

F. No. Stds/SP-05/Orders/FSSAI (E1317)
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety & Standards Act, 2006)
FDA Bhawan, Kotla Road, New Delhi-110 002

Dated 10th February, 2022

ORDER

Sub. : Standards of *Foods for Infants with Inborn Errors of Metabolism (IEM)* specified under Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020.

Reference is drawn to the Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020 published in Gazette of India on 4th December, 2020, having standards for foods for infants including IEM and the date of compliance of these regulations was extended up to 01st April, 2022. In this regard, a direction dated 30.06.2021 was issued to allow the import of food products for IEM conditions till 31.03.2022.

2. Whereas the regulation 16(1) (e) of the above mentioned Regulations provides that “*the Food Authority shall specify the IEM conditions as approved by it after undertaking proper scientific evaluation. No Food Business Operator (FBO) shall manufacture, sell, market, or import products for IEM conditions except those specified by the Food Authority from time to time.*”
3. In exercise of the power mentioned in the regulation 16(1) (e) as above, the Food Authority has approved the list of IEM conditions as per **Annexure I**. The list will come into effect from 01st April, 2022. Till such time, the direction issued on 30.06.2021 will continue to be in force.
4. This issues with the approval of the Competent Authority.



Bhaskar N
Advisor (Science and Standards)
FSSAI, New Delhi

To

1. ED (CS) with a request to communicate to Food Safety Commissioners of all States/UTs
2. Advisor (QA)
3. Head (RCD) / Head (Regulations) / Head (Legal)
4. Director (TICD) – with a request to communicate to all Authorized Officers
5. All Regional Directors, FSSAI
6. All Central Licensing Authorities, FSSAI
7. CITO, FSSAI – with a request to upload this direction on FSSAI website

Copy to:

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

ANNEXURE-I

Inborn Errors of Metabolism (IEM) Conditions		
S. No	Medical condition	Description
1	Amino acid metabolic disorders	Protein and amino acid free diet powder (with and without fat)
2	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
3	Disaccharidase deficiencies; Disorders of carbohydrate metabolism Sucrase/ isomaltase deficiency, Fructose intolerance	Protein hydrolysate formula base powder with iron for use with added carbohydrate.
4	Galactosemia	Galactose free formula
5	Glucose transport defect (Glut1 def), Pyruvate dehydrogenase complex deficiency	Low carbohydrate, sucrose, fructose, sugar free formula
6	Glutaric Acidemia Type I	Lysine free and Tryptophan low/free diet powder
7	Homocystinuria	Methionine free diet powder
8	3-Hydroxy Long Chain Acyl-CoA Dehydrogenase Deficiency	LCHAD Deficiency
9	Isovaleric Acidemia, 3-Methylcrotonyl-CoA, Carboxylase Deficiency, 3-Methylglutaconyl-CoA, Hydratase Deficiency	Leucine free diet powder
10	Maple syrup urine disease	Isoleucine, Leucine and Valine free diet powder
11	Methylmalonic Acidemias, Propionic Acidemia	Isoleucine, Methionine, Threonine and Valine free diet powder
12	Non-ketotic Hyperglycinemia, Lysinuric protein intolerance	Protein free formula
13	Phenylketonuria (PKU)	Phenylalanine free diet powder
14	Tyrosinemia	Phenylalanine and Tyrosine free diet powder
15	Urea Cycle Disorders, Argininemia, Argininosuccinic Aciduria, Carbamoylphosphate Synthetase Deficiency1, Citrullinemia	Non-essential amino acid free diet powder

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