



**STATEMENT OF AUTHORITY
AND
CONFIDENTIALITY COMMITMENT FROM
THE UNITED STATES FOOD AND DRUG ADMINISTRATION
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION
SHARED BY
THE EUROPEAN MEDICINES AGENCY**

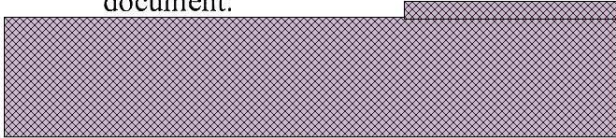
The European Medicines Agency (EMA) has affirmed that it has the authority, within the scope of its activities to protect non-public information, including commercial confidential information, provided to its officials or representatives in confidence by the United States Food and Drug Administration (FDA), and will protect such information as information not to be disclosed under Article 4.1(a) of Regulation (EC) No 1049/2001.

FDA has affirmed that it has the authority to protect non-public information, including commercial confidential information, provided to its officials or representatives by EMA, 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, is authorized under 21 C.F.R. § 20.89 to disclose non-public information to the European Medicines Agency (EMA) regarding FDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

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

Therefore, FDA certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to FDA in confidence by EMA;
2. will not publicly disclose such EMA-provided non-public information without prior agreement from the EMA, or written authorization from the individual who is the subject of the personal privacy information, or a written statement from EMA that the information no longer has non-public status;
3. will inform EMA promptly of any effort made by judicial or legislative mandate to obtain EMA-provided non-public information from FDA. If such judicial or legislative mandate orders disclosure of EMA-provided non-public information, FDA 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; and
4. will promptly inform EMA of any changes to FDA's laws, or to any relevant policies or procedures that would affect FDA's ability to honor the commitments in this document.



14 Sept 2010

Murray M. Lumpkin, M.D.
Deputy Commissioner for International Programs
US Food and Drug Administration
Silver Spring, Maryland

Date