

**CONFIDENTIALITY COMMITMENT
STATEMENT OF LEGAL AUTHORITY
AND COMMITMENT FROM THE AUSTRALIAN THERAPEUTICS GOODS
ADMINISTRATION NOT TO PUBLICLY DISCLOSE NON-PUBLIC
INFORMATION SHARED
BY THE U. S. FOOD AND DRUG ADMINISTRATION (USFDA), U.S.
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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

The Australian Therapeutic Goods Administration understands that some of the information it receives from USFDA 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. The Australian Therapeutic Goods Administration understands that this non-public information is shared in confidence, and that USFDA considers it critical that the Australian Therapeutic Goods Administration maintains the confidentiality of the information. Public disclosure of this information by the Australian Therapeutic Goods Administration could seriously jeopardize any further scientific and regulatory interactions between USFDA and the Australian Therapeutic Goods Administration. US FDA will advise the Australian Therapeutic Goods Administration of the non-public status of the information at the time that the information is shared.

Therefore, the Australian Therapeutic Goods Administration certifies that it:

1. has the authority to protect the non-public information provided to the Australian Therapeutic Goods Administration in confidence by the USFDA from public disclosure;
2. will not publicly disclose the USFDA-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 USFDA that the information no longer has non-public status;
3. will inform USFDA within two working days of any effort made to obtain USFDA-provided non-public information from the Australian Therapeutic Goods Administration by judicial or legislative mandate. If such judicial or legislative

mandate orders disclosure of USFDA-provided non-public information, the Australian Therapeutic Goods Administration will take 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 USFDA of any changes to Australian laws, the Australian Therapeutic Goods Administration policies or procedures that would affect the Australian Therapeutic Goods Administration's ability to honor the agreements in this document.



Signature of foreign government official

11/8/14

Date

Mr Terry Slater
National Manager
The Australian Therapeutic Goods Administration

Address: Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
AUSTRALIA

Telephone: +61 2 6232 8444 (Phone)
facsimile: +61 2 6232 8239 (Fax)