NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

Herbal Medicine and Related Products Labelling Regulations 2019

ARRANGEMENT OF REGULATIONS

Commencement:

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Sections 5 and 30 of the NAFDAC Act Cap N1 LFN 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 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:-

1. **Scope**

   These Regulations shall apply to all labelling of complementary and alternative medicine manufactured, imported, exported, distributed, advertised, displayed for sale or used in Nigeria.

2. **Prohibition.**

   No person shall manufacture, import, export, distribute, advertise or sell any complementary and alternative medicine unless it is labelled in accordance with the provision of these Regulations.

3. **Labelling Information**

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

   (2) Each product shall have a distinct design not similar to any other registered product.

   (3) The labelling shall be based whenever possible on data derived from human experience.

   (4) No implied claims or suggestions of Herbal Medicine and Related Products may be made, if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness.

   (5) Where a claim of effectiveness or therapeutic indication labelling is made for any Herbal Medicine and Related Products, it shall carry boldly and in close proximity to the claim, a statement to the fact that such claim has not been evaluated by NAFDAC, unless such claim has been clinically proven and deemed satisfactory by the Agency.

4. **Name and Address of Manufacturer, Packer or Distributor**

   (1) Where a Herbal Medicine and Related Products 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.

   (2) The label of Herbal Medicine and Related Products shall specify conspicuously in the information panel the name and full location address of the Certificate of Registration Holder.

5. **No reference to International Bodies**

No reference, direct or indirect to international bodies shall be made upon any label of Herbal Medicine and Related Products, except as prescribed by the Agency.

6. **Declaration of Ingredients.**

(1) A quantitative list of ingredients of the Herbal Medicine and Related Products by their botanical names or, by their common names, shall be declared quantitatively on the label.

(2) Name or index number of colour used in the preparation of Herbal Medicine and Related Products shall be declared on the label.

7. **Brand name/ Trade mark**

(1) Where a Herbal Medicine and Related Products has a brand name or trade mark displayed on the label, the brand name or trade mark shall not give a wrong impression of the nature, quality or substance of the Herbal Medicine and Related Products, neither should it mislead the user nor be suggestive of any therapeutic use.

(2) Where the brand name or trade mark registration is in conflict with any Regulations or requirements of the Agency, the Regulations or requirements shall supersede.

8. **Registration Number assigned by the Agency**

(1) The outer and inner labels of Herbal Medicine and Related Products shall show clearly the Agency's registration number (NAFDAC Reg. No.) assigned to it as indicated on the Certificate of Registration in a manner prescribed by the Agency.

(2) Where a Herbal Medicine and Related Products has tertiary, secondary and primary packaging materials, and the content of a unit pack is reasonably considered to be dispensed or sold to an end-user as a whole or is for a single use, the NAFDAC Reg. No. shall be shown on the tertiary and secondary packaging materials only.

9. **Identification mark**

(1) Where tablets, capsules, caplets and similar dosage forms bear identification marks, the identification marks shall be traceable to the Certificate of Registration Holder or the manufacturer of the herbal product.

(2) Requests for exemptions shall be made in writing to the Agency giving reasons why a waiver is justified.

10. **Adequate Labelling**

Herbal Medicine and Related Products shall be properly labelled with the following information displayed clearly on the principal display panel or information panel as the case may apply on the inner and outer package 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 thereof.
(2) A quantitative list of all ingredients of the product by their botanical or common names.
(3) The net content of the product in terms of weight, measure, or numerical count and shall be in metric unit.
(4) The name and full factory location address of the manufacturer.
(5) Adequate directions for safe use of the product, including amount for use in specific age groups.
(6) The lot or batch number.
(7) The manufacture and expiration dates.
(8) The storage conditions
(9) Dosage, route and frequency of administration.
(10) Indication for the product,

And any other requirements specified by the Agency.

11. **Labelling of bulk package**

Where a Herbal Medicine and Related Products is sold in bulk for further manufacturing, provisions of these 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 and related product.
(2) The botanical or common name of the herbal medicines and related product.
(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".

12. **Labelling Information for Practitioners**

All Herbal Medicine and Related Products may be accompanied by an outer label and package insert with relevant information to practitioners for the safe use of the products.

13. **Information on Package insert**

Relevant information required to appear on the package insert for Practitioners shall include:

(1) Product name

(2) Description;

(3) Clinical Pharmacology or as applicable;

(4) Indications and usage;

(5) Contraindications;

(6) Warnings;

(7) Precautions;

(8) Dosage and administration;

(9) Side effects and Adverse reactions;

(10) Drug abuse and dependence, or as applicable;

(11) Symptoms of over dosage and treatment;

(12) Presentation;

(13) Storage conditions;

14. **Prohibition of Labelling of Herbal Medicine and Related Products for certain treatments.**

(1) No person shall label Herbal Medicine and Related Products as a treatment, preventive or cure for any of the diseases, disorders or abnormal states as identified in schedule 1 to CAP F32 LFN 2004.

(2) No person shall sell, advertise, display or orally present any Herbal Medicine and Related Products to the general public whose label contains such words as "for vitality".

15. **Herbal Medicine and Related Products not for use in pregnancy & children [below 5 years]**

Both the inner and outer labels of all Herbal Medicine and Related Products shall carry a warning statement directing pregnant women and children [below 5 years of age] not to use them, except there is adequate evidence of safety in pregnancy and children under 5 years of age.

16. **Warning for Children.**

The label of all Herbal Medicine and Related Products shall carry a warning "Keep this medicine out of reach of children".

17. **Misleading Information and Misinformation**

(1) No person shall sell, advertise, display or use any Herbal Medicine and Related Products with a name suggestive of the symptom, disorders, diseases or abnormal states that it is supposed to treat, prevent or cure.

(2) The label of Herbal Medicine and Related Products with antipyretic and analgesic property shall not bear the indication "for fever" but shall be labelled "for feverish conditions" or "feverish feeling".

18. **Penalty.**

(1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction. In case of :

(a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N50,000 or to both such imprisonment and fine; and

(b) a body corporate, to a fine not exceeding N100, 000.

(2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals every:-

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

(b) partner or officer of the firm or

(c) trustee of the body concerned ;or

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

(e) 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.

19. **Forfeiture after conviction**

(1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government-

(a) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence;

(b) any of the person's property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.

(2) In this section, **"proceeds"** means any property derived or obtained, directly or indirectly, through the commission of the offence.

20. **Interpretation.**

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 the plant is identified;

"**Common name**" means, with reference to Herbal Medicine and Related Products, the name in English language or other such language by which the product is commonly known;

"Herbal Medicine" means:

(a) finished medicinal product containing plant and their preparation presented with therapeutic or prophylactic claim and includes all preparations containing a plant material in part or wholly.

(b) finished medicinal product containing only animal material in part or wholly and their preparation presented with therapeutic or prophylactic claim;

(c) finished medicinal product containing only inorganic minerals and their preparations presented with prophylactic or therapeutic claim;

(d) preparation or admixture of herbal, animal and mineral medicinal products presented with prophylactic or therapeutic claim; and

(e) preparation or admixture used for restoring, correcting or modifying organic functions in man or in animal.

"**Expiration date**" means any date after which Herbal Medicine and Related Products is not recommended for use;

"**Herbal Medicine and Related Products**" means:

(a) finished medicinal product containing plant and their preparation presented with therapeutic or prophylactic claim and includes all preparations containing a plant material in part or wholly.

(b) preparation or admixture of herbal medicinal products presented with prophylactic or therapeutic claim; and

(c) 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 and Related Products;

"Principal display panel" means:

(a) in the case of a container that is mounted on a display card, that part of the label applied to all or part of the principal display surface of the container; or part of the side of the display card that is displayed or visible under normal or customary conditions of sale or use; or to both such parts of the container and the display card

(b) in the case of an ornamental container, that part of the label applied to all or part of the bottom of the container; or to all or part of the principal display surface; or to all or part of a tag that is attached to the container, and

(c) in the case of all other containers, that part of the label applied to all or part of the principal display surface

(d) "Manufacturer" means The person who performs all of the following operations that are required to produce the product:

(1) Mixing, (2) granulating, (3) milling, (4) molding, (5) lyophilizing, (6) tableting, (7) encapsulating, (8) coating, (9) sterilizing, and (10) filling into dispensing containers, (11)extraction.

"**Package**" includes anything in which any Herbal Medicine and Related Products is wholly or partly contained, placed or packed;

"**Practitioners**" means any person authorized by the appropriate governmental body to practice Herbal Medicine and Related Products; and

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

21. **Repeal of Herbal Medicine and Related Products Labelling Regulations 2019**

(1) The Herbal Medicine and Related Products Labelling Regulations 2005 is hereby repealed.

(2) The repeal of these Regulations 21 (1) shall not affect anything done or purported to be done under the repealed Regulations

22. **Citation**

These Regulations may be cited as the Herbal Medicine and Related Products Labelling Regulations 2019

MADE at Abuja this …….day of ……..2019

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Inuwa Abdulkadir Esq

Chairman Governing Council

National Agency for Food and Drug Administration and Control (NAFDAC)