rule concerning Executive Order 12866 and the Regulatory Flexibility Act, Executive Orders 12372 and 12988, and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived the review process required by Executive Order 12866.

List of Subjects in 9 CFR Part 78

Animal diseases, Bison, Cattle, Hogs, Quarantine, Reporting and recordkeeping requirements, Transportation.

PART 78—BRUCELLOSIS

Accordingly, we are adopting as a final rule, without change, the interim rule that amended 9 CFR part 78 and that was published at 63 FR 44544–44545 on August 20, 1998.

Authority: 21 U.S.C. 111–114a–1, 114g, 115, 117, 120, 121, 123–126, 134b, and 134f; 7 CFR 2.22, 2.80, and 371.2(d).

Done in Washington, DC, this 29th day of December 1998.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 99–114 Filed 1–4–99; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 96–CE–54–AD; Amendment 39–10821; AD 98–08–25 R1]

RIN 2120–AA64

Airworthiness Directives; Twin Commander Aircraft Corporation 500, 680, 690, and 695 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This action confirms the effective date of Airworthiness Directive (AD) 98–08–25 R1, which applies to certain Twin Commander Aircraft Corporation (Twin Commander) 500, 680, 690, and 695 series airplanes. AD 98–08–25 R1 requires replacing the nose landing gear (NLG) drag link bolt with an approved heat-treated bolt that has the manufacturer's serial number, manufacture date, and the last three digits of the drawing number (055) on the bolt head; and changing the bolt part number (P/N) to be installed on Models 690D and 695A from P/N ED10055 to P/N 750076–1. This AD was the result of the FAA inadvertently transposing the serial numbers of the 4 affected Model 695A airplanes. The actions specified in this AD are intended to prevent the NLG from collapsing due to failure of a drag link bolt, which could result in loss of control of the airplane during landing operations.

EFFECTIVE DATE: January 5, 1999.

FOR FURTHER INFORMATION CONTACT: Jeffrey Morfitt, Aerospace Engineer, FAA, Seattle Aircraft Certification Office, 1601 Lind Ave. S.W., Renton, Washington, 98055–4056; telephone: (206) 227–2595; facsimile: (206) 227–1181.

SUPPLEMENTARY INFORMATION: The FAA published this direct final rule with request for comments in the **Federal Register** on October 9, 1998 (63 FR 54347). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA anticipates that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, was received within the comment period, the regulation would become effective on January 5, 1999. No adverse comments were received, and thus this notice confirms that this final rule becomes effective on that date.

Issued in Kansas City, Missouri, on December 29, 1998.

Marvin R. Nuss,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–45 Filed 1–4–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–CE–40–AD; Amendment 39–10681; AD 98–11–01 R2]

RIN 2120–AA64

Airworthiness Directives; Pilatus Aircraft Ltd. Models PC–12 and PC–12/45 Airplanes; Correction

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document makes a correction to Airworthiness Directive (AD) 98–11–01 R2, which was published in the **Federal Register** on July 31, 1998 (63 FR 40807), and concerns Pilatus Aircraft Ltd. (Pilatus) Models PC–12 and PC–12/45 airplanes. Certain references to the AD number and amendment number in the document are incorrect. The AD currently requires replacing the fuel tank vent valves and drilling a 4.8 millimeter (0.1875 inch) hole in each fuel filler cap on certain Pilatus Models PC–12 and PC–12/45 airplanes. AD 98–11–01 R2 also requires inserting a temporary revision in the Pilot's Operating Handbook (POH) that specifies checking to assure that the fuel filler cap hole is clear of ice and foreign objects. This action corrects the AD to reflect the correct reference to the AD number and amendment number throughout the entire document.

EFFECTIVE DATE: September 22, 1998.

FOR FURTHER INFORMATION CONTACT: Mr. Roman T. Gabrys, Aerospace Engineer, FAA, Small Airplane Directorate, 1201 Walnut, suite 900, Kansas City, Missouri 64106; telephone: (816) 426–6934; facsimile: (816) 426–2169.

SUPPLEMENTARY INFORMATION:

Discussion

On July 23, 1998, the FAA issued AD 98–11–01 R2, Amendment 39–10681 (63 FR 40807, July 31, 1998), which applies to certain Pilatus Models PC–12 and PC–12/45 airplanes. This AD requires replacing the fuel tank vent valves and drilling a 4.8 millimeter (0.1875 inch) hole in each fuel filler cap on certain Pilatus Aircraft Ltd. (Pilatus) Models PC–12 and PC–12/45 airplanes. AD 98–11–01 R2 also requires inserting a temporary revision in the Pilot's Operating Handbook (POH) that specifies checking to assure that the fuel filler cap hole is clear of ice and foreign objects.

Need for the Correction

Certain references to the AD number and amendment number in the document are incorrect. As written, owners/operators of the affected airplanes, may enter the incorrect AD number and amendment number into their logbook when showing compliance with the AD.

Correction of Publication

Accordingly, the publication of July 31, 1998 (63 FR 40807), of Amendment 39–10681; AD 98–11–01 R2, which was the subject of FR Doc. 98–20439, is corrected as follows:

§ 39.13 [Corrected]

On page 40808, in the third column, section 39.13, the third line, correct ''98–11–01 R1'' to ''98–11–01 R2''.

On page 40808, in the third column, section 39.13, the ninth line, correct ''Amendment 39–34565'', to ''Amendment 39–10192.''

Action is taken herein to correct this reference in AD 98–11–01 R2 and to add this AD correction to section 39.13 of the Federal Aviation Regulations (14 CFR 39.13).

The effective date remains September 22, 1998.

Issued in Kansas City, Missouri, on December 29, 1998.

Marvin R. Nuss,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–43 Filed 1–4–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 2, 3, 5, 10, 12, 16, 20, 25, 50, 54, 56, 58, 60, 70, 71, 200, 201, 202, 206, 207, 210, 211, 299, 300, 310, 312, 314, 316, 320, 333, 369, 510, 514, 520, 522, 524, 529, 800, 801, 807, 809, 812, and 860

[Docket No. 98N–0720]

Conforming Regulations Regarding Removal of Section 507 of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to remove references to the repealed statutory provision of the Federal Food, Drug, and Cosmetic Act (the act) under which the agency certified antibiotic drugs. FDA is also removing references to the repealed antibiotic monograph regulations and to those regulations dealing with antibiotic applications. The agency is taking this action in accordance with provisions of 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 May 20, 1999. Submit written comments on or before March 22, 1999. If no timely significant adverse comments are received, the agency will publish a document in the **Federal Register** before April 20, 1999, confirming the effective date of the direct final rule. The agency intends to make the direct final rule effective 30 days after publication of the confirmation document in the **Federal Register**. If timely significant adverse comments are received, the agency will publish a document of significant adverse comment in the **Federal Register** withdrawing this direct final rule before April 20, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

For human drugs, Christine F. Rogers or Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

For animal drugs, Richard L. Arkin, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0141.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 1997, the President signed FDAMA (Pub. L. 105–115). Section 125(b) of FDAMA repealed section 507 of the act (21 U.S.C. 357). Section 507 of the act was the statutory provision under which the agency certified antibiotic drugs. Section 125(b) of FDAMA also made conforming amendments to other sections of the act. With the repeal of section 507 of the act, antibiotic drugs previously regulated under section 507 will be subject to the provisions of section 505 of the act (21 U.S.C. 355).

FDA has determined that it will be most efficient to make changes in its regulations to reflect the repeal of section 507 of the act in phases. In the first phase, FDA published in the **Federal Register** of May 12, 1998 (63 FR 26066), a direct final rule removing parts 430 through 460 (21 CFR parts 430 through 460), which had provided the procedures and standards used to certify antibiotic drugs. This direct final rule is the second phase of rulemaking in which the agency is making various, noncontroversial conforming amendments to the balance of Title 21 of the Code of Federal Regulations. The rule removes citations to section 507 of the act. It removes references to the certification of antibiotics, to the antibiotic certification regulations, and to specific antibiotic monographs. It also removes references to antibiotic drug applications, abbreviated antibiotic drug applications, and supplemental drug antibiotic applications.

The agency recognizes that as it implements the transition from regulating the premarket review and approval of antibiotic drugs under section 507 of the act to section 505 of the act, other issues may arise that could require additional rulemaking. These issues will be addressed in the third phase of implementation.

II. Direct Final Rulemaking

FDA has determined that the subject of this rulemaking is suitable for a direct final rule. The repeal of section 507 of the act eliminates the statutory provision on which the agency relied to certify antibiotic drugs. FDA will, therefore, remove all provisions of Title 21 of the Code of Federal Regulations that were issued primarily to carry out the agency's certification of antibiotic drugs under former section 507 of the act. All direct references to section 507 of the act will be removed, as well as all references to regulations that were issued to carry out programs under section 507 and all references to forms and applications that were unique to the regulation of antibiotics under section 507. The actions taken should be noncontroversial, and the agency does not anticipate receiving any significant adverse comments on this rule.

If FDA does not receive significant adverse comment on or before March 22, 1999, the agency will publish a document in the **Federal Register** before April 20, 1999, confirming the effective date of the direct final rule. The agency intends to make the direct final rule effective 30 days after publication of the confirmation document in the **Federal Register**. A significant adverse comment is one that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment recommending a rule change in addition to this rule will not be considered a significant adverse comment unless the comment states why this rule would be ineffective without the additional change. If timely significant adverse comments are received, the agency will publish a document of significant adverse comment in the **Federal Register** withdrawing this direct final rule before April 20, 1999.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule, which is identical to the direct final rule, that provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn