



**STATEMENT OF AUTHORITY
AND
CONFIDENTIALITY COMMITMENT FROM
THE UNITED STATES FOOD AND DRUG ADMINISTRATION
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED
BY
THE NATIONAL INSTITUTE FOR PUBLIC HEALTH AND THE ENVIRONMENT
(RIJKSINSTITUUT VOOR VOLKSGEZONDHEID EN MILIEU), AN AGENCY OF
THE STATE OF THE NETHERLANDS**

The National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu) (RIVM), acting as an agency of the State of the Netherlands, is authorized to disclose non-public information to the United States Food and Drug Administration (FDA) regarding RIVM-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

FDA understands that some of the information it receives from RIVM may include non-public information exempt from public disclosure under the laws and regulations of the Netherlands, which is confidential commercial 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 RIVM 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 RIVM and FDA. RIVM 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 FDA in confidence by RIVM;
2. will not publicly disclose such RIVM-provided non-public information 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 RIVM that the information no longer has non-public status;
3. will inform RIVM promptly of any effort made by judicial or legislative mandate to obtain RIVM-provided non-public information from FDA. If such judicial or legislative mandate orders disclosure of RIVM-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 RIVM 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 will take effect when signed by FDA and will continue to be in effect until terminated by FDA on 30 days' written notice to RIVM except that all non-public information received by FDA from RIVM will continue to be covered by this Statement of Authority and Confidentiality Commitment.

Signed on behalf of FDA:



12/1/16

Date

Deputy Commissioner
Office of Global Regulatory Operations and Policy

The United States Food and Drug Administration
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