S. I. of 2005

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT 1993 (AS AMENDED)

Herbal Medicines and Related Products (Advertisement) Regulations 2005

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 29 of the National Agency for Food and Drug Administration and Control Act 1993, as amended, 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:-

Prohibition of Advertisement of Herbal Medicines and Related Products.

No person shall advertise –

(a) any herbal medicine and related product unless it has been registered by the Agency;

(b) any herbal medicine and related product unless the advertisement has been given pre-clearance and approval by the Agency;

(c) any extemporaneous herbal and related medicinal preparations; and

(e) a product as a cure for any disease conditions listed in Schedule 1 to these regulations.

Nature of Advertisement.

2. The advertisement in Nigeria of any herbal medicine or related product shall be accurate, complete, clear and designed to promote credibility and trust by the general public and health care practitioners and statements illustration shall not be misleading directly or by implication.

Non-referential Advertisement.

3. No advertisement of a herbal medicine or related product shall:

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

(b) be framed in such a manner as to exploit any superstitions or be calculated to induce fear among consumers, causing them to purchase herbal medicine or related product being advertised.

Application for the Approval of Advertisements

4. (1) All advertisement materials including scripts, storyboards, artwork, audio and video tapes, etc. shall be submitted under confidential cover along with an application, to the Director-General of the Agency.

(2) Where advertisement materials are submitted through any of the state officers of the Agency, it shall be in accordance with sub-regulation.

Particulars of application.

5. An application, submitted by any advertisement agent, distributor, manufacturer or the sponsor of the advert shall contain the following information the:

(a) artwork containing the common name of the herbal medicine or related product;

(b) botanical name of herbal medicine or related product;

(c) dosage form available;

(d) place of importation or local manufacture;

(e) name and location address of the manufacturer;

(f) name and address of the local distributor;

(g) name and location address of the advertising company;

(h) date of first introduction of the herbal medicine or related product to the Nigerian Market;

(i) previous advertisement of the herbal medicine or related product in Nigeria if any;
(j) copy of the script, audio, video tapes and story-board of the advert;
(k) The proposed media for the advertisement.
(l) A copy of the registration certificate of the herbal medicine or related product;
(m) A copy of the registration certificate of the premises of the sponsors; and
(n) Justification for any special claims on the products.

Validity of Approval. 6. The approval of an advert shall be valid for a period of one year beginning from the date of the approval.

Alteration in approved script. 7. Any alteration in the format of the approved script, story-board, artwork, audio or video tapes without the approval of the Agency shall render the approval null and void.

Unacceptable Advertisement. 8. Where an advertisement is considered unacceptable by the Agency, the words "unacceptable as presented" shall be stamped on it and it shall be returned to the sponsor with the unacceptable information or illustration clearly identified.

Appeal in case of withdrawal of approval Within the one year specified. 9. If the approval of an advertisement is withdrawn during the one year period of approval, an appeal may be lodged within thirty days after the receipt of the with-drawal to the Governing Council of the Agency in writing and accompanied by supportive information.

Advertisement to Effect Caution in Product Usage Specified 10. Herbal Medicine and Related Product advertisements 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.

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

11. (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 "herbal medicine" or "related product of choice" etc, shall not be used.

Restriction.

12.(1) No advertisement for any herbal medicine or 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 or related product;

(c) vague, unsubstantiated statements, or suggestions of superiority over other competing herbal medicine or 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 or related product in the same category.

(2). No herbal medicine or 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.

Penalty. 13.(1) A 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 ₦100,000.

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

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

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

(c) every trustee of the body concerned ;or

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

(e) every 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.

Forfeiture **14.** In addition to the penalty specified in regulation 13 of 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.

Interpretation. 15. 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 upon the immediate containers to 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.

SCHEDULE 1

Acquired immune deficiency syndrome
Alcoholism
Appendicitis
Arteriosclerosis
Asthma
Blood Disorders
Cancer
Cataract
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

Citation. 15. These Regulations may be cited as the Herbal medicines and Related Products (Advertisement) Regulations 2005.

MADE at Abuja this day of 2005

DR. ANDEM NYONG ANDEM
Chairman Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)

EXPLANATORY NOTE

(This note does not form part of the above Regulations but is intended to explain its purpose.)

These Regulations apply to all advertisements or promotion of Herbal medicines and Related Products (both single entity and compound) imported into Nigeria or locally manufactured, distributed or sold in Nigeria.