S. I. of 2005

DRUGS AND RELATED PRODUCTS (REGISTRATION, ETC.) ACT 1996 (AS AMENDED)

Herbal Medicines and Related Products (Registration) 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 Section 8 of the Drugs and Related Products (Registration, Etc.) Act 1996, 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 . **1**. (1) No herbal medicine and related product shall be manufactured, imported, advertised, sold or distributed in Nigeria unless it has been registered in accordance with the provisions of these regulations.

(2) Notwithstanding the provisions of sub-regulation (1), the National Agency for Food and Drug Administration and Control may grant a permit for the importation or manufacture of samples of herbal medicines and related products for the purpose of registration or clinical trial, and the importation or manufacture shall be in accordance with the conditions specified in the permit.

Application for Registration . **2**. (1) Application for the registration of a Herbal medicine and related product shall be made in writing to the

Agency in such form as the Agency may, from time to time, prescribe and shall:

(a) contain the particulars and description of the Herbal medicine and related product in respect of which the application is made;

(b) be accompanied by the evidence of payment of such fee as the Agency may, from time to time prescribe.

(2) The Agency, in considering an application:

(a) may demand from an applicant such other information as may be required to process the application;

(b) shall satisfy itself that there is need to have the herbal medicine and related product, registered in Nigeria.

(3) Where the Agency is satisfied that there is need to register the Herbal medicine and related product, it shall do so and issue the applicant a certificate of registration.

Confidentiality of Information.

3. No person shall disclose any information supplied to the Agency in pursuance of Regulation 2 of these Regulations except:

(a) with the written consent of the person who supplied the information; or

(b) in accordance with the directive of the Agency; or

(c) for the purpose of a proceeding under these regulations.

Penalty. **4**(1). A person who contravenes any of the provisions of these Regulations is guilty of an offence and liable on conviction:-

(a) in the case of an individual, to imprisonment for a term not exceeding two years or to a fine not exceeding ₦50,000 or to both such imprisonment and fine; or

(b) in the case of body corporate, to a fine not exceeding ₦100,000.

(2) Where an offence under these Regulations is committed by a body corporate or 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. **5**. In addition to the penalty specified in regulation 4 of these Regulations, a person convicted of an offence under these Regulations shall forfeit to the Agency the herbal medicine or related product and whatsoever is used in connection with the commission of the offence.

Interpretation. **6**. In these regulations, unless the context otherwise requires:

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

"Herbal Medicines and Related Products" includes:

(a) Herbal Medicinal Products which shall be defined as finished and labelled medicinal products containing plant or their preparation presented with therapeutic or prophylactic claim and include all preparations containing a plant material in part or wholly;

(b) Animal medicinal products which shall be defined as finished and labelled related medicinal products containing only animal material in part or wholly and their preparation being presented with therapeutic or prophylactic claim;

(c) Mineral Medicinal Products which shall be defined as finished and labelled medicinal products containing only in-organic minerals and/or their preparations;

(d) Preparation or admixture thereof manufactured, sold or advertised for use in the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or animal; and

(e) Preparation or admixture used for restoring, correcting or modifying organic functions in man or in animal.

Citation **7**. This may be cited as Herbal Medicines and Related Products (Registration) 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)