



**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 AGENCY FOR MEDICINES AND MEDICAL DEVICES - ROMANIA**

The National Agency for Medicines and Medical Devices – Romania (NAMMD) is authorized to disclose non-public information to the United States Food and Drug Administration (FDA) regarding SAM-regulated drugs, including pre- and post-market activities, as appropriate, as part of cooperative law enforcement or cooperative regulatory activities.

FDA is authorized under 21 C.F.R. § 20.89¹ to disclose non-public information to NAMMD regarding FDA-regulated drugs, including pre- and post-market activities, as appropriate, as part of cooperative law enforcement or cooperative regulatory activities. FDA is further authorized under section 708(c) of the Federal Food, Drug, and Cosmetic Act² to share with a foreign government, as it deems appropriate and under limited circumstances, certain types of trade secret information.

The Commissioner of Food and Drugs has certified NAMMD as having the authority and demonstrated ability to protect trade secret information from disclosure. FDA therefore may provide NAMMD with certain types of trade secret information at FDA’s discretion and upon request by NAMMD based on the following certifications.

FDA understands that some of the information it receives from NAMMD may include non-public information exempt from public disclosure, such as commercially confidential 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 it is critical that FDA maintains the confidentiality of exchanged non-public information. Public disclosure of exchanged non-public information by FDA could seriously jeopardize any further scientific and regulatory interactions between NAMMD and FDA. The NAMMD 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 it in confidence³;

¹ United States Code of Federal Regulations, Title 21, section 20.89.

² United States Code, Title 21, section 379(c).

³ FDA has the authority to protect non-public information under several statutory provisions, including



2. will not publicly disclose such 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 NAMMD providing that the information no longer has non-public status;
3. will promptly inform NAMMD of any effort made by judicial or legislative mandate to obtain non-public information exchanged under the terms of this Statement of Authority and Confidentiality Commitment. If such judicial or legislative mandate orders disclosure of such non-public information, FDA will take all appropriate 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 NAMMD of any changes to the United States of America's laws, or to any relevant policies or procedures, that would affect its ability to honor the commitments in this document.

This text is not intended to create rights and obligations under international or other law.

Signed on behalf of the
United States Food and Drug Administration

_____/S/_____
Dara A. Corrigan
Acting Deputy Commissioner
for Global Regulatory Operations and Policy

Date

U.S. Food and Drug Administration
10903 New Hampshire Avenue,
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United States