DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA 225–05–8008]

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 Health Products and Food Branch, Health Canada of Canada

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a protocol regarding the sharing of the Phonetic and Orthographic Computer Analysis Tool to support review and evaluate proprietary names of therapeutic products between FDA and the Health Products and Food Branch, Health Canada of Canada (the Protocol). This Protocol is intended to enable, enhance, and strengthen the exchange of information about computerized software programs developed by FDA to minimize medication errors due to similar proprietary names of therapeutic products (Phonetic and Orthographic Computer Analysis).

DATES: The Protocol became effective December 1, 2005.

FOR FURTHER INFORMATION CONTACT: Matthew E. Eckel, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480, FAX: 301–480–0716.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(a) and (c), which states that all written agreements and understandings signed by FDA and other departments, agencies, and organizations shall be published in the **Federal Register**, except those agreements and memoranda of understanding between FDA and State or local government agencies that are cooperative work-sharing agreements, the agency is publishing notice of this Protocol.

Dated: January 4, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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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 Sates 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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0386 (formerly Docket No. 03D–0386)]

Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP.'' The guidance describes a formal, two-tiered dispute resolution process intended to resolve disputes of scientific and technical issues relating to current good manufacturing practice (CGMP) that arise during FDA inspections of pharmaceutical manufacturers.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448; or Communications Staff (HFV–12), Center for Veterinary Medicine, 7519 Standish Pl., Rockville, MD 20855.

The guidance may also be obtained by mail by calling the Center for Biologics Evaluation and Research at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 28052. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Edward M. Sherwood, Center for Drug Evaluation and Research (HFD–3), Food and Drug Administration, White Oak 21, rm. 3528, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–1605.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP.'' The guidance was developed as part of the FDA initiative ''Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach,'' which was announced in August 2002. The initiative focuses on FDA's current CGMP program and covers the manufacture of veterinary and human drugs, including human biological drug products.

The agency formed the Dispute Resolution Working Group comprising representatives from the Office of Regulatory Affairs (ORA), the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Center for Veterinary Medicine (CVM). The working group met weekly on issues related to the dispute resolution process