



CONFIDENTIALITY COMMITMENT

**STATEMENT OF LEGAL AUTHORITY
AND COMMITMENT**

FROM

**THE U. S. FOOD AND DRUG ADMINISTRATION,
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED
BY**

THE MEDICINES CONTROL COUNCIL OF SOUTH AFRICA

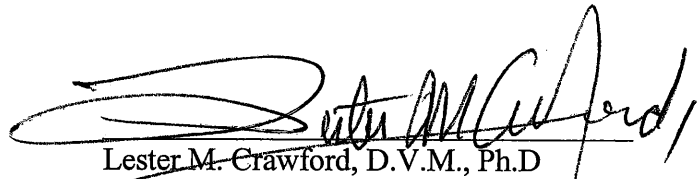
The Medicines Control Council (MCC) of South Africa is authorized to disclose non-public information to the U.S. Food and Drug Administration (USFDA) regarding MCC regulated products as part of cooperative law enforcement or cooperative regulatory activities.

USFDA understands that some of the information it receives from MCC may include non-public information exempt from public disclosure under the laws and regulations of South Africa, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information. USFDA understands that this non-public information is shared in confidence and that MCC considers it critical that USFDA maintains the confidentiality of the information. Public disclosure of this information by USFDA could seriously jeopardize any further scientific and regulatory interactions between MCC and USFDA. MCC 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 the non-public information provided to USFDA in confidence by MCC;
2. will not publicly disclose the MCC-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 MCC that the information no longer has non-public status;

3. will inform MCC within two working days of any effort made to obtain MCC-provided non-public information from USFDA by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of MCC-provided non-public information, USFDA 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 MCC of any changes to United States laws, USFDA policies, or USFDA procedures that would affect USFDA's ability to honor the commitments in this document.



Lester M. Crawford, D.V.M., Ph.D

Acting Commissioner of Food and Drugs
United States Food and Drug Administration
United States Department of Health and Human Services

DEC - 6 2004

Date

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