Acta Scientific NUTRITIONAL HEALTH (ISSN:2582-1423)

Volume 6 Issue 6 June 2022

Review Article

A Comparative Study of Food for Dietary Use and Food for Medicinal Purpose Regulation in India, China, USA

Kanchan Subhashchandra Gond[1]* and Sanjay Chauhan[2]

[1]Student, Graduate School of Pharmacy, Gujarat Technological University, Gandhinagar Campus, Nr Government Polytechnic, Gujarat India

[2]Director of Graduate School of Pharmacy, Gandhinagar, Gujarat, India

***Corresponding Author:** Kanchan Subhashchandra Gond, Student, Graduate School of Pharmacy, Gujarat Technological University, Gandhinagar Campus, Nr Government Polytechnic, Gujarat India.

Received: March 16, 2022

Published: May 24, 2022

Abstract

Food for Special Dietary Use and Food for Medicinal Purpose optimization approaches are becoming more well-known around the world for decreasing health risks and improving health quality. The pharmaceutical and nutritional sectors recognise the financial advantages of employing food for special dietary purposes as well as food for medicinal purposes. Foods for special dietary purposes have been proved to offer health benefits, and their consumption will help humans maintain a healthy lifestyle by preventing illness. Both at home and abroad, functional foods and international products offer a value-added growth opportunity. When more well-characterized and research-proven commodities are developed, consumer confidence in food for special dietary usage and food for medicinal purposes will improve. However, it is clearly clear that clinical proof and product safety criteria cannot be decreased. Poor fruit and vegetable diet causes around 16 million disability-adjusted life years and 2.8 percent of yearly world mortality, according to the World Health Organization (WHO). These numbers reveal that today's people are at a far higher risk of developing a variety of lifestyle-related ailments. An increase in smoking prevalence, particularly among working people around the world, exacerbates unhealthy eating behaviours. These numbers reveal that today's people are at a far higher risk of developing a variety of lifestyle-related ailments. An increase in smoking prevalence, particularly among working people around the world, exacerbates unhealthy eating behaviours.

Keywords: Food for Special Dietary Use; Food for Medicinal Purpose; FSSAI; USFDA

Introduction

Definition

Food for special dietary use

Food prepared or made specifically to suit a specific dietary requirement for a physiological or medical condition is known as food for special dietary purposes. Dietary elements in the food for particular dietary needs were as follows: Schedules I and II, III, IV, VI, VII, and VIII.

Food for medicinal purpose

Food made specifically for weight loss and intended to replace a normal diet shall be considered food for special medical purposes. A food business owner may manufacture food in a manner designed for oral feeding through intestinal tubes for special medical purposes.

Food for specific dietary purposes was found to contain Schedules I, II, III, IV, VI, VII, VIII, and potentially enzymes primarily from Schedule VI. The food for medicinal reasons is supplied via the parenteral route, rather than the oral way, which is specified in the meal for specific dietary consumption [1-7].

List of ingredients

List of Ingredient Schedule		
1	Schedule-I	List of vitamins and minerals and their components
2	Schedule-II	List of amino acids and other nutrients
3	Schedule-III	Values for vitamins, minerals and trace elements allowed
4	Schedule-IV	List of plant or botanical ingredients
5	Schedule-VI	List of ingredients as nutraceuticals
6	Schedule-VII	List of strains as probiotics (live micro-organisms)
7	Schedule-VIII	List of prebiotic compounds

Table 1: List of Ingredient Schedue.

Labelling requirement

Food for special dietary use

In the label, the phrases "FOOD FOR SPECIAL DIETARY USE" are followed by "Food for....."

A Clearly worded advisory warning 'NOT FOR MEDICINAL USE' food particularly prepared for weight management and control a declaration "for weight control and management".

Food for medicinal purpose

In the label, the phrases "FOOD FOR MEDICAL PURPOSE" are followed by "FOOD FOR....."

An warning statement on the label that reads "RECOMMENDED TO BE USED UNDER MEDICAL ADVICE ONLY" in large characters in a separate space from any other written, printed, or graphic information.

Where applicable, the amount of nutrients expressed as a percentage of the recommended daily intakes. Administration of routes It should be noted on the label.

Differences Between FSDU and FSMP

Sr.no	Parameter	Food for Special Dietary use	Food for Medicinal Purpose
1	Route	FSDU are Generally given by oral Route	FSMP are Generally given by Parenteral Route
2	Medical Supervision	May or may not be	Mandatory
3	USE	It's Generally use in the following condition or people sport Person, aging Group	Person with specific Disease which are unable to digest or metabolized
4	Purpose	Build as per the specific people to meet the Particular Dietary Requirement	Built as per the specific to provide Nutritional support

Table 2: Comparison Between FSDU and FSMP.

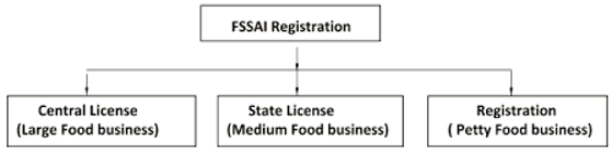
Registration process in India

Introduction to FSSAI

The Food Safety and Standards Authority of India (FSSAI) was founded under the Food Safety and Standards Act, 2006, which brought together many rules, regulations, and orders that previously dealt with food and its regulation in several Ministries and Departments. Fssai has developed a scientifically based standard for food manufacturing, storage, distribution, sale, and import to assure the availability of safe and wholesome food for human consumption.

Food ingredients obtained through modern biotechnology, such as genetically modified or engineered organisms that may also contain the same, have also been included in the act, rather than food ingredients obtained through modern biotechnology, such as genetically modified or engineered organisms that may also contain the same.

Procedure for registration



FSSAI Basic Registration – FBOs with yearly revenues of less than Rs.12 lakh are required to register with the FSSAI. The FSSAI registration form, Form A, must be completed by the applicant in order to get FSSAI basic registration.

FSSAI State License – FBOs with annual turnover of more than Rs.12 lakh but less than Rs.20 crore must apply for a state licence from the FSSAI.

FormB is the FSSAI registration form that must be completed in order for the applicant to get an FSSAI state licence.

FSSAI Central License - FBOs with annual revenues of more above Rs.20 crore must obtain an FSSAI central licence. Form B is the FSSAI registration form that the applicant must complete in order to receive an FSSAI central licence.

Registration and licensing requirements

A manufacturer cannot begin operations until he or she has been properly registered or licenced.

The examination of the premises was carried out after the safety officer issued an ID number in accordance with the FSSAI Act.

Unless otherwise provided in the regulations, the licence granted shall be valid and in effect for a term of fifteen years.

Manufacturers must register with the state office commissioner, and those with a turnover of more than $12 million must obtain a valid licence from the FSSAI office. The same can be said for a small food company

A licence application must be submitted. In order for a licence to be granted, a licence application in form B of schedule 2 must be completed. This licence must be issued within 60 days after receiving the application ID number.

Registration procedure in China

Introduction

On July 1, 2016, the CFDA's "Administration Measures on Foods for Special Medical Purpose (FSMP) Registration" went into effect. All foods for Special Medicinal Purpose (FSMP) must now apply for CFDA registration, and only after receiving clearance from the CFDA may they be imported into China.

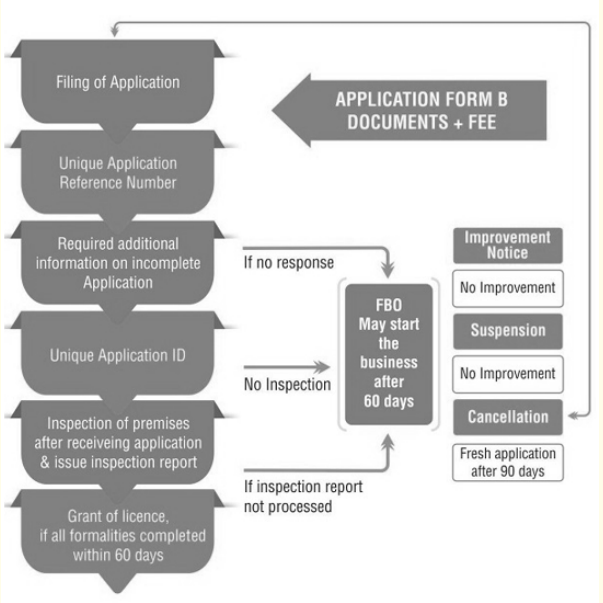


Figure 1: Registration procedure in India.

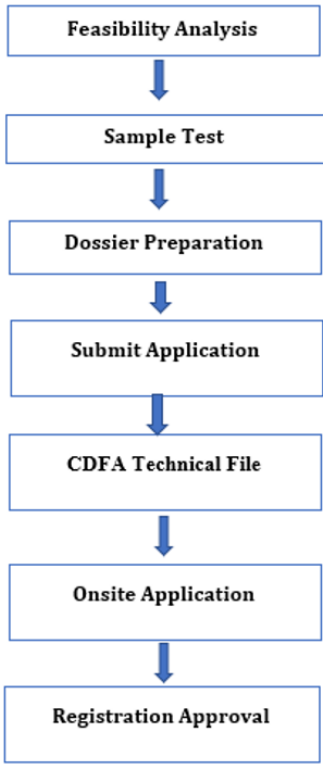
While FSMP manufacturers may apply for registration, the applicants listed above must meet all three of the following standards

- Built the R and D institution and should be equipped with full-time product R and D personnel
- According to good manufacturing Practices Standards requirements, establish corresponding production quality management system
- Have the ability to complete all test items according to the safety national standard (GB)for FSMP

Application document list

- FSMP Registration application form
- Product R and D report, Formula Design and its theoretical foundation
- Manufacturing process material
- Requirement for product quality Standard
- Product Label sample and specification sample
- Sampling testing Reports R and D
- Manufacturing and testing capability proof materials
- Other material that can improve product safety,
- Nutritional sufficient and special medical Clinical effect
- Clinical trial report
- Registration application relevant certificate
- Other relevant material

Registration process in China



Flow chart of Registration Process of China

Registration process for USFDA

Introduction

The Food and Drug Administration (FDA) regulates dietary supplements in the United States through its several food regulatory centres. The Food and Drug Cosmetic Act later controlled or amended the DSHEA, or dietary supplement health education act of 1994. Furthermore, the DSHEA stipulates a number of conditions that must be met by a dietary supplement.

The Food and Drug Administration (FDA) regulates dietary supplements in the United States through its several food regulatory centres. The Food and Drug Cosmetic Act later controlled or amended the DSHEA, or dietary supplement health education act of 1994. Furthermore, the DSHEA stipulates a number of conditions that must be met by a dietary supplement.

Foods for special dietary uses

Foods for special dietary purposes are now defined as foods that

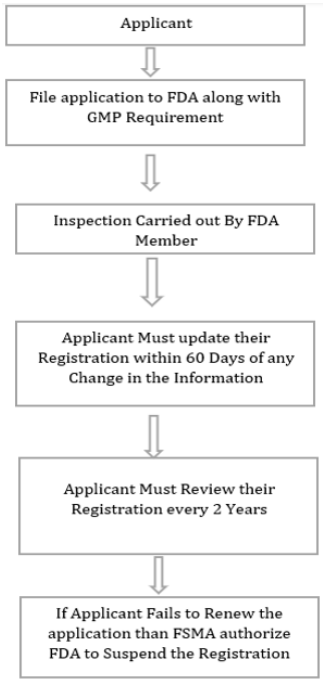
- Meet a specific dietary requirement arising from a physical or physiological condition, such as convalescence, pregnancy, lactation, infancy, or specific diseases and disorders;
- Supply a vitamin, mineral, or other dietary property to supplement the diet by increasing total dietary intake; or
- Meet a special dietary need when such foods are the sole item of food consumed.

Labelling for food for special dietary uses

The percentage of the US RDA for proteins, vitamins, and minerals must be stated on the labels of special dietary foods.

A prominent statement about the food's utility must also be included on the label, limited to a list of the dietary qualities.

Registration Procedure in USA



Comparison of regulatory guidelines of INDIA, CHINA, USA

Parameter	India	USA	China
Regulation for licensing and registration	By Food Safety and Standard Authority of India (FSSAI)	By United States Food, and Drug Administration (USFDA)	By China food and drug administration
Act/Regulatory authority for registration of nutraceuticals	Food Safety and Standard Authority of India	Dietary Safety and Health Education Act	CFDA-China Food and Drug Authority
Regulations	2011	1994	2016
Regulatory requirements for registration	Product evaluations, licenses, health and label claims	Product licensing, evidence requirements for safety & efficacy, labelling, health claims, GMP, adverse reaction reporting and clinical trails	Product licensing, evidence requirements for safety & efficacy, labelling, health claims, GMP
Form for registration	Form A, B. and C	Form 3537	Application Form

Table 3

Conclusion

As there marketing of food for special Dietary Use and food for Medicinal Purpose are Increasing Globally so there is need of proper Guideline and Regulation should be implement in Future.

Acknowledgment

I express my gratitude to my co-authors, Graduate School of Pharmacy, Dr.Sanjay Chauhan for their support in carrying out this work.

Conflict of Interest

The author declares that there are no conflicts of interest.

Bibliography

1. Food Safety and Standards Authority of India.
2. Code of Federal Regulation.
3. https://ebizfiling.com/blog/documents-required-for-fssai-registration-ofhealth-supplements-nutraceuticals-and-novel-foods
4. Fssai Registration Process.
5. Food For Medicinal Purpose Registration.
6. FDA Rules and Regulation.
7. FoSCoS-Fssai.