Federal Republic of Nigeria Official Gazette

No. 107 **Lagos - 27th September, 2021** **Vol. 108**

Government Notice No. 176

The following is published as Supplement to this *Gazette* :

Printed and Published by The Federal Government Printer, Lagos, Nigeria
FGP 166/092021/150

Annual Subscription from 1st January, 2021 is Local : ₦45,000.00 Overseas : ₦60,500.00 [Surface Mail] ₦75,000.00 [Second Class Air Mail]. Present issue ₦2,500 per copy. Subscribers who wish to obtain *Gazette* after 1st January should apply to the Federal Government Printer, Lagos for amended Subscriptions.

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004

HERBAL MEDICINE AND RELATED PRODUCTS ADVERTISEMENT REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

Regulation :

S. I. No. 75 of 2021

NATIONAL AGENCY FOR FOOD AND DRUGS ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004

HERBAL MEDICINE AND RELATED PRODUCTS ADVERTISEMENT REGULATIONS, 2021

[*7th Day of July,* 2021] Commencement.

In exercise of the powers conferred on it by sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act (Cap. N1 LFN) 2004 and section 12 of the Food, Drug and Related Products (Registration, Etc.) Act (Cap. F33 LFN) 2004 and all other 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 Minister of Health makes the following Regulations—

Scope of application.

1. These Regulations shall apply to all advertisements or promotion of Herbal Medicine and Related Product manufactured, imported, exported, distributed, advertised, sold, or used in Nigeria.

Prohibition.

2. A person shall not advertise—

(*a*) Herbal Medicines and any Related Products unless it has been registered by the Agency ;

(*b*) herbal medicines and any related products unless the advertisement has been approved by the Agency ;

(*c*) extemporaneous herbal medicines and related products ; and

(*d*) herbal medicines and any related products as a cure, prevention, treatment for any disease conditions listed in the Schedule to these Regulations or as may be prescribed by the Agency.

Nature of advertisement.

3. The advertisement of any herbal medicine and related product shall be accurate, complete, clear and designed to promote credibility and trust of the general public and health care practitioners, therefore statements or illustrations shall not mislead directly, indirectly or by implication.

Non-referential advertisement.

4.—(1) An advertisement of herbal medicine and related product shall not—

(*a*) imitate the general layout, text, slogan or visual presentation of another herbal medicine and related product in a way that is likely to mislead or confuse the consumer ; or

(*b*) be framed in such a manner as to exploit any superstitions or calculated to induce fear among consumers causing them to purchase the Herbal Medicine and Related Product being advertised.

(2) Herbal medicine and any related products advertisement shall strictly be in line with indications registered by the Agency.

Application for the approval of advertisements.

5.—(1) Advertisement materials including script store boards, artwork, radio scripts and any other advertisement material shall be submitted along with an application in a manner as may be prescribed by the Agency.

(2) Materials submitted under regulation 5 of these Regulations shall be authenticated by the Chief Executive or by the appropriate technical person of the Herbal Medicines and Related Products company sponsoring the advertisement.

Particulars of an application.

6. Application for Herbal Medicine and Related Productadvertisement 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 address of manufacturer ;

(*f*) name and address of local distributor ;

(*g*) name and 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, storyboards, artwork, 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.

Validity of approval.

7.—(1) The approval for herbal medicine and related product advert shall be valid for a period of 1 year from the date of the approval.

(2) Subsequent application for advertisement shall be valid for 2 years, provided no alteration is made and conditions of renewal approval remain the same.

Withdrawal of an approval.

8. The Agency may withdraw an approval for advertisement of herbal medicine and related products, where—

(*a*) the grounds on which the approval is granted was later found to be false or incomplete ;

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8. The Agency may withdraw an approval for advertisement of herbal medicine and related products, where—

(*a*) the grounds on which the approval is granted was later found to be false or incomplete ;

(*b*) any of the conditions under which the approval was granted have been contravened ;

(*c*) new scientific evidence against claims contained in the advertisement can no longer be substantiated or are no longer correct ; or

(*d*) there is an order of court.

Advertisement to effect caution in product usage specified.

9. 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.

Cautionary label or disclaimer statement.

10. Cautionary label or disclaimer statement must be displayed on the label and advertisement materials ofherbal medicine and related products.

Product advertisement stating that it is "Safe or non-toxic".

11.—(1) Advertisement for herbal medicine and related product shall notstate 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.

Product launch and press release.

12. All product launch materials or press release of herbal medicines and related products shall be as approved by the Agency for the product advertising materials.

Restriction.

13.—(1) An advertisement for herbal medicine and related product shall not contain—

(*a*) any false or misleading information ;

(*b*) false statement, 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 ; or

(*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) Herbal medicine and related product advertisement shall not—

(*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 message where the reader or viewer or listener does not use a particular product his disease or ailment may be aggravated ;

(*c*) over dramatize any symptoms or unfairly attack any competitive Herbal Medicine and related product.

Offences and Penalties.

14.—(1) A person who contravenes any of the provisions of these Regulations commits an offence and isliable on conviction, in the case of—

(*a*) an individual, to imprisonment for a term not exceeding 1year or to a fine not exceeding ₦800,000.00 or to both ; and

(*b*) a body corporate, to a fine not exceeding ₦5,000,000.00.

(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 ;

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

(*c*) trustee of the body concerned ;

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

(*e*) person who purports to act in a capacity referred to in paragraphs (*a*) to (*d*) of this sub-regulation,

is liable to be proceeded against and punished for the offence in the same manner as if the person committed the offence, unless the person proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Forfeiture after conviction.

15. Any person convicted of an offence under these Regulations shall forfeit to the Federal Government—

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

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

Revocation.

16.—(1) The Herbal Medicine and Related Products (Advertisement) Regulations 2005 is revoked.

(2) The revocation of the Regulations mentioned in sub-regulation (1) of this regulation shall not affect anything done or purported to have been done under the revoked Regulations.

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Enforcement of these Regulations.

17. The Agency shallbe responsible for the enforcement of these Regulations.

Interpretation.

18. In these Regulations—

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

"*Advertisement*" means a form of communication through the media about products, services or ideas paid for by an identified sponsor and It is used to encourage, persuade or manipulate an audience, such as viewers, readers or listeners, to continue with or take some new action ;

"*Advertising*" means the publicity of goods and description of all products, which includes any form of notices in circulars, handouts, labels, wrappers, catalogues and price lists, bill boards, posters, newspapers, magazines, digital and social media, and any other documents, made orally, online or otherwise or by means of projected light and sound recordings ;

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

"*Claim*" means any representation, 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, which includes all preparations containing a plant material in part or whole,

(*b*) preparation or admixture of herbal medicinal products presented with prophylactic or therapeutic claim, or

(*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 currentknowledge acceptable to the Agency ;

"*Label*" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to, a package or container of herbal medicine or related product ;

"*Media*" means newspaper, magazine, medicaljournal, television, radio, the internet, vehicle branding, posters, handbills, cinema, point of sale material, online, digital and social media, any form of projected light and sound recordings or any of such means of communication ; and

"*Proceeds*" means any property derived or obtained, directly or indirectly, through the commission of the offence.

Citation.

19. These Regulations may be cited as the Herbal Medicines and Related Products Advertisement Regulations, 2021.

SCHEDULE [*Regulation* 2 (*d*)]

DISEASE CONDITIONS

(1) Acquired immune deficiency syndrome.
(2) Alcoholism.
(3) Appendicitis.
(4) Arteriosclerosis.
(5) Asthma.
(6) Blood Disorders.
(7) Cancer.
(8) Cataract.
(9) Cholera.
(10) Diabetes.
(11) Diphtheria.
(12) Disorders of menstrual Flow.
(13) Disorders of prostate gland.
(14) Dysentery.
(15) Encephalitis.
(16) Enteric Fever.
(17) Epilepsy.
(18) Erysipelas.
(19) Filariasis.
(20) Gallstones, Kidney Stones, and Bladder Stones Gangrene.
(21) Any genital or urinary diseases not mentioned elsewhere in this schedule.
(22) Glaucoma.
(23) Goitre.
(24) Hay fever.
(25) Heart disease.
(26) Hernia.
(27) High blood pressure.
(28) Infective hepatitis.
(29) Influenza.
(30) Jaundice.
(31) Kidney disease.
(32) Leprosy.
(33) Loco motor ataxis.
(34) Loss of youth.
(35) Measles.
(36) Meningitis.
(37) Mental conditions.
(38) Mumps.
(39) Nervousness.
(40) Nutritional disorders.

(41) Obesity.
(42) Onchocerciasis.
(43) Paralysis.
(44) Plague.
(45) Pleurisy.
(46) Pneumonia.
(47) Poliomyelitis.
(48) Rabies.
(49) Rheumatic fever.
(50) Schistosomiasis;
(51) Sexual impotence, loss of virility or sterility.
(52) Sleeping sickness.
(53) Small pox.
(54) Snake bite.
(55) Syphilis.
(56) Tetanus.
(57) Trachoma.
(58) Tuberculosis.
(59) Tumors.
(60) Typhoid fever.
(61) Undulant fever.
(62) Ulcers of the gastro-intestinal tract.
(63) Veneral diseases.
(64) Yaws.
(65) Yellow Fever.

MADE at Abuja this 7th day of July, 2021.

DR. OSAGIE E. EHANIRE, MD, FWACS
Honourable Minister of Health