



IRISH MEDICINES BOARD

**CONFIDENTIALITY COMMITMENT AND STATEMENT OF AUTHORITY
FROM IRISH MEDICINES BOARD
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED
BY THE U.S. FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT
OF HEALTH AND HUMAN SERVICES**

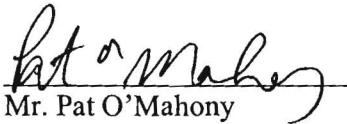
The United States Food and Drug Administration, a part of the United States Department of Health and Human Services (HHS/FDA), is authorized under 21 C.F.R. § 20.89 (“Communications with Foreign Government Officials”) to disclose non-public information to the Irish Medicines Board (IMB) regarding HHS/FDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

IMB 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. IMB understands that this non-public information is shared in confidence, and that HHS/FDA considers it critical that IMB maintains the confidentiality of the information. Public disclosure of this information by IMB could seriously jeopardize any further scientific and regulatory interactions between HHS/FDA and the IMB. HHS/FDA will advise IMB of the non-public status of the information at the time that the information is shared.

Therefore, IMB certifies that it:

1. has the authority to protect from public disclosure the non-public information provided to IMB in confidence by HHS/FDA;
2. will not publicly disclose 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 within two working days of any effort made by judicial or legislative mandate to obtain HHS/FDA-provided non-public information from IMB. If such judicial or legislative mandate orders disclosure of HHS/FDA-provided non-public information, IMB 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 IMB's laws, or to any relevant policies or procedures, that would affect the IMB's ability to honor the commitments in this document.



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20 Sept 2005.
Date



**STATEMENT OF AUTHORITY AND CONFIDENTIALITY COMMITMENT
FROM
UNITED STATES FOOD AND DRUG ADMINISTRATION OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED
BY THE IRISH MEDICINES BOARD**

The Irish Medicines Board (IMB) 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 IMB-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

HHS/FDA understands that some of the information it receives from IMB 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 IMB considers it critical that HHS/FDA maintains the confidentiality of the information. Public disclosure of this information by HHS/FDA could seriously jeopardize any further scientific and regulatory interactions between HHS/FDA and IMB. IMB 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 the non-public information provided to HHS/FDA in confidence by IMB;
2. will not publicly disclose the IMB-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 IMB that the information no longer has non-public status;
3. will inform IMB within two working days of any effort made by judicial or legislative mandate to obtain IMB-provided non-public information from HHS/FDA. If such judicial or legislative mandate orders disclosure of IMB-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 IMB 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.

Murray M. Lumpkin
for.

Lester M. Crawford, D.V.M., Ph.D.
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20 Sept 05
Date