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 small airplanes, gliders, balloons, airships, domestic business jet transport airplanes, and associated appliances to the Director of the Policy and Innovation 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 adding the following new airworthiness directive (AD):

Gulfstream Aerospace Corporation: Docket No. FAA–2018–0690; Product Identifier 2018–CE–022–AD.

(a) Comments Due Date

We must receive comments by May 17, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Gulfstream Aerospace Corporation Model G–IV airplanes, certificated in any category, serial numbers 1000 through 1535; and Model GIV–X airplanes, certificated in any category, serial numbers 4001 through 4363.

Note 1 to paragraph (c) of this AD: Model G–IV airplanes are also referred to by the marketing designations G300 and G400. Model GIV–X airplanes are also referred to by the marketing designations G350 and G450.

(d) Subject

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 27, Flight Controls; 32, Landing Gear; 52, Doors; 53, Fuselage; 55, Stabilizers; 57, Wings; 71, Power Plant-General; and 78, Engine Exhaust.

(e) Unsafe Condition

This AD was prompted by a revision to the airworthiness limitations section (ALS) of the Model G–IV and Model GIV–X aircraft maintenance manuals based on fatigue and damage tolerance testing and updated analysis. We are issuing this AD to detect and correct fatigue cracking of principal structural elements (PSEs). This unsafe condition, if unaddressed, could result in reduced structural integrity of a PSE or critical component and lead to loss of control of the airplane.

(f) Compliance

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

(g) Airplane Maintenance Manual Revisions

Within 12 months after the effective date of this AD, revise the ALS of your maintenance or inspection program (*e.g.,* maintenance manual) to incorporate the airworthiness limitations specified in Gulfstream Document No. GIV–GER–0008, Summary of Changes to the GIV Series and GIV–X Series Airworthiness Limitations, Revision D, dated August 20, 2018, as applicable to your model and serial number airplane.

(h) No Alternative Actions or Intervals

After the maintenance or inspection program (*e.g.,* maintenance manual) has been revised as required by paragraph (g) of this AD, no alternative inspections or intervals may be used unless approved as an alternative method of compliance in accordance with the procedures specified in paragraph (i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Atlanta 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 certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD.

(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.

(j) Related Information

(1) For more information about this AD, contact Ronald ''Ron'' Wissing, Airframe Engineer, Atlanta ACO Branch, FAA, 1701 Columbia Avenue, College Park, Georgia 30337; phone: 404–474–5552; fax: 404–474–5606; email: *ronald.wissing@faa.gov*.

(2) For service information identified in this AD, contact Gulfstream Aerospace Corporation, P.O. Box 2206, Savannah, Georgia 31402–2206; telephone: (800) 810–4853; fax 912–965–3520; email: *pubs@gulfstream.com*; Internet: *http://www.gulfstream.com/product-support/technical-publications*. You may view this referenced service information at the FAA, Policy and Innovation Division, 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 March 25, 2019.

Melvin J. Johnson,

Aircraft Certification Service, Deputy Director, Policy and Innovation Division, AIR–601

[FR Doc. 2019–06275 Filed 4–1–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0203; Product Identifier 2018–CE–052–AD]

RIN 2120–AA64

Airworthiness Directives; Diamond Aircraft Industries GmbH Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Diamond Aircraft Industries GmbH Model DA 42 NG and Model DA 42 M–NG airplanes. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The unsafe condition in the MCAI is insufficient clearance of the gust lock mounts on the pilot side rudder pedals. We are issuing this proposed AD to require actions to

address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by May 17, 2019.

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 proposed AD, contact Diamond Aircraft Industries GmbH, N.A. Otto-Straße 5, A–2700 Wiener Neustadt, Austria, telephone: +43 2622 26700; fax: +43 2622 26780; email: *office@diamond-air.at*; Internet: *http://www.diamondaircraft.com*. You may review this referenced service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

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–2019–0203; or in person at Docket Operations 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 Docket Operations (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Mike Kiesov, Aerospace Engineer, FAA, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4144; fax: (816) 329–4090; email: *mike.kiesov@faa.gov*.

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–2019–0203; Product Identifier 2018–CE–052–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://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

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued AD No. 2018–0214, dated October 4, 2018 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> During production check-out of two DA 42 NG aeroplanes, it was noticed that, with the adjustable rudder pedals in full forward position, the gust lock mounts slightly touched the canopy gas spring damper. The subsequent investigation found that this was due to an unfavourable combination of production tolerances on these two aeroplanes. [Diamond Aircraft Industries GmbH] DAI determined that other aeroplanes of the same build standard (configuration) may also be affected.
>
> This condition, if not corrected, could lead to restricted rudder travel, possibly resulting in reduced control of the aeroplane.
>
> Prompted by these findings, DAI published the [mandatory service bulletin] MSB, providing modification instructions to remove the gust lock mounts on the pilot (left-hand, LH) side rudder pedals to ensure sufficient clearance, regardless of production tolerances and rudder pedal position.
>
> For the reason described above, this [EASA] AD requires implementation of a temporary revision (TR) to the applicable Airplane Flight Manual (AFM) and a modification, removing the pilot (LH) side rudder pedal gust lock mounts.

You may examine the MCAI on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0203.

Related Service Information Under 1 CFR Part 51

We reviewed Diamond Aircraft Temporary Revision TR–MÄM 42–1097 Gustlock on Co-Pilot Side only, Doc. #7.01.15–E, dated July 18, 2018 (TR–MAM 42–1097), which contains amended figures related to the gust lock belt. We also reviewed Diamond Aircraft Industries GmbH Work Instruction WI–MSB 42NG–077, dated August 20, 2018, which contains procedures for removing the pilot (LH) side rudder pedal gust lock mounts and specifies inserting a copy of TR–MAM 42–1097 into the airplane flight manual (AFM). 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 this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

We estimate that this proposed AD would affect 53 products of U.S. registry. We also estimate that it would take about 1 work-hour per product to comply with the removal of the pilot side rudder pedal gust lock mounts and to insert copy of TR–MAM 42–1097 into the AFM. The average labor rate is $85 per work-hour. Required parts would cost about $10 per product.

Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $5,035, or $95 per product.

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 small airplanes, gliders, balloons, airships, domestic business jet transport airplanes, and associated appliances to the Director of the Policy and Innovation 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 adding the following new airworthiness directive (AD):

Diamond Aircraft Industries GmbH: Docket No. FAA–2019–0203; Product Identifier 2018–CE–052–AD.

(a) Comments Due Date

We must receive comments by May 17, 2019.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Diamond Aircraft Industries GmbH (Diamond) Model DA 42 NG and Model DA 42 M–NG airplanes, serial numbers 42.N202, 42.N203, 42.N205 through 42.N207, 42.N210 through 42.N214, 42.N229 through 42.N338, 42.N340, 42.MN055, 42.MN057, and 42.MN058, certificated in any category.

(d) Subject

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

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The unsafe condition reported by the MCAI is insufficient clearance of the gust lock mounts on the pilot side rudder pedals. We are issuing this AD to prevent restricted rudder travel, which could result in reduced control of the airplane.

(f) Actions and Compliance

Unless already done, do the following actions in paragraphs (f)(1) and (2) of this AD.

(1) Within the next 100 hours time-in-service after the effective date of this AD:

(i) Remove the pilot (left-hand) side rudder pedal gust lock mounts in accordance with steps 1 through 5 of the Instructions in Diamond Aircraft Industries GmbH Work Instruction WI–MSB 42NG–077, dated August 20, 2018.

(ii) Revise the airplane flight manual (AFM) by adding the figures on page 8–11a of Diamond Aircraft Temporary Revision TR–MÄM 42–1097 Gustlock on Co-Pilot Side only, Doc. #7.01.15–E, dated July 18, 2018, into Chapter 8 of the AFM.

(2) As of the effective date of this AD, do not install on any airplane a pilot (left-hand) side rudder pedal gust lock mount.

(g) 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: Mike Kiesov, Aerospace Engineer, FAA, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4144; fax: (816) 329–4090; email: *mike.kiesov@faa.gov*. Before using any approved AMOC on any airplane 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 instead be accomplished using a method approved by the Manager, Small Airplane Standards Branch, FAA, or the European Aviation Safety Agency (EASA).

(h) Related Information

Refer to MCAI EASA AD No. 2018–0214, dated October 4, 2018; and Diamond Mandatory Service Bulletin MSB 42NG–077, dated August 20, 2018, for related information. You may examine the MCAI on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0203. For service information related to this AD, contact Diamond Aircraft Industries GmbH, N.A. Otto-Straße 5, A–2700 Wiener Neustadt, Austria, telephone: +43 2622 26700; fax: +43 2622 26780; email: *office@diamond-air.at*; internet: *http://www.diamondaircraft.com*. You may review this referenced service information at the FAA, Policy and Innovation Division, 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 March 25, 2019.

Melvin J. Johnson,

Aircraft Certification Service, Deputy Director, Policy and Innovation Division, AIR–601.

[FR Doc. 2019–06280 Filed 4–1–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. FDA–2018–N–4757]

RIN 0910–AH95

Revocation of the Test for Mycoplasma

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is proposing to amend the biologics regulations by removing the specified test for the presence of *Mycoplasma* for live virus vaccines and inactivated virus vaccines produced from in vitro living cell cultures. FDA is proposing this action because the existing test for *Mycoplasma* is restrictive in that it identifies only one test method in detail to be used even though other methods also may be appropriate. More sensitive and specific methods exist and are currently being practiced, and removal of the specific method to test for *Mycoplasma* provides flexibility for accommodating new and evolving technology and capabilities without