

(e) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(f) Required Actions

(1) Before further flight, and thereafter at intervals not to exceed 100 hours time-in-service, visually inspect the flange in the ribbed area for cracks using a 5-power or higher magnifying glass in accordance with paragraphs 2.A.1 and 2.A.2 of the Accomplishment Instructions in Airbus Helicopters Alert Service Bulletin No. ASB-MBB-BK 117-10-114, Revision 1, dated July 28, 2017.

(2) If a crack is found as a result of the inspections specified in paragraph (f)(1) of this AD, remove the cracked M/R mast and replace it with an airworthy M/R mast.

(g) Credit for Previous Actions

Actions accomplished before the effective date of this AD in accordance with the procedures specified in AD 97-26-03, Amendment 39-10246 (62 FR 65750, December 16, 1997), are acceptable for compliance with the corresponding actions specified in paragraphs (f)(1) and (f)(2) of this AD.

(h) Special Flight Permit

A special flight permit will not be permitted.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Section, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: 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 9-ASW-FTW-AMOC-Requests@faa.gov.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(j) Additional Information

(1) Airbus Helicopters Alert Service Bulletin No. ASB MBB-BK 117-10-114, dated August 27, 1997, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone (972) 641-0000 or (800) 232-0323; fax (972) 641-3775; or at http://www.helicopters.airbus.com/website/en/ref/Technical-Support_73.html. You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD

No. 2017-0193, dated September 29, 2017. You may view the EASA AD on the internet at <http://www.regulations.gov> in Docket No. FAA-2017-1126.

(k) Subject

Joint Aircraft Service Component (JASC) Code: 6300, Main Rotor Drive System.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference 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) Airbus Helicopters Alert Service Bulletin No. ASB MBB-BK117-10-114, Revision 1, dated July 28, 2017.

(ii) [Reserved]

(3) For Airbus Helicopters service information identified in this AD, contact Airbus Helicopters, 2701 N Forum Drive, Grand Prairie, TX 75052; telephone (972) 641-0000 or (800) 232-0323; fax (972) 641-3775; or at http://www.helicopters.airbus.com/website/en/ref/Technical-Support_73.html.

(4) You may view this service information at FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N-321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222-5110.

(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 Fort Worth, Texas, on March 1, 2019.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2019-04530 Filed 3-12-19; 8:45 am]

BILLING CODE 4910-13-P

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

[Docket No. FAA-2019-0092; Product Identifier 2019-SW-022-AD; Amendment 39-19585; AD 2019-05-03]

RIN 2120-AA64

Airworthiness Directives; Leonardo S.p.A. Helicopters

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

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for

Leonardo S.p.A. Model AB139, AW139, AW169, and AW189 helicopters. This AD requires removing certain part-numbered and serial-numbered tail rotor (T/R) duplex bearings from service. This AD is prompted by a report of a failed T/R duplex bearing roughness inspection. The actions of this AD are intended to address an unsafe condition on these products.

DATES: This AD becomes effective March 28, 2019.

We must receive comments on this AD by May 13, 2019.

ADDRESSES: You may send comments by any of the following methods:

- **Federal eRulemaking Docket:** Go to <http://www.regulations.gov>. Follow the online instructions for sending your comments electronically.

- **Fax:** 202-493-2251.

- **Mail:** Send comments to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE, Washington, DC 20590-0001.

- **Hand Delivery:** Deliver to the "Mail" address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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-2019-0092; 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 AD, the European Aviation Safety Agency (EASA) AD, the economic 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 service information identified in this final rule, contact Leonardo S.p.A. Helicopters, Matteo Ragazzi, Head of Airworthiness, Viale G. Agusta 520, 21017 C. Costa di Samarate (Va) Italy; telephone +39-0331-711756; fax +39-0331-229046; or at <http://www.leonardocompany.com/-/bulletins>. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N-321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT:

David Hatfield, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5110; email david.hatfield@faa.gov.

SUPPLEMENTARY INFORMATION:**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 prior to it becoming effective. However, we invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that resulted from adopting this AD. The most helpful comments reference a specific portion of the AD, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit them only one time. We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this rulemaking during the comment period. We will consider all the comments we receive and may conduct additional rulemaking based on those comments.

Discussion

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD No. 2019-0022, dated February 1, 2019, and corrected February 4, 2019, to correct an unsafe condition for Leonardo S.p.A. (formerly Finmeccanica S.p.A., AgustaWestland S.p.A., Agusta S.p.A.) Model AB139, AW139, AW169, and AW189 helicopters. EASA advises of a report of a failed T/R duplex bearing roughness inspection. Investigation revealed that one of the bearing balls installed in the T/R duplex bearing did not conform to design and that a batch of T/R duplex bearings has been identified that may be affected by the same nonconformity. Information issued by Leonardo Helicopters advises that the defective T/R duplex bearings may prematurely degrade and result in excessive drive torque and loss of tail rotor control under certain circumstances.

EASA states that this condition, if not corrected, could result in loss of control of the helicopter. Accordingly, the EASA AD requires removing from service certain serial-numbered T/R duplex bearings with part number (P/N) 3G6430V00153 installed on Model AB139 and AW139 helicopters and certain serial-numbered T/R duplex bearings with P/N 4F6430V00551 installed on Model AW169 and AW189

helicopters. The EASA AD also requires returning any affected T/R duplex bearings to Leonardo Helicopters and prohibits installing the affected T/R duplex bearings on any helicopter. Depending on your model helicopter, the EASA AD also requires immediately providing to Leonardo Helicopters photos of the removed affected T/R duplex bearings and any grease leaked from the T/R duplex bearing.

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to our bilateral agreement with the European Union, EASA has notified us of the unsafe condition described in the EASA AD. We are issuing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs.

Related Service Information

We reviewed Leonardo Helicopters Service Bulletin (SB) Alert No. 139-571, Leonardo Helicopters SB Alert No. 169-134, and Leonardo Helicopters SB Alert No. 189-221, each dated February 1, 2019. This service information contains procedures to replace T/R duplex bearing P/N 3G6430V00153 and P/N 4F6430V00551 with certain serial numbers and instructions to return all affected T/R duplex bearings to Leonardo Helicopters. Depending on your model helicopter, the service information also specifies emailing photos of removed affected T/R duplex bearings to Leonardo Helicopters and returning leaked T/R duplex bearing grease to Leonardo Helicopters.

AD Requirements

This AD requires removing certain serial-numbered T/R duplex bearing P/N 3G6430V00153 installed on Model AB139 and AW139 helicopters and certain serial-numbered T/R duplex bearing P/N 4F6430V00551 installed on Model AW169 and AW189 helicopters from service. This AD also prohibits the installation of the affected T/R duplex bearings.

Differences Between This AD and the EASA AD

The EASA AD requires returning any affected T/R duplex bearing to Leonardo Helicopters. Depending on your model helicopter, the EASA AD also requires emailing photos of removed affected T/R duplex bearings to Leonardo Helicopters and returning leaked T/R duplex bearing grease to Leonardo

Helicopters. This AD does not require any of those actions.

Costs of Compliance

We estimate that this AD affects 130 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this AD. Labor costs are estimated at \$85 per work-hour.

Replacing an affected T/R duplex bearing takes about 2 work-hours and parts cost about \$1,500. Based on these numbers, we estimate a total cost of \$1,670 per helicopter and \$217,100 for the U.S. fleet, assuming every helicopter in the fleet has an affected bearing installed.

According to Leonardo Helicopter's service information, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage by Leonardo Helicopters. Accordingly, we have included all costs in our cost estimate.

FAA's Justification and Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD without providing an opportunity for public comments prior to adoption. The FAA has found that the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because it requires removal of affected T/R duplex bearings within 30 hours time-in-service and further prohibits installation of those T/R duplex bearings. Therefore, we find good cause that notice and opportunity for prior public comment are impracticable. In addition, for the reasons stated above, we find that good cause exists for making this amendment effective in less than 30 days.

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 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, 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.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

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 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):

2019-05-03 Leonardo S.p.A.: Amendment 39-19585; Docket No. FAA-2019-0092; Product Identifier 2019-SW-022-AD.

(a) Applicability

This AD applies to the following helicopters, certificated in any category:

(1) Model AB139 and AW139 helicopters with a tail rotor (T/R) duplex bearing part number (P/N) 3G6430V00153, and serial number (S/N) 16181 through 16225, S/N 16237 through 16259, S/N 17101 through 17110, S/N 17182 through 17194, S/N 17204 through 17217, and S/N 17251 through S/N 17260; and

(2) Model AW169 and AW189 helicopters with a T/R duplex bearing P/N

4F6430V00551, and S/N 16165 through 16169, S/N 16171, and S/N 17101 through 17121.

(b) Unsafe Condition

This AD defines the unsafe condition as failure of a T/R duplex bearing ball. This condition could result in premature degradation of the T/R duplex bearing, loss of T/R control, and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective March 28, 2019.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) Within 30 hours time-in-service, remove from service any T/R duplex bearing with a P/N and S/N listed in paragraphs (a)(1) or (a)(2) of this AD.

(2) After the effective date of this AD, do not install a T/R duplex bearing with a P/N and S/N listed in paragraphs (a)(1) or (a)(2) of this AD on any helicopter.

(f) Special Flight Permits

Special flight permits are prohibited.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Section, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: David Hatfield, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222-5110; email 9-ASW-FTW-AMOC-Requests@faa.gov.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(h) Additional Information

(1) Leonardo Helicopters Service Bulletin (SB) Alert No. 139-571, Leonardo Helicopters SB Alert No. 169-134, and Leonardo Helicopters SB Alert No. 189-221, each dated February 1, 2019, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact Leonardo S.p.A. Helicopters, Matteo Ragazzi, Head of Airworthiness, Viale G. Agusta 520, 21017 C. Costa di Samarate (Va) Italy; telephone +39-0331-711756; fax +39-0331-229046; or at <http://www.leonardocompany.com/-/bulletins>. You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N-321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. No. 2019-0022, dated February 1, 2019,

and corrected February 4, 2019. You may view the EASA AD on the internet at <http://www.regulations.gov> by searching for and locating it in Docket No. FAA-2019-0092.

(i) Subject

Joint Aircraft Service Component (JASC) Code: 6400, Tail Rotor System.

Issued in Fort Worth, Texas, on March 6, 2019.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2019-04529 Filed 3-12-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 526, 529, 556, and 558

[Docket No. FDA-2018-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Changes of Sponsorship

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during July, August, and September 2018. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to make technical amendments to improve the readability of the regulations.

DATES: This rule is effective March 13, 2019, except for amendatory instruction 25 to 21 CFR 520.2041, which is effective March 25, 2019.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July, August, and September 2018, as listed