



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Robert Madelin
Director General
Health and Consumer Protection Directorate-General
European Commission
Rue de la Loi 200 / Wetstraat 200
B-1049 Brussels
BELGIUM

Dear Mr. Madelin,

The United States Food and Drug Administration (FDA) is pleased to facilitate the sharing, by the European Commission's Health and Consumer Protection Directorate General (DG SANCO), of non-public documents and/or information related to products that are regulated by both FDA and DG SANCO.

FDA notes that it is an essential element of sharing information that confidential information emanating from DG SANCO will be treated as such.

On each occasion where there is a request for disclosure to third parties of non public information received from DG SANCO, FDA will consult with DG SANCO.

Some of the nonpublic documents or information that SANCO may share may contain confidential commercial information, trade secret information, personal privacy information, law enforcement information, or internal predecisional information. FDA affirms that it has the authority to protect the confidentiality of non-public information 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. Under the FOIA, the above non-public information shared by DG SANCO with FDA can be withheld from public disclosure. FDA, therefore, in accordance with these statutes, consents not to disclose such non-public information provided to FDA by DG SANCO absent the written permission or written confirmation by DG SANCO that the non-public information no longer has confidential status. The term "confidential commercial information" includes information referred to in the FOIA, 5 U.S.C. § 552(b) (4) and in Regulation (EC) No. 1049/2001.

Lester M. Crawford
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Acting Commissioner of Food and Drugs
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