

Santé Canada

Health Products and Food Branch

Direction générale des produits de santé et des aliments

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 (USFDA), U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

The United States Food and Drug Administration (USFDA), a part of the United States Department of Health and Human Services is authorized under 21 C.F.R. § 20.89 ("Communications with Foreign Government Officials") to disclose non-public information to Health Canada regarding USFDA regulated products as part of cooperative law enforcement or cooperative regulatory activities.

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

Therefore, Health Canada certifies that it:

- 1. has the authority to protect the non-public information provided to Health Canada in confidence by the USFDA from public disclosure;
- 2. will not publicly disclose the USFDA-provided non-public information 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 USFDA that the information no longer has non-public status;

- 3. will inform USFDA within two working days of any effort made to obtain USFDA-provided non-public information from Health Canada by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of USFDA-provided non-public information, Health Canada 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 USFDA of any changes to Canadian laws, or Health Canada policies or procedures, that would affect Health Canada's ability to honor the agreements in this document.

Diane C. Gorman

Assistant Deputy Minister

Date