

**PROTOCOL
REGARDING THE SHARING OF THE PHONETIC AND
ORTHOGRAPHIC COMPUTER ANALYSIS TOOL TO SUPPORT
REVIEW AND EVALUATE PROPRIETARY NAMES OF
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. PURPOSE

The Food and Drug Administration, Department of Health and Human Services of the United States of America (USFDA) and the Health Products and Food Branch, Health Canada of Canada (Canada HPFB) (collectively, "the Participants") intend this Protocol to implement section II.J of the 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 signed on November 18th, 2003 (MOU).

This Protocol is intended to enable, enhance and strengthen the exchange of information about computerized software programs developed by USFDA to minimize medication errors due to similar proprietary names of therapeutic products (Phonetic and Orthographic Computer Analysis (POCA)).

II. PROCEDURES

USFDA intends to:

1. provide Canada HPFB a CD copy of the POCA program.
2. provide Canada HPFB written documentation of the POCA program.
3. provide Canada HPFB all future modules (e.g., Spanish module) and enhancements of the POCA program.
4. develop a web-based version of POCA for use by the public, if possible.
5. cooperate with Canada HPFB to make POCA available with a French module.

Canada HPFB intends to:

1. provide USFDA all future modules (e.g., French module) and enhancements of the POCA program.
2. acknowledge the rights and ownership of POCA by USFDA in all references to POCA by Canada HPFB.

III. CONFIDENTIALITY

Any nonpublic information exchanged under this Protocol is subject to the Confidentiality Commitment, Statement of Legal Authority and Commitment from Health Canada Not to Publicly Disclose Non-Public Information Shared by the U.S. Food and Drug Administration, U.S. Department of Health and Human Services, signed November 18, 2003.

IV. SOURCE OF FUNDING

Each Participant to this Protocol is responsible for funding and carrying out its own activities. All activities undertaken pursuant to this protocol are to be conducted in accordance with the laws and regulations of the United States and Canada and are subject to the availability of appropriated funds, personnel, and other resources. Technical issues (e.g., installation, system failures) are the sole responsibility of the Participant receiving the information.

V. DURATION AND PROCESS

Implementation of the Protocol 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 Agreement and make adjustments as necessary. This Protocol may be modified by mutual consent of the Participants or terminated by either Participant upon 30-days' written notification to the other Participant. The Protocol may be extended for additional 10-year periods, with periodic reviews as needed and as decided by the Participants in the interim.

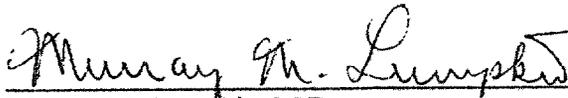
The Participants intend to establish a mechanism for regular bilateral meetings for the development of plans for joint work.

This Protocol 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 such arrangements.

Nothing in this Protocol is intended to diminish or otherwise affect the authority of either Participant to carry out its regulatory responsibilities and programs.

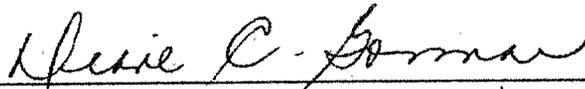
Signed at Ottawa, Ontario, Canada on the 1st day of December in duplicate in the English language.

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



Murray M. Lumpkin, M.D.
Deputy Commissioner (International and Special Programs)

**FOR THE HEALTH PRODUCTS AND FOOD BRANCH
HEALTH CANADA
OF CANADA**



Diane C. Gorman
Assistant Deputy Minister