

**STATEMENT OF AUTHORITY  
AND  
CONFIDENTIALITY COMMITMENT FROM  
THE MINISTRY OF HEALTH OF GUINEA  
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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Dr. Kabiné Souaré,  
Directeur National de la Pharmacie et des Laboratoires,  
Ministère de la Santé et de L'Hygiene Publique,  
Conakry, Guinea

Telephone: