



CONFIDENTIALITY COMMITMENT STATEMENT OF LEGAL AUTHORITY AND
COMMITMENT NOT TO DISCLOSE NON-PUBLIC INFORMATION SHARED
BETWEEN THE FEDERAL COMMISSION FOR PROTECTION AGAINST
SANITARY RISKS (COFEPRIS) AND THE U. S. FOOD AND DRUG
ADMINISTRATION (FDA)

FDA may share non-public information concerning its law enforcement or regulatory investigation of the safety, effectiveness, or quality of a product with the Federal Commission for Protection against Sanitary Risks (COFEPRIS – Spanish acronym for that Federal Commission), in accordance with 21 C.F.R. § 20.89 (“Communications with Foreign Government Officials”). This sharing is in the interest of public health and is for the limited purpose of conducting cooperative law enforcement or regulatory efforts. This commitment is in accordance with the Cooperative Arrangement among the Department of Health and Human Services and the Department of Agriculture of the United States of America and the Secretariat of Health and the Secretariat of Agriculture, Livestock, Rural Development, Fish, and Food of the United Mexican States regarding cooperative efforts to enhance the safety of foods for human consumption signed on September 4, 2001.

COFEPRIS understands that some or all of the non-public information is considered to be confidential commercial or trade secret information, personal privacy information, or pre-decisional or other non-public information exempt from disclosure under the laws and regulations of the United States, and that FDA considers it extremely important that COFEPRIS maintains the confidentiality of the information.

COFEPRIS understands that FDA will follow its regulatory procedures before sharing non-public information with COFEPRIS, and that non-public information that FDA shares remains FDA's property. FDA may take steps at any time to retrieve the information from COFEPRIS. COFEPRIS also understands that further disclosure of information shared by FDA is protected by United States law.

Therefore, COFEPRIS certifies that it:

1. has the authority to protect the non-public information from disclosure,
2. if requested, would provide copies of the relevant statutes, regulations, court decisions, or other documents that establish this authority or has provided a summary of its legal authority.



3. shall not disclose the non-public information without the written authorization of the sponsor of this confidential commercial or trade secret information, the written authorization from the individual who is the subject of the information, or a written statement from FDA that the information no longer has non-public status. COFEPRIS shall inform FDA within 48 hours of any effort made to obtain the information from it by subpoena, court order, or other compulsory process, including a request under any Freedom of Information type of law. COFEPRIS may disclose the information to a court of competent jurisdiction if the court orders such disclosure, COFEPRIS has taken legal measures in an effort to ensure that the information shall be disclosed in a manner that protects the information from public disclosure, and has notified FDA.
4. shall promptly inform FDA of any changes to its laws, policies or procedures that would affect its ability to maintain the confidentiality of the information FDA shares, and

Signed in Mexico City, Federal District, this 15 day of April, 2002, in quadruplicate, in the English and Spanish languages.

Ernesto Enríquez Rubio.

Federal Commissioner for Protection Against Sanitary Risks

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