Committee Name	Date(s) of Meetings	Advisory Committee 10-Digit Information Line Code
Dietary Supplements Subcommittee	September 14–15	3014510564
Infant Formula	June 22–23	3014510564
Nutrition Subcommittee	March 30–31	3014510564
CENTER FOR VETERINARY MEDICINE		
Veterinary Medicine Advisory Committee	September 23–24	3014512548
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH		
Science Advisory Board to National Center for Toxicological Research	August 11	3014512559
Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Herbicides and Contaminants	January 21, April 12, August 3, October 26	3014512560

Dated: December 23, 2003.

Peter J. Pitts,

Associate Commissioner for External Relations.

[FR Doc. 03–32103 Filed 12–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Biological Response Modifiers Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Biological Response Modifiers Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 18, 2004, from approximately 8:30 a.m. and 5 p.m.; and on March 19, 2004, from approximately 8:30 a.m. to 3 p.m.

Location: Hilton Hotel, 8727 Colesville Rd., Silver Spring, MD.

Contact Person: Gail Dapolito or Rosanna Harvey, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3014, e-mail *dapolito@cber.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 18 and 19, 2004, the committee will discuss issues related to the design of early phase clinical trials of cellular therapies for the treatment of cardiac diseases.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 11, 2004. Oral presentations from the public will be scheduled on March 18, 2004, between approximately 4:30 p.m. and 5 p.m.; and on March 19, 2004, between approximately 9:50 a.m. and 10:20 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 11, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gail Dapolito at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 22, 2003.

Peter J. Pitts,

Assoicate Commissioner for External Relations.

[FR Doc. 03–32242 Filed 12–30–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–04–8004]

Memorandum of Understanding Between the Food and Drug Administration, Department of Health and Human Services of the United States of America and Swissmedic of the Swiss Confederation Regarding Exchange of Information About Pharmaceutical Products for Human and Animal Use and Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the Food and Drug Administration, Department of Health and Human Services of the United States of America and Swissmedic of the Swiss Confederation. The purpose of this MOU is to further enhance and strengthen communication and existing public health promotion and protection cooperative activities related to the regulation of human or animal pharmaceutical products and human medical devices in Switzerland and the United States of America.

DATES: The agreement became effective September 22, 2003.

FOR FURTHER INFORMATION CONTACT: Naomi Kawin, Office of International

Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0590.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: December 18, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

MEMORANDUM OF UNDERSTANDING

BETWEEN THE FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES OF AMERICA

AND

SWISSMEDIC OF THE SWISS CONFEDERATION

REGARDING EXCHANGE OF INFORMATION ABOUT PHARMACEUTICAL PRODUCTS FOR HUMAN AND ANIMAL USE, AND MEDICAL DEVICES

PREAMBLE

The Food and Drug Administration (FDA), of the United States Department of Health and Human Services (HHS) and Swissmedic (collectively "the Participants") recognize the importance of timely communication between U.S. and Swiss governmental authorities. These communications are especially important on matters relating to the safety, quality, and efficacy of: (a) pharmaceutical products for human use (including active pharmaceutical ingredients and finished dosage products and biological products, such as vaccines and blood products); (b) pharmaceutical products for animal use (not including biological products for animals because FDA/HHS and Swissmedic do not have oversight authority for such products in the United States of America or Switzerland respectively); and (c) medical devices for human use. The Participants share a mutual high regard for the critical role of one another's regulatory systems in the review and approval of these products for marketing. To that end, the Participants to this Memorandum of Understanding (MOU) intend to establish mechanisms by which the exchange of documents and/or information between staffs during the review and evaluation of investigational and marketing applications and the post-marketing surveillance of these products would be facilitated as agreed to by the Participants.

I. PURPOSE

This MOU is intended to further enhance and strengthen communication and existing public health promotion and protection cooperative activities related to the regulation of human or animal pharmaceutical products and human medical devices in Switzerland and the United States of America.

II. SCOPE

The products covered under this MOU include (as defined in the Preamble): pharmaceutical products for human use; pharmaceutical products for animal use; and, medical devices. The Participants intend to develop specific procedures for the exchange of regulatory (including enforcement) and public health information related to these products. The types of information that may be shared include, but are not limited to, the following:

A. Drafts of pending laws, regulations, guidance documents, procedures, and other technical documents available to the individual Participants that are related to such pharmaceutical and medical device products.

B. Post-marketing data and information that could have an impact on the public health, such as pharmacovigilance data or information about impending regulatory actions.

C. Information on quality defects or product recalls of human or animal pharmaceutical products or medical devices known by the FDA/HHS to have been manufactured or distributed in Switzerland, and products known by Swissmedic to have been manufactured or distributed in the United States of America.

D. Information contained in or related to marketing or investigational applications for human or animal pharmaceutical products or medical devices, including the various discipline reviews. This also includes information on maximum residue levels of animal drugs in tissues of animals intended for human consumption.

E. Inspection reports and product sample test results such as those describing the conformity of a human or animal pharmaceutical product or medical device, or a facility that manufactures these products, with applicable regulatory requirements.

F. Information on facilities registered or authorised in each Participant's country that then market product to the other Participant' s country.

G. Information related to import refusals for reasons related to the safety, quality, or integrity of the shipment.

Such information shall not be used for purposes other than those envisaged by this MOU.

III. CONFIDENTIALITY

Information exchanged under this MOU may include non-public information exempt from public disclosure under the laws and regulations of Switzerland or the United States of America. Information that is not appropriate for public dissemination will be shared according to the procedures and policies of the Participants as permitted by their respective laws. FDA/HHS and Swissmedic are not able to share trade secret information without the consent of the owner of the information. With regard to any other types of non-public information that may be provided to Swissmedic by FDA/HHS or to FDA/HHS by Swissmedic, such transmissions will be made in accordance with the specific signed confidentiality commitments and other requirements of the Participants.

The personnel of the agencies shall be required, even after their duties have ceased, not to disclose non-public information acquired under this MOU, including information which is of the kind covered by the obligation of professional secrecy in Switzerland and information and activities covered by 18 U.S.C. § 207 in the United States of America.

IV. SOURCE OF FUNDING

Each Participant to this MOU 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 MOU is to be performed in accordance with applicable laws and regulations.

V. DURATION

Cooperation under this MOU commences upon signature of the Participants and continues in effect for a period of ten (10) years unless modified by mutual consent of the Participants or terminated earlier by either Participant upon a 30 calendar-day written notification to the other Participant.

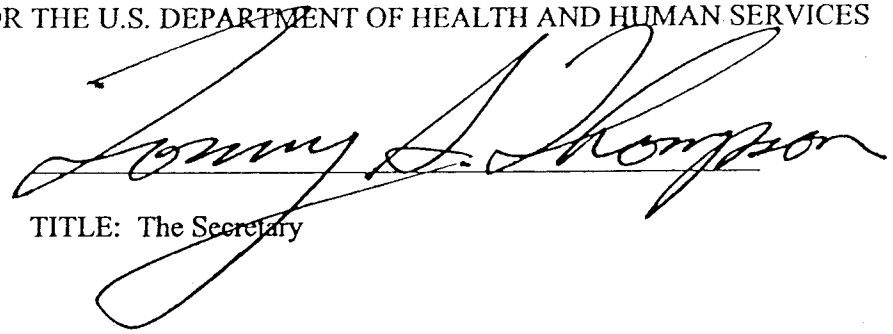
After the first year of operation, the Participants may jointly evaluate the MOU. Periodic reviews may be conducted as deemed necessary by the Participants. The MOU may be extended for additional 10-year periods, with periodic reviews as needed and agreed to by the Participants.

This MOU does not modify existing cooperative activities nor does it preclude entering into separate arrangements for special programs that can be handled more efficiently and expeditiously by special arrangements.

Nothing in this MOU is intended to diminish or otherwise affect the authority of either Participant to conduct its regulatory responsibilities and programs. In addition, no provision of this MOU restricts either Participant from conducting its own inspection of a pharmaceutical or medical device manufacturing facility within the jurisdictional boundaries of the other country when needed to meet the needs of its own pharmaceutical or medical device regulatory program.

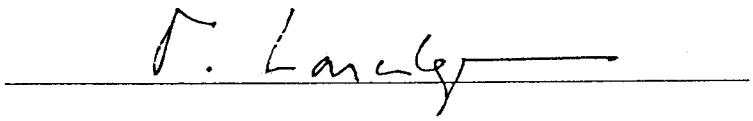
Signed in New York, in duplicate, this twenty-second day of September 2003, in the English language.

FOR THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES



TITLE: The Secretary

FOR THE SWISS AGENCY FOR THERAPEUTIC PRODUCTS, SWISSMEDIC, OF THE SWISS CONFEDERATION



TITLE: President of the Swiss Confederation and
Chief Executive of the Department of Home Affairs (EDI)

[FR Doc. 03–32006 Filed 12–30–03; 8:45 am]
BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–04–8003]

Memorandum of Understanding Between the Food and Drug Administration and the Health Products and Food Branch, Health Canada of Canada Regarding Sharing and Exchange of Information about Therapeutic Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration is providing notice of a memorandum of understanding (MOU) between the Food and Drug Administration (FDA), Department of Health and Human Services of the United States of America and the Health Products and Food Branch, Health Canada of Canada. The purpose of this MOU is to enhance and strengthen the exchange of information and existing public health protection cooperative activities related to the regulation of the specified therapeutic products.

DATES: The agreement became effective November 18, 2003.

FOR FURTHER INFORMATION CONTACT: Beverly Corey, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0855.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: December 17, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S