(2) For helicopters with less than 250 hours TIS, compliance is required prior to attaining 300 hours TIS.

(d) Install the over-temperature indicators at the next 300 hours TIS driveshaft coupling inspection and lubrication in accordance with Part I of the Accomplishment Instructions of BHTI ASB 206–93–76, Revision B, dated September 6, 1994.

(e) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used when approved by the Manager, Rotorcraft Certification Office, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Rotorcraft Certification Office.

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

(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 helicopter to a location where the requirements of this AD can be accomplished.

Issued in Fort Worth, Texas, on August 31, 1995.

Daniel P. Salvano,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 95–22338 Filed 9–7–95; 8:45 am]

BILLING CODE 4910–13–P

14 CFR Part 39

[Docket No. 94–NM–237–AD]

Airworthiness Directives; Jetstream Model 4101 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the supersedure of an existing airworthiness directive (AD), applicable to certain Jetstream Model 4101 airplanes, that currently requires repetitive purging of the hydraulic system and installation of a spoiler actuator that has been previously certified. That AD was prompted by a report of damage to the locking mechanisms on some pistons of the spoiler actuators. The actions specified by the AD are intended to prevent uncommanded extension of the lift spoiler in the event of loss of hydraulic pressure in the spoiler actuator. This action would establish an increased life limit for certain spoiler actuators, and provide an optional terminating action for the requirements of the AD. It would also limit the applicability of the rule to fewer airplanes.

DATES: Comments must be received by October 16, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 94–NM–237–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) 227–2148; fax (206) 227–1320.

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 94–NM–237–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. 94–NM–237–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

On August 12, 1994, the FAA issued AD 94–17–12, amendment 39–9007 (59 FR 43025, August 22, 1994), applicable to certain Jetstream Model 4101 airplanes, to require repetitive purging of the hydraulic system and repetitive installation of an actuator that has been previously certified. That action was prompted by a report of damage to the locking mechanisms on some pistons of the spoiler actuators. The cause of this damage has been attributed to inadequate purging of the spoiler hydraulic system. In some instances, the spoiler operation was out of sequence and may have caused damage to the locking mechanisms on the pistons of the spoiler actuators. The requirements of that AD are intended to prevent uncommanded extension of the lift spoiler in the event of loss of hydraulic pressure in the spoiler actuator.

Since the issuance of that AD, the Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, has advised the FAA that a standard life limit has been established for Lucas Aerospace spoiler actuators having part numbers TY1763–01A and TY1763–01B. The new life limit has been established at the current declaration of design performance (DDP) life of 5,000 hours time-in-service since new. Therefore, unless a spoiler actuator would fail to perform correctly beforehand, these actuators are permitted to remain installed on the airplane for an interval not to exceed 5,000 hours time-in-service, at which time they must be replaced. The CAA also has advised that compliance with this 5,000-hour life limit on these particular spoiler actuators terminates the need for the currently required repetitive purging of the actuators' hydraulic system and repetitive installation of newly-certified actuators (those marked with an ''R'' after the serial number) each 500 hours time-in-service.

Additionally, the CAA has advised that, based on further review, fewer airplanes are subject to the identified unsafe condition than previously considered.

Jetstream has issued Service Bulletin J41–A27–034, Revision 1, dated October 28, 1994, which describes procedures for a one-time removal of the left and

right spoiler actuators, purging the hydraulic system, and installation of a previously certified spoiler actuator. This revised service bulletin specifies a life limit of 5,000 hours time-in-service for certain Lucas Aerospace spoiler actuators; if these spoiler actuators are replaced at this life limit, the need for repetitive purging of the hydraulic system and repetitive installation of newly-certified actuators is eliminated. Additionally, the effectivity listing of the revised service bulletin eliminates certain airplanes that were specified in the original issue of the service bulletin; these airplanes have been eliminated because they have been determined not to be subject to the addressed unsafe condition. The CAA classified this revised service bulletin as mandatory in order to assure the continued airworthiness of these airplanes in the United Kingdom.

Jetstream has also issued Service Bulletin J41–27–037, dated November 7, 1994, which describes the installation of Modification JM 41381. This modification involves the installation of improved spoiler actuators (having improved purging capability) on the left and right wings. Installation of these improved actuators eliminates: (1) the need for repetitive purging of the hydraulic system and repetitive installation of newly-certified actuators; and (2) the need for a 5,000 hour time-in-service life limit on the (Lucas Aerospace) actuators. The CAA classified this revised service bulletin as optional.

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 airplanes of the same type design registered in the United States, the proposed AD would supersede AD 94–17–12. It would continue to require repetitive purging of the hydraulic system and installation of an actuator that has been previously certified marked with an ''R'' after the serial number. These actions are required to be performed every 500 landings.

This proposal would revise the existing AD by requiring that certain Lucas Aerospace spoiler actuators be replaced at intervals of 5,000 hours time-in-service (on the actuator). Such replacement would terminate the current requirement to repetitively purge the hydraulic system and install newly-certified actuators every 500 landings. It would also revise the applicability of the existing rule to delete certain airplanes. The actions would be required to be accomplished in accordance with Jetstream Service Bulletin J41–A27–034, Revision 1, described previously.

This proposal would also provide for an optional action to terminate both the repetitive purging and installation requirements, as required by the existing AD; and the 5,000 hour time-in-service life limit on certain actuators, as required by this new AD. This optional terminating action consists of installing improved actuators (Modification JM 41381) in accordance with Jetstream Service Bulletin J41–27–037, described previously.

As a result of recent communications with the Air Transport Association (ATA) of America, the FAA has learned that, in general, some operators may misunderstand the legal effect of AD's on airplanes that are identified in the applicability provision of the AD, but that have been altered or repaired in the area addressed by the AD. The FAA points out that all airplanes identified in the applicability provision of an AD are legally subject to the AD. If an airplane has been altered or repaired in the affected area in such a way as to affect compliance with the AD, the owner or operator is required to obtain FAA approval for an alternative method of compliance with the AD, in accordance with the paragraph of each AD that provides for such approvals. A note has been included in this notice to clarify this long-standing requirement.

The FAA estimates that 17 airplanes of U.S. registry would be affected by this proposed AD.

The repetitive purging and installation actions that are currently required by AD 94–17–12 take approximately 6 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the total cost impact on U.S. operators of the actions currently required is estimated to be $6,120, or $360 per airplane.

Replacement of the spoiler actuator at the newly established life limit would add no new costs to affected operators. In fact, it would reduce the economic burden for most operators, since: (1) Repetitive purging of the actuators would be eliminated, and (2) replacement of the actuators will not have to be accomplished as often as was previously required. Additionally, some of the replacement actuators would be provided to operators free of charge by the manufacturer.

Further, since this proposed AD would be applicable to fewer airplanes than was AD 94–17–12, the total cost impact of the AD would be reduced by the amount of labor and parts costs that would previously have been applied to those additional airplanes.

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), 40101, 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by removing amendment 39–9007 (59 FR

43025, August 22, 1994), and by adding a new airworthiness directive (AD), to read as follows:

Jetstream Aircraft, Limited: Docket 94–NM–237–AD. Supersedes AD 94–17–12, Amendment 39–9007.

Applicability: Model 4101 airplanes; having constructors numbers 41004 through 41015 inclusive, 41018 through 41026 inclusive, 41028 through 41030 inclusive, and 41032; 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 use the authority provided in paragraph (d) of this AD to request approval from the FAA. This approval may address either no action, if the current configuration eliminates the unsafe condition; or different actions necessary to address the unsafe condition described in this AD. Such a request should include an assessment of the effect of the changed configuration on the unsafe condition addressed by this AD. In no case does the presence of any modification, alteration, or repair remove any airplane from the applicability of this AD.

Compliance: Required as indicated, unless accomplished previously.

To prevent uncommanded extension of the lift spoiler in the event of loss of hydraulic pressure in the spoiler actuator, accomplish the following:

(a) Within 21 days after September 6, 1994 (the effective date of AD 94–17–12, amendment 39–9007), remove the spoiler actuators in accordance with Jetstream Alert Service Bulletin J41–A27–034, dated June 9, 1994, or Revision 1, dated October 28, 1994. Following removal of the actuators, accomplish the requirements of paragraphs (a)(1) and (a)(2) of this AD, in accordance with the service bulletin. Thereafter, repeat the requirements of this paragraph at intervals not to exceed 500 landings.

(1) Prior to further flight, purge the hydraulic system to ensure that there is no contamination.

(2) Prior to further flight, install a spoiler actuator that has been previously certified and marked with an ''R'' after the serial number on the nameplate of the actuator.

(b) For spoiler actuators having Lucas Aerospace part number (P/N) TY1763–01A or P/N TY1763–01B: Prior to the accumulation of 5,000 total hours time-in-service on the spoiler actuator, or within 30 days after the effective date of this AD, whichever occurs later, replace the actuator with a new or serviceable part, in accordance with Jetstream Service Bulletin J41–A27–034, Revision 1, dated October 28, 1994. Thereafter, prior to the accumulation of 5,000 hours time-in-service on the spoiler actuator, replace the actuator with a new or serviceable part, in accordance with the service bulletin. Such replacement constitutes terminating action for the repetitive purging and repetitive installation requirements of paragraph (a) of this AD.

(c) Installation of improved spoiler actuators (Modification JM 41381) on the left and right wings, in accordance with Jetstream Service Bulletin J41–27–037, dated November 7, 1994, constitutes terminating action for the requirements of paragraphs (a) and (b) of this AD.

(d) 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.

(e) 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 September 1, 1995.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–22302 Filed 9–7–95; 8:45 am]

BILLING CODE 4910–13–O

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 312 and 314

[Docket No. 95N–0010]

Investigational New Drug Applications and New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations pertaining to investigational new drug applications (IND's) and new drug applications (NDA's). The proposed rule would clearly define in the NDA format and content requirements the need to present effectiveness and safety data for important demographic subgroups, specifically gender, age, and racial subgroups. The rule would codify expectations that FDA has previously described in guidance. The proposed amendments would also require IND sponsors of drugs, including biological products, to characterize, in their annual reports, the number of subjects in a clinical study according to age group, gender, and race. The proposed rule does not address the requirements for the conduct of clinical studies and would not require sponsors to conduct any more studies than they have already conducted. It also would not require the inclusion of particular numbers of individuals from specific subgroups in any study or overall. The rule refers only to the presentation of data already collected. The scope of this proposal does not extend to requiring additional studies or data.

DATES: Written comments by December 7, 1995.

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: Deborah A. Wolf, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1046.

SUPPLEMENTARY INFORMATION: The proposed rule would amend the NDA content and format regulations at 21 CFR 314.50 to explicitly require that sponsors submit effectiveness and safety data by gender, age, and racial subgroups and other subgroups of the population of patients treated, as appropriate, such as patients with renal failure or patients with different levels of severity of disease. In the **Federal Register** of July 22, 1993 (58 FR 39406), FDA published a guideline entitled ''Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs.'' The guideline provided guidance on FDA's expectations regarding inclusion of both men and women in drug development, analyses of clinical data by gender, assessment of potential pharmacokinetic differences between genders, and conduct of specific additional studies in women, where indicated. The preamble to the guideline described the development of the agency's policy regarding the evaluation of clinical data by gender. The guideline noted that over the preceding decade there had been growing concern that the drug development process did not produce adequate information about the effects of drugs in women (58 FR 39406). Analyses of published clinical trials in certain therapeutic areas had indicated that there had been little or no participation by women in many of the studies. There had also been little study of the effects of such aspects of female