



**STATEMENT OF AUTHORITY  
AND CONFIDENTIALITY COMMITMENT**

**FROM**

**THE UNITED STATES FOOD AND DRUG ADMINISTRATION  
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED**

**BY**

**THE MEDICAL PRODUCTS AGENCY OF SWEDEN**

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

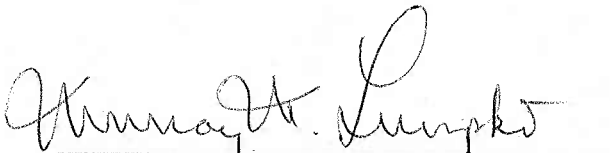
HHS/FDA understands that some of the information it receives from MPA may include non-public information exempt from public disclosure under the laws and regulations of Sweden, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information. HHS/FDA understands that this non-public information is shared in confidence and that MPA 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 MPA and HHS/FDA. MPA 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 MPA;
2. will not publicly disclose such MPA-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 MPA that the information no longer has non-public status;

3. will inform MPA promptly of any effort made by judicial or legislative mandate to obtain MPA-provided non-public information from HHS/FDA. If such judicial or legislative mandate orders disclosure of MPA-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 MPA of any changes to HHS/FDA's 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 MPA's signing of a similar commitment and will remain in effect until cancelled by HHS/FDA or MPA upon 30 days' written notice.

  
Murray M. Lumpkin, M.D., M.Sc.

31 March 06  
Date

Deputy Commissioner  
International and Special Programs  
Food and Drug Administration  
Department of Health and Human Services  
UNITED STATES OF AMERICA

5600 Fishers Lane  
Rockville, MD 20857  
(301) 827-5709 (ph)  
(301) 443-3100 (fax)