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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 95–CE–71–AD]

RIN 2120–AA64

Airworthiness Directives; SOCATA-Groupe AEROSPATIALE Models TB10 and TB200 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 SOCATA-Groupe AEROSPATIALE (Socata) Models TB10 and TB200 airplanes. The proposed AD would require inspecting the wing rear attachment fittings for cracks, replacing any cracked fitting, and incorporating wing rear attachment fitting reinforcement kits. The proposed AD is the result of mandatory continued airworthiness information (MCAI) issued by the airworthiness authority for France. The actions specified by the proposed AD are intended to prevent structural failure of the wing rear attachment fittings caused by cracks in this area, which could result in a wing separating from the airplane with consequent loss of control of the airplane.

DATES: Comments must be received on or before January 11, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 95–CE–71–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 the Socata-Groupe Aerospatiale, Socata Product Support, Aeroport Tarbes-Ossun-Lourdes, B P 930, 65009 Tarbes Cedex, France; telephone 62.41.74.26; facsimile 62.41.74.32; or the Product Support Manager, Socata-Groupe Aerospatiale, North Perry Airport, 7501 Pembroke Road, Pembroke Pines, Florida 33023; telephone (954) 964–6877; facsimile (954) 964–1668. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. Karl Schletzbaum, Aerospace Engineer, FAA, Small Airplane Directorate, 1201 Walnut Street, suite 900, Kansas City, Missouri 64106; telephone (816) 426–6934; 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–71–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. 95–CE–71–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

The Direction Generale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, recently notified the FAA that an unsafe condition may exist on certain Socata Models TB10 and TB200 airplanes. The DGAC reports three incidents of cracks on the wing rear attachment fittings and one incident of rear wing attachment fitting deformation. These conditions, if not detected and corrected, could result in a wing separating from the airplane with consequent loss of control of the airplane.

Relevant Service Information

Socata has issued Service Bulletin No. SB 10–082, Amdt. 1, dated April 1996, which specifies procedures for inspecting the wing rear attachment fittings for cracks. Also included in this service bulletin is reference to wing rear attachment fitting reinforcement kits that should be incorporated on the Socata Models TB10 and TB200 airplanes. The procedures for incorporating these reinforcement kits are in the technical instructions included with each kit.

The DGAC classified this service bulletin as mandatory and issued French AD 94–249(A)R1, dated June 19, 1996, 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 Socata Models TB10 and TB200 airplanes of the same type design registered in the United States, the FAA is proposing AD action. The proposed AD would require inspecting the wing rear attachment fittings for cracks, replacing any cracked fitting, and incorporating wing rear attachment fitting reinforcement kits. Accomplishment of the proposed inspections would be in accordance with Socata Service Bulletin No. SB 10–082, Amdt. 1, dated April 1996. Accomplishment of the proposed reinforcement kits would be in accordance with the technical instructions included with each kit.

Differences Between the French AD, the Service Bulletin, and This Proposed AD

French AD 94–249(A)R1, dated June 19, 1996, and Socata Service Bulletin No. SB 10–082, Amdt. 1, dated April 1996, both give the owners/operators of certain Models TB10 and TB200 airplanes the option of accomplishing one of the following if no cracks are found during the inspections:

—Incorporating the wing rear attachment fitting reinforcement kit No. OPT10 920300; or

—Reinspecting at certain intervals until cracks are found at which time the incorporation of a wing rear attachment fitting reinforcement kit would be mandatory.

The FAA's policy is to provide corrective action that will eliminate the need for repetitive inspections. The FAA has determined that long-term operational safety will be better assured by design changes that remove the source of the problem, rather than by repetitive inspections or other special procedures.

Because the incorporation of wing rear attachment fitting reinforcement kit No. OPT10 920300 on the affected airplanes eliminates the need for repetitive inspections, the proposed AD differs from the service bulletin and French AD in that it would mandate incorporation of two of these kits on each wing.

Cost Impact

The FAA estimates that 71 airplanes in the U.S. registry would be affected by the proposed AD.

Accomplishing the actions of the proposed AD (both the inspection and incorporation of the reinforcement kits) would take approximately 11 workhours per airplane (3 workhours for the inspection of all four wing rear attachment fitting areas, and 2 workhours to incorporate the reinforcement kit at each of the four wing rear attachment fitting areas), at an average labor rate of approximately $60 an hour. Parts to accomplish the proposed AD cost approximately $200 per airplane ($50 per kit × 4 kits). Based on these figures, the total cost impact of the proposed initial inspection on U.S. operators is estimated to be $61,060 or $860 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 USC 106(g), 40113, 44701.

§ 39.13 [Amended]

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

Socata-Groupe Aerospatiale: Docket No. 95–CE–71–AD.

Applicability: Models TB10 and TB200 airplanes, serial numbers 804; 807; 808; 816 through 819; 823 through 1701; 1707 through 1733; and 1737 through 1761, 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 in the body of this AD, unless already accomplished.

To prevent structural failure of the rear wing attachment fittings caused by cracks in this area, which could result in a wing separating from the airplane with consequent loss of control of the airplane, accomplish the following:

Note 2: The compliance times of this AD are presented in landings instead of hours time-in-service (TIS). If the number of landings is unknown, hours TIS may be used by multiplying the number of hours TIS by 0.67.

Note 3: The paragraph structure of this AD is as follows:

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

Level 2 and Level 3 structures are designations of the Level 1 paragraph they immediately follow.

(a) Upon accumulating 3,000 landings on each wing rear attachment fitting (total of four; two per wing) or within the next 75 landings after the effective date of this AD, whichever occurs later, inspect the wing rear attachment fittings for cracks in accordance with the accomplishment instructions section of Socata Service Bulletin (SB) No. SB 10–082, mdt. 1, dated April 1996.

(1) If any fitting is found cracked on the wing side, prior to further flight, replace the cracked fitting and incorporate wing rear attachment fitting reinforcement kit No. OPT10 920300 in accordance with the Technical Instruction of Modification, OPT10 9203-57, Wing Rear Attachment Bracket, dated April 1996.

(2) If any fitting is found cracked on the fuselage side, prior to further flight, accomplish the following:

(i) Incorporate wing rear attachment fitting reinforcement kit No. OPT10 920500 in accordance with the Technical Instruction of

Modification, OPT10 9205–57, Wing Rear Attachment Bracket, dated April 1996; and

(ii) Incorporate wing rear attachment fitting reinforcement kit No. OPT10 920300 in accordance with the Technical Instruction of Modification, OPT109203–57, Wing Rear Attachment Bracket, dated April 1996.

(3) If any fitting is not found cracked, prior to further flight, incorporate wing rear attachment fitting reinforcement kit No. OPT10 920300 in accordance with the Technical Instruction of Modification, OPT109203–57, Wing Rear Attachment Bracket, dated April 1996.

(b) 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.

(c) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be 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 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Small Airplane Directorate.

(d) All persons affected by this directive may obtain copies of the documents referred to herein upon request to Socata—Groupe Aerospatiale, Socata Product Support, Aeroport Tarbes-Ossun-Lourdes, B P 930, 65009 Tarbes Cedex, France; or Perry Airport, 7501 Pembroke Road, Pembroke Pines, Florida 33023. These documents may also be examined at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Note 5: The subject of this AD is addressed in French AD 94–249(A)R1, dated June 19, 1996.

Issued in Kansas City, Missouri, on December 10, 1997.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–32727 Filed 12–15–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 97N–0481]

Gastroenterology-Urology Devices: Reclassification of the Penile Rigidity Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the penile rigidity implant, a medical device intended to provide penile rigidity in men diagnosed as having erectile dysfunction, from class III to class II. The special controls identified in this proposed rule are the physician and patient labeling, biocompatibility testing, mechanical reliability performance testing, clinical testing, and sterilization requirements described in FDA's guidance document entitled ''Guidance for the Content of Premarket Notifications for Penile Rigidity Implants.'' This reclassification is being proposed on the agency's own initiative based on new information. This action is being taken under 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).

DATES: Written comments by March 16, 1998. FDA proposes that any final regulation based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

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: 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. Regulatory Authorities

The act, as amended by the 1976 amendments (Pub. L. 94–295) and the SMDA (Pub. L. 101–629), 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 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 post amendment devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, 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 21 CFR part 807 of the regulations.

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. Section 515(b) of the act describes a two step regulatory process. A notice of proposed rulemaking in the Federal Register, which includes the proposed regulation, proposed findings of risks and benefits of the device, an opportunity for the submission of comments and an opportunity to request reclassification, is followed by the final rule which issues the regulation.

In 1990, the SMDA added section 515(i) to the act. This section requires FDA to issue an order to manufacturers of preamendment class III devices for which no final regulation requiring the submission of PMA's has been issued to submit to the agency a summary of, and a citation to any information known or otherwise available to them respecting such devices, including adverse safety and effectiveness information which has not been submitted under section 519 of the act (21 U.S.C. 360i). Section 519 of the act requires manufacturers, importers, distributors and device user facilities to submit adverse event reports of certain device-related events. Section 515(i) of the act also directs FDA to either revise the classification of the device into class I or class II or require the device to remain in class III and establish a schedule for the issuance of a rule requiring the submission of PMA's for those devices remaining in class III.