

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

The United States Food and Drug Administration (FDA), is authorized under 21 C.F.R. § 20.89 to disclose non-public information to 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, regarding FDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

RIVM 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, which is confidential commercial information; trade secret information; personal privacy information; law enforcement information; designated national security information; or internal, pre-decisional information. RIVM understands that this non-public information is shared in confidence and that FDA considers it critical that RIVM maintain the confidentiality of the information. Public disclosure of this information by RIVM could seriously jeopardize any further scientific and regulatory interactions between FDA and RIVM. FDA will advise RIVM of the non-public status of the information at the time that the information is shared.

Therefore, RIVM certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to RIVM in confidence by FDA;
2. will not publicly disclose such FDA-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 FDA that the information no longer has non-public status;
3. will inform FDA promptly of any effort made by judicial or legislative mandate to obtain FDA-provided non-public information from RIVM. If such judicial or legislative mandate orders disclosure of FDA-provided non-public information, RIVM 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 Dutch laws, or to any relevant policies or procedures, that would affect RIVM's ability to honor the commitments in this document.

This Statement of Authority and Confidentiality Commitment will take effect when signed by RIVM and will continue to be in effect until terminated by RIVM on 30 days' written notice to the FDA except that all non-public information received by RIVM from FDA will continue to be covered by this Statement of Authority and Confidentiality Commitment.

Signed on behalf of the Dutch Minister of Public Health, Welfare and Sport:

A black rectangular box redacting the signature of Professor Emeritus A.N. van der Zande.

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