SUBJECT:

Good Laboratory Practices

(FDA Agreement Number 225-79-4011)

(Previously CPG 7156c.02)

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 Resources

MEMORANDUM OF UNDERSTANDING

Between the

SWEDISH NATIONAL BOARD OF HEALTH AND WELFARE

and the

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

In a significant number of cases the bioresearch data submitted to one national authority are 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 in such research should be those universally recognized in the applicable research fields as good laboratory practices 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 the other 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 Sweden and the United States to develop standards or guidelines of good laboratory practices (GLPs) for non-clinical laboratories with respect to drugs 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 the two national authorities with respect to drugs.

II. ITEMS FOR FUTURE DISCUSSION

The overall goal of the parties to the 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 a framework for future negotiations concerning future memoranda between the parties to provide for reciprocal recognition of non-clinical laboratory inspection programs and reports.

Such future memoranda shall provide for the following specific matters:

Notes:

A. Adequate inspection programs by the national authorities, which would involve inspection approximately every two years of non-clinical 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 the national authorities.

B. Procedures by which either party to this agreement can request the other to conduct an inspection or data audit of a non-clinical 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 practices 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.

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:

Notes:

For the Swedish National Board of Health and Welfare:

Chief Inspector Lars Gunnar Kinnander
Department of Drugs
National Board of Health and Welfare
Box 607, S-751 25 UPPSALA

For the Food and Drug Administration:

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

Ernest L. Brisson
Director, Bioresearch Monitoring Staff
Office of Regulatory Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 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 two parties. Any party may withdraw from this Memorandum by written notice to the other party.