U.S. FOOD & DRUG ADMINISTRATION

STATEMENT OF AUTHORITY AND CONFIDENTIALITY COMMITMENT FROM THE UNITED STATES FOOD AND DRUG ADMINISTRATION NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED BY THE HEALTH PRODUCTS AND FOOD BRANCH AND THE REGULATORY OPERATIONS AND ENFORCEMENT BRANCH OF THE DEPARTMENT OF HEALTH OF CANADA

The Health Products and Food Branch (HPFB) and the Regulatory Operations and Enforcement Branch (ROEB) of the Department of Health of Canada (hereafter referred to as "HPFB and ROEB") is authorized to disclose non-public information to the United States Food and Drug Administration (FDA) regarding HPFB and/or ROEB -regulated drugs, including pre- and post-market activities, as appropriate, as part of cooperative regulatory activities or law enforcement.

This Confidentiality Commitment partially replaces two previously signed Confidentiality Commitments with respect to drugs regulated by HPFB and/or ROEB: the *Confidentiality Commitment Statement of Legal Authority and Commitment from the United States Food and Drug Administration (USFDA) United States Department of Health and Human Services Not to Publicly Disclose Non-Public Information Shared by the Health Products and Food Branch (HPFB) of Health Canada* signed on November 18, 2003, and the *Statement of Authority and Confidentiality Commitment from the United States Food and Drug Administration Not to Publicly Disclose Non-Public Information Shared by the Regulatory Operations and Regions Branch of the Department of Health of Canada* signed on February 28, 2018[1]. The above mentioned Confidentiality Commitments from 2003 and 2018 will remain in effect for all other non-public information exchanged relating to HPFB and ROEB-regulated products that are not HPFB and ROEB-regulated drugs.

FDA is authorized under 21 C.F.R. § 20.89[2] to disclose non-public information to HPFB and ROEB regarding FDA-regulated drugs, including pre- and post-market activities, as appropriate, as part of cooperative law enforcement or cooperative regulatory activities. FDA is further authorized under section 708(c) of the Federal Food, Drug, and Cosmetic Act[3] to share with a foreign government, as it deems appropriate and under limited circumstances, certain types of trade secret information.

The Commissioner of Food and Drugs has certified HPFB and ROEB as having the authority and demonstrated ability to protect trade secret information from disclosure. FDA therefore may provide HPFB and ROEB certain types of trade secret information at FDA's discretion and upon request by HPFB and ROEB, based on the following certifications.

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[1] The Regulatory Operations and Regions Branch of the Department of Health of Canada was renamed to the Regulatory Operations and Enforcement Branch (ROEB) of Health Canada on January 30, 2019.
[2] United States Code of Federal Regulations, Title 21, section 20.89.
[3] United States Code, Title 21, section 379(c).

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FDA understands that some of the information it receives from HPFB and ROEB may include non-public information exempt from public disclosure, such as commercially confidential information; trade secret information; personal privacy information; law enforcement information; designated national security information; or internal, pre-decisional information. FDA understands that this non-public information is shared in confidence and that it is critical that FDA maintains the confidentiality of exchanged non-public information. Public disclosure of exchanged non-public information by FDA could seriously jeopardize any further scientific and regulatory interactions between HPFB and ROEB and FDA. HPFB and ROEB will advise FDA of the non-public status of the information at the time that the information is shared.

Therefore, FDA certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to it in confidence[4];

2. will not publicly disclose such non-public information, including trade secrets, 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 HPFB or ROEB providing that the information no longer has non-public status;

3. with respect to trade secret information concerning the inspection of a drug facility, has the authority to otherwise obtain such information and will use such HPFB and ROEB -provided information only for civil, administrative regulatory purposes in the context of its mandate;

4. will inform HPFB or ROEB promptly of any effort made by judicial or legislative mandate to obtain HPFB and ROEB-provided non-public information, including trade secret information, exchanged under the terms of this Statement of Authority and Confidentiality Commitment. If such judicial or legislative mandate requires disclosure of such non-public information, 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;

5. will promptly inform HPFB and ROEB of any changes to the United States of America's laws, or to any relevant policies or procedures, that would affect the FDA's ability to honor the commitments in this document;

6. has established and will maintain compliance with current United States federal government National Institute of Standards and Technology (NIST) Risk Management and Cybersecurity Frameworks[5] which are Information Technology security guidelines and standards that focus on protecting information systems and shared sensitive information;

[4] FDA has the authority to protect non-public information under several statutory provisions, including 5 U.S.C. § 552a; 5 U.S.C. § 552(b)(1) – (9); 18 U.S.C. § 1905; and 21 U.S.C. § 331(j).

[5] The National Institute of Standards and Technology (NIST) Risk Management and Cybersecurity Frameworks provide a process that integrates

7. will safeguard information systems that contain HPFB and ROEB-provided non-public information in compliance with current NIST guidelines and standards to promote 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;

8. will destroy HPFB and ROEB -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 in accordance with federal records retention requirements;

9. will restrict access to HPFB and ROEB -provided non-public information to the employees, and officials of FDA 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 HPFB or ROEB. FDA 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

10. will, in the event of a suspected or confirmed incident or breach[6], including a cybersecurity[7] incident, or any other type of breach, whether it is intentional or inadvertent,

(a) endeavour to protect all HPFB and ROEB-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 HPFB or ROEB-provided non-public information in any medium or form, including paper, oral, or electronic, to HPFB or ROEB as soon as possible and without unreasonable delay, no later than one (1) business day of discovery or detection; and

(c) provide to HPFB or ROEB 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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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.

[6] 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.

[7] 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 is not intended to create rights and obligations under international or other law.

Signed on behalf of the
United States Food and Drug Administration

_____/s/_____ 01/14/2025_____

Mark Abdoo
Associate Commissioner
for Global Policy and Strategy

Date

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United States