



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**

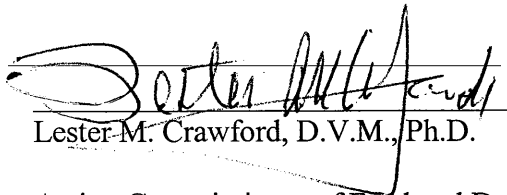
THE PHARMACEUTICALS AND MEDICAL DEVICES AGENCY (PMDA)

The Food and Drug Administration, Department of Health and Human Services, Government of the United States of America (USFDA) understands that some of the information it receives from the Pharmaceuticals and Medical Devices Agency (PMDA) may include non-public information on pharmaceutical and medical device affairs (hereinafter referred to as "non-public information") exempt from public disclosure under the laws and regulations of the 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 PMDA 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 PMDA and USFDA. PMDA 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 PMDA from public disclosure;
2. will not publicly disclose the PMDA-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 PMDA that the information no longer has non-public status;
3. will inform PMDA within two working days of any effort made to obtain the PMDA-provided non-public information from USFDA by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of the PMDA-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 PMDA of any changes to United States laws, USFDA policies or procedures that would affect USFDA's ability to honor the commitments in this document.



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SEP 15 2007

Date

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