ANNEX 5: Marketing of Infant and Young Children Food and Other Designated Products (Registration, Sales, Etc.) Regulations 2005:

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

Marketing of Infant and Young Children Food and Other Designated Products (Registration, Sales, Etc.) Regulations 2005

Commencement: 1st January, 2005

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 –

Registration of Designated Product

1. –(1) Every Designated Product manufactured, imported, exported, sold or distributed in Nigeria shall be registered in accordance with the provisions of Marketing Breast Milk Substitute Act of 1990 and these Regulations.

(2) Notwithstanding the provisions of subregulation (1) of this Regulation, the manufacture or importation of any Designated Infant Feeding Product as a sample for registration shall be undertaken with the approval of the Agency.

Application for registration

2.-(1) The application for registration of any Designated Product shall be made in such form as may be stipulated from time to time by the Agency.
(2) An application shall be accompanied by –
(a) a non refundable fee as may be stipulated by the Agency;
(b) samples of the Designated Product as may be stipulated by the Agency; the original certificate of analysis of the Designated Product;
(d) evidence of any special labelling of the character, quality and safety of the Designated Product;
(e) a copy of certificate of manufacture and sale for the imported Designated Product from the statutory body in the country of origin responsible for the safety of the Designated Product duly authenticated by the Nigeria Mission in that country;
(f) the radiation-free test certificate;
(g) a copy of Evidence of Trademark ownership;
(h) a notarised declaration that the information contained in the Registration form are correct and that all the documents submitted are genuine;
(i) a power of attorney or an agreement from the manufacturer signed by a General Manager or Director of the manufacturing company and notarised in the country of manufacture authorizing a Nigerian representative to register the Designated products in Nigeria; and

(j) an undertaking that the Designated Product shall not be advertised.

Invalidation of certificate of registration

(3) The Agency may suspend, withdraw or cancel the certificate of registration of a Designated Product if –

(a) the grounds on which the Designated Products was registered were found to be false or incomplete, or
(b) the circumstances under which the Designated Product was registered no longer exist; or
(c) any of the conditions or undertaking under which the Designated Product was registered has been contravened; or
(d) the standard of quality, safety or efficacy as stipulated in the documentation for registration is not being complied with; or
(e) the premises in which the Designated Product is imported, processed, manufactured or stored by or on behalf of the holder of the certificate of registration are unsuitable for the importation, processing, manufacturing or storage of the Designated Product; or
(f) the Designated Product is promoted or advertised.

Information and educational materials on infant feeding

4.-(1) the Agency shall have the responsibility for the control of the production, provision, planning, design and dissemination of information and education materials on infant and young child feeding for use by families and those involved in the field of infant and young children health and nutrition.

(2) Information and educational materials whether written, audio or visual, dealing with the feeding of infants and intended to reach pregnant women, mothers of infants and young children or members of their families shall include clear and appropriate information on all the following points:

(a) the benefits and superiority of breastfeeding;
(b) how to prepare for and maintain breastfeeding including maternal nutrition'
(c) the negative effects which the introduction of artificial feeding has on lactation;
(d) the danger of inappropriate use of designated products and bottle-feeding; and
(e) the difficulty of returning to breastfeeding after a period of artificial feeding.

Restrictions regarding information, educational materials and equipments.

5.-(1) Information and educational materials shall contain only factual and current information and shall not use any picture or text that encourages artificial feeding or use of bottles for feeding or discourages breast feeding.

(2) Information and educational materials shall be written in English, Hausa, Igbo and Yoruba languages.

(3) Information and educational materials shall not make reference to any brand of Designated Product, but may, contain the name or logo of any manufacturer or distributor of Designated Product, provided the name or logo is not more than 3 *per cent* of the material outlay.

(4) Any material containing information about the use of Designated Products shall point out the risks that shall arise for the child's health due to these products.

(5) Donation of information and educational materials or equipment by manufacturers or distributors shall be with the approval of the Agency and in accordance with these Regulations

Restrictions on healthcare facility

6.-(1) The health care facility system shall not be used to promote Designated Products, display of such products, placards or posters concerning such products or for the distribution of materials concerning these items provided by a manufacturer or distributor.

(2) Notwithstanding the provisions of sub-regulation (1) of this Regulation, the restrictions prescribed shall not preclude the dissemination of information to Health professionals as provided for in these Regulations.

(3) Feeding with Designated Products, whether manufactured or home prepared, shall be demonstrated by health workers or community workers if necessary and only to the mothers or family members for whom it has been prescribed and the information given shall include a clear explanation of the hazard of improper use.

(4) The head of a health care facility shall –
(a) present to the Agency in writing, a full disclosure of any contribution made by a distributor or manufacturer of Designated Products to the Health Care System or Health Care Workers therein, and
(b) prohibit acceptance into the Health care facility, of gifts in the form of samples of Infant and Young Children Designated Products or supplies of the same or gift of any article which may idealise or promote the use of Designated Products.

Donation to be approved by the Agency

7. –(1) Donation, low-price sales or supplies of Designated Products to social welfare institutions shall be accepted with the written approval of the Agency.

(2) The supply or donation made under sub-regulation (1) of this Regulation, shall
(a) only be used or distributed for infants for whom it has been prescribed to be fed on Designated Products; and
(b) be continued for as long as the infant needs them.

(3) Health workers shall –
(a) encourage and protect breast feeding; and
(b) make a disclosure to their employers in writing of any contribution made by a distributor or a manufacturer on behalf of the health worker, for fellowship, study tour, research grant, attendance at professional conference or for other similar purposes.

8. And Health professional who has a technical question with regard to the use of products within the scope of these Regulations may, seek information from a manufacturer in writing and the manufacturer shall respond in writing specifically to such professional enquiries, except that, general promotional literature about the Product or Designated Product shall not be included, unless it answers directly the questions asked.

Questions as regards the use of products

9.-(1) No person shall advertise or promote any Designated Product in Nigeria.

(2) No manufacturer, distributor or any other person shall provide directly or indirectly to pregnant women, mothers or members of their immediate families or health workers, samples of products which may promote the use of Designated Products.

Prohibition of the advertise-ment or promotion of Designated Products.

10. Manufacturers or distributor of Designated Products shall, subject to the approval of the Agency, disclose to the institution to which a recipient health worker is affiliated, any contribution made to or on his behalf for fellowship, study tour, research grant, attendance at professional conference, or the like and similar disclosure shall be made by the recipient to his employers.

Manufacturers to disclose their contributions.

11.-(1) No manufacturer or distributor shall promote Designated Products within a Health Care Facility or otherwise.

(2) No manufacturer, distributor or retailer of Designated products under these Regulations shall –
(a) use a system of sales incentive for the marketing personnel, which includes the volume of sales of any of the products under these Regulations for the purpose of the calculation of bonuses:
(b) set quotas specifically for the sale of any of the products under these Regulations, and
(c) have special display of any of the products under these Regulations.

Prohibition of promotion by manufacturers and distributors

12. Persons employed in marketing products under these Regulations shall not as part of their responsibilities, perform educational functions in relation to pregnant women, mothers of infants, young children and the general public.

Prohibition of persons employed by manufacturers and distributors

13. The composition of Designated Products shall be in accordance with the existing prescribed standard or where such standard does not exist for the particular product, in accordance with any international standard laid down under the directive of Codex Alimentarius Commission.

Composition of Designated Products

14. No person shall import, distribute, display for sale or sell Designated Products which:
(a) has in it or upon it any substance which may cause injury to the health of the user when the Designated Product is consumed; or

Prohibition of the sale of unwholesome product

(b) consists wholly or in part of any filthy, disgusting, rotten or diseased substance or of any foreign matter; or
(c) is unfit for human consumption; or
(d) is adulterated, fake, expired or substandard; or
(e) revalidates any information originally indicated on its label or container by the manufacturer.

What labels and marks on Designated Products shall include, etc.

15.-(1) In addition to compliance with the Agency Prepackaged Food (Labelling) Regulation 2005, the following shall apply;

(a) labels shall be clear, easily readable, printed or firmly attached to the container of the Designated Products;
(b) the label of the Designated Product shall include:
(i) trade name of the product;
(ii) name and address of the manufacturer;
(iii) net content by 'mass/volume';
(iv) country of manufacturer
(v) batch number;
(vi) instruction for use;
(vii) storage condition;
(viii) date of manufacture;
(ix) "Best before" date;
(x) nutritional information;
(xi) the age after which the product is recommended in numeric figures;
(xii) the words "important notice" or their equivalent which shall be conspicuous;
(xiii) a statement of the superiority of breast-feeding;
(xiv) a statement that the product should be used only on the advice of a health professional as to its use and the proper method of use, provided that such statement shall not appear on feeding bottles, teats pacified complementary food and the like;
(xv) instructions for appropriate preparation and warning against the health hazards of inappropriate preparation, and
(xvi) a statement that Breastmilk is the best food for the child.

(2) The label shall not show any baby, photograph, drawing or other graphic representation to idealise or promote the use of Designated Products.

(3) The use of graphics shall be permitted only for the purpose of illustrating the method of preparation of Designated Products.

Self monitoring by manufacturers and distributors, etc.

16.- (1) Notwithstanding any other measures taken by the Agency with regard to the implementation of these Regulations, manufacturers and distributors of Designated Product shall be responsible for monitoring their practices according to the provisions of these Regulations and for taking steps to ensure that their conduct at every level conforms to these Regulations.

(2) Every manufacturer and distributor of Designated Products shall regularly apprise each member of their marketing personnel of these Regulations and their responsibilities under it.

Offences

17. A person who contravenes a provision 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 N50,000 or imprisonment and; fine and
(b) in the case of a body corporate, to a fine not exceeding N100,000.

Offences by bodies corporate, etc.

18. 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 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 shall be found guilty of that offence and liable to be proceeded against and punished for that offence, in same manner as if he had himself committed the offence, unless it is proved that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Forfeiture after conviction

19.-(1) A person convicted of an offence under these regulations shall forfeit to the Federal Government –
(a) any asset or property constituting, or derived from any proceeds the person obtained directly or indirectly, as a result of the offence; and
(b) any of his property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.

Forfeiture of Designated Products seized

20. Any Designated Product seized by the Agency shall be forfeited to the Federal Government and shall be dealt with in such manner as the Minister may from time-to time determine.

Interpretation

21. In these Regulations, unless the context otherwise requires –

"*advertisement"* includes advertising in a publication, by television, internet, radio, film, video or telephone, traditional communication media, by display or signs, bills boards, notices or goods, by exhibition of pictures or models and in any other manner;

"Agency" means National Agency for Food and Drug Administration and Control **(NAFDAC)**

"complementary food" means any food whether manufactured, or locally prepared, suitable as complement to breast milk or infant formula when either becomes insufficient from six months to satisfy the nutritional requirements of an infant as such food is introduced from six months of life;

"container" includes every form of packaging of Designated Products for distribution or sale as a retail unit including wrappers;

"distributor" means a person, a corporation or any other entity in the public or private sector either distributing or engaged in such business whether wholesale or retail, or marketing any Designated Product and includes any person engaged in the business of providing information, or public relations services in relation to Designated Product:

"*Designated Product" means –*

(a) infant formula; or
(b) follow up formula; or
(c) any product marketed otherwise represented or commonly used for feeding of infant; or
(d) any product to be fed by use of a feeding bottle; or
(e) beverages, milk, cereals, and other foods intended for use by infant and young children whether industrially made or occurring naturally; or
(f) feeding bottles, teats, and pacifiers; or
(g) products stated to promote breast feeding; and
(h) such other products as may be specified by the Agency;

"follow up formula" means a milk or milk-like product of animal or vegetable origin formulated industrially in accordance with the prescribed standard or in the absence of such prescribed standard, in accordance with Codex Alimentarus Standard, and marketed or otherwise represented as suitable for feeding infants and young children older than six months of age;

"health care facility" means government, non government or private institutions or organizations engaged, directly or indirectly in health care for mothers, infants, young children and pregnant women, and nurseries of child-care institutions but not including pharmacies;

"health professional" means any technical personnel involved in matters of human health, nutrition or both;

"health worker" means a person working In a component of such a health care system, whether professional or non professional, including voluntary unpaid workers;

"infant" means a person of not more than twelve months of age:

"infant formula" means a milk-like product of animal or vegetable origin formulated industrially in accordance with the prescribed standard or in the absence of such prescribed standard, in accordance with Codex Alimentarus Standard, to satisfy the normal nutritional requirements of infants up to six months of age, and adapted to their physiological characteristics and infant formula may also be prepared at home, in which case it is described as "home-prepared".

"label" means any tag, mark, pictorial or other descriptive matter written, printed, stenciled, marked, embossed, attached, or otherwise appearing on a container of a Designated Product;

"manufacturer" means a person or corporation or other entity in the public or private sector, engaged in the business of manufacturing of a Designated Product whether directly, through an agent, or a person controlled by or under an agreement;

"marketing" means any method of introducing or selling a Designated Product, including promotion, distribution, advertising, display on shelves, production, distribution of samples, product public relations and product information services;

"Minister" means Minister charged with the responsibility for health;

"prescribed" means as prescribed by the National Agency For Food and Drug Administration and Control;

"proceeds" means any property derived or obtained directly or indirectly through the commission of an offence;

"promote" includes advertising, giving of samples or gifts of Designated Products, or materials or information or decorations related thereto;

"promotion" means any methods of introducing, familiarizing or encouraging a person to purchase a Designated ;Products;

"prohibited promotional practice" includes –

(a) special displays of Designated Products;
(b) discount coupons;
(c) the selling of Designated Products at a reduced price, unless such reduction in price is intended to be permanent;
(d) the distribution of gifts or items of little or no cost, bearing the name or logo of a manufacturer or distributor;
(e) the use of printed matter including books, pamphlets, or posters bearing the name, logo, graphic or other representation of a proprietary product or the name or logo of a manufacturer or distributor;

(f) tie-in-sales, extra weight formula etc; or

(g) in any other manner;

"sample" means a single or small quantity of Designated Products, provided without cost; and

"young children" means persons from the age of more than 12 months up to the age of three years.

22. These Regulations may be cited as Marketing of Infant and Young Children Food and other Designated Products (Registration, Sales, Etc.) Regulations 2005.

Citation

MADE at Abuja this 1st day of January, 2005.

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