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 and substances as part of cooperative law enforcement or cooperative regulatory activities, including regulatory compliance activities.

HECSB 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, 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 that FDA considers it critical that HECSB maintain the confidentiality of the information. Public disclosure of this information by HECSB 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 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) written statement from FDA that the information no longer has non-public status;
- 3. will notify FDA promptly of any effort made by judicial or legislative mandate to obtain FDA-provided non-public information from HECSB. 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

4. 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 honor the commitments in this document.

This Statement of Authority and Confidentiality Commitment does not compromise the regulatory authority of HECSB 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 HECSB on July 4, 2015. HECSB will continue to provide the same protections to any non-public information provided by FDA under the 2015 Statement of Authority and Confidentiality Commitment.

| Signed on behalf of HECSB: | |
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| /s/ | 2023-08-08 |
| Matt Jones Assistant Deputy Minister Healthy Environments and Consumer Safety Branch | Date |
| Health Canada | |

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