

**STATEMENT OF AUTHORITY
AND CONFIDENTIALITY COMMITMENT**

FROM

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

NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED

BY

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

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

The Administration understands that some of the information it receives from HHS/FDA 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. The Administration understands that this non-public information is shared in confidence, and that HHS/FDA considers it critical that the Administration maintain the confidentiality of the information. Public disclosure of this information by the Administration could seriously jeopardize any further scientific and regulatory interactions between the Administration and HHS/FDA. HHS/FDA will advise the Administration of the non-public status of the information at the time that the information is shared.

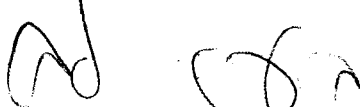
Therefore, the Administration certifies that it:

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

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

The Administration and HHS/FDA 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 the Administration to carry out its regulatory responsibilities and programs. In addition, no provision of this commitment restricts the Administration from conducting its own inspection of a therapeutic product manufacturing facility within the jurisdictional boundaries of HHS/FDA when needed to meet the needs of its own regulatory programs.



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Date

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