



CONFIDENTIALITY COMMITMENT

**STATEMENT OF LEGAL AUTHORITY
AND COMMITMENT**

FROM

THE U.S. FOOD AND DRUG ADMINISTRATION (USFDA)

NOT TO

**PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED BY
THE HEALTH SCIENCES AUTHORITY (HSA)
SINGAPORE**

The Singapore Health Sciences Authority (HSA) is authorized under The Medicines Act (Chapter 176) Section 19B 1(b) ("Circumstances where protection under section 19A does not apply") to disclose non-public information to the USFDA regarding HSA regulated products as part of cooperative law enforcement or cooperative regulatory activities.

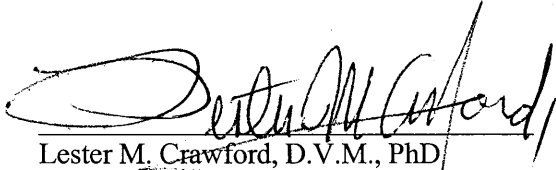
USFDA understands that some of the information it receives from HSA may include non-public information exempt from public disclosure under the laws and regulations of Singapore, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information. USFDA understands that this non-public information is shared in confidence, and that HSA 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 HSA and USFDA. HSA 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 the non-public information provided to USFDA in confidence by the HSA from public disclosure;
2. will not publicly disclose the HSA-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 HSA that the information no longer has non-public status;
3. will inform HSA within two working days of any effort made to obtain HSA-provided non-public information from USFDA by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of HSA-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 HSA of any changes to United States laws, USFDA policies or procedures that would affect USFDA's ability to honor the agreements in this document.



Lester M. Crawford, D.V.M., PhD

AUG 25 2004
Date

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

HF-1
5600 Fishers Lane
Rockville, Maryland
Telephone: +1 301-827-2410
Fax: +1 301-827-3100