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

The European Food Safety Authority (EFSA) of the European Union (EU) founded under Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 which under Article 38 and 39 regulates the dissemination and protection of information, is authorised to share non-public information with the United States Food and Drug Administration, Department of Health and Human Services (FDA/HHS).

EFSA is pleased to facilitate the sharing with FDA/HHS 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.

EFSA understands that some of the information it receives from FDA/HHS 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 US Freedom of Information Act, 5 U.S.C. §552(b)(4).

In the European Union, the basis and grounds for exemptions from public disclosure are laid down in Regulation (EC) No. 1049/2001 of the European Parliament and of the Council regarding public access and include:

1. Commercial interests of a natural or legal person, including intellectual property;
2. Privacy and integrity of individuals notably as regards protection of personal data;
3. Internal decision-making and preliminary consultations;
4. Court proceedings and legal advice; and
5. The European Union or EFSA's public interests, international relations, or financial interests.

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

EFSA affirms that it has the authority to protect non-public information, including confidential commercial information, provided to its officials or representatives in confidence by FDA/HHS, and will protect such information as information not to be disclosed under Article 4.1(a) of Regulation (EC) No. 1049/2001 and other applicable laws.

EFSA will inform FDA/HHS promptly of any judicial initiative to obtain FDA/HHS-provided non-public information from EFSA. In the event of a court order to disclose FDA/HHS-provided non-public information, EFSA 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.

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

2/07/07

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Date

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 to 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 US 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 Freedom of Information Act (FOIA) (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.

Andrew C. von Eschenbach

2 July 2007

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