26, 2017 (the effective date of AD 2017–08–09) following Solo Kleinmotoren GmbH Technische Mitteilung (English translation: Service Bulletin), Nr. 4600–5, Ausgabe 1 (English translation: Issue 1), dated November 24, 2014.

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Small Airplane Standards Branch, 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: Jim Rutherford, Aerospace Engineer, FAA, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4165; fax: (816) 329–4090; email: *jim.rutherford@faa.gov.* Before using any approved AMOC on any glider to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, Small Airplane Standards Branch, FAA; or the European Aviation Safety Agency (EASA).

(i) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2014–0269, dated December 11, 2014, for related information. You may examine the MCAI on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0014. For service information related to this AD, contact Solo Kleinmotoren GmbH, Postfach 600152, 71050 Sindelfingen, Germany; telephone: +49 703 1301–0; fax: +49 703 1301–136; email: *aircraft@solo-germany.com;* internet: *http://aircraft.solo-online.com.* You may review this referenced service information at the FAA, Small Airplane Standards Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on January 8, 2018.

Melvin Johnson,

Deputy Director, Policy and Innovation Division, Aircraft Certification Service.

[FR Doc. 2018–00476 Filed 1–12–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–1246; Product Identifier 2017–NM–086–AD]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2014–02–01, which applies to certain Bombardier, Inc., Model CL–600–2C10 (Regional Jet Series 700, 701, & 702), Model CL–600–2D15 (Regional Jet Series 705), and Model CL–600–2D24 (Regional Jet Series 900) airplanes. AD 2014–02–01 requires repetitive inspections of the rudder travel limiter (RTL) return springs and primary actuator, and corrective actions if necessary; and replacement of certain RTL return springs. Since we issued AD 2014–02–01, we received reports that when installing the RTL return springs, the RTL limiter arm assembly lug can become deformed. This proposed AD would require an inspection of the RTL return springs for signs of chafing; an inspection of the casing of the primary actuator for signs of chafing or missing paint; replacement of the RTL return springs; and an inspection of the lugs of the RTL limiter arm assembly for cracks, and modification or replacement, as applicable; and applicable corrective actions. This proposed AD would also add airplanes to the applicability. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by March 2, 2018.

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 NPRM, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free telephone: 1–866–538–1247 or direct-dial telephone: 1–514–855–2999; fax: 514–855–7401; email: *ac.yul@aero.bombardier.com;* internet: *http://www.bombardier.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 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–2017–1246; 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 Operations 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: Cesar Gomez, Aerospace Engineer, Airframe and Mechanical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7318; fax: 516–794–5531.

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–2017–1246; Product Identifier 2017–NM–086–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 based on 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 issued AD 2014–02–01, Amendment 39–17729 (79 FR 7382, February 7, 2014) (''AD 2014–02–01''), for certain Bombardier, Inc., Model CL–

600–2C10 (Regional Jet Series 700, 701, & 702), Model CL–600–2D15 (Regional Jet Series 705), and Model CL–600–2D24 (Regional Jet Series 900) airplanes. AD 2014–02–01 was prompted by reports of failure of the RTL return spring. AD 2014–02–01 requires repetitive inspections of the RTL return springs and primary actuator, and corrective actions if necessary; and replacement of certain RTL return springs, including related investigative and corrective actions, if necessary. We issued AD 2014–02–01 to prevent failure of the RTL, which would permit an increase of rudder authority beyond normal structural limits and consequently affect the controllability of the airplane.

Since we issued AD 2014–02–01, we received reports that when installing RTL return spring part number BA670–93468–1, the RTL limiter arm assembly lugs can become deformed when the RTL return spring attachment bolt is torqued. We have also determined that additional airplanes are affected by the unsafe condition.

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF–2017–19, dated June 6, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Bombardier, Inc., Model CL–600–2C10 (Regional Jet Series 700, 701, & 702), Model CL–600–2D15 (Regional Jet Series 705), and Model CL–600–2D24 (Regional Jet Series 900) airplanes. The MCAI states:

> Transport Canada AD CF–2010–18R1 [which corresponds to FAA AD 2014–02–01] mandated a repetitive inspection and introduced a new rudder travel limiter (RTL) return spring, part number (P/N) BA670–93468–1, to correct the potential dormant RTL spring failure. This [Canadian] AD is issued to supersede the repetitive inspection and the replacement of the RTL spring due to discoveries made after the issuance of [Canadian] AD CF–2010–18R1.
>
> When installing the RTL return spring P/N BA670–93468–1 as mandated by [Canadian] AD CF–2010–18R1, it was found that it is possible for the RTL limiter arm assembly lug to be deformed. The lugs become bent when the RTL return spring attachment bolt is torqued. This condition, if not corrected, can lead to failure of the limiter arm assembly lug. In combination with failure of the RTL, failure of the limiter arm assembly lug could affect the controllability of the aeroplane.
>
> This [Canadian] AD mandates the inspection for cracked RTL limiter arm lugs and modification of the RTL limiter arm to prevent the RTL limiter arm lugs from bending during RTL assembly.

Required actions include: A detailed visual inspection of the RTL return springs for signs of chafing; a detailed visual inspection of the casing of the primary actuator for signs of chafing or missing paint; replacement of the RTL return springs; an eddy current inspection of the lugs of the RTL limiter arm assembly for cracks, and modification or replacement of the RTL limiter arm assembly, as applicable; and applicable corrective actions. Corrective actions include: replacement of the RTL return springs, repair of the primer and topcoat of the primary actuator, and replacement of the primary actuator. You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1246.

Related Service Information Under 1 CFR Part 51

Bombardier, Inc., has issued Bombardier Service Bulletin 670BA–27–070, Revision B, dated March 31, 2017. The service information describes procedures for an inspection of the RTL return springs for signs of chafing; an inspection of the casing of the primary actuator for signs of chafing or missing paint; replacement of the RTL return springs; and an inspection of the lugs of the RTL limiter arm assembly for cracks, and modification or replacement, as applicable; and applicable corrective actions. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Costs of Compliance

We estimate that this proposed AD affects 544 airplanes of U.S. registry.

We estimate that it would take about 16 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $2,960 per product. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $2,350,080, or $4,320 per product.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this proposed AD.

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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes to the Director of the System Oversight Division.

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 removing Airworthiness Directive (AD) 2014–02–01, Amendment 39–17729 (79 FR 7382, February 7, 2014), and adding the following new AD:

Bombardier, Inc.: Docket No. FAA–2017–1246; Product Identifier 2017–NM–086–AD.

(a) Comments Due Date

We must receive comments by March 2, 2018.

(b) Affected ADs

This AD replaces AD 2014–02–01, Amendment 39–17729 (79 FR 7382, February 7, 2014) (''AD 2014–02–01'').

(c) Applicability

This AD applies to the airplanes identified in paragraphs (c)(1) and (c)(2) of this AD, certificated in any category.

(1) Bombardier, Inc., Model CL–600–2C10 (Regional Jet Series 700, 701, & 702) airplanes, serial number 10002 through 10344 inclusive.

(2) Bombardier, Inc., Model CL–600–2D15 (Regional Jet Series 705) airplanes and Model CL–600–2D24 (Regional Jet Series 900) airplanes, serial numbers 15001 through 15397 inclusive.

(d) Subject

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

(e) Reason

This AD was prompted by reports that when installing the rudder travel limiter (RTL) return springs, the RTL limiter arm assembly lug can become deformed. We are issuing this AD to prevent deformed RTL limiter arm assembly lugs, which can lead to failure of the limiter arm assembly lug. In combination with failure of the RTL, failure of the limiter arm assembly lug could result in reduced controllability of the airplane.

(f) Compliance

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

(g) Inspections, Modification, and Replacement

(1) For airplanes equipped with RTL return spring part number BA–670–93465–1 or E0650–069–02750S: Within 800 flight hours or 4 months after the effective date of this AD, whichever occurs first, do a detailed visual inspection of the casing of the primary actuator for signs of chafing or missing paint, and all applicable corrective actions; replace the RTL return springs; and do an eddy current inspection of the lugs of the RTL limiter arm assembly for cracks, and modify or replace the RTL limiter arm assembly, as applicable; in accordance with Part A of the Accomplishment Instructions of Bombardier Service Bulletin 670BA–27–070, Revision B, dated March 31, 2017. Accomplishment of the actions specified in Bombardier Service Bulletin 670BA–27–059 does not meet the requirements of this paragraph.

(2) For airplanes equipped with RTL return spring part number BA–670–93468–1: Within 8,000 flight hours after the effective date of this AD, do a detailed visual inspection of the RTL return springs for signs of chafing, and applicable corrective actions; a detailed visual inspection of the casing of the primary actuator for signs of chafing or missing paint, and all applicable corrective actions; and do an eddy current inspection of the lugs of the RTL limiter arm assembly for cracks, and modify or replace the RTL limiter arm assembly, as applicable; in accordance with Part B of the Accomplishment Instructions of Bombardier Service Bulletin 670BA–27–070, Revision B, dated March 31, 2017. Accomplishment of the actions specified in Bombardier Service Bulletin 670BA–27–059 does not meet the requirements of this paragraph.

(h) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using the service information specified in paragraph (h)(1) or (h)(2) of this AD.

(1) Bombardier Service Bulletin 670BA–27–070, dated December 17, 2015.

(2) Bombardier Service Bulletin 670BA–27–070, Revision A, dated September 01, 2016.

(i) Other FAA AD Provisions

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, 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 ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7300; fax: 516–794–5531. 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. 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.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier Inc.'s TCCA Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2017–19, dated June 6, 2017, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1246.

(2) For more information about this AD, contact Cesar Gomez, Aerospace Engineer, Airframe and Mechanical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7318; fax: 516–794–5531.

(3) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; Widebody Customer Response Center North America toll-free telephone: 1–866–538–1247 or direct-dial telephone: 1–514–855–2999; fax: 514–855–7401; email: *ac.yul@aero.bombardier.com*; internet: *http://www.bombardier.com*. You may view this service information at the FAA, Transport Standards Branch, 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 December 28, 2017.

John P. Piccola, Jr.,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–00340 Filed 1–12–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 801, and 1100

[Docket No. FDA–2015–N–2002]

RIN 0910–AH94

Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding ''Intended Uses''; Proposed Partial Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.