SUBJECT:

Cooperation in the Scientific and Regulatory Fields of Health

(FDA Agreement Number 225-96-4001)

Notes:

The FDA contact for this MOC is Walter Batts, HFG-1

Tel. No. 301-827-4480

This MOC is in effect indefinitely .

MEMORANDUM OF COOPERATION

Between The

Subsecretaría de Regulación y Fomento Sanitario
Secretaría de Salud (SSA)
of the United Mexican States

And The

Food and Drug Administration (FDA)
Department of Health and Human Services
of the United States of America

And The

Health Protection Branch (HPB)
Health Canada
of Canada

REGARDING
Cooperation in the Scientific and Regulatory Fields of Health

PREAMBLE

The Subsecretaría de Regulación y Fomento Sanitario, the Food and Drug Administration and the Health Protection Branch seek to expand and strengthen communications among the three governments in the scientific and regulatory fields of health.

I. PURPOSE

The Subsecretaría de Regulación y Fomento Sanitario of the Secretaría de Salud (SSA) of the United Mexican States, the Food and Drug Administration (FDA) of the Department of Health and Human Services of the United States of America, and the Health Protection Branch (HPB) of the Department of Health of Canada affirm by this document their intention to strengthen existing mutual cooperation in the scientific and regulatory areas of regulated products, specifically foods (including dietary supplements), drugs (including biologics), cosmetics, medical devices, radiation-emitting electronic products and related products. The parties intend to enhance, expand, and develop joint efforts to exchange information in health and in regulatory areas related to regulated products and prevention of health fraud related to the following areas:

A. The exchange of information at the earliest feasible stages of investigations into the safety of regulated products.

Notes:

B. The exchange of information (including, for example, legislation, regulations, proposed amendments, guidelines, and technical documents such as evaluations of foreign suppliers of regulated products and enforcement decisions, including recalls or rejected shipments of products, and training material for regulatory officers) with respect to regulated products.

C. Communication on evaluation of the safety and nutritional quality of food, of the safety, effectiveness, and quality of drugs (including biologics) and medical devices, of the chemical and microbiological safety of cosmetics. The activities are intended to include, for example, communications on clinical protocols, new product approvals, and withdrawal of marketing approval due to concerns about safety, lack of proof of effectiveness, bioequivalence problems, etc.

D. The parties also intend to communicate on the evaluation of the chemical and microbiological safety of foods and cosmetics by exchanging information on chemical and microbiological analytical methods and criteria for safety evaluation.

E. Exchange of information on areas where two or more of the countries' regulatory requirements are equivalent, with a view to working toward the development of a common approach in determining compliance status. The participants also intend to discuss their standards with a view toward considering whether it would be appropriate to undertake harmonization activities.

F. Strive through increased dialogue to achieve a common position in meetings of international organizations.

G. Communicate concerning the development of research and monitoring protocols and projects (including, for example, such areas as epidemiology, dietary surveys and health hazard related issues) and pre- and post-market surveillance activities.

H. Communicate concerning the development of programs to increase consumer protection related to health fraud.

II. SPECIFIC PLANS

As the need arises in areas described in Section I, the participants may develop and agree upon specific plans of cooperation which will be incorporated in written agreements or arrangements.

III. SOURCE OF FUNDING

Each party to the Memorandum of Cooperation intends to fund its own activities subject to the availability of appropriated funds, personnel, and other resources. Any exchange of information or other activity under this Memorandum of Cooperation are to be performed in accordance with applicable laws and regulations.

Notes:

IV. PARTICIPATING PARTIES

A. Subsecretaría de Regulación y Fomento Sanitario
Secretaría de Salud
Lieja 7, 1er. Piso
Col. Juarez
06696 Mexico, D.F.

B. Food and Drug Administration
Department of Health and Human Services
5600 Fishers Lane
Rockville, Maryland 20857

C. Health Protection Branch
Health Canada
Tunney's Pasture
Ottawa, Ontario K1A 0L7

V. LIAISON OFFICERS

A. Coordinador de Asesores
Subsecretaría de Regulación and Fomento Sanitario
Lieja 7, 1er. Piso
Col. Juarez
06696 Mexico, D.F.
(525) 553-73-28 and (525) 553-6979
FAX (525) 553-69-96

B. Currently:
Walter Batts
Tel. No.
301-827-4480
Fax No.
301-443-0235

B. Director, International Affairs Staff
Office of External Affairs
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
(301) 443-4480
FAX (301) 443-0235

C. Advisor to the Assistant Deputy Minister
Health Protection Branch
Health Canada
Tunney's Pasture
Ottawa, Ontario K1A 0L7
(613) 957-1804
FAX (613) 957-3954

VI. DURATION

Cooperation under this Memorandum will commence upon signature of all participants. This memorandum may be revised by mutual written consent of all participants. Cooperation under this Memorandum may be terminated upon thirty days advance written notice to the other participants.

Notes:

FOR THE FOOD AND DRUG ADMINISTRATION OF THE UNITED STATES OF AMERICA

BY: Sharon Smith-Holston /s/

TITLE: Deputy Commissioner for External Affairs

DATE: October 30, 1995

PLACE: Ottawa, Canada

FOR THE SUBSECRETARIA DE REGULACION Y FOMENTO SANITARIO OF THE UNITED MEXICAN STATES

BY: Rafael Camacho Solis /s/

TITLE: Subsecretatio de Regulacion y Fomento

DATE: October 30, 1995

PLACE: Ottawa, Canada

FOR THE HEALTH PROTECTION BRANCH OF CANADA

Currently: Joseph Losos, M.D.

BY: Kenneth R. Foster /s/

TITLE: Assistant Deputy Minister, Health Protection Branch

DATE: October 30, 1995

PLACE: Ottawa, Canada