



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

CONFIDENTIALITY COMMITMENT

**STATEMENT OF LEGAL AUTHORITY
AND COMMITMENT**

FROM

**THE UNITED STATES FOOD AND DRUG ADMINISTRATION (US FDA)
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED
BY THE CANADIAN FOOD INSPECTION AGENCY (CFIA)**

The CFIA is authorized to disclose non-public information to the US FDA regarding products regulated by CFIA as part of cooperative law enforcement or cooperative regulatory activities.

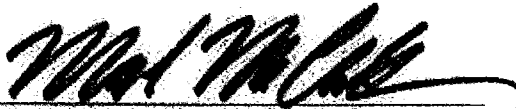
US FDA understands that some of the information it receives from CFIA may include non-public information exempt from public disclosure under Canadian laws, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal advice and recommendations. US FDA understands that this non-public information is shared in confidence, and that Canada considers it critical that US FDA maintains the confidentiality of the information. Public disclosure of this information by US FDA could seriously jeopardize any further scientific and regulatory interactions between USFDA and CFIA. CFIA will advise US FDA of the non-public status of the information at the time the information is shared.

Therefore, US FDA certifies that it:

1. has the authority to protect the non-public information provided to US FDA in confidence by CFIA from public disclosure;
2. will not publicly disclose the non-public information provided by CFIA without the written authorization of the owner of the information, the written authorization from the individual who is the subject of the personal privacy information, or a written statement from the CFIA that the information no longer has non-public status;
3. will inform CFIA within two working days of any effort made to obtain CFIA-provided non-public information from US FDA by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of CFIA-provided non-

public information, US FDA will take all measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure, and

4. will promptly inform CFIA of any changes to United States laws and regulations, or US FDA policies or procedures that would affect US FDA's ability to honor the agreements in this document.



Mark B. McClellan, M.D., Ph.D.

12/22/03

Date

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(Printed name)

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