



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

The Therapeutic Goods Administration (TGA) of Australia is authorized to disclose non-public information to the United States Food and Drug Administration (FDA) relating to TGA's regulatory functions as part of cooperative law enforcement or cooperative regulatory activities.

The FDA understands that information it receives from the TGA may include sensitive non-public information, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information. FDA understands that this non-public information is shared in confidence and that the TGA considers it critical that the FDA maintain the confidentiality of the information. Public disclosure of this information by FDA could seriously jeopardize any further scientific and regulatory interactions between TGA and FDA. TGA will advise FDA of the non-public status of the information at the time that the information is shared.

Therefore, FDA certifies that it:

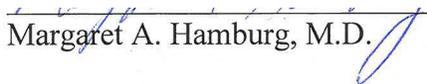
1. has the authority to protect from public disclosure such non-public information provided to FDA in confidence by TGA;
2. will not publicly disclose such TGA-provided non-public information without the written authorization of the owner of the information, the written authorization from any individual who is the subject of the personal privacy information, or a written statement from TGA that the information no longer has non-public status;
3. will inform TGA promptly of any effort made by judicial or legislative mandate to obtain TGA-provided non-public information from FDA. If such judicial or legislative mandate orders disclosure of TGA-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 TGA of any changes to relevant laws, regulations, policies, or procedures that would affect FDA's ability to honor the commitments in this document.

This document supersedes the Statement of Authority and Confidentiality Commitment signed by FDA on March 5, 2008. FDA acknowledges that information shared under that Commitment will remain subject to the terms of that Commitment.

FDA intends to negotiate with TGA an additional instrument that will describe some of the information that FDA and TGA intend to share with each other in accordance with this document and some of the processes by which this sharing will occur.

---/s/---

  
Margaret A. Hamburg, M.D.

August 25, 2014  
Date

Commissioner of Food and Drugs  
Department of Health and Human Services  
UNITED STATES OF AMERICA

**Contact details:**

Address: Food and Drug Administration  
10903 New Hampshire Avenue  
Building 1, Room 2217  
Silver Spring, MD 20993  
United States

Telephone: +301-796-5000

Email: [Commissioner@fda.hhs.gov](mailto:Commissioner@fda.hhs.gov)