

### CONFIDENTIALITY COMMITMENT

## STATEMENT OF LEGAL AUTHORITY AND COMMITMENT

### **FROM**

## THE AUSTRALIAN PESTICIDES AND VETERINARY MEDICINES AUTHORITY

# NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED BY

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

The U.S. Food and Drug Administration of the Department of Health and Human Services (USFDA) is authorized to disclose non-public information to the Australian Pesticides and Veterinary Medicines Authority (APVMA) regarding USFDA-regulated products as part of cooperative law enforcement or cooperative regulatory activities.

APVMA 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 USA, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information. APVMA understands that this non-public information is shared in confidence, and that USFDA considers it critical that APVMA maintains the confidentiality of the information. Public disclosure of this information by APVMA could seriously jeopardize any further scientific and regulatory interactions between USFDA and APVMA. USFDA will advise APVMA of the non-public status of the information at the time that the information is shared.

### Therefore, APVMA certifies that it:

- 1. has the authority to protect from public disclosure the non-public information provided to APVMA in confidence by USFDA;
- 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 working days of any effort made by judicial or legislative mandate to obtain USFDA-provided non-public information from APVMA. If such judicial or legislative mandate orders disclosure of USFDA-provided non-public information, APVMA 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 USFDA of any changes to APVMA laws, and any relevant policies or procedures that would affect APVMA's ability to honor the agreements in this document.

Roland J Smith, PhD

Chief Executive Officer

Australian Pesticides and Veterinary Medicines Authority

20 October 2005

Date

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