Page No.	Revision level shown on page	Date shown on page
List of Effective Pages	Not Shown	November 1997.

(Note: The revision level is indicated only on the Title page; no other page contains this information.) This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from The Boeing Company, Douglas Products Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Technical Publications Business Administration, Dept. C1–L51 (2–60). Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Transport Airplane Directorate, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(f) This amendment becomes effective on October 8, 1999.

Issued in Renton, Washington, on August 27, 1999.

Vi L. Lipski,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–22922 Filed 9–2–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–ANE–54–AD; Amendment 39–11286; AD 99–18–20]

RIN 2120–AA64

Airworthiness Directives; General Electric Company CF6–50, –80A1/A3, and –80C2A Series Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to General Electric Company (GE) CF6–50, –80A1/A3, and –80C2A series turbofan engines installed on Airbus A300 and A310 series airplanes, that requires initial and repetitive thrust reverser inspections and checks, and allows extended repetitive inspection intervals if an optional double p-seal configuration is installed. This amendment is prompted by the report of a higher than anticipated center drive unit (CDU) cone brake failure rate which reduces the overall thrust reverser system protection against inadvertent deployment. The actions specified by this AD are intended to prevent inadvertent in-flight thrust reverser deployment, which can result in loss of control of the airplane.

DATES: Effective November 2, 1999.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of November 2, 1999.

ADDRESSES: The service information referenced in this AD may be obtained from Middle River Aircraft Systems, Mail Point 46, 103 Chesapeake Park Plaza, Baltimore, MD, 21220–4295, attn: Warranty Support, telephone: (410) 682–0094, fax: (410) 682–0100. This information may be examined at the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: William S. Ricci, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone (781) 238–7742, fax (781) 238–7199.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to General Electric Company (GE) CF6–50, –80A1/A3, and –80C2A series turbofan engines installed on Airbus A300 and A310 series airplanes was published in the **Federal Register** on February 23, 1999 (64 FR 8762). That action proposed to require initial and repetitive thrust reverser inspections and checks, and allow extended repetitive inspection intervals if an optional double p-seal configuration is installed.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the comments received.

One commenter requests an initial inspection interval of at least 860 hours time-in-service (TIS). The commenter states that it performs B-checks at intervals of 430 hours TIS and opens the fan reverser at every other B-check (at intervals of 860 hours TIS) for engine accessibility. The FAA does not concur. The thrust reverser system safety analysis indicates that extending the initial compliance interval would increase the probability of an inadvertent deployment of the thrust reverser in-flight and provide an unacceptable level of safety. The FAA determined the need to establish system integrity in the fleet, and the 600 hour TIS initial compliance interval for CF6–80C2A series engines provides that level of safety. The desire to conform inspections to an operator's scheduled maintenance, by itself, is not sufficient to change the initial inspection interval.

One commenter requests inspections performed in accordance with Revision 1 of Middle River Aircraft Systems CF6–80A1/A3 Service Bulletin (SB) No. 78–1002 be accepted for compliance with the proposed rule. The FAA does not concur. Revision 3 of SB No. 78–1002 includes inspections of electrical cables, the aft frame, and the ball screw housing that are not included in earlier revisions.

One commenter states that airplanes that have not had components removed, replaced, or modified which could alter the actuation system rigging, or that have undergone previous health check inspections, should not be required to have the fan reverser operational check portion of the initial inspection performed. The FAA does not concur. The purpose of a fan reverser operational check is to ensure that the system has been restored to operational status after inspections have been completed.

One commenter requests that the reporting requirement, contained in the Accomplishment Instructions of the SB, should be omitted from the proposed rule. The FAA does not concur. The instruction to report inspection results is to the manufacturer, not the FAA. The FAA did not impose a specific reporting requirement in the proposed rule. However, the FAA recommends reporting inspection results to the manufacturer in accordance with the SB, as reporting inspection results is important to ensure that the failure rate data used in the risk analysis to establish inspection requirements and intervals remain valid.

One commenter believes it is not necessary to start the engine to perform the operational check. The FAA concurs. Connection of an external pneumatic power source to the airplane ground connection, or auxiliary power unit (APU), in accordance with the

applicable aircraft maintenance manual, is allowed for fan reverser operational checks.

One commenter requests that specific revision numbers and part numbers be omitted from the proposed rule and that the phrase ''current or later revision'' be added. The FAA does not concur. It is the FAA's policy not to issue blanket approvals for documents that have not been published yet. Each document is reviewed individually to make sure it fulfills all requirements. Operators may request an alternate method of compliance (AMOC) to utilize later revisions of SBs in accordance with paragraph (b) of this final rule.

One commenter (the manufacturer of the thrust reverser system) requests that the mail stop and telephone number for its technical publications department be changed. The FAA concurs and the information has been changed in this final rule.

One commenter (the engine manufacturer) requests that the engine model designation of the GE CF6–80C2 engine be changed to –80C2A. The FAA concurs and this final rule has been corrected.

After careful review of the available data, including the comments noted above, the FAA has determined that air safety and the public interest require the adoption of the rule with the changes described previously. The FAA has determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

There are approximately 849 engines of the affected design in the worldwide fleet. The FAA estimates that 193 engines installed on aircraft of US registry will be affected by this AD, that it will take approximately 5 work hours per engine to accomplish the required actions, and that the average labor rate is $60 per work hour. Based on these figures, the total cost impact of the AD on US operators is estimated to be $57,900.

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.

For the reasons discussed above, I certify that this action (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 it 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, Incorporation by reference, 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 adding the following new airworthiness directive:

99–18–20 General Electric Company: Amendment 39–11286. Docket 98–ANE–54–AD.

Applicability: General Electric Company (GE) CF6–50, –80A1/A3, and –80C2A series turbofan engines, installed on Airbus A300 and A310 series airplanes.

Note 1: This airworthiness directive (AD) applies to each engine 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 engines 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 inadvertent in-flight thrust reverser deployment, which can result in loss of control of the airplane, accomplish the following:

(a) Perform initial and repetitive thrust reverser inspections and checks as follows:

(1) For GE CF6–50 series engines, perform inspections and checks in accordance with paragraph 2, Accomplishment Instructions, of Middle River Aircraft Systems CF6–50 Service Bulletin (SB) No. 78–3001, Revision 2, dated December 18, 1997, as follows:

(i) Perform the initial inspections and checks within 1,500 hours time-in-service (TIS) after the effective date of this AD.

(ii) Thereafter, perform inspections and checks at intervals not to exceed 6,000 hours TIS since last check.

(2) For CF6–80A1/A3 series engines, perform inspections and checks in accordance with paragraph 2, Accomplishment Instructions, of Middle River Aircraft Systems CF6–80A1/A3 SB No. 78–1002, Revision 3, dated January 21, 1999, as follows:

(i) Perform the initial inspections and checks within 1,500 hours TIS after the effective date of this AD.

(ii) Thereafter, perform inspections and checks at intervals not to exceed 7,000 hours TIS since last check.

(3) For CF6–80C2A series engines, perform inspections and checks in accordance with paragraph 2, Accomplishment Instructions, of Middle River Aircraft Systems CF6–80C2 Alert Service Bulletin (ASB) No. 78A1015, Revision 5, dated January 21, 1999, as follows:

(i) Perform the initial inspections and checks within 600 hours TIS after the effective date of this AD.

(ii) Thereafter, perform repetitive inspections and checks as follows:

(A) For engines with a double p-seal configuration, having translating cowl part numbers 491B1613000–109 or D52B1000–9, perform repetitive inspections and checks at intervals not to exceed 7,000 hours TIS since last inspection.

(B) For all other engines, perform repetitive inspections and checks at intervals not to exceed 600 hours TIS since last inspection.

(4) Perform corrective actions or deactivate the fan reverser in accordance with paragraph 2, Accomplishment Instructions, of the applicable SB or ASB prior to further flight.

(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, Engine Certification Office. Operators shall submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Engine Certification Office.

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

(c) 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 aircraft to a location where the requirements of this AD can be accomplished.

(d) The actions required by this AD shall be done in accordance with the following Middle River Aircraft Systems service documents:

Document No.	Pages	Revision	Date
CF6–50 SB 78–3001 ..... Total Pages: 43.	1–43	2	December 18, 1997.
CF6–80A1/A3 SB 78–1002 ..... Total Pages: 31.	1–31	3	January 21, 1999.
CF6–80C2 ASB 78A1015 ..... Total Pages: 32.	1–32	5	January 21, 1999.

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Middle River Aircraft Systems, Mail Point 46, 103 Chesapeake Park Plaza, Baltimore, MD, 21220–4295, attn: Warranty Support, telephone: (410) 682–0094, fax: (410) 682–0100. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC.

(e) This amendment becomes effective on November 2, 1999.

Issued in Burlington, Massachusetts, on August 26, 1999.

Jorge A. Fernandez,

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

[FR Doc. 99–22967 Filed 9–2–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 92C–0348]

Listing of Color Additives for Coloring Bone Cement; FD&C Blue No. 2–Aluminum Lake on Alumina

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of FD&C Blue No. 2–Aluminum Lake on alumina to color bone cement. This action responds to a petition filed by Biomet, Inc. The agency also is transferring the listing for FD&C Blue No. 2 in sutures to reflect the suture in which this color additive is used are devices not drugs.

DATES: This regulation is effective October 5, 1999; except as to any provisions that may be stayed by the filing of proper objections; written objections and requests for a hearing by October 4, 1999.

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

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS–215), 200 C St. SW., Washington, DC 20204, 202–418–3089.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of November 19, 1992 (57 FR 54598), FDA announced that a color additive petition (CAP 2C0239) had been filed by Biomet, Inc., P.O. Box 587, Warsaw, IN 46581–0587. The petition proposed to amend the color additive regulations to provide for the safe use of FD&C Blue No. 2–Aluminum Lake to color bone cement. The petition was filed under section 706(d)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 376(d)(1)), presently designated as 721(d)(1) of the act (21 U.S.C. 379e(d)(1)).

The agency is changing the name of the color additive used in the filing notice to FD&C Blue No. 2–Aluminum Lake on alumina to make it conform to the nomenclature proposed for the permanent listing of color additive lakes (61 FR 8372, March 4, 1996). To reflect that sutures in which this color additive is used are devices, not drugs, the agency also is transferring the listing for the use of FD&C Blue No. 2 in sutures from § 74.1102 *FD&C Blue No. 2* (21 CFR 74.1102) under subpart B—Drugs to new § 74.3102 *FD&C Blue No. 2* (21 CFR 74.3102) under subpart D—Medical Devices and is making nonsubstantive amendments to § 74.1102. This transfer will provide for all medical device uses of FD&C Blue No. 2 and its lake to be listed uniformly and more correctly under subpart D—Medical Devices. Section 74.1102(c)(1)(iv) is being removed because it is no longer applicable.

The Medical Device Amendments (Public Law 94–295) (the amendments) were enacted into law on May 28, 1976, to provide a comprehensive system of regulation for devices. These amendments (21 U.S.C. 321, *et seq.*) expanded the definition of device, under section 201(h) of the act (21 U.S.C. 321(h)), to include many products that were previously regarded as drugs. These products are known as ''transitional'' devices and are subject to regulation under section 520(l) of the act (21 U.S. C. 360j(l)). In the **Federal Register** of December 16, 1977 (42 FR 63472), FDA published a notice listing those products that had previously been considered to be drugs that FDA now considered to be devices under the amendments. FDA listed nonabsorbable surgical sutures, and absorbable surgical sutures as transitional devices in the December 1977 notice (42 FR 63472 at 63474). Various types of surgical sutures are classified as devices in 21 CFR 878.4493, 878.4830, 878.5000, 878.5010, 878.5020, and 878.5030. Because all surgical sutures are regulated as devices, FDA is redesignating its listing of FD&C Blue No. 2 in sutures from § 74.1102 under subpart B—Drugs to new § 74.3102 under subpart D—Medical Devices.

II. Regulatory History and Current Listings

In a final rule published in the **Federal Register** on February 13, 1971 (36 FR 2967), FDA added 21 CFR 8.4022 (presently § 74.1102) to list FD&C Blue No. 2 for use to color nylon sutures for general surgery. In this final rule, FDA also added specifications for FD&C Blue No. 2 for use to color sutures.

In the **Federal Register** of February 4, 1983 (48 FR 5252), FDA issued a final rule adding § 74.102 and amending § 74.1102 to permanently list the color additive FD&C Blue No. 2 for use in food and ingested drugs, respectively. In the February 4, 1983, final rule, FDA also added new specifications for FD&C Blue No. 2 for use in food and ingested drugs that identified the color additive more precisely than those specifications that had previously been included in the provisional listing for FD&C Blue No. 2 in 21 CFR part 82. Further, to provide adequate assurance of safety, the agency specified in the February 4, 1983, final rule (48 FR 5252 at 5259–5260), through a general description, the manufacturing process for FD&C Blue No. 2.

III. Applicability of the Act

With the passage of the Medical Device Amendments of 1976 (Public