



**STATEMENT OF AUTHORITY  
AND  
CONFIDENTIALITY COMMITMENT FROM  
THE UNITED STATES FOOD AND DRUG ADMINISTRATION  
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED  
BY  
THE HEALTH PRODUCTS REGULATORY AUTHORITY OF IRELAND**

The Health Products Regulatory Authority of Ireland (HPRA) is authorized to disclose non-public information to the United States Food and Drug Administration (FDA) regarding HPRA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

FDA understands that some of the information it receives from the HPRA may include non-public information exempt from public disclosure under the laws and regulations applicable to the HPRA, 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 the HPRA 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 the HPRA and FDA. The HPRA 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 the HPRA;
2. will not publicly disclose such HPRA-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 the HPRA that the information no longer has non-public status;
3. will inform the HPRA promptly of any effort made by judicial or legislative mandate to obtain HPRA-provided non-public information from FDA. If such judicial or legislative mandate orders disclosure of HPRA-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 the HPRA 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.



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
Silver Spring, Maryland 20993

Signed on behalf of FDA:

A handwritten signature in blue ink that reads "Howard R. Sklamberg".

Howard R. Sklamberg, J.D.  
Deputy Commissioner  
Office of Global Regulatory Operations and Policy

6/8/2015  
Date

The United States Food and Drug Administration  
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THE UNITED STATES FOOD AND DRUG ADMINISTRATION**

The United States Food and Drug Administration (FDA), is authorized under 21 C.F.R. § 20.89 to disclose non-public information to the Health Products Regulatory Authority of Ireland (HPRA) regarding FDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

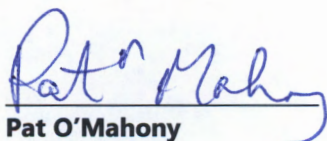
The HPRA understands that some of the information it receives from FDA may include non-public information exempt from public disclosure under the laws and regulations of the United States of America, which is confidential commercial information; trade secret information; personal privacy information;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

Therefore, the HPRA certifies that it:

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

Signed on behalf of the HPRA:



**Pat O'Mahony**  
**Chief Executive**

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