

**MEMORANDUM OF UNDERSTANDING
BETWEEN THE
UNITED STATES FOOD AND DRUG
ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND THE
AUSTRALIAN PESTICIDES AND
VETERINARY MEDICINES AUTHORITY
AUSTRALIA**



U.S. Food and Drug Administration



I. PREAMBLE

Whereas the United States Food and Drug Administration (USFDA), Department of Health and Human Services, and the Australian Pesticides and Veterinary Medicines Authority (APVMA), Australia, hereinafter “the Participants,” are responsible for the regulation of animal drugs in their respective countries;

Noting that the Participants have a strong record of cooperation in various international fora to advance the effective regulation of animal drugs and a history of ad hoc direct cooperation on technical regulatory matters;

Acknowledging that the Participants recognize that there is mutual advantage to increasing the scope of, and strengthening the framework for, such cooperation; and

Recognizing that APVMA (a statutory authority established under the *Australian Agricultural and Veterinary Chemicals Code Act 1994 (the Code Act)*) and the USFDA (under authority of the U.S. Federal Food, Drug, and Cosmetic Act 1938 and its amendments) have similar approaches to regulation of veterinary medicines (animal drugs) in the broad sense and at the practical level in relation to the type of data required by both organizations;

The Participants have reached the following Understanding.

II. PURPOSE

This Memorandum of Understanding (MOU) is intended to establish an information-sharing arrangement between APVMA and USFDA. The Participants intend to strengthen the exchange of knowledge and expertise to enhance the efficiency and effectiveness of their respective roles. This MOU focuses on cooperation in relation to the operational aspects of animal drug regulation and is not intended to cover broader government regulatory policy or to cover areas not falling under the common jurisdictional purview of the Participants.

III. SCOPE

1. The Participants may exchange information on risk assessment and risk management options with respect to animal drugs that are approved in each country and may work concurrently, and exchange information, to conduct scientific risk assessments.
2. The exchange of information and cooperative action between the Participants is intended to relate to veterinary drug regulatory matters of mutual interest, with a focus on the following modes of cooperation:
 - (i) Developing a system for early information exchange on upcoming animal drug issues that may impact on Australia and the United States. This may involve exchange of information on routine issues and agency initiatives that may be of mutual interest such as the quality of animal drugs, issues of public health concern, risk reduction, minor uses, and efficiency and process measures;

- (ii) Promoting scientific discussions among technical staffs in cooperative efforts, including visits by scientists from one Participant to the other;
- (iii) Meeting on the margins of existing international fora, as appropriate, to discuss matters of mutual interest;
- (iv) Promoting discussion of new animal drugs under evaluation and existing animal drugs under re-evaluation and, as appropriate, exchanging assessment reports prepared for animal drugs of common interest; and
- (v) Exchanging information and experience in relation to information technology, particularly in the area of electronic data submission and templates.

IV. CONFIDENTIALITY

Information exchanged under this MOU may include non-public information exempt from public disclosure under the laws and regulations of the United States or Australia. Information that is not appropriate for public dissemination is only to be shared according to the procedures and policies of the Participants and as permitted by their respective laws. Neither USFDA nor APVMA are to share trade secret information without the consent of the owner. USFDA and APVMA may also obtain the consent of the owner or individual prior to sharing other types of information. With regard to any non-public information that may be provided to APVMA by the USFDA or to the USFDA by APVMA, such transmissions are to be made in accordance with the specific signed confidentiality commitments and other requirements of the Participants.

V. COOPERATIVE ACTIVITIES

Any exchange of information or other activity under this MOU is to be performed in accordance with applicable laws and regulations.

1. The Participants intend to meet as appropriate to develop and implement specific areas of cooperation and to update existing protocols to ensure they are consistent with the intent and principles contained within this MOU.
2. The Participants may, as warranted by particular circumstances and if possible within their respective resources, form Working Groups to address specific issues bearing on the successful implementation of this MOU.
3. The Participants may meet via teleconference or videoconference to develop and implement a work program governing specific areas of cooperation and to update existing understandings to ensure that they are consistent with the intent and principles contained within this MOU.

VI. FUNDING OF COOPERATION

Each Participant intends to cover its own costs and recognizes the other's responsibility to fund and carry out its own activities subject to, and to the extent made possible by, the availability of appropriated funds, personnel, and other resources.

VII. CONTACT POINTS

1. The officers responsible for the administration of this MOU are:

- (i) Dr. Roland Smith
Chief Executive Officer
Australian Pesticides and Veterinary Medicines Authority
22 Brisbane Avenue
BARTON ACT 2600
(PO Box E240 KINGSTON ACT 2604)
AUSTRALIA
Tel: 61-2-62724277
Fax: 61-2-62723195

- (ii) Dr. Stephen Sundlof, Director
Center for Veterinary Medicine,
U.S. Food and Drug Administration
7519 Standish Place, HFV-1
Rockville, MD 20855
UNITED STATES OF AMERICA
Tel: 1-301- 827-2950
Fax: 1-301-827-4401

2. The officers responsible for the day-to-day operations under this MOU are:

- (i) Mr. Martin Holmes
Program Manager Veterinary Medicines
Australian Pesticides and Veterinary Medicines Authority
22 Brisbane Avenue
BARTON ACT 2600
(PO Box E240 KINGSTON ACT 2604)
AUSTRALIA
Tel: 61-2-62723471
Fax: 61-2-62723195

- (ii) Mr. Russell Campbell Jr.
Associate Director for International Policy
Office of International Programs
U.S. Food and Drug Administration
5600 Fishers Lane, HFG-1
Room 15-A-55
Rockville MD, 20857
UNITED STATES OF AMERICA
Tel: 1-301-827-4480
Fax: 1-301-480-0716

VIII. FINAL PROVISIONS

Cooperation under this MOU commences upon signature by both Participants and is effective for a period of five (5) years from that date. It may be extended for additional five-year periods by mutual written agreement of the Participants. The MOU should be evaluated at least once in every five-year period by the Participants.

The Participants may amend this document by mutual written consent. This non-binding document may be terminated upon notice. Termination of this MOU should not affect the completion of cooperative activities that may have been formalized prior to termination.

The Participants do not intend this MOU to create legally binding obligations between them under international or other law.

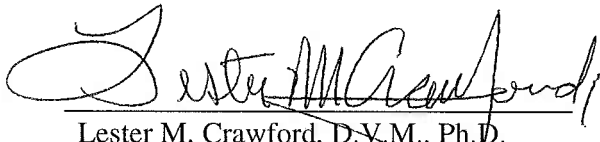
Any disagreement regarding the interpretation or implementation of this MOU is to be resolved by consultation between the Participants and is not to be referred to an international tribunal or third party settlement.

Nothing in this MOU limits or otherwise affects the rights or obligations of the United States of America or of Australia under the Agreement establishing the World Trade Organization and its Annexes, including the Agreement on the Application of Sanitary and Phytosanitary Measures, or the rights and obligations under the Australia – United States Free Trade Agreement, or any other agreement of the Participants.

IN WITNESS WHEREOF the undersigned have signed this MOU.

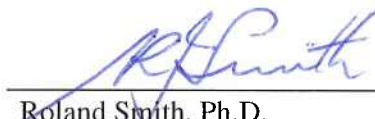
For the United States Food and Drug Administration
Department of Health and Human Services:

For the Australian Pesticides and Veterinary
Medicines Authority:



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

Commissioner of Food and Drugs
Food and Drug Administration
Department of Health and Human Services
UNITED STATES OF AMERICA



Roland Smith, Ph.D.

Chief Executive Officer
Australian Pesticides and Veterinary Medicines
Authority
AUSTRALIA

Date: SEP 23 2005

Date: 20 October 2005

Place: Rockville, Maryland

Place: Canberra, Australia