

the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120-0056.

Related Information

(h) Refer to MCAI Brazilian Airworthiness Directive 2008-09-02, effective September 30, 2008; MCAI Brazilian Airworthiness Directive 2008-10-04, effective November 10, 2008; and Embraer Service Bulletins 170-54-0007 and 190-54-0008, both dated December 21, 2007; for related information.

Issued in Renton, Washington, on April 27, 2009.

Stephen P. Boyd,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2009-0411; Directorate Identifier 2008-NM-190-AD]

RIN 2120-AA64

Airworthiness Directives; Boeing 737-600, -700, -700C, and -800 Series Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Boeing Model 737-600, -700, -700C, and -800 series airplanes. This proposed AD would require repetitive lubrications of the right and left main landing gear (MLG) forward trunnion pins. This proposed AD also would require an inspection for discrepancies of the transition radius of the MLG forward trunnion pins, and corrective actions if necessary. For certain airplanes, this proposed AD would also require repetitive detailed inspections for discrepancies (including finish damage, corrosion, pitting, and base metal scratches) of the transition radius of the left and right MLG trunnion pins, and corrective action if necessary. Replacing or overhauling the trunnion pins would terminate the actions required by this AD. This proposed AD results from a report that the protective finishes on the forward trunnion pins for the left and right MLG might have been damaged during final assembly. We are proposing this AD to prevent stress corrosion cracking of the forward trunnion pins, which could result in

fracture of the pins and consequent collapse of the MLG.

DATES: We must receive comments on this proposed AD by June 19, 2009.

ADDRESSES: You may send comments by any of the following methods:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov>. Follow the instructions for submitting comments.
- **Fax:** 202-493-2251.
- **Mail:** U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- **Hand Delivery:** U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H-65, Seattle, Washington 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; e-mail me.boecom@boeing.com; Internet <https://www.myboeingfleet.com>.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov>; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Nancy Marsh, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 917-6440; fax (425) 917-6590.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2009-0411; Directorate Identifier 2008-NM-190-AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will

consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to <http://www.regulations.gov>, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We have received a report indicating that the protective finishes on the main landing gear (MLG) forward trunnion pins might have been damaged during final assembly of certain Boeing Model 737-600, -700, -700C, and -800 series airplanes. The protective coating could be damaged at one location because the pins were not handled correctly. The MLG forward trunnion pins may have been delivered to operators with compromised corrosion protection in one critical area: The transition radius between the chrome-plated outer diameter and the spherical ball bearing surface. Damage to the protective finish puts the base metal of the trunnion pins at risk from corrosion pitting. This condition, if not corrected, could lead to stress corrosion cracking of the forward trunnion pins, which could result in fracture of the pins and consequent collapse of the MLG.

Relevant Service Information

We have reviewed Boeing Special Attention Service Bulletin 737-32-1402, dated August 6, 2008. The service bulletin describes procedures for repetitive lubrication of the MLG forward trunnion pins. The service bulletin states that accomplishing the inspections and applicable repairs/replacements described below, or overhauling the trunnion pins, eliminates the need for the repetitive lubrication. The service bulletin also describes procedures for a detailed inspection for discrepancies (including finish damage, corrosion, pitting, and base metal scratches) of the transition radius of the left and right MLG trunnion pins, and applicable corrective actions. The corrective actions include repairing the finish if finish damage is found without corrosion, pitting, or base metal scratches, and replacing the trunnion pins. For airplanes on which the finish repair is done, the service bulletin describes procedures for repeating the detailed inspections for discrepancies of the MLG trunnion pins and doing applicable corrective actions. Replacement or overhaul of the trunnion pins eliminates need for the actions specified in the service bulletin.

The service bulletin also specifies that the corrective actions should be done before further flight. For airplanes on which the finish repair is done, the service bulletin specifies doing the detailed inspection within 24 months after doing the repair and thereafter at intervals not to exceed 24 months.

FAA's Determination and Requirements of This Proposed AD

We are proposing this AD because we evaluated all relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same

type design. This proposed AD would require accomplishing the actions specified in the service information described previously, except as discussed under "Differences Between the Proposed AD and Service Bulletin."

Differences Between the Proposed AD and Service Bulletin

Although Boeing Special Attention Service Bulletin 737-32-1402, dated August 6, 2008, specifies to send inspection reports to the manufacturer, this proposed AD would not require that action.

Explanation of Terminology

Although Boeing Special Attention Service Bulletin 737-32-1402, dated August 6, 2008, refers to "stress cracking," this proposed AD refers to "stress corrosion cracking."

Costs of Compliance

We estimate that this proposed AD would affect 100 airplanes of U.S. registry. The following table provides the estimated costs for U.S. operators to comply with this proposed AD.

TABLE—ESTIMATED COSTS

Action	Work hours	Average labor rate per hour	Parts	Cost per product	Number of U.S.-registered airplanes	Fleet cost
Repetitive lubrication	1	\$80	\$0	\$80	100	\$8,000.
Inspections	8	80	0	\$640 per inspection cycle	100	\$64,000 per inspection cycle.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect 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.

For the reasons discussed above, I certify 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. 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.

You can find our regulatory evaluation and the estimated costs of compliance in the AD Docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 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. The FAA amends § 39.13 by adding the following new AD:

Boeing: Docket No. FAA-2009-0411; Directorate Identifier 2008-NM-190-AD.

Comments Due Date

(a) We must receive comments by June 19, 2009.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 737-600, -700, -700C, and -800 series airplanes, certificated in any category; as identified in Boeing Special Attention Service Bulletin 737-32-1402, dated August 6, 2008.

Subject

(d) Air Transport Association (ATA) of America Code 32: Landing gear.

Unsafe Condition

(e) This AD results from a report indicating that the protective finishes on the main landing gear (MLG) forward trunnion pins might have been damaged during final assembly. We are issuing this AD to prevent stress corrosion cracking of the forward trunnion pins, which could result in fracture of the pins and consequent collapse of the MLG.

Compliance

(f) Comply with this AD within the compliance times specified, unless already done.

Lubrication

(g) Within 30 days after the effective date of this AD: Lubricate the left and right MLG forward trunnion pins in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737-32-1402, dated August 6, 2008. Repeat the lubrication at intervals not to exceed 30 days until all applicable requirements of paragraph (h) of this AD have been accomplished.

Inspection and Corrective Actions

(h) Within 60 months after the date of issuance of the original airworthiness certificate or date of issuance of the original export certificate of airworthiness, or within 6 months after the effective date of this AD, whichever occurs later: Except as provided

by paragraph (i) of this AD, do a detailed inspection for discrepancies (including finish damage, corrosion, pitting, and base metal scratches) of the transition radius of the left and right MLG trunnion pins, in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737-32-1402, dated August 6, 2008. At the times specified in paragraph 1.E., “Compliance,” of the service bulletin, do all applicable repetitive inspections and corrective actions, in accordance with the service bulletin. Accomplishing the detailed inspections (initial and repetitive) and all applicable corrective actions specified in this paragraph terminates the repetitive lubrication requirements of paragraph (g) of this AD.

No Report Required

(i) Although Boeing Special Attention Service Bulletin 737-32-1402, dated August 6, 2008, specifies to send inspection reports to the manufacturer, this AD does not include that requirement.

Optional Terminating Action

(j) Overhauling or replacing a trunnion pin in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 737-32-1402, dated August 6, 2008, ends the repetitive lubrication requirements of paragraph (g) of this AD, and the actions required by paragraph (h) of this AD, for that pin. Replacement or overhaul of the left and right MLG trunnion pins in accordance with Boeing Special Attention Service Bulletin 737-32-1402, dated August 6, 2008, terminates the requirements of this AD.

Alternative Methods of Compliance (AMOCs)

(k)(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Nancy Marsh, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Seattle ACO, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 917-6440; fax (425) 917-6590. Or, e-mail information to 9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.

(2) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Before using any approved AMOC on any airplane to which the AMOC applies, notify your principal maintenance inspector (PMI) or principal avionics inspector (PAI), as appropriate, or lacking a principal inspector, your local Flight Standards District Office. The AMOC approval letter must specifically reference this AD.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane and the approval must specifically refer to this AD.

Issued in Renton, Washington, on April 27, 2009.

Stephen P. Boyd,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E9-10303 Filed 5-4-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 601

[Docket No. FDA-2009-N-0100]

Revision of the Requirements for Publication of License Revocation; 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 the biologics regulations to clarify the regulatory procedures for notifying the public about the revocation of a biologics license to be consistent with current practices. This proposed rule is a companion document to the direct final rule published elsewhere in this issue of the **Federal Register**.

DATES: Submit written or electronic comments on or before July 20, 2009. If FDA receives any significant adverse comments, the agency will publish a document withdrawing the direct final rule within 30 days after the comment period ends. FDA will then proceed to respond to comments under this proposed rule using the usual notice and comment procedures.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2009-N-0100, by any of the following methods: *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting

comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal, as described previously, in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Request for Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 25, 1977 (42 FR 4680), FDA issued a final rule revising, among other things, the procedures under part 601 (21 CFR part 601) for issuing, revoking, and suspending biologics licenses; and publishing license revocations. FDA revised these procedures in order to simplify and codify existing practices, establish new requirements where appropriate, and ensure that practices and procedures would be consistently applied throughout the agency.

A provision under the January 25, 1977, final rule provided that a “Notice of revocation of a license, with statement of the cause therefor, shall be issued by the Commissioner and published in the **Federal Register**” (§ 601.8). FDA interprets this requirement to apply only to a license which the Commissioner of Food and Drugs (the Commissioner) has found grounds to revoke under § 601.5(b). FDA has not routinely published, in the **Federal Register**, a notice of revocation of a biologics license resulting from a manufacturer’s voluntary request for revocation for reasons unrelated to a finding by the Commissioner that