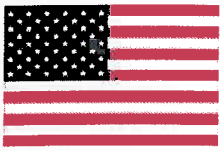

CONFIDENTIALITY ARRANGEMENT
BETWEEN
THE UNITED STATES FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
THE BELGIAN FEDERAL AGENCY FOR MEDICINES
AND HEALTH PRODUCTS

The United States Food and Drug Administration (USFDA) and the Federal Agency for Medicines and Health Products (FAMH) (hereinafter the Participants) are each authorized, under their respective legislation, to share certain non-public information with the other Participant regarding USFDA- and FAMH-regulated products as part of cooperative law enforcement or cooperative regulatory activities. Examples of such cooperative law enforcement or cooperative regulatory activities could involve, but are not limited to, the sharing of information related to product approval or registration applications, inspection reports, and safety/surveillance information.

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

Therefore, each Participant certifies that the Participant:

1. has the authority to protect from public disclosure such non-public information provided in confidence by the other Participant;

2. will not publicly disclose such non-public information provided by the other Participant without the written authorization of the owner of the information, the 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. will inform the other Participant promptly of any effort made by judicial or legislative mandate to obtain such provided non-public information from the Participant. If such judicial or legislative mandate orders disclosure of such provided non-public information, the receiving Participant will take all appropriate legal measures available 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 the other Participant of any changes to the Participant's laws, or to any relevant policies or procedures that would affect the Participant's ability to honor the commitments in this document.

Accepted on behalf of USFDA:

Andrew C. von Eschenbach, M.D.

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

Date: 23 April 07

Accepted on behalf of FAMH:

Piet Vanthemsche, médecin vétérinaire

Administrateur général
Federal Agency for Medicines and Health Products
Belgium

Date: 23.04.2007