



**STATEMENT OF AUTHORITY  
AND  
CONFIDENTIALITY COMMITMENT FROM  
THE OFFICE FOR REGISTRATION OF MEDICINAL PRODUCTS, MEDICAL  
DEVICES AND BIOCIDAL PRODUCTS OF POLAND  
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 Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of Poland (Urządowi Rejestracji Leków, Produktów Leczniczych i Wyrobów Medycznych, henceforth URPLWMiPB) regarding FDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

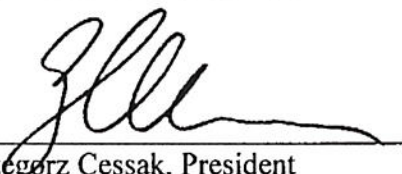
URPLWMiPB understands that some of the information it receives from FDA may include non-public information exempt from public disclosure under the laws and regulations of the United States of America, which is confidential commercial information; trade secret information; personal privacy information;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

Therefore, URPLWMiPB certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to URPLWMiPB 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 URPLWMiPB. If such judicial or legislative mandate orders disclosure of FDA-provided non-public information, URPLWMiPB 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 Poland's laws, or to any relevant policies or procedures, that would affect URPLW MiPB's ability to honor the commitments in this document.

Signed on behalf of URPLW MiPB:



Grzegorz Cessak, President  
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Date