SUBJECT:

GLP Mutual Recognition

Notes:

The FDA contact for this MOU is David K. Haggard, HFC-230

Tel. No. 301-827-0393

This Note Verbal is in effect indefinitely.

April 15, 1983

Japanese Note Verbal

The Embassy of Japan presents its compliments to the Department of State and has the honor to inform the Department that the Government of Japan intends to cooperate with the Government of the United States represented by the Department of Health and Human Services in the field of implementing standards or guidelines of good laboratory practices (GLPs) for laboratories conducting nonclinical safety studies, and establishing national inspection programs to enforce those standards or guidelines in order to promote the mutual acceptance of data between the two countries. The details of the cooperation are described in the attached document.

The Embassy has further the honor to state that the Government of Japan intends to facilitate, in accordance with the relevant laws and regulations in force in Japan, the implementation of the cooperation mentioned above, and that any alteration of the document mentioned above will be made through the diplomatic channels.

The Embassy of Japan avails itself of this opportunity to renew to the Department of State the assurances of its highest consideration.

The Department of State presents its compliments to the Embassy of Japan and has the honor to inform the Embassy that the Department of Health and Human Services intends to cooperate with the Ministry of Health and Welfare in the field of implementing standards or guidelines of good laboratory practices (GLPs) for laboratories conducting nonclinical safety studies, and establishing national inspection programs to enforce those standards or guidelines in order to promote the mutual acceptance of data between the two countries. The details of the cooperation are described in the attached document.

The Department has further the honor to state that the United States intends to facilitate, in accordance with the relevant laws and regulations in force in the United States, the implementation of the cooperation mentioned above, and that any alteration of the document mentioned above will be made through the diplomatic channels.

The Department of State avails itself of this opportunity to renew to the Embassy of Japan the assurances of its highest consideration.

Attachment

Arrangement between the Pharmaceutical Affairs Bureau, Ministry of Health and Welfare of the Japanese Government and The Food and Drug Administration, U.S. Department of Health and Human Services

Notes:

I. Purpose

This Arrangement reflects the concern of the responsible agencies of Japan and the United States for assuring the quality and integrity of safety evaluation data submitted to them to support the approval of marketing and research applications for pharmaceutical products. This arrangement is a statement of intent by both parties to implement standards or guidelines of good laboratory practices (GLPs) for laboratories conducting nonclinical safety studies, and to establish national inspection programs to enforce those standards or guidelines in order to promote the mutual acceptance of data between the two countries.

II. Background

Safety evaluation data submitted to one national authority are frequently based on studies conducted by laboratories located in another country. Therefore, the standards observed by those laboratories that produce data which are submitted to the authorities of the other country should be those universally recognized as good laboratory practices. Where the safety evaluation data submitted to a national authority originate from a laboratory within another country, the national authority of the country of origin should be able to provide the other with information that assures that the laboratory is operated in accordance with recognized good laboratory practices.

III. Substance of the Arrangement

A. Cooperation between the Parties and Exchange of Information

To promote mutual acceptance of data and the mutual understanding of their respective inspection programs, inspection practices and assessments, and to facilitate the implementation of their respective regulations or guidelines, the parties are prepared to exchange information on matters concerning GLPs as applied to the safety assessment of pharmaceutical products. The parties are prepared to exchange summaries of records and reports relating to inspections or data audits of laboratories conducting nonclinical safety evaluation experiments, to the extent necessary for the implementation of their respective regulations or guidelines.

Each party also accepts for regulatory purpose, nonclinical safety studies of pharmaceutical products, which have been carried out in accordance with the GLP standards established by the other party.

Notes:

B. Items for Future Discussion

By this Arrangement the parties aim at reaching a position in which they establish substantially consistent GLP standards or guidelines applicable to laboratories conducting nonclinical safety evaluation experiments within their respective jurisdictions and implement mutually comparable programs of inspections of such laboratories to determine compliance with GLP standards or guidelines. These inspections are to be carried out by the respective national authorities.

This Arrangement is intended to serve as the framework for future talks concerning future arrangements between the parties to provide for reciprocal recognition of nonclinical laboratory inspections programs. Such arrangements may include the following specific matters:

1. Adequate inspection programs by national authorities, which would involve inspection approximately every two years of laboratories conducting studies intended to be submitted to national authorities. Inspections may include an assessment of laboratory procedures and operations, and also, as appropriate, audits of data from completed studies submitted to national authorities.

2. Procedures by which either party to this Arrangement can request the other to conduct an inspection of a laboratory or data audit of a nonclinical study.

3. Procedures for exchange and acceptance of summary records and reports relating to inspections, data audits or other relevant matters. It is the shared view of the parties that adequate account must be taken of the laws of each country such as the Freedom of Information Act in the U.S., with respect to confidentiality and public disclosure of certain kinds of information. The parties recognize the need to protect trade secrets.

4. Consultation between the parties to resolve differences of views with respect to GLP compliance matters that may be occasioned by the differences in practices between the two countries.

5. Consultation between the parties on contemplated changes in GLP standards or guidelines.

Notes:

IV. Liaison Officers

The parties respectively appoint the following officials to serve as liaisons for all communications regarding matters relative to this Arrangement.

For the Ministry of Health and Welfare:

Minister of Health and Welfare is currently: Mr. Jun'ichiro Koizumi

Director, Evaluation and Registration Division
(currently Mr. Kumeo Shirota)
Pharmaceutical Affairs Bureau Ministry of Health and Welfare 2-2, 1-Chome, Kasumigaseki, Chiyoda-Ku
Tokyo 100 Japan

For the Food and Drug Administration:

Director, Division of Compliance Policy (Currently David K. Haggard)

Director, Bioresearch Monitoring Staff (currently Mr. Ernest Brisson)
Office of Regulatory Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857 U.S.A

V. Termination

Either party may terminate the measures taken in accordance with this Arrangement by giving two months' notice in writing to the other party through diplomatic channel.