

**CONFIDENTIALITY COMMITMENT
STATEMENT OF LEGAL AUTHORITY
AND COMMITMENT FROM THE FEDERAL INSTITUTE FOR DRUGS AND
MEDICAL DEVICES (BfArM) NOT TO PUBLICLY DISCLOSE NON-PUBLIC
INFORMATION SHARED
BY THE U. S. FOOD AND DRUG ADMINISTRATION (USFDA), U.S.
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

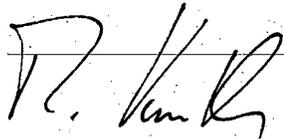
The United States Food and Drug Administration (USFDA), a part of the United States Department of Health and Human Services, is authorized under 21 C.F.R. § 20.89 (“Communications with Foreign Government Officials”) to disclose non-public information to the Federal Institute for Drugs and Medical Devices (BfArM) regarding USFDA regulated products as part of cooperative law enforcement or cooperative regulatory activities.

BfArM 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. BfArM understands that this non-public information is shared in confidence, and that USFDA considers it critical that BfArM maintains the confidentiality of the information. Public disclosure of this information by BfArM could seriously jeopardize any further scientific and regulatory interactions between USFDA and BfArM. US FDA will advise BfArM of the non-public status of the information at the time that the information is shared.

Therefore, BfArM certifies that it:

1. has the authority to protect the non-public information provided to BfArM in confidence by the USFDA from public disclosure;
2. will not publicly disclose 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 BfArM by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of USFDA-provided non-public information, BfArM 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 laws, BfArM policies or procedures that would affect BfArM's ability to honor the agreements in this document.



Signature of foreign government official

2 FEB. 2005

Date

Reinhard Kurth

Print or Type foreign government official

Präsident

Title of foreign government agency official

Federal Institute for Drugs and Medical Devices

Name of foreign government agency

Address: **Prof. Dr. Reinhard Kurth**
Kommissarischer Leiter
Bundesinstitut für Arzneimittel
und Medizinprodukte

(BfArM)

Telephone and facsimile: **Bundesinstitut für**
Arzneimittel und Medizinprodukte
Kurt-Georg-Kiesinger-Allee 3
53175 Bonn
Germany

Tel: + 49-228-207 3204

Fax: + 49-228-207 5514