



**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 MINISTRY OF HEALTH AND PUBLIC HYGIENE OF GUINEA**

The Ministry of Health and Public Hygiene of Guinea is authorized to disclose non-public information to the U.S. Food and Drug Administration (FDA) regarding medical products used, or proposed to be used, for Ebola-related purposes as part of cooperative law enforcement or cooperative regulatory activities.

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

Therefore, FDA certifies that it:

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

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

Sept 1, 2015
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**STATEMENT OF AUTHORITY
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CONFIDENTIALITY COMMITMENT FROM
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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 Ministère de la Santé et de L'Hygiene Publique (Ministry of Health, Guinea) regarding medical products used, or proposed to be used, for Ebola-related purposes as part of cooperative law enforcement or cooperative regulatory activities.

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

Therefore, the Ministry of Health, Guinea certifies that it:

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

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24/08/2015

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