Note 4: The subject of this AD is addressed in German airworthiness directive 1998–137, dated March 26, 1998.

Issued in Renton, Washington, on July 24, 1998.

S.R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–20435 Filed 7–30–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–NM–339–AD]

RIN 2120–AA64

Airworthiness Directives; British Aerospace (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 all British Aerospace (Jetstream) Model 4101 airplanes, that currently requires repetitive functional testing of the main entrance door, cleaning and lubricating of the ''speed'' lock and ''G'' lock systems, and repair, if necessary. This action would add a requirement for replacement of the ''G'' lock rollers with new, improved ''G'' lock rollers. This proposal is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by the proposed AD are intended to prevent inability of the main entrance door to open, which could delay or impede passengers exiting the airplane, or rescue personnel from entering the airplane during an emergency.

DATES: Comments must be received by August 31, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 97–NM–339–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 AI(R) American Support, Inc., 13850 Mclearen Road, Herndon, Virginia 20171. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 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 97–NM–339–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–339–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

On September 3, 1997, the FAA issued AD 97–19–02, amendment 39–10122 (62 FR 47362, September 9, 1997), applicable to all British Aerospace (Jetstream) Model 4101 airplanes, to require repetitive functional testing of the main entrance door, cleaning and lubricating of the ''speed'' lock and ''G'' lock systems, and repair, if necessary. That action was prompted by reports of flightcrews and ground crews being unable to open the main entrance door. The requirements of that AD are intended to prevent inability of the main entrance door to open, which could delay or impede passengers exiting the airplane, or rescue personnel from entering the airplane during an emergency.

Actions Since Issuance of Previous Rule

In the preamble to AD 97–19–02, the FAA specified that the actions required by that AD were considered ''interim action'' and that once a modification is developed, approved, and available, the FAA may consider additional rulemaking action. The manufacturer now has developed such a modification, and the FAA has determined that further rulemaking action is indeed necessary; this proposed AD follows from that determination.

Explanation of Relevant Service Information

British Aerospace Regional Aircraft has issued Jetstream Alert Service Bulletins J41–A–52–059, dated September 12, 1997, and Revision 2, dated January 23, 1998, which describe procedures for replacement of the ''G'' lock rollers with rollers having increased diameters. The installation of ''G'' lock rollers with increased diameters provides a means to prevent jamming of the main entrance door by increasing the mechanism clearance when the door handle is operated. The Civil Aviation Authority (CAA), which is the airworthiness authority for the United Kingdom, classified these alert service bulletins as mandatory and issued British airworthiness directive 001–09–97 in order to assure the continued airworthiness of these airplanes in the United Kingdom.

FAA's Conclusions

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.

Explanation of Requirements of Proposed Rule

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 97–19–02 to continue to require repetitive functional testing of the main entrance door, cleaning and lubricating of the ''speed'' lock and ''G'' lock systems, and repair, if necessary. The proposed AD would add a requirement for replacement of the ''G'' lock rollers with new, improved ''G'' lock rollers. The actions would be required to be accomplished in accordance with the alert service bulletins described previously.

Cost Impact

There are approximately 57 airplanes of U.S. registry that would be affected by this proposed AD.

The actions that are currently required by AD 97–19–02 take approximately 1 work hour per airplane to accomplish, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the currently required actions on U.S. operators is estimated to be $3,420, or $60 per airplane, per functional test cycle.

The new actions that are proposed in this AD action would take approximately 3 work hours per airplane to accomplish, at an average labor rate of $60 per work hour. Required parts would be provided by the manufacturer at no cost to the operator. Based on these figures, the cost impact of the proposed requirements of this AD on U.S. operators is estimated to be $10,260, or $180 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the current or 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 removing amendment 39–10122 (62 FR 47362, September 9, 1997), and by adding a new airworthiness directive (AD), to read as follows:

British Aerospace Regional Aircraft [Formerly Jetstream Aircraft Limited; British Aerospace (Commercial Aircraft) Limited]: Docket 97–NM–339–AD. Supersedes AD 97–19–02, Amendment 39–10122.

Applicability: All Jetstream Model 4101 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 (d) 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 inability of the main entrance door to open, which could delay or impede passengers exiting the airplane, or rescue personnel from entering the airplane during an emergency, accomplish the following:

Restatement of Requirements of AD 97–19–02, Amendment 39–10122:

(a) Within 30 days after September 24, 1997 (the effective date of AD 97–19–02, amendment 39–10122), perform a functional test to verify proper operation of the main entrance door (including the ''G'' lock system) and the ''speed'' lock system of the main entrance door, in accordance with Section 52–10–05 of BAe Jetstream Series 4101 Maintenance Manual (MM).

(1) If the ''speed'' lock and the ''G'' lock function satisfactorily: Within 60 days after September 24, 1997, perform the actions specified in paragraphs (a)(1)(i) and (a)(1)(ii) of this AD.

(i) Clean (remove existing contaminants and lubricant) and re-lubricate (with a dry lubricant) the ''speed'' lock and main entrance door ''G'' lock systems in accordance with Jetstream Service Bulletin J41–52–058, dated July 14, 1997. And,

(ii) Following accomplishment of paragraph (a)(1)(i) of this AD, and prior to further flight, repeat the functional test specified in paragraph (a) of this AD.

(A) If the ''G'' lock and the ''speed'' lock function satisfactorily in the functional test required by paragraph (a)(1)(ii) of this AD, accomplish the requirements of paragraph (b) of this AD.

(B) If the ''G'' lock and the ''speed'' lock do not function satisfactorily in the functional test required by paragraph (a)(1)(ii) of this AD: Prior to further flight, repair the ''G'' lock and the ''speed'' lock in accordance with a method approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate.

(2) If either the ''speed'' lock and/or the ''G'' lock do not function correctly: Prior to further flight, perform the actions specified in paragraphs (a)(2)(i) and (a)(2)(ii) of this AD.

(i) Clean (remove existing contaminants and lubricant) and re-lubricate (with a dry lubricant) the main entrance door ''speed'' lock and ''G'' lock systems in accordance with Jetstream Service Bulletin J41–52–058, dated July 14, 1997. And,

(ii) Following accomplishment of paragraph (a)(2)(i) of this AD, and prior to further flight, repeat the functional test of the main entrance door (including the ''G'' lock system) and the ''speed'' lock system, in accordance with the MM.

(A) If the ''G'' lock and ''speed'' lock function satisfactorily in the functional test required by paragraph (a)(2) of this AD, accomplish the requirements of paragraph (b) of this AD.

(B) If the ''G'' lock and ''speed'' lock do not function satisfactorily in the functional tests required by paragraph (a)(2) of this AD: Prior to further flight, repair the ''G'' lock and ''speed'' lock in accordance with a method approved by the Manager, International Branch, ANM–116.

(b) Perform the actions specified in paragraphs (b)(1) and (b)(2) of this AD within 1,500 hours time-in-service following accomplishment of the initial functional test

of the main entrance door required by paragraph (a) of this AD. Repeat the actions specified in paragraphs (b)(1) and (b)(2) of this AD, thereafter, at intervals not to exceed 1,500 hours time-in-service.

(1) Clean (remove contaminants and dry lubricant) and re-lubricate (with dry lubricant) the main entrance door ''speed'' lock and ''G'' lock systems in accordance with Jetstream Service Bulletin J41–52–058, dated July 14, 1997.

(2) Following accomplishment of paragraph (b)(1) of this AD and prior to further flight, perform a functional test of the main entrance door (including the ''G'' lock system) and the ''speed'' lock system, in accordance with the MM. If the ''G'' lock or ''speed'' lock system do not perform satisfactorily: Prior to further flight, repair the ''G'' lock or ''speed'' lock system in accordance with a method approved by the Manager, International Branch, ANM–116.

New Requirements of This AD:

(c) Within 60 days after the effective date of this AD, replace the ''G'' lock rollers on the main entrance door with new, improved ''G'' lock rollers in accordance with Jetstream Alert Service Bulletin J41–A–52–059, dated September 12, 1997, or Revision 2, dated January 23, 1998.

(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, International Branch, ANM–116. 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.

(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.

Note 3: The subject of this AD is addressed in British airworthiness directive 001–09–97.

Issued in Renton, Washington, on July 24, 1998.

S. R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–20430 Filed 7–30–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 3, 5, 10, 20, 207, 310, 312, 316, 600, 601, 607, 610, 640, and 660

[Docket No. 98N–0144]

RIN 0910–AB29

Biological Products Regulated Under Section 351 of the Public Health Services Act; Implementation of Biologics License; Elimination of Establishment License and Product License

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations to eliminate references to establishment licenses and product licenses for all products regulated under the Public Health Service Act (PHS Act). In lieu of filing an establishment license application (ELA) and product license application (PLA) in order to market a biological product in interstate commerce, a manufacturer would file a single biologics license application (BLA) with the agency. Upon approval of the BLA, a manufacturer would receive a biologics license to market the product in interstate commerce. This action is part of FDA's continuing effort to achieve the objectives of the President's ''Reinventing Government'' initiatives and is intended to reduce unnecessary burdens for industry without diminishing public health protection. This action also proposes regulations to implement certain sections of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written comments by October 14, 1998. Submit written comments on the information collection requirements by August 31, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written comments on the information collection requirements to the Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

Currently, most manufacturers requesting approval to market a biological product in interstate commerce must submit a PLA and an ELA to FDA. FDA's Center for Biologics Evaluation and Research (CBER) currently requires manufacturers to use one of three ELA forms and 1 of 16 PLA forms for each biological product (see the **Federal Register** of July 8, 1997 (62 FR 36558)). Upon approval of the ELA and PLA, the agency issues a product license and an establishment license to the manufacturer. As discussed in the next three paragraphs, FDA has reviewed its process of licensing biological products and has already taken a number of actions to reduce the regulatory burdens imposed by the licensing process and to make the licensing process more consistent with the process for the approval of new drugs.

Manufacturers of certain biological products are already required to submit a BLA and obtain FDA approval of the BLA before the product may be introduced into interstate commerce. In the **Federal Register** of May 14, 1996 (61 FR 24227), FDA issued a final rule to amend the biologics regulations by eliminating the ELA requirement for specified biotechnology and synthetic biological products licensed under section 351 of the PHS Act (42 U.S.C. 262 *et seq.*). The specified biotechnology and synthetic biological products are: (1) Therapeutic deoxyribonucleic acid (DNA) plasmid products; (2) therapeutic synthetic peptide products of 40 or fewer amino acids; (3) monoclonal antibody products for in vivo use; and (4) therapeutic recombinant DNA-derived products. This provision applies only to those products that FDA determines pursuant to principles articulated in the ''Intercenter Agreement Between the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research'' (effective on October 31, 1991) to be subject to licensure under Section 351 of the PHS Act. Thus, upon approval, manufacturers of the specified biotechnology and synthetic biological products receive a single biologics license instead of a product license and an establishment license (see § 601.2(c) (21 CFR 601.2(c))).

In the **Federal Register** of July 8, 1997 (62 FR 36558), FDA announced the availability of a revised FDA Form 356h. FDA Form 356h was revised as a ''Reinventing Government'' initiative to