PSEHB/MDED Notification No. 0530-1
May 30, 2019

To: Director-General, Prefectural Health Department (Bureau)

Director of the Medical Device Evaluation Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare (PSEHB/MDED)
(official seal omitted)

About Handling of Drug Master Files of Raw Materials for Medical Devices

Raw materials used in medical devices had been handled under the medical device master file system (hereinafter referred to as "Former MF system") established in accordance with the "Development of Database of Raw Materials Used in Medical Devices (medical device master file system)" (PMSB/ELD Notification No. 1286, dated December 6, 2000, of the Evaluation and Licensing Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health and Welfare). Since April 1, 2005, the medical device master file (hereinafter referred to as "MF") system has been operated based on Article 80-6 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960. Hereinafter referred to as "the PMD Act") and "Guidelines on Utilization of Master File for Drug Substances, etc." (Joint PFSB/ELD Notification No. 1117-3 and CMS Notification No. 1117-1, dated November 17, 2014, of the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau and Counsellor to the Minister's Secretariat [in charge of review management of medical devices and regenerative medical products], Ministry of Health, Labour and Welfare [MHLW]) (hereinafter referred to as "MF Guidelines"). From now on, the MHLW will handle utilization of the system concerned as provided below. Please ensure that related parties under your jurisdiction are thoroughly informed.

Please note that copies of this Notification will be sent to directors of Regional Bureaus of Health and Welfare, the Chief Executive of the Pharmaceuticals and Medical Devices Agency (PMDA), the Chairperson of the Japan Federation of Medical Devices Associations, the President of the Federation of Pharmaceutical Manufacturers' Associations of JAPAN, the President of the Japan Association of Clinical Reagents Industries, the Chairperson of the American Medical Devices and Diagnostics Manufacturers' Association in Japan, the Chairperson of the Medical Equipment & Diagnostics Committee of the European Business Council in Japan, and the representative of the Certification Bodies Association for Products Including Pharmaceuticals and Medical Devices.

This notification will supersede the "Points to Note for Registration in The Medical Device Master File" (PMSB/ELD Notification No. 265, dated March 22, 2001, of the Evaluation and Licensing Division, Pharmaceutical and Medical Safety Bureau, MHLW).

***

1. Application for registration based on the MF system

An application for MF registration should be handled in accordance with the MF Guidelines and also as provided below.

(1) Materials eligible for registration in the former MF system were limited to polyvinyl chloride, polyethylene, and polypropylene, but in the MF system, the other raw materials for medical devices should be deemed eligible for registration if appropriate. However, drugs used in medical devices, such as anticancer agents and immunosuppressive agents, should not be handled as raw materials for medical devices eligible for registration but should be registered as drug substances for pharmaceuticals in the MF system.

(2) Items to be registered should represent information identifying the raw material, and the information should be registered with reference to the guidance for entry of information of raw materials provided in the "Report on 'Information of Raw Materials to be Entered in Application Forms for Approval of Manufacturing (import) of Medical Devices' under the International Harmonization Research on Approaches for Evaluating Efficacy and Safety of Medical Devices" (Administrative Notice, dated November 15, 2004, by the Office of Medical Device Evaluation, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW).

(3) In the application form, "Registration category of manufacturer or of foreign manufacturer," "Registration number," and "Date of registration" fields should be filled with "Medical device registration," "99BZ888888," and "(Japanese imperial era) YYMMDD" (date of application for MF registration), respectively.

(4) The "Name of drug substance, etc." field should have both "Generic name (ordinary name)" and "Commercial name (trade name, product name).

(5) The "Ingredients and their quantities or nature" field should have the following information. (If the field in the system is not large enough to include the information, the free-text field should be used)

1) Chemical Abstracts Service Registry Number (CAS Registry Number) or Class Reference Number in the Gazette List published based on the Act on the Regulation of Manufacture and Evaluation of Chemical Substances (Act No. 117 of 1973) (the entry may be omitted if neither is available).
2) Chemical structural formula (it should be provided in an appendix)
3) Molecular weight (if the material to be registered has no definite molecular weight, such as polymer, the melt index, viscosity, or other index values may be entered.)
4) Types and amounts of main additives
5) Other information allowing identification of the material to be registered

2. Master files registered based on the former MF system

If a master file registered based on the former MF system is utilized in a new application for approval of medical devices, an application form for registration of this file should be submitted in accordance with the MF Guidelines based on Article 80-6 of the PMD Act. In this case, the original registration certificate and a document on the information registered based on the former MF system should be attached to the application form for registration, in which the remarks field has "Registered medical device master file Registration No. XX" (original registration number in the former MF system).

In addition, when the above submitted application form is accepted, and the master file registered based on the former MF system is registered based on the current system, a new MF registration number will be given, which requires submission of a minor change notification for the approval certificate of the medical devices using the concerned master file.

For the master files registered based on the former MF system that are neither currently utilized nor planned to be utilized in any medical device, the registration certificates based on the former system should be returned in accordance with the "Streamlining of Products Registered in the Drug Master File Database" (PFSB/ELD Notification No. 0208001, dated February 8, 2006, of the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW) as appropriate.

3. Others

The containers and packaging materials that are classified as medical devices should be handled as provided in Section 1 above.