



CONFIDENTIALITY COMMITMENT

**STATEMENT OF LEGAL AUTHORITY
AND COMMITMENT**

**FROM
THE U.S. FOOD AND DRUG ADMINISTRATION (USFDA),
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED
BY**

**THE PHARMACEUTICAL AND FOOD SAFETY BUREAU, MINISTRY OF
HEALTH, LABOUR, AND WELFARE, GOVERNMENT OF JAPAN (PFSB)**

The Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour, and Welfare, Government of Japan (PFSB) is authorized to disclose non-public information to the U.S. FDA regarding PFSB regulated products as part of cooperative law enforcement or cooperative regulatory activities.

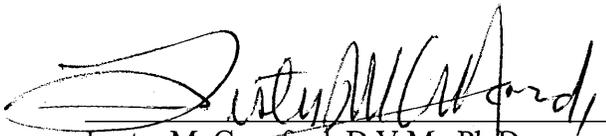
USFDA understands that some of the information it receives from PFSB may include non-public information exempt from public disclosure under the laws and regulations of Government of Japan, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information. USFDA understands that this non-public information is shared in confidence, and that PFSB considers it critical that USFDA maintains the confidentiality of the information. Public disclosure of this information by USFDA could seriously jeopardize any further scientific and regulatory interactions between PFSB and USFDA. PFSB will advise USFDA of the non-public status of the information at the time that the information is shared.

Therefore, USFDA certifies that it:

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

public information, USFDA will take all 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 PFSB of any changes to United States laws, USFDA policies or procedures that would affect USFDA's ability to honor the agreements in this document.



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SEP 15 2004

Date

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