Regulations on Inspection Registration of Special Nutritious Foods

特殊营养食品查验登记相关规定

MOHW

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Regulations on Inspection Registration of Special Nutritious Foods

FDA No. 0900080575 Announcement on December 27, 2001

Amendment to FDA Granted No. 1021301305 Decree on June 18, 2013

Amendment to MOHW Granted No. 1021350814 Decree on November 19, 2013

Amendment to Granted No. 1061300765 Decree on June 19, 2017

I. Preface

In accordance with Article 21 of the *Food Safety Hygiene Management Act* and the *Administrative Measures for Inspection Registration and Licenses of Foods and Related Products*, the *Regulations on Inspection Registration of Special Nutritious Foods* was promulgated in order to manage the hygiene, safety, quality and identification of special nutritious foods. The Regulations are applicable to the special nutritious foods below:

1. Infant and older infant formulae include infant formula, older infant formula supplements, and infant formulas for special medical uses.

2. Formulas for specific diseases refer to the balanced meals that have been specially processed or formulated (refer to the meals that provide the applicable objects with sugar, protein, fat, vitamins and minerals equivalent to the calorie ratio) or the single nutrient formulas (refer to the formulas that provide a certain or a certain type of nutrient for the nutritional needs of a specific disease, and food ingredients or excipients are used for such formulas according to the requirement of taste adjustment or processing); based on balanced nutrition, the specific nutrients in such formulas are adjusted (increased or reduced) to provide the patients who are unable to eat, digest, absorb or metabolize the general foods or the specific nutrients in general foods due to physiological dysfunction with the basic heat, nutrients, etc. necessary for maintaining the physiology. Formulas for specific diseases include foods that regulate protein, amino acids, fats or minerals, as well as hypoallergenic foods, weight-control meal replacements, and tube-filled foods.

II. Application for new projects

1. The following written documents and materials shall be submitted for applying for inspection registration of special nutritious foods:

(1) One application form.

(2) One original and one photocopy each of ingredient content table of raw materials, product specification and nutritional ingredient analysis table.

Notes:

a. The table of ingredient content of raw materials shall be issued by the original manufacturer within one year, listing the detailed names and contents of all raw materials and food additives.

b. The product specification shall be issued by the original manufacturer within one year, listing the relevant hygiene and nutritional ingredient specifications of the final products.

c. The nutritional ingredient analysis table shall be issued by the original manufacturer or the inspection agencies accepted to the Ministry within one year, listing the analysis data of each nutrient ingredient.

(3) One original of documentary evidence for selling the products abroad and one product or relevant product trial report.

Note:

For the product trial report of the general formula products, there shall be at least 20 valid samples of applicable testers for the product in principle. For the product trial report of the adjusted formula products specific to special patients (dialysis patients, chronic lung disease patients, short bowel patients, etc.), there shall be at least 30 valid samples of applicable patients for the product in principle.

(4) One critical data of the manufacture process.

(5) One official documentary evidence proving that the original manufacturer is a legal manufacture and sales factory.

Notes:

a. If the original manufacturer is a domestic manufacturer, a photocopy of the factory registration documents shall be submitted.

b. If the original manufacturer is a foreign manufacturer, the original documentary evidence proving that the manufacturer is a legal manufacture and sales factory, which is issued by the government agency of the country of origin that manages the product hygiene and safety or reviews and issues the licenses to the manufacturer, shall be submitted. Such documentary evidence shall contain the manufacturer's name, address, items of operation, product category, hygiene condition of the factory, full name of

the issuing government agency, signature and seal of the registrant or the officer-in-charge, etc. If the documentary evidence is a photocopy, it shall be subject to the signature and seal of the notary organ of the country of origin.

(6) 2 copies each of product label, outer packaging, instructions for use, and Chinese label.

Note:

For products applying for different quantities of packages, it shall submit the materials stated in this clause for each package quantity; if the instruction contents for such products are the same, it's unnecessary to submit the materials repeatedly.

(7) One photocopy of the applicant manufacturer's registration documents for profit-making enterprises.

Note:

The registration documents for profit-making enterprises shall register the business items of the relevant foods.

(8) One complete sample.

Note:

For the products with different package quantity which are under application for inspection registration, one product for each kind of package quantity shall be submitted respectively.

(9) For the high protein food adjusting protein for special diseases, the method for determination of protein shall be provided; for weight-control meal replacement, the clinical trial report shall be submitted; according to the product property, the other relevant data required by special nutritious foods shall be submitted according to the separate notification.

Note:

The determination of protein shall be done in Protein Efficiency Ratio (PER), Protein Digestibility Corrected Amino Acid Score (PDCAAS) or other internationally recognized methods.

(10) If the products under application for inspection registration need to be sub-packaged, the following documents shall be submitted at the same time:

a. One original letter of consent on authorized sub-package issued by the original manufacturer.

b. One original letter of consent issued by the domestic sub-package factory, one photocopy each of registration documents for profit-making enterprises and factory registration documents.

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