

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

**HERBAL MEDICINES AND RELATED PRODUCTS (ADVERTISEMENT) REGULATIONS 2018**

**COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 DAYS.**

**PLEASE SEND ALL INPUT TO**[**REGULATORYAFFAIRS@NAFDAC.GOV.NG**](mailto:regulatoryaffairs@nafdac.gov.ng)

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**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 medicines and related products manufactured, imported, exported, distributed, advertised, sold, or used in Nigeria.

1. **Prohibition of Advertisement of Herbal Medicines and Related Products**
2. No person shall advertise any:–
3. herbal medicines and related products unless it has been registered by the Agency;.
4. herbal medicines and related products unless the advertisement has approval of the Agency.
5. extemporaneous herbal and related medicinal preparations; and
6. herbal medicine products as a cure, prevention, treatment for any disease conditions listed in Schedule 1 or as may be prescribed by the Agency.
7. **Nature of Advertisement**

The advertisement of any herbal medicines and related products 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.

1. **Non-Referential Advertisement**
2. No advertisement of a herbal medicine or related product shall-
3. imitate the general layout, text, slogan or visual presentation of another herbal medicine or related products in a way likely to mislead or confuse the consumer; or
4. 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 or related product being advertised.
5. All herbal medicine products advertisements shall strictly be in line with claimed indications as registered by the Agency
6. **Application for the Approval of Advertisements**

All advertisement materials for herbal medicine or 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.

1. **Particulars of An Application**
2. 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
3. Artwork containing the product name of the herbal medicine or related product.
4. Botanical name of the herbal medicine or related product.
5. Dosage form available
6. Place of importation or local manufacture
7. Name and location address of manufacturer
8. Name and location address of local distributor
9. Name and location address of the advertising company
10. Date of first introduction of the herbal medicine or related product to the Nigerian market
11. Previous advertisement of the herbal medicine or related product in Nigeria if any
12. Copy of the scripts, story-boards, art work, radio scripts of the advert
13. The proposed media for the advertisement
14. A copy of the Certificate of Registration of the herbal medicine or related product.
15. A copy of the registration certificate of the premise of the sponsors and
16. Justification for any special claims on the product
17. **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.

1. **Alteration in approved script.**

Any alteration in the format of the advert of herbal medicine and related product approved script or recording without the approval of the Agency shall render the approval null and void.

1. **Appeal in Case of Withdrawal of Approval Within the One year Specified**

If the approval of an advertisement of herbal medicine and related product is withdrawn during the one year period of approval, an appeal shall be lodged in writing and accompanied with supporting documents within thirty days after the receipt of the withdrawal to the Agency.

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

Herbal medicines and related products shall reflect an overall attitude of the caution in respect to the herbal medicine or related product usage with emphasis on rational therapy and shall also provide sufficient and balanced information to permit assessment of risk or benefit.

1. **Cautionary Label or Disclaimer Statement**

Cautionary label or disclaimer statement must be displayed on the label and advertisement materials of a herbal medicines and related products.

1. **Product Advertisement stating that it is "Safe or Non-toxic".**
   1. No advertisement for herbal medicine or related product shall state or imply in absolute terms or by quotation out of context, that any herbal medicine or 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 for “herbal medicines and related products of choice” shall not be used.
2. **Restriction**
3. No advertisement for any herbal medicine or related product shall contain –
4. Any false or misleading information;
5. Half-truths, inadequate qualification and limitations regarding safety or effectiveness of the herbal medicine or related product;
6. Vague, unsubstantiated statements, or suggestions of superiority over other competing herbal medicine or related product;
7. 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 or related product in the same category.
8. No herbal medicine or related product advertisement shall:
   1. 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;
   2. contain a message that if the reader/viewer or listener does not use a particular product his disease/ailment shall be aggravated;
   3. 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;
   4. disparage or attack unfairly, any competitive products, goods or services.
9. **Penalty.** 
   1. A person who contravenes any of the provisions of these Regulations shall be prohibited from carrying on the advertisement of the herbal medicines or related product either absolutely of for such a period of time as the Agency may declare, in addition to a fine of N50, 000 per medium, per version, per slot.
   2. The Agency shall in addition to sub-section 14.1 of these Regulations, confiscate, destroy or dispose of in any manner whatsoever any herbal medicine or related product contravening the provisions of these Regulations.
   3. Where an offence under these Regulations is committed by a body corporate firm or other association of individuals :-
10. every director, manager, secretary or other similar officer of the body corporate; or;
11. every partner or officer of the firm; or (c) every trustee of the body concerned ;or
12. every person concerned in the management of the affairs of the association ;or
13. every person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this Regulations, 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**

In addition to the penalty specified in these Regulations, a person convicted of an offence under these regulations shall forfeit to the Agency the advertising materials and whatsoever is used in connection with the commission of the offence.

1. **Interpretation**.

In these Regulations, unless the context otherwise requires:

1. **"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;
2. **"Agency"** means the National Agency for Food and Drug Administration and Control;
3. **"Claim"** means any presentation, which states, suggests or implies that the product has particular qualities relating to its origin, nutritional properties, nature, processing,
4. composition or any other quality;
5. **"Justification"** means written explanation in respect of any claim, which shall be in the light of current knowledge acceptable to the Agency;
6. **"Label"** means a display of written, printed, graphic matter upon on a product, the immediate containers, wrappers or accompanying the product; and
7. **"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.
8. **Repeal of Herbal Medicines and Related Products (Advertisement) Regulations 2005**
   1. The Herbal Medicines and Related Products (Advertisement) Regulations 2005 is hereby repealed.
   2. The repeal of these Regulations specified in sub-section 17 shall not affect anything done or purported to be done under the repealed Regulations
9. **Citation**

These Regulations may be cited as the Herbal medicines and Related Products (Advertisement) Regulations 2018.

**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……………2018

**Inuwa Abdulkadir Esq**

**Chairman Governing Council**

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