Public manual: Application for permission of a product and correction of permitted items: for Modified Milk for Infant, Modified Milk of follow up Formula for Infant and Young Children, Infant Food and Food of Follow up Formula for Infant and Young Children.

Service agency: Food and Drug Administration, Ministry of Public Health.

Criteria, Procedure, Conditions (if any) for application and consideration of permission

Criteria

1. Products shall be categorized as Modified Milk for Infant, Modified Milk of follow up Formula for Infant and Young Children, Infant Food and Food of Follow up Formula for Infant and Young Children according to Notification of Ministry of Public Health regarding Modified Milk for Infant, Modified Milk of follow up Formula for Infant and Young Children, Infant Food and Food of Follow up Formula for Infant and Young Children (see additional details in criteria and guideline for permission for Modified Milk for Infant, Modified Milk of follow up Formula for Infant and Young Children, Infant Food and Food of Follow up Formula for Infant and Young Children, page 1 - 3 and 8 - 9).

2. Modified milk for infant and modified milk of follow up formula for infant and young children means food manufactured by modification of cow’s milk composition to contain sufficient and suitable nutrients to feed infants and young children which can be classified as follows:

2.1 Modified milk for infant means modified milk which its intended use to feed newborn baby to 12 months old to replace or substitute breast milk;

2.2 Modified milk of follow up formula for infant and young children means modified milk which its intended use to feed infant at age from 6 to 12 months or young children at age 1 to 3 years.

3. Infant food and food of follow up formula for infant and young children means food other than modified milk for infant and modified milk of follow up formula for infant and young children manufactured to contain optimum and sufficient nutrients for feeding of infants and young children which can be classified as follows:

3.1 Infant food means food intended use to feed infant from new born to 12 months to replace or substitute breast milk;

3.2 Food of follow up formula for infant and young children means food intended use to feed infant from age of 6 months to 12 months or young children from age of 1 year up to 3 years.

4. Applying product;

4.1 Production or import premise of the applying product shall previously have permission and its license still valid. If it is a food production premise, it shall also be complied with Good Manufacturing Practice according to relevant Notification of Ministry of Public Health.
4.2 If the product is in scope of food intended for special purpose such as product intended to feed infant or young children that have abnormal digestive system or allergy to some nutrients, etc., an additional detail in Public manual regarding application for permission and correction of items of food intended for special purpose shall also be studied.

4.3 Shall not be in scope of novel food and food contained novel ingredients, study additional details in public manual regarding application for safety assessment of food.

4.4 Shall have qualities or standards of products complied with Notification of Ministry of Public Health regarding Modified Milk for Infant, Modified Milk of follow up Formula for Infant and Young Children, Infant Food and Food of Follow up Formula for Infant and Young Children and other related Notifications of Ministry of Public Health (study additional details in criteria and guideline for permission of modified milk for infant, modified milk of follow up formula for infant and young children, infant food and food of follow up formula for infant and young children, page 9 – 10 and 20 - 23).

4.5 If use of food additives, it shall be complied with Notification of Ministry of Public Health regarding Modified milk for infant, Modified Milk of follow up Formula for Infant and Young children, Infant Food and food of follow up formula for Infants and Young Children and Food additives.

4.6 Shall not use of prohibited substances to use in food and/or food prohibited to produce, import or sell according to relevant Notifications of Ministry of Public Health.

4.7 Shall have details of food recipe complied with Notification of Ministry of Public Health regarding Modified milk for infant, Modified Milk of follow up Formula for Infant and Young children, Infant Food and food of follow up formula for Infants and Young Children (study additional details in criteria and guideline for permission of Modified milk for infant, Modified Milk of follow up Formula for Infant and Young children, Infant Food and food of follow up formula for Infants and Young Children, page 7 - 8).

5. Food products contained health claim shall be assessed according to public manual regarding application for health claim assessment.

6. Use of food containers shall follow Notification of Ministry of Public Health regarding Containers and use of plastic containers and colored plastic covers contacted with liquid or semi-solid food shall have analysis report of plastic containers and colored plastic covers according to Notification of Ministry of Public Health regarding Plastic containers (study additional details in criteria and guideline for permission of Modified milk for infant, Modified Milk of follow up Formula for Infant and Young children, Infant Food and food of follow up formula for Infants and Young Children, page 6 - 7).
7. Entitling of food name or brands or trademarks, or registered trademarks shall follow Notification of Ministry of Public Health regarding Modified milk for infant, Modified Milk of follow up Formula for Infant and Young children, Infant Food and food of follow up formula for Infants and Young Children, Labeling of prepackaged food, and Criteria on marketing of food for infant and young children and relevant products B.E.2551 (2008) (study additional details in criteria and guideline for permission of Modified milk for infant, Modified Milk of follow up Formula for Infant and Young children, Infant Food and food of follow up formula for Infants and Young Children, page 4 - 6).

8. Food labeling shall follow Notification of Ministry of Public Health regarding Modified milk for infant, Modified Milk of follow up Formula for Infant and Young children, Infant Food and food of follow up formula for Infants and Young Children, Labeling of prepackaged food, and Criteria on Marketing of Food for Infant and Young Children and relevant products B.E.2551 (2008) (study additional details in criteria and guideline for permission of Modified milk for infant, Modified Milk of follow up Formula for Infant and Young children, Infant Food and food of follow up formula for Infants and Young Children, page 11 - 18).

9. In case of complicated product or overlapping with many regulations, it shall be considered by working group/committee/or experts. Therefore, its duration will be increased from the specified duration in this manual about 15 to 45 working days as the case maybe.

Procedure

For application for permission and correction items of permitted products, applicant shall prepare documents and evidence together with fill complete and accurate data in a specified form as follows:

1. Application for product permission
   1.1 In case of import or production premise has already been permitted, 1 copy of application form for food recipe registration (Orr. 17 Form) shall be submitted together with supplementary evidence and documents for permission application.
   1.2 In case of production premise not fall in a scope of factory received a number of food production premise, 2 copies of application form for use of food label (SorBor. 3 Form and typed only) shall be submitted together with supplementary evidence and documents for application.

2. Correction of permitted items of products
   2.1 In case of import or production premise has been received a document for food recipe registration of products, an applicant shall apply 1 copy for correction of registered food recipe items Form (Orr. 19 Form) with supplementary document and evidence for permission application.
2.2 In case of production premise not fall in a scope of permitted factory for use of food label of product, an applicant shall apply 2 copies of Form for correction details of permitted food to use food label (SorBor. 4 Form and typed only) with supplementary document and evidence for permission application.

2.3 In case of correction for permitted items of product not relevant to beneficial characteristic, qualities, properties, standards or safety of food according to list 4 No.7 annex to Food and Drug Administration Regulation on operation relevant to Food Serial Number B.E.2557 (2014).

2.3.1 Case of product has been received a document for food recipe registration (Orr. 18 Form), an applicant shall apply for 2 copies of correction registered items of food recipe Form (Orr. 19 Form and typed only) by specifying only part intended to correct with supplementary document and evidence for permission application.

2.3.2 Case of product has been permitted to use food label (SorBor. 3 Form), an applicant shall apply for 2 copies of correction details of food permitted to use label Form (Sor Bor. 4 Form and typed only) by specifying only part intended to correct with copy of SorBor. 3 Form and/or SorBor. 4 Form as permitted.

2.4 Addition of label for export.

2.4.1 Case of product has been received a document for food recipe registration (Orr. 18 Form), an applicant shall apply for 2 copies of declaration letter for addition of food label produced for export to outside of the Kingdom (typed only) with supplementary document and evidence for permission application.

2.4.2 Case of product has been received permission to use food label (SorBor. 3 Form), an applicant shall apply for 2 copies of correction of details of food permitted to use food label form (SorBor. 4 Form and typed only) with supplementary document and evidence for permission application.

3. Signing in application forms.

3.1 Person who has authorization to sign in application forms includes a business operator as receiving permission in Forms of SorBor. 1/Orr. 2/ Orr. 7 or;

3.2 A director who has authorization to oblige legal entity as in legal registration document (a copy of legal entity registration document done by the Ministry of Commerce no longer than 6 months till the date of application for permission the document shall be enclosed).

4. Supplementary document and evidence for permission application as procedure no.1 and no.2 shall also be submitted as specified in this public manual.

Conditions

1. Products shall be complied with above criteria.
2. An applicant shall be an owner of business or authorized person with knowledge on legislation, Notification of Ministry of Public Health, and other relevant regulations and ready to provide details of applied products and have authorization to sign for defectives acceptance. If he/she is not the business operator or authorized director of legal entity, letter of authorization to be authorized person shall be issued.

3. An applicant of modified milk for infant, modified milk of follow up formula for infant and young children, infant food and food of follow up formula for infants and young children shall submit an application for permission and correction of permitted item at One Stop Service Center (OSSC), Food and Drug Administration only.

4. Document shall be signed by business operator as permitted in Form of SorBor.1/ Orr. 2 /Orr. 7, or director authorized to oblige legal entity such as:
   - Application form for food recipe registration (Orr. 17 Form), Application Form for Permission for use of food label (SorBor. 3 Form).
   - Application Form for Correction of items in food recipe registration (Orr. 19 Form), Form of correction details of permitted food to use food label (SorBor. 4 Form)
   - A copy of letter notifying recipe and production method from foreign producer, in case of import.
   - Letter of certifying food name or brand/trade mark complied with Notification of Ministry of Public Health regarding Labeling of Prepackaged Food.
   - Letter of requesting and allowance to use common documents.
   - Letter of certifying labeling for export to be complied with legislation in an ordering country, etc.

   If a person who signed is authorized director to oblige a legal entity, a copy of legal entity registration no longer than 6 months shall also be enclosed.

5. An applicant shall assess his/ her product by ownself as specified and also arrange all supplementary documents, evidence and check against checking document and defect record with completeness and accuracy.

6. In case details of product are not clear or complied with data specified in application form or evidence documents, sample of the products, documents presenting unclear details or non-compliance of the products shall be also submitted for consideration.