

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

The United States Food and Drug Administration, an agency within the Department of Health and Human Services (HHS/FDA), is authorized under 21 C.F.R. § 20.89 to disclose non-public information to the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) regarding HHS/FDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

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

Therefore, Medsafe agrees that it:

1. has the authority to treat and will treat such non-public information provided to Medsafe in confidence by the HHS/FDA as information not to be disclosed in accordance with sections 6 and 18 of the Official Information Act 1982 unless Medsafe receives 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;
2. will inform HHS/FDA promptly of any effort made by judicial or legislative mandate to obtain HHS/FDA-provided non-public information from Medsafe. If such judicial or legislative mandate orders disclosure of HHS/FDA-provided non-public information, Medsafe 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. Medsafe understands that non-public information shared with Medsafe by HHS/FDA should be protected to the greatest extent feasible. Therefore, Medsafe commits to taking all appropriate measures to protect such information from public disclosure including, but not limited to, seeking an opinion from the Prime Minister as to

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the sensitivity of the information should the Ombudsman order disclosure of non-public information provided by the FDA; and

3. will promptly inform HHS/FDA of any changes to New Zealand's laws, or to any relevant policies or procedures, that would affect Medsafe's ability to honor the commitments in this document.


Signature of foreign agency official

2 MARCH 2007
Date

STEWART S JESSAMINE
Print or Type name of foreign agency official

INTERIM MANAGER
Title of foreign agency official

MEDSAFE
NEW ZEALAND MEDICINES AND MEDICAL DEVICES
SAFETY AUTHORITY
Name of foreign agency

Address: LEVEL 6, 10 BRANSON ST -
WELLINGTON
NEW ZEALAND

Telephone and facsimile: +64 4 819 6804