



**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 DANISH MEDICINES AGENCY**

The Danish Medicines Agency (DMA) is authorized to disclose non-public information to the United States Food and Drug Administration, an agency within the Department of Health and Human Services (HHS/FDA), regarding DMA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

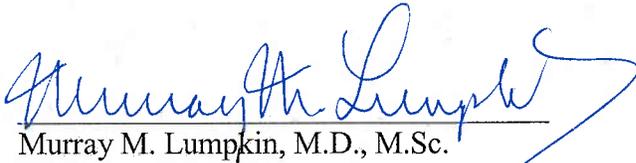
HHS/FDA understands that some of the information it receives from DMA may include non-public information exempt from public disclosure such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information. HHS/FDA understands that this non-public information is shared in confidence, and that DMA considers 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 USFDA and DMA. DMA 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 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 HHS/FDA. If such judicial or legislative mandate orders disclosure of DMA-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 DMA 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.

This commitment will become effective upon DMA's signing of a similar commitment and will remain in effect until cancelled by DMA or HHS/FDA upon 30 days written notice. However, even following such cancellation, DMA will continue to protect from public disclosure all nonpublic information that was shared by HHS/FDA with DMA while the commitment was in effect.



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Deputy Commissioner
International and Special Programs
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UNITED STATES OF AMERICA

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Date

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