

**STATEMENT OF AUTHORITY  
AND  
CONFIDENTIALITY COMMITMENT FROM  
THE STATE OF ISRAEL  
MEDICAL TECHNOLOGY, HEALTH INFORMATION AND RESEARCH  
DIRECTORATE  
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED  
BY  
THE UNITED STATES FOOD AND DRUG ADMINISTRATION**

The United States Food and Drug Administration (FDA) is authorized under 21 C.F.R. § 20.89 to disclose non-public information to the State of Israel Medical Technology, Health Information and Research Directorate (MTIR) regarding FDA-regulated medical products and cosmetics as part of cooperative law enforcement or cooperative regulatory activities.

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

Therefore, MTIR certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to MTIR in confidence by FDA;
2. will not publicly disclose such 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 FDA that the information no longer has non-public status;
3. will inform FDA promptly of any effort made by judicial or legislative mandate to obtain FDA-provided non-public information from MTIR. If such judicial or legislative mandate orders disclosure of FDA-provided non-public information, MTIR 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;

4. will promptly inform FDA of any changes to the State of Israel's laws, or to any relevant policies or procedures, that would affect MTIR's ability to honor the commitments in this document;
5. has established and will maintain compliance with standards consistent with current United States federal government National Institute of Standards and Technology (NIST) Risk Management and Cybersecurity Frameworks<sup>1</sup> and/or International Organization for Standardization and International Electrotechnical Commission (ISO/IEC)<sup>2</sup> Information Technology security guidelines and standards that focus on protecting information systems and shared sensitive information;
6. will safeguard information systems that contain FDA-provided non-public information consistent with current NIST and/or ISO/IEC guidelines and standards to ensure confidentiality and integrity. Confidentiality means preventing unauthorized access to and disclosure of non-public information, and integrity means guarding against improper information modification or destruction. Integrity includes ensuring information non-repudiation and authenticity based on the security terms found in this Statement of Authority and Confidentiality Commitment, including means for protecting non-public information;
7. will destroy FDA-provided non-public information, whether in electronic form or hard copy form, once the information has been utilized and is no longer needed for official purposes;
8. will restrict access to FDA-provided non-public information to the employees, and officials of MTIR who require access to such non-public information to perform their official duties in accordance with authorized uses of the non-public information unless otherwise authorized in writing by FDA. MTIR will advise all such employees and officials (1) of the non-public nature of the information; and (2) the obligation to keep such information non-public; and

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<sup>1</sup> The National Institute of Standards and Technology (NIST) Risk Management and Cybersecurity Frameworks provide a process that integrates security, privacy, and cyber supply chain risk management activities into the system development life cycle and provides guidance based on standards, guidelines, and practices for organizations to manage and reduce cybersecurity risk, respectively. These frameworks are primarily intended to manage and mitigate cybersecurity risk for critical infrastructure organizations based on standards, guidelines, and practices.

<sup>2</sup> The International Organization for Standardization and International Electrotechnical Commission (ISO/IEC) is an international standard that assists organizations in managing the security of their information assets. It provides a management framework for implementing an information security management system to ensure the confidentiality of all corporate data. Foreign counterparts are strongly encouraged to meet the ISO 27001 standard requirements, or the most recent standard, and to be certified by an accredited certification body.

9. will, in the event of a suspected or confirmed incident or breach<sup>3</sup>, including a cybersecurity<sup>4</sup> incident, or any other type of breach, whether it is intentional or inadvertent:

- (a) protect all FDA-provided non-public information, including any non-public information created, stored, or transmitted, to avoid a secondary information incident;
- (b) report all suspected and confirmed incidents or breaches involving FDA-provided non-public information in any medium or form, including paper, oral, or electronic, to FDA as soon as possible and without unreasonable delay, no later than one (1) day of discovery or detection; and
- (c) provide to FDA impact and severity assessments of incidents or breaches, upon occurrence, including a description of the actions taken, including preventative security measures employed to address and remediate the incident.

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<sup>3</sup> An incident is defined as “an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the confidentiality of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies.” Incidents can be events involving cybersecurity and privacy threats, such as viruses, malicious user activity, loss of confidentiality or integrity, unauthorized disclosure or destruction of information. For the purposes of this agreement, breach is defined as an actual compromise of security that results in the unauthorized disclosure of, loss, accidental or unlawful destruction, alteration, or access to protected data transmitted, stored, or otherwise processed. Breaches can be intentional or inadvertent.

<sup>4</sup> Cybersecurity is the prevention of damage to, protection of, and restoration of computers, electronic communications systems, electronic communications services, wire communication, and electronic communication, including information contained therein, to ensure its availability, integrity, authentication, confidentiality, and nonrepudiation.

This text partially replaces the Statement of Authority and Confidentiality Commitment between the Pharmaceutical Administration, the Medical Devices Department, and the Food & Nutrition Services of the Israel Ministry of Health and the FDA concluded on 15 December 2005 in as far as FDA-regulated medical products and cosmetics and MTIR-regulated medical products and cosmetics are concerned. As a result, the 2005 Statement of Authority and Confidentiality Commitment will remain in effect with respect to information exchanged with respect to food products. Information that was considered non-public information under the 2005 Statement of Authority and Confidentiality Commitment will continue to be treated as such. The names of the following units under the Israel Ministry of Health have changed since the 2005 Statement of Authority and Confidentiality Commitment was signed: the Medical Devices Department has been renamed to the Medical Devices Division (in 2016); the Pharmaceutical Administration has been renamed to the Pharmaceutical Division (in 2016); and the Food & Nutrition Services was renamed to the National Food Services (in 2006).

Signed on behalf of MTIR

\_\_\_\_\_/s/\_\_\_\_\_  
Dr. Osnat Luxenburg  
Head  
Medical Technology, Health Information  
and Research Directorate  
Israel Ministry of Health

June 9, 2024  
Date

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Israel