

**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)**

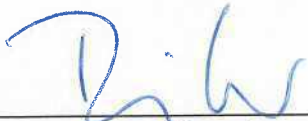
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1. has the authority to protect the non-public information provided to Swissmedic in confidence by USFDA from public disclosure;

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



Date



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