S. I. of 2005

DRUGS AND RELATED PRODUCTS (REGISTRATION, ETC.) ACT 1996 (AS AMENDED)

Herbal Medicines and Related Products (Labelling) Regulations 2005

Commencement:

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Section 8 of the Drugs and Related Products (Registration, Etc.) Act 1993, as amended, and of all the powers enabling it in that behalf, THE GOVERNING COUNCIL OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL with the approval of the Honourable Minister of Health hereby makes the following Regulations:-

Scope.

1. These Regulations shall apply to all labelling of herbal medicines and related products used as diagnostic, therapeutic or prophylactic agents.

Prohibition.

2. No person shall manufacture, import, export, distribute, advertise or sell any herbal medicine or related product that is not labelled as required by the provisions of these Regulations.

Adequate and clear labelling information

3.(1) All information on a label shall be -

(a) clearly and prominently displayed thereon; and

(b) readily discernible to the consumer.

(2) All labelling information shall be in English language and may include other languages.

(3) Herbal medicines and related products labeling shall be informative and accurate and neither promotional in tone nor false or misleading.

(4) The labeling shall be based whenever possible on data derived from human experience.

(5) No implied claims or suggestions of herbal medicines or related products may be made, if there is in-adequate evidence of safety or a lack of substantial evidence of effectiveness.

(6) Where a claim of effectiveness or therapeutic indication labelling is made by a herbal medicine or related product, it shall carry boldly and in close proximity to the claim, a statement to the fact that such claim have not been evaluated by the Agency, unless such claims has been clinically proven and deemed satisfactory by the Agency.

Name and Address Of Manufacturer, Packer or Distributor

4.(1) The label of herbal medicines and related products in package form shall specify conspicuously the name and place of business of the manufacturer, and may include the distributor or packer.

(2) Where a herbal medicine or related product is not manufactured by a person whose name appears on the label, the name shall reveal the connection between the person and the manufacturer, such as "*Manufactured for ….……..", Distributed by……...",* or any other wording that expresses the facts.

No reference to International Bodies etc.

5. No reference, direct or indirect to international bodies shall be made upon any label of herbal medicine or related product, except as prescribed by the Agency.

Declaration of Ingredients.

6.(1) Name or index number of colour used in the preparation shall be declared on the label.

(2) A quantitative list of ingredients of the herbal medicines by their botanical names or, by their common names, shall be declared quantitatively on the label.

Trade mark .

7. (1) Where a herbal medicine or related product have a trade mark displayed on the label, the trade mark shall not give a wrong impression of the nature, quality or substance of the herbal medicine or related product.

(2) Where the trade mark registration is in conflict with any regulations or requirements of the Agency, the latter shall supercede.

Identification Number assigned by the Agency.

8. The inner and outer labels of a herbal medicine or related product shall show, in a clear terms, the Agency registration number (NAFDAC REG. NO.) assigned to it as indicated on the certificate of registration in a manner prescribed by the Agency.

Identification mark on tablets, capsules etc.

9. (1) All tablets, capsule, caplets and similar dosage forms of herbal medicines and related products shall bear identification marks traceable to the manufacturer or holder of a certificate of registration of the herbal medicine or related product unless otherwise exempted by the Agency.

(2) Exemptions request shall be made in writing to the Agency giving reasons why a waiver is justified.

Adequate Labelling

10. Herbal medicines and related products shall

for Herbal Medicines and Related Products.

be properly labelled with the following information on the inner and outer labels:

(1) The brand name, botanical or common name if any shall be qualified as herbal, homeopathic, animal or mineral medicinal product and or admixture there of.

(2) The name shall not be suggestive of therapeutic claim .

(3) Each product shall have a distinct design.

(4) A quantitative list of all ingredients of the product by their botanical or common names.

(5) The net content of the product in terms of weight, measure, or numerical count and shall be in metric unit.

(6) The name and address of the manufacturer.

(7) Adequate directions for safe use of the product, including amount for use in specific age groups.

(8) The lot or batch number of the product.

(9) The manufacture and expiration dates.

(10) The storage conditions.

(11) Dosage, route and frequency of administration.

(12) Indication for the product.

Labelling of bulk package.

10. Where a herbal medicine or related product is sold in bulk for further manufacturing, provisions of this regulation shall not apply, provided that, the label of the bulk product contains the following information:

(1) The proprietary or brand name of the herbal medicines.

(2) The botanical or common name of the herbal medicines.

(3) A statement of net contents.

(4) An identifying lot or batch number.

(5) The manufacture and expiration dates.

(6) Statement of caution e.g. "manufacturing purpose only".

Labelling Information for Practitioners.

11. All herbal medicines or related products may be accompanied by an outer label and package insert with relevant information to practitioners for the safe use of the products.

Adequate information on the insert.

12.(1) Relevant information required to appear on the package insert for Practitioners shall include:

(a) Description;
(b) Clinical Pharmacology;
(c) Indications and usage;
(d) Contraindications;
(e) Warnings against misuse;
(f) Precautions;
(g) Dosage and administration;
(h) Adverse reactions;

(i) Drug abuse and dependence;

(j) Symptoms of over dosage and antidote;

(k) How supplied;

(l) Animal Pharmacology and/or Animal;

(m) Toxicology;

(n) Clinical studies;

(o) Storage conditions;

(p) References.

(2) The labeling shall contain a "Product Title" section preceding the "Description" section.

Prohibition of Labelling of Herbal Medicines or Related Products for certain treatments.

13 (1) No person shall label a herbal medicine or related product as a treatment, preventive or cure for any of the diseases, disorders or abnormal states as identified in schedule 1 to the Food and Drug Act 1990 (as amended.)

(2) No person shall sell, advertise, display or orally present any herbal medicine or related product to the general public whose label contains such words as "for vitality".

Penalty

14.(1) A person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction :-

(a) in case of an individual to imprisonment for a term not exceeding two years or to a fine not exceeding N50,000. or to both such imprisonment and fine.

(b) in the case of a body corporate to a fine not exceeding N100,000.

(2) Where an offence under these regulation is

Committed by a body corporate, firm, or other

association of individual-

(a) every director, manager, secretary or other similar officer of the body corporate; or

(b) every partner or officer of the firm; or

(c) every trustee of the body concerned; or

(d) every person concerned in the management of the affairs of the association; or

(e) every person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Forfeiture 15. In addition to the penalty specified in regulation 14 of these Regulations, a person convicted of an offence under these Regulations shall forfeit to the Agency, the herbal medicine or related product and whatsoever is used in connection with the commission of the offence.

Herbal medicines and related products not for use in pregnancy. 16. Both the inner and outer labels of all herbal medicines and related products shall carry a warning statement directing pregnant women not to use them, except there is adequate evidence of safety in pregnancy.

Warning for Children. 17. The label of all herbal medicines and related Products shall carry a warning "keep this medicine out of reach of children".

Mis-leading and Misinformation. 18. (1) The label of a herbal medicine or related product with antipyretic and analgesic property shall not bear the indication "for fever" but shall be labelled "for feverish conditions" or "feverish feeling".

(2) No person shall sell, advertise, display any herbal medicine or related product with a name suggestive of the symptom, disorders, diseases or abnormal states that it is supposed to treat, prevent or cure e.g. "…. Backache Tablets".

Interpretation. 19. In these regulations, unless the context otherwise requires –

"**Agency"** means the National Agency for Food and Drug Administration and Control;

"Botanical name" means the scientific name by which plant is identified;

"Common name" means, with reference to herbal medicine or related product, the name in English language or other such language by which the product is commonly known;

"Expiration date" means any date after which a herbal medicine or related product is not recommended for use;

"Herbal Medicines and Related Products" include:

(a) Finished medicinal products containing plant and/or their preparation presented with therapeutic or prophylactic claim and include all preparations containing a plant material in part or wholly;

(b) Animal medicinal product which shall be defined as a finished medicinal product containing only animal material and their preparations presented with therapeutic or prophylactic claim;

(c) Mineral medicinal product which shall be defined as finished medicinal product containing only in-organic minerals and/or their preparations;

(d) Preparation or admixture thereof manufactured, sold or advertised for use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or animal; and

(e) Preparation or admixture used for restoring, correcting or modifying

organic functions in man or in animal;

"Label" includes any legend, word or mark attached to, included in, belonging to or accompanying any herbal medicine or related product;

"Package" includes anything in which any herbal medicine or related product is wholly or partly contained, placed or packed;

"Practitioners" means any person authorized by the appropriate governmental body to practice herbal medicine; and

"Sell" includes sell, offer for sale, expose for sale, have in possession for sale.

Citation 20. These regulations may be cited as the Herbal Medicines and Related Products (Labelling) Regulations 2005.

MADE at Abuja this day of 2005

DR. ANDEM NYONG ANDEM
Chairman Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)