

File No. Stds/IEM (Pristine)/FSSAI-2017  
**Food Safety and Standards Authority of India**  
(Regulatory Compliance Division)  
FDA Bhawan, Kotla Road, New Delhi – 110002

Dated: 21<sup>st</sup> November, 2017

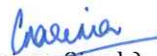
**Sub: Issuance of License to specialty foods for IEM disorders under FSS Act, 2006 - reg.**

This is with reference to the direction issued under Section 16 (5) of Food Safety and Standards Act, 2006 dated 2<sup>nd</sup> November, 2016 regarding import of specialty foods for Inborn Errors of Metabolism (IEM) disorders under FSS Act, 2006, Rules and Regulations made thereunder (copy enclosed). In this regard, this is to inform that the products (food for special medical purpose) with labels listed at Sr. No. 1 to 27 in the Annexure are permitted for licensing under FSS Act, 2006. Whereas, the product mentioned at Sr. No. 28 in the Annexure i.e. "Balance metanutrition LPS (for infants & children)" is not approved and cannot be considered for licensing under FSS Act, 2006.

2. Further, it is also requested to ensure that the license for manufacturing/sale of aforementioned approved products shall be granted for the period of two years from the date of direction issued vide letter dated 02.11.2016 or till the standards for the same are developed and notified, whichever is earlier.

3. This issues with the approval of the Competent Authority.

Yours faithfully,

  
(Garima Singh)  
Director (RCD)

To:

1. Commissioner of Food Safety of all States/UTs.
2. All Central Licensing Authorities, FSSAI
3. CITO-w.r.t. upload on FSSAI website

Copy to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI

F. No. Stds/Nutra-IEM/FSSAI-2016 (Pt. F1)  
**Food Safety and Standards Authority of India**  
(A Statutory Authority under the Ministry of Health and Family Welfare, Govt. of India)  
FDA Bhawan, Kotla Road, New Delhi-110 002

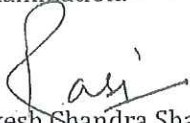
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Dated, the <sup>02</sup> ~~October~~ <sup>Nov.</sup>, 2016

**Subject: Direction under Section 16(5) of Food Safety and Standards Act, 2006 regarding import of specialty foods for IEM disorders - reg.**

1. Inborn Errors of Metabolism (IEM) and Hypoallergenic conditions are special medical conditions which requires specialty foods. Such specialty foods are not readily available in the country. The hospitals need these specialty foods for the management of infants and children suffering from such conditions.
2. These specialty foods are globally available. However, in the absence of Standards for such foods, it is difficult to import them into India. FSSAI has been receiving representations from various organizations for allowing these foods in the country.
3. And whereas, taking these issues into consideration, the Scientific Panel of FSSAI on "Functional Foods, Nutraceuticals, Dietetic Products and Other Similar Products" has initiated work on for setting the Standards for these products. However, it is likely to take long time to finalize these Standards in view of the complexity of this subject. Taking note of the seriousness of the issue, the Scientific Panel has, therefore, recommended that import of these products may be permitted by FSSAI for two years or till their Standards are developed and notified, whichever is earlier. The Panel, after careful consideration, recommended for allowing the import of foods for fifteen "Inborn Errors of Metabolism" and two Hypoallergenic conditions as per the Annexure.
4. It has been decided to allow the import of foods for special medical purposes, as listed in the Annexure to this Order, for a period of two years or till their Standards are developed and notified, whichever is earlier, under the following conditions:
  - a. The importing firm would submit to FSSAI well in advance, all the necessary documents related to the composition, label and claims for the product they intend to import. FSSAI after due examination, would allow the import of such foods on a case to case basis for a period of two years from the date of this Order or till their Standards are developed and notified, whichever is earlier. Once a particular composition, label & claims is permitted by FSSAI for import, future consignments strictly adhering to the requirements can be imported on the basis of this one time permission.
  - b. The labels on these foods shall clearly mention the medical conditions for which they have to be used.
  - c. The importer/manufacturer of such foods shall ensure that they are consumed only under supervision of health care professionals.

5. The above conditions shall also apply to domestically produced specialty food products for which FSSAI shall grant permission after due examination.

  
Rakesh Chandra Sharma  
Director (Imports)

Enclosure: as above

To

1. Sh. Zubair Riaz, Director (Customs), Ministry of Finance
2. All Commissioners of Food Safety
3. All Authorized Officers, FSSAI
4. All Central Licensing Authorities of FSSAI

Copy for information to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI
3. All Directors, FSSAI.

## ANNEXURE

Inborn Errors of Metabolism (IEM) and Hypoallergenic conditions

S. No	Medical condition	Description
<b>A. IEM Conditions</b>		
1.	Maple syrup urine disease	Isoleucine, Leucine and Valine free diet powder
2.	Glutaric Acidemia Type I	Lysine and Tryptophan free diet powder
3.	Homocystinuria	Methionine free diet powder
4.	Isovaleric Acidemia, 3-Methylcrotonyl-CoA, Carboxylase Deficiency, 3-Methylglutaconyl-CoA, Hydratase Deficiency	Leucine free diet powder
5.	Methylmalonic Acidemias, Propionic Acidemia	Isoleucine, Methionine, Threonine and Valine free diet powder
6.	Amino acid metabolic disorders	Protein and amino acid free diet powder (with and without fat)
7.	Phenylketonuria (PKU)	Phenylalanine free diet powder
8.	Urea Cycle Disorders, Argininemia, Argininosuccinic Aciduria, Carbamoylphosphate Synthetase Deficiency1, Citrullinemia	Non-essential amino acid free diet powder
9.	Tyrosinemia	Phenylalanine and Tyrosine free diet powder
10.	Galactosemia	Galactose free formula
11.	3-Hydroxy Long Chain Acyl-CoA Dehydrogenase Deficiency	LCHAD Deficiency
12.	Defects in the intraluminal hydrolysis of fat; defective mucosal fat absorption; defective lymphatic transport of fat	Milk protein-based powder with medium-chain triglycerides (MCT) for children and adults
13.	Disaccharidase deficiencies; Disorders of carbohydrate metabolism Sucrase/ isomaltase deficiency, Fructose intolerance	Protein hydrolysate formula base powder with iron for use with added carbohydrate.

14.	Non-ketotic Hyperglycinemia, Lysinuric protein intolerance	Protein free formula
15.	Glucose transport defect(Glut1 def), Pyruvate dehydrogenase complex deficiency	Low carbohydrate, sucrose, fructose , sugar free formula
<b>B. Hypoallergenic Conditions</b>		
1	Severe allergy due to multiple food protein intolerance that cannot be effectively managed by extensively hydrolyzed formula	Amino acid based Hypoallergenic formula
2	Severe allergy due to intact milk protein & soya protein	For Cow's milk allergy Hypoallergenic Formula

M/s. Pristine Organics Pvt. Ltd.		
A. The products approved/agreed for licensing		
S. No.	Product	Medical Condition
1.	Balance metanutrition PKU 1 (for infants & children)	Phenylketonuria
2.	Balance metanutrition PKU 2 (for children & adults)	Phenylketonuria
3.	Balance metanutrition PKU 3 (for children & adults)	Phenylketonuria
4.	Balance metanutrition MSUD 1 (for infants & children)	Maple Syrup urine disease
5..	Balance metanutrition MSUD 2 (for children & adults)	Maple Syrup urine disease
6.	Balance metanutrition HCY 1 (for infants & children)	Homocystinuria
7.	Balance metanutrition HCY 2 (for children & adults)	Homocystinuria
8.	Balance metanutrition IVA 1 (for infants & children)	Isovaleric Acidemia
9.	Balance metanutrition IVA 2 (for children & adults)	Isovaleric Acidemia
10.	Balance metanutrition MMA/PA 1 (for infants & children)	Methylmalonic Acidemias/ Propionic Acidemia
11.	Balance metanutrition MMA/PA 2 (for children & adults)	Methylmalonic Acidemias/ Propionic Acidemia
12.	Balance metanutrition UCD 1 (for infants & children)	Urea Cycle Disorders
13.	Balance metanutrition UCD 2 (for children & adults)	Urea Cycle Disorders
14.	Balance metanutrition TYROS 1 (for infants & children)	Tyrosinemia
15.	Balance metanutrition TYROS 2 (for children & adults)	Tyrosinemia
16.	Balance metanutrition GA 1 (for infants & children)	Glutaric Acidemia Type I
17.	Balance metanutrition GA 2 (for children & adults)	Glutaric Acidemia Type I
18.	Balance metanutrition AAMD 1 (for infants & children)	Amino acid metabolic disorders
19.	Balance metanutrition AAMD 2 (for children & adults)	Amino acid metabolic disorders
20.	Balance metanutrition GLC (for infants & children)	Galactosemia
21.	Balance metanutrition LCHAD (for infants & children)	LCHAD Deficiency
22.	Balance metanutrition LD (for infants & children)	Defects in the intraluminal hydrolysis of fat, defective mucosal fat absorption, defective lymphatic transport of fat
23.	Balance metanutrition CMD (for infants & children)	Disorders of carbohydrate metabolism
24.	Balance metanutrition HLP (for infants & children)	Non-ketotic Hyperglycinemia
25.	Balance metanutrition GTD (for infants & children)	Glucose transport defect
26.	Balance metanutrition MFPI (for infants & children)	Amino acid based hypoallergenic formula
27.	Balance metanutrition SA MP/SP (for infants & children)	Severe allergy due to intact milk protein and soya protein
B. The products not approved/agreed for licensing		
28.	Balance metanutrition LPS (for infants & children)	Low protein supplement, amino acid free