CONFIDENTIALITY ARRANGEMENT

BETWEEN

THE UNITED STATES FOOD AND DRUG ADMINISTRATION

AND

THE FRENCH HEALTH PRODUCTS SAFETY AGENCY

The United States Food and Drug Administration (USFDA) and the French Health Products Safety Agency (Afssaps) (hereinafter the Participants) consider it to be a necessity to establish and maintain a high level of co-operation between USFDA and Afssaps in order to increase medical safety and the protection of public health. In order to attain that high level of co-operation, it is essential to be able to share information that is protected from public disclosure by French or U.S. law (non-public information) as part of cooperative law enforcement or regulatory activities.

Such non-public information includes documents held or prepared by the USFDA or Afssaps, whether final or pre-decisional, containing: 1) information the public disclosure of which would be likely to harm the personal privacy of an individual or the secrecy of personal files or would constitute a clearly unwarranted invasion of personal privacy, such as medical files; 2) trade secret information, including any commercially valuable plan, formula, "recipe," process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort, for example, information relating to the manufacturing process; 3) confidential commercial or financial information of a type that the submitter would customarily not release to the public or the disclosure of which would be likely to cause substantial harm to the competitive position of the submitter; 4) information compiled during or about an investigation for purposes of conducting any potential or actual enforcement activities; or 5) internal, pre-decisional information, for example opinions and recommendations that are part of agency deliberations. Such information may be in statistical, technical, legal, or operational form and shared either orally or in writing, whatever the medium used for the capture, storage, or transmission of the information.

Both Participants consider that such information is shared in confidence, consider it critical that the other maintains the confidentiality of such information, and recognize that public disclosure of this information could seriously jeopardize any further scientific and regulatory interactions between the Participants.

The Participants commit as follows:

1. The Participants have the authority to protect from public disclosure the above-mentioned non-public information without prejudice to the application of legal provisions currently in force under which the courts may order the Participants to release a given document. The Participants will ensure that such information that is received from the other Participant will only be made available to employees or contractors of the Participants who have a

need to know for the purpose of achieving the Participants' missions of medical safety and who are bound by an obligation to maintain the confidentiality of the information.

2. The Participants will not publicly disclose such non-public information without written authorization from the owner of the information, written authorization from the individual who is the subject of the personal privacy information, or a written statement from the other Participant that the information no longer has non-public status;

3. Each Participant will inform the other promptly of any effort made by judicial or legislative mandate to obtain non-public information received from the other Participant. If such judicial or legislative mandate orders disclosure of such non-public information, the Participant 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.

4. Each Participant will promptly inform the other of any changes to the Participant's laws, regulations, or any relevant policies or procedures that would affect the Participant's ability to honor the commitments in this document.

5. Requests for non-public information will be made in written form (mail, electronic mail, telefax. etc.) and the documents requested pursuant to this agreement will be supplied in language of the Participant supplying the information.

6. This agreement shall become effective on the date of the signature of both Participants and shall thereafter continue for 5 years, renewable upon mutual written consent.

Agreed and accepted on behalf of USFDA:

Andrew C. von Eschenbach, M.D. for

Acting Commissioner of Food and Drugs
Food and Drug Administration
Department of Health and Human Services
United States of America

Date: 30 Jun 06

Agreed and accepted on behalf of Afssaps:

Jean MARIMBERT

Directeur Général
Agence française de sécurité sanitaire des produits de santé (Afssaps)
FRANCE

Date: 08 Fe. 06