body of this AD, unless already accomplished.

To prevent the inability of the bulkhead to carry its ultimate design load because of cracks in the canted bulkhead, which, if not detected and corrected, could affect rudder cable tension and result in reduced rudder power, accomplish the following:

Note 2: The paragraph structure of this AD is as follows:

Level 1: (a), (b), (c), etc.
Level 2: (1), (2), (3), etc.

Level 2 structures are designations of the Level 1 paragraph they immediately follow.

(a) Upon the accumulation of 5,000 hours time-in-service (TIS) or within the next 600 hours TIS, whichever occurs later, inspect the canted bulkhead at Fuselage Station 588.10. Accomplish this inspection in accordance with the Accomplishment Instructions section of Beech Service Bulletin (SB) No. 2564, Revision 1, dated April 1995.

(b) If, during the inspection, one or more of the limits specified in paragraphs (b)(1), (b)(2), or (b)(3) of this AD are found (also specified in Beech SB No. 2564), prior to further flight, incorporate Beech Kit No. 129–4005–1 S, which reinforces the canted bulkhead at Fuselage Station 588.10.

(1) Any one crack that is greater than 2.5 inches in length.

(2) The sum of all crack lengths in any 12 inches of consecutive frame length is greater than 4.0 inches

(3) Any crack that progresses through the width of the bulkhead.

(c) If no cracks are found during an inspection or a crack is found that does not exceed one of the limits specified in paragraphs (b)(1), (b)(2), or (b)(3) of this AD, accomplish one of the following:

(1) Repeat the inspection specified in paragraph (a) of this AD at intervals not to exceed 600 hours TIS, and prior to further flight, reinforce the canted bulkhead as specified in paragraph (b) of this AD if cracks are found that exceed one or more of the limits specified in paragraphs (b)(1), (b)(2), or (b)(3) of this AD; or

(2) Within 600 hours after the last canted bulkhead inspection, incorporate Beech Kit No. 129–4005–1 S. Incorporating this kit reinforces the canted bulkhead at Fuselage Station 588.10.

(d) Special flight permits may be issued in accordance with §§ 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.

(e) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Wichita Aircraft Certification Office (ACO), 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Wichita ACO.

(f) All persons affected by this directive may obtain copies of the document referred to herein upon request to the Beech Aircraft Corporation, P.O. Box 85, Wichita, Kansas 67201–0085; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on September 26, 1995.

Henry A. Armstrong,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–24605 Filed 10–3–95; 8:45 am]

BILLING CODE 4910–13–U

14 CFR Part 39

[Docket No. 95–CE–50–AD]

Airworthiness Directives; I.A.M. Rinaldo Piaggio S.p.A. Model P 180 Series 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 certain I.A.M. Rinaldo Piaggio S.p.A. (Piaggio) Model P 180 series airplanes. The proposed action would require installing a shield on the front section of the engine cradle. A report of power control jamming as a result of freezing conditions during a high altitude flight prompted this AD action. The actions specified by the proposed AD are intended to prevent loss of engine power or the propeller controls from jamming as a result of freezing rain entering the engine nacelle, which, if not detected and corrected, could result in loss of control of the airplane.

DATES: Comments must be received on or before December 5, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–50–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 I.A.M. Rinaldo Piaggio, S.p.A., Via Cibrario, 4 16154, Genoa, Italy. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Delano D. Castle, Program Manager, Brussels Aircraft Certification Office, FAA, Europe, Africa, and Middle East Office, c/o American Embassy, B–1000 Brussels, Belgium; telephone (322) 513.3830, ext. 2716; facsimile (322) 230.6899; or Mr. J. Mike Kiesov, Project Officer, Small Airplane Directorate, Airplane Certification Service, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64105; 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. 95–CE–50–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 Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–50–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

The Registro Aeronautico Italiano (RAI), which is the airworthiness authority for Italy, recently notified the FAA that an unsafe condition may exist on certain Piaggio Model P 180 series airplanes. The RAI advised of an incident in which water entered the accessory gearbox zone during heavy rain conditions, and passed through the starter generator air discharge port or

through the interstices between the nacelle inspection hutch and the nacelle itself. The trapped water on the power and propeller controls resulted in the controls freezing and jamming while flying at high altitudes.

Piaggio has issued Service Bulletin (SB) 80–0066; Original Issue December 12, 1994, which specifies modifying the nacelle by installing a shield on the front section of the engine cradle to prevent water from getting into the power and propeller controls.

The RAI classified this service bulletin as mandatory and issued its AD number 95–087, dated April 6, 1995, in order to assure the continued airworthiness of these airplanes in Italy.

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

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

Since an unsafe condition has been identified that is likely to exist or develop in other Piaggio Model P 180 series airplanes of the same type design, the proposed AD would require modifying the nacelle by installing a shield on the front section of the engine cradle in accordance with Piaggio SB 80–0066; Original Issue: December 12, 1994.

The FAA estimates that 5 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 2 workhours per airplane to accomplish the proposed action, and that the average labor rate is approximately $60 an hour. Parts will be furnished by the manufacturer at no cost to the owner/operators. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $600. This figure is based on the assumption that none of the affected airplanes have shields installed and that none of the affected owners/operators have modified the airplanes.

The compliance time of this AD is presented in both hours time-in-service (TIS) and calendar time. The FAA has determined that including calendar time compliance is also necessary because the unsafe condition is the result of adverse weather conditions which can affect the nacelle and power controls while not in use as well as in flight. Therefore, to ensure that the above-described condition is detected and corrected on all airplanes within a reasonable period of time without inadvertently grounding any airplanes, a compliance schedule based upon both TIS and calendar time instead of hours TIS is required.

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 USC 106(g), 40101, 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

I.A.M. Rinaldo Piaggio S.P.A.: Docket No. 95–CE–50–AD.

Applicability: Model P 180 Series Airplanes (serial numbers 1001, 1002, 1004, and 1006 through 1033), 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 (c) 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 initially within the next 100 hours time-in service (TIS), or within the next 3 calendar months, whichever occurs later, after the effective date of this AD, unless already accomplished.

Note 2: The initial compliance time in this AD takes precedence over the compliance time reflected in Piaggio Service Bulletin 80–0066, Original Issue, December 12, 1994.

To prevent loss of engine power or the propeller controls from jamming, as a result of freezing rain entering the engine nacelle, which, if not detected and corrected, could result in loss of control of the airplane, accomplish the following:

(a) Modify the nacelle by installing a shield on the front section of the engine cradle, in accordance with the ACCOMPLISHMENT INSTRUCTIONS section in Piaggio Service Bulletin (SB) No. 80–0066; Original Issue: December 12, 1994.

(b) Special flight permits may be issued in accordance with §§ 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.

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

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 Office.

(d) All persons affected by this directive may obtain copies of the document referred to herein upon request to I.A.M. Rinaldo Piaggio, S.p.A., Via Cibrario, 4 16154, Genoa, Italy; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on September 26, 1995.

Henry A. Armstrong,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–24640 Filed 10–3–95; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 95N–0176]

Orthopedic Devices: Classification, Reclassification, and Codification of Pedicle Screw Spinal Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify certain unclassified preamendments pedicle screw spinal systems into class II (special controls), and to reclassify certain postamendments pedicle screw spinal systems from class III (premarket approval) to class II. FDA is also issuing for public comment the recommendations of the Orthopedic and Rehabilitation Devices Panel (the Panel) concerning the classification of pedicle screw spinal systems, and the agency's tentative findings on the Panel's recommendations. After considering any public comments on the Panel's recommendations and FDA's proposed classification, in addition to any other relevant information that bears on this action, FDA will publish a final regulation classifying the device. This action is being taken because the agency believes that there is sufficient information to establish special controls that will provide reasonable assurance of its safety and effectiveness.

DATES: Written comments by January 2, 1996.

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

FOR FURTHER INFORMATION CONTACT: Mark N. Melkerson, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

SUPPLEMENTARY INFORMATION:

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I. Highlights of the Proposal

FDA is issuing for public comment several recommendations of the Panel concerning the classification of pedicle screw spinal systems. The Panel recommended that FDA classify into class II the unclassified preamendments pedicle screw spinal system intended for the treatment of severe spondylolisthesis (grades 3 and 4) of the fifth lumbar vertebra in patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of the implant after the attainment of a solid fusion. The Panel also recommended that FDA reclassify the postamendments pedicle screw spinal system intended for degenerative spondylolisthesis and spinal trauma from class III to class II. For all other indications, pedicle screw spinal systems are considered postamendments class III devices for which premarket approval is required. The Panel made its recommendations after reviewing information presented at two public meetings on August 20, 1993 and July 23, 1994, and after reviewing information which was solicited in response to an April 3, 1995, letter. FDA is also issuing for public comment its tentative findings on the Panel's recommendations. FDA is proposing to expand the intended uses of the device identified by the Panel to include pedicle screw spinal systems intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of acute and chronic instabilities and deformities, including spondylolisthesis, fractures and dislocations, scoliosis, kyphosis, and spinal tumors. Finally, FDA is proposing to codify the classification of both the preamendments and the postamendments device in one regulation. Comments received in response to this proposed rule, along with other relevant information that the agency may obtain, will be relied upon by the agency in formulating a final position on each of the foregoing issues and provide the basis for a final agency regulation.

II. Background

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) and the Safe Medical Devices Act of 1990 (the SMDA) 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 are as follows: Class I, general controls; class II, special controls; and class III, premarket approval. Devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments) are classified under section 513 of the act (21 U.S.C. 360c) 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. A device that is first offered for commercial distribution after May 28, 1976, and is substantially equivalent to a device classified under this scheme, is also classified into the same class as the device to which it is substantially equivalent.

A device that was not in commercial distribution prior to May 28, 1976, and that is not substantially equivalent to a preamendments device, is classified by statute into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

The pedicle screw spinal system intended for indications other than severe spondylolisthesis is a postamendment device classified into class III under section 513 (f) of the act (21 U.S.C. 360c(f)). In accordance with sections 513(e) and (f) of the act and 21 CFR 860.134, based on new information with respect to the device, FDA, on its own initiative, is proposing to reclassify this device from class III to class II when intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of acute and chronic instabilities and deformities, including spondylolisthesis, fractures and dislocations, scoliosis, kyphosis, and