscosity
- Minimum fill
- pH
- Microbial test

5.5 Ointment / cream / semi-solid preparation
- Palpability
- Homogeneity
- pH
- Melting point
- Allergenicity and primary irritation test
- Microbial test

5.6 Suppository / pessary
- Allergenicity and primary irritation test
- Microbial test

6. Galenicals, including decoctions, infusions, extracts (liquids, pillulars, powdered), tinctures, syrups, lotions and emulsions shall pass all the requirements specified in the Pharmacopeias official in the country.

ANNEX B

Label Sample for Traditionally-Used Herbal Products

INFORMATION PANEL	PRINCIPAL DISPLAY PANEL	INFORMATION PANEL
Formulation: Each capsule contains: *Zingiber officinale* L.-200 mg (Ginger Rhizome) **Folkloric Use/ Claimed Application:** For relief of motion sickness THPR No. (Traditionally-Used Herbal Product Registration Number) Batch/Lot No.: Date Mfd.: Expiry: Store at temperature not exceeding 30 °C The traditional application/use of this product has not been evaluated by the Bureau of Food and Drugs.	Net Content 100 capsules ***Zingiber officinale* L.** **Ginger Rhizome** Brand name, if any 200 mg Capsule For relief of motion sickness Manufactured by: For:	**Dosage:** **Precautions:** **Side Effects:** **Contraindications:** "Not allowed for use in pregnant, lactating mothers, and children below 18 years." "If symptoms persist, consult your doctor."

The "Principal Display Panel" of the label shall be that part which, either through design or general use, is presented or shown to the consumer under customary conditions of display for retail sale.

The "Information Panel" of the label shall be that part immediately contiguous to the principal display panel and in the case of rectangular, cylindrical or four-sided containers, any of the sides adjacent to the principal display panel except the bottom side which serves as the base of package.

ANNEX C

Packaging Requirements

1. For Liquid and Semi-Solid Products in Plastic Container, the following information shall be submitted:

    1.1 General Information
        - shall include the name of materials, name of manufacturer, chemical structure and physico-chemical properties
    1.2 Test Procedures and Limits
        - shall include methods on how different tests were conducted, limits for each tests and results
    1.3 Studies Done on Plastic (to substantiate the claim that the product is safe to use)
        - shall include chemical tests, physical tests, and biological tests (cell toxicity, tissue implantation) for parenteral and ophthalmic preparations

2. For Products in Special Packaging Materials (including materials for accessories), the following information shall be provided:

    2.1 List of different components and maximum allowable content
    2.2 Types of materials used in different parts
    2.3 Nature of polymers
    2.4 Official standards and requirements (must be compliant)
    2.5 Toxicity data
    2.6 Technical properties of materials
    2.7 Detailed construction of non-standardized containers

CHECKLIST for REGISTRATION of TRADITIONALLY-USED HERBAL PRODUCTS*

REQUIREMENTS	TYPE OF APPLICATION	
	INITIAL	RENEWAL
1. Letter of Application as B.C. No. 01 s. 2002	√	√
2. Form No. 8 (Revised)	√	√
3. Copy of valid Certificate of Brand Name Clearance	√	
4. Copy of valid agreement between the manufacturer & trader/distributor/importer/exporter	√	
5. a) Copy of latest Certificate of Product Registration		√
b) For A.O. No. 54 - valid original Certificate of Product Registration	√	
6. Copy of valid LTO of the manufacturer/trader/importer/distributor, reflecting the product source(s)	√	√
7. Unit Dose and Batch Formulation	√	√
8. Technical Specifications of ALL Raw Materials	√	
9. Certificate of Analysis of Active Raw Material		
a) From the supplier of the active raw material (if applicable)	√	
b) From the manufacturer of the finished product	√	
c) Certification of Authenticity of Plant Specimen from the National Museum (Philippines) or any BFAD-recognized taxonomist	√	
In case of imported products, the certificate shall be issued by the authorized government agency in the country of origin, duly authenticated by the Philippine Consulate.		
10. Technical Specifications of Finished Product	√	√
11. Certificate of Analysis of Finished Product (from the same batch or lot of the representative sample submitted)	√	√
12. Master Manufacturing Procedure, Production Equipment, Sampling and In-Process Controls, and Master Packaging Procedure	√	
13. Identity and Purity Tests including Assay (if applicable)	√	
14. Stability Studies		
a) Accelerated - at least 6 months data, minimum of 2 batches at 40°C±2°C/75%RH±5% RH	√	
b) Real Time - at least 12 months data, minimum of 2 batches at 30°C±2°C/75%RH±5%RH		√
c) For products intended to be stored in a refrigerator.		
c.1) Accelerated - at least 6 months data, minimum of 2 batches, 25°C±2°C/60%RH±5%RH	√	
c.2) Real Time - at least 12 months data, minimum of 2 batches, 5°C±3°C		√
15. Representative Sample in market or commercial presentation (at least 1 year before expiry)	√	√
16. Labeling Materials		
a) Facsimile labels with actual color text (3 copies)	√	
b) Actual/Commercial labeling materials (3 copies)		√
17. For Imported Products (an English translation shall accompany any document not written in English)		
- Original Certificate of Traditionally-Used Herbal Product (or its equivalent) from the country of manufacture (issued at least 1 year from the date the application for registration was filed)	√	
- For countries not issuing the above, the following may be accepted:		
a) Government Certificate attesting the Registration Status of the Manufacturer, duly authenticated by the Philippine Consulate	√	
b) Certificate of Free Sale from the country of origin, duly authenticated by the Philippine Consulate.	√	
For products not freely sold in the country of origin, original Certificate of Traditionally-Used Herbal Product (or its equivalent) from a country where the product is freely sold shall be submitted.	√	
18. For Liquid and Semi-solid Products in Plastic Container or in Special Packaging Materials, refer to Annex C of A.O. ___ s. 2004.	√	
19. Evidence of Safety (based on documentation of prolonged and apparently uneventful use of the traditionally-used herbal product, and the absence of unsuspected potential for sytematic toxicity, carcinogenicity and teratogenicity)	√	
20. Evidence of Claimed Application (based on medical/ pharmaceutical literature or similar sources or a documentation of the knowledge on the application of such product through medical, historical, and ethnological documents)	√	

*Any changes, revisions or modifications shall require prior approval from the BFAD.