

**STATEMENT OF AUTHORITY  
AND  
CONFIDENTIALITY COMMITMENT FROM  
INSTITUTUL PENTRU CONTROLUL PRODUSELOR BIOLOGICE SI  
MEDICAMENTELOR DE UZ VETERINAR (ICBMV)  
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. § 20.891 to disclose non-public information to *Institutul pentru Controlul Produselor Biologice si Medicamentelor de Uz Veterinar (ICBMV) - Institute for Control of Biological Products and Veterinary Medicines* 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 *ICBMV* as having the authority and demonstrated ability to protect trade secret information from disclosure. FDA therefore may provide *ICBMV* with certain types of trade secret information at FDA's discretion and upon request by *ICBMV*, based on the following certifications.

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

Therefore, *ICBMV* certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to *ICBMV* in confidence by FDA;

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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).

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 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 *ICBMV* 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 *ICBMV*. If such judicial or legislative mandate requires disclosure of FDA-provided non-public information, *ICBMV* 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 *ROMANIA* laws, or to any relevant policies or procedures, that would affect *ICBMV* ability to honor the commitments in this document.

*ICBMV* 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. *ICBMV* 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 *ICBMV*

\_\_\_\_\_/s/\_\_\_\_\_  
Valentin VOICU  
Director

Date 5.12.2022

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