an exempt multiple savings and loan holding company merges its savings association subsidiaries to become a unitary savings and loan holding company, the resulting savings association subsidiary will be considered to have been acquired in a non-supervisory transaction, unless all the savings associations merged were acquired by the holding company in supervisory transactions.

(2)(i) For purposes of paragraph (a)(1)(ii)(B) of this section and subject to the restrictions therein, if any savings association subsidiary that was acquired in a supervisory acquisition engages in any acquisition, merger, or consolidation after the subsidiary's own supervisory acquisition, the Director, in determining whether that savings association has existed continuously since such supervisory acquisition, will consider the following factors, as appropriate:

(A) The corporate identity of the surviving savings association as specified in its charter;

(B) The relative sizes of the holding companies, savings associations or other depository institutions involved in terms of assets or liabilities, or both; and

(C) Such other factors on a case-by-case basis as the Director considers appropriate.

(ii) The supervisory status of a savings association may not be transferred from the initial acquiring holding company to a succeeding acquiror, unless the succeeding acquisition itself qualifies as a supervisory acquisition under section 10(e) of the Home Owners' Loan Act, or unless an internal reorganization of the initial acquiror causes an acquisition by a newly formed holding company.

(iii) A holding company that believes it is or may become entitled to exempt multiple status based on rulings or opinions that the OTS issued prior to [insert effective date of regulation] may request confirmation of that status from the OTS prior to [insert date 60 days after effective date of regulation]. Such requests must contain a detailed explanation of the basis for exempt multiple status. After [insert date 60 days after effective date of regulation], the OTS will apply only the provisions in paragraphs (a)(1)(ii) and (a)(2) of this section to requests for exempt multiple status. A multiple holding company that does not receive confirmation of exempt multiple status from the OTS and that does not qualify for exempt status under the regulation, will have two years after the effective date of the final rule to cease or divest any activities that are not permissible for multiple holding companies under section 10(c).

* * * * *

Dated: February 1, 1999.

By the Office of Thrift Supervision.

Ellen Seidman,

Director.

[FR Doc. 99–2834 Filed 2–5–99; 8:45 am]

BILLING CODE 6720–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–CE–80–AD]

RIN 2120–AA64

Airworthiness Directives; Avions Pierre Robin Model R2160 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to all Avions Pierre Robin Model R2160 airplanes. The proposed AD would require repetitively inspecting the aileron/flap common support bracket for cracks, loose rivets, or separation of the bracket from the skin, and reinforcing the bracket either immediately or at a certain time period depending on whether discrepancies are found during the inspections. Reinforcing the aileron/flap common support bracket terminates the repetitive inspection requirement. The proposed AD is the result of mandatory continuing airworthiness information (MCAI) issued by the airworthiness authority for France. The actions specified by the proposed AD are intended to detect defects in the aileron/flap common support bracket (cracks, loose rivets, or separation of the bracket from the skin), which could result in reduced or loss of control of the airplane.

DATES: Comments must be received on or before March 11, 1999.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 98–CE–80–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 Avions Pierre Robin, 1, route de Troyes, 21121 Darois-France; telephone: 33–3 80 44 20 50; facsimile: 33–3 80 35 60 80. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. Karl M. Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 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. 98–CE–80–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 98–CE–80–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, notified the FAA that an unsafe condition may exist on all Avions Pierre Robin Model R2160 airplanes. The DGAC reports cracks found in the area of the attachment points of the aileron/flap common support brackets and corresponding wing skin areas.

This condition, if not corrected, could result in these brackets separating from the wing skin with possible reduced or loss of control of the airplane.

Relevant Service Information

Avions Pierre Robin has issued Service Bulletin No. 90, dated May 3, 1982, which specifies procedures for inspecting the aileron/flap common support bracket. In addition, Avions Pierre Robin has developed repair kits that include all the parts and procedures for reinforcing the aileron/flap common support bracket.

The DGAC classified this service bulletin as mandatory and issued French AD 82–70–(A), dated May 19, 1982, in order to assure the continued airworthiness of these airplanes in France.

The FAA's Determination

This airplane model is manufactured in France and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above.

The FAA has examined the findings of the DGAC; reviewed all available information, including the service information referenced above; and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of the Provisions of the Proposed AD

Since an unsafe condition has been identified that is likely to exist or develop in other Avions Pierre Robin Model R2160 airplanes of the same type design registered in the United States, the FAA is proposing AD action. The proposed AD would require repetitively inspecting the aileron/flap common support bracket for cracks, loose rivets, or separation of the bracket from the skin, and reinforcing the bracket either immediately or at a certain time period depending on whether discrepancies are found during the inspections.

Accomplishment of the proposed inspections would be required in accordance with Avions Pierre Robin Service Bulletin No. 90, dated May 3, 1982. The reinforcement specified in this proposed AD would be accomplished in accordance with Avions Pierre Robin Repair Kit No. 97.40.16, as specified in Avions Pierre Robin Service Bulletin No. 90, dated May 3, 1982.

Cost Impact

The FAA estimates that 10 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 4 workhours per airplane to accomplish the proposed action, and that the average labor rate is approximately $60 per work hour. Parts cost approximately $100 per airplane. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $3,400, or $340 per airplane.

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 adding a new airworthiness directive (AD) to read as follows:

Avions Pierre Robin: Docket No. 98–CE–80–AD.

Applicability: Model R2160 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 as indicated in the body of this AD, unless already accomplished.

To detect defects in the aileron/flap common support bracket (cracks, loose rivets, or separation of the bracket from the skin), which could result in reduced or loss of control of the airplane, accomplish the following:

(a) Within the next 50 hours time-in-service (TIS) after the effective date of this AD, and thereafter at intervals not to exceed 50 hours TIS until the reinforcement required by paragraph (b) of this AD is accomplished, inspect the aileron/flap common support brackets for cracks, loose rivets, or separation of the bracket from the skin. Accomplish this inspection in accordance with Avions Pierre Robin Service Bulletin No. 90, dated May 3, 1982.

(b) At whichever of the compliance times in paragraphs (b)(1) and (b)(2) of this AD that occurs first, reinforce the left-hand and right-hand aileron/flap common support bracket in accordance with the instructions in Avions Pierre Robin Repair Kit No. 97.40.16 , as specified in Avions Pierre Robin Service Bulletin No. 90, dated May 3, 1982.

(1) Prior to further flight if any crack(s), loose rivet(s), and/or separation of the bracket from the skin are/is found during any inspection required by paragraph (a) of this AD; or

(2) Within the next 12 calendar months after the effective date of this AD.

(c) Reinforcing the aileron/flap common support bracket as specified in paragraph (b) of this AD is considered terminating action for the repetitive inspection requirement of this AD.

(d) As of the effective date of this AD, no person may install, on any affected airplane, an aileron/flap common support bracket that has not been reinforced as specified in paragraph (b) of this AD.

(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 requirements of this AD can be accomplished.

(f) An alternative method of compliance or adjustment of the compliance times that provides an equivalent level of safety may be used if approved by the Manager, Small Airplane Directorate, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64106. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Small Airplane Directorate.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(g) Questions or technical information related to the service information referenced in this AD should be directed to Avions Pierre Robin, 1, route de Troyes, 21121 Darois-France; telephone: 33–3 80 44 20 50; facsimile: 33–3 80 35 60 80. This service information may be examined at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Note 3: The subject of this AD is addressed in issued French AD 82–70–(A), dated May 19, 1982.

Issued in Kansas City, Missouri, on February 2, 1999.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–2902 Filed 2–5–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 98N–1134]

Gastroenterology and Urology Devices; Reclassification of the Extracorporeal Shock Wave Lithotripter

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment its proposal to reclassify from class III to class II the extracorporeal shock wave lithotripter, when intended for use to fragment kidney and ureteral calculi, and the recommendation of the Gastroenterology and Urology Devices Advisory Panel (the Panel) regarding this reclassification. The Panel made this recommendation after reviewing the relevant publicly available information and the proposed reclassification. FDA is also issuing for public comment its tentative findings on the Panel's recommendation. After considering any public comments on the Panel's recommendation and FDA's tentative findings, FDA will reclassify the device or retain it in class III. FDA's decision on the proposed reclassification will be announced in the **Federal Register**.

DATES: Written comments by May 10, 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: John H. Baxley, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et. seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629), and the Food and Drug Administration Modernization Act of 1997 (the FDAMA) (Pub. L. 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act (21 U.S.C. 360c(f))) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C.360e(b)) requiring premarket approval.

Reclassification of classified postamendments devices is governed by section 513(f)(2) of the act (21 U.S.C. 360c(f)(2)). This section provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of a device may petition the Secretary of Health and Human Services (the Secretary) for the issuance of an order classifying the device in class I or class II. FDA's regulations in 21 CFR 860.134 set forth the procedures for the filing and review of a petition for reclassification of such class III devices. In order to change the classification of the device, it is necessary that the proposed new class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Section 216 of FDAMA replaced the ''four of a kind'' rule in the old section 520(h)(4) of the act (21 U.S.C. 360j(h)(4)) with a provision that frees agency use of data in PMA's approved 6 or more years before FDA undertakes certain regulatory actions, including device reclassifications. Under section 520(h)(4) of the act, as amended by FDAMA, the agency has supplemented other sources of information that support reclassification of the extracorporeal shock wave lithotripter with data contained in PMA's approved 6 or more years before the date of this proposal. In this instance, FDA has only used data that would have been available to the agency under the superseded four of a kind rule.

Under section 513(f)(2)(B)(i) of the act (21 U.S.C. 360c(f)(2)(B)(i)), the Secretary, for good cause shown, may refer a proposed reclassification to a