



**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), as part of its responsibilities for the regulation of substances, pet foods, cosmetics and personal care products and radiation-emitting products in Canada under the mandate of HECSB, may disclose non-public information to the FDA regarding the above-noted HECSB-regulated products as part of cooperative law enforcement or cooperative regulatory activities, including regulatory compliance activities.

FDA understands that, unless otherwise specified by HECSB, 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 products under the mandate of FDA.

FDA understands that some of the shared 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 understands that public disclosure of this information by it 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 protect such non-public information from public disclosure in accordance with its applicable laws and policies;
3. 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) a written statement from HECSB 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 HECSB of the occurrence, and will prevent a recurrence of the event;

6. will notify HECSB promptly of any effort made by judicial or legislative mandate to obtain from FDA non-public information provided by HECSB. If such judicial or legislative mandate orders disclosure of non-public information provided by HECSB, 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

7. 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 protect the non-public information.

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

Signed on behalf of FDA;

---/S/---

7/8/2015

Howard R. Sklamberg
Deputy Commissioner
Global Regulatory Operations and Policy
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
UNITED STATES OF AMERICA

Date

Tel. +1.301.796.4600
Facsimile: +1.301.595.7937