

(a) Effective Date

This AD becomes effective February 19, 2019.

(b) Affected ADs

This AD removes AD 2014-05-06 R1, Amendment 39-19529 (83 FR 64734, December 18, 2018).

(c) Applicability

This AD applies to the following Airbus Helicopters Deutschland GmbH (type certificate previously held by Eurocopter Deutschland GmbH) helicopters, certificated in any category:

(1) Model EC135 P1, P2, P2+, T1, T2, and T2+ helicopters, serial number (S/N) 0005 through 00829, with a tail rotor control lever, part number (P/N) L672M2802205 or L672M1012212; cyclic control lever, P/N L671M1005250; collective control lever assembly, P/N L671M2020108; or collective control plate, P/N L671M5040207; installed, and

(2) Model MBB-BK 117 C-2 helicopters, S/N 9004 through 9310, with a tail rotor control lever assembly, P/N B672M1007101 or B672M1807101; tail rotor control lever, P/N B672M1002202 or L672M2802205; or lateral control lever assembly, P/N B670M1008101, installed.

(d) Subject

Joint Aircraft Service Component (JASC) Code: 6710, Main Rotor Control.

(e) Related Information

For more information about this AD, contact Matt Fuller, Senior Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5110; email matthew.fuller@faa.gov.

Issued in Fort Worth, Texas, on December 20, 2018.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2019-02631 Filed 2-15-19; 8:45 am]

BILLING CODE 4910-13-P

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

[Docket No. FAA-2019-0048; Product Identifier 2018-NE-19-AD; Amendment 39-19556; AD 2019-03-04]

RIN 2120-AA64

Airworthiness Directives; Engine Alliance Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are superseding Airworthiness Directive (AD) 2018-11-

16 for all Engine Alliance (EA) GP7270 and GP7277 turbofan engines with a certain engine fan hub assembly. AD 2018-11-16 required a one-time eddy current inspection (ECI) of the engine fan hub blade slot bottom and blade slot front edge for cracks, a visual inspection of the engine fan hub assembly for damage, and removal of parts if damage or defects are found that are outside serviceable limits. This AD retains these requirements, but expands the population of affected engine fan hub assemblies and revises the compliance time for the inspections. This AD was prompted by the FAA's determination that inspections need to be expanded to all EA GP7270 and GP7277 turbofan engines. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective March 6, 2019.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of March 6, 2019.

We must receive comments on this AD by April 5, 2019.

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 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this final rule, contact Engine Alliance, 411 Silver Lane, East Hartford, CT 06118; phone: 800-565-0140; email: help24@pw.utc.com; website: www.engineallianceportal.com. You may view this service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781-238-7759. It is also available on the internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2019-0048.

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-2019-0048; 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 final rule, the regulatory evaluation, any comments received, and other information. The street address for Docket Operations (phone: 800-647-5527) is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Matthew Smith, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA, 01803; phone: 781-238-7735; fax: 781-238-7199; email: matthew.c.smith@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

We issued AD 2018-11-16, Amendment 39-19304 (83 FR 27891, June 15, 2018), ("AD 2018-11-16"), for certain EA GP7270 and GP7277 turbofan engines. AD 2018-11-16 required a one-time ECI of the engine fan hub blade slot bottom and blade slot front edge for cracks, a visual inspection of the engine fan hub assembly for damage, and removal of parts if damage or defects are found that are outside serviceable limits. AD 2018-11-16 resulted from an uncontained failure of the engine fan hub assembly. We issued AD 2018-11-16 to detect defects, damage, and cracks that could result in an uncontained failure of the engine fan hub assembly.

Actions Since AD 2018-11-16 was Issued

Since we issued AD 2018-11-16, we determined that inspections need to be expanded to all EA GP7270 and GP7277 turbofan engines with a certain engine fan hub assembly because all engines are subject to the unsafe condition. As a result, EA published EA Alert Service Bulletin (ASB) EAGP7-A72-389, Revision No. 3, dated October 18, 2018, to expand the population of engine fan hub assemblies that require inspection. We also determined that we could remove the EA GP7272 turbofan engine from the Applicability paragraph of this AD because the engine was not manufactured. The Applicability paragraph of this AD aligns with the EA service information. We are issuing this AD to address the unsafe condition on these products.

Related Service Information Under 14 CFR Part 51

We reviewed EA ASB EAGP7-A72-389, Revision No. 3, dated October 18, 2018. The ASB describes procedures for ECI and visual inspection of the GP7270

and GP7277 engine fan hub assembly. 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

We are issuing 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.

AD Requirements

This AD requires a one-time ECI of the GP7270 and GP7277 engine fan hub blade slot bottom and blade slot front edge for cracks, a visual inspection of the engine fan hub assembly for damage, and removal of the engine fan hub assembly if damage or defects are found that are outside of serviceable limits.

FAA’s Justification and Determination of the Effective Date

No domestic operators use this product. Therefore, we find good cause that notice and opportunity for prior public comment are unnecessary. In addition, for the reason stated above, we find that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not provide you with notice and an opportunity to provide your comments before it becomes effective. However, we invite you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under the **ADDRESSES** section. Include the docket number FAA-2019-0048 and product identifier

2018-NE-19-AD at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this final rule. We will consider all comments received by the closing date and may amend this final rule 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 final rule.

Costs of Compliance

We estimate that this AD affects zero engines installed on airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
ECI and visual inspection	14 work-hours × \$85 per hour = \$1,190	\$0	\$1,190	\$0

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 engines, propellers, and

associated appliances to the Manager, Engine and Propeller Standards Branch, Policy and Innovation Division.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will 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 that this AD:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Is not a “significant rule” under 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.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends part 39 of the Federal Aviation Regulations (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) 2018-11-16, Amendment 39-19304 (83 FR 27891, June 15, 2018) and adding the following new AD:

2019-03-04 Engine Alliance: Amendment 39-19556; Docket No. FAA-2019-0048; Product Identifier 2018-NE-19-AD.

(a) Effective Date

This AD is effective March 6, 2019.

(b) Affected ADs

This AD replaces AD 2018-11-16, Amendment 39-19304 (83 FR 27891, June 15, 2018).

(c) Applicability

This AD applies to Engine Alliance (EA) GP7270 and GP7277 model turbofan engines with engine fan hub assembly, part number (P/N) 5760221 or P/N 5760321, installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 7230, Turbine Engine Compressor Section.

(e) Unsafe Condition

This AD was prompted by the FAA's determination that inspections need to be expanded to all EA GP7270 and GP7277 turbofan engines. We are issuing this AD to detect defects, damage, and cracks that could result in an uncontained failure of the engine fan hub assembly. The unsafe condition, if not addressed, could result in uncontained failure of the engine fan hub assembly, damage to the engine, and damage to the airplane.

(f) Compliance

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

(g) Required Actions

Within 3,000 cycles since new after the effective date of this AD, or by August 15, 2019, whichever is later:

(1) For engine fan hubs at the low-pressure compressor (LPC) module assembly level:

(i) Perform a visual inspection of the engine fan hub assembly, in accordance with the Accomplishment Instructions, For Fan Hubs at LPC Module Assembly Level, paragraphs 1.A.(1), 1.A.(4), and 1.A.(6)(a), of EA ASB EAGP7-A72-389, Revision No. 3, dated October 18, 2018.

(ii) Perform an eddy current inspection (ECI) of the engine fan hub blade slot bottoms and front edges, in accordance with the Accomplishment Instructions, For Fan Hubs at LPC Module Assembly Level, paragraphs 2.A and 2.B, of EA ASB EAGP7-A72-389, Revision No. 3, dated October 18, 2018.

(2) For engine fan hub assemblies at the piece part level:

(i) Perform a visual inspection of the engine fan hub assembly, in accordance with the Accomplishment Instructions, For Fan Hubs at Piece Part Level, paragraphs 1.A.(1) and 1.A.(3), of EA ASB EAGP7-A72-389, Revision No. 3, dated October 18, 2018.

(ii) Perform an ECI of the engine fan hub blade slot bottoms and front edges, in accordance with the Accomplishment Instructions, For Fan Hubs at Piece Part Level, paragraphs 2.A and 2.B, of EA ASB EAGP7-A72-389, Revision No. 3, dated October 18, 2018.

(3) For engine fan hub assemblies installed in an engine (on-wing or off-wing):

(i) Perform a visual inspection of the engine fan hub assembly, in accordance with the Accomplishment Instructions, For Fan Hubs Installed in an Engine, paragraphs 1.C.(1), 1.C.(5), and 1.C.(7)(a), of EA ASB EAGP7-A72-389, Revision No. 3, dated October 18, 2018.

(ii) Perform an ECI of the engine fan hub blade slot bottoms and front edges, in accordance with the Accomplishment Instructions, For Fan Hubs Installed in an Engine, paragraphs 1.D.(1) and 1.D.(2), of EA ASB EAGP7-A72-389, Revision No. 3, dated October 18, 2018.

(4) If the engine fan hub assembly visual inspection reveals defects or damage to the

engine fan hub assembly that are found outside the serviceable limits specified in Table 6 in the Accomplishment Instructions of EA ASB EAGP7-A72-389, Revision No. 3, dated October 18, 2018, remove the engine fan hub assembly from service and replace with a part that is eligible for installation, before further flight.

(5) If the engine fan hub assembly ECI results in a rejectable indication, per the Appendix, Added Data, of EA ASB EAGP7-A72-389, Revision No. 3, dated October 18, 2018, remove the engine fan hub assembly from service and replace with a part that is eligible for installation, before further flight.

(h) Credit for Previous Actions

You may take credit for the inspection required by paragraph (g) of this AD if you performed the inspection before the effective date of this AD, using EA ASB EAGP7-A72-389, Original Issue, dated December 19, 2017; EA ASB EAGP7-A72-389, Revision No. 1, dated January 19, 2018; or EA ASB EAGP7-A72-389, Revision No. 2, dated April 17, 2018.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO 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) of this AD. You may email your request to: ANE-AD-AMOC@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) AMOCs approved for AD 2018-11-16 (83 FR 27891, June 15, 2018) are approved as AMOCs for the corresponding provisions of this AD.

(j) Related Information

For more information about this AD, contact Matthew Smith, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA, 01803; phone: 781-238-7735; fax: 781-238-7199; email: matthew.c.smith@faa.gov.

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Engine Alliance (EA) Alert Service Bulletin EAGP7-A72-389, Revision No. 3, dated October 18, 2018.

(ii) [Reserved]

(3) For EA service information identified in this AD, contact Engine Alliance, 411 Silver Lane, East Hartford, CT, 06118; phone: 800-565-0140; email: help24@pw.utc.com; website: www.engineallianceportal.com.

(4) You may view this service information at FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA, 01803. For information on the availability of this material at the FAA, call 781-238-7759.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Burlington, Massachusetts, on February 12, 2019.

Robert J. Ganley,

Manager, Engine & Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2019-02654 Filed 2-15-19; 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-2016-N-3464]

RIN 0910-AH29

List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing a final rule to establish criteria for and identify an initial list of bulk drug substances that can be used to compound drug products in accordance with certain compounding provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), although they are neither the subject of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph nor components of FDA-approved drugs. Specifically, the Agency is placing six bulk drug substances on the list. This final rule also identifies four bulk drug substances that FDA has considered and is not including on the list. Additional bulk drug substances nominated by the public for inclusion on this list are currently under consideration and will be the subject of a future rulemaking.

DATES: This rule is effective March 21, 2019.

ADDRESSES: For access to the docket to read background documents or