

Unsafe Condition

(d) This AD results from the discovery of a hole in the upper frame of the firewall for the auxiliary power unit (APU). We are issuing this AD to ensure that the APU compartment is isolated from the rest of the airplane in the event of an APU fire. If the APU compartment is not isolated, smoke could enter the passenger cabin in the event of an APU fire.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Modification

(f) Within 2,500 flight hours or 365 days after the effective date of this AD, whichever occurs later, modify the APU firewall upper frame, part number 145-51249-001 or 120-10731-001, in accordance with the Accomplishment Instructions of EMBRAER Service Bulletin 145LEG-53-0020, Revision 01, dated September 21, 2005 (for Model EMB-135BJ airplanes); or EMBRAER Service Bulletin 145-53-0057, Revision 01, dated September 20, 2005 (for Model EMB-135ER, -135KE, -135KL, and -135LR airplanes; and Model EMB-145, -145ER, -145MR, -145LR, -145XR, -145MP, and -145EP airplanes); as applicable.

Modifications Accomplished According to Previous Issue of Service Bulletins

(g) Modifications accomplished before the effective date of this AD according to EMBRAER Service Bulletin 145LEG-53-0020, dated November 30, 2004; and EMBRAER Service Bulletin 145-53-0057, dated November 30, 2004; are considered acceptable for compliance with the corresponding action specified in this AD.

Alternative Methods of Compliance (AMOCs)

(h)(1) The Manager, International Branch, ANM-116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(i) Brazilian airworthiness directive 2005-04-03, dated April 30, 2005, also addresses the subject of this AD.

Material Incorporated by Reference

(j) You must use EMBRAER Service Bulletin 145LEG-53-0020, Revision 01, dated September 21, 2005; or EMBRAER Service Bulletin 145-53-0057, Revision 01, dated September 20, 2005; as applicable, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference of these documents in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Contact Empresa Brasileira de Aeronautica S.A. (EMBRAER),

P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil, for a copy of this service information. You may review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., room PL-401, Nassif Building, Washington, DC; on the Internet at <http://dms.dot.gov>; or at the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741-6030, or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

Issued in Renton, Washington, on November 9, 2005.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05-22792 Filed 11-18-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

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 new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The NADA provides for the use of florfenicol by veterinary feed directive in catfish feed for the control of mortality due to enteric septicemia of catfish.

DATES: This rule is effective November 21, 2005.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.gov.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed NADA 141-246 that provides for use of AQUAFLO (florfenicol) Type A medicated article by veterinary feed directive to formulate Type C medicated feeds for the control of mortality due to enteric septicemia of catfish associated with *Edwardsiella ictaluri*. The NADA is approved as of October 24, 2005, and the regulations are amended in 21 CFR 556.283 and in part 558 (21 CFR part 558) by revising § 558.4 and by adding new § 558.261 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 573(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ccc-2), this approval qualifies for 7 years of exclusive marketing rights beginning October 24, 2005, because the new animal drug has been declared a designated new animal drug by FDA under section 573(a) of the act.

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

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

21 CFR Part 556

Animal drugs, Foods.

21 CFR Part 558

Animal drugs, Animal feeds.

■ 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 parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 2. Add paragraphs (b)(3) and (c) in § 556.283 to read as follows:

§ 556.283 Florfenicol.

* * * * *

(b) * * *

(3) *Catfish*. The tolerance for florfenicol amine (the marker residue) in muscle (the target tissue) is 1 ppm.

(c) *Related conditions of use*. See §§ 520.955, 522.955, and 558.261 of this chapter.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 4. In paragraph (d) of § 558.4, in the “Category II” table, add an entry in

alphabetical order for “Florfenicol” to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

CATEGORY II

| Drug | Assay limits percent ¹ Type A | Type B maximum (100x) | Assay limits percent ¹ Type B/C ² |
|-------------|--|-----------------------|---|
| Florfenicol | 90–110 | n/a | 80–110 |

¹ Percent of labeled amount.

² Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make Type C medicated feed.

* * * * *

■ 5. Add § 558.261 to read as follows:

§ 558.261 Florfenicol.

(a) *Specifications*. Type A medicated article containing 500 grams florfenicol per kilogram.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Special considerations*—(1) Federal law limits this drug to use under the professional supervision of a licensed veterinarian. See § 558.6 of this chapter for additional requirements.

(2) The expiration date of veterinary feed directives (VFDs) for florfenicol must not exceed 15 days from the date of issuance. VFDs for florfenicol shall not be refilled.

(d) *Related tolerances*. See § 556.283 of this chapter.

(e) *Conditions of use*—(1) *Catfish*—(i) *Amount*. 10 milligrams per kilogram of fish daily for 10 consecutive days.

(ii) *Indications for use*. For the control of mortality due to enteric septicemia of catfish associated with *Edwardsiella ictaluri*.

(iii) *Limitations*. Feed containing florfenicol shall not be fed to catfish for more than 10 days. Following 10 days administration, fish should be re-evaluated by a licensed veterinarian before reinitiating a further course of therapy. A dose-related decrease in hematopoietic/lymphopoietic tissue may occur. The time required for the hematopoietic/lymphopoietic tissues to regenerate was not evaluated. The effects of florfenicol on reproductive performance have not been determined.

Feeds containing florfenicol must be withdrawn 12 days prior to slaughter.
(2) [Reserved]

Dated: November 8, 2005.

Andrew J. Beaulieu,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 05–22935 Filed 11–18–05; 8:45 am]

BILLING CODE 4160–01–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[R04–OAR–2005–KY–0001–200521(c); FRL–7999–5]

Approval and Promulgation of Implementation Plans and Designation of Areas for Air Quality Planning Purposes; Kentucky; Redesignation of the Christian County, Kentucky Portion of the Clarksville-Hopkinsville 8-Hour Ozone Nonattainment Area to Attainment for Ozone; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: On October 21, 2005, at 70 FR 61232, EPA published a withdrawal action of a direct final rule approving the redesignation of the Christian County, Kentucky portion of the Clarksville-Hopkinsville 8-hour ozone nonattainment area to attainment for ozone. This document corrects a Code of Federal Regulations (CFR) reference contained in the withdrawal action.

DATES: This correction is effective November 21, 2005.

FOR FURTHER INFORMATION CONTACT: Mr. Sean Lakeman, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9043. Mr. Lakeman can also be reached via electronic mail at lakeman.sean@epa.gov.

SUPPLEMENTARY INFORMATION: EPA is making a correction to the document published October 21, 2005 (70 FR 61232), which withdrew the direct final rule published September 22, 2005, (70 FR 55550) approving the redesignation of the Christian County, Kentucky portion of the Clarksville-Hopkinsville 8-hour ozone nonattainment area to attainment for ozone. EPA is correcting the citation to the CFR contained in the October 21, 2005, withdrawal action to exclude an erroneous reference to 40 CFR 52.919. The last paragraph after the signature block on page 61232 should read as follows: “Accordingly, the amendment to 40 CFR 52.920 and 40 CFR 81.318 (which published in the **Federal Register** on September 22, 2005, at 70 FR 55550) is withdrawn as of October 21, 2005.”

Dated: November 15, 2005.

J.I. Palmer Jr.,

Regional Administrator, Region 4.

[FR Doc. 05–23086 Filed 11–18–05; 8:45 am]

BILLING CODE 6560–50–P