Provisional Translation (as of December 14, 2007)[1]

PFSB/ELD Notification No. 1024002
October 24, 2005

Director of Evaluation and Licensing Division,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

To: Directors-General, Department of Health,
Prefectural Governments

Documents to Be Attached to Applications for Accreditation of Foreign Manufacturers of Drugs and Quasi-Drugs

The documents to be attached to applications for accreditation of foreign manufacturers have been set out in the Notification of Director-General, Pharmaceutical and Food Safety Bureau, MHLW: "Enforcement of the Law for Partial Revision of the Pharmaceutical Affairs Law and Blood Collection and Donation Services Control Law, etc." (PFSB Notification No. 0709004, dated July 9, 2004) [hereinafter referred to as "the Enforcement Notification"] etc.

In addition to the above-mentioned directions, the documents to be attached to the applications for accreditation of foreign manufactures of drugs (excluding *in vitro* diagnostics) and quasi-drugs shall reflect the following items. Accordingly, you are requested to inform relevant businesses and organizations under your jurisdiction of this notification.

Please note that the copies of this notification are also to be sent to the Chairpersons/Directors of related organizations separately listed.

1. For "The curriculum vitae for the responsible person at the manufacturing establishment" in the item 4 (2) of Section 4 in the Enforcement Notification

   The responsible person shall be a person with a direct responsibility for manufacturing control and quality control at the manufacturing establishment, and the document shall describe the name of the responsible person, his/her past career and responsibility at this manufacturing establishment, etc. The information in the document shall be necessary and sufficient to support the judgment that the person has an appropriate ability for manufacturing control and quality control at the manufacturing establishment.

   In addition, if the person has a short career/work experience at the manufacturing establishment, information relating to his/her previous employment shall be also provided.

2. For "List of product(s) to be manufactured (a list of product(s) to be exported to Japan is acceptable) and documents on the manufacturing process" in the item 4 (3) of Section 4 in the Enforcement Notification

   The list of product(s) to be manufactured shall contain the product items to the extent that they are known at the time of the accreditation application.

   The descriptions in the documents on the manufacturing process shall indicate which kinds of operations are included in the manufacturing processes for each of the product(s) to be

[1] This document is a provisional translation of the original Japanese version of the Notification. MHLW is not held responsible for the correctness of this translation.

manufactured at the relevant establishment. The documents shall provide necessary and sufficient information to make a judgment that the accreditation category and the buildings and facilities are adequate for the product(s) to be manufactured at the manufacturing establishment.

3. For "Documents on the buildings and facilities of the manufacturing establishment" in the item 4 (4) of Section 4 in the Enforcement Notification

The documents to be submitted shall be prepared in accordance with application documents for a license for manufacturing drugs and quasi-drugs pursuant to the Notification of Director-General, Pharmaceutical Affairs Bureau, MHW: "Enforcement of Ministerial Ordinance etc. of Partial Revision of the Regulations for Manufacturing Control and Quality Control of Drugs and Regulations for Buildings and Facilities for Pharmacies, etc." (PAB Notification No. 1332, dated October 9, 1980).

List of Related Organizations

Directors-General of Regional Bureau of Health and Welfare
Chief Executive of Pharmaceuticals and Medical Devices Agency
Chairperson of Federation of Pharmaceutical Manufacturers' Associations of Japan
Chairperson of Japan Cosmetic Industry Association
Chairperson of Executive Committee in Japan, European Federation of Pharmaceutical Industries and Associations
Chairperson of Cosmetics Committee, European Business Council
Representative of Technical Committee in Japan, Pharmaceutical Research and Manufacturers of America
Chairperson of Cosmetics Committee, American Chamber of Commerce in Japan
Chairperson of Japan Hygiene Products Industry Association