Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 1 and 3

[Docket No. 93–076–8]

RIN 0579–AA59

Animal Welfare; Marine Mammals

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The purpose of this notice is to announce the second and final meeting of the Marine Mammal Negotiated Rulemaking Advisory Committee.

DATES: April 1 through 3, 1996, from 8:30 a.m. to 4:30 p.m. each day.

ADDRESSES: The meeting will be held at the USDA Center at Riverside, Conference Center Rooms A and B, 4700 River Road, Riverdale, Maryland 20737, (301) 734–7833.

FOR FURTHER INFORMATION CONTACT: Dr. Barbara Kohn, Senior Staff Veterinarian, Animal Care Staff, REAC, APHIS, 4700 River Road Unit 84, Riverdale, MD 20737–1234, (301) 734–7833.

SUPPLEMENTARY INFORMATION: In a Federal Register notice published on May 22, 1995 (60 FR 27049–27051, Docket No. 93–076–3), we announced our intent to establish a Marine Mammal Negotiated Rulemaking Advisory Committee (Committee), chartered under the Federal Advisory Committee Act (Pub. L. 92–463). The Committee will review the current regulations and standards under the Animal Welfare Act concerning the care and maintenance of captive marine mammals, and provide consensus language to amend the regulations. The first meeting of the Committee, which was announced in a Federal Register notice published on September 8, 1995 (60 FR 46783–46784, Docket No. 93–076–7), was held on September 25–26, 1995. This notice announces the second and final meeting of the Committee.

The purpose of the meeting is to bring together members of the Animal and Plant Health Inspection Service, representatives of the marine mammal public display community, the marine mammal research community, the animal welfare community, and members of other Federal agencies with a definable stake in marine mammal care issues to frame a recommended rulemaking proposal to amend the current regulatory program concerning care and maintenance standards for captive marine mammals.

The Committee will determine the final agenda for the meeting at its beginning. The tentative agenda for the meeting is as follows:

First Day

Morning Session—8:30 a.m.

Establish Agenda for Meeting
Discussion of Marine Mammal Regulations

Afternoon Session—1 p.m.

Discussion of Marine Mammal Regulations
Public Comments

Second Day

Morning Session—8:30 a.m.

Establish Agenda for Day
Committee Administrative Issues
Discussion of Marine Mammal Regulations

Afternoon Session—1 p.m.

Discussion of Marine Mammal Regulations
Public Comments

Third Day

Morning Session—8:30 a.m.

Establish Agenda for Day
Committee Administrative Issues
Discussion of Marine Mammal Regulations

Afternoon Session—1 p.m.

Discussion of Marine Mammal Regulations
Public Comments

The meeting will be open to the public. Public participation at the meeting will be allowed during periods announced at the meeting for this purpose.

This notice is given pursuant to section 10 of the Federal Advisory Committee Act.

Done in Washington, DC, this 4th day of March 1996.

Lonnie J. King,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–5580 Filed 3–7–96; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 95–NM–160–AD]

Airworthiness Directives; Jetstream BAe Model ATP Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Jetstream BAe Model ATP airplanes. This proposal would require repetitive inspections to detect damage of the antenna mounting reinforcing plates and surrounding fuselage skin. If any damage is detected, the proposed AD would require replacement of the reinforcing plate with a new reinforcing plate and/or repair the surrounding fuselage skin, which would terminate the repetitive inspection requirements. This proposal is prompted by reports of corrosion found at the antenna reinforcing plates, which was caused by the ingress of water at the plates. The actions specified by the proposed AD are intended to prevent such corrosion, which could result in reduced structural integrity of the fuselage pressure vessel.

DATES: Comments must be received by April 18, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 95–NM–160–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Jetstream Aircraft, Inc., P.O. Box 16029,

Dulles International Airport, Washington, DC 20041–6029. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: William Schroeder, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–2141; fax (206) 227–1149.

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 shall 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 summarizing 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 Number 95–NM–160–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, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 95–NM–160–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, recently notified the FAA that an unsafe condition may exist on certain Jetstream BAe Model ATP airplanes. The CAA has received a report indicating that corrosion was found on at least two airplanes at the antenna reinforcing plates. The cause of such corrosion has been attributed to the ingress of water at the plates. Corrosion of the antenna reinforcing plates, if not detected and corrected in a timely manner, could result in reduced structural integrity of the fuselage pressure vessel.

Jetstream has issued Service Bulletin ATP–53–31, dated July 1, 1995, which describes procedures for repetitive detailed external visual inspections to detect damage (i.e., corrosion, cracks, pillowing, and rivet pulling) of the antenna mounting reinforcing plates and surrounding fuselage skin. For cases where any damage is detected during the inspection, the service bulletin describes procedures for replacement of the reinforcing plate with a new reinforcing plate and/or repair the surrounding fuselage skin. Accomplishment of the replacement/repair would eliminate the need for the repetitive inspections. The CAA classified this service bulletin as mandatory in order to assure the continued airworthiness of these airplanes in the United Kingdom.

This airplane model is manufactured in the United Kingdom 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 CAA has kept the FAA informed of the situation described above. The FAA has examined the findings of the CAA, 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 on other products of this same type design, the proposed AD would require repetitive detailed external visual inspections to detect damage (i.e., corrosion, cracks, pillowing, and rivet pulling) of the antenna mounting reinforcing plates and surrounding fuselage skin. For cases where any damage is detected during the inspection, the proposed AD would require replacement of the reinforcing plate with a new reinforcing plate and/or repair the surrounding fuselage skin; this replacement/repair would constitute terminating action for the repetitive inspection requirements. The actions would be required to be accomplished in accordance with the service bulletin described previously.

The FAA estimates that 10 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 2 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $1,200, or $120 per airplane, per inspection cycle.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

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 proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the 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 is contained 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), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Jetstream Aircraft Limited (Formerly British Aerospace Commercial Aircraft Limited): Docket 95–NM–160–AD.

Applicability: BAe Model ATP airplanes having constructor's numbers 2002 through 2063 inclusive, 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 as indicated, unless accomplished previously.

To prevent corrosion of the antenna mounting reinforcing plates and surrounding skin, which could result in reduced structural integrity of the fuselage pressure vessel, accomplish the following:

(a) Within 6 months after the effective date of this AD, perform a detailed external visual inspection to detect damage (i.e., corrosion, cracks, pillowing, and rivet pulling) of the antenna mounting reinforcing plates and surrounding fuselage skin in accordance with PART A of the Accomplishment Instructions of Jetstream Service Bulletin ATP–53–31, dated July 1, 1995.

(1) If no damage is detected, repeat the inspection thereafter at intervals not to exceed 1 year.

(2) If any damage is detected, replace the reinforcing plate with a new reinforcing plate and/or repair the surrounding fuselage skin at the applicable times specified in Figure 4 of the service bulletin, and in accordance with PART B of the Accomplishment Instructions of the service bulletin. Accomplishment of the replacement/repair constitutes terminating action for the repetitive inspection requirements of paragraph (a) of this AD.

(b) Accomplishment of the replacement/repair procedures specified in PART B of the Accomplishment Instructions of Jetstream Service Bulletin ATP–53–31, dated July 1, 1995, constitutes terminating action for the requirements of this AD.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(d) 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.

Issued in Renton, Washington, on March 4, 1996.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–5526 Filed 3–7–96; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. 93P–0277]

Ophthalmic Devices; Reclassification of Neodymium:Yttrium:Aluminum:Garnet (Nd:YAG) Laser for Peripheral Iridotomy

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; notice of panel recommendation.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the ophthalmic neodymium:yttrium:aluminum:garnet (Nd:YAG) laser (mode-locked or Q-switched) intended for peripheral iridotomy from class III (premarket approval) into class II (special controls). The agency is also issuing for public comment the recommendation of the Ophthalmic Devices Panel (the Panel) regarding the reclassification of this device. The Panel made this recommendation after reviewing the reclassification petition submitted by Intelligent Surgical Lasers, Inc. (ISL). FDA is also issuing for public comment its tentative findings on the Panel's recommendation and its intent to change the generic designation of the device from Nd:YAG laser for posterior capsulotomy to Nd:YAG laser for posterior capsulotomy and peripheral iridotomy. After considering any public comments on the Panel's recommendation and FDA's tentative findings, FDA will approve or deny the reclassification petition by order in the form of a letter to the petitioner. FDA's decision on the petition will be announced in the Federal Register. If the petition is approved and the device is reclassified into class II, FDA will publish a final rule to codify the reclassification.

DATES: Written comments by June 6, 1996.

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: Morris Waxler, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2018.

SUPPLEMENTARY INFORMATION:

I. Introduction

On March 2, 1993, ISL submitted a petition under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)), requesting that the ophthalmic Nd:YAG laser (mode-locked or Q-switched) intended for peripheral iridotomy be reclassified from class III into class II.

The subject device is automatically classified into class III under section 513(f)(1) of the act because it is not within a type of device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, it is not substantially equivalent to such a device, and it is not substantially equivalent to a device placed in commercial distribution since May 28, 1976, which was subsequently reclassified into class II or class I.

Section 513(f)(2) of the act 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 the device may petition the agency to reclassify the device into class I or class II. FDA's regulations in 21 CFR 860.134 set forth the procedures for filing and review of a petition to reclassify these class III devices. In order to reclassify the ophthalmic Nd:YAG laser (mode-locked or Q-switched) for peripheral iridotomy into class II, it is necessary that the proposed new class has sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

II. Background

Nd:YAG lasers originally were developed for industrial applications, and were successfully employed in such industries as watchmaking prior to the initiation of clinical trials in Europe and the United States. Therefore, the basic principles of operation of the device