Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–3781; Directorate Identifier 2015–SW–048–AD]

RIN 2120–AA64

Airworthiness Directives; Agusta S.p.A. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for Agusta S.p.A. (Agusta) Model A109A, A109A II, A109C, A109E, A109K2, A109S and AW109SP helicopters. This proposed AD would require visually inspecting the tail rotor drive shaft assembly (drive shaft) for a crack. This proposed AD is prompted by the discovery of three cracks on the drive shaft of a Model A109S helicopter. The proposed actions are intended to detect a crack on the drive shaft to prevent failure of the driveshaft, failure of the tail rotor, and subsequent loss of helicopter control.

DATES: We must receive comments on this proposed AD by May 23, 2016.

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–2015–3781; or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the European Aviation Safety Agency (EASA) AD, the economic 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 service information identified in this proposed rule, contact AgustaWestland, Product Support Engineering, Via del Gregge, 100, 21015 Lonate Pozzolo (VA) Italy, ATTN: Maurizio D'Angelo; telephone 39–0331–664757; fax 39–0331–664680; or at *http://www.agustawestland.com/technical-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: Martin R. Crane, Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *martin.r.crane@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

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 might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, 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 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 proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

EASA, which is the aviation authority for Italy, has issued AD No. 2015–0054, dated March 27, 2015, to correct an unsafe condition for Model A109A with retrofit kit part number 109–0820–27–101 installed, and Model A109A II, A109C, A109E, A109K2, A109LUH, A109S, and AW109SP helicopters.

EASA advises that during scheduled maintenance on a Model A109S helicopter, three cracks were found on the drive shaft. An investigation could not determine the cause of the cracking but concluded it could not have been caused by fatigue. This condition, if not detected and corrected, could lead to tail rotor failure, possibly resulting in loss of helicopter control, EASA advises. EASA AD No. 2015–0054 consequently requires a one-time inspection of the drive shaft, and replacing the drive shaft if cracks are found.

FAA's Determination

These helicopters have been approved by the aviation authority of Italy and are approved for operation in the United States. Pursuant to our bilateral agreement with Italy, EASA, its technical representative, has notified us of the unsafe condition described in its AD. We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other products of the same type design.

Related Service Information Under 1 CFR Part 51

We reviewed AgustaWestland Bollettino Tecnico (BT) No. 109–147 for Model A109A helicopters with retrofit kit P/N 109–0820–27–101 installed, Model A109A II, and Model A109C helicopters; BT No. 109EP–143 for Model A109E helicopters; BT No. 109K–68 for Model A109K2 helicopters; BT No. 109S–067 for Model A109S

helicopters; and BT No. 109SP–094 for Model AW109SP helicopters. All of the BTs are dated March 25, 2015. AgustaWestland reports that during a scheduled servicing of an A109S helicopter, three cracks were found on drive shaft P/N 109–8412–02–1. The BTs prescribe a one-time drive shaft inspection for cracks.

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.

Proposed AD Requirements

This proposed AD would require, within 50 hours time-in-service, visually inspecting the drive shaft for a crack and replacing the drive shaft if it is cracked.

Differences Between This Proposed AD and the EASA AD

The EASA AD applies to Agusta Model A109LUH helicopters. This proposed AD would not because that model does not have an FAA type certificate.

Interim Action

We consider this proposed AD to be an interim action. The design approval holder has not determined the cause of the unsafe condition identified in this proposed AD. If a cause is determined and actions developed to address the cause, we might consider additional rulemaking.

Costs of Compliance

We estimate that this proposed AD would affect 142 helicopters of U.S. Registry and that labor costs average $85 per work-hour. Based on these estimates, we expect the following costs:

• Inspecting the drive shaft would require 9 work-hours and no parts. The estimated cost would be $765 per helicopter and $108,630 for the U.S. fleet.

• Replacing the drive shaft would not require additional labor hours. Parts would cost $6,082 per helicopter.

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

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, 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 to the extent that it justifies making a regulatory distinction; 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 proposed 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.

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):

Agusta S.p.A.: Docket No. FAA–2015–3781; Directorate Identifier 2015–SW–048–AD.

(a) Applicability

This AD applies to Agusta S.p.A. Model A109A, A109A II, A109C, A109E, A109K2, A109S, and AW109SP helicopters with a tail rotor drive shaft assembly (drive shaft), part number 109–8412–02–1 or 109–8412–02–3, installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a crack in a drive shaft. This condition could result in failure of a drive shaft, failure of the tail rotor, and subsequent loss of helicopter control.

(c) Comments Due Date

We must receive comments by May 23, 2016.

(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

Within 50 hours time-in-service:

(1) Visually inspect each drive shaft in accordance with the Compliance Instructions, paragraph 4, of AgustaWestland Bollettino Tecnico (BT) No. 109–147, dated March 25, 2015; BT No. 109EP–143, dated March 25, 2015; BT No. 109K–68, dated March 25, 2015; BT No. 109S–067, dated March 25, 2015; or BT No. 109SP–094, dated March 25, 2015, as applicable for your model helicopter.

(2) If there is a crack, replace the drive shaft before further flight.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Martin R. Crane, Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, 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.

(g) Additional Information

The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2015–0054, dated March 27, 2015. You may view the EASA AD on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2015–3781.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 6510, Tail Rotor Drive Shaft.

Issued in Fort Worth, Texas, on March 15, 2016.

Scott A. Horn,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2016–06373 Filed 3–21–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 73 and 74

[Docket No. FDA–2016–F–0821]

Milton W. Chu, M.D.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Milton W. Chu, M.D., proposing that the color additive regulations be amended to provide for the safe use of titanium dioxide and [phthalocyaninato (2-)] copper as orientation marks for intraocular lenses.

DATES: The color additive petition was filed on February 19, 2016.

FOR FURTHER INFORMATION CONTACT: Laura Dye, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1275.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 6C0305), submitted by Milton W. Chu, M.D., 5800 Santa Rosa Rd., Suite 111, Camarillo, CA 93012. The petition proposes to amend the color additive regulations in § 73.3126 *Titanium dioxide* (21 CFR 73.3126) and § 74.3045 *[Phthalocyaninato (2-)] copper* (21 CFR 74.3045) to provide for the safe use of titanium dioxide and [phthalocyaninato (2-)] copper as orientation marks for intraocular lenses.

We have determined under 21 CFR 25.32(l) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: March 17, 2016.

Dennis M. Keefe,

Director, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition.

[FR Doc. 2016–06397 Filed 3–21–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 878, 880, and 895

[Docket No. FDA–2015–N–5017]

RIN 0910–AH02

Banned Devices; Proposal To Ban Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling. Consequently, FDA is proposing these devices be banned.

DATES: Submit either electronic or written comments by June 20, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–N–5017 for ''Banned Devices; Proposal to Ban Powdered Surgeon's Gloves, Powdered Patient Examination Gloves, and Absorbable Powder for Lubricating a Surgeon's Glove.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of