DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

STATEMENT OF LEGAL AUTHORITYAND COMMITMENT

FROM

THE UNITED STATES FOOD AND DRUG ADMINISTRATION UNITED STATES OF AMERICA

NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED

BY

THE PAUL-EHRLICH-INSTITUT GERMANY

The Paul-Ehrlich-Institut (PEI), a Senior Federal Authority reporting to the German Federal Ministry of Health, is authorized under Section 68 Paragraph 4 of the German Medicinal Products Act (§68(4) Arzneimittelgesetz - AMG) to disclose information to the U.S. Food and Drug Administration (USFDA), U.S. Department of Health and Human Services regarding PEI regulated products as part of cooperative law enforcement or cooperative regulatory activities.

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

Therefore, the USFDA certifies that it:

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

2. will not publicly disclose PEI-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 PEI that the information no longer has non-public status;

3. will inform the PEI promptly of any effort made to obtain PEI -provided non-public information from the USFDA by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of PEI- 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 the PEI of any changes to US laws, or the USFDA policies or procedures, that would affect the USFDA's ability to honour the commitments in this document.

Murray M. Lumpkin, M.D., M.Sc.

23 Jan 06
Date

Deputy Commissioner
International and Special Programs
Food and Drug Administration
Department of Health and Human Services
UNITED STATES OF AMERICA

5600 Fishers Lane
Rockville, MD 20857
(301) 827-5709 (ph)
(301) 443-3100 (fax)