

**STATEMENT OF AUTHORITY
AND
CONFIDENTIALITY COMMITMENT FROM
THE UNITED STATES FOOD AND DRUG ADMINISTRATION
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED
BY
THE HEALTHY ENVIRONMENTS AND CONSUMER SAFETY BRANCH OF
HEALTH CANADA**

The United States Food and Drug Administration (FDA) understands that the Healthy Environments and Consumer Safety Branch of Health Canada (HECSB), may disclose non-public information to the FDA regarding products and substances within HECSB's mandate as part of cooperative law enforcement or cooperative regulatory activities, including regulatory compliance activities.

FDA understands that some of the information that it receives from HECSB may include non-public information exempt from public disclosure under the laws and regulations of Canada, including, but not limited to, confidential commercial information, trade secret information, personal privacy information, law enforcement information, or internal, pre-decisional information; HECSB will advise FDA of the non-public status of the information at the time that the information is shared.

FDA understands that the information is provided in confidence and HECSB considers it critical that FDA maintain the confidentiality of the information. Public disclosure of this information by FDA could seriously jeopardize any further scientific and regulatory interactions between HECSB and FDA.

Therefore, FDA certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to it in confidence by HECSB;
2. will not publicly disclose such HECSB-provided non-public information without:
(a) the written authorization of HECSB or, if HECSB cannot provide that authorization, from the individual or entity that can provide such authorization, as determined by HECSB and FDA on a case-by-case basis; or (b) written statement from HECSB that the information no longer has non-public status;
3. will notify HECSB promptly of any effort made by judicial or legislative mandate to obtain HECSB-provided non-public information from FDA. If such judicial or legislative mandate orders disclosure of HECSB-provided 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; and

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

This Statement of Authority and Confidentiality Commitment does not compromise the regulatory authority of FDA to carry out its responsibilities.

This Statement of Authority and Confidentiality Commitment is not legally binding.

This Statement of Authority and Confidentiality Commitment supersedes the Statement of Authority and Confidentiality Commitment signed by FDA on July 8, 2015. FDA will continue to provide the same protections to any non-public information provided by HECSB under the 2015 Statement of Authority and Confidentiality Commitment.

Signed on behalf of FDA:

_____/s/_____

August 8, 2023

Mark Abdoo
Associate Commissioner
Office of Global Policy and Strategy

Date

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
UNITED STATES OF AMERICA