SUBJECT:

Nonclinical Laboratories

(FDA Agreement Number 225-86-8400)

(Previously CPG 7156j.01)

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

FRENCH MINISTRY OF SOCIAL AFFAIRS AND NATIONAL SOLIDARITY
OFFICE OF PHARMACEUTICALS AND MEDICINES

And The

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

I. PURPOSE

The Food and Drug Administration of the Department of Health and Human Services and the Office of Pharmaceuticals and Medicines of the Ministry of Social Affairs and National Solidarity fully acknowledge that collaboration and cooperation will, to their mutual benefit, further science and technology in the interest of public health, contribute towards improving the quality of medicines in international commerce, and strengthen the bonds of friendship between the United States and France.

II. BACKGROUND

Very often the research data on experimental toxicology submitted to the governmental authority of one of the parties to this agreement in support of a request for approval to market a pharmaceutical product for human consumption are based on studies conducted by laboratories in the country of the other party to the agreement.

This agreement reflects the desire of the appropriate agencies of the United States and France to ensure the quality and the accuracy of such data.

At the present time, the United States and France each have regulations governing good laboratory practice and inspectional personnel specializing in this area, and the French and American regulations are quite similar and entirely compatible. The Council of the Organization for Economic Cooperation and Development has encouraged its member countries to conclude agreements on the mutual recognition of data.

This agreement will make it possible to reduce the number of animals used in experiments by eliminating the need to repeat the experiment in the other country.

Notes:

III. SUBSTANCE OF AGREEMENT

Considering the advantages that will accrue to both their countries, the two agencies have agreed as follows:

Article 1. The parties to this agreement undertake to provide, as promptly as possible, information on an inspection of a toxicology laboratory or a study audit whenever the other party so requests.

Article 2. The inspectors of the Food and Drug Administration will rely on the texts relating to Good Laboratory Practice for Nonclinical Laboratory Studies (21 CFR Part 58) in evaluating the laboratories and the data from studies conducted in their country.

The inspectors of the Office of Pharmaceuticals and Medicines of the Ministry of Social Affairs and National Solidarity will rely on the texts of the Instruction of September 3, 1984*, relative to good laboratory practice in evaluating the laboratories and the data from studies conducted in their country.

Each party to this agreement will inform the other of changes in their respective good laboratory practice regulations or to their respective inspection programs.

* and of the Instructions of May 1983

Article 3. Each party to this agreement agrees that studies conducted in accordance with respective standards of good laboratory practice promulgated by either country are to be acceptable to both parties for evaluation of product applications submitted for approval.

Article 4. Should a special problem arise, at the request of either party a joint inspection will, on an exceptional basis, be organized by the two offices.

Article 5. Ongoing cooperation will be developed between the Food and Drug Administration and of the Office of Pharmaceuticals and Medicines in such a way as to strengthen the ties between the two agencies, to increase exchanges, and to advance still further the quality of nonclinical experimentation in both countries.

Article 6. Each year, as the need arises, the Food and Drug Administration and the Office of Pharmaceuticals and Medicines will examine the issues raised by the implementation of this agreement, evaluate the progress achieved, and determine the work to be done.

Notes:

IV. LIAISON

The parties will appoint the following representatives as liaison officers for all communications on issues relating to this agreement:

A. For the Office of Pharmaceuticals and Medicines:
Chief, Pharmaceutical Inspection Unit
(currently Mr. Jacques Cordonnier)
1 Place Fontenoy, 75007 Paris
4-567-55-44, Extension 52-06

B. Currently Mr. David K. Haggard

B. For the Food and Drug Administration:
Director, Division of Compliance Policy
(currently Mr. Ernest Brisson)
Office of Regulatory Affairs
5600 Fishers Lane
Rockville, MD 20857
301-443-2390

V. DURATION OF AGREEMENT

This agreement shall become effective upon acceptance by both parties. It may be amended by mutual written consent or terminated by either party upon written notice to the other party.

APPROVED AND ACCEPTED FOR THE OFFICE OF PHARMACEUTICALS AND MEDICINES

BY: /s/
Pr. J. Dangoumau
TITLE: Le Directeur de la Pharmacie et du Medicament

DATE: March 18 1986

APPROVED AND ACCEPTED FOR THE FOOD AND DRUG ADMINISTRATION

The ACRA is currently Mr. Ronald G. Chesemore

BY: Joseph P. Hile /s/

TITLE: Associate Commissioner for Regulatory Affairs

DATE: March 7, 1986