14 CFR Part 39

[Docket No. 86–CE–23–AD]

RIN 2120–AA64

Airworthiness Directives; Pilatus Britten-Norman Ltd. (formerly Britten-Norman) BN2A MK. 111 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to revise AD 86–07–02, which currently requires repetitively inspecting the junction of the torque link lug and upper case of the main landing gear (MLG) torque link assemblies for cracks on Pilatus Britten-Norman Ltd. (Pilatus Britten-Norman) BN–2A, BN–2B, BN–2T, and BN2A MK. 111 series airplanes, and replacing any part found cracked with a like part. The proposed AD would remove from the applicability the BN–2A, BN–2B, and BN–2T series airplanes, and would retain the repetitive inspection and replacement (if necessary) requirements of AD 86–07–02 for the BN2A MK. 111 series airplanes. The proposed AD results from the Federal Aviation Administration's determination that additional AD action needs to be taken on the BN–2A, BN–2B, and BN–2T series airplanes. This additional action will be addressed in a separate AD. The actions specified by the proposed AD are intended to prevent failure of the main landing gear caused by cracks in the torque link area, which could lead to loss of control of the airplane during landing operations.

DATES: Comments must be received on or before May 12, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 86–CE–23–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from Pilatus Britten-Norman Limited, Bembridge, Isle of Wight, United Kingdom PO35 5PR; telephone 44–1983 872511; facsimile 44–1983 873246. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. Tom Rodriguez, Program Officer, Brussels Aircraft Certification Division, FAA, Europe, Africa, and Middle East Office, c/o American Embassy, B–1000 Brussels, Belgium; telephone (32 2) 508.2717; facsimile (32 2) 230.6899; or Mr. S.M. Nagarajan, Project Officer, Small Airplane Directorate, Airplane Certification Service, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64106; telephone (816) 426–6932; facsimile (816) 426–2169.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed 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 proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 86-CE–23-AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRM's

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 86-CE–23-AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

The FAA has determined that reliance on critical repetitive inspections on aging commuter-class airplanes carries an unnecessary safety risk when a design change exists that could eliminate or, in certain instances, reduce the number of those critical inspections. In determining what inspections are critical, the FAA considers (1) the safety consequences if the known problem is not detected during the inspection; (2) the probability of the problem not being detected during the inspection; (3) whether the inspection area is difficult to access; and (4) the possibility of damage to an adjacent structure as a result of the problem.

These factors have led the FAA to establish an aging commuter-class aircraft policy that requires incorporating a known design change when it could replace a critical repetitive inspection. With this policy in mind, the FAA conducted a review of existing AD's that apply to Pilatus Britten-Norman BN–2A, BN–2B, BN–2T, and BN2A MK. 111 series airplanes. Assisting the FAA in this review were (1) Pilatus Britten-Norman; (2) the Regional Airlines Association (RAA); (3) the Civil Aviation Authority of the United Kingdom; and (4) several operators of the affected airplanes.

From this review, the FAA has identified AD 86–07–02, Amendment39–5382, as one which falls under the FAA's aging aircraft policy. AD 86–07–02 currently requires repetitively inspecting the junction of the torque link lug and upper case of the main landing gear (MLG) torque link assemblies for cracks on Pilatus Britten-Norman BN–2A, BN–2B, BN–2T, and BN2A MK. 111 series airplanes, and replacing any cracked part.

Pilatus Britten-Norman has developed a modification that, when incorporated, would eliminate the need for the repetitive inspection requirement of AD 86–07–02 for the Pilatus Britten-Norman BN–2A, BN–2B, and BN–2T series airplanes. The requirements of AD 86–07–02 should still apply for the Pilatus Britten-Norman BN2A MK. 111 series airplanes.

Applicable Service Information

Fairey Hydraulics Limited has issued Service Bulletin (SB) 32–7, Issue 3, dated January 30, 1990, and Fairey Hydraulics Limited SB 32–10, Issue 2, dated November 10, 1992. These SB's include procedures for inspecting the junction of the torque link lug and upper case of the MLG torque link assemblies on Pilatus Britten-Norman BN2A MK. 111 series airplanes. Pilatus Britten-Norman SB BN–2/SB. 173, Issue 3, dated November 16, 1990, references Fairey Hydraulic Limited SB 32–7; and Pilatus Britten-Norman SB BN–2/SB.209, Issue 1, datedNovember 30, 1992, references Fairey Hydraulic Limited SB 32–10.

The FAA's Determination

The FAA has examined all available information related to this subject matter and has determined that:

- AD 86–07–02 should be revised to remove the BN–2A, BN–2B, and BN–2T series airplanes from the applicability of the AD (the BN2A MK. 111 series airplanes should still apply); and
- separate AD action should be taken for the Pilatus Britten-NormanBN–2A, BN–2B, and BN–2T series airplanes to require a modification to the main landing gear torque link assembly.

Explanation of the Provisions of the Proposed AD

Since an unsafe condition has been identified that is likely to exist or develop in other Pilatus Britten-Norman BN2A MK. 111 series airplanes of the same type design, the proposed AD would revise AD 86–07–02 by removing the BN–2A, BN–2B, and BN–2T series airplanes from the applicability of that AD. The requirement of repetitively inspecting the junction of the torque link lug and upper case of the MLG torque link assemblies would be retained for the BN2A MK. 111 series airplanes. The FAA will propose separate AD action for the BN–2A and BN–2T series airplanes to require a modification that, when incorporated, would eliminate the repetitive inspection requirement currently required by AD 86–07–02. Accomplishment of the proposed inspections and would be accomplished in accordance with the previously referenced service bulletins.

Cost Impact

The FAA estimates that nine airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately one workhour per airplane to accomplish the proposed initial inspection, and that the average labor rate is approximately $60 an hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $540 or $60 per airplane. This figure only takes into account the cost of the proposed initial inspection and does not take into account the cost of the proposed repetitive inspections. The FAA has no way of determining the number of repetitive inspections each of the owners/operators would incur over the life of the affected airplanes.

In addition, the proposed inspections are currently required on the nine affected airplanes. The proposed AD would not require any additional actions over that already required by AD 86–07–02.

Regulatory Impact

The regulations proposed herein would 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 proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (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) if promulgated, 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. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting 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.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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 removing Airworthiness Directive (AD) 86–07–02, Amendment 39–5382, and by adding a new AD to read as follows:

Pilatus Britten-Norman LTD.: Docket No. 86–CE–23–AD. Revises AD 86–07–02, Amendment 39–5382.

Applicability: Models MK. 111, BN2A MK. 111–2, and BN2A MK. 111–3 airplanes (all serial numbers), certificated in any category.

Note 1: This AD applies to each airplane 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 airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (f) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required prior to further flight after the effective date of this AD (see Note 2) or within 100 hours time-in-service (TIS) after the last inspection accomplished in accordance with AD 86–07–02, whichever occurs later, and thereafter at intervals not to exceed100 hours TIS.

Note 2: The ''prior to further flight after the effective date of this AD'' compliance time was the original initial compliance time of AD 86–07–02, and is being retained to provide credit and continuity for already-accomplished and future inspections.

To prevent failure of the main landing gear caused by cracks in the torque link assembly area, which could lead to loss of control of the airplane during landing operations, accomplish the following:

(a) Inspect the junction of the torque link lug and upper case for cracks (using a 10-power magnifying glass or by dye penetrant methods) in accordance with Fairey Hydraulics Limited Service Bulletin (SB) 32–7, Issue 3, dated January 30, 1990, or Fairey Hydraulics SB 32–10, Issue 2, dated November 10, 1992, as applicable. Pilatus Britten-Norman SB BN–2/SB. 173, Issue 3, dated November 16, 1990, references Fairey Hydraulic Limited SB 32–7; and Pilatus Britten-Norman SB BN–2/SB.209, Issue 1, dated November 30, 1992, references Fairey Hydraulic Limited SB 32–10.

(b) If cracked parts are found during any of the inspections required by this AD, prior to further flight, replace the cracked parts with airworthy parts in accordance with the applicable maintenance manual.

(c) If the landing gear is replaced, only equal pairs of the same manufacturer are approved as replacement parts. Mixing of different manufacturer landing gears is not authorized.

(d) The intervals between the repetitive inspections required by this AD may be adjusted up to 10 percent of the specified interval to allow accomplishing these actions along with other scheduled maintenance on the airplane.

(e) 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 inspection requirements of this AD can be accomplished.

(f) An alternative method of compliance or adjustment of the initial or repetitive compliance times that provides an equivalent level of safety may be approved by the Manager, Brussels Aircraft Certification Division, Europe, Africa, Middle East office, FAA, c/o American Embassy, 1000 Brussels, Belgium. The request should be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Brussels Aircraft Certification Division. Alternative methods of

compliance approved for AD 86–07–02 are considered approved as alternative methods of compliance for this AD.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Brussels Aircraft Certification Division.

(g) All persons affected by this directive may obtain copies of the documents referred to herein upon request to Fairey Hydraulics Limited, Claverham, Bristol, England; or Pilatus Britten-Norman Limited, Bembridge, Isle of Wight, United Kingdom PO35 5PR, as applicable; or may examine these documents at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

(h) This amendment revises AD 86–07–02, Amendment 39–5382.

Issued in Kansas City, Missouri, on February 25, 1997.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–5491 Filed 3–5–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2

[Docket No. 97N–0023]

RIN 0910–AA99

Chlorofluorocarbon Propellants in Self-Pressurized Containers; Determinations That Uses Are No Longer Essential; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is seeking public comment on the policy it is considering for adoption on making and implementing determinations that uses of chlorofluorocarbons (CFC's) currently designated essential will no longer be deemed essential under the Clean Air Act due to the availability of safe and effective medical product technology that does not use CFC's. Essential-use products are exempt from FDA's ban on the use of CFC propellants in FDA-regulated products and the Environmental Protection Agency's (EPA's) ban on the use of CFC's in pressurized dispensers. The agency is taking this action because it is responsible for determining which products containing CFC's or other ozone-depleting substances are an essential use under the Clean Air Act. FDA is soliciting comments on this policy to assist the agency in striking an appropriate balance that will best protect the public health, both by ensuring the availability of an adequate number of treatment alternatives and by curtailing the release of ozone-depleting substances.

DATES: Written comments by May 5, 1997.

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

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

Under § 2.125 (21 CFR 2.125), any food, drug, device, or cosmetic in a self-pressurized container that contains a CFC propellant for a nonessential use is adulterated, or misbranded, or both, under the Federal Food, Drug, and Cosmetic Act. This prohibition is based on scientific research indicating that CFC's reduce the amount of ozone in the stratosphere and thereby increase the amount of ultraviolet radiation reaching the earth. An increase in ultraviolet radiation will increase the incidence of skin cancer, and produce other adverse effects of unknown magnitude on humans, animals, and plants. Section 2.125(d) exempts from the adulteration and misbranding provisions of § 2.125(c) certain products containing CFC propellants that FDA determines provide unique health benefits that would not be available without the use of a CFC.

These products are referred to in the regulation as essential uses of CFC's and are listed in § 2.125(e). Under § 2.125(f), any person may petition FDA to request additions to the list of uses considered essential. To demonstrate that the use of a CFC is essential, the petition must be supported by an adequate showing that: (1) There are no technically feasible alternatives to the use of a CFC in the product; (2) the product provides a substantial health, environmental, or other public benefit that would not be obtainable without the use of the CFC; and (3) the use does not involve a significant release of CFC's into the atmosphere or, if it does, the release is warranted by the consequence if the use were not permitted.

EPA regulations implementing the provisions of section 610 of the Clean Air Act (42 U.S.C. 7671i) contain a general ban on the use of CFC's in pressurized dispensers, such as metered-dose inhalers (MDI's) (40 CFR 82.64(c) and 82.66(d)). These EPA regulations exempt from the general ban ''medical devices'' that FDA considers essential and that are listed in § 2.125(e). Section 601(8) of the Clean Air Act (42 U.S.C. 7671(8)) defines ''medical device'' as any device (as defined in the Federal Food, Drug, and Cosmetic Act), diagnostic product, drug (as defined in the Federal Food, Drug, and Cosmetic Act), and drug delivery system, if such device, product, drug, or drug delivery system uses a class I or class II ozone-depleting substance for which no safe and effective alternative has been developed (and, where necessary, approved by the Commissioner of Food and Drugs (the Commissioner)); and if such device, product, drug, or drug delivery system has, after notice and opportunity for public comment, been approved and determined to be essential by the Commissioner in consultation with the Administrator of EPA (the Administrator). Class I substances include CFC's, halons, carbon tetrachloride, methyl chloroform, methyl bromide, and other chemicals not relevant to this document (see 40 CFR part 82, appendix A to subpart A). Class II substances include hydrochlorofluorocarbons (HCFC's) (see 40 CFR part 82, appendix B to subpart A).

Production of ozone-depleting substances is being phased out worldwide under the terms of the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol), Sept. 16, 1987, S. Treaty Doc. No. 10, 100th Cong., 1st sess., 26 I.L.M. 1541 (1987). In accordance with the provisions of the Montreal Protocol, under authority of Title VI of the Clean Air Act (section 601 *et seq.*), manufacture of CFC's in the United States was generally banned as of January 1, 1996. To receive permission to manufacture CFC's in the United States after the phaseout date, manufacturers must obtain an exemption from the phaseout requirements from the Parties to the Montreal Protocol. Procedures for securing an essential-use exemption under the Montreal Protocol are described in the most recent request by EPA for applications for exemptions (60 FR 54349, October 23, 1995). Firms that wish to use CFC's manufactured after the phaseout date in medical devices (as