

**STATEMENT OF AUTHORITY AND  
CONFIDENTIALITY COMMITMENT FROM  
THE U.S. FOOD AND DRUG ADMINISTRATION  
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION  
REGARDING MEDICAL PRODUCTS USED, OR PROPOSED TO BE USED,  
FOR EBOLA-RELATED PURPOSES SHARED BY  
THE PHARMACY BOARD OF SIERRA LEONE**

The Pharmacy Board of Sierra Leone (PBSL) is authorized to disclose non-public information to the U.S. Food and Drug Administration (USFDA) regarding medical products used, or proposed to be used, for Ebola-related purposes as part of cooperative law enforcement or cooperative regulatory activities.

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

Therefore, USFDA certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to USFDA in confidence by PBSL;
2. will not publicly disclose such PBSL -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 PBSL that the information no longer has non-public status;
3. will inform PBSL promptly of any effort made by judicial or legislative mandate to obtain PBSL-provided non-public information from USFDA. If such judicial or legislative mandate orders disclosure of PBSL -provided non-public information, USFDA 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 PBSL of any changes to the United States laws, or to any relevant policies or procedures, that would affect USFDA's ability to honor the commitments in this document.

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Howard R. Sklamberg, J.D.  
Deputy Commissioner for Global Regulatory  
Operations and Policy  
United States Food and Drug Administration

3/18/15  
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**STATEMENT OF AUTHORITY AND  
CONFIDENTIALITY COMMITMENT FROM  
THE PHARMACY BOARD OF SIERRA LEONE  
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION ON MEDICAL  
PRODUCTS USED, OR PROPOSED TO BE USED, FOR EBOLA-RELATED  
PURPOSES 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 Pharmacy Board of Sierra Leone (PBSL) regarding medical products used, or proposed to be used, for Ebola-related purposes as part of cooperative law enforcement or cooperative regulatory activities.

PBSL understands that some of the information it receives from FDA on Ebola medical products 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. PBSL understands that this non-public information on Ebola medical products is shared in confidence and that FDA considers it critical that PBSL maintain the confidentiality of the information. Public disclosure of this information by PBSL could seriously jeopardize any further scientific and regulatory interactions between FDA and PBSL. FDA will advise PBSL of the non-public status of the information at the time that the information is shared.

Therefore, PBSL certifies that it:

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

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12<sup>th</sup> March, 2015  
Date

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