3. Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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. The FAA amends § 39.13 by removing Amendment 39–14275 (70 FR 54622, September 16, 2005) and by adding a new airworthiness directive, to read as follows:

Turbomeca: Docket No. FAA–2005–22430; Directorate Identifier 2005–NE–34–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this airworthiness directive (AD) action by March 19, 2007.

Affected ADs

(b) This AD supersedes AD 2005–19–10, Amendment 39–14275.

Applicability

(c) This AD applies to Turbomeca Arrius 2 F turboshaft engines with fuel control units (FCUs) not incorporating modification Tf 55. These engines are installed on, but not limited to, Eurocopter EC120B helicopters.

Unsafe Condition

(d) This AD results from the European Aviation Safety Agency (EASA) and Turbomeca expanding the applicability to the full population of FCUs installed on Arrius 2 F turboshaft engines. FCUs not incorporating modification Tf 55 are susceptible to having an improperly assembled constant delta pressure (delta P) diaphragm. We are issuing this AD to prevent an uncommanded engine in-flight shutdown on a single-engine helicopter, resulting in a forced autorotation landing or an accident.

Compliance

(e) You are responsible for having the actions required by this AD performed as soon as practicable after the effective date of this AD but no later than July 31, 2007, unless the actions have already been done.

(f) Replace all FCUs not incorporating modification Tf 55 with FCUs that incorporate modification Tf 55.

Alternative Methods of Compliance

(g) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Related Information

(h) Contact Christopher Spinney, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7175, fax (781) 238–7199; e-mail: *christopher.spinney@faa.gov* for more information about this AD.

(i) EASA AD No. 2006–0237, dated August 9, 2006, addresses the subject of this AD.

(j) Turbomeca Mandatory Service Bulletin, Update No. 1, dated March 17, 2006, pertains to the subject of this AD.

Issued in Burlington, Massachusetts, on January 10, 2007.

Francis A. Favara,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. E7–494 Filed 1–16–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

RIN 2120–AA64

[Docket No. FAA–2006–25896; Directorate Identifier 2006–NE–33–AD]

Airworthiness Directives; General Electric Company CF34–10E Series Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede an existing airworthiness directive (AD) for General Electric Company (GE) CF34–10E series turbofan engines. That AD currently requires removing the fuel inlet strainer from main fuel pump (MFP) part number (P/N) 2043M12P03, installing a certain replacement flange as an interim repair, remarking the MFP to P/N 2043M12P04, and performing initial and repetitive visual inspections of the main fuel filter. This proposed AD would require removing MFPs, P/N 2043M12P03 and 2043M12P04 from service and installing an improved MFP with a different P/N. This proposed AD results from GE determining that the cause of MFP fuel strainer failure is a design problem with the strainer. We are proposing this AD to prevent engine in-flight shutdown due to MFP malfunctions.

DATES: We must receive any comments on this proposed AD by March 19, 2007.

ADDRESSES: Use one of the following addresses to comment on this proposed AD.

- *DOT Docket Web site:* Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street, SW., Nassif Building, Room PL–401, Washington, DC 20590–0001.
- *Fax:* (202) 493–2251.
- *Hand Delivery:* Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Contact General Electric Company via Lockheed Martin Technology Services, 10525 Chester Road, Suite C, Cincinnati, Ohio 45215, telephone (513) 672–8400, fax (513) 672–8422, for the service information identified in this proposed AD.

FOR FURTHER INFORMATION CONTACT: Tara Fitzgerald, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone: (781) 238–7130, fax: (781) 238–7199.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments regarding this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2006–25896; Directorate Identifier 2006–NE–33–AD'' in the subject line of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the proposed AD. We will consider all comments received by the closing date and may amend the proposed AD in light of those comments.

We will post all comments we receive, without change, to *http://dms.dot.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA

personnel concerning this proposed AD. Using the search function of the DMS Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *http://dms.dot.gov*.

Examining the AD Docket

You may examine the docket that contains the proposal, any comments received and any final disposition in person at the DMS Docket Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone (800) 647–5227) is located on the plaza level of the Department of Transportation Nassif Building at the street address stated in **ADDRESSES**. Comments will be available in the AD docket shortly after the DMS receives them.

Discussion

On September 21, 2006, we issued AD 2006–20–06, Amendment 39–14775 (71 FR 60663, October 16, 2006). That AD requires removing the MFP inlet strainer from the MFPs, installing a certain replacement flange as an interim repair, remarking the MFP to P/N 2043M12P04, and performing initial and repetitive visual inspections of the main fuel filter. That AD was the result of three reports of release of the tripod support legs on the MFP inlet strainer, leading to engine in-flight shutdown. That condition, if not corrected, could result in engine in-flight shutdown due to MFP malfunctions.

Actions Since AD 2006–20–06 Was Issued

Since AD 2006–20–06 was issued, GE determined that the cause of MFP fuel inlet strainer failure is a design problem with the strainers installed in the MFPs. GE has introduced MFP P/N 2043M12P05, which has a more robust design fuel inlet strainer.

FAA's Determination and Requirements of the Proposed AD

We have evaluated all pertinent information and identified an unsafe condition that is likely to exist or develop on other products of this same type design. For that reason, we are proposing this AD, which would require removing MFPs, P/N 2043M12P03 and 2043M12P04 from service and installing an improved MFP, not later than April 30, 2007.

Costs of Compliance

We estimate that this proposed AD would affect 50 CF34–10E series turbofan engines installed on airplanes of U.S. registry. We also estimate that it would take about 3 work-hours per engine to perform the proposed actions, and that the average labor rate is $80 per work-hour. Required parts would cost about $4,226 per engine to upgrade the MFP to a different P/N to make it serviceable. Based on these figures, we estimate the total upgrade cost of the proposed AD to U.S. operators to be $223,300.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect 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.

For the reasons discussed above, I certify that the 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. Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Under the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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. The FAA amends § 39.13 by removing Amendment 39–14775 (71 FR 60663, October 16, 2006) and by adding a new airworthiness directive to read as follows:

General Electric Company: Docket No. FAA–2006–25896; Directorate Identifier 2006–NE–33–AD.

Comments Due Date

(a) The Federal Aviation Administration (FAA) must receive comments on this airworthiness directive (AD) action by March 19, 2007.

Affected ADs

(b) This AD supersedes AD 2006–20–06, Amendment 39–14755.

Applicability

(c) This AD applies to General Electric Company (GE) CF34–10E2A1, –10E5, –10E5A1, –10E6, –10E6A1, and –10E7 turbofan engines, with main fuel pump (MFP) part number (P/N) 2043M12P03 or P/N 2043M12P04, installed. These engines are installed on, but not limited to, Embraer ERJ 190–100–STD, ERJ 190–100–LR, and ERJ 190–100–IGW airplanes.

Unsafe Condition

(d) This AD results from GE determining that the cause of MFP fuel strainer failure is a design problem with the strainer. We are issuing this AD to prevent engine in-flight shutdown due to MFP malfunctions.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified unless the actions have already been done.

MFP Removal and Installation

(f) Not later than April 30, 2007, remove MFPs, P/N 2043M12P03 and 2043M12P04, from service and install a serviceable MFP.

Definition

(g) For the purpose of this AD, a serviceable MFP is one that does not have P/N 2043M12P03 or 2043M12P04.

Recommended Actions

(h) We recommend that operators avoid performing the actions in this AD on both

engines installed on the same airplane at the same time, if at all possible.

Alternative Methods of Compliance

(i) The Manager, Engine Certification Office, FAA, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Related Information

(j) GE Service Bulletin No. CF34–10E S/B 73–0013, dated December 15, 2006, pertains to the subject of this AD.

(k) Contact Tara Fitzgerald, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; telephone (781) 238–7138, fax (781) 238–7199; e-mail: *tara.fitzgerald@faa.gov* for more information about this AD.

Issued in Burlington, Massachusetts, on January 10, 2007.

Francis A. Favara,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. E7–498 Filed 1–16–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 2005P–0121]

Orthopedic Devices; Reclassification of Non-Invasive Bone Growth Stimulator

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of panel recommendation.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment the recommendation of the Orthopaedic and Rehabilitation Devices Panel to deny a petition to reclassify the non-invasive bone growth stimulator from class III to class II. The Panel made this recommendation after reviewing the reclassification petition submitted by RS Medical Corp., as well as consideration of presentations made at the Panel meeting by the petitioner, FDA, and members of the public. FDA is also issuing for public comment its findings on the Panel's recommendation. After considering any public comments on the Panel's recommendation and FDA's 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 reclassification petition will be announced in the **Federal Register**.

DATES: Submit written or electronic comments by April 17, 2007.

ADDRESSES: You may submit comments, identified by Docket No. 2005P–0121, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No. 2005P–0121 for this notice. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michel Janda, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3600.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

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) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 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 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, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate 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).

Reclassification of classified postamendments devices is governed by section 513(f)(3) of the act. 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