(2) If any cracking is found, before further flight, repair per a method approved by the Manager, Seattle ACO, FAA; or per data meeting the type certification basis of the airplane approved by a Boeing an AR for the Boeing DOA Organization who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved, the approval must specifically reference this AD. Thereafter, repeat the inspection at intervals not to exceed 3,000 flight cycles.

Terminating Action for Certain Requirements

(s) For Groups 1, 2, and 3 airplanes, identified in Boeing Service Bulletin 757–54A0039, Revision 3, dated January 13, 2005: Accomplishment of paragraphs (t) and (u) of this AD constitutes terminating action for the repetitive inspections of paragraphs (g), (h), (o), and (p) of this AD.

Replacement of Shims and Sleevebolts

(t) For Groups 1, 2, and 3 airplanes, identified in Boeing Service Bulletin 757–540039, Revision 3, dated January 13, 2005: Replace all laminated shims with solid shims; replace existing sleevebolts with new, oversized sleevebolts; and perform a general visual and HFEC inspection to detect cracking and deformation in the sleevebolt holes and in the fittings; as specified in Part II of the Accomplishment Instructions of Boeing Service Bulletin 757–54A0039, Revision 3, dated January 13, 2005. If any shim cannot be removed, or if any cracking or deformation is found: Before further flight, repair in accordance with a method approved by the Manager, Seattle ACO, FAA; or according to data meeting the certification basis of the airplane approved by an AR for the Boeing DOA Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the approval must specifically reference this AD.

One-Time HFEC Inspection

(u) For Groups 1, 2, and 3, as identified in Boeing SB 757–54A0039, Revision 3, dated January 13, 2005: Perform a one-time HFEC inspection for cracking in and around the bolt holes of the right and left side of the mid-bulkhead lower flanges, in accordance with Part III of the Accomplishment Instructions of Boeing SB 757–54A0039, Revision 3, dated January 13, 2005.

(1) If no cracking is found: Before further flight, install oversized bolts per Figure 10 of the SB.

(2) If any cracking is found that is within the limits of the SB: Before further flight, repair per the SB.

(3) If any cracking is found that is outside the limits of the SB and the SB specifies to contact Boeing for appropriate action: Before further flight, repair in accordance with a method approved by the Manager, Seattle ACO, FAA; or according to data meeting the certification basis of the airplane approved by an AR for the Boeing DOA Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the approval must specifically reference this AD.

Alternative Methods of Compliance (AMOCs)

(v)(1) The Manager, Seattle ACO, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an AR for the Boeing DOA Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the approval must specifically reference this AD.

Material Incorporated by Reference

(w) You must use Boeing Alert Service Bulletin 757–54A0039, Revision 1, dated June 20, 2002; Boeing Service Bulletin 757–54A0039, Revision 2, dated December 2, 2004; or Boeing Service Bulletin 757–54A0039, Revision 3, dated January 13, 2005; to perform the actions that are required by this AD, unless the AD specifies otherwise.

(1) The incorporation by reference of Boeing Service Bulletin 757–54A0039, Revision 2, dated December 2, 2004; and Boeing Service Bulletin 757–54A0039, Revision 3, dated January 13, 2005, is approved by the Director of the **Federal Register** in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of Boeing Alert Service Bulletin 757–54A0039, Revision 1, dated June 20, 2002, was approved previously by the Director of the **Federal Register** as of April 18, 2003 (68 FR 16200, April 3, 2003).

(3) For copies of the service information, contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207. For information on the availability of this material at the National Archives and Records Administration (NARA), call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*. You may view the AD docket at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., room PL–401, Nassif Building, Washington, DC.

Issued in Renton, Washington, on February 14, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–3558 Filed 2–25–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 526

Intramammary Dosage Forms; Ceftiofur

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 Pharmacia & Upjohn Co., a Division of Pfizer, Inc. The NADA provides for the veterinary prescription use of ceftiofur hydrochloride suspension, by intramammary infusion, for the treatment of clinical mastitis in lactating dairy cattle.

DATES: This rule is effective February 28, 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: Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–238 for SPECTRAMAST LC (ceftiofur hydrochloride) Sterile Suspension. The NADA provides for the veterinary prescription use of ceftiofur hydrochloride suspension, by intramammary infusion, for the treatment of clinical mastitis in lactating dairy cattle associated with coagulase-negative staphylococci, *Streptococcus dysgalactiae*, and *Escherichia coli*. The application is approved as of February 9, 2005, and the regulations are amended in 21 CFR part 526 by adding new § 526.314 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.

FDA has determined under 21 CFR 25.33(d)(5) 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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning February 9, 2005.

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 526

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 526 is amended as follows:

PART 526—INTRAMAMMARY DOSAGE FORMS

■ 1. The authority citation for 21 CFR part 526 continues to read as follows:

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

■ 2. Section 526.314 is added to read as follows:

§ 526.314 Ceftiofur.

(a) *Specifications*—(1) Each 10-milliliter (mL) syringe contains ceftiofur hydrochloride suspension equivalent to 125 milligrams (mg) ceftiofur.

(2) [Reserved]

(b) *Sponsor*. See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.113 of this chapter.

(d) *Conditions of use in cattle*—(1) *Lactating cows*—(i) *Amount*. 125 mg per affected quarter using product described in paragraph (a)(1) of this section. Repeat treatment in 24 hours. Once daily treatment may be repeated for up to 8 consecutive days.

(ii) *Indications for use*. For the treatment of clinical mastitis in lactating dairy cattle associated with coagulase-negative staphylococci, *Streptococcus dysgalactiae*, and *Escherichia coli*.

(iii) *Limitations*. Milk taken from cows during treatment (a maximum of eight daily infusions) and for 72 hours after the last treatment must not be used for human consumption. Following label use for up to 8 consecutive days, no preslaughter withdrawal period is required. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: February 17, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–3834 Filed 2–25–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 803

[Docket No. 2004N–0527]

Medical Devices; Medical Device Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending its regulation governing reporting of deaths, serious injuries, and certain malfunctions related to medical devices. We are revising the regulation into plain language to make the regulation easier to understand, and we are making technical corrections. Elsewhere in this issue of the **Federal Register**, we are 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 we receive any significant adverse comment and withdraw the direct final rule.

DATES: This rule is effective July 13, 2005, with the exception of 21 CFR 803.55(b)(9) and (b)(10) and 21 CFR 803.58, which remain stayed indefinitely, in accordance with the stays of effective date published in the **Federal Registers** of July 31, 1996 (61 FR 39868), and July 23, 1996 (61 FR 38346). Submit written or electronic comments by May 16, 2005. If we receive no significant adverse comments within the specified comment period, we intend 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. If we receive any timely significant adverse comment, we will withdraw this final rule in part or in whole by publication of a document in the **Federal Register** within 30 days after the comment period ends.

ADDRESSES: You may submit comments, identified by Docket No. 2004N–0527, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov*. Include Docket No. 2004N–0527 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Howard Press, Center for Devices and Radiological Health (HFZ–531), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2983.

SUPPLEMENTARY INFORMATION:

I. What Is the Background of This Rule?

FDA's regulations governing device adverse event reporting, codified at part 803 (21 CFR part 803), implement section 519 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i). That statutory provision has undergone several changes since its enactment as part of the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295). As a result, FDA's regulations at part 803 have also undergone multiple revisions.

In the **Federal Register** of September 14, 1984 (49 FR 36326), FDA first issued final medical device reporting (MDR) regulations (part 803) under section 519 of the act for manufacturers and importers, requiring reports of deaths, serious injuries, and certain malfunctions involving devices.

To address shortcomings in the 1976 amendments, and to better protect the public health by ensuring more complete reporting of device-related adverse events, Congress enacted the Safe Medical Devices Act of 1990 (Public Law 101–629), which amended the statute to add requirements for medical device user facilities and distributors to report certain device-related adverse events. The reporting regulation for user facilities and for