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 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–8348 (57 FR 38432, August 25, 1992), and by adding a new airworthiness directive (AD), to read as follows:

Fokker: Docket 98–NM–16-AD. Supersedes AD 92–18–04, Amendment 39–8348.

Applicability: Model F.28 Mark 1000, 2000, 3000, and 4000 series airplanes; equipped with Menasco horizontal stabilizer actuators having part number (P/N) 11100-( ); 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 (e) 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 uncommanded trimming or failure of the trim system of the horizontal stabilizer, and consequent reduced controllability of the airplane, accomplish the following:

(a) Within 20 days after September 9, 1992 (the effective date of AD 92–18–04, amendment 39–8348), perform an inspection of the servo-valve sub-assembly rod-end bearing and servo-valve sub-assembly for movement, in accordance with Fokker Service Bulletin F28/27–180, dated July 3, 1992.

(1) If the servo-valve sub-assembly rod-end bearing and servo-valve sub-assembly move freely within the load limits specified in the service bulletin, reassemble and conduct a functional test, in accordance with the service bulletin.

(2) If the servo-valve sub-assembly rod-end bearing or servo-valve sub-assembly require higher loads for movement than specified in the service bulletin, prior to further flight, remove and replace the horizontal stabilizer control unit with a serviceable control unit that has been inspected and found to be within the load limits of the service bulletin, or that has been inspected and repaired in accordance with Chapter 27–42–4 of the Menasco Overhaul Manual (OHM), as revised by Temporary Revision Number 3, dated July 10, 1992.

(b) Within 6 months after the effective date of this AD, perform a one-time inspection to determine the residual strength of the servo-valve sub-assembly of the horizontal stabilizer actuator, in accordance with Part 1 of the Accomplishment Instructions of Fokker Service Bulletin F28/27–183, dated November 21, 1994. If any discrepancy is found, prior to further flight, replace the actuator with a new or serviceable actuator in accordance with the service bulletin.

(c) Within 3 years after the effective date of this AD, replace the horizontal stabilizer actuator with an actuator that has been modified and re-marked in accordance with Part 2 of the Accomplishment Instructions of Fokker Service Bulletin F28/27–183, dated November 21, 1994.

(d) As of the effective date of this AD, no person shall install a horizontal stabilizer control unit on any airplane, unless the horizontal stabilizer actuator has been modified and re-marked in accordance with Part 2 of the Accomplishment Instructions of Fokker Service Bulletin F28/27–183, dated November 21, 1994.

(e) 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, International Branch, ANM–116, 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, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

(f) 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.

Note 3: The subject of this AD is addressed in Dutch airworthiness directive 1992–007/2(A), dated January 31, 1995.

Issued in Renton, Washington, on April 21, 1998.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–11092 Filed 4–24–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–NM–302–AD]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace Corporation Model G–159 (G–I) 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 all Gulfstream Aerospace Corporation Model G–159 (G–I) airplanes. This proposal would require revising the Airplane Flight Manual (AFM) to modify the limitation that prohibits positioning the power levers below the flight idle stop during flight, and to provide a statement of the consequences of positioning the power levers below the flight idle stop during flight. This proposal is prompted by incidents and accidents involving airplanes equipped with turboprop engines in which the ground propeller beta range was used improperly during flight. The actions specified by the proposed AD are intended to prevent loss of airplane controllability, or engine overspeed and consequent loss of engine power caused by the power levers being positioned below the flight idle stop while the airplane is in flight.

DATES: Comments must be received by May 27, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 97–NM–302–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.

This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA,

Small Airplane Directorate, Atlanta Aircraft Certification Office, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia.

FOR FURTHER INFORMATION CONTACT: Wayne A. Shade, Aerospace Engineer, Airframe and Propulsion Branch, ACE–117A, FAA, Small Airplane Directorate, Atlanta Aircraft Certification Office, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349; telephone (770) 703–7337; fax (770) 703–6097.

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 97–NM–302–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–114, Attention: Rules Docket No. 97–NM–302–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

In recent years, the FAA has received reports of 14 incidents and/or accidents involving intentional or inadvertent operation of the propellers in the ground beta range during flight on airplanes equipped with turboprop engines. (For the purposes of this proposal, beta is defined as the range of propeller operation intended for use during taxi, ground idle, or reverse operations, as controlled by the power lever settings aft of the flight idle stop.)

Five of the fourteen in-flight beta occurrences were classified as accidents. In each of these five cases, operation of the propellers in the beta range occurred during flight. Operation of the propellers in the beta range during flight could result in loss of airplane controllability, or engine overspeed with consequent loss of engine power.

Communication between the FAA and the public during a meeting held on June 11–12, 1996, in Seattle, Washington, revealed a lack of consistency of the information on in-flight beta operation contained in the FAA-approved Airplane Flight Manual (AFM) for airplanes that are not certificated for in-flight operation with the power levers below the flight idle stop. (Airplanes that are certificated for this type of operation are not affected by the above-referenced conditions.)

FAA's Determinations

The FAA has examined the circumstances and reviewed all available information related to the incidents and accidents described previously. The FAA finds that the Limitations Section of the AFM's for certain airplanes must be revised to prohibit positioning the power levers below the flight idle stop while the airplane is in flight, and to provide a statement of the consequences of positioning the power levers below the flight idle stop. The FAA has determined that the affected airplanes include those that are equipped with turboprop engines and that are not certificated for in-flight operation with the power levers below the flight idle stop. Since turbopropeller-powered Gulfstream Aerospace Corporation Model G–159 (G–I) airplanes meet these criteria, the FAA finds that the AFM's for these airplanes must be revised to include the limitation and statement of consequences described previously.

Explanation of the Requirements of the Proposed AD

Since an unsafe condition has been identified that is likely to exist or develop in other turbopropeller-powered Gulfstream Aerospace Corporation Model G–159 (G–I) airplanes of the same type design, the proposed AD would require revising the Limitations Section of the AFM to modify the limitation that prohibits the positioning of the power levers below the flight idle stop while the airplane is in flight, and to add a statement of the consequences of positioning the power levers below the flight idle stop while the airplane is in flight.

Interim Action

This is considered interim action until final action is identified, at which time the FAA may consider further rulemaking.

Cost Impact

There are approximately 143 Gulfstream Model G–159 (G–I) airplanes of the affected design in the worldwide fleet. The FAA estimates that 63 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour 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 $3,780, or $60 per airplane.

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.

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 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 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

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

Gulfstream Aerospace Corporation (Formerly Grumman): Docket 97–NM–302–AD.

Applicability: All Model G–159 (G–I) airplanes, 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 (b) 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 loss of airplane controllability, or engine overspeed and consequent loss of engine power, caused by the power levers being positioned below the flight idle stop while the airplane is in flight, accomplish the following:

(a) For turbopropeller-powered Gulfstream Model G–159 (G–1) airplanes: Within 30 days after the effective date of this AD, revise the Limitations Section of the FAA-approved Airplane Flight Manual (AFM) to include the following statements. This action may be accomplished by inserting a copy of this AD into the AFM.

''Positioning of the propeller flight fine pitch lock selector to the ground interlock position in flight is PROHIBITED. Such positioning may lead to loss of airplane control.''

(b) 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, FAA, Small Airplane Directorate, Atlanta Aircraft Certification Office (ACO). Operators shall submit their requests through an appropriate FAA Principal Operations Inspector, who may add comments and then send it to the Manager, Atlanta ACO.

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

(c) 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.

Issued in Renton, Washington, on April 21, 1998.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–11102 Filed 4–24–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. 98N–0168]

Medical Devices; 30–Day Notices and 135–Day PMA Supplement Review; Companion Document to Direct Final Rule

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations governing the submission and review of premarket approval application (PMA) supplements to allow for the submission of a 30-day notice for modifications to manufacturing procedures or methods of manufacture. Amendments are being made to implement revisions to the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written comments on or before July 13, 1998. Submit written comments on the information collection requirements on or before June 26, 1998.

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

FOR FURTHER INFORMATION CONTACT: Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**. This proposed rule is substantively identical to its companion direct final rule. The proposed rule will provide the procedural framework to finalize the rule in the event the companion direct final rule receives any significant adverse comment and is withdrawn. The comment period for this companion proposed rule runs concurrently with that for the direct final rule. All comments on this proposed rule will also be considered as comments on the companion direct final rule. FDA is publishing the direct final rule because the rule contains noncontroversial changes, and FDA anticipates that it will receive no significant adverse comments. If no significant comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead, FDA will publish a confirmation notice within 30 days after the comment period ends confirming that the direct final rule will go into effect on September 9, 1998. Because this rule makes noncontroversial changes to an existing regulation in order to implement changes required by FDAMA, FDA believes that publication of a direct final rule is appropriate. Additional information about FDA's direct final rulemaking procedures is set forth in a guidance published in the **Federal Register** of November 21, 1997 (62 FR 62466).

If FDA receives a significant adverse comment regarding this rule, FDA will publish a document withdrawing the direct final rule within 30 days after the comment period ends and will proceed to respond to all of the comments received under this companion rule using usual notice-and-comment procedures. The comment period for this companion proposed rule runs concurrently with the direct final rule's comment period. Any comments received under this companion proposed rule will also be considered comments regarding the direct final rule.

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether