

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Correction

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Corrected]

2. Section 39.13 is amended by correctly adding the following airworthiness directive (AD):

2001-23-13 Boeing: Amendment 39-12512. Docket 2000-NM-350-AD.

Applicability: Model 747 series airplanes, line numbers 0001 through 1207, certificated in any category; excluding the airplanes having line number 1174 and Model 747SP series airplanes.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent damage to the flap system, adjacent systems, or structural components; or excessive skew of the trailing edge flap; which could result in flap asymmetry and consequent reduced controllability of the airplane, accomplish the following:

Part Verification/Replacement/Modification

(a) Within 18 months or 7,500 flight hours after December 31, 2001, whichever occurs later: Inspect the flap drive transmission of the trailing edge flaps at positions 2 and 7 to determine if a discrepant ("Belleville" spring design) torque brake is installed in the transmission, by verifying the transmission part number, per Boeing Service Bulletin 747-27-2374, dated November 18, 1999. Then do the actions specified in paragraphs (a)(1) and (a)(2) of this AD, as applicable.

(1) If the part number of the flap drive transmission shows that no discrepant torque brake is installed, no further action is required by this AD.

(2) If the part number of the flap drive transmission shows that a discrepant torque brake may be installed, within the compliance time required by paragraph (a) of this AD: Inspect the part number of the torque brake to verify whether it is a discrepant torque brake, per the Accomplishment Instructions of the service bulletin.

(i) If the part number of the torque brake shows that it is not a discrepant torque brake, no further action is required by this AD.

(ii) If the part number of the torque brake shows that it is a discrepant torque brake: Within the compliance time required by paragraph (a) of this AD either replace the transmission with a new, improved transmission or rework the existing transmission by replacing the torque brake with a new or reworked torque brake having the part number specified in the service bulletin; per the Accomplishment Instructions of the service bulletin.

Spares

(b) As of December 31, 2001, no person shall install on any airplane any transmission or torque brake assembly of the trailing edge flaps at positions 2 or 7, as identified in the "Existing Part Number" column of Paragraph 2.E. of Boeing Service Bulletin 747-27-2374, dated November 18, 1999.

Alternative Methods of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permit

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Incorporation by Reference

(e) The actions shall be done in accordance with Boeing Service Bulletin 747-27-2374, dated November 18, 1999. This incorporation by reference was approved previously by the Director of the Federal Register as of December 31, 2001 (66 FR 58918, November 26, 2001). Copies may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124-2207. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Effective Date

(f) The effective date of this amendment remains December 31, 2001.

Issued in Renton, Washington, on February 7, 2002.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02-3588 Filed 2-13-02; 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; Carprofen**

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 supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for a once daily, 2-milligram per pound (mg/lb) dosage of carprofen, by oral chewable tablet, for the relief of pain and inflammation associated with osteoarthritis in dogs.

DATES: This rule is effective February 14, 2002.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540, e-mail: mberson@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed a supplement to approved NADA 141-111 that provides for veterinary prescription use of RIMADYL (carprofen) Chewable Tablets for the relief of pain and inflammation associated with osteoarthritis in dogs. The supplemental NADA provides for a once daily, 2-mg/lb dosage for the oral chewable tablet dosage form. The supplemental application is approved as of November 26, 2001, and the regulations are amended in 21 CFR 520.309 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 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 Dockets Management Branch (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.

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 520.309 is amended in paragraph (a) by removing "of" and by revising paragraph (d)(1) to read as follows:

§ 520.309 Carprofen.

* * * * *

(d) * * *

(1) *Amount.* 2 mg per pound (lb) of body weight once daily or 1 mg/lb twice daily.

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Dated: February 5, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02–3682 Filed 2–13–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Florfenicol

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 supplemental new animal

drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplement provides for changing a pathogen genus from *Pasteurella* to *Mannheimia* on labeling of florfenicol injectable solution.

DATES: This rule is effective February 14, 2002.

FOR FURTHER INFORMATION CONTACT:

Naba K. Das, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7569, e-mail: ndas@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., P.O. Box 3182, Union, NJ 07083, is the sponsor of NADA 141–063 that provides for use of NUFLO (florfenicol) Injectable Solution in cattle. Schering-Plough Animal Health Corp. filed a supplemental NADA providing for changing a pathogen genus from *Pasteurella* to *Mannheimia* on product labeling. The NADA is approved as of November 8, 2001, and the regulations are amended in § 522.955 (21 CFR 522.955) to reflect the approval. Section 522.955 is also being amended to reflect an updated format. Approval of this supplemental NADA did not require review of safety or effectiveness data; therefore, a freedom of information summary is not required.

The agency 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 the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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

2. Section 522.955 is amended by revising the section heading and by revising paragraphs (a), (d)(1)(i),

(d)(1)(ii), and (d)(1)(iii) to read as follows:

§ 522.955 Florfenicol.

(a) *Specifications.* Each milliliter of solution contains 300 milligrams (mg) of florfenicol.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* 20 mg per kilogram (kg) of body weight as an intramuscular injection. A second dose should be administered 48 hours later.

(A) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Mannheimia* (*Pasteurella*) *haemolytica*, *P. multocida*, and *Haemophilus somnus*. For treatment of bovine interdigital phlegmon (foot rot, acute interdigital necrobacillosis, infectious pododermatitis) associated with *Fusobacterium necrophorum* and *Bacteroides melaninogenicus*.

(B) [Reserved]

(ii) *Amount.* 40 mg/kg body weight as a single subcutaneous injection.

(A) *Indications for use.* As in paragraph (d)(1)(i)(A) of this section; for control of respiratory disease in cattle at high risk of developing BRD associated with *M. (Pasteurella) haemolytica*, *P. multocida*, and *H. somnus*.

(B) [Reserved]

(iii) *Limitations.* Do not slaughter within 28 days of last intramuscular treatment or within 38 days of subcutaneous treatment. Do not use in female dairy cattle 20 months of age or older. Use may cause milk residues. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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Dated: January 31, 2002.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 02–3680 Filed 2–13–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Zeranol

AGENCY: Food and Drug Administration, HHS.