

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 767-200, -300, -300F, and -400ER series airplanes; certificated in any category; as identified in Boeing Service Bulletin 767-28-0105, Revision 1, dated February 6, 2013.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Unsafe Condition

This AD was prompted by reports indicating that a standard access door was located where an impact-resistant access door was required, and stencils were missing from some impact-resistant access doors. We are issuing this AD to prevent foreign object penetration of the fuel tank from uncontained engine failure or tire debris, which could cause a fuel leak near an ignition source (e.g., hot brakes or engine nozzle), consequently leading to a fuel-fed fire.

(f) Compliance

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

(g) Inspections

Within 72 months after the effective date of this AD, do the actions specified in paragraphs (g)(1) and (g)(2) of this AD, in accordance with the Accomplishment Instructions of Boeing Service Bulletin 767-28-0105, Revision 1, dated February 6, 2013.

(1) Do either a general visual inspection or ultrasonic non-destructive test of the left- and right-hand wing fuel tank access doors to determine whether impact-resistant access doors are installed in the correct locations. If any standard access door is found, before further flight, replace with an impact-resistant access door.

(2) Do a general visual inspection of the left- and right-hand wing fuel tank impact-resistant access doors to verify stencils and index markers are applied. If a stencil or index marker is missing, before further flight, apply a stencil or index marker, as applicable.

(h) Maintenance or Inspection Program Revision

Within 60 days after the effective date of this AD, revise the maintenance or inspection program, as applicable, to incorporate critical design configuration control limitation (CDCCL) Task 57-AWL-01, "Impact-Resistant Fuel Tank Access Door," of Section 9, Airworthiness Limitations (AWLs) and Certification Maintenance Requirements (CMRs) of Boeing 767 Maintenance Planning Data Document D622T001-9, Revision January 2013.

(i) No Alternative Actions, Intervals, and/or CDCCLs

After accomplishing the revision required by paragraph (h) of this AD, no alternative actions (e.g., inspections), intervals, and/or CDCCLs may be used unless the actions, intervals, and/or CDCCLs are approved as an alternative method of compliance (AMOC) in

accordance with the procedures specified in paragraph (k) of this AD.

(j) Credit for Previous Actions

This paragraph provides credit for the actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Service Bulletin 767-28-0105, dated January 12, 2012, which is not incorporated by reference in this AD.

(k) Alternative Methods of Compliance (AMOCs)

(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. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (l)(1) of this AD. Information may be emailed to: 9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(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 the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that 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.

(4) AMOCs for ADs 2008-11-01 R1, Amendment 39-16145 (74 FR 68515, December 28, 2009); 2010-06-10, Amendment 39-16234 (75 FR 15322, March 29, 2010); or 2011-25-05, Amendment 39-16881 (77 FR 2442, January 18, 2012); that meet the conditions specified in paragraphs (k)(4)(i) and (k)(4)(ii) of this AD are approved as AMOCs for the corresponding provisions of paragraph (h) of this AD.

(i) AMOCs that are approved after November 2, 2012.

(ii) AMOCs that include incorporation of CDCCL Task 57-AWL-01, "Impact-Resistant Fuel Tank Access Door."

(l) Related Information

(1) For more information about this AD, contact Suzanne Lucier, Aerospace Engineer, Propulsion Branch, ANM-140S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6438; fax: 425-917-6590; email: suzanne.lucier@faa.gov.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For

information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on June 25, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2014-15530 Filed 7-1-14; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 39**

[Docket No. FAA-2014-0428; Directorate Identifier 2014-NM-067-AD]

RIN 2120-AA64

Airworthiness Directives; the Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 787-8 airplanes. This proposed AD was prompted by reports of deficiencies in the flight control module (FCM) software. This proposed AD would require installing certain FCM software. We are proposing this AD to correct deficiencies in the FCM software, which, if not corrected, could prevent continued safe flight and landing.

DATES: We must receive comments on this proposed AD by August 18, 2014.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, 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:** Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at

the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2014-0428; 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 (phone: 800-647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Marie Hogestad, Aerospace Engineer, Systems and Equipment Branch, ANM-130S, Seattle Aircraft Certification Office (ACO), FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6418; fax: 425-917-6590; email: marie.hogestad@faa.gov.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA-2014-0428; Directorate Identifier 2014-NM-067-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 reports of in-service incidents and identified an indicating system shortcoming due to deficiencies in the FCM software, which have been determined to be safety issues in Model 787-8 airplanes.

We have received several reports of FCM airborne resets that occurred

during trailing edge variable camber operation which, due to a software deficiency, incorrectly resulted in the flaps being shut down and the "FLAPS DRIVE" (caution) message, which directs the flightcrew to execute a flaps up landing. The flaps up landing procedure requires a high speed landing and, in combination with abnormal landing conditions such as a short runway or adverse weather conditions, could result in a runway excursion.

Additionally, we received a report of a single flap position sensor failure which, due to a software deficiency, incorrectly resulted in flap position data being declared invalid. Invalid flap data causes the primary flight controls to transition to secondary mode, the spoiler droop commands to default to flaps up (i.e., no-droop) position, the autopilot to disengage, the flaps to remain in the last commanded position, and loss of flap position on the displays. This failure could prevent continued safe flight and landing if it occurs during final approach below approximately 100 feet due to the combination of high workload, the flight control mode change, and the wing lift loss, which may result in a high airplane sink rate landing or a ground impact short of the runway.

We have also determined that a single spoiler failure requires an engine indication and crew alerting system (EICAS) alert because a single spoiler failure with flaps down can result in significant levels of buffet, which, without annunciation, the flightcrew might interpret either as a stall, landing gear damage, structural damage, or other external damage.

These conditions, if not corrected, could prevent continued safe flight and landing.

Relevant Service Information

We reviewed Boeing Alert Service Bulletin B787-81205-SB270020-00, Issue 001, dated February 6, 2014. For information on the procedures and compliance times, see this service information at <http://www.regulations.gov> by searching for Docket No. FAA-2014-0428.

Concurrent Service Information

For certain airplanes, Boeing Alert Service Bulletin B787-81205-SB270020-00, Issue 001, dated February 6, 2014, specifies concurrent accomplishment of the FCM software installation specified in Boeing Alert Service Bulletin B787-81205-SB270017-00, Issue 001, dated September 18, 2013. For information on

the procedures, see Boeing Alert Service Bulletin B787-81205-SB270017-00, Issue 001, dated September 18, 2013, at <http://www.regulations.gov> by searching for Docket No. FAA-2014-0428.

FAA's Determination

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

Proposed AD Requirements

This proposed AD would require installing certain FCM software as specified in the service information described previously.

Explanation of "RC" Steps in Service Information

The FAA worked in conjunction with industry, under the Airworthiness Directives Implementation Aviation Rulemaking Committee, to enhance the AD system. One enhancement was a new process for annotating which steps in the service information are required for compliance with an AD. Differentiating these steps from other tasks in the service information is expected to improve an owner's/operator's understanding of crucial AD requirements and help provide consistent judgment in AD compliance. The actions specified in the service information described previously include steps that are labeled as RC (required for compliance) because these steps have a direct effect on detecting, preventing, resolving, or eliminating an identified unsafe condition.

As noted in the specified service information, steps labeled as RC must be done to comply with the proposed AD. However, steps that are not labeled as RC are recommended. Those steps that are not labeled as RC may be deviated from, done as part of other actions, or done using accepted methods different from those identified in the service information without obtaining approval of an alternative method of compliance (AMOC), provided the steps labeled as RC can be done and the airplane can be put back in a serviceable condition. Any substitutions or changes to steps labeled as RC will require approval of an AMOC.

Costs of Compliance

We estimate that this proposed AD affects 11 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
FCM BP3 software installation	2 work-hours × \$85 per hour = \$170	\$0	\$170	\$1,870
Concurrent FCM BP2 software installation (Group 1 airplanes).	2 work-hours × \$85 per hour = \$170	\$630	\$800	\$8,800

According to the manufacturer, all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

The parts cost for the FCM BP3 software installation is not included in our cost estimate. It is considered Boeing-provided loadable software, which is referenced in Boeing Alert Service Bulletin B787–81205–SB270020–00, Issue 001, dated February 6, 2014, under “Parts & Materials Supplied by the Operator.”

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),

(3) Will not affect intrastate aviation in Alaska, and

(4) 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.

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 airworthiness directive (AD):

The Boeing Company: Docket No. FAA–2014–0428; Directorate Identifier 2014–NM–067–AD.

(a) Comments Due Date

We must receive comments by August 18, 2014.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 787–8 airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin B787–81205–SB270020–00, Issue 001, dated February 6, 2014.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight Controls.

(e) Unsafe Condition

This AD was prompted by reports of deficiencies in the flight control module (FCM) software. We are issuing this AD to correct deficiencies in the FCM software,

which, if not corrected, could prevent continued safe flight and landing.

(f) Compliance

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

(g) Flight Control Module (FCM) Software Installation

Within 6 months after the effective date of this AD: Use the onboard data load function (ODLF) to install FCM operational program software (OPS), FCM loadable diagnostic information (LDI) database (DB) software, and FCM air data reference function (ADRF) DB software, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787–81205–SB270020–00, Issue 001, dated February 6, 2014.

(h) Concurrent Requirements

For Group 1 airplanes, as identified in Boeing Alert Service Bulletin B787–81205–SB270020–00, Issue 001, dated February 6, 2014: Prior to or concurrently with accomplishing the actions required by paragraph (g) of this AD, use the ODLF to install FCM OPS, FCM LDI DB, and central maintenance computer function (CMCF) LDI DB software, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787–81205–SB270017–00, Issue 001, dated September 18, 2013.

(i) Parts Installation Prohibition

After installation of the new software specified in paragraphs (g) and (h) of this AD, no person may install any previous versions of the FCM OPS, FCM LDI DB, FCM ADRF DB, or CMCF LDI DB software, on any airplane.

(j) Alternative Methods of Compliance (AMOCs)

(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. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed to: 9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) If the service information contains steps that are labeled as RC (Required for

Compliance), those steps must be done to comply with this AD; any steps that are not labeled as RC are recommended. Those steps that are not labeled as RC may be deviated from, done as part of other actions, or done using accepted methods different from those identified in the specified service information without obtaining approval of an AMOC, provided the steps labeled as RC can be done and the airplane can be put back in a serviceable condition. Any substitutions or changes to steps labeled as RC require approval of an AMOC.

(k) Related Information

(1) For more information about this AD, contact Marie Hogestad, Aerospace Engineer, Systems and Equipment Branch, ANM-130S, Seattle Aircraft Certification Office (ACO), FAA, 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6418; fax: 425-917-6590; email: marie.hogestad@faa.gov.

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P. O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>. You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

Issued in Renton, Washington, on June 24, 2014.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate,
Aircraft Certification Service.

[FR Doc. 2014-15505 Filed 7-1-14; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 216

[Docket No. FDA-1999-N-0194 (Formerly 99N-4490)]

RIN 0910-AH10

Additions and Modifications to the List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal of previous proposed rule.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is proposing to amend its regulations to revise the list of drug products that may not be compounded under the exemptions provided by the Federal Food, Drug, and Cosmetic Act (the

FD&C Act) because the drug products have been withdrawn or removed from the market after the drug products or components of such drug products were found to be unsafe or not effective.

Specifically, the proposed rule would add 25 drug products to this list of drug products and modify the description of one drug product on this list to add an exception. These revisions are necessary because new information has come to the Agency's attention since March 8, 1999, when FDA published the original list as a final rule. FDA is also withdrawing the previous proposed rule regarding additions to this list (see the **Federal Register** of January 4, 2000).

DATES: Submit either electronic or written comments on the proposed rule by September 2, 2014. The January 4, 2000, proposed rule (65 FR 256) is withdrawn as of July 2, 2014.

ADDRESSES: You may submit comments, identified by Agency name and Docket No. FDA-1999-N-0194 and/or Regulatory Information Number (RIN) number 0910-AH10, 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:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, Docket No. FDA-1999-N-0194, and RIN 0910-AH10 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: Edisa Gozun, Center for Drug Evaluation

and Research (HFD-310), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5199, Silver Spring, MD 20993-0002, 301-796-3110.

SUPPLEMENTARY INFORMATION:

I. Background

Section 503A of the FD&C Act (21 U.S.C. 353a) describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following three sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

One of the conditions that must be satisfied to qualify for the exemptions under section 503A of the FD&C Act is that the licensed pharmacist or licensed physician does not compound a drug product that appears on a list published by the Secretary in the **Federal Register** of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (see section 503A(b)(1)(C) of the FD&C Act).

A. Court Decisions Regarding the Pharmacy Compounding Provisions of the FD&C Act

As originally enacted, section 503A of the FD&C Act included prohibitions on the advertising and solicitation of prescriptions for any particular compounded drug, class of drug, or type of drug. Seven compounding pharmacies challenged the advertising and solicitation provisions of section 503A of the FD&C Act as an impermissible regulation of commercial speech. In February 2001, the U.S. Court of Appeals for the Ninth Circuit held that the prohibition on advertising and promotion in section 503A(c) and the provision of section 503A(a) of the FD&C Act that requires that the prescription be "unsolicited," were unconstitutional restrictions on commercial speech. (See *Western States Med. Ctr. v. Shalala*, 238 F.3d 1090 (9th Cir. 2001).) Furthermore, the Ninth Circuit held that the advertising and solicitation provisions could not be severed from the rest of section 503A and, as a result, found section 503A of the FD&C Act to be invalid in its