

**Execution law No. (25) for the year 2007**

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There shall be no imprisonment for pregnant women until three months after delivery and the mother of an infant until the infant reaches two years of age

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Instructions, bases, and standards for approval or cancelation of the distribution of Infant formula, special formula and Complementary food No.3614/2003  
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*Article 1.*

***Definitions, the following words will have the following definition unless otherwise proved not***

The establishment: the general establishment for food and drug

The manager: the manager of the general establishment for food and drug

The committee: the committee formed in accordance to the temporary pharmacy law No.80 for the year 2001, for infant formula, Infant formula for babies With special needs, and Complementary food

Infant milk: any food presented as replacement for breast milk, as part of wean nutrition or when necessary to satisfy the normal nutritional requirements of the infant up to one year of age manufactured from cow or other animal milk and /or plant or/and animal ingredients suitable for baby and infant nutrition and only treated physically for preservation and contaminants under all normal conditions for handling, storage and distribution

Infant formula for babies with special needs: Product formulated industrially to satisfy special nutritional needs of infants that suffer from disorder and diseases, and the treatment thereof

Complementary food: Any food suitable as a complement to breast milk or to infant formula, when either become insufficient to satisfy the nutritional requirements of the infant

Circulation: production, manufacturing, preparation, treatment, packing or wrapping food and its transportation, offering, sales, or donation

The factory: infant milk, special formula, and infant food factory: the corporation which prepare, formulate, and manufacture raw material, or finished product on industrial scale for whole sale

### *Article 2*

It is prohibited to circulate infant milk, special formula or/and their complementary food unless approved by the establishment. Any quantities that is imported, locally manufactured, or cleared from customs without prior approval from concerned committee will be confiscated

### *Article 3*

#### *The committee's tasks*

1/3 the approval of the infant milk, special formula or/and their complementary food and refer it to the pricing committee

2/3 the study of any objections to circulate these products and submit it to the general manager

3/3 to determine the way of dispensing these products

4/3 submit to the general manager for dissension, their recommendations to bane the importation of any of these products or its circulation or suspending or cancelation of approval of circulation

5/3 to evaluate manufacturing facilities for these products whither locally or outside Jordan. and the evaluation of factories which produce the finished product ( which will be Packed locally) or semi finished product ( which will be finished and packed locally) before the approval of the manufacturer and submit its recommendations to the manufacturing sites approval committee to take the appropriate decision

### *Article 4*

Any of the products in article 2 or its row material should not be cleared from customs or issued an importation license before the approval of the general manger or his nominee

### *Article 5*

No approval could be given to these products unless it is manufactured by authorized company

### *Article 6*

Importation of these products is only allowed from manufacturing or distribution sites that are approved by the establishment. In exceptional cases the general manager can approve the importation of these produces from manufacturing or distribution sites that are not approved by the establishment upon the reasoned recommendation of the committee.

### *Article 7*

The dealer or local manufacturer can grant the right of distribution of these products to licensed companies . The dealer or local manufacturer will take the responsibility for these products therefore , inform the establishment of the distribution contracts ant the items included in the such contracts

### *Article 8*

Consignments which are donations to societies , charity organization, or public organizations should be approved by the general manger , and they should have a permanent seal with the name of the recipient indicating that it is donation

#### *Article 9*

Applications for registration can only be submitted by the technical specialist of the manufacturer or by the importing agent who should be (pharmacist , agricultural engineer, dietitian, veterinary doctor , or nutrition specialist with university degree)

#### *Article 10*

The importing agent of infant milk, special formula or/and their complementary food manufacturer, should submit a written application to registrar the manufacturer, the application should be accompanied with

- 1/10 the required information form from manufacturer of infant milk, special formula or/and their complementary food , filled by the manufacture and sealed by the official authorities
- 2/10 the required information form for the evaluation of the manufacturing site filled and signed by authorized company official and sealed with the company seal
- 3/10 original certified manufacturing license for the manufacturing site
- 4/10 original certified valid certificate indicating that the company adapt the minimum requirements of the recommended international code of hygienic practice for food for infants and children
- 5/10 commercial agency registration certificate from the appropriate Jordanian authorities and letter of appointment from the producing company

#### *Article 11*

After the committee study the requirement in article 10 it can recommend using a special form to be prepared for that purpose that the manufacturing site could be evaluated by special committee formed of three members (An inspector and two other members that the committee believe that they have the need qualifications) after which it could be determined whether or not the manufacturing site would be approved

#### *Article 12*

The importers and agents should submit a written application to register the infant milk, special formula or/and their complementary food, the application should be accompanied with

- 1/12 application form to register the ingredients of infant milk, special formula or/and their complementary food, filled by the manufacturer and every paper signed by authorized company official and sealed with the company seal
- 2/12 certificate issued by the official authorities in the country of origin and authenticated by the Jordanian embassy or any other Arab embassy where there is no Jordanian embassy to show that the product required to be registered with the same ingredients can be freely sold in the country of origin. In case that the said certificate could not be obtained with the sentence “**can be freely sold**”, the following should be obtained
  - 1/2/12. a certificate issued by the official authorities to show the ingredients of the product that is sold in the country of origin and its empirical analyses
  - 2/2/12. an explanation from the manufacture as for why the ingredients that are sold in the country of origin cannot be sold in Jordan
  - 3/2/12. a list of all countries where the product is sold with the same ingredient to be sold in Jordan and its retail price
  - 3/12. date and number of registration of the product in the country of origin
  - 4/12. composition and complete empirical analyses

- 5/12. authenticated certificate of analysis to show the compliance of the ingredients( qualitative and quantitative ) of the product to be sold in Jordan with the label of the product
- 6/12.Export price list of the manufacturer
- 7/12 .Retail price list at the country of origin
- 8/12. The final specification of the product from the manufacturer
- 9/12. All the investigations that was carried on the product including the method of its analysis
- 10/12. 10 copies of the outer cover
- 11/12. an original package

#### *Article 13*

It is required to obtain the necessary license from the appropriate concerned authorities when constructing a factory for infant milk, special formula or/and their complementary food infant

#### *Article 14*

Local manufactures should submit original written request with the following attachments

- 1/14. the required information form from manufacturer of infant milk, special formula or/and their complementary food , filled by the manufacture signed by company official and sealed by the company seal
- 2/14. the required information form for the evaluation of the manufacturing site filled and signed by authorized company official and sealed with the company seal

#### *Article 15*

15-a. After the committee study the application , the manufacturing site is inspected by special committee ( with at least two members of the committee) to insure that it is in compliance with sanitary conditions to license food factories and the requirements of the recommended international code of hygienic practice for food for infants and children and the general rules of health aspects issued by the organization of standard specifications, as minimum requirement after which it could be determined whether or not the manufacturing site would be approved

15-b. in case of denial of approval of the company or licensing its product the reasons for the denial should be provided and the applicant has the right to contest the denial within maximum two months of being informed of the denial, after witch the committee's decision is final

#### *Article 16*

Factories which produce products by packing from finished product raw material or semi finished product raw material should comply with all the requirement of article 12

#### *Article 17*

in case of complete manufacturing locally the product should be registered as in articles 1/12,4/12,5/12,6/12,7/12,8/12,9/12,10/12,11/12

#### *Article 18*

Local factories should employ specialized general technical manager to supervise its different departments

*Article 19*

Agents and local manufacturers should take the necessary action to change the price tag with the change of price

*Article 20*

No changes in registered product name, or any changes, alteration, addition to the ingredients, label, packing, or name to be made without the prior approval of the committee, and in case of denial the product should be re-registered as if it was new product.

*Article 21*

When any improvement is made by the manufacture of infant milk, special formula or/and their complementary food the old registration will be void and its importation will be banned

*Article 22*

The committee has the right to take samples of the product for analysis after it has been circulated

*Article 23*

The size of free sample should be equivalent to the original package and it should be permanently marked free sample not for sale and its distribution should be limited to doctors, hospitals and charity organizations with a special form

*Article 24*

The agent should abide by the rules and regulations set by establishment for the transportation and storage of food materials

*Article 25*

The registration of infant milk, special formula or/and their complementary food will be void by the committee if it is found that its registration was based on false information

## **Instructions issued by the ministry of health in 1996 that regulate marketing practices for mother milk substitutes and related practices**

Instructions that have been generalized by the ministry of health technical committee for drug control On 16/10/1966 which applies to marketing practices for of the following products:

mother milk substitutes that include infant formula, follow-on formula and other liquids that are administered by the feeding bottles when it is marketed and presented with or without alteration as a partial or total replacement for breast milk. In addition to feeding bottles and Pacifier

1-Donations of informational or educational equipment or materials should be made only with approval of the ministry of health. Such equipment or materials may bear the donating company's name or logo, but should not refer to trade name of the product.

2-There should be no advertising or other form of promotion to the general public of products within the scope of this instructions.

3-Samples of products directly or indirectly within the scope of this instructions, should not be provided to pregnant women, mothers of infants and young children, or members of their families. and should not be distributed to clinics, and departments of pediatrics and maternity hospitals in the Kingdom, in addition to motherhood and childhood centers also to health workers or members of their families.

4- Pediatricians in children hospitals and pediatric departments in the hospital can request limited quantities of sample for official use under their supervision and only within the hospital, using the special form prepared for that purpose . The size of free sample should be equivalent to the original package and it should be permanently marked by the manufacture **free sample not for sale** .

5-No financial or material inducements to promote the use of Breast-milk substitute or feeding bottles

6- Neither the container nor the label should have pictures of infants, nor should they have other pictures or text which may idealize the use of the products within the scope of this instructions, but rather it should have statement of the superiority of breastfeeding; and that the product should be used only on the advice of a health worker

7- Marketing personnel, in their business capacity, should not seek direct or indirect contact of any kind with pregnant women or with mothers of infants and young children

8- No financial or material inducements to promote products within the scope of this instructions should be offered by manufacturers or distributors to health workers or members of their families.

9-Information provided by manufacturers and distributors to health professionals regarding the products within the scope of this instructions should be restricted to scientific and factual matters,

10- With the written approval of the ministry of health, donations or low-price sales of products within the scope of this instruction to institutions or organizations is permitted whether for use in the institutions or for distribution outside them, may be made. Such supplies should only be used or distributed for infants who have to be fed on breast-milk substitutes. Such donations or low-price sales should not be used by manufacturers or distributors as a sales inducement.

11- Manufacturers and distributors of products within the scope of this instructions should consider themselves responsible to monitor their marketing practice to conform with the goals of these instructions and make this known to all their marketing personnel for implementation and responsibilities that arise from that.