

**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  
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 Danish Medicines Agency (DMA) regarding HHS/FDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

The DMA 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. The DMA understands that this non-public information is shared in confidence and that HHS/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 HHS/FDA and DMA. HHS/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 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 DMA. If such judicial or legislative mandate orders disclosure of HHS/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 HHS/FDA of any changes to DMA's laws, or to any relevant policies or procedures, that would affect DMA'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 HHS/FDA or DMA upon 30 days written notice. However, even following such cancellation, HHS/FDA will continue to protect from public disclosure all nonpublic information that was shared by DMA with HHS/FDA while the commitment was in effect.

  
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Jytte Lyngvig

Chief Executive Officer  
Danish Medicines Agency

Axel Heides Gade 1  
Copenhagen 2300 S  
Denmark

+ 45 44 88 95 95 (ph)  
+ 45 44 88 95 99 (fax)

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Date

