

**Material Incorporated by Reference**

(m) You must use Bombardier-Rotax GmbH Mandatory Service Bulletin SB-912-036/SB-914-022 Revision 1, dated August 2002, to perform the venting and inspecting required by this AD. The Director of the Federal Register previously approved the incorporation by reference of this Mandatory Service Bulletin in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, on October 23, 2002 (67 FR 65033). You can get a copy from Bombardier-Rotax GmbH, Guns kirchen, Austria; telephone 7246-601-423; fax 7246-601-760. You can review a copy at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

**Related Information**

(n) Austro Control airworthiness directives No. 113R1, dated August 30, 2002, and No. 116, dated September 15, 2003, and Rotax Service Instruction SI-04-1997, Revision 3, dated September 2002 also address the subject of this AD.

Issued in Burlington, Massachusetts, on January 3, 2005.

**Francis A. Favara,**

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.  
[FR Doc. 05-486 Filed 1-10-05; 8:45 am]

**BILLING CODE** 4910-13-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 520****Oral Dosage Form New Animal Drugs; Ivermectin Meal**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Merial, Ltd. The NADA provides for use of ivermectin meal for the control of various species of internal parasites in horses.

**DATES:** This rule is effective January 11, 2005.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7543, e-mail: [melanie.berson@fda.gov](mailto:melanie.berson@fda.gov).

**SUPPLEMENTARY INFORMATION:** Merial, Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640, filed NADA 141-241 for ZIMECTERIN-EZ (ivermectin) 0.6% w/w for Horses. The application provides for use of ivermectin meal for the control of various species of internal parasites in horses. The NADA is approved as of December 16, 2004, and part 520 (21 CFR part 520) is amended by adding new § 520.1194 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning December 16, 2004.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

**List of Subjects in 21 CFR Part 520**

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

**PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS**

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

■ 2. Section 520.1194 is added to read as follows:

**§ 520.1194 Ivermectin meal.**

(a) *Specifications.* Each gram of meal contains 6 milligrams ivermectin (0.6 percent).

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use in horses—(1) Amount.* Administer 136 micrograms (mcg) ivermectin per pound (lb) body weight (300 mcg/kilogram) as a single dose on approximately 2 lb grain or sweet feed.

(2) *Indications for use.* For treatment and control of Large Strongyles (adults): *Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds): *Coronocylus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocylus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles (fourth-stage larvae); Pinworms (adults and fourth stage larvae): *Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae): *Parascaris equorum*; Hairworms (adults): *Trichostrongylus axei*; Large Mouth Stomach Worms (adults): *Habronema muscae*; Bots (oral and gastric stages): *Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae): *Dictyocaulus arnfieldi*; Intestinal Threadworms (adults): *Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

(3) *Limitations.* Do not use in horses intended for human consumption.

Dated: December 29, 2004.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 05-523 Filed 1-10-05; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

#### Oral Dosage Form New Animal Drugs; Lincomycin Hydrochloride Soluble Powder

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The ANADA provides for oral use of lincomycin soluble powder to make medicated drinking water for administration to swine for the treatment of swine dysentery or to broiler chickens for the control of necrotic enteritis.

**DATES:** This rule is effective January 11, 2005.

**FOR FURTHER INFORMATION CONTACT:**

Lonnie W. Luther, Center for Veterinary Medicine (HFV 104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: [lonnie.luther@fda.gov](mailto:lonnie.luther@fda.gov).

**SUPPLEMENTARY INFORMATION:** Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200-377 for LINCAMED (lincomycin hydrochloride) Soluble Powder. The application provides for oral use of lincomycin soluble powder to make medicated drinking water for administration to swine for the treatment of swine dysentery or to broiler chickens for the control of necrotic enteritis. Cross Vetpharm Group Ltd.'s LINCAMED Soluble Powder is approved as a generic copy of Pharmacia & Upjohn Co.'s LINCOMUX Soluble Powder, approved under NADA 111-636. ANADA 200-377 is approved as of December 6, 2004, and the regulations are amended in 21 CFR 520.1263c to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part

20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to congressional review requirements in 5 U.S.C. 801-808.

#### List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

#### PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

■ 2. Section 520.1263c is amended by revising paragraph (b) to read as follows:

#### § 520.1263c Lincomycin hydrochloride soluble powder.

\* \* \* \* \*

(b) *Sponsors.* See Nos. 000009, 046573, 054925, 059130, and 061623 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

\* \* \* \* \*

Dated: December 29, 2004 .

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 05-524 Filed 1-10-05; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF COMMERCE

### Patent and Trademark Office

#### 37 CFR Parts 1 and 3

[Docket No.: 2004-P-034]

RIN 0651-AB76

#### Changes To Implement the Cooperative Research and Technology Enhancement Act of 2004

**AGENCY:** United States Patent and Trademark Office, Commerce.

**ACTION:** Interim rule.

**SUMMARY:** The Cooperative Research and Technology Enhancement Act of 2004 (CREATE Act) amends the patent laws to provide that subject matter developed by another person shall be treated as owned by the same person or subject to an obligation of assignment to the same person for purposes of determining obviousness if three conditions are met: The claimed invention was made by or on behalf of parties to a joint research agreement that was in effect on or before the date the claimed invention was made; the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement; and the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement. The United States Patent and Trademark Office (Office) is revising the rules of practice in patent cases to implement the CREATE Act.

**DATES:** Effective Date: December 10, 2004.

*Comment Deadline Date:* To be ensured of consideration, written comments must be received on or before February 10, 2005. No public hearing will be held.

**ADDRESSES:** Comments should be sent by electronic mail message over the Internet addressed to: [ab76comments@uspto.gov](mailto:ab76comments@uspto.gov). Comments may also be submitted by mail addressed to: Box Comments—Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA, 22313-1450, or by facsimile to (571) 273-7735, marked to the attention of Robert A. Clarke. Although comments may be submitted by mail or facsimile, the Office prefers to receive comments via the Internet. If comments are submitted by mail, the Office prefers that the comments be submitted on a DOS formatted 3½ inch disk accompanied by a paper copy.

Comments may also be sent by electronic mail message over the Internet via the Federal eRulemaking Portal. See the Federal eRulemaking