



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

**COMPLEMENTARY AND ALTERNATIVE MEDICINE
(ADVERTISEMENT) REGULATIONS 2018**

COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 CALENDAR DAYS

(ending 29th August, 2018).

PLEASE SEND ALL INPUT TO REGULATORYAFFAIRS@NAFDAC.GOV.NG

ARRANGEMENT OF REGULATIONS

Commencement:

1. Scope:
2. Prohibition
3. Nature of Advertisement
4. Non-Referential Advertisement
5. Application for the Approval of Advertisements
6. Particulars of an Application
7. Validity of Approval
8. Alteration in approved script.
9. Appeal in Case of Withdrawal of Approval Within the One year Specified
10. Advertisement to Effect Caution in Product Usage Specified advertisements
11. Cautionary Label or Disclaimer Statement
12. Product Advertisement stating that it is "Safe or Non-toxic".
13. Restriction
14. Penalty.
15. Forfeiture
16. Interpretation.
17. Repeal
18. Citation

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 complementary and alternative medicine manufactured, imported, exported, distributed, advertised, sold, or used in Nigeria.

2. Prohibition

(1) No person shall advertise any:-

- (a) complementary or alternative medicine unless it has been registered by the Agency;
- (b) complementary or alternative medicine unless the advertisement has approval of the Agency;
- (c) extemporaneous complementary or alternative medicine; and
- (d) complementary or alternative medicine 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 complementary and alternative medicine 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 complementary and alternative medicine shall-

- (a) imitate the general layout, text, slogan or visual presentation of another complementary and alternative medicine 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 complementary and alternative medicine being advertised.

(2) All complementary and alternative medicines 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 complementary and alternative medicine 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 complementary and alternative medicine 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 complementary and alternative medicine
- (b) Botanical name of the complementary and alternative medicine
- (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 complementary and alternative medicine to the Nigerian

market

- (i) Previous advertisement of the complementary and alternative medicine 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 complementary and alternative medicine
- (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 complementary and alternative medicine advert shall be valid for a period of one year beginning from the date of the approval.

8. Alteration in approved script.

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

9. Appeal in case of withdrawal of approval

- (1) If the approval of an advertisement of complementary and alternative medicine is withdrawn within the validity period of approval, the applicant may, within 30 days of the receipt of the withdrawal notice, lodge an appeal to the Governing Council of the Agency in writing and accompanied by supportive information; if no appeal is made after thirty days, the withdrawal stands as issued.
- (2) Where no appeal is made after thirty days, the withdrawal stands as issued.

10. Advertisement to Effect Caution in Product Usage Specified

Complementary and alternative medicine shall reflect an overall attitude of the caution in respect to the complementary and alternative medicine usage with emphasis on rational therapy and shall also provide sufficient and balanced information to permit assessment of risk or benefit.

11. Cautionary Label or Disclaimer Statement

Cautionary label or disclaimer statement must be displayed on the label and advertisement materials of complementary and alternative medicine.

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

- (1) No advertisement for complementary and alternative medicine shall state or imply in absolute terms or by quotation out of context, that any complementary and alternative medicine 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 "complementary or alternative medicine of choice" shall not be used.

13. Restriction

- (1) No advertisement for any complementary and alternative medicine shall contain –
 - (a) Any false or misleading information;
 - (b) Half-truths, inadequate qualification and limitations regarding safety or effectiveness of the complementary and alternative medicine;
 - (c) Vague, unsubstantiated statements, or suggestions of superiority over other competing complementary and alternative medicine;
 - (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 complementary and alternative medicine in the same category.

- (2) No complementary and alternative medicine 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.

14. **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 50,000 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.

15. **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.

16. **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;

"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.

17. 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.

18. Citation

These Regulations may be cited as the Complementary an Alternative Medicine (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

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Inuwa Abdulkadir Esq
Chairman Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)