[DOH ADMINISTRATIVE ORDER NO. 172, S. 2004, September 16, 2004]

GUIDELINES ON THE REGISTRATION OF HERBAL MEDICINES

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 herbal medicines.

II. SCOPE/COVERAGE

The Department of Health through its Bureau of Food and Drugs (BFAD) shall ensure the safety, efficacy and good quality of Herbal Medicines.

This Order shall be applicable to all herbal medicines except as provided herein:

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

Herbal Medicines are finished, labeled medicinal products that contain as active ingredient(s) aerial or underground part(s) of plants or any

other plant material, or combination thereof, whether in the crude state or as plant preparations. Herbal medicines may contain excipients in addition to the active ingredient(s).

Additionally, such medicinal plant products shall have specific therapeutic claim(s) and shall be intended for use in the diagnosis, alleviation, cure or treatment of disease, promotion of health or intended to affect or modify the structure or any function of the body of humans or animals.

Drug preparations containing plant material(s) combined with chemically defined therapeutically active substances, including chemically defined isolated constituents of plants used in conventional/western medicines are not considered to be herbal medicines.

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 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 herbal medicine (ex. vitex negundo L. Lagundi Leaf). Note: This definition also refers to the Official Title as stated in the Philippine Pharmacopoeia.

IV. POLICIES AND GUIDELINES

1. Only establishments for herbal medicines with a valid license to operate can apply for registration of such product. 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 herbal medicines 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 an Herbal Medicine 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 Herbal Medicine 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 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 the 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 Herbal Medicines

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 the 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:	300C + 20C, 75% RH + 5% RH
Elevated Temperature:	400C + 20C, 75% RH + 5% RH
Cool Temperature:	8-150C

11. Labels and other labelling materials

The labeling materials for herbal medicines 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 Therapeutic claim/pharmacologic category

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 Rx symbol, for prescription product

11.1.4.7 Formulation

11.1.4.8 Indication/s

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

11.1.4.10 Mode of administration/direction for use

11.1.4.11 Batch and/or Lot number

11.1.4.12 Date of manufacture and expiry/expiration date

11.1.4.13 Registration number

11.1.4.14 Storage conditions

11.1.4.15 For (Rx products) Food, Drugs, Devices and Cosmetics Act