



**STATEMENT ON CONFIDENTIALITY ARRANGEMENTS BY  
THE UNITED STATES FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
TO FACILITATE THE SHARING OF NON-PUBLIC INFORMATION  
WITH  
THE EUROPEAN FOOD SAFETY AUTHORITY**

The United States Food and Drug Administration, an agency within the Department of Health and Human Services (FDA/HHS), is authorized under 21 C.F.R. § 20.89 to share non-public information with the European Food Safety Authority (EFSA) of the European Union regarding FDA/HHS-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

FDA/HHS is pleased to facilitate the sharing with EFSA of non-public documents and/or information related to products or substances that are in the field of competence of both EFSA and FDA/HHS.

FDA/HHS understands that some of the information it receives from EFSA may include non-public information exempt from public disclosure under the laws and regulations of the United States of America, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information.

The term "confidential commercial information" includes information referred to in the U.S. Freedom of Information Act, 5 U.S.C. § 552(b)(4) and in Regulation (EC) No. 1049/2001.

FDA/HHS notes that it is an essential element of sharing information that confidential information emanating from EFSA be treated as such. FDA/HHS understands that EFSA considers it crucial that this non-public information be protected from disclosure.

FDA/HHS affirms that it has the authority to protect non-public information, including confidential commercial information, provided to its officials or representatives in confidence by EFSA, under the U.S. Freedom of Information Act (5 U.S.C. § 552); the Trade Secrets Act (18 U.S.C. § 1905); section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 331(j)), and other applicable laws, and will protect such information from public disclosure.

FDA/HHS will inform EFSA promptly of any effort made by judicial or legislative mandate to obtain EFSA-provided non-public information from FDA/HHS. If such judicial or legislative mandate orders disclosure of EFSA-provided non-public information, FDA/HHS will take all appropriate legal measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure.

FDA/HHS will promptly inform EFSA of any changes to laws, policies, or procedures that would affect FDA/HHS's ability to honor the commitments in this document.



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Date