



**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 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 Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour, and Welfare, Government of Japan (PFSB) 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 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 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 the 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 commitments in this document.

Lester M. Crawford, D.V.M., Ph.D.

SEP 15 2004

Date

Acting Commissioner of Food and Drugs  
United States Food and Drug Administration  
United States Department of Health and Human Services

HF-1  
5600 Fishers Lane  
Rockville, Maryland  
USA-20857

Telephone: +1 301 827 2410  
Facsimile: +1 301 827 3100



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**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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