Aviation Safety Agency Airworthiness Directive 2014–0164, dated July 11, 2014, 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–2015–0243.

(2) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this 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 February 2, 2015.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–02922 Filed 2–17–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–0086; Directorate Identifier 2014–NM–191–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for all Airbus Model A310–203 airplanes. This proposed AD is intended to complete certain mandated programs intended to support the airplane reaching its limit of validity (LOV) of the engineering data that support the established structural maintenance program. This proposed AD was prompted by reports that side link clevis bolts of the front engine mount do not meet the Design Service Goal (DSG) requirements on airplanes equipped with General Electric Company CF6–80A3 engines. This proposed AD would require repetitive replacement of all side link clevis engine mount bolts. We are proposing this AD to prevent failure of the front engine mount, and consequent possible departure of the engine.

DATES: We must receive comments on this proposed AD by April 6, 2015.

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: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com*; Internet *http://www.airbus.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–2015–0086; 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: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone 425–227–2125; fax 425–227–1149.

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–2015–0086; Directorate Identifier 2014–NM–191–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

As described in FAA Advisory Circular 120 104 (*http://www.faa.gov/documentLibrary/media/Advisory_Circular/120-104.pdf*), several programs have been developed to support initiatives that will ensure the continued airworthiness of aging airplane structure. The last element of those initiatives is the requirement to establish a LOV of the engineering data that support the structural maintenance program under 14 CFR 26.21. This proposed AD is the result of an assessment of the previously established programs by Airbus during the process of establishing the LOV for Airbus Model A310–203 airplanes. The actions specified in this proposed AD are necessary to complete certain programs to ensure the continued airworthiness of aging airplane structure and to support an airplane reaching its LOV.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA Airworthiness Directive 2014–0191, dated August 29, 2014 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus Model A310–203 airplanes. The MCAI states:

> During fatigue analysis performed in the scope of the Extended Service Goal, taking into account the certification loads and the new lift-off loads, Airbus determined that side link clevis engine mount bolts do not meet the Design Service Goal (DSG) requirements on aeroplanes equipped with CF6–80A3 engines.
>
> This condition, if not corrected, could lead to failure of the front engine mount, possibly resulting in-flight separation of the engine from the aeroplane.
>
> To address this potential unsafe condition, Airbus issued Service Bulletin (SB) A310–71–2038 to introduce a life limit on the side link clevis engine mount bolts.
>
> For the reason described above, this [EASA] AD requires implementation of the new life limit and replacement of all side link clevis engine mount bolts that have exceeded the new limit.

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–2015–0086.

Relevant Service Information Under 1 CFR Part 51

Airbus has issued Mandatory Service Bulletin A310–71–2038, including Appendices 01 and 02, dated April 8, 2014. The service information describes procedures for replacement of all side link clevis bolts on the CF6–80A3 front engine mount and subsequent re-identification of the newly installed bolts with a cross (to differentiate them from the old ones). The actions described in this service information are intended to correct the unsafe condition identified in the MCAI. This service information is reasonably available; see **ADDRESSES** for ways to access this service information.

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 the same type design.

Costs of Compliance

We estimate that this proposed AD affects 13 airplanes of U.S. registry.

We also estimate that it would take about 142 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 $2,900 per product. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $194,610, or $14,970 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.

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):

Airbus: Docket No. FAA–2015–0086; Directorate Identifier 2014–NM–191–AD.

(a) Comments Due Date

We must receive comments by April 6, 2015.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus Model A310–203 airplanes, certificated in any category, all manufacturer serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 71, Powerplant.

(e) Reason

This AD was prompted by reports that side link clevis bolts of the front engine mount do not meet the Design Service Goal (DSG) requirements on airplanes equipped with General Electric Company CF6–80A3 engines. We are issuing this AD to prevent failure of the front engine mount, and consequent possible departure of the engine.

(f) Compliance

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

(g) Repetitive Bolt Replacement

Within 18 months after the effective date of this AD, replace the side link clevis bolts, nuts, and bushings of the front engine mount on both engines, and re-identify the new installed bolts with a cross (to differentiate them from the old ones), in accordance with the Accomplishment Instructions of Airbus Mandatory Service Bulletin A310–71–2038, including Appendices 01 and 02, dated April 8, 2014. Repeat the replacement thereafter at intervals not to exceed 29 years.

(h) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, Transport Airplane Directorate, 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 International Branch, send it to ATTN: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone 425–227–2125; fax 425–227–1149. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* 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. The AMOC approval letter must specifically reference this AD.

(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, International Branch, ANM–116, Transport Airplane Directorate, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA Airworthiness Directive 2014–0191, dated August 29, 2014, 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–2015–0086.

(2) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAW, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* Internet *http://www.airbus.com.* You may view this 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 January 30, 2015.

Jeffrey E. Duven,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–02683 Filed 2–17–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 314 and 601

[Docket No. FDA–2013–N–0500]

Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products; Public Meeting; Request for Comments; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is announcing a 1-day public meeting entitled ''Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products.'' The purpose of the meeting is to provide a public forum for FDA to listen to comments on the proposed rule on ''changes being effected'' supplements that was published in the **Federal Register** of November 13, 2013, and alternatives offered to this proposed rule. FDA is also reopening the comment period for the proposed rule to receive submissions of additional written comments on the proposed rule as well as alternative proposals presented during the public meeting.

DATES: *Meeting.* The public meeting will be held on March 27, 2015, from 8 a.m. to 5 p.m. Registration to attend the meeting must be received by March 20, 2015. See the **SUPPLEMENTARY INFORMATION** section for information on how to register for the meeting.

Comments. The comment period for the proposed rule publilshed November 13, 2013 (78 FR 67985), is reopened. Submit either electronic or written comments regarding proposed alternatives to the proposed rule by April 27, 2015.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave, Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments 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 Docket No. FDA–2013–N–0500 for the proposed rule. 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 ''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: Ellen Molinaro, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 51, Rm. 6218, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3601, FAX: 301–847–8440.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 13, 2013 (78 FR 67985), FDA proposed regulations to revise and clarify procedures for application holders of an approved drug or biological product to change the product labeling to reflect certain types of newly acquired safety-related information in advance of FDA's review of the change by submitting a changes being effected (CBE–0) supplement to FDA. The need to promptly communicate certain safety-related labeling changes based on newly acquired information is the basis for the ''changes being effected'' exception to the general requirement for FDA approval of revised labeling prior to distribution. The proposed rule, if finalized, would enable abbreviated new drug application (ANDA) holders for generic drugs to update product labeling promptly to reflect certain types of newly acquired safety-related information, irrespective of whether the revised labeling differs from that of the corresponding reference listed drug (RLD or brand drug) upon submission of a CBE–0 supplement to FDA. FDA's proposed revisions to its regulations to allow generic drug manufacturers to update product labeling through CBE–0 supplements in the same manner as brand drug manufacturers are intended to improve communication of important, newly acquired drug safety information to health care professionals and the public. For further information about this and other proposed regulatory changes described in the proposed rule, see 78 FR 67985.

FDA received numerous comments on the proposed rule from a diverse group of stakeholders, including comments proposing alternative approaches to communicating newly acquired safety-related information in a multisource environment. In November 2014, FDA received a request from two trade associations for a listening meeting with FDA to present an alternative to the proposed regulatory changes described in the proposed rule that they described as intended to meet shared public health goals regarding multisource drugs (see Ref. 1). In December 2014, an explanatory statement accompanying the Consolidated and Further Continuing Appropriations Act, 2015