



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Director-General

SANCO

06. 06. 2005

Brussels, 6 June 2005
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Dear Dr. Crawford,

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

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

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

DG SANCO affirms that it has the authority to protect non-public information, including confidential commercial information, provided to its officials or representatives by FDA, and will protect such information as information not to be disclosed under Article 4.1(a) of Regulation (EC) No. 1049/2001. DG SANCO understands that FDA considers it crucial that this non-public information be protected from disclosure; otherwise, it could endanger the international relations between DG SANCO and FDA. 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.

Your sincerely -

Robert Madelin

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