SUBJECT:

Good Laboratory Practices

(FDA Agreement Number 225-79-8400)

(Previously CPG 7156a.05)

Notes:

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

Tel. No. 301-827-0393

This MOU is in effect indefinitely.

Dept. of Health, Education, and Welfare is now Dept. of Health and Human Services

MEMORANDUM OF UNDERSTANDING

Between The

HEALTH AND WELFARE CANADA
HEALTH PROTECTION BRANCH

And The

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION

In a significant number of cases the bioresearch data submitted to one national authority were based on studies conducted by laboratories located in the country of another national authority. Therefore, the standards observed by all non-clinical laboratories in each country that engage(s) in such research should be those universally recognized in the applicable research fields as good laboratory practice so that there is substantial uniformity between the two countries as to the standards observed by the non-clinical laboratories located therein. Where the bioresearch data submitted to one national authority originate from a laboratory within the country of another national authority, the latter should be able to provide the former with the kind of information that the former may need to be assured that the laboratory is operated in accordance with recognized good laboratory practices.

I. PURPOSE

This Memorandum of Understanding constitutes a statement of intent by the signatory agencies of Canada and the United States to develop standards or guidelines of good laboratory practices (GLPs) for non-clinical laboratories and to establish programs of inspection to implement those standards or guidelines. This Memorandum reflects the concern of the parties for assuring the quality and integrity of bioresearch data submitted to national authorities with respect to products within their respective areas of responsibility.

II. ITEMS FOR FUTURE DISCUSSION

The overall goal of the parties to this Memorandum is to reach a position in which they will respectively establish substantially consistent GLP standards or guidelines applicable to non-clinical laboratories within their respective jurisdictions and will carry out mutually acceptable programs of inspections of such laboratories to determine compliance with such standards or guidelines. This Memorandum will serve as the framework for future negotiations concerning future memoranda between the parties to provide for reciprocal recognition on non-clinical laboratory inspection programs and reports.

Notes:

Such future memoranda shall provide for the following specific matters:

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

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

C. Procedures for exchange and acceptance of records and reports relating to inspections, data audits or other relevant matters. The parties understand that adequate account must be taken of the laws of each other with respect to confidentiality and Freedom of Information. (In the case of materials transmitted to the Food and Drug Administration, adequate account must be taken of the U.S. Freedom of Information Act.) The parties recognize the need to protect trade secrets.

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

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

III. INSPECTIONS FOR MUTUAL UNDERSTANDING AND CONSISTENCY

The parties agree that it is desirable that inspections be conducted for the purpose of promoting mutual understanding of their respective inspection programs and consistency of inspection practices and assessments. The parties, intend to conduct such inspections beginning in the near future.

Neither party shall initiate an inspection or data audit of a laboratory located in the other country without having first obtained the consent of the national authority of that country. Joint inspections shall be conducted under the auspices of the host country.

Notes:

IV. LIAISON

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

Bureau of Field Operations has been divided into several regions. For proper designation, please refer to:

Mrs. Michele S. Jean, Deputy Minister, Health Protection Branch, Health Canada, Brooke Claxton Bldg., 15th Floor, Tunney's Pasture, Ottawa, Ontario, Canada K1AOK9

For Health Protection Branch:

Director, Bureau of Field Operations
(currently Dr. C. Broughton)
Field Operations Directorate
Health Protection Branch
Health and Welfare
255 Argyle Street
Ottawa, Canada.

For the Food and Drug Administration:

For FDA:

Director, Division of Compliance Policy, HFC-230

(Currently: David K. Haggard)

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

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 parties. Either party may withdraw from this Memorandum by written notice to the other.

APPROVED AND ACCEPTED FOR THE
HEALTH PROTECTION BRANCH

Assistant Deputy Minister is currently Joseph Losos, M.D.

A.B. Morrison /s/
Assistant Deputy Minister

Date: 10 May, 1979

Currently, the Deputy Commissioner/Senior Advisor to the Commissioner is Mary Pendergast

APPROVED AND ACCEPTED FOR THE
FOOD AND DRUG ADMINISTRATION

Sherwin Gardner /s/
Deputy Commissioner

Date: May 10, 1979