

Guidance Note on Food for Special Medical Purpose (FSMP)

The Authority has observed that a large number of applications are being received for approval under the Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017 (herein after referred as NSF Regulations) which are categorised or fall under FSMP under the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 (herein after referred as Nutraceutical Regulations). Most of the FSMP formulations are made up of one or more purified and well characterized ingredient(s) from a botanical source, or a synthetic molecule having pharmacological activity, and are often formulated in tablets, capsules or liquids formats. Unlike drug which is used to prevent or treat disease, FSMP is a special dietary formulation intended for supporting nutritional needs of person with diseases or disorders through a food route. However, due to technological limitations of size/volume of the formats (tablets, capsules), these products do not always meet the requirements of being nutritionally complete or even nutritionally incomplete category of FSMP.

2. To provide further clarity of on the FSMP products the following guidelines have been laid out:

- i. FSMP is a food formulation intended to provide nutritional support to persons who suffer from a specific disease, disorder or a medical condition, as a part of their dietary management.
- ii. These products are to be used under the directions of a medical practitioner, with proper indication of the disease, disorder or medical condition.
- iii. These product(s) should be administered orally or using enteral route (nasogastric tube feeding). It is a common practice to have these products in food formats including powder or liquid.
- iv. FSMP products should be either nutritionally complete food with a standard nutrient formulation, or nutritionally complete food with a nutrient adopted formulation, or nutritionally incomplete food with a standard formulation or a nutrient adopted formulation. Thus, the FBO applying under NSF Regulations should clearly specify the FSMP category the product falls into and the disease, disorder or medical condition for which it is intended along with the scientific and technical justification. The FSMP formulation shall also fulfil partial or complete nutritional requirement of the intended individual.
- v. The FBOs formulating the FSMP should preferably provide the product in a food format to deliver the desired benefit of nutrients to the target audience.
- vi. FSMP formulation should include essential nutrients such as carbohydrates/proteins/fats/vitamins/minerals/amino acids and other nutrients to contribute nutritional benefits to the end-user and they can customise the formulation based on the medical condition, disease and disorder of the target audience.

- vii. FSMP products, may have nutrients at levels higher than the Recommended Daily Allowance (RDA), but not exceeding the limits of vitamins and minerals as specified in Schedule III of the Nutraceutical Regulations.
- viii. Formulation with vitamin or mineral singly or in mere combination, within RDA or exceeding the limits of RDA, shall not be considered as FSMP.
- ix. Formulations, containing vitamin or mineral singly or in mere combination up to the Tolerable Upper limit (TUL), is a drug and shall not be classified under FSMP.
- x. FSMP formulation with a single molecule/ chemical with pharmacological activity in a format like tablet, capsule and liquid shall not be accepted by the Authority as food, as such a formulation is akin to a drug.
- xi. Label of the FSMP products shall specify the statements such as 'RECOMMENDED TO BE USED UNDER MEDICAL ADVICE ONLY' and "For the dietary management of _____" (the specific disease, disorder or medical condition for which the product is intended, and shown to be effective).
- xii. It is the responsibility of the FBO to ensure that there are no potential interactions amongst a combination of ingredients leading to adverse impact on stability, bioavailability, safety, and efficacy. Such combinations should be avoided, that otherwise can potentially be antagonistic to functional outcome of the product.
- xiii. The examples of products falling under FSMP category are dietary formulations for weight reduction and intended as total replacement of complete diet; persons suffering from metabolic disorders including food protein allergy, gastrointestinal disorders etc.

3. Examining FSMP applications under NSF Regulations: Considering the above clarifications/guidelines, the Authority shall critically examine the products potentially falling under FSMP categories with one or more ingredients of botanicals, herbs and ingredients of animal origin, which may also have a drug like activity, to determine whether these products would be best suited under food regulations or drug regulations. In cases of ambiguity, the Authority will err on the side of caution and categorise such ingredients/products to be more akin to drug. Their use will not be permitted under Food Safety and Standards Regulations, as an abundant caution to protect consumers.

4. Further, the following table has been developed to distinguish different categories of products covered under Nutraceutical Regulations:

Parameters	Health supplement	Nutraceutical	FSDU	FSMP
Description	<p>Health supplements are intended to supplement the normal diet of a person, with concentrated sources of one or more nutrients with known nutritional or beneficial physiological effect</p> <p>Health supplements may be preferred when the normal diet is not enough to meet the nutrient requirements</p>	<p>Nutraceuticals are naturally occurring ingredients that are extracted, isolated and purified from food or non-food sources. The consumption in measured amounts, provides physiological benefit and help maintain good health.</p>	<p>Foods for Special Dietary Uses (FSDU) are foods specially processed or formulated to satisfy particular dietary requirements for certain physiological or specific health conditions.</p>	<p>Foods for Special Medical Purpose (FSMP) are foods intended for exclusive or partial feeding of people with limited or impaired capacity to digest, absorb, metabolize ordinary food stuff and whose nutritional requirements cannot be met by normal foods.</p> <p>These foods shall be used only under medical supervision. Such foods can either supplement or replace the diet entirely to provide patients with the essential nutrients that they need to survive and recover.</p>
Age group	Applicable for 5 years and above	Applicable for 2 years and above	Applicable for 2 years and above	Applicable for 2 years and above
Target population	Healthy individuals	Healthy individuals	<p>Specific Physiological Conditions: For individuals like sports persons, pregnant and lactating women, aging population etc.</p> <p>Specific Health Conditions: Underweight, obesity, hypertension and</p>	<p>Persons with specific disease, disorder or medical conditions with limited or impaired capacity to digest, absorb, metabolize ordinary food stuff and whose dietary management cannot be achieved only by modification of the normal</p>

			celiacdisease population etc.	diet, by food for specific nutritional use, or a combination of them.
Purpose/Intended use	To boost the overall health and energy in Healthy individuals and forSupplementation of nutrients such as proteins, vitamins, minerals etc. in other group of people.	For Supplementation of botanicals, herbs and nutrients to support health functions.	Customised as per the target audience to meet the particular dietary requirements.	Customised as per the target audience(diagnosed with different disease condition) to provide nutritional supports. It may be a 1) Nutritionally Complete Formulation 2) Nutritionally Incomplete formulation
Direction of use	To be taken orally	To be taken orally	To be taken orally or through tube feeding	To be taken orally or through tube feeding with mandatory medical supervision
Duration of use	Daily intake as given in the label of the pack	Daily intake as given in the label of the pack	Daily intake as given in the label of the pack or for the specific duration as advised by doctor or clinical dietician	Shall be used for the specific duration as advised by doctor or clinical dietician
Format/Matrix	Capsules, tablets, pills, sachets; jelly or gel, semi-solids and other similar forms of liquids and powders or other form	Granules, powder, tablet,capsule, liquid, jelly or gel, semi-solids and other formats	Granules,capsules, tablets, pills, jelly, semi-solid and other similar forms, sachets of powder, or any other similar forms of liquids and powders	Food format. At present, the most common dosage forms are powder and liquid as other formats are not suitable to deliver the required dietary nutrients.
Does the product to be taken under medical advise	No	No	May or may not be. Based on the product formulation as declared by the FBO in the label.	Yes (strictly under medical advice)

Is claim regarding health function is allowed?	Yes	Yes	Yes	No.
Can the labelling, presentation and advertisement mention that this product has the property of preventing, treating or curing a human disease, or refer to such properties.	No	No	No	No
Level of nutrients allowed	Less than one RDA	Less than one RDA	May go beyond one RDA but have to comply with Schedule III of the Nutraceutical regulations	May go beyond one RDA but have to comply with Schedule III of the Nutraceutical regulations
Formulations containing mere combination of vitamins and minerals in tablets, capsules, syrup formats	No	No	No	No
Formulations made on Single vitamin and mineral	No	No	No	No
Formulations made on Single bioactive based products in tablet, capsule or	No	May be	No	No

liquid				
Can the formulation contain hormones or steroids or psychotropic ingredients	No	No	No	No
Examples	Protein supplements, vitamin and mineral formulations with food components intended for general population.	Formulation made out of plant or botanical extracts or other ingredients specified under Schedule VI of the regulations.	Meal replacement products intended for slimming/weight management/weight control products, sport supplements, specifically designed dietary formulation for pregnant and lactating women, geriatric population, celiac disease, etc.	<p>Nutritionally complete food with standard nutrient formulation Food specially prepared for weight reduction and intended as total replacement of complete diet, People suffering or recovering from serious illness such as patients recovering from stroke or severe food allergies, for patients with trauma, infection and surgery, enteral formulas for gastroenterological conditions</p> <p>Nutritionally complete food with nutrient adopted formulation Special dietary formulas for persons suffering from chronic metabolic disorders including food protein</p>

				<p>allergy, fatty acid metabolism, gastrointestinal disorders, kidney disease, MCT (Medium Chain Triglycerides) containing formulas for malabsorption conditions, patients with inflammatory bowel disease etc.</p> <p>Nutritionally incomplete food with standard formulation or a nutrient adopted formulation</p> <p>For persons suffering from acute metabolic disorders, gastrointestinal disorders, kidney disease, protein substitute for metabolic conditions etc.</p>
Ingredient Schedules applicable	I, II, IV, only enzymes listed in VI, VII, VIII	I, II, IV, VI, VII, VIII (Primarily products based on schedule VI)	I, II, III, IV, VI, VII, VIII	I, II, IV, enzymes listed in VI, VII, VIII
Additive Schedules applicable	VA, VE, and VF (only for tablets/capsules/syrups)	VA, VE, and VF (only for tablets/capsules/syrups)	VB, VE, and VF (only for tablets/capsules/syrups)	VC, VD (weight reduction products), VE, VF (only for Tablets/capsules/ syrups)

Note: The definition and the requirements of the FSMP and other categories including the labelling can be referred from Nutraceutical Regulations which is available on FSSAI website www.fssai.gov.in. Link for accessing the same is <https://fssai.gov.in/cms/food-safety-and-standards-regulations.php>. Frequently Asked Questions (FAQs) on the said regulations is also available at FSSAI website and link for accessing is the same is <https://fssai.gov.in/cms/standardsfaq.php>
