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

HERBAL MEDICINE AND RELATED ADVERTISEMENT 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 apply to all advertisements or promotion of Herbal Medicine and Related Product manufactured, imported, exported, distributed, advertised, sold, or used in Nigeria.

2. **Prohibition**
   (1) No person shall advertise any:–
      (a) herbal medicines and related products unless it has been registered by the Agency;
      (b) herbal medicines and related products unless the advertisement has approval of the Agency;
      (c) extemporaneous herbal medicines and related products; and
      (d) herbal medicines and related products as a cure, prevention, treatment for any disease conditions listed in Schedule 1 or as may be prescribed by the Agency.

3. **Nature of Advertisement**
   The advertisement of any Herbal Medicine and Related Product shall be accurate, complete, clear and designed to promote credibility and trust by the general public and health care practitioners, therefore statements or illustrations shall not mislead directly, indirectly or by implication.

4. **Non-Referential Advertisement**
   (1) No advertisement of a Herbal Medicine and Related Product shall-
      (a) imitate the general layout, text, slogan or visual presentation of another Herbal Medicine and Related Product in a way likely to mislead or confuse the consumer; or
      (b) be framed in such a manner as to exploit any superstitions or be calculated to induce fear among consumers causing them to purchase the Herbal Medicine and Related Product being advertised.
   (2) All Herbal Medicine and Related Products advertisement shall strictly be in line with claimed indications as registered by the Agency

5. **Application for the Approval of Advertisements**
   All advertisement materials for Herbal Medicine and Related Product including scripts, story-boards, art work, radio scripts and any other such advertisement material as may be required by the Agency shall be submitted along with an application, to the Agency.

6. **Particulars of An Application**

(1) An application for Herbal Medicine and Related Product advertisement submitted by an advertisement agent, distributor, manufacturer or the sponsor of the advert shall contain the following information

(a) Artwork containing the product name of the Herbal Medicine and Related Product
(b) Botanical name of the Herbal Medicine and Related Product
(c) Dosage form available
(d) Place of importation or local manufacture
(e) Name and location address of manufacturer
(f) Name and location address of local distributor
(g) Name and location address of the advertising company
(h) Date of first introduction of the Herbal Medicine and Related Product to the Nigerian market
(i) Previous advertisement of the Herbal Medicine and Related Product in Nigeria if any
(j) Copy of the scripts, story-boards, art work, radio scripts of the advert
(k) The proposed media for the advertisement
(l) A copy of the Certificate of Registration of the Herbal Medicine and Related Product
(m) A copy of the registration certificate of the premise of the sponsors and
(n) Justification for any special claims on the product

7. **Validity of Approval**

The approval of Herbal Medicine and Related Product advert shall be valid for a period of one year beginning from the date of the approval.

8. **Withdrawal of an approval**

The Agency may withdraw the approval for an advertisement of Herbal Medicine and Related Product products if-

(1) the grounds on which the approval is granted was later found to be false or incomplete; or
(2) any of the conditions under which the approval was granted has been contravened; or
(3) in the light of new scientific evidence against claims contained in the advertisement can no longer be substantiated or are no longer correct.

9. **Advertisement to Effect Caution in Product Usage Specified**

Herbal Medicine and Related Product shall reflect an overall attitude of the caution in respect to the Herbal Medicine and Related Product usage with emphasis on rational therapy and shall also provide sufficient and balanced information to permit assessment of risk or benefit.

10. **Cautionary Label or Disclaimer Statement**

Cautionary label or disclaimer statement must be displayed on the label and advertisement materials of Herbal Medicine and Related Products.

11. **Product Advertisement stating that it is "Safe or Non-toxic".**

(1) No advertisement for Herbal Medicine and Related Product shall state or imply in absolute terms or by quotation out of context, that any Herbal Medicine and Related Product is "safe" or has "guaranteed efficacy" or special status.

(2) Any statement claiming or implying a superlative function such as "most effective" "least toxic, "best tolerated" or other special status such as "herbal medicines and related products' of choice" shall not be used.

12. **Restriction**

(1) No advertisement for any Herbal Medicine and Related Product shall contain –

(a) Any false or misleading information;

(b) Half-truths, inadequate qualification and limitations regarding safety or effectiveness of the Herbal Medicine and Related Product;

(c) Vague, unsubstantiated statements, or suggestions of superiority over other competing Herbal Medicine and Related Product;

(d) Any false impression that the advertised herbal medicine or related product is for universal cure or should be regarded as a more effective and safer alternative to other Herbal Medicine and Related Product in the same category.

(2) No Herbal Medicine and Related Product advertisement shall:

(a) contain such word as "magic" "miracle" or an exotic description such as "upper potency" or such other words as to induce the daily or continuous use of the product;

(b) contain a message that if the reader/viewer or listener does not use a particular product his disease/ailment shall be aggravated;

(c) over dramatize any symptoms by way of drawing a picture of a pregnant woman, patient with backache, or use throbbing sounds like heartbeats, coughing or agonizing cries;

(d) disparage or attack unfairly, any competitive products, goods or services.

13. **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.

14. **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.

15. **Interpretation**.

In these Regulations, unless the context otherwise requires:

"Advertising" means the publicity of goods and description of all products which includes, labels, wrappers, catalogues and price lists, billboards, posters, newspapers, magazines and any other documents) made orally or otherwise by means of projected light and sound recordings;

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

"Claim" means any presentation, which states, suggests or implies that the product has particular qualities relating to its origin, nutritional properties, nature, processing, composition or any other quality;

"GMP" means Good Manufacturing Practice

"Herbal Medicine and Related Product" 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.

"Justification" means written explanation in respect of any claim, which shall be in the light of current knowledge acceptable to the Agency;

"Label" means a display of written, printed, graphic matter on a product, the immediate containers, wrappers or accompanying the product; and

"Location Address" means a place where the business of manufacture, sale, distribution, storage and display of herbal and related medicinal products is carried out which includes the house number, plot number, street name, town or city, state, country etc.

16. **Repeal of Herbal Medicines and Related Products (Advertisement) Regulations 2005**

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

(2) The repeal of these Regulations specified in Regulations 17(1) shall not affect anything done or purported to be done under the repealed Regulations.

17. **Citation**

These Regulations may be cited as the Herbal Medicines and Related Products (Advertisement) Regulations 2019.

SCHEDULE 1

Acquired immune deficiency syndrome
Alcoholism
Appendicitis
Arteriosclerosis
Asthma
Blood Disorders
Cancer
Cataract
Cholera
Diabetes
Diphtheria
Disorders of Menstrual Flow
Disorders of Prostate Gland
Dysentery
Encephalitis
Enteric Fever
Epilepsy
Erysipelas
Filariasis
Gallstones, Kidney Stones, and Bladder Stones Gangrene
Any genital or urinary diseases not mentioned elsewhere in this schedule
Glaucoma
Goitre
Hay Fever
Heart Disease
Hernia
High Blood Pressure
Infective Hepatitis
Influenza
Jaundice
Kidney Disease
Leprosy
Loco motor ataxis
Loss of Youth
Measles
Meningitis
Mental Conditions
Mumps
Nervousness
Nutritional disorders
Obesity
Onchocerciasis
Paralysis
Plague

Pleurisy
Pneumonia
Poliomyelitis
Rabies
Rheumatic Fever
Schistosomiasis
Sexual impotence, loss of virility or sterility
Sleeping sickness
Small pox
Snake bite
Syphilis
Tetanus
Trachoma
Tuberculosis
Tumors
Typhoid Fever
Undulant fever
Ulcers of the gastro-intestinal tract
Veneral Diseases
Yaws
Yellow Fever

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)