

**STATEMENT OF AUTHORITY  
AND  
CONFIDENTIALITY COMMITMENT FROM**

**THE ITALIAN MINISTRY OF HEALTH  
DIRECTION GENERAL FOR ANIMAL HEALTH AND VETERINARY  
MEDICINAL PRODUCTS (DGSAF)**

**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<sup>1</sup> to disclose non-public information to **the Italian Ministry of Health - Direction General for Animal Health and Veterinary Medicinal Products (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<sup>2</sup> 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.

**DGSAF** understands that some of the information it receives from FDA 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. **DGSAF** understands that this non-public information is shared in confidence and that it is critical that **DGSAF** maintains the confidentiality of exchanged non-public information. Public disclosure of exchanged non-public information by **DGSAF** could seriously jeopardize any further scientific and regulatory interactions between **DGSAF** and FDA. FDA will advise **DGSAF** of the non-public status of the information at the time that the information is shared.

Therefore, **the Italian Ministry of Health - Direction General for Animal Health and Veterinary Medicinal Products (DGSAF)** certifies that it:

- I. has the authority to protect from public disclosure such non-public information provided to **DGSAF** 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

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<sup>1</sup> United States Code of Federal Regulations, Title 21, section 20.89.

<sup>2</sup> United States Code, Title 21, section 379(c).

individual who is the subject of the personal privacy information, or a written statement from FDA providing that the information no longer has non-public status;

3. will protect trade secret information that FDA may provide from disclosure unless and until **DGSAF** is in possession of a written permission for disclosure by the sponsor of the information provided by FDA, or alternatively of a declaration from the Commissioner of Food and Drugs of a public health emergency under section 319 of the Public Health Service Act that is relevant to the information;
4. with respect to trade secret information concerning the inspection of a drug facility, has the authority to otherwise obtain such information and will use such FDA-provided information only for civil, administrative regulatory purposes in the context of its mission;
5. will inform FDA promptly of any effort made by judicial or legislative mandate to obtain FDA-provided non-public information from **DGSAF**. If such judicial or legislative mandate requires disclosure of FDA-provided non-public information, **DGSAF** 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
6. will promptly inform FDA of any changes to the **Italian** laws, or to any relevant policies or procedures, that would affect **DGSAF's** ability to honor the commitments in this document.

**DGSAF** understands that FDA-provided information may come to it from the European Medicines Agency (EMA) and/or the European Commission's Directorate-General for Health and Food Safety (DG SANTE) as a result of the Cooperation Agreement between EMA and the EU Member States Regulatory Authorities. **DGSAF** will protect such FDA-provided non-public information from public disclosure to the same extent that it will protect non-public information provided to it directly by FDA.

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

Signed on behalf of **the Italian Ministry of Health - Direction General for Animal Health and Veterinary Medicinal Products (DGSAF)**

Rome 24.10.2022



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/s/