Regulations Governing *Ad-hoc* Import Applications of Special Nutritional Foods for Rare Diseases Patients

Order Wei-shu-shi-zi No.0960400463, on June 5th, 2007

Article 1

These Regulations are prescribed in accordance with the provisions of Article 34 of the Rare Disease and Orphan Drug Act.

Article 2

Ad-hoc import applications of special nutritional foods for rare disease patients may be filed to the central competent authority when it is really difficult to do so according to the provisions of the Act Governing Food Safety and Sanitation, and when it is suggested by medical institutions as helpful for the maintenance of lives of patients with rare diseases.

Article 3

The product certification documents referred to in these Regulations refer to documents such as factory certifications, product sales certificates in other countries, or certificates of approval for clinical treatment.

Article 4

Ad-hoc import applications for special nutritional foods which have been announced by the central competent authority for rare disease patients may be filed to the central competent authority by medical institutions with certificates indicating that the users are patients with rare diseases and containing information of the product name, quantity, packaging specifications, the entrusted importer, and the consent letter of the patients.

Article 5

Ad-hoc import applications for special nutritional foods which have not been announced by the central competent authority for rare disease patients may be filed to the central competent authority by medical institutions with the following documents and certificates, and upon receiving which, the central competent authority shall forward the information of import applications to the Review Committee for Rare Diseases and Orphan Drugs for review and decision.

(1) The medical record summary issued by the medical institution with the reasons why the products listed are considered necessary for the rare disease patients

(2) The content of ingredients of the product

(3) The product labels, fact sheet, and related information of safety and description

(4) Product certification documents

(5) A copy of the business registration certificate of the entrusted importer

(6) Consent letter from the patients

(7) Other matters that should be supplemented

Article 6

Ad-hoc import applications for special nutritional foods which have been announced by the central competent authority for rare disease patients may be exempted from the requirements of inspection and Chinese label affixation.

Article 7

These Regulations shall take effect on the day of promulgation.