DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–04–8003]

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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.

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Dated: 12/17/03
December 17, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[Insert MOU]

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

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CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

MEMORANDUM OF UNDERSTANDING

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

AND THE
HEALTH PRODUCTS AND FOOD BRANCH
HEALTH CANADA
OF CANADA

REGARDING SHARING AND
EXCHANGE OF INFORMATION ABOUT THERAPEUTIC PRODUCTS

PREAMBLE

The Food and Drug Administration (USFDA), Department of Health and Human Services of the United States of America and the Health Products and Food Branch (HPFB), Health Canada of Canada (collectively "the Participants") recognize the importance of timely and effective communication and collaboration between U.S. and Canadian governmental authorities. These communications are especially important on matters relating to the safety, quality, and efficacy of therapeutic products. Therapeutic products are defined as: pharmaceutical products for human and animal use (including active pharmaceutical ingredients, finished dosages and radiopharmaceutical products); biological products for human use (including gene, cell, blood, tissue, and organ therapies and products intended for transplantation or transfusion; vaccines; xenografts); and medical devices for human and animal 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. To that end, the Participants to this Memorandum of Understanding (MOU) intend to establish mechanisms by which the sharing and exchange of documents and/or information between staffs relating to the review and evaluation of investigational and marketing applications, establishment compliance, and post-marketing surveillance of these products would be facilitated as decided to by the Participants.

I. PURPOSE

This MOU is intended to enhance and strengthen the exchange of information and existing public health protection cooperative activities related to the regulation of the specified therapeutic products.

II. SCOPE

As defined in the Preamble, this MOU covers therapeutic products. The Participants intend to develop specific procedures for the sharing and exchange of regulatory, emergency management, 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, policies, procedures, and other technical documents available to the individual Participants that are related to such therapeutic products for which the Participants have responsibility.

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 including proposed market withdrawals and product recalls.

C. Information on quality defects or product recalls of therapeutic products known by the USFDA to have been manufactured or distributed in Canada, and products known by Canada HPFB to have been manufactured or distributed in the United States.

D. Information contained in clinical trials or related to marketing or investigational applications for therapeutic products, 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. Information related to orphan drug designations.

F. Inspection reports and product sample test results such as those describing the conformity of therapeutic products, or of a facility that manufactures, distributes, wholesales, tests, or imports these products, with applicable regulatory requirements.

G. Information on facilities registered or authorized in each Participant's country that then market product to the other Participant's country, including facilities that only export their products.

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

I. Information on activities that feature major public involvement.

J. Information on technology (e.g. information systems, database systems, and other related computer applications) that support the evaluation/review of the safety, quality, and efficacy of therapeutic products.

K. Information related to enforcement activities and product investigations. An area to be looked at in this regard relates to cross-border issues, including internet pharmacies, finished pharmaceutical controlled substances and counterfeit drugs.

Such information should 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 the United States and Canada. Information that is not appropriate for public dissemination is only to be shared according to the procedures and policies of the Participants as permitted by these respective laws. Neither the USFDA nor Canada HPFB may divulge trade secret information without the consent of the owner. With regard to any non-public information that may be provided to Canada HPFB by USFDA or to the USFDA by Canada HPFB, such transmissions are to be made in accordance with the specific signed confidentiality commitments and other requirements of the Participants.

IV. SOURCE OF FUNDING

Each Participant to this MOU recognizes the other's responsibility to fund and carry out its own activities subject to, and to the extent made possible, by the availability of appropriated funds, personnel, and other resources. Any sharing or exchange of information or other activity under this MOU is to be performed in accordance with applicable laws and regulations.

V. DURATION AND PROCESS

Cooperation under this MOU commences upon signature of the Participants and continues in effect for a period of ten (10) years. After an initial period of operation of one year, the Participants intend to jointly review the MOU and make adjustments as necessary.

The MOU may be modified by mutual consent of the Participants or terminated earlier by either Participant upon a 30-day written notification to the other Participant. The MOU may be extended for additional 10-year periods, with periodic reviews as needed and as decided by the Participants in the interim.

The Participants should establish a mechanism for regular bilateral meetings for the development of plans for joint work.

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 carry out its regulatory responsibilities and programs. In addition, no provision of this MOU restricts either Participant from conducting its own inspection of a therapeutic product manufacturing facility within the jurisdictional boundaries of the other country when needed to meet the needs of its own regulatory programs.

Signed at Ottawa, Canada on this eighteenth day of November 2003 in duplicate in the English language.

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

Mark B. McClellan, M.D., Ph.D.
Commissioner of Food and Drugs

FOR THE HEALTH PRODUCTS AND FOOD BRANCH
HEALTH CANADA
OF CANADA

Diane C. Gorman,
Assistant Deputy Minister