

**STATEMENT OF AUTHORITY AND CONFIDENTIALITY COMMITMENT
FROM
THE MEDICAL PRODUCTS AGENCY OF SWEDEN
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED
BY
THE UNITED STATES FOOD AND DRUG ADMINISTRATION
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

The United States Food and Drug Administration, a part of the Department of Health and Human Services (HHS/FDA), is authorized under 21 C.F.R. § 20.89 (“Communications with Foreign Government Officials”) to disclose non-public information to the Medical Products Agency of Sweden (MPA) regarding HHS/FDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

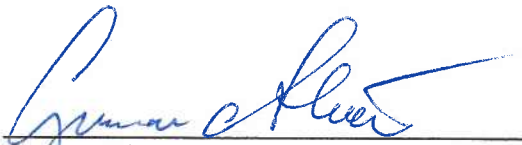
MPA understands that some of the information it receives from HHS/FDA may include non-public information exempt from public disclosure under the laws and regulations of the United States of America, such as confidential commercial information; trade secret information; personal privacy information; law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

Therefore, MPA certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to MPA in confidence by 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 unless otherwise specifically ordered by the Administrative Court of Appeal in Stockholm;
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 MPA. If such judicial or legislative mandate orders disclosure of HHS/FDA-provided non-public information, MPA 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 HHS/FDA of any changes to MPA's laws, or to any relevant policies or procedures that would affect MPA's ability to honor the commitments in this document.

This commitment will become effective upon HHS/FDA's signing of a similar commitment and will remain in effect until cancelled by MPA or HHS/FDA upon 30 days' written notice.



Gunnar Alvan
Director General
Medical Products Agency
P.O. Box 26
SE-751 03 Uppsala
Sweden
Phone: +46 18 174600
Fax: +46 18 548566

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Date