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

FOOD AND RELATED PRODUCTS REGISTRATION REGULATIONS, 2019

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FOOD AND RELATED PRODUCTS REGISTRATION REGULATIONS, 2019
ARRANGEMENT OF REGULATIONS

Regulations

FOOD AND RELATED PRODUCTS REGISTRATION REGULATIONS, 2019

[ ] **Commencement**

In exercise of the powers conferred on it Sections 5 and 30 of the National Agency for Food and Drugs Administration and Control Act Cap N1 Laws of the Federation of Nigeria (LFN) 2004 and Section 12 of the Food, Drugs 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 Honorable Minister of Health makes the following Regulations -

1. **Scope of application**
   These Regulations shall apply to all food products manufactured, imported, exported, advertised, sold, distributed or used in Nigeria

2. **Prohibition**
   (1) A person shall not manufacture, import, export, advertise, sell, distribute or use a food product in Nigeria unless it has been registered in accordance with the provisions of these Regulations.
   (2) Notwithstanding the provisions of sub regulation 1 of these Regulations, the Agency may grant a permit or Certificate for the importation or manufacture of a sample of food product for the purpose of -
      (a) registration;
      (b) donation for humanitarian interventions;
      (c) bulk food items;
      (d) global listing of supermarket items and fastfood and restaurant operators; and
      (e) the importation or manufacture of products as provided in Regulation (1) shall be in accordance with the conditions specified by the Agency.

3. **Application for registration**
   (1) Application for the registration of a food product shall be made by submitting a complete application form, accompanied by relevant documents as the Agency may, from time to time, prescribe and shall -
      (a) contain the particulars and description of the food product, in respect of which the application is made;
      (b) be accompanied by such fee as the Agency may, from time to time, prescribe.

   (2) The food product particulars and description shall be detailed enough to consist of all administrative and technical information in sufficient details as may be required to allow the Agency make informed decision about the food product

   (3) The Agency, in considering an application-
      (a) may ask the applicant to supply such other information as it may require to enable it reach a decision on the application;
      (b) shall satisfy itself that there is need to have the food product registered in Nigeria.

(c) may register the food product in accordance with the provisions of Food, Drug and Related Products (Registration etc.) Act cap F33 LFN 2004.

(4) The registration of a food product under these Regulations shall, unless cancelled earlier, be valid for a period of five years and may be renewed or as may be prescribed by the Agency.

(5) The Agency shall, from time to time, publish the list of registered foods or food products on the Agency's official website, notifying the registration of a food or food product.

(6) The Agency may refuse or reject an application for registration if:

(a) it is found that the method, facilities or controls used in the manufacture, processing, and packaging of the food product are inadequate to ensure and preserve its identity, characteristic, quality and safety consistently;

(b) laboratory report for the product is unsatisfactory;

(c) good manufacturing practice inspection report is unsatisfactory;

(d) product labeling contravenes the Pre-packaged Food Product, Water and Ice Labeling Regulations 2019

4. **Disclosure of information supplied by applicant**

A person shall not disclose any information supplied to the Agency in pursuance of Regulation 3 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.

5. **Post-registration changes**

(1) Except as prescribed in these Regulations, no change shall be carried out to the terms and conditions under which a food product was registered without prior approval of the Agency.

(2) Every application for change to an approved product shall be submitted to the Agency describing in detail the changes to be carried out.

(3) Depending on the type of change, the Certificate of Registration holder shall apply to the Agency about the change through a variation application along with the payment of the prescribed fee as may be determined by the Agency or by a way of notification.

(4) As may be determined by the Agency, a post-registration change may be accomplished through;

(a) Change in product name;

(b) Change in packaging materials or additional packaging material;

(c) change in pack-size or additional pack size;

(d) change in label design;

(e) special authorization;

(f) or any other change as approved by the Agency.

(5) Where a change is to be effected, the Certificate of Registration holder shall not distribute the food or food product unless:

(a) The effect of the change has been duly assessed and duly approved by the Agency

(b) The product label has been revised to reflect the change, where applicable.

6. **Changes requiring new application**

For the purpose of these Regulations, the following changes herein listed (or as may be

prescribed by the Agency) shall require a new application -

(a) change in formulation
(b) change in manufacturing site
(c) additional variant
(d) additional manufacturing site

7. **Suspension or cancellation of certificate of registration**

(1) The Agency may suspend or cancel the registration of a food product if -

(a) the grounds on which the food product was registered were later found to be false or incomplete; or the circumstances under which the food product was registered no longer exist;
(b) any of the conditions under which the food product was registered has been contravened;
(c) the standard of quality and safety as prescribed in the documentation for registration is not being complied with;
(d) the premises in which the food product or part thereof is manufactured, assembled or stored on behalf of the holder of the certificate of registration are not in compliance with the requirements of current Good Manufacturing Practice (cGMP), or as may be determined by the Agency.
(e) the Certificate of Registration holder has given a notice to the Agency in writing of any intentions to suspend product registration for a period not exceeding the validity of the certificate of registration.

(2) Where the registration of food product is suspended or cancelled, the Agency shall order the withdrawal from circulation of that food product and shall accordingly cause the suspension, cancellation or withdrawal to be published.

(3) Consequent upon the provisions in Regulations 7 (1)(a), a Certificate of Registration holder may notify the Agency of his intention to resume marketing of a registered product and shall submit relevant document and pay the prescribed renewal fee for product registration where the product registration certificate has expired.

8. **Multi-branding**

(1) A person shall not import the same food product from the same manufacturer under different brand names.
(2) Notwithstanding the provision in regulation 8 (1) of these Regulations, a food product can be registered under contract manufacturing agreement.

9. **Stability testing, shelf life, expiration dating and storage statement.**

(1) A storage statement shall be established for the label based on the shelf life study of the product. Where applicable, specific instructions shall be provided, particularly for food product that require freezing. Terms such as “ambient conditions” or “room temperature” shall be avoided.
(2) In general, for food or related food product not requiring temperature controlled storage, the required storage conditions shall be specified on the label.
(3) Ancillary cautionary storage statements may be required as shall be determined based on results from shelf life studies.

10. **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 500,000 or to both such imprisonment and fine; and

(b) a body corporate, to a fine not exceeding N750, 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;

(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 severally 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.

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

12. **Interpretation**

In this Regulations, unless the context otherwise requires –

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

Food means any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes water and other drinks, chewing gum and any substance which has been used in the manufacture, preparation or treatment of “food” but does not include cosmetics or tobacco or substances used only as drugs.

Best Before Date or Best Quality Before Date means the date which signifies the end of the period, under any stated storage conditions, during which the unopened product will remain fully marketable and will retain any specific qualities for which implied or express claims have been made. However, beyond the date the food may still be acceptable for consumption.

Certificate of Registration means a document describing the particulars and conditions under which a product is registered and indicate the assigned NAFDAC Reg. No. for a product;

Registered product means a food or food related product which has been approved by the agency and assigned a NAFDAC Reg. No. to be manufactured, imported, exported, sold, distributed or advertised.

13. **Revocation**
    (1) The Foods and Related Products (Registration, Etc.) 1993 is revoked.
    (2) The revocation of the Regulations specified in Regulations 13 (1) shall not affect anything done or purported to be done under the repealed Regulations

14. **Citation**
    These Regulations may be cited as the Foods and Related Products (Registration) Regulations, 2019.

MADE at Abuja this ……day of ……..2019

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