



CIRS

Compliance Guideline on Food for Special Medical Purpose

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Preface

Food for special medical purposes (FSMP) have been used in China for about 40 years as "intestinal nutrition preparations", and had been supervised as medicines in China before 2012. The long-term applying experiences from developed countries show that, however, FSMP mainly play the role of nutrition support and supplement, thereby effectively improving the nutritional status of patients, increasing the recovery rate, reducing the complications caused by malnutrition and the number of hospitalization periods. Thus, in reality, they do not have specific therapeutic effects. In addition, if registered as drugs, most of FSMP cannot meet the corresponding requirements, thus, a large number of foreign products are not able to be imported into China to benefit the Chinese consumers with increasing demand.

Therefore, relevant Chinese departments have gradually managed FSMP as food, and the 2015 version of the Food Safety Law also clarified the legal status of FSMP as special food. Based on the experiences from developed countries and relevant domestic regulations, a series of standards and regulations have been promulgated as well, providing corresponding legal basis for the production, sale and supervision of FSMP in China.

CIRS Group Food team systematically introduces the definition, development status, laws and regulations, as well as market access of FSMP in this guideline based on the relevant domestic and foreign laws and regulations. It is expected that the guideline will help enterprises better understand the relevant standards and regulations of FSMP in China, so as to develop and/or import high-quality products to the Chinese market, serving Chinese consumers.



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Chapter 1 Introduction of FSMP in China

1.1 Definition and category of FSMP

As required by *Food Safety Law of PRC*, food for special medical purposes (FSMP) are categorized as special food. When normal diet cannot meet the nutritional needs of the patients, FSMP can play the nutritional support role for the maintenance of body functions, disease treatment and rehabilitation of the applicable population. Therefore, in order to better meet the nutritional needs of people in different ages and diseases, FSMP are divided into two groups, one is the products applicable for the population over 1 year old, and another is the products applicable for infants. Based on relevant standards, they are defined as below:

For over one year old: When the normal diet cannot meet the nutritional needs of the target population, FSMP can serve as nutritional supplement/support role. Thus, FSMP for the population over 1 year old, are a category of foods for special dietary uses which are specially processed or formulated for the nutritional and/or dietary management of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foodstuffs, or under special medical conditions. They can be used only under the guidance of doctor or clinical dietitian, for the exclusive or partial feeding of the patients.

For infants: Due to various diseases, some newborns cannot be fed with breast milk or ordinary infant formula. Thus, FSMP for infants are the only or primary source of nutrients on which these infants depend for a considerable period of time after birth. Therefore, FSMP for infants are a category of foods for special dietary uses which are specially processed or formulated as powder or liquid, for the nutritional and/or dietary management of infants with disorders, diseases or special medical conditions. They can be used only under the guidance of doctor or clinical dietitian, for the exclusive or partial feeding of the infants.

Categories of FSMP for the population over one year old

Category	Definition	Category
Nutritionally complete food	can be used as sole source of nutrients for the target population	-
Specific nutritionally complete food	can be used as sole source of nutrients for the target population who are under special diseases or medical conditions	Specific Nutritionally Complete Foods for Diabetes
		Specific Nutritionally Complete Foods for Respiratory Disease
		Specific Nutritionally Complete Foods for Kidney Disease
		Specific Nutritionally Complete Foods for Cancer
		Specific Nutritionally Complete Foods for Liver Disease
		Specific Nutritionally Complete Foods for Sarcopenia
		Specific Nutritionally Complete Foods for Trauma, Infection, Surgery, and other Stressful Situations