

**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 MIDDLE EAST RESPIRATORY SYNDROME CORONAVIRUS
PURPOSES SHARED BY
THE SAUDI FOOD AND DRUG AUTHORITY**

The Saudi Food and Drug Authority, Kingdom of Saudi Arabia (SFDA) 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 Middle East Respiratory Syndrome Coronavirus (MERS-CoV) purposes as part of cooperative law enforcement or cooperative regulatory activities.

USFDA understands that some of the information it receives from the SFDA may include non-public information exempt from public disclosure under the laws and regulations of the Kingdom of Saudi Arabia, 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 the SFDA 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 the SFDA and USFDA. The SFDA 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 the SFDA;
2. will not publicly disclose such non-public information provided by the SFDA 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 SFDA that the information no longer has non-public status;
3. will inform the SFDA promptly of any effort made by judicial or legislative mandate to obtain non-public information provided by the SFDA from USFDA. If such judicial or legislative mandate orders disclosure of non-public information provided by the SFDA, 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 SFDA 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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October 20, 2015

Howard Sklamberg, J.D.
Deputy Commissioner for Global Regulatory
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Date

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THE SAUDI FOOD AND DRUG AUTHORITY
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION ON MEDICAL
PRODUCTS USED, OR PROPOSED TO BE USED, FOR MIDDLE EAST
RESPIRATORY SYNDROME CORONAVIRUS 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 Saudi Food and Drug Authority (SFDA) regarding medical products used, or proposed to be used, for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) as part of cooperative law enforcement or cooperative regulatory activities.

The Saudi Food and Drug Authority (SFDA) understands that some of the information it receives from FDA on MERS-CoV 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 SFDA understands that this non-public information on MERS-CoV medical products is shared in confidence and that FDA considers it critical that the SFDA maintain the confidentiality of the information. Public disclosure of this information by the SFDA could seriously jeopardize any further scientific and regulatory interactions between FDA and the SFDA. FDA will advise the SFDA of the non-public status of the information at the time that the information is shared.

Therefore, the SFDA certifies that it:

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

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October 11, 2015

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Date