



CONFIDENTIALITY COMMITMENT

**STATEMENT OF LEGAL AUTHORITY
AND COMMITMENT**

**NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED
AMONG**

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

**THE U. S. FOOD AND DRUG ADMINISTRATION (USFDA), U.S.
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

AND

**FEDERAL COMMISSION FOR THE PROTECTION FROM SANITARY RISKS
(COFEPRIS)**

MINISTRY OF HEALTH OF THE UNITED MEXICAN STATES

Health Canada, USFDA and COFEPRIS, are herein referred to collectively as “the Participants”.

The Health Products and Food Branch of Health Canada is authorized by Common Law and paragraph 8(2)(f) of the *Privacy Act* to disclose non-public information to COFEPRIS and USFDA regarding products regulated by Health Canada as part of cooperative law enforcement or cooperative regulatory activities.

The United States Food and Drug Administration 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 COFEPRIS and HPFB regarding USFDA regulated products as part of cooperative law enforcement or cooperative regulatory activities.

The Federal Commission for Protection From Sanitary Risks of the Ministry of Health of the United Mexican States is authorized to disclose non-public information, in accordance with the Federal Law of Transparency and Access to Public Governmental Information, to HPFB and USFDA regarding products regulated by COFEPRIS as part of cooperative law enforcement or cooperative regulatory activities.

Information that is not appropriate for public dissemination is only to be shared according to the procedures and policies of the Participants as permitted by these respective laws. None of the Participants may divulge trade secret information without the consent of the owner.



The Participants understand that some of the information a Participant receives from another Participant may include non-public information exempt or restricted from public disclosure under the laws and regulations of the country providing the information, such as confidential commercial information; trade secret information; personal information; law enforcement information; or internal, pre-decisional information. Each Participant understands that this non-public information is shared in confidence, and expects that the other Participants will maintain its confidence. Participants consider it critical that the confidentiality of the information be maintained. Public disclosure of this information by any Participant could seriously jeopardize any further scientific and regulatory interactions between the Participants. Each Participant will advise the recipient of the non-public status of the information at the time that the information is shared.

The participants will use the non-public information exclusively for the purposes of the Trilateral Cooperation Charter, signed on the twenty-seventh day of February 2004, and any amendments or modifications to that Charter.

Therefore, Health Canada certifies that it:

1. has the authority to protect the non-public information provided to Health Canada in confidence by the other Participants from public disclosure;
2. will not publicly disclose the non-public information provided by the other Participants without 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 Participant that provided the information that the information no longer has non-public status;
3. will inform a Participant that provides non-public information within two working days of any effort made to obtain, by judicial or legislative mandate, the non-public information. If such judicial or legislative mandate orders disclosure of non-public information a Participant provided, 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 each Participant of any changes to Canadian laws and regulations, or Health Canada policies or procedures that would affect Health Canada's ability to honor the agreements in this document.

Therefore, USFDA certifies that it:

1. has the authority to protect the non-public information provided to USFDA in confidence by the other Participants from public disclosure;



2. will not publicly disclose the non-public information provided by the other Participants without 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 Participant that provided the information that the information no longer has non-public status;
3. will inform a Participant that provides non-public information within two working days of any effort made to obtain, by judicial or legislative mandate, the non-public information. If such judicial or legislative mandate orders disclosure of non-public information a Participant provided, USFDA 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 each Participant of any changes to United States laws and regulations, or USFDA policies or procedures that would affect USFDA's ability to honor the agreements in this document.

Therefore, COFEPRIS certifies that it:

1. has the authority to protect the non-public information provided to COFEPRIS in confidence by the other Participants from public disclosure;
 2. will not publicly disclose the non-public information provided by the other Participants without 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 Participant that provided the information that the information no longer has non-public status;
 3. will inform a Participant that provides non-public information within two working days of any effort made to obtain, by judicial or legislative mandate, the non-public information. If such judicial or legislative mandate orders disclosure of non-public information a Participant provided, COFEPRIS 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 each Participant of any changes to Mexican laws and regulations, or COFEPRIS policies or procedures that would affect COFEPRIS's ability to honor the agreements in this document.
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Signed on this 21 day of June 2004, in the English, French and Spanish languages, each version being equally valid.

For The Health Products and Food Branch
HEALTH CANADA
CANADA:

Diane C. Gorman
Assistant Deputy Minister
Head of Delegation (Canada)

For The Food and Drug Administration
DEPARTMENT OF HEALTH AND HUMAN SERVICES
THE UNITED STATES OF AMERICA:

Lester M. Crawford, D.V.M., Ph.D
Acting Commissioner of Food and Drugs
Head of Delegation (United States of America)

For La Comision Federal para la Proteccion contra Riesgos Sanitarios
SECRETARIA DE SALUD
MEXICO:

Ernesto Enriquez Rubio
Federal Commissioner
Head of Delegation (Mexico)