



**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 HEALTH PRODUCTS AND FOOD BRANCH (HPFB)
OF HEALTH CANADA**

Acknowledgement

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

It is the information management policy of the HPFB to treat all information provided by an applicant in support of an application, including the notification process, as confidential information. HPFB's reviewers and assessment reports are also considered confidential information. More specifically, the HPFB treats all information received as if it were confidential information for purposes of the *Access to Information Act* and the *Privacy Act*. HPFB will obtain the written consent of the applicant prior to providing any information from submission filed in support of seeking market authorization in Canada. The HPFB will advise the FDA at the time of the sharing of the information of the nature of the information it is providing.

US FDA understands that some of the information it receives from HPFB 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 Health Canada and the confidence of regulated stakeholders and consumers. Health Canada will advise US FDA of the non-public status of the information at the time the information is shared.

statement of legal authority and commitment

Therefore, US FDA certifies that it:

1. has the authority to protect the non-public information provided to US FDA in confidence by the Health Canada from public disclosure;
2. will not publicly disclose the non-public information provided by Health Canada 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 Health Canada that the information no longer has non-public status;
3. will inform Health Canada within two working days of any effort made to obtain Health Canada-provided non-public information from US FDA by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of Health Canada-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 Health Canada 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.

Nov. 18, 2003
Date

Mark McClellan

(Printed name)

Commissioner of Food and Drugs
United States Food and Drug Administration
United States Department of Health and Human Services

HF-1
5600 Fishers Lane
Rockville, Maryland
USA-20957
Telephone: +1 301-827-2410
Facsimile: +1 301-827-3100