



**CONFIDENTIALITY COMMITMENT
STATEMENT OF LEGAL AUTHORITY
AND COMMITMENT**

FROM

**THE UNITED STATES FOOD AND DRUG ADMINISTRATION
(THE UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES)**

NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION

SHARED BY

SWISSMEDIC

The Swiss Agency for Therapeutic Products, Swissmedic, is authorized under the Swiss Federal Law on Therapeutic Products (LTP) Article 64 ("International administrative assistance") to disclose non-public information to the United States Food and Drug Administration (USFDA), a part of the United States Department of Health and Human Services, regarding Swissmedic regulated products as part of cooperative law enforcement or cooperative regulatory activities.

USFDA understands that some of the information it receives from Swissmedic may include non-public information exempt from public disclosure under the laws and regulations of Switzerland, 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 Swissmedic 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 Swissmedic and USFDA. Swissmedic 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 Swissmedic from public disclosure;

2. will not publicly disclose the Swissmedic-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 Swissmedic that the information no longer has non-public status;
3. will inform Swissmedic within two working days of any effort made to obtain Swissmedic-provided non-public information from USFDA by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of Swissmedic-provided non-public information, the 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 Swissmedic of any changes to US laws or USFDA policies or procedures that would affect USFDA's ability to honor the agreements in this document.

---/s/---

Mark. B. McClellan, M.D., Ph.D.

9/5/03

Date

---/s/---

(Printed name)

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

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