<This English translation was prepared with efforts to better translation, however, in case of inconsistency, the original Japanese text shall prevail.>

YAKUSHOKUKIHATSU No.0331006
March 31, 2006

To: Directors of Prefectural Health Departments (Bureaus)
From: Director, Office of Medical Devices Evaluation
Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

Handling of clinical study data on medical devices which was carried out in foreign countries

In accordance with the provision of Article 14, Clause 3 of The Pharmaceutical Affairs Law(1960 Law No.145; hereinafter referred to as the "Law"), those who apply for approval under the provision of Article 14, Clause 1 of the Law have to attach material on clinical study data to their application form. Handling of data on the clinical studies for medical devices conducted in the foreign countries or regions, has been based on "Handling of the data of clinical studies for medical devices conducted in foreign countries (YAKUHATU No.479 Notification by Director General of Pharmaceutical Affairs Bureau dated March 31, 1997)". However, based on "the Ministerial ordinance regarding Good Clinical Practice principles for medical devices (2005, Ministry of Health, Labour and Welfare Ordinance No.36; hereinafter referred to as "Medical Device GCP") which was issued afterward, the decision has been made to handle it as described below. Please note it and thoroughly inform to relevant companies and organizations under your jurisdiction.
Please note that a copy of this notification is being sent to chief executive of Incorporated Administrative Agency-Pharmaceuticals and Medical Devices Agency, Chairperson of the Japan Federation of Medical Devices Associations, Chairperson of Medical Devices and IVD Committee, American Chamber of Commerce in Japan, Chairperson of Medical Devices Committee, European Business Council and Representative of Council of Registered Certification Bodies under PAL.

1, Acceptable countries or regions

In case GCP principles for medical devices which are equivalent to or better than Japanese Medical Device GCP are established under device regulation laws in the country or region where the clinical study was conducted, material on the clinical study data conducted in accordance with that GCP principles or of equivalent clinical studies may be attached to the application form for approval.

2, Relevant notes in making use of clinical studies conducted in foreign countries

In case data of clinical studies conducted in foreign countries or regions are used as application material for approval, the following points should be noted.

(1) Implementation and management of the clinical study

a. Documents equivalent to or better than essential documents laid down in Medical Device GCP have to be prepared for on- or off-site "inspection" stipulated in Article 14, Clause 5 of the Law.

b. Sponsor of the clinical study, trial sites (medical institutions) and other parties involved in the clinical study have to be ready for necessary cooperation in on- or off-site "inspection" stipulated in Article 14, Clause 5 of the Law.

c. Applicants have to ensure reliability of the entire clinical study by audit or other means.

d. If the countries or regions, where the clinical study was conducted, require higher standards of trial subject protection than Medical Device GCP, the clinical study has to be conducted in accordance with those standards.

(2)Application material for approval

a. When the original text of clinical study data is written in a language other than Japanese, "Clinical Study Report", one of the attached materials, requires no more than a summary in Japanese attached to a copy of its original text. In this case, Incorporated Administrative Agency-Pharmaceuticals and Medical Devices Agency may request a Japanese translation of part or whole of "Clinical Study Report" as needed.

b. "Clinical Study Report" has to carry the signature of the responsible person that sponsored the clinical study.

c. If inspection has already been conducted by authorities in foreign countries or regions, a copy of the notification of the inspection result or similar document has to be attached in principle.

d. If there are differences between Japanese Medical Device GCP and those in other

countries or regions where the clinical study was conducted, those differences have to be listed and attached to the material. In addition, comments on influences that the differences might have on the credibility of the clinical study and the quality of the medical device used in the clinical study have to be made. If there is no such influence, please state so.

e. If the sites where medical charts are stored or operations were performed, or other sites related to the clinical study are different from the medical institution where the clinical study was conducted, then a document showing that fact has to be attached to the application.

f. Material on quality of the medical device used in the clinical study has to be attached.

(3)Others

Clinical studies conducted in foreign countries or regions before the enforcement of Japanese Medical Device GCP are to be handled according to the earlier practice based on the transitional measures stipulated in Article 2 and 3 of supplementary provisions of the Medical Device GCP.