GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT NO. 48 OF 2006

The Food and Drug Act
(Laws, Volume 17, Cap. 303)

The Food and Drugs (Marketing of Breast Milk Substitutes) Regulations, 2006

IN EXERCISE of the powers contained in section *twenty-three* of the Food and Drugs Act, the following Regulations are hereby made:

Title

1. These Regulations may be cited as the Food and Drugs (Marketing of Breast Milk Substitutes) Regulations, 2006.

Interpretation

2. In these regulations, unless the context otherwise requires—

" advertise " means to make any representation for the purpose of promoting directly or indirectly the sale or disposal of any breast milk substitute or designated product;

" advertisement " means any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug or device;

" artificial feeding " means feeding an infant on breast milk substitutes;

" breast milk substitute " means any food being marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose and includes infant formula and follow up formula;

" care giver " means a person responsible for the feeding and general well-being of an infant;

" complementary food " means any food, manufactured and suitable as a complement to breast milk or to infant formula, when either becomes insufficient to satisfy the

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nutritional requirements of an infant;

" designated product " includes complementary food, follow-up formula, feeding bottles, teats, pacifiers, cups with spouts and any other item marketed or or represented for use in the feeding of infants, and any other product the Minister may, by statutory instrument prescribe to be a designated product;

" distributor " means a person, corporation or any other entity engaged in the business, whether wholesale or retail, of marketing a designated product;

" exclusive breast-feeding " means giving an infant no food or drink other than breast milk up to six months;

" follow-up formula " means a milk or similar product of an animal or vegetable origin, formulated industrially, and marketed or represented as suitable for feeding infants and young children;

" health care facility " means a public or private institution or organisation engaged directly or indirectly in the provision of health care or health promotion and include a nursery or other infant and child care facility;

" health worker " means a person providing, or in training to provide health services whether professional or non professional, including voluntary worker;

" infant formula " means a milk or similar product of animal or plant origin formulated industrially to satisfy the nutritional requirements of infants up to six months of age;

" label " includes any tag, brand, mark, or other descriptive matter written, printed, stencilled, marked, embossed on or attached to the outside of a package of breast milk substitute or designated product;

" loss leaders " means products that are sold at such low prices compared to similar products that they entice the targeted market;

" manufacturer " means a person, corporation or other entity who, under their own trade name or other name, or under a trade, design or word mark controlled by the manufacturer, manufactures a breast milk substitute or a designated product;

" marketing " means product promotion, distribution, selling, product public relations and information services;

" marketing personnel " means a person who is employed by a manufacturer or a distributor of a designated product and whose duties as such an employee involve the marketing of the designated product; and

" promote " means to employ any method of directly or indirectly encouraging a person to purchase or use a designated product.

Manufacturer or distributor not to advertise breast milk substitute and other designated products

3. A manufacturer or a distributor of breast milk substitute and other designated products shall not—

(a) advertise or promote the breast milk substitutes and other designated products to the public;

(b) provide pregnant women, mothers of infants, their families and care givers with samples of such;

(c) entice sales to consumers and health care facilities in the form of special displays, discount coupons, premiums, rebates, special sales, loss leaders, tie-in sales, prizes and gifts of such products; or

(d) dispense to pregnant women, mother of infants of their families any gifts or articles which may promote the use of breast milk substitutes and other designated products.

Health care facility not to be used for promoting breast milk substitutes and other designated products

4. A Health care facility shall not use its premises for —

(a) the purpose of promoting breast milk substitutes and other designated products;

(b) the display of breast milk substitutes and other designated products;

(c) the distribution of material provided by a manufacturer or a distributor other than that specified in regulation (5);

(d) the distribution of equipment or material within the health care facility that bears the name, logo of the company or trade mark or any designated product; and

(e) the distribution within a health care facility of material including but not limited to note pads, pens, calenders posters, growth charts and toys.

Prohibition for manufacture and distributor and or to their agents

5. A manufacturer and distributor and or their agents shall not—

(a) offer or give any gift, in kind or in cash, to the general public or a health worker for the purpose of promoting a designated product;

(b) pay wholly or in part salary, wages or other income of a person employed in a health care facility if that person's duties bring that person into contact with pregnant women, mothers of infants or their families;

(c) donate or sell at a price lower than eighty percent of the retail price, any quantity of a designated product to a health worker or to a health care facility;

(d) sponsor an event, contest, telephone counselling line or campaign aimed at pregnant women, mothers of infants or their families.

Prohibition for health workers and proprietors

6. A health worker or proprietor shall not—

(a) distribute or display a material within a health care facility if such material refers to or may promote the use of a designated product;

(b) accept any gifts, contributions or benefits, financial or otherwise, of whatever value, from a manufacturer, distributor or any person on their behalf;

(c) accept or give a gift of a designated product to any person; and

(d) accept scholarships.

Power of relevant authority to permit donations

7. (1) Subject to Regulations (5) the relevant authority may, in writing, permit any manufacturer, distributor or health worker to supply any designated product the supply of which would otherwise be prohibited under these Regulations.

(2) The relevant authority shall not grant permission for the supply of any donation of designated product unless it is satisfied that—

(a) the supply of the designated product is necessitated by a medical condition of the infant or mother;

(b) the designated product is to be used on orphaned infants, infants and orphanages, abandoned infants in the event of disasters or other relief operations; or

(c) permission has been granted for the donation of any designated products:

Provided that the supplies shall be as long as the infant needs them that for a minimum period of twelve months.

Manufacturer or distributor not to offer financial gifts

8. A manufacturer or distributor of breast milk substitutes and other designated products shall not offer financial or material gifts to pregnant women, mothers or infants and their families or health care facilities.

Marketing personnel

9. Marketing personnel shall not—

(a) seek or obtain access to any pregnant woman, mother of infants or their families for the purpose of supplying them with or encouraging them to use a designated product;

(b) instruct any pregnant woman, mother of infants or their families in any matter relating to the nutrition or feeding of infants, for the purpose of supplying them with or encouraging them to use breast milk substitutes or any designated product; or

(c) solicit any pregnant woman or mother of an infant or young child to use a designated product.

Examination for screening information and educational material

10. (1) A person who produces or distributes information and educational material in written, audio or visual form on infant and young child nutrition shall ensure that the materials clearly explains the following points:

(a) the importance, benefit and superiority of breast-feeding;

(b) how to prepare for, and initiate and maintain breast feeding and maternal nutrition in general;

(c) how and why artificial feeding interferes with breast feeding;

(d) how and why early introduction of other liquids interferes with breast feeding;

(e) the health hazards of using a bottle to feed an infant or young child;

(f) the health hazards of improper preparation of the product;

(g) how to feed an infant or a young child using a cup without a spout; and

(h) materials that include the following points:

(i) the importance of exclusive breast feeding;

(ii) the importance of introducing complementary foods at six months; and

(iii) that complementary foods can easily be prepared at home using available local ingredients.

Labelling of designated product

11. No manufacturer or distributor shall offer for sale a designated product if the container or label affixed to it—

(a) includes a photograph, drawing or other graphic representation other than for illustrating the method of preparation;

(b) does not indicate in a clear and easily legible manner in English or any other additional language the following—

(i) introductions for the appropriate preparation and use in words and easily understanding graphics;

(ii) the age of the infant or young child for which the product is recommended in numeric figures;

(iii) the ingredients used, specifying the origin of any milk;

(iv) the composition and nutritional analysis;

(v) the required storage conditions; and

(vi) any other particulars the Minister may prescribe.

Labelling of infant formula and other breast milk substance

12. (1) The label on a container of infant formula and other breast milk substitute shall bear the following information—

(a) " importance notice: " " breast milk is the best food for your baby " and the notice shall be in bold capital letters of not less than one third the size of characters in the products's name and in no case less than 2 millilitres in height;

(b) the word " warning " followed by the words " follow the cleaning and sterlisation instructions carefully " and the label shall contain the warning in bold capital letters of not less than one third the size of characters in the product's name and in no case less than 1.5 millilitres in height;

(c) a statement that the product shall be used only on the advice of a health worker as to the need for its use and the proper method of use;

(d) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation;

(e) shall indicate the age at which the product is recommended, subject to rules that shall be prescribed from time to time;

(f) shall be written in the English language in addition to another language which may be used on the label;

(g) shall indicate the ingredients, specifying the origins of any milk product, the composition and analysis of the products, the required storage conditions, the batch number, the date of manufacture and the expiry date.

(2) No label on a container of an infant formula or a breast milk substitute shall contain pictures of an infant which are intended to promote the use of such infant formula or breast milk substitute:

Provided that graphics for easy identification of the product as an infant formula or a breast milk substitute and for illustrating methods of preparation may be placed on the container, with inserts giving additional information on the product and its proper use.

(3) The label of whole milk shall contain the words in bold capital letters " this product is not suitable for infants below the age of six months ";

(4) The label on a sweetened, condensed or skimmed milk, low fat milk, evaporated milk or filled milk shall contain a notice with the words in bold capital letters " this product is not suitable for infants below six moths of age ".

Breast milk substitute to be of recognised standard

13. (1) The quality of the breast milk substitutes to which these Regulations apply shall conform to the standards set by—

(a) the Food and Drugs Act;

(b) the Standards Act;

(c) the Codex Alimentarius Commission; and

(d) the Codex Code of Hygienic Practice for Foods for Infants and Children.

S. T. MASEBO,
Minister of Health

LUSAKA
21st April, 2006