

**CONFIDENTIALITY COMMITMENT
STATEMENT OF LEGAL AUTHORITY
AND COMMITMENT FROM THE PHARMACEUTICAL AND FOOD SAFETY
BUREAU, MINISTRY OF HEALTH, LABOUR AND WELFARE,
GOVERNMENT OF JAPAN (PFSB), NOT TO PUBLICLY DISCLOSE NON-
PUBLIC INFORMATION SHARED
BY THE FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH
AND HUMAN SERVICES, GOVERNMENT OF THE UNITED STATES OF
AMERICA (USFDA)**

The Food and Drug Administration, Department of Health and Human Services, Government of the United States of America (USFDA) is authorized under 21 C.F.R. § 20.89 ("Communications with Foreign Government Officials") to disclose non-public information to the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, Government of Japan (PFSB) regarding USFDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

The PFSB understands that some of the information it receives from the USFDA may include non-public information exempt from public disclosure under the laws and regulations of the Government 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 PFSB understands that this non-public information is shared in confidence, and that the USFDA considers it critical that the PFSB maintain the confidentiality of the information. Public disclosure of this information by the PFSB could seriously jeopardize any further scientific and regulatory interactions between the USFDA and PFSB. The US FDA will advise the PFSB of the non-public status of the information at the time that the information is shared.

Therefore, the PFSB certifies that it:

1. has the authority to protect the non-public information provided to the PFSB 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 the USFDA that the information no longer has non-public status;
3. will inform the USFDA within two working days of any effort made to obtain the USFDA-provided non-public information from the PFSB by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of the USFDA-provided non-public information, the PFSB 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 the USFDA of any changes to laws, policies or procedures that would affect the PFSB's ability to honor the agreements in this document.

Signature of foreign government official

July 23, 2004
Date

Mr. Shinji Asonuma
Print or Type foreign government official

Director General of Pharmaceutical and Food Safety Bureau
Title of foreign government agency official

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Name of foreign government agency

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Pharmaceuticals and Medical Devices Agency
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**CONFIDENTIALITY COMMITMENT
STATEMENT OF LEGAL AUTHORITY
AND COMMITMENT FROM THE PHARMACEUTICALS AND MEDICAL
DEVICES AGENCY (PMDA), NOT TO PUBLICLY DISCLOSE NON-PUBLIC
INFORMATION SHARED
BY THE FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH
AND HUMAN SERVICES, GOVERNMENT OF THE UNITED STATES OF
AMERICA (USFDA)**

The Food and Drug Administration, Department of Health and Human Services, Government of the United States of America (USFDA) is authorized under 21 C.F.R. § 20.89 ("Communications with Foreign Government Officials") to disclose non-public information to the Pharmaceuticals and Medical Devices Agency (PMDA), which is affiliated with the Ministry of Health Labour and Welfare of Japan in the approval of pharmaceuticals and medical devices, regarding the USFDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

The PMDA working together with MHLW understands that some of the information it receives from the USFDA may include non-public information exempt from public disclosure under the laws and regulations of the Government 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 PMDA understands that this non-public information is shared in confidence, and that the USFDA considers it critical that the PMDA maintain the confidentiality of the information. Public disclosure of this information by the PMDA could seriously jeopardize any further scientific and regulatory interactions between the USFDA and PMDA. The US FDA will advise the PMDA of the non-public status of the information at the time that the information is shared.

Therefore, the PMDA certifies that it:

1. has the authority to protect the non-public information provided to the PMDA 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 the USFDA that the information no longer has non-public status;

3. will inform the USFDA within two working days of any effort made to obtain the USFDA-provided non-public information from the PMDA by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of the USFDA-provided non-public information, the PMDA 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 the USFDA of any changes to laws, policies or procedures that would affect the PMDA's ability to honor the agreements in this document.

Signature of foreign government official

July 29, 2004
Date

Akira Miyajima
Print or Type foreign government official

Chief Executive
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