or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it 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:

2001–24–03 Dassault Aviation: Amendment 39–12519. Docket 2001–NM–330–AD.

Applicability: Model Mystere-Falcon 50 series airplanes having serial numbers 11, 16, 67, 107, 128, 138, 175, 183, 184, 185, 190, 222, and 225; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent near misses or collision with other aircraft during flight, due to incorrect altitude information, accomplish the following:

Airplane Flight Manual (AFM) Revision

(a) Within 10 days after the effective date of this AD, revise the Limitations Section of the FAA-approved AFM to include the following (this may be accomplished by inserting a copy of this AD in the AFM):

''The reduced vertical separation minimum (RVSM) approval is suspended until testing and corrective actions, if necessary, are accomplished in accordance with a method approved by the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, or by the Direction Générale de l'Aviation Civile (DGAC).''

Alternative Methods of Compliance

(b) 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, International Branch, ANM–116. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 1: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(c) 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.

Note 2: The subject of this AD is addressed in French airworthiness directive T2001–524–037(B), effective date, October 27, 2001.

Effective Date

(d) This amendment becomes effective on December 11, 2001.

Issued in Renton, Washington, on November 19, 2001.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–29342 Filed 11–23–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble Powder; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Bimeda, Inc., that provides for a revised withdrawal time for use of oxytetracycline hydrochloride soluble powder in the drinking water of turkeys and swine. The regulations are also being amended to reflect approval of an additional pail size, which was approved under ANADA 200–144 on June 26, 1995; however, inadvertently this change has not yet been made in title 21 CFR. This document corrects that omission and improves the accuracy of the regulations.

DATES: This rule is effective November 26, 2001.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Bimeda, Inc., 288 County Rd. 28, LeSueur, MN 56058–9322, filed a supplement to ANADA 200–144 that provides for use of TETROXY® (oxytetracycline HCl) Soluble Powder for making medicated drinking water for the treatment of various bacterial diseases of livestock. The supplemental ANADA provides for a zero-day withdrawal time after the use of the product in the drinking water of turkeys and swine. The ANADA is approved as of September 17, 2001, and the regulations are amended in 21 CFR 520.1660d to reflect the approval.

Section 520.1660d is also being amended to reflect approval of a 3.09-pound pail size, which was approved under ANADA 200–144 on June 26, 1995.

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(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 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.

§ 520.1660d [Amended]

2. Section 520.1660d *Oxytetracycline hydrochloride soluble powder* is amended in paragraph (a)(9) by adding ''3.09 and '' after ''pails:''; in paragraphs (d)(1)(ii)(A)(*3*), (d)(1)(ii)(B)(*3*), and (d)(1)(ii)(C)(*3*) by removing ''and 053389'' and by adding in its place '', 053389, and 061133''; and in paragraph (d)(1)(iii)(C) by removing ''No. 046573'' and by adding in its place ''Nos. 046573 and 061133.''

Dated: November 8, 2001.

Claire M. Lathers,

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

[FR Doc. 01–29351 Filed 11–23–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Fenbendazole

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to restore indications for fenbendazole medicated feeds for cattle that have been inadvertently deleted from the regulations. Changes to a table format are also being made. This action is being taken to correct these errors and to improve the accuracy of the regulations.

DATES: This rule is effective November 26, 2001.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4567, e-mail: ghaibel@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: FDA has discovered that an error has become incorporated into the agency's regulation for part 558 (21 CFR part 558). A portion of the list of indications for fenbendazole medicated feeds for cattle was inadvertently deleted as a publication error beginning with the April 1, 1996, edition of the CFR. At this time, the regulations are being amended in § 558.258 to correct this error, to format some portions of this section as a table, and to restructure other portions to more closely resemble similar regulations for free-choice medicated feeds for cattle. Indications for the control of certain swine parasites, inadvertently removed in a previous revision of the regulations in the **Federal Register** of November 20, 1990 (55 FR 48230), are also being added. The entire text of § 558.258 is being provided for the convenience of the reader.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

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 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 part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

2. Section 558.258 is revised to read as follows:

§ 558.258 Fenbendazole.

(a) *Specifications.* Type A medicated articles: 4 percent (18.1 grams per pound (g/lb)), 8 percent (36.2 g/lb), and 20 percent (90.7 g/lb) fenbendazole.

(b) *Approvals.* See No. 057926 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.275 of this chapter.

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

(e) *Conditions of use*—(1) *Turkeys.*

Amount fenbendazole in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
14.5 (16 parts per million).	.....	Growing turkeys: For the removal and control of gastrointestinal worms: round worms, adult and larvae (*Ascaridia dissimilis*); cecal worms, adult and larvae (*Heterakis gallinarum*), an important vector of *Histomonas meleagridis* (Blackhead).	Feed continuously as the sole ration for 6 days. For growing turkeys only.	057926

(2) *Swine.*