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Review Article **Open Access**

Comparative evaluation of Food for Special Dietary Use (FSDU) and Food for Special Medical Purpose (FSMP) product regulatory framework in India, EU and US

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Abstract

Nutraceuticals are naturally occurring compounds that is used globally due to its varied health benefits that extends beyond to basic nutrition. Various types of compounds are included in the umbrella term of nutraceuticals, including vitamins, minerals, herbal extracts, and dietary supplements. For better understanding and defined use of specific nutraceuticals in specific conditions, nutraceuticals are classified into various types, including Foods for Special Medicinal Purpose (FSMP) and Foods for Special Dietary Use (FSDU). FSMP are foods or nutraceuticals that are formulated in such a way to meet specific nutritional needs for managing medical conditions. FSMPs are designed to complement medical treatments, aiding in recovery, and improving quality of life. FSDU are formulated to meet the nutritional needs of individuals with specific dietary requirements or restrictions. FSDU are essential for ensuring individuals receive adequate nutrition while adhering to dietary restrictions. The regulatory framework for FSDU and FSMP varies significantly between countries. Each country has its own set of laws and regulations governing the production, labelling, and distribution of these products. These regulations ensure that FSDUs and FSMPs meet specific safety, efficacy, and nutritional standards relevant to local health policies and consumer protection laws. The review aimed to compare the regulatory frameworks for FSMP and FSDU across India, the US, and the EU. It focused on understanding differences in regulatory requirements for these products in each jurisdiction. By analyzing these regulatory landscapes, the study sought to highlight variations that impact manufacturers, healthcare providers, and consumers in these regions.

Keywords: Regulatory affairs, USFDA, EU, Foods for Special Medicinal Purpose (FSMP), Foods for Special Dietary Use (FSDU), Nutraceuticals, FSSAI

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1. Introduction

Nutraceuticals represent a diverse group of products derived from natural sources that offer both nutritional and therapeutic benefits. They are distinct from conventional pharmaceuticals in that they are generally consumed as part of the diet, either as food components or supplements, with the intention of providing physiological health benefits beyond basic nutrition. (1,2)

Nutraceuticals are globally used in various health conditions, including (3,4)

- Cardiovascular Health (omega fatty acids, coenzyme Q10)
- Bone and joint health (calcium and vitamin D)
- Digestive health (probiotics and prebiotics)
- Immune support (vitamin C and zinc)
- Cognitive function (ashwagandha and *Ginkgo biloba*)
- Metabolic health (alpha-lipoic acid and multivitamins)
- Skin health (collagen peptides and vitamin E)

Nutraceuticals play important role in supporting the current healthcare ecosystem by (3,4)

- Providing health benefits: Help to prevent chronic diseases by addressing nutritional deficiencies.
- Support for conventional treatments: To complement the mechanism of action of standard therapies.

Individualized health solutions: They can be designed as per the patients' requirements to meet specific nutritional needs.

- Consumer empowerment: Individuals with disease conditions constantly seek natural therapies and nutraceuticals are the best therapeutic option in this context.
- Scientific research and development: With more research, the science of nutraceuticals is constantly expanding the knowledge horizon of various scientists globally.

The nutraceutical industry contributes significantly to the global economy as well, encompassing manufacturing, distribution, and healthcare expenditures related to these products.

Nutraceuticals are of various types and based on their availability and their use in specific conditions they are divided into various categories, including health supplements, dietary supplements, Foods for Special Medicinal Purpose (FSMP), Foods for Special Dietary Use (FSDU), and others. As the regulatory framework for various nutraceuticals is different in different countries, it becomes a challenge to understand and overcome the regulatory roadmap in varied countries. The current comparative study was conducted to analyse the regulatory framework of India, US, and the EU for the FSMP and FSDU products.

2. Introduction to Foods for Special Medicinal Purpose

Foods for Special Medicinal Purpose (FSMP) are specialized food products designed to meet the nutritional needs of individuals with specific medical conditions or diseases. They are distinct from regular foods and dietary supplements due to their composition, which is tailored to provide therapeutic benefits and support medical treatments. (5,6)

FSMPs encompass a wide range of products formulated to address various health conditions. They may include:

- Enteral nutrition formulas for individuals who cannot consume regular food orally.
- Oral nutritional supplements enriched with vitamins, minerals, and other nutrients to support specific medical needs.
- Specialized products for metabolic disorders, gastrointestinal conditions, and malnutrition. FSMP is used in various health conditions, including (5,6)
  - Malnutrition and Malabsorption
  - Cancer and Oncology Support
  - Gastrointestinal Disorders
  - Metabolic Disorders
  - Elderly Nutrition

3. Regulatory framework of FSMP products

3.1 Framework in India

In India, the Food safety and standards Authority of India (FSSAI) is the regulatory body responsible for the regulation of FSMP products. FSSAI regulates many categories of food such as Nutraceuticals, Health supplements, Food for special dietary Use, Food for special Medical purpose. which includes all the products that contain vitamins, minerals, amino acids etc. The FSSAI has classified the FSMP into various categories as shown in Figure 1. (7)

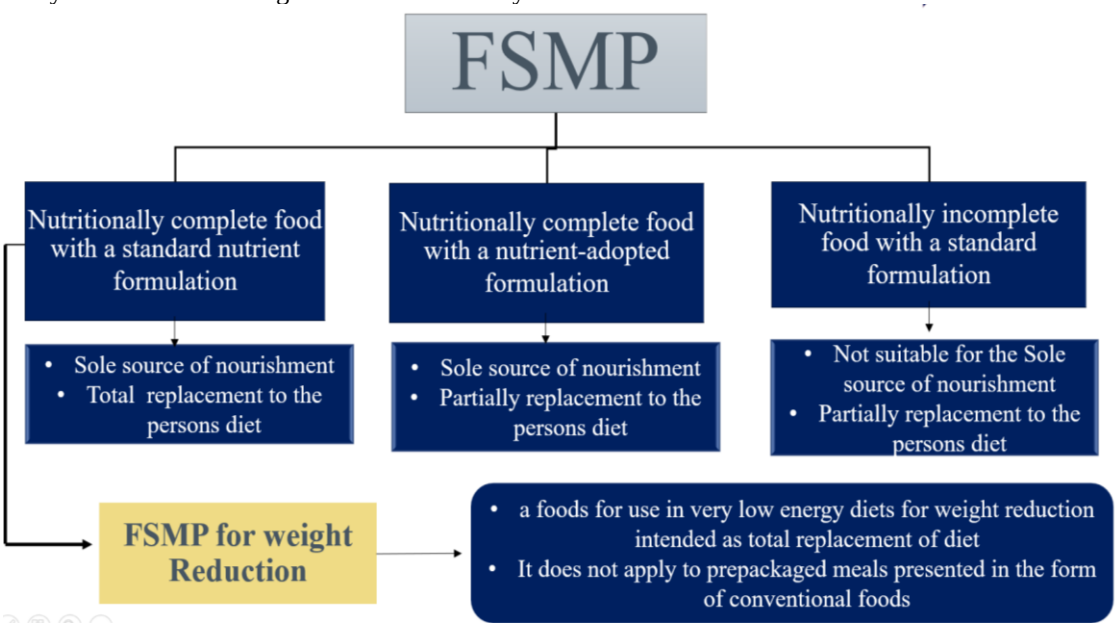

Figure 1. Classification of FSMP as per FSSAI

Definition of FSMP

Food for special medical purpose, other than those intended for infants, may either be nutritionally complete food which, when used in accordance with the manufacturer's instructions, shall constitute the sole source of nourishment for the persons for whom they are intended or nutritionally incomplete food with formulation specific for a disease, disorder, or medical condition, but are not suitable to be used as the sole source of nourishment. (7)

Registration process

On 31st August 2022, FSSAI issued a notice that all the applications for FSMP shall be submitted through ePASS (electronic product & Claim Approval Application system) portal only. The ePASS portal (Figure 2) facilitates FBO to submit requisite fee and application and also helps to track the application status.

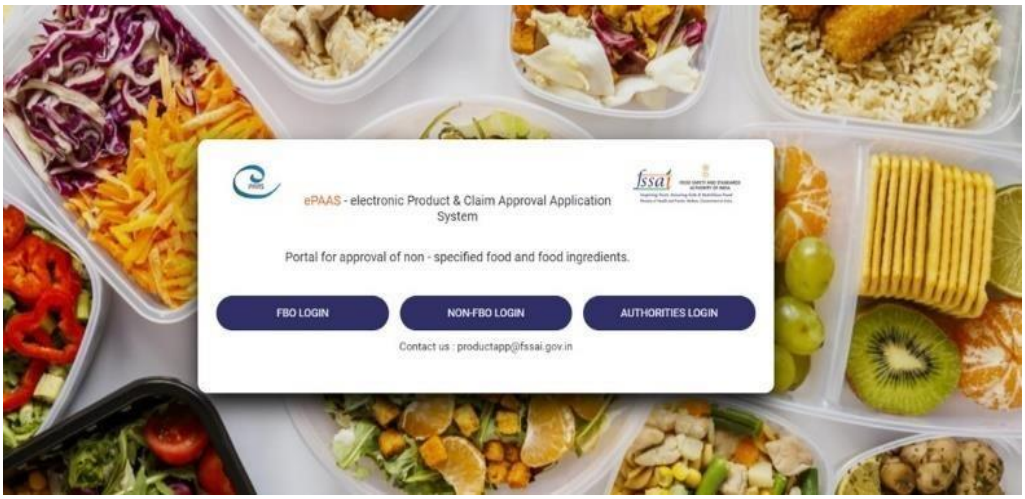

Figure 2. ePASS portal for FSMP registration in FSSAI

3.2 Framework in EU

In EU, the Commission has adopted, through delegated act, specific compositional and labelling rules for FSMP, which will replace Directive 1999/21/EC. Commission delegated Regulation (EU) 2016/128 was adopted on 25 September 2015 and will start to apply on 22 February 2019. Until that date, the rules of Directive 1999/21/EC remain applicable. The new delegated Regulation. (8,9)

Definition

FSMP means food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolize or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone.

Registration process

The complete registration process of FSMP products in EU member states is depicted in Figure 3.

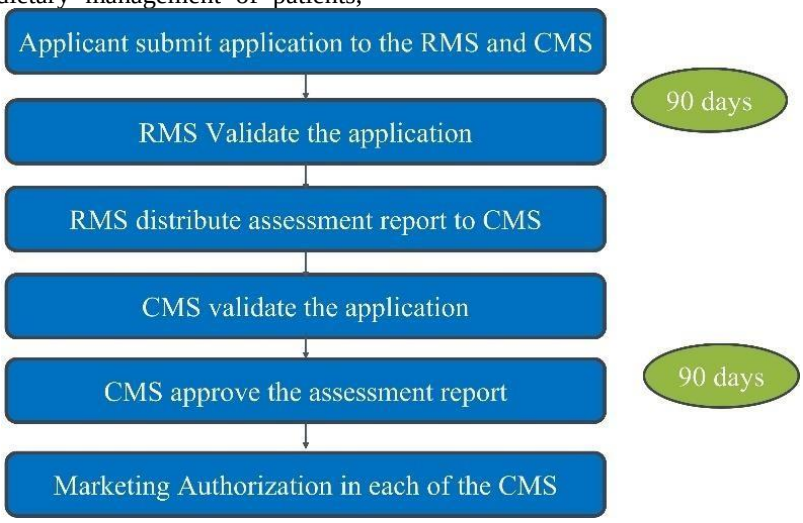

Figure 3. FSMP registration process in EU member states

3.3 Framework in US

In US, the USFDA has set certain specific requirements for the registration of FSMP products (which are called medical foods as per US regulations). (10,11)

Definition

As per the USFDA and defined within the 1988 Orphan Drug Act amendments, a medical food is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

Registration process

Determine if the product requires FDA approval: Not all medical products require FDA approval. Some products

can be marketed in the USA without approval, while others require pre-market approval. Foreign companies should determine if their product requires FDA approval before beginning the registration process.

Appoint a US agent: Foreign companies must appoint a US agent who is responsible for communicating with the FDA on their behalf. The agent must be a US citizen or legal resident and must have a physical address in the USA.

Submit application: Foreign companies must submit application to the FDA that includes information about the product, such as its composition, manufacturing process, and intended use. The FDA will review the application and may request additional information or data.

Conduct clinical trials: If the product requires pre-market approval, foreign companies must conduct clinical trials to demonstrate the safety and efficacy of the product. The trials must be conducted in accordance with FDA regulations and guidelines.

Receive FDA approval: If the product meets the FDA's standards for safety and efficacy, the FDA will issue approval for the product to be marketed in the USA.

Maintain compliance: Foreign companies must maintain compliance with FDA regulations and guidelines once their product is approved for marketing in the USA. This includes reporting adverse events and complying with labelling requirements.

4. Introduction to Foods for Special Dietary Use

FSDU are products formulated to meet the specific dietary needs of individuals with particular health conditions, allergies, intolerances, or cultural and religious dietary restrictions. They are designed to provide nutritional alternatives that accommodate these special dietary requirements. (12,13)

FSDUs encompass a diverse range of products tailored to different dietary needs, including

- Gluten-free products for individuals with celiac disease or gluten intolerance.
- Lactose-free and dairy-free alternatives for those with lactose intolerance or dairy allergies.
- Low-sodium or salt-free options for individuals with hypertension or cardiovascular conditions.

Sugar-free or diabetic-friendly products for individuals managing diabetes or insulin resistance.

5. Regulatory framework for FSDU products

5.1 Framework in India

In India, the FSSAI is the regulatory body responsible for the regulation of FSDU products. FSSAI regulates many categories of food such as Nutraceuticals, Health supplements, Food for special dietary Use, Food for special Medical purpose. which includes all the products that contain vitamins, minerals, amino acids etc. (14)

Definition

FSDU are specially processed or formulated foods intended to satisfy particular dietary requirements which may exist or arise because of certain physiological or specific health conditions namely:

a) low weight, obesity, diabetes, high blood pressure

b) pregnant and lactating women

c) geriatric population and celiac disease and other health conditions other than infants, and those products intended to be taken under medical advice.

Registration process

On 31st August 2022, FSSAI issued a notice that all the applications for FSDU shall be submitted through ePASS (electronic product & Claim Approval Application system) portal only. The ePASS portal (Figure 2) facilitates FBO to submit requisite fee and application and also helps to track the application status.

5.2 Framework in US

In US, the USFDA has set certain specific requirements for the registration of FSDU products. (15)

Definition

The term "special dietary use," as applied to food used by man, means a particular use for which a product purports or is represented to be used, including but not limited to the following uses:

(a) Supplying a special dietary need that exists by reason of a physical, physiological, pathological, or other condition, including but not limited to the condition of disease, convalescence, pregnancy, lactation, infancy, allergic hypersensitivity to food, underweight, overweight, or the need to control the intake of sodium

(b) Supplying a vitamin, mineral, or other ingredient for use by man to supplement his diet by increasing the total dietary intake

(c) Supplying a special dietary need by reason of being a food for use as the sole item of the diet.

Registration process

The complete registration process of FSDU products in US is depicted in Figure 4.

5.3 Framework in EU

In EU, there is no regulatory framework for FSDU products. Products are sold as Dietary supplement, cereal-based foods, baby foods, total diet replacement product and weight control product.

There is no legal status of FSDU in Europe.

6. Comparative evaluation for FSMP between India, US, and the EU

Table 1. Comparison of FSMP regulatory framework between India, US and the EU

No	Parameter	Countries		
		INDIA	EU	US
1	**Definition**	food for special medical purpose, other than those intended for infants, may either be nutritionally complete food which, when used in accordance with the manufacturer's instructions, shall constitute the sole source of nourishment for the persons for whom they are intended or nutritionally incomplete food with formulation specific for a disease, disorder, or medical condition, but are not suitable to be used as the sole source of nourishment	food for special medical purposes' means food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolize or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone	A medical food is a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation
2	**Known as**	Food for special medical purpose (FSMP)	Food for special medical purpose (FSMP)	Medical food
3	**Responsible Regulatory Authority for Registration of FSDU**	FSSAI (Food safety and standard authority of India)	EFSA (European food safety authority)	As per the US Food and Drug Administration (FDA) and defined within the 1988 Orphan Drug Act amendments
4	**Rules and regulation Applied**	Non-specified Food Regulation (NSF) 2016	Food for specific group (FSG) regulation	As per FDA orphan drug amendment act
5	**Regulatory Agency website**	https://fssai.gov.in/	https://www.efsa.europa.eu/en	https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/medical-foods-guidance-documents-regulatory information
6	**Fees required registration**	INR 50000	____	___
8	**Language**	English	As per member state	English
9	**Classification**	Three different categories	Three different categories	Three different categories
10	**Delivery format**	Only powder	Tablets Capsules Gummies Sachets Mouth dissolving strips Stick	Tablet Capsule Gummies Sachets Strips Stick
11	**Allergen declaration**	Not declared	Mandatory	Mandatory

12	**Dossier format**	No	Yes	No
13	**Major class of FSMP**	Weight Reduction	No class	No class
14	**Labelling Requirement**	The statement FOOD FOR SPECIAL MEDICAL PURPOSE is mentioned in front of the pack The statement under the medical advice is mentioned in front of the pack the statement "For the dietary management of ------ ---_" supported by appropriate scientific, and clinical or epidemiological data, and subject to its approval by the Food Authority	The statement FOOD FOR SPECIAL MEDICAL PURPOSE is mentioned in front of the pack The statement under the medical advice is mentioned in front of the pack The statement "For the dietary management of--_" supported by appropriate scientific, and clinical or epidemiological data, and subject to its approval by the Food Authority Specific disease condition is mentioned in front of pack Mentioned infant formulas and other category which is mentioned in front of the pack	The statement MEDICAL FOOD is mentioned in front of the pack The statement under the medical advice is mentioned in front or back of the pack Specific nutrient fact panel and principal display panel regulation
		Specific disease condition is mentioned in front of pack FSSAI logo and license mentioned a statement 'NUTRITIONALLY COMPLETE' if the food is intended to be used as a nutritionally complete food a statement on the rationale for use of the product by the target consumer group and a description of the properties or characteristics that make it useful a warning that the product is not for parenteral use a statement specifying the nutrient which have been reduced, deleted, increased or otherwise modified, relating to normal requirements, and the rationale for the reduction, deletion, increase or other modification. the quantity of nutrients expressed in terms of percentages of the recommended daily allowances, where it is appropriate		
15	**logo**	FSSAI logo mentioned in front or back of the pack	No logo mentioned	No logo mentioned
16	**FSMP market**	No wide range of products Available	Wide range of products available	No wide range of products Available
17	**Nutritional level**	As per RDA	As per DRV	As per RDI
18	**Registration process**	Online Epass portal	Mutual recognition process	FDA online portal for the submission

7. Comparative evaluation for FSDU between India, US, and the EU

Table 2. Comparison of FSDU regulatory framework between India, US, and the EU

Sr.No	Parameter	Countries	
		INDIA	**US**
1	**Definition**	It is specially processed or formulated to satisfy particular dietary requirements which may exist or arise because of certain physiological or specific health conditions, namely: - (a) low weight, obesity, diabetes, high blood pressure; (b) pregnant and lactating women; and (c) geriatric population and celiac disease and other health conditions.	Foods for special dietary use, which include foods represented as the only item in a diet and foods represented as being used only under medical supervision in the dietary management of particular diseases and disorders, were not well suited for the nutrition labeling that was developed for foods meant for consumption by the general public
2	**Known as**	Food for special dietary Use (FSDU)	Food for special dietary Use (FSDU)
3	**Responsible Regulatory Authority for Registration of FSDU**	FSSAI (Food safety and standards Authority of India	Regulation covered under21CFR Part 105
4	**Rules and regulation Applied**	Non-specified Food Regulation (NSF) 2016	Regulation covered under21CFR Part 105
5	**Regulatory Agency website**	https://www.fssai.gov.in/	https://www.fda.gov/
6	**Fees required registration**	INR 50000	---
7	**Health claim**	Allowed Ingredients, Nutrition Claims, Function Claims, Health Claims	Allowed Ingredients, Nutrition Claims, Function Claims, Health Claims
8	**Language**	English	English
9	**Classification**	It is divided into the two different categories 1)weight management 2)FSDU for sports person	---
10	**Labelling Requirement**	Statements which are mandatory on the front	Statements which are mandatory on the front
		Front pack - The words “FOOD FOR SPECIAL DIETARY USE” followed by “Food for ” a statement “FOR SPORTSPERSON ONLY" in close proximity to the name of the articles of food Whether or not the food for special dietary use is to be taken under medical advice of physician or certified dietician or nutritional professional A prominent statement indicating the target consumer group and/or age group if the product has been formulated for a specific age group Front or Back of the Pack The statement “NOT FOR MEDICINAL USE” in capital and bold letters prominently written on label ‘Recommended usage level’ Duration of usage’, where applicable ‘Not to exceed the recommended daily usage’ prominently written.	Front pack The words “FOOD FOR SPECIAL DIETARY USE” followed by “Food for ” Front or Back of the Pack The statement “NOT FOR MEDICINAL USE” Hypoallergic Foods T The common or usual name and the quantity or proportion of each ingredient (including spices, flavoring, and coloring) in case the food is fabricated from two or more ingredients Infant food If a food (other than a dietary supplement of vitamins and/or minerals alone) purports to be or is represented for special dietary use for infants, the label shall bear, if such food is fabricated from two or more

			ingredients, the common or usual name of each ingredient, including spices, flavoring and Coloring
		Every package of Food for Special Dietary Use intended for weight management shall carry the following information on the label a statement "Meal Replacement for Weight Control Management " in close proximity to the name of the articles of food. a warning that the product is not for parenteral use or for oral use only. FSSAI logo and license number of the brand owner shall be displayed on the label Declaration of veg and Non-veg logo Prohibited substances declared by the World Anti-Doping Agency (WADA) mentioned.	Front or Back of the Pack Not to exceed the recommended daily usage' prominently written
11	**Delivery format**	Tablets, capsules, powder, Strips, sachet, jelly, gummies	Tablets, capsules, powder, Strips, sachet, jelly, gummies
12	**Allergen declaration**	Not Mandatory	Mandatory
13	**Dossier format**	Not specified	Not specified
14	**FSDU market**	Large market with variety of the products including sport supplement	Less variety of products are available in the market

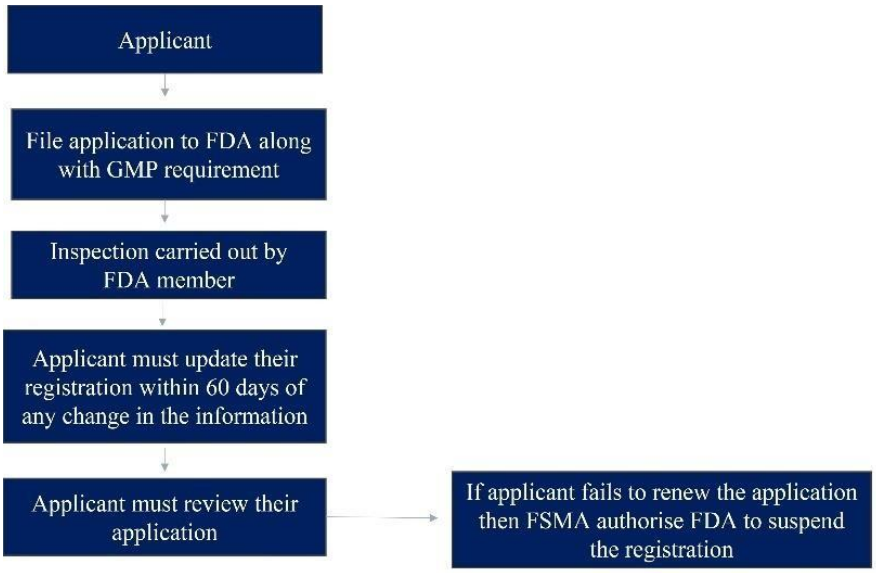

Figure 4. FSDU registration process in US

8. Identified loopholes in the regulatory framework

8.1 In FSDU regulations

- The FSDU product registration requirements vary among the aforementioned nations.
- In Europe and the US, there are numerous gaps in product registration.
- FSDU products are not subject to any laws or regulations in Europe. Because there are so many distinct categories on the market, such as baby foods, infant formulas, the whole weight reduction category, cereal foods, nutritional supplements, and health supplements, it is difficult to register FSDU products.
- There are fewer products available in the US market because so many are marketed as health and dietary supplements because consumers are unaware of the need for labelling.
- No specific Sports supplement category covered in the Europe and US.

8.2 In FSMP regulations

- There is different regulation to register the FSMP product in mentioned countries
- There are some limitations in the India to register the FSMP product. The only powder form is permitted under the regulation. There is prohibition of the tablets, capsules, gummies, mouth dissolving strips under the regulation.
- No specific dossier format available is available in the India and US
- Less availability of products in the Indian and US market

- Different regulations for the infant formulas in India.
- Less variety of products available in the India and US
- Not well structed Regulation in US

9. Conclusion

The FSMP plays an important in public health and many people are using these products on everyday basis therefore they should be regulated in a correct manner and this work will be beneficial for that. It is wide umbrella term and they do not have stringent regulations, Also the regulatory and legislative requirements are different in all the countries mentioned above. The regulation varies but if we see in comparison of all the countries that have been mentioned above, Europe is strict in terms of regulations and regulatory requirements for registration among others, it also requires highest number of documents and variety of the products register in the market.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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