



Health Santé
Canada Canada

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

The Healthy Environments and Consumer Safety Branch of Health Canada (HECSB) understands that the United States Food and Drug Administration (FDA), is authorized under 21 C.F.R. § 20.89 to disclose non-public information to HECSB regarding FDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities, including regulatory compliance activities.

HECSB understands that, unless otherwise specified by FDA, the information shared under this Statement of Authority and Confidentiality Commitment, (“Statement of Authority”) is authorized for use only for cooperative law enforcement or cooperative regulatory activities, namely the regulation of substances, pet foods, cosmetics and personal care products and radiation-emitting products under the mandate of HECSB.

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

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

Therefore, HECSB certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to it in confidence by FDA;
2. will protect such non-public information from public disclosure in accordance with its applicable laws and policies;

3. will not publicly disclose such FDA provided non-public information without: (a) the written authorization of FDA, or if FDA cannot provide that authorization, from the individual or entity that can provide such authorization, as determined by FDA and HECSB on a case-by-case basis; or (b) a written statement from FDA that the non-public information has become publicly available;
4. will ensure the security and integrity of the non-public information entrusted to it and safeguard the information against accidental or unauthorized access, disclosure, or use;
5. in the event of accidental or unauthorized access, disclosure, or use of the shared non-public information, will promptly take all reasonable steps to minimize the extent of the unauthorized access, disclosure, or use; will contact the recipients of the accidental or unauthorized disclosure of information and request that the recipients destroy or return all aforesaid information in whatever form it exists, including copies and request written confirmation that the aforesaid information was not further distributed to other third parties; will promptly notify FDA of the occurrence, and will prevent a recurrence of the event;
6. will notify FDA promptly of any effort made by judicial or legislative mandate to obtain from HECSB non-public information provided by FDA. If such judicial or legislative mandate orders disclosure of non-public information provided by FDA, HECSB 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
7. will promptly inform FDA of any changes to Canada's laws, or to any relevant policies or procedures, that would affect HECSB's ability to protect the non-public information.

Notwithstanding any other provision or commitment, this Statement of Authority does not compromise the regulatory authority of HECSB to carry out its respective responsibilities, nor does it create legally binding obligations on HECSB to share information with FDA.

Signed on behalf of HECSB:

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CANADA

Date

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