



**STATEMENT OF AUTHORITY
AND CONFIDENTIALITY COMMITMENT**

FROM

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

NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED

BY

**THE PHARMACEUTICAL ADMINISTRATION,
THE MEDICAL DEVICES DEPARTMENT,
AND THE FOOD & NUTRITION SERVICES
OF THE ISRAEL MINISTRY OF HEALTH**

The Pharmaceutical Administration, the Medical Devices Department, and the Food & Nutrition Services of the Israel Ministry of Health (collectively "the Administration") is authorized to disclose non-public information to the United States Food and Drug Administration of the Department of Health and Human Services (HHS/FDA) regarding Administration-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

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

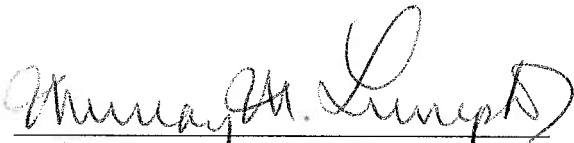
Therefore, HHS/FDA certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to HHS/FDA in confidence by the Administration;
2. will not publicly disclose the Administration-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 the Administration that the information no longer has non-public status;

3. will inform the Administration within two working days of any effort made by judicial or legislative mandate to obtain Administration-provided non-public information from HHS/FDA. If such judicial or legislative mandate orders disclosure of Administration-provided non-public information, HHS/FDA will take all appropriate legal 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 Administration of any changes to HHS/FDA's laws, or to any relevant policies or procedures, that would affect HHS/FDA's ability to honor the commitments in this document.

HHS/FDA and the Administration should establish a mechanism for regular meetings to develop plans for joint work.

Nothing in this commitment is intended to diminish or otherwise affect the authority of HHS/FDA to carry out its regulatory responsibilities and programs. In addition, no provision of this commitment restricts HHS/FDA from conducting its own inspection of a therapeutic product manufacturing facility within the jurisdictional boundaries of the Administration when needed to meet the needs of its own regulatory programs.


Andrew C. von Eschenbach, M.D.

15 Dec 2005
Date

Acting Commissioner of Food and Drugs
Food and Drug Administration
Department of Health and Human Services
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