

correct an unsafe condition in aircraft, and is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

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 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

2001-24-12 Rolls-Royce Corporation (formerly Allison Engine Company):
Amendment 39-12529. Docket No. 2001-NE-38-AD.

Applicability

This airworthiness directive (AD) is applicable to Rolls-Royce Corporation (formerly Allison Engine Company) models 250-C20, -C20B, -C20F, -C20J, -C20R, -C20R/1, -C20R/2, -C20S, and -C20W turboshaft engines, and 250-B17, -B17C, -B17D, -B17E, -B17F, -B17F/1, and -B17F/2 turboprop engines. These engines are used on, but not limited to Aerospatiale AS355; Agusta A109; A109A, A109C; Bell 206B, 206L, 206LT; Enstrom TH28; McDonnell Douglas 500C, 500D, 500E, 520N; Rogerson-Hiller FH1100; Schweizer TH330; Soloy Conversions Bell 47/47G, Hiller UH-12; American Jet Industries/Cessna 402, 414; and ASTA/GAF Nomad N-22 aircraft.

Note 1: This AD applies to each engine 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 engines 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 (d) 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

Compliance with this AD is required as indicated, unless already done.

To prevent uncontained release of power turbine blades and disk fragments caused by engine overspeed, resulting in an uncommanded engine shutdown, engine fire, and damage to the aircraft, do the following:

(a) Before further flight, remove helical torque-meter gearshaft assemblies part numbers (P/N's) 23035299 and 23038191 that have accumulated 100 hours or less time-since-new (TSN). Replace with a serviceable helical torque-meter gearshaft assembly.

(b) After the receipt of this AD, do not install any helical torque-meter gearshaft assembly P/N 23035299 or 23038191 that has accumulated 100 hours or less TSN.

Definition

(c) For the purposes of this AD, the following helical torque-meter gearshaft assemblies are considered serviceable parts:

(1) P/N's 23035299 and 23038191 that have greater than 100 hours TSN.

(2) An assembly with a P/N other than P/N's 23035299 and 23038191.

Alternative Methods of Compliance

(d) 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, Chicago Aircraft Certification Office. Operators must submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Chicago Aircraft Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Chicago Aircraft Certification Office.

Special Flight Permits

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

Effective Date of This AD

(f) This amendment becomes effective December 19, 2001.

Issued in Burlington, Massachusetts, on November 27, 2001.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 01-29950 Filed 12-3-01; 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 for Use in Animal Feeds; Diclazuril

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 NADA provides for use of the approved diclazuril Type A medicated article to make Type B and Type C medicated feeds used for prevention of coccidiosis in growing turkeys. Also, tolerances for diclazuril residues in turkey liver, muscle, and skin with adherent fat are being established.

DATES: This rule is effective December 4, 2001.

FOR FURTHER INFORMATION CONTACT:

Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., P.O. Box 3182, Union, NJ 07083, filed a supplement to NADA 140-951 that provides for use of CLINACOX (0.2 percent diclazuril) Type A medicated article to make Type B and Type C medicated turkey feeds used for the prevention of coccidiosis caused by *Eimeria adenoeides*, *E. gallopavonis*, and *E. meleagrimitis*. The NADA is approved as of September 21, 2001, and the regulations are being amended in §§ 556.175 and 558.198 (21 CFR 556.175 and 558.198) to reflect the approval. In addition, § 556.175 is being redesignated as § 556.185 to place it in alphabetical order in 21 CFR part 556. 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 each 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning September 21, 2001, because the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the application and conducted or sponsored by the applicant.

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 Dockets Management Branch (address above) 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, Food.

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.

§ 556.175 [Redesignated as § 556.185]

2. Section 556.175 is redesignated as § 556.185 and is amended by revising paragraph (b)(1) and by adding paragraph (b)(2) to read as follows:

§ 556.185 Diclazuril.

* * * * *

(b) *Tolerances*—(1) *Chickens*—(i) *Liver*. The tolerance for parent diclazuril (the marker residue) is 3 parts per million (ppm).

(ii) *Muscle*. The tolerance for parent diclazuril (the marker residue) is 0.5 ppm.

(iii) *Skin/fat*. The tolerance for parent diclazuril (the marker residue) is 1 ppm.

(2) *Turkeys*—(i) *Liver*. The tolerance for parent diclazuril (the marker residue) is 3 ppm.

(ii) *Muscle*. The tolerance for parent diclazuril (the marker residue) is 0.5 ppm.

(iii) *Skin/fat*. The tolerance for parent diclazuril (the marker residue) is 1 ppm.

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. Section 558.198 is amended in paragraph (b) by removing "556.175" and by adding in its place "556.185"; and in paragraph (d)(1) by adding a heading and by revising the introductory text, and by adding paragraph (d)(2) to read as follows:

§ 558.198 Diclazuril.

* * * * *

(d) *Conditions of use*—(1) *Chickens*. For chickens it is used as follows:

* * * * *

(2) *Turkeys*. For turkeys it is used as follows:

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91 (1 ppm)		Growing turkeys: For the prevention of coccidiosis caused by <i>E. adenoeides</i> , <i>E. gallopavonis</i> and <i>E. meleagrimitis</i> ..	Feed continuously as the sole ration. Do not feed to breeding turkeys. Not for use in hens producing eggs for human consumption..	000061
(ii) [Reserved]				

Dated: November 9, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 944

[SPATS No. UT–037–FOR]

Utah Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is approving a proposed amendment to the Utah regulatory program (hereafter, the "Utah program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or "the Act"). Utah proposed changes to definitions and engineering and hydrology provisions in its rules about subsidence control plans, subsidence control, and water replacement. Utah intended to revise its program to be consistent with the corresponding Federal regulations.

EFFECTIVE DATE: December 4, 2001.

FOR FURTHER INFORMATION CONTACT:

James F. Fulton, Chief, Denver Field Division; telephone: (303) 844–1424; e-mail address: jfulton@osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Utah Program

II. Submission of the Proposed Amendment

III. Director's Findings

IV. Summary and Disposition of Comments

V. Director's Decision

VI. Procedural Determinations

I. Background on the Utah Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its program includes, among other things, " * * * a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act * * * ; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act." See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Utah