



**STATEMENT OF LEGAL AUTHORITY AND COMMITMENT**

**FROM**

**THE PAUL-EHRLICH-INSTITUT  
REPORTING TO THE FEDERAL MINISTRY OF HEALTH, GERMANY  
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED**

**BY**

**THE UNITED STATES FOOD AND DRUG ADMINISTRATION  
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
UNITED STATES OF AMERICA**

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 Paul-Ehrlich-Institut (PEI) reporting to the German Federal Ministry of Health (BMG) regarding USFDA regulated products as part of cooperative law enforcement or cooperative regulatory activities.

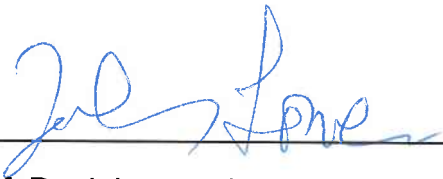
The PEI understands that some of the information it receives from the USFDA may include non-public information exempt from public disclosure under the laws and, regulations of the United States of America, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information. The PEI understands that this non-public information is shared in confidence, and that USFDA considers it critical that the PEI maintains the confidentiality of the information. Public disclosure of this information by the PEI could seriously jeopardize any further scientific and regulatory interactions between USFDA and the PEI. USFDA will advise the PEI of the non-public status of the information at the time that the information is shared.

Therefore, the PEI certifies that it:

1. has the authority to protect such non-public information provided to the PEI 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 the USFDA promptly of any effort made to obtain USFDA provided non-public information from the PEI by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of USFDA- provided non-public information, the PEI 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 Germany's laws, or the PEI policies or procedures, that would affect the PEI's ability to honor the commitments in this document.



Prof. Dr. Johannes Löwer

30 January 2006

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