SUBJECT:

Good Laboratory Practice (GLP) Inspections and the Reciprocal Recognition to Each Country's GLP Program

(FDA Agreement Number 225-85-8401)

(Previously CPG 7156d.03)

Notes:

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

Tel. No. 301-827-0393

This MOU is in effect indefinitely.

MEMORANDUM OF UNDERSTANDING

Between

THE FEDERAL OFFICE FOR FOREIGN ECONOMIC AFFAIRS,
FEDERAL DEPARTMENT OF PUBLIC ECONOMY
OF THE SWISS CONFEDERATION

And

THE FOOD AND DRUG ADMINISTRATION
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

I. PURPOSE

The signatory agencies of Switzerland and the United States have a concern for assuring the quality and integrity of safety evaluation data that support the approval of applications for research and/or marketing permits for human and animal drugs. The agencies recognize that such data must be collected under principles of good laboratory practice that are internationally recognized and that are monitored by mutually acceptable national inspection programs. Accordingly, this Memorandum affords reciprocal recognition to each country's good laboratory practice program, provides for the mutual acceptance of safety test data collected in either country, and sets forth procedures for continuing ccoperative efforts for achieving quality safety data. As a consequence, it will not be necessary for either party to conduct nonclinical laboratory inspections in the other country.

II. BACKGROUND

On March 5, 1980, the agencies signed a Memorandum of Understanding that constituted a statement of intent to develop standards or guidelines of good laboratory practice applicable to nonclinical laboratories and to establish national programs of inspection to implement those standards or guidelines. Subsequently, each agency has endeavored to satisfy the intent of the Memorandum. Sufficient progress has been made to permit the following comparisons of the respective national programs.

A. Good Laboratory Practices

Both agencies have published comparable standards of good laboratory practice (GLP) that encompass nonclinical laboratory studies for safety evaluation of human and animal drugs. These standards also satisfy the Principles of Good Laboratory Practice recommended by the Organization for Economic Cooperation and Development (OECD), and are adequate to foster the collection of quality data.

Notes:

The Swiss International Office for the Control of Medicaments (IKS) has published the GLPs as guidelines whereas the U.S. Food and Drug Administration (FDA) has published them as regulations.

B. National Inspection Programs

Both agencies assess adherence to the principles of good laboratory practice through the conduct of periodic laboratory inspections approximately every two years by a trained government inspectorate. The inspection programs permit assessment of current laboratory operations (surveillance) as well as the audit of final reports of selected studies. Laboratories are pre-notified and inspectional procedures are mutually acceptable and consistent with those adopted as a recommendation on July 26, 1983, by the OECD. The product of an inspection is a report that describes laboratory operations and addresses compliance with good laboratory practice standards.

C. Compliance

Both agencies have established satisfactory procedures for obtaining compliance with the principles of good laboratory practice. The procedures include, notifying a laboratory of the deficiencies observed and requesting corrective action within a specified time frame. Failure to correct deficiencies is dealt with by the FDA in a variety of ways that include the rejection of specific studies from scientific consideration to the disqualification of the laboratory. IKS denies statements of compliance to deficient laboratories that fail to take corrective action.

III. SUBSTANCE OF THE UNDERSTANDING

A. The parties understand that:

1. adherence to adequate principles of good laboratory practice is essential to the conduct of high quality safety testing;

2. a national program of periodic inspections conducted by a trained inspectorate is required to monitor adherence to the standards of good laboratory practice;

3. appropriate compliance procedures are necessary to assure adherence to the standards of good laboratory practice; and

4. studies conducted in accordance with the respective standards of good laboratory practice promulgated by either country shall be acceptable to both parties to satisfy regulatory requirements.

Notes:

B. Each party will:

1. inform the other party of significant changes in their good laboratory practice standards and their national inspection program;

2. provide the other party, annually, with the names and addresses of nonclinical laboratories operating within their national boundaries, which are inspected under the good laboratory practice program, along with the dates of inspection;

3. upon request, provide the other party with information regarding whether or not a specific laboratory or study is in compliance with the good laboratory practice standards. In exceptional situations, in which the requesting party can justify a special concern, the other party may invite, with the consent of the sponsor, the test facility, and the competent authorities, a scientist of the requesting country to participate as an observer in the audit of a study. The parties recognize the need to protect the confidentiality of trade secrets and commercial information.

IV. LIAISON

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

A. For the Federal Office for Foreign Economic Affairs:
Through the Embassy of Switzerland
2900 Cathedral Avenue, N.W.
Washington, D.C. 20008

On behalf of:

The Federal Office for Health Affairs
(currently Dr. Bertino Somaini)
for serums and vaccines

The Intercantonal Office for the Control of Medicaments
(currently Director Dr. Peter Fischer)
for pharmaceutical products.

B. Currently: David K. Haggard

B. For the Food and Drug Administration
Office of Regulatory Affairs
(currently Dr. Paul D. Lepore)
5600 Fishers Lane
Rockville, Maryland 20857

Notes:

V. DURATION

This Memorandum shall become effective on the date of the last signature and shall continue in effect unless modified by mutual written consent of the two parties. Either party may withdraw from this Memorandum by written notice to the other party.

APPROVED AND ACCEPTED FOR THE FEDERAL OFFICE FOR FOREIGN ECONOMIC AFFAIRS

Ambassador of Switzerland is currently Mr. Carlo Jhemetti

BY: /s/

TITLE: Ambassador

DATE: 29 April 1985

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

FDA Commissioner is currently David A. Kessler, MD

BY: Frank E. Young /s/

TITLE: Commissioner of FDA

DATE: April 29, 1985