

**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 LIBERIAN MEDICINES AND HEALTH PRODUCTS REGULATORY
AUTHORITY**

The Liberian Medicines and Health Products Regulatory Authority (LMHRA) 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 LMHRA may include non-public information exempt from public disclosure under the laws and regulations of the Republic of Liberia, 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 LMHRA 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 LMHRA and USFDA. LMHRA 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 LMHRA;
2. will not publicly disclose such LMHRA-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 LMHRA that the information no longer has non-public status;
3. will inform LMHRA promptly of any effort made by judicial or legislative mandate to obtain LMHRA-provided non-public information from USFDA. If such judicial or legislative mandate orders disclosure of LMHRA-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 LMHRA 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.

---/S/---

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

Date:

2/3/2015

WO 1 RM2326
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002


Telephone: +1 301 796 7460

**STATEMENT OF AUTHORITY AND
CONFIDENTIALITY COMMITMENT FROM
THE LIBERIAN MEDICINES AND HEALTH PRODUCTS REGULATORY
AUTHORITY
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION REGARDING
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 Liberian Medicines and Health Products Regulatory Authority (LMHRA) regarding medical products used, or proposed to be used, for Ebola-related purposes as part of cooperative law enforcement or cooperative regulatory activities.

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

Therefore, LMHRA certifies that it:

1. has the authority to protect from public disclosure such non-public information provided to LMHRA 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 LMHRA. If such judicial or legislative mandate orders disclosure of FDA-provided non-public information, LMHRA 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 

---/S/---

4. will promptly inform FDA of any changes to the Republic of Liberia's laws, or to any relevant policies or procedures, that would affect LMHRA's ability to honor the commitments in this document.

---/S/---

Jan. 28, 2015

David Sumo
Managing Director
Liberian Medicines and Health Products Regulatory Authority
V. P. Road, Old Road
Congo Town
Monrovia, Liberia

Date

Telephone: (+231) 886 562 019