U.S. FOOD & DRUG ADMINISTRATION

STATEMENT OF AUTHORITY AND CONFIDENTIALITY COMMITMENT FROM THE UNITED STATES FOOD AND DRUG ADMINISTRATION NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED BY THE ITALIAN MINISTRY OF HEALTH DIRECTION GENERAL FOR ANIMAL HEALTH AND VETERINARY MEDICINAL PRODUCTS

The Italian Ministry of Health Direction General for Animal Health and Veterinary Medicinal Products (DGSAF) is authorized to disclose non-public information to the United States Food and Drug Administration (FDA) regarding DGSAF-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. § 20.89[1] to disclose non-public information to DGSAF 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 Act[2] 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 DGSAF as having the authority and demonstrated ability to protect trade secret information from disclosure. FDA therefore may provide DGSAF with certain types of trade secret information at FDA's discretion and upon request by DGSAF, based on the following certifications.

FDA understands that some of the information it receives from DGSAF 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 DGSAF and FDA. DGSAF will advise FDA of the non-public status of the information at the time that the information is shared.

[1] United States Code of Federal Regulations, Title 21, section 20.89.
[2] United States Code, Title 21, section 379(c).

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Therefore, FDA certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to it in confidence[3];

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 DGSAF providing that the information no longer has non-public status;

3. will promptly inform DGSAF of any effort made by judicial or legislative mandate to obtain non-public information exchanged under the terms of this Statement 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 DGSAF 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/_____ 3/21/23

Mark Abdoo
Associate Commissioner
for Global Policy and Strategy

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[3] FDA has the authority to protect non-public information under several statutory provisions, including 5 U.S.C. § 552a; 5 U.S.C. § 552(b)(1) – (9); 18 U.S.C. § 1905; and 21 U.S.C. § 331(j).