

**STATEMENT OF AUTHORITY AND CONFIDENTIALITY COMMITMENT
FROM
THE NETHERLANDS MEDICINES EVALUATION BOARD,
THE NETHERLANDS MEDICINES EVALUATION BOARD AGENCY
AND
THE NETHERLANDS HEALTH CARE INSPECTORATE
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED BY THE
UNITED STATES FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

The United States Food and Drug Administration, an agency within the Department of Health and Human Services (HHS/FDA), is authorized under 21 C.F.R. § 20.89 to disclose non-public information to the Netherlands Medicines Evaluation Board (MEB), the Netherlands Medicines Evaluation Board Agency (MEB Agency), and the Netherlands Health Care Inspectorate (IGZ) regarding HHS/FDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

The MEB, the MEB Agency, and the IGZ understand that some of the information they receive from HHS/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. The MEB, the MEB Agency, and the IGZ understand that this non-public information is shared in confidence and that HHS/FDA considers it critical that the MEB, the MEB Agency, and the IGZ maintain the confidentiality of the information. Public disclosure of this information by the MEB, the MEB Agency, or the IGZ could seriously jeopardize any further scientific and regulatory interactions between HHS/FDA, on the one hand, and the MEB, the MEB Agency, and the IGZ, on the other hand. HHS/FDA will advise the MEB, the MEB Agency, or the IGZ of the non-public status of the information at the time that the information is shared.

Therefore, the MEB, the MEB Agency and the IGZ certify that they:

1. have the authority to protect from public disclosure such non-public information provided to the MEB, the MEB Agency or the IGZ in confidence by the HHS/FDA;
2. will not publicly disclose such HHS/FDA-provided non-public information 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 HHS/FDA that the information no longer has non-public status;
3. will inform HHS/FDA promptly of any effort made by judicial or legislative mandate to obtain HHS/FDA-provided non-public information from the MEB, the MEB Agency or the IGZ. If such judicial or legislative mandate orders disclosure of HHS/FDA-provided non-public information, the MEB, the MEB Agency and the IGZ 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 HHS/FDA of any changes to the Netherlands' laws, or to any relevant policies or procedures, that would affect the MEB's, the MEB Agency's or the IGZ's ability to honor the commitments in this document.

Accepted on 2 October 2006 by:



Frits (J.F.F.) Lekkerkerker
Chairman
Medicines Evaluation Board

Accepted on 2 October 2006 by:

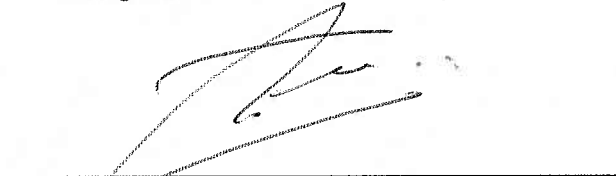


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