

**CONFIDENTIALITY COMMITMENT  
STATEMENT OF LEGAL AUTHORITY  
AND COMMITMENT FROM  
THE MEDICINES CONTROL COUNCIL (MCC) OF SOUTH AFRICA  
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED  
BY THE U.S. FOOD AND DRUG ADMINISTRATION (USFDA), U.S.  
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

The United States Food and Drug Administration (USFDA), a part of the United States Department of Health and Human Services, is authorized under 21 C.F.R. § 20.89 (“Communications with Foreign Government Officials”) to disclose non-public information to the Medicines Control Council (MCC) of South Africa regarding USFDA regulated products as part of cooperative law enforcement or cooperative regulatory activities.

The MCC understands that some of the information it receives from USFDA may include non-public information exempt from public disclosure under the laws and regulations of the United States of America, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information. The MCC understands that this non-public information is shared in confidence, and that USFDA considers it critical that the MCC maintains the confidentiality of the information. Public disclosure of this information by the MCC could seriously jeopardize any further scientific and regulatory interactions between USFDA and the MCC. USFDA will advise the MCC of the non-public status of the information at the time that the information is shared.

Therefore, the MCC certifies that it:

1. has the authority to protect the non-public information provided to MCC in confidence by the USFDA from public disclosure.
2. will not publicly disclose the USFDA-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 USFDA that the information no longer has non-public status;
3. will inform USFDA within two days of any effort made to obtain USFDA-provided non-public information from MCC by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of USFDA-provided non-public information. MCC will take all 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 USFDA of any changes to South African laws, MCC policies or procedures that would affect the MCC ability to honor the agreements in this document.

