IMPLEMENTATION PLAN

For
The Memorandum of Understanding
Regarding the Sharing and Exchange of Information
about Therapeutic Products

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

I. Introduction

On November 18, 2003, the Health Products and Food Branch (HPFB) of Health Canada and the U.S. Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services concluded a Memorandum of Understanding (MOU) and respective Confidentiality Commitments. The intent of this implementation plan is to confirm the necessary governance and management elements to facilitate cooperation and the successful exchange of otherwise not public information between FDA and HPFB in accordance with the terms of the MOU and respective Confidentiality Commitments. The duration of this implementation plan is the same as that of the MOU.

The specific objectives of this Implementation Plan are to establish: (a) a governance structure for directing and monitoring the implementation of the MOU; (b) clear process by which each party will undertake the exchange of otherwise not public information; and (c) the process for setting and monitoring mutually agreed upon annual priorities for cooperation.

II. Governance

In order to ensure the smooth implementation of the MOU, an appropriate governance structure is required. The agreed governance structure for the MOU includes Senior Officials, a Steering Committee, and Coordinators.

Senior Officials

The **Assistant Deputy Minister of HPFB** and the **Deputy Commissioner for International and Special Programs of the FDA** will meet as needed, but will hold one formal Senior Officials' Meeting in January of each year. Each country will host the meeting on an annual rotating basis (starting with Canada hosting the 2006 meeting and so on). The objectives of these meetings are to:

- review progress in the implementation of the MOU in the previous year;
- set priorities for the year; and
- if deemed necessary, host policy discussions with key senior managers from both organizations.

Steering Committee

The Steering Committee will be co-chaired by the **Director General, Office of Regulatory and International Affairs (ORIA) of HPFB**, and the **Assistant Commissioner, Office of International Program (OIP) of the FDA**. In addition to the above, the Steering Committee will consist of the:

- Director of International Affairs, ORIA, HPFB
- coordinator from each organization; and
- senior managers of the centres/directorates of both organizations as appropriate.

The Steering Committee will hold quarterly discussions (either in-person meetings, teleconferences or videoconferences). During the discussions, the presiding chair will be the co-chair from the country hosting the Senior Officials' Meeting. The key responsibilities of the Steering Committee are:

- Recommendation of an annual work plan with priorities and strategic directions to the Senior Officials.
- Management of significant issues arising from the implementation of the MOU and Confidentiality Commitments not adequately addressed by the Coordinators.
- Evaluation and communication of the MOU implementation.
- Discussion of any request for disclosure of non-public information to third parties prior to the release of such information. Clearly such discussion will need to occur on an ad hoc basis as the situations arise. These discussions will by necessity occur most often outside the routinely scheduled discussions of the committee.

Coordinators

Each organization will identify a **coordinator** to track and monitor the implementation of the MOU. The coordinators will be the **Senior Policy Analyst, International Affairs, ORIA of HPFB**, and the **Associate Director for the Americas, OIP of the FDA.** The key responsibilities of the coordinators are to:

- Be the primary point of contact for each organization for all requests for non-public information to be shared or exchanged and for all other activities under the MOU (*see Section III*).
- Support, and provide advice to the Steering Committee and Senior Officials as required.
- Provide advice within their organization on what may or may not be exchanged under the auspices of the MOU (*see Section III*).
- Draft annual (calendar year) work plans with key priorities that will be presented for discussion at the Steering Committee, and ultimately presented for approval by Senior Officials.
- Create, within his/her own organization, a working group to help draft and monitor the implementation of the annual work plan as deemed appropriate.

III. Process for the Exchange of Otherwise Not Public Information

The process for the exchange of otherwise not public information will consist of the following three key elements:

3.1. The establishment of focal point of contacts

The coordinators are to be considered as the primary points of contact for all requests for otherwise not public information to be shared or exchanged and for all other activities under the MOU.

The main purpose of the focal points is to be able to track and monitor all non-public information exchanges (functionary) and to oversee the requests in order to assure they fall under the MOU and that they are handled procedurally in an appropriate manner (substantive) as stipulated in the procedures in *Section 3.2.*

3.2. The establishment of procedures for the exchange of information and documents

Procedures will be developed to ensure that all requests for otherwise not public information is shared or exchanged in accordance with the terms of the respective Confidentiality Commitments. These procedures will also:

- Delineate the steps for tracking priorities and activities.
- Confirm the officials in each organization who are able to authorize the sharing of non-public information.
- Identify key individuals within each organization who will be responsible, with the coordinators, for sharing non-public information.

3.3. The establishment of an orientation session

An orientation session will be established, and held on a regular basi,s to promote the goals and advantages of strengthening and the conditions for implementing regulatory cooperation between the two organizations. The session should be presented to the key officials from HPFB and the FDA who will be responsible for managing and coordinating the flow of information and work of the MOU. It will also address the general principles, responsibilities, and implications of the agreement, and the procedures highlighted in *Section 3.2.*

IV. Process for Establishing and Monitoring Mutually Agreed-Upon Priorities for Cooperation

The process for establishing mutual agreed-upon priorities for cooperation will include the following two elements:

4.1. The establishment of annual work plan with priorities

The Senior Officials will approve an annual (calendar year) work plan with key priorities based on the areas of cooperation highlighted in *Section V* during their meeting in January of each year *(see Section II)*.

This work plan may include activities established by specific program areas through their own cooperation frameworks (e.g., draft cooperation frameworks on product quality (TPD/CDER) and on medical devices (TPD/CDRH)).

4.2. The establishment of a tool to assess progress

The Steering Committee *(see Section II)* will establish a tool for assessing results and performance of annual priorities and other cooperation under the MOU. The assessment will include a summary of achievements realized to date and identification of areas where further improvements can be made. Based on this assessment, consideration may be given to either broadening or narrowing the scope of interaction between the organizations.

V. Areas of Cooperation and Types of Activities

In accordance with the scope of the MOU, the annual priorities should focus on the following four areas of cooperation, which will be reviewed by the Senior Officials on a regular basis:

- pre-market product review (e.g., applications reviews);
- post-market product safety (e.g., pharmacovigilance, compliance and enforcement);
- regulatory and public health policy and approaches (e.g., regulations, international policy and emerging public health issues); and
- regulatory infrastructure (e.g., E-review, regulatory databases, procedures for sharing information under the MOU).

In general, the types of activities to be undertaken under the above-mentioned areas of cooperation will include:

A) Information Exchange:

Regular exchange:

Regularly scheduled sharing of agreed routine quantitative and qualitative information on applications (both pre- and post-authorization) and status of regulatory documents under development.

Ad-hoc exchange:

Ad-hoc exchanges, while they may not be predicted, can be important for specific issues arising. Regardless of their frequency, they should be tracked for accountability and performance measurement. Examples of these kinds of information that might be exchanged include encountered difficulties in evaluating applications, significant safety issues that arise pre- and post-marketing, and significant advisories and warnings.

B) Scientific Meetings and Collaboration:

Invitations to staff members of HPFB and FDA to attend each other's scientific meetings, including advisory committees, and training sessions will be extended to the extent possible. Staff exchanges to study respective review processes and joint projects will also be explored.

Signed at Ottawa, Ontario, Canada, on this 1st day of December 2005 in duplicate in the English language.

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

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