



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

FROM

SWISSMEDIC

NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION

SHARED BY

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

The United States Food and Drug Administration (USFDA), a part of the United States Department of Health and Human Services, is authorized under 21 CFR 20.89 ("Communications with Foreign Government Officials") to disclose non-public information to The Swiss Agency for Therapeutic Products, Swissmedic, regarding USFDA regulated products as part of cooperative law enforcement or cooperative regulatory activities.

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

Therefore, Swissmedic certifies that it:

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

Dr. Klaus-Jörg Dogwiler

17.09.03

Date

(Printed name)

Executive Director
Swiss Agency for Therapeutic Products
Swissmedic

Erlachstrasse 8
CH-3000 Bern 9

Telephone: +41 - 31 - 322 0201

Facsimile: +41 - 31 - 322 0430



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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