



**STATEMENT OF AUTHORITY
AND CONFIDENTIALITY COMMITMENT**

FROM

**THE UNITED STATES FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED

BY

**THE NETHERLANDS MEDICINES EVALUATION BOARD,
THE NETHERLANDS MEDICINES EVALUATION BOARD AGENCY,
AND
THE NETHERLANDS HEALTH CARE INSPECTORATE**

The Netherlands Medicines Evaluation Board (MEB), the Medicines Evaluation Board Agency (MEB Agency) and the Netherlands Health Care Inspectorate (IGZ) are authorized to disclose non-public information to the United States Food and Drug Administration, Department of Health and Human Services (HHS/FDA), regarding MEB-, MEB Agency-, and IGZ-regulated products as part of cooperative law enforcement or cooperative regulatory activities.


HHS/FDA understands that some of the information it receives from the MEB, the MEB Agency, and the IGZ may include non-public information exempt from public disclosure under the laws and regulations of the Netherlands, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information. HHS/FDA understands that this non-public information is shared in confidence and that the MEB, the MEB Agency, and the IGZ consider it critical that HHS/FDA maintain the confidentiality of the information. Public disclosure of this information by HHS/FDA could seriously jeopardize any further scientific and regulatory interactions between the MEB, the MEB Agency, and the IGZ, on the one hand, and HHS/FDA, on the other hand. The MEB, the MEB Agency, and the IGZ will advise HHS/FDA of the non-public status of the information at the time that the information is shared.

Therefore, HHS/FDA certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to HHS/FDA in confidence by the MEB, the MEB Agency, and the IGZ;

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

Accepted by:



Andrew C. von Eschenbach, M.D.
Acting Commissioner for Food and Drugs
United States of America

02 Oct 06
Date

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