DuPont™ Tyvek® Transition Project

Japan Regulatory Guidance Update

PFSB/ELD Notification No. 0601-1 was published on June 1, 2015, by the Counsellor, Minister's Secretariat, Ministry of Health, Labor and Welfare (MHLW) (Director of the Medical Device and Regenerative Medicine Product Evaluation Division).

The following translation is provided for your convenience by DuPont. The original document in Japanese is the prevailing document. It can be downloaded at: http://kensaku.mhlw.go.jp/search?q=cache:v_EOYfFjBwwJ:www.mhlw.go.jp/file/06-Seisakujouhou-11120000-Iyakushokuhinkyoku/270601kiki06011.pdf+%96%F2%90H%8B%400601&site=mhlw_collection&client=mhlw_frontend_J&proxystylesheet=mhlw_frontend_J&output=xml_no_dtd&ie=sjis&access=p&oe=UTF-8

English Translation of Preface:

To: Prefectural Health Department (Bureau) Heads

From: Counsellor, Minister's Secretariat, Ministry of Health, Labor and Welfare (MHLW)
(Director of Medical Device and Regenerative Medicine Product Evaluation Division)

Question and Answer Guide on Documentation and Appendices for Medical Device Manufacturing and Marketing Approval Filings

The handling of documentation and appendices for medical device manufacturing and marketing approval filings is specified in:

- PFSB/ELD Notification No. 1120-1* dated November 20, 2014, *"Items of Note When Preparing Documentation for Manufacturing and Marketing Approval Filings for Medical Devices"*
- PFSB/ELD Notification No. 0120-9* dated January 20, 2015, *"Items of Note when Preparing Appendices for Manufacturing and Marketing Approval Filings for Medical Devices"*

A question and answer (Q&A) guide on the documentation and appendices for medical device manufacturing and marketing approval filings has been prepared and is attached here to be disseminated within your organizations and to other relevant organizations.

A copy of this Notification has also been forwarded to the Chief Executive of the Pharmaceuticals and Medical Devices Agency (PMDA), the Chair of the Japan Federation of Medical Devices Associations (JFMDA), the Chair of the American Medical Devices and Diagnostics Manufacturers' Association (AMDD), the Chair of the Medical Equipment Committee of the European Business Council in Japan (EBC), and the Representative Executive Secretary of the Association of Registered Certification Bodies (ARCB) under the Pharmaceutical and Medical Device Law.

*Published by the Counsellor, Minister's Secretariat, MHLW (Director of Medical Device and Regenerative Medicine Product Evaluation Division).

English Translation of Q&As Pertaining to Packaging Materials:

Q2: In general, is it appropriate to assume that it is not necessary to provide a block diagram of medical electrical equipment in accordance with the PAB/MDD Notification No. 63 dated March 31, 1997, from the Director of the Medical Devices Division, Pharmaceutical Affairs Bureau, Ministry of Health, Labor and Welfare, *"Handling of Electrical Diagrams When Applying for Approval to Manufacture (Import) Medical Electrical Equipment"?*

A2: If conformity to the official standards regarding electrical safety is included in the items to be approved, a block diagram does not need to be provided as an item to be approved. If electrical safety is ensured in a manner other than conformity to the official standards, a block diagram may need to be provided; however, a schematic diagram must be used in the description if it is needed to explain the principle of the product for which approval is sought.

Q3: In general, is it appropriate to assume that it is not necessary to provide details of the sterile packaging materials for sterile products?

A3: This is correct. However, for products such as contact lens primary containers, information must be provided on the packaging materials that may come into indirect contact with blood, body fluids, and mucous membranes via the filling liquid.

Q8: It is stated that "b. If the intended use, performance, etc. of the product is affected by manufacturing conditions for a process, the manufacturing conditions must be provided even when the process is performed at a site other than one belonging to the licensed manufacturer." What cases fall under this statement? In an applicable case, is it necessary to provide a diagram, such as a process flowchart? Also, is it appropriate to assume that it is not necessary to provide information regarding the manufacturing site where the process is performed, and information on clean controls?

A8: As an example, chemical coating falls under this case. It is recommended that diagrams such as a flowchart are used to describe manufacturing conditions and processing conditions. However, information does not need to be provided regarding the manufacturing site where the process is performed, or regarding clean controls.

Q14: For previously approved products where the authorization document now states that details are not required (regarding the items covered in Q2, Q3, and Q8), is it appropriate to delete this specification when other required notifications are submitted for minor revisions or partial revisions to the approval filing?

A14: Yes.