PFSB/ELD Notification No. 0322001
March 22, 2007

Handling in application for marketing approval of crude drug products, which have been widely used as OTC drugs in foreign countries

(Notification from the Director of the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare to the Director of the Prefectural Health Department (Bureau))

The data to be attached to applications for marketing approval of OTC drugs are handled in accordance with PFSB Notification No. 0331015 from the Director-General of the Pharmaceutical and Food Safety Bureau dated March 31, 2005, "Approval Applications of Pharmaceuticals." This time, handling when the crude drug products widely used as OTC drugs in foreign countries (countries that have approval systems that are considered at a level equivalent to that in Japan or other equivalent systems; the same shall apply hereinafter) are applied for marketing approval as OTC drugs is summarized as follows. Please be aware of the following and make sure that related businesses and medical institutions under your jurisdiction are thoroughly informed of this.

Note

1. Application category

"(1) Drugs with New Active Ingredients" shall be used as the application category for crude drug products containing the active ingredients that are not contained as active ingredients in approved drugs in Japan.

2. Data to be attached to the application for marketing approval

(1) Clinical studies shall be conducted using the preperation considered to have equivalent quality to crude drug products for which application for approval is planned in Japan, and precise and objective clinical study results such as comparative clinical studies conducted with the same indications and dosage and administration and submitted as approval application data to foreign regulatory authorities are available, or there are papers on precise and objective clinical studies such as comparative clinical study results that can be used as scientific grounds published in internationally reputable academic journals. For crude drug products for which these clinical study results or papers can be submitted, it may be possible to judge the propriety of approval by submitting clinical study results mainly intended to confirm the safety in Japanese subjects.

The reasons why the quality of the drug product used in the aforementioned clinical study is equivalent to that of the drug product to be applied shall be discussed on the basis of the original plant, plant part used, cultivation/processing method, etc.

(2) A part of the application data may be omitted if it is scientifically appropriate in view of the characteristics of the crude drug products, the current level of science and technology, etc. In this case, the reason for omission shall be specified.

(3) As the attached document b1 (Structural determination and physicochemical properties, etc.), the data on the original plant source of crude drug and the plant part used (including the identification method if identification of the raw crude product by scientific method is possible), and cultivation/processing methods, etc., shall be submitted, and they shall be specified by the specifications and test methods, manufacturing methods, etc., of the proposed drug product where necessary. If an indicator ingredient is specified in the specifications and test methods, the data on the physicochemical properties of the relevant ingredient shall also be submitted.

3. Handling of Clinical Trial Notifications

When a clinical trial of a drug falling under the above 1 is conducted, a clinical trial notification shall be submitted in advance to the Minister of Health, Labour and Welfare based on the provisions of Article 80, Paragraph 2, Item 2 of the Pharmaceutical Affairs Act.