

**STATEMENT OF AUTHORITY
AND
CONFIDENTIALITY COMMITMENT FROM
THE DANISH MEDICINES AGENCY
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED
BY
THE UNITED STATES FOOD AND DRUG ADMINISTRATION**

The United States Food and Drug Administration (FDA), is authorized under 21 C.F.R. § 20.89 to disclose non-public information to the Danish Medicines Agency (DMA) regarding FDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

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

Therefore, DMA certifies that it:

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

Signed on behalf of DMA:



Thomas Senderovitz
Director General
Danish Medicines Agency

Axel Heides Gade 1
2300, Copenhagen,
Denmark

09 MAY 2016
Date