

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

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

TGA understands that some of the information it receives from FDA 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. TGA understands that this non-public information is shared in confidence and that FDA considers it critical that TGA maintain the confidentiality of the information. Public disclosure of this information by TGA could seriously jeopardize any further scientific and regulatory interactions between FDA and TGA. FDA will advise TGA of the non-public status of the information at the time that the information is shared.

Therefore, TGA certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to TGA 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 any 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 TGA. If such judicial or legislative mandate orders disclosure of FDA-provided non-public information, TGA 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 relevant laws, regulations, policies, or procedures that would affect TGA's ability to honor the commitments in this document.

This document supersedes the Statement of Authority and Confidentiality Commitment signed by TGA on November 8, 2004. TGA acknowledges that information that has been shared under that Commitment will remain subject to the terms of that Commitment.

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

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Date

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