communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 98–SW–09–AD.'' The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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, Incorporation by reference, 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 a new airworthiness directive to read as follows:

98–04–40 Eurocopter France: Amendment 39–10479. Docket No. 98–SW–09–AD.

Applicability: Model SA.315B, SA.316B, SA.316C, SA.319B, and SE.3160 helicopters, with main rotor blades, part numbers 3160S11–10000 all dash numbers, 3160S11–30000 all dash numbers, 3160S11–35000 all dash numbers, 3160S11–40000 all dash numbers, 3160S11–45000 all dash numbers, 3160S11–50000 all dash numbers, 3160S11–55000 all dash numbers, installed, certificated in any category.

Note 1: This AD applies to each helicopter 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 helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must use the authority provided in paragraph (d) to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition, or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any helicopter from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously, for helicopters with main rotor blades (blades) having 400 or more hours time-in-service (TIS).

To prevent separation of a blade and subsequent loss of control of the helicopter, accomplish the following:

(a) Within 25 hours TIS, inspect each blade spar for cracks using a dye-penetrant method in accordance with paragraphs CC.1 through CC.4 of the Operational Procedures in Eurocopter France Service Telex No. 00055/0034/98, dated February 3, 1998 (Eurocopter Service Telex: 316/319 No. 01–64 and 315 No. 01–29).

(b) Within 25 hours TIS, visually inspect the upper and lower surfaces of each blade cuff for cracks, especially around the attachment pins, using a 10-power or higher magnifying glass.

(c) If a crack is found in a blade spar or cuff, remove the blade and replace it with an airworthy blade prior to further flight.

(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, Rotorcraft Standards Staff, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Standards Staff.

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

(e) Special flight permits will not be issued.

(f) The inspection shall be done in accordance with paragraphs CC.1 through CC.4 of the Operational Procedures in Eurocopter France Service Telex No. 00055/0034/98, dated February 3, 1998 (Eurocopter Service Telex: 316/319 No. 01–64 and 315 No. 01–29). This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from American Eurocopter Corporation, 2701 Forum Drive, Grand Prairie, Texas 75053–4005, telephone (972) 641–3460, fax (972) 641–3527. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment becomes effective on May 4, 1998, to all persons except those persons to whom it was made immediately effective by Priority Letter AD 98–04–40, issued February 12, 1998, which contained the requirements of this amendment.

Note 3: The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD 98–088–055(A) and 98–089–038(A), dated February 25, 1998.

Issued in Fort Worth, Texas, on April 3, 1998.

Henry A. Armstrong,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 98–10175 Filed 4–16–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Bacitracin Zinc; 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 regulation for use of bacitracin zinc Type A medicated articles to make Type C medicated feeds

in combination with other drugs to include certain other drugs that have been approved elsewhere in the animal drug regulations. This action is being taken to ensure the accuracy and consistency of the regulation because the cross-references were not updated at the time the combination drug uses were approved.

EFFECTIVE DATE: April 17, 1998.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1739.

SUPPLEMENTARY INFORMATION: In § 558.78(d)(3) (21 CFR 558.78(d)(3)) FDA codified a list of combinations in which bacitracin zinc is approved for use with certain drugs that have been approved elsewhere in 21 CFR part 558. Several cross-references to approved combination drug uses were not included in that list. Section 558.78(d)(3) is amended to add those cross-references.

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 558.78 is amended by revising paragraph (d)(3) to read as follows:

§ 558.78 Bacitracin zinc.

* * * * *

(d) * * *

(3) Bacitracin zinc may be used as approved in combination as follows:

(i) Amprolium as in § 558.55.

(ii) Amprolium and roxarsone as in § 558.55.

(iii) Amprolium and ethopabate as in § 558.58.

(iv) Amprolium and ethopabate with roxarsone as in § 558.58.

(v) Carbarsone as in § 558.120.

(vi) Clopidol as in § 558.175.

(vii) Clopidol and roxarsone as in § 558.175.

(viii) Decoquinate as in § 558.195.

(ix) Decoquinate and roxarsone as in § 558.195.

(x) Hygromycin B as in § 558.274.

(xi) Hygromycin B and penicillin as in § 558.274.

(xii) Lasalocid sodium and roxarsone as in § 558.311.

(xiii) Monensin as in § 558.355.

(xiv) Monensin and roxarsone as in § 558.355.

(xv) Robenidine as in § 558.515.

(xvi) Salinomycin as in § 558.550.

(xvii) Salinomycin and roxarsone as in § 558.550.

(xviii) Zoalene as in § 558.680.

(xix) Zoalene and arsanilic acid as in § 558.680.

(xx) Zoalene and roxarsone as in § 558.680.

Dated: March 31, 1998.

Andrew J. Beaulieu,

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

[FR Doc. 98–10251 Filed 4–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. 98N–0171]

Medical Devices; Humanitarian Use of Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations governing humanitarian use devices. These amendments are being made to implement provisions of the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, under FDA's usual procedures for notice and comment, to provide a procedural framework to finalize the rule in the event the agency receives any significant adverse comment and withdraws the direct final rule.

DATES: This rule is effective August 31, 1998. Submit written comments on or before July 1, 1998. Submit written comments on the information collection provisions on or before June 16, 1998. If FDA receives no significant adverse comments within the specified comment period, the agency intends to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends.

ADDRESSES: Submit written comments on the direct final rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joanne R. Less, Center for Devices and Radiological Health (HFZ–403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20857, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

The Safe Medical Devices Act of 1990 (Pub. L. 101–629) added section 520(m) to the act (21 U.S.C. 360j(m)). Section 520(m) creates an incentive for the development of humanitarian use devices (HUD) for use in the treatment or diagnosis of diseases or conditions affecting a small number of individuals. Section 520(m) authorizes FDA, by regulation, to exempt a HUD from the effectiveness requirements of section 514 and 515 of the act (21 U.S.C. 360d and 360e) (i.e., ''reasonable assurance that the device is effective'') provided that: (1) The device is to be used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; (2) the device would not be available to a person with such a disease or condition unless the exemption is granted; (3) no comparable device (other than a device that has been granted such an exemption) is available to treat or diagnose the disease or condition; and (4) the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices to alternative forms of treatments.

In the **Federal Register** of June 26, 1996 (61 FR 33232), FDA published a final rule prescribing the procedures for submitting humanitarian device exemption (HDE) applications, amendments, and supplements; procedures for obtaining an extension of the exemption; and the criteria for FDA review and approval of HDE's. This rule amended part 814 (21 CFR part 814) of FDA's regulations.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105–115). Section 203 of FDAMA made the following changes to section 520(m) of the act:

(1) FDAMA added a new provision to section 520(m) of the act that requires FDA to issue an order approving or denying an HDE within 75 days after receiving the application.

(2) FDAMA provided for an exemption from the requirement that a