DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2006–25929 Directorate Identifier 2006–CE–54–AD; Amendment 39–14919; AD 2007–03–08]

RIN 2120–AA64

Airworthiness Directives; Pilatus Aircraft Ltd., PC–6 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as the discovery of exfoliation corrosion in the fittings of some PC–6 airplanes. These fittings are installed exterior to the bottom skin of the wing skin. If not corrected, undetected corrosion in this area could lead to failure of the fitting and subsequent loss of control of the airplane. We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective March 8, 2007.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of March 8, 2007.

ADDRESSES: You may examine the AD docket on the Internet at *http://dms.dot.gov* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust Street, Room 301, Kansas City, Missouri 64106; *telephone:* (816) 329–4059; *fax:* (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Streamlined Issuance of AD

The FAA is implementing a new process for streamlining the issuance of ADs related to MCAI. The streamlined process will allow us to adopt MCAI safety requirements in a more efficient manner and will reduce safety risks to the public. This process continues to follow all FAA AD issuance processes to meet legal, economic, Administrative Procedure Act, and **Federal Register** requirements. We also continue to meet our technical decision-making responsibilities to identify and correct unsafe conditions on U.S.-certificated products.

This AD references the MCAI and related service information that we considered in forming the engineering basis to correct the unsafe condition. The AD contains text copied from the MCAI and for this reason might not follow our plain language principles.

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on November 3, 2006 (71 FR 64653). That NPRM proposed to require repetitive inspections of the wing strut fitting and the replacement of corroded wing strut fittings with new retrofit wing strut fittings.

Comments

We gave the public the opportunity to participate in developing this AD. We have considered the comments received.

Comment Issue: Summary

Clay Lacy asks if there is a planned hourly minimum or just calendar time for the compliance. He notes that he has a PC–6 that was built by Fairchild in 1967, has only 1,600 hours total time, and has always been hangared. Mr. Lacy added, ''We have never detected any corrosion at any location.''

We are relying on the Federal Office for Civil Aviation (FOCA), which is the state of design authority, and the manufacturer's (Pilatus) determination that calendar time compliance for this type of corrosion inspection is appropriate. The FOCA AD requires a one-time inspection, and the corresponding service bulletin (SB) states the required repetitive inspection will be included in Chapter 5 of the Aircraft Maintenance Manual (AMM). Both initial and repetitive compliance times are specified in calendar time. We do not have information for this issue to correlate between Time-In-Service (TIS) and calendar time.

Comment Issue: What Prompted AD

Clay Lacy states if possible he would like more information that prompted this proposed AD.

Further information on what prompted this proposed AD may be found in the Docket Management System (DMS). This action was initiated as a result of FOCA AD HB–2006–400. We have checked the DMS and this document is electronically available.

Conclusion

We reviewed the available data, including the comments received, and determined that air safety and the public interest require adopting the AD as proposed.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are described in a separate paragraph of the AD, and take precedence over the actions copied from the MCAI.

Costs of Compliance

We estimate that this AD will affect about 49 products of U.S. registry. We also estimate that it will take 27 work-hours per product to comply with this AD. The average labor rate is $80 per work-hour. Required parts will cost about $2,500 per wing per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these parts. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of this AD to the U.S. operators to be $350,840 or $7,160 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation

is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect 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.

For the reasons discussed above, I certify this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866;

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD Docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://dms.dot.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5227) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 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. The FAA amends § 39.13 by adding the following new AD:

2007–03–08 Pilatus Aircraft Ltd., PC–6 Series Airplanes: Amendment 39–14919; Docket No. FAA–2006–25929; Directorate Identifier 2006–CE–54–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective March 8, 2007.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Models PC–6, PC–6–H1, PC–6–H2, PC–6/350, PC–6/350–H1, PC–6/350–H2, PC–6/A, PC–6/A–H1, PC–6/A–H2, PC–6/B–H2, PC–6/B1–H2, PC–6/B2–H2, PC–6/B2–H4, PC–6/C–H2, and PC–6/C1–H2 airplanes; manufacturer serial numbers (MSN) 101 through 949, MSN 951, and MSN 2001 through 2092; that are certificated in any category. These airplanes are also identified as Fairchild Republic Company PC–6 airplanes, Fairchild Industries PC–6 airplanes, Fairchild Heli Porter PC–6 airplanes, or Fairchild-Hiller Corporation PC–6 airplanes.

Reason

(d) The mandatory continuing airworthiness information (MCAI) states that exfoliation corrosion in the fittings of some PC–6 airplanes was found. These fittings are installed exterior to the bottom skin of the wing skin. If not corrected, undetected corrosion in this area could lead to failure of the fitting and subsequent loss of control of the airplane.

Actions and Compliance

(e) Unless already done, do the following actions.

(1) Within 12 months after the effective date of this AD and repetitively thereafter at intervals not to exceed 12 months, perform an inspection required by paragraph 3.B.(2) of PILATUS PC–6 Service Bulletin (SB) No. 57–003, dated June 13, 2006, of the fittings Part Number (P/N) 6102.0041.00, P/N 111.35.06.055 or P/N 111.35.06.056 for signs of corrosion. Repair of minor surface corrosion is permitted according to the Repair and Overhaul Manual (ROM) (Report No. 1391), Chap. 2 and 4. Corrosion outside these limits is not permitted.

(2) If during any of the inspections required by paragraph (e)(1) of this AD, any minor surface corrosion is found, prior to further flight, remove the minor surface corrosion (Ref. ROM. Chap. 2 and 4).

(3) If during any of the inspections required by paragraph (e)(1) of this AD, any corrosion out of limits is found (Ref. ROM, Chap. 2 and 4), prior to further flight, replace the fittings in accordance with paragraph 4 of PILATUS PC–6 SB No. 57–003, dated June 13, 2006, with new (retrofit) fittings P/N 111.35.06.185 and/or P/N 111.35.06.186.

(4) Replacement of the fittings with new (improved) fittings P/N 111.35.06.185 (left hand side) and/or 111.35.06.186 (right hand side) terminates the repetitive inspection for that side.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows:

(1) The FAA AD is requiring repetitive inspections, not just a one-time inspection as required in the MCAI.

(2) The Service Bulletin specifies ''subsequent inspections for corrosion will be included in Chapter 5 of the Aircraft Maintenance Manual (AMM).'' The only way we (FAA) can mandate these repetitive inspections is through an AD.

Other FAA AD Provisions

(f) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Staff, FAA, ATTN: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et.seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(g) Refer to FOCA AD HB–2006–400, effective date September 28, 2006, which references Pilatus Aircraft Ltd. SB No. 57–003, dated June 13, 2006, for related information.

Material Incorporated by Reference

(h) You must use PILATUS PC–6 Service Bulletin (SB) No. 57–003, dated June 13, 2006, to do the actions required by this AD, unless the AD specifies otherwise.

(1) The Director of the Federal Register approved the incorporation by reference of this service information under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) For service information identified in this AD, contact Pilatus Aircraft Ltd., Customer Liaison Manager, CH–6371 Stans, Switzerland; telephone: +41 41 619 63 19; fax: +41 41 619 6224.

(3) You may review copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Kansas City, Missouri, on January 24, 2007.

Kim Smith,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–1494 Filed 1–31–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. 2007N–0024]

Medical Devices; Hematology and Pathology Devices; Classification of Cord Blood Processing System and Storage Container

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying a cord blood processing system and storage container into class II (special controls). The special control that will apply to this device is the guidance document entitled ''Class II Special Controls Guidance Document: Cord Blood Processing System and Storage Container.'' FDA is classifying this device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of this device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for this device.

DATES: This rule is effective March 5, 2007. The classification of this device into class II became effective on January 3, 2007.

FOR FURTHER INFORMATION CONTACT: Denise Sánchez, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. FDA determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on October 6, 2006, classifying into class III the Biosafe SA Sepax Cell Separation System and single use kits because this device is not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or to a device which was subsequently reclassified into class I or class II. On November 1, 2006, Biosafe SA submitted to FDA a petition requesting classification of the Sepax Cell Separation System and single use kits under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the Biosafe SA Sepax Cell Separation System and single use kits, when used in the processing and the storage of cord blood, can be classified into class II with the establishment of special controls. FDA believes that special controls, in addition to general controls, are adequate to provide reasonable assurance of the safety and effectiveness of this device and that there is sufficient information to establish special controls to provide such assurance.

This device is assigned the generic name ''cord blood processing system and storage container.'' It is identified as a device intended for use in the processing and the storage of cord blood. This device is a functionally closed processing system that includes containers, other soft goods, and a centrifugation system for cord blood concentration, and a final container for the cryopreservation and the storage of a cord blood product.

FDA has identified the risks to health associated with the use of a cord blood processing system and storage container. These risks include lack of biocompatible components; toxicity of residual chemical sterilants used to sterilize device components; toxicity of leached materials from or that permeate through plastic device components; insufficient mechanical strength of device containers, tubing, and seals resulting in integrity failure of the device; contamination; instability of soft goods over time; physical damage to or loss of the cord blood product; software failure; operator/user injury; electromagnetic interference; and electrical hazards.

FDA believes that the class II special controls guidance document will aid in mitigating the potential risks to health by providing recommendations for describing the device, validating performance characteristics, and labeling. The guidance document provides recommendations for fulfilling the premarket (510(k)) submission requirements for this device. FDA believes that the special controls guidance document, in addition to general controls, addresses the risks to health identified in the previous paragraph and provides reasonable assurance of the safety and effectiveness of a cord blood processing system and storage container. Therefore, on January 3, 2007, FDA issued an order to the petitioner classifying the device into class II. FDA is codifying this device classification at 21 CFR 864.9900.

Following the effective date of this final classification rule, manufacturers submitting a 510(k) premarket notification for a cord blood processing system and storage container will need to address the issues covered in the