

column, "April 4, 1998" is corrected to read "April 4, 1997".

On page 35796, in the second column, in the Compliance Section, in paragraph (a), in the eleventh line from the top of the column, "April 4, 1998" is corrected to read "April 4, 1997".

On page 35796, in the first column, in the Compliance Section, in the table in paragraph (e), in the first entry under "Date", "April 4, 1998" is corrected to read "April 4, 1997".

Issued in Burlington, Massachusetts, on October 1, 1998.

Ronald L. Vavruska,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98-CE-70-AD; Amendment 39-10825; AD 98-21-16]

RIN 2120-AA64

Airworthiness Directives; British Aerospace Model H.P. 137 Jetstream Mk. 1, Jetstream Series 200, and Jetstream Models 3101 and 3201 Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: This amendment supersedes Airworthiness Directive (AD) 98-12-23, which currently requires replacing the windshield wiper arm attachment bolts and windshield wiper arm on all British Aerospace (BAe) Model H.P. 137 Jetstream Mk. 1, Jetstream Series 200, and Jetstream Models 3101 and 3201 airplanes. AD 98-12-13 also requires measuring the material thickness of the upper and lower toggle attachment brackets on the nose landing gear of the affected airplanes, and replacing the toggle attachment bracket lugs. This AD

is the result of additional mandatory continuing airworthiness information (MCAI) pertaining to this subject received from the airworthiness authority for the United Kingdom. This AD would retain the actions of AD 98-12-23; would make certain actions repetitive; and would change the reference to certain service information currently utilized. The actions specified in this AD are intended to prevent the windshield wiper arm from corroding, detaching from the airplane during flight, and penetrating the fuselage, which could result in possible injury to the pilot and passengers; and to prevent collapse of the nose landing gear caused by the current design, which could result in loss of control of the airplane during landing operations.

DATES: Effective January 6, 1999.

The incorporation by reference of the following service information was previously approved by the Director of the **Federal Register** as of July 28, 1998 (63 FR 32119, June 12, 1998):

—Jetstream Series 3100/3200 Service Bulletin 30-JA 950641, which incorporates the following pages:

Pages	Revision level	Date
1	Revision 1	March 18, 1997.
2 through 8 ...	Revision 2	March 18, 1997.

—Jetstream Series 3100/3200 Alert Service Bulletin No. 32-JA 960601, Original Issue: October 25, 1996, Revision No. 1: dated April 11, 1997; and

—APPH Precision Hydraulics Service Bulletin No. 32-66, which incorporates the following pages:

Pages	Revision level	Date
1,3,4, and 5 ..	Revision 1	October 1996.
2 and 6	Revision 2	March 1997.

Comments for inclusion in the Rules Docket must be received on or before November 10, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 98-CE-70-AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Service information that applies to this AD may be obtained from British Aerospace Regional Aircraft, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland; telephone: (01292) 479888; facsimile: (01292) 479703. This information may also be examined at the Federal Aviation Administration (FAA), Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 98-CE-70-AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. S. M. Nagarajan, Aerospace Engineer, Small Airplane Directorate, Aircraft Certification Service, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64106; telephone: (816) 426-6934; facsimile: (816) 426-2169.

SUPPLEMENTARY INFORMATION:

Discussion

On June 3, 1998, the FAA issued AD 98-12-23, Amendment 39-10577 (63 FR 32119, June 12, 1998), which currently requires the following on BAe Model H.P. 137 Jetstream Mk. 1, Jetstream Series 200, and Jetstream Models 3101 and 3201 airplanes:

- Replacing the windshield wiper arm and windshield wiper arm attachment bolt;
- Measuring the outer wall thickness of the nose landing gear (NLG) toggle bracket lugs and axle bracket lugs; and
- Replacing the toggle bracket lugs and axle bracket lugs immediately and/or at the end of their fatigue life limit, depending on the condition of the parts.

Accomplishment of the actions specified in AD 98-12-23 is required in accordance with the following:

—Jetstream Series 3100/3200 Service Bulletin (SB) 30-JA 950641, which incorporates the following pages:

Pages	Revision level	Date
1	Revision 1	March 18, 1997.

Pages	Revision level	Date
2 through 8 ...	Revision 2	March 18, 1997.

This service bulletin specifies following the procedures provided in Rosemont Aerospace Inc. Service Bulletin No. 2314M-30-16, dated December, 1996;

—APPH Precision Hydraulics SB No. 32-66, which incorporates the following pages:

Pages	Revision level	Date
1,3,4, and 5 ..	Revision 1	October 1996.

Pages	Revision level	Date
2 and 6	Revision 2	March 1997.

This service bulletin is referenced in the Accomplishment Instructions section of Jetstream Series 3100/3200 Alert Service Bulletin No. 32-JA 960601, Original Issue: October 25, 1996, Revision No. 1: dated April 11, 1997.

AD 98-12-23 was the result of mandatory continuing airworthiness information (MCAI) issued by the Civil Airworthiness Authority (CAA), which is the airworthiness authority for the United Kingdom.

Events Leading to the Issuance of This AD

The CAA recently notified the FAA that part of the information it shared with the FAA is incorrect, and consequently there are mistakes in AD 98-12-23. These mistakes are:

- The procedures included in Rosemont Aerospace Inc. Service Bulletin No. 2314M-30-16, dated December 1996, are incorrect, and should not be used to accomplish the windshield wiper arm assembly and wiper arm attachment bolt replacements; and
- The requirement of replacing the windshield wiper arm, attachment bolt, and assembly should be repetitive instead of a one-time action.

The FAA's Determination

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 information received from the CAA; reviewed all available information, including the service information referenced above; and determined that AD action is necessary for products of this type design.

Explanation of the Provisions of This AD

Since an unsafe condition has been identified that is likely to exist or develop in other BAe Model HP.137 Jetstream Mk.1, Jetstream Series 200, and Jetstream Models 3101 and 3201 airplanes of the same type design

registered in the United States, the FAA is issuing an AD to supersede AD 98-12-23. This AD would retain the actions of AD 98-12-23; would make certain actions repetitive; and would change the reference to certain service information currently utilized in AD 98-12-23. Accomplishment of the actions of this AD would be required in accordance with the previously referenced service bulletins, except for Rosemont Aerospace Inc. Service Bulletin No. 2314M-30-16, dated December 1996.

Cost Impact

The FAA estimates that 314 airplanes in the U.S. registry will be affected by the windshield wiper portion of this AD, that it will take approximately 2 workhours per airplane to accomplish the replacement required by this AD, and that the average labor rate is approximately \$60 an hour. Parts will be provided at by the manufacturer at no cost to the owners/operators of the affected airplanes. Based on these figures, the total cost impact for the windshield wiper portion of this AD on U.S. operators is estimated to be \$37,680, or \$120 per airplane.

The FAA estimates that 284 airplanes in the U.S. registry will be affected by the nose landing gear portion of this AD, that it will take approximately 2 workhours per airplane to accomplish the measurement required by this AD, and that the average labor rate is approximately \$60 an hour. The cost impact only takes into account the cost of the initial inspection. The FAA has no way of determining the number of parts that may be found damaged or in need of replacement during the initial inspection. Therefore, the FAA is not estimating the cost of parts or the workhours to accomplish a part replacement for this AD. Based on these

figures, the total cost impact for the inspection of the nose landing gear portion of this AD on U.S. operators is estimated to be \$34,080, or \$120 per airplane.

The only difference between the cost impact of AD 98-12-23 and this AD is the difference between the expense of a one-time replacement of the windshield wiper arm attachment bolt and assembly and the expense of repetitive replacements, respectively. The FAA has no way of determining how many replacements each owner/operator of the affected airplanes would incur over the life of the airplane. Therefore, the cost impact upon the public is the same as was presented in AD 98-12-23.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and therefore is issuing it as a direct final rule. The requirements of this direct final rule address an unsafe condition identified by a foreign civil airworthiness authority and do not impose a significant burden on affected operators. In accordance with Section 11.17 of the Federal Aviation Regulations (14 CFR 11.17) unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment, is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA

does receive, within the comment period, a written adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Although this action is in the form of a final rule and was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this 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 under the caption **ADDRESSES**. All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the 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 AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 98-CE-70-AD." The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will 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 final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is noncontroversial and

unlikely to result in adverse or negative comments. For reasons discussed in the preamble, I certify that this regulation (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) 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 final evaluation has been prepared for this action and is contained in the Rules Docket. A copy of it may be obtained from 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.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 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 airworthiness directive (AD) 98-12-23, Amendment 39-10577 (63 FR 32119, June 12, 1998), and by adding a new AD to read as follows:

98-21-16 British Aerospace: Amendment 39-10825; Docket No. 98-CE-70-AD; Supersedes AD 98-12-23, Amendment 39-10577.

Applicability: Model H.P. 137 Jetstream Mk. 1, Jetstream Series 200, and Jetstream Models 3101 and 3201 airplanes, all serial numbers, 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 in the body of this AD, unless already accomplished.

To prevent the windshield wiper arm from corroding, detaching from the airplane during flight, and penetrating the fuselage, which could result in possible injury to pilot and passengers; and to prevent collapse of the nose landing gear caused by design deficiency, which could result in loss of control of the airplane during landing operations, accomplish the following:

(a) Within the next 90 days after the effective date of this AD, unless already accomplished, and thereafter at intervals not to exceed 90 days, replace the windshield wiper arm attachment bolt and windshield wiper arm assembly.

(1) Accomplish these actions in accordance with the appropriate aircraft maintenance manual (AMM) 30-42-02, as specified in the Accomplishment Instructions section of Jetstream Series 3100/3200 Service Bulletin (SB) No. 30-JA 950641, which incorporates the following pages:

Pages	Revision level	Date
1	Revision 1	March 18, 1997.
2 through 8 ...	Revision 2	March 18, 1997.

(2) Do not utilize Rosemont Aerospace Inc. SB No. 2314M-30-16, dated December 1996, which is referenced in Jetstream Series 3100/3200 SB No. 30-JA 950641. The procedures in the Rosemont service bulletin are incorrect.

(b) Within the next 90 days after the effective date of this AD, measure the outer wall thickness of the nose landing gear (NLG) toggle bracket lugs and the axle bracket lugs in accordance with the Accomplishment Instructions section of APPH Precision Hydraulics SB No. 32-66, which incorporates the following pages:

Pages	Revision level	Date
1,3,4, and 5 ..	Revision 1	October 1996.
2 and 6	Revision 2	March 1997.

Note 2: The APPH SB is referenced in the Accomplishment Instructions in Jetstream Series 3100/3200 Alert Service Bulletin No. 32-JA 960601, Revision No. 1, April 11, 1997, Original Issue, October 25, 1996.

(c) Replace the NLG toggle bracket lugs and axle bracket lugs at the applicable compliance times in either paragraph (c)(1) or (c)(2) of this AD, as specified below:

(1) *If the measurements of the outer wall thickness do not meet the criteria set out in the Table contained in paragraph B. (5) of the Accomplishment Instructions section in APPH Precision Hydraulics SB No. 32-66, as referenced in paragraph (b) of this AD:* Prior to further flight and, thereafter, at the end of the fatigue life limits of the part, as specified in the Table referenced above.

(2) *If the measurements of the outer wall thickness are within the criteria set out in the Table contained in paragraph B. (5) of the Accomplishment Instructions section in APPH Precision Hydraulics SB 32-66, as referenced in paragraph (b) of this AD:* At the end of the fatigue life limits of the part, as

specified in the Table referenced above, or within the next 50 landings after the measurement is taken, whichever occurs later; and thereafter at the end of the referenced fatigue life limits of the part.

Note 3: The compliance time in this AD takes precedence over the compliance times published in the applicable service bulletins.

(d) 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.

(e) An alternative method of compliance or adjustment of the initial and repetitive compliance times that provides an equivalent level of safety may be used if approved by the Manager, Small Airplane Directorate, Aircraft Certification Service, 1201 Walnut, suite 900, Kansas City, Missouri 64106.

(1) 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.

(2) Alternative methods of compliance approved in accordance with AD 98-12-23 are considered approved as alternative methods of compliance for this AD.

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.

(f) The replacements required by this AD shall be done in accordance with Jetstream Series 3100/3200 Service Bulletin 30-JA 950641, which incorporates the following pages:

Pages	Revision level	Date
1	Revision 1	March 18, 1997.
2 through 8 ...	Revision 2	March 18, 1997.

—Jetstream Series 3100/3200 Alert Service Bulletin No. 32-JA 960601, Original Issue: October 25, 1996, Revision No. 1: dated April 11, 1997, and

—APPH Precision Hydraulics Service Bulletin No. 32-66, which incorporates the following pages:

Pages	Revision level	Date
1,3,4, and 5 ..	Revision 1	October 1996.
2 and 6	Revision 2	March 1997.

(1) This incorporation by reference was previously approved by the Director of the **Federal Register** as of July 28, 1998 (63 FR 32119, June 12, 1998).

(2) Copies of these service bulletins may be obtained from British Aerospace Regional Aircraft, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland. Copies may be inspected at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri, or at the Office of the **Federal Register**, 800 North

Capitol Street, NW, suite 700, Washington, DC.

Note 5: The subject of this AD is addressed in British AD 002-10-96, not dated, for the nose landing gear condition; and British AD 006-08-96, not dated, for the windshield wiper condition.

(g) This amendment supersedes AD 98-12-23, Amendment 39-10577.

(h) This amendment becomes effective on January 6, 1999.

Issued in Kansas City, Missouri, on September 30, 1998.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98-26971 Filed 10-7-98; 8:45 am]

BILLING CODE 4910-13-P

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing the submission and review of premarket approval (PMA) supplements to provide 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).

EFFECTIVE DATE: November 9, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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

On November 21, 1997, the President signed FDAMA (Pub. L. 105-115) into law. As one of its provisions, FDAMA added section 515(d)(6) to the act (21 U.S.C. 360e(d)(6)). This new section

provides that PMA supplements are required for any change to a device that affect safety and effectiveness unless such change involves modifications to manufacturing procedures or method of manufacture. Such changes to manufacturing procedures or method of manufacture will require a 30-day notice or, where FDA finds such notice inadequate, a 135-day PMA supplement.

The agency has developed guidance on this issue entitled "CDRH Guidance for 30-Day notices and 135-Day PMA Supplements for Manufacturing Method or Process Changes for Use by OC, ODE, and Industry," and has announced the availability of the guidance in the **Federal Register** of February 26, 1998 (63 FR 9570).

On April 27, 1998, FDA published a proposed rule (63 FR 20558) and a direct final rule (63 FR 20530) to implement the amendments to the PMA provisions. FDA received a single comment, which the agency deemed to be significant. Accordingly, consistent with FDA's procedures on direct final rulemaking, FDA is withdrawing the direct final rule and is addressing the comment in this final rule based upon the April 27, 1998, proposed rule previously referenced. This rule incorporates the provisions for a 30-day notice and 135-day PMA supplements into FDA's regulations at § 814.39 (21 CFR 814.39).

II. Summary of Comments

The agency received one comment, which stated that the list of examples of changes affecting the safety or effectiveness of a device which would require the submission of a PMA supplement, provided in § 814.39(a), should not include the language in proposed § 814.39(a)(4) which states: "Changes in manufacturing facilities, methods, or quality control procedures that do not meet the requirements for a submission under paragraphs (e) or (f) of this section." The comment states that no submissions are required for changes that do not affect safety or effectiveness and, under FDAMA, changes in manufacturing facilities, methods, or quality control procedures which DO affect the safety or effectiveness of the device may be filed with a 30-day notice. Therefore, proposed § 814.39(a)(4) does not apply to any submissions, and should be removed.

The agency agrees and is removing proposed § 814.39(a)(4) from the list of changes which require the submission of a PMA supplement. The agency stresses, however, that the 30-day notice procedure is restricted to changes only in manufacturing procedures and