

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

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

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

Therefore, FDA certifies that it:

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

Signed on behalf of FDA:

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5/19/2016

Date

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