



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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

The United States Food and Drug Administration (FDA), has affirmed that it has the authority to protect non-public information, including commercial confidential information, provided to its officials or representatives in confidence by the European Medicines Agency (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 EMA regarding FDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

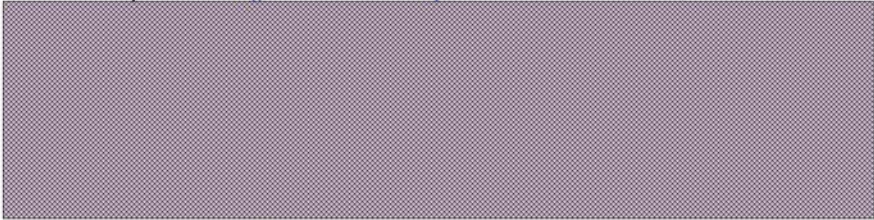
EMA has affirmed that it has the authority, within the scope of its activities to protect non-public information, including commercial confidential information, provided to its officials or representatives in confidence by the United States Food and Drug Administration (FDA), and will protect such information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

EMA understands that some of the information it receives from FDA 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. EMA understands that this non-public information is shared in confidence and that FDA considers it critical that EMA maintain the confidentiality of the information. Public disclosure of this information by EMA could seriously jeopardise any further confidential scientific and regulatory interactions between FDA and EMA. FDA will advise EMA of the non-public status of the information at the time that the information is shared.



Therefore, EMA certifies that it:

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



Thomas Lönngren
Executive Director
European Medicines Agency
London, United Kingdom

14/9 2010

Date