

1. The aims of enacting the General Rules for Infant Formula Food for Special Medical Purpose

In every year, there are approximate 15 million new infants born in our nation. Some of them cannot be fed with breast milk or ordinary infant formulas because of many kinds of diseases. Infant formulas for special medical purpose are the main food which these infants live by during their early life stage or quite a long time.

For the purposes of satisfying the nutrition needs of infants with special medical conditions, and guiding and standardizing the production and management of infant formula food for special medical purpose in our nation, according to the provisions in the Food Safety Law and its Implementation regulation, the Ministry of Health organized and formulated the General Rules for Infant Formula Food for Special Medical Purpose (GB25596–2010).

2. The enacting principles of the General Rules for Infant Formula Food for Special Medical Purpose

The first principle is to show the legislation purpose of the Food Safety Law and to highlight the requirements of food safety. Infants are the weakest people, and more attention should be paid to infants in special medical states. This standard strictly follows the requirements in the Food Safety Law, to highlight the safety requirements related to the health of infants in special medical states. The second principle is to satisfy the special nutrition requirements of infants in special medical states. Based on the specific situations and characteristics that commonly seen in infants in special medical conditions in our nation, the nutritional requirements of the formula foods of corresponding categories are determined in order to satisfy the nutrition needs of infants in special medical states. The third principle is to highlight the use provisions of infant formula food for special medical purpose. The category of the infant formula food for special medical purpose and the medical state for use should be indicated on the product label. It should be marked clearly that “please use under the guidance of doctor or clinical dietitian”. The forth principle is to completely refer to the international management experience. The management experience of infant formula food for special medical purpose is still lacking in our country. During the enacting process of question & answer, we referred to the stipulations and standards of Codex Alimentarius Commission, and international organizations, countries and districts in America, European Union, etc., and the authoritative books at home and abroad.

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