Schering has not discontinued manufacture of Celestone Soluspan injection; however, as a result of a May 2002 consent decree addressing manufacturing concerns, Schering's manufacture and distribution of Celestone Soluspan injection has been limited to providing the drug for certain medically necessary uses under a limited distribution program. Celestone Soluspan injection is being distributed as medically necessary for the following uses: (1) Neonatal use (fetal lung maturation), (2) epidural route for the management of pain due to radiculopathy in patients not responsive to systemic drug therapy and other adjunctive therapies, and (3) intra-articular and soft tissue injections for synovitis of osteoarthritis, acute gouty arthritis, nonspecific tenosynovitis, and acute and subacute bursitis. Information regarding the current distribution for Celestone Soluspan injection by Schering can be found on FDA's Drug Shortage Web site: *http://www.fda.gov/cder/drug/shortages/celestone.htm*.

FDA has reviewed its records and, under § 314.161, has determined that Celestone Soluspan (betamethasone sodium phosphate and betamethasone acetate) injection and Celestone (betamethasone sodium phosphate) injection were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list betamethasone sodium phosphate in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to betamethasone sodium phosphate may be approved by the agency. ANDAs that refer to betamethasone sodium phosphate and betamethasone acetate injection also may be approved by the agency; however, FDA recommends that in considering whether to file an ANDA for this drug product, future applicants be advised that the RLD may not be commercially available because it is being made available in certain instances of medical necessity only. An ANDA applicant who is unable to obtain Celestone Soluspan injection for bioequivalence testing must contact the Office of Generic Drugs for a determination of what showing is necessary to satisfy the requirements of section 505(j)(2)(A)(iv) of the act. If an ANDA is approved without a showing of bioequivalence, the approved product will not be granted an AB rating in the Orange Book. Future applicants for betamethasone sodium phosphate and betamethasone acetate injection are advised that if the RLD product becomes commercially available prior to ANDA approval, the ANDA applicant will need to show bioequivalence to the RLD product.

Dated: January 4, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–178 Filed 1–11–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA–225–05–8006]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between the United States Food and Drug Administration, Department of Health and Human Services and the Australian Pesticides and Veterinary Medicines Authority (APVMA), Australia. This MOU is intended to establish an information-sharing arrangement between APVMA and FDA. 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 relations 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.

DATES: The agreement became effective October 20, 2005.

FOR FURTHER INFORMATION CONTACT: Matthew E. Eckel, Office of International Programs, Food and Drug Administration, 5600 Fishers Lane (HFG–1), Rockville MD, 20857, 301–827–4480, FAX 301–480–0716.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 20.108(c), which states that all written agreements and MOUs between FDA and others shall be published in the **Federal Register**, the agency is publishing notice of this MOU.

Dated: January 4, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

BILLING CODE 4160–01–S

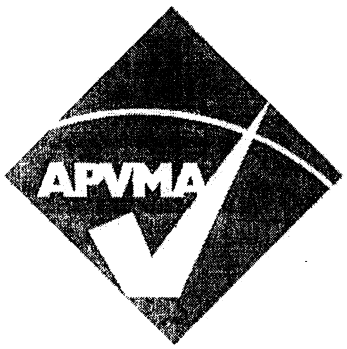
MEMORANDUM OF UNDERSTANDING BETWEEN THE

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:

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

Date: SEP 2 3 2005

Place: Rockville, Maryland

For the Australian Pesticides and Veterinary
Medicines Authority:

Roland Smith, Ph.D.

Chief Executive Officer
Australian Pesticides and Veterinary Medicines
Authority
AUSTRALIA

Date: 20 October 2005

Place: Canberra, Australia

[FR Doc. 06–251 Filed 1–11–06; 8:45 am]
BILLING CODE 4160–01–S