numbers 0001 through 1670; and R44 II helicopters, serial numbers 10001 through 11570, certificated in any category.

Compliance

Required as indicated.

To detect main rotor blade (blade) skin debond and prevent blade failure and subsequent loss of control of the helicopter, do the following:

(a) Within 10 hours time-in-service (TIS), unless accomplished previously:

(1) Using a 10x or higher magnification, visually inspect for skin separation along the leading edge of any exposed (bare metal) blade skin aft of the skin-to-spar bond line on the lower surface of each blade. If there is any skin separation, the blade is unairworthy.

(2) Perform a ''tap test'' to detect any separation or void on the skin-to-spar bonded areas on the lower blade skin aft of the skin-to-spar bond line of each blade using a 1965 or later U.S. quarter-dollar coin. If there is any separation or any void, the blade is unairworthy.

(3) Remove both blade tip covers. Using a 10x or higher magnification, visually inspect the blade tip area exposed when the blade tip covers were removed. ''Tap test'' the skin to cap bond joints on both upper and lower surfaces. If corrosion, separation, or any void is detected, the blade is unairworthy.

(4) Repaint any exposed area of the blade according to the Compliance Procedure, paragraphs 3 through 7, of R22 Service Letter SL–56 and R44 Service Letter SL–32, Revision A, dated March 29, 2007.

(b) Before further flight, replace any unairworthy blade with an airworthy blade.

(c) Thereafter, if the rotor blade has been found airworthy by the inspections in paragraph (a), before each flight, visually check for any exposed (bare metal) skin-to-spar bonded area on the lower surface of each blade within the outboard 24 inches paying particular attention to the last 10 inches before the tip. An owner/operator (pilot) holding at least a private pilot certificate may perform this visual check and must enter compliance into the aircraft maintenance records in accordance with 14 CFR 43.11 and 91.417(a)(2)(V). If a pilot finds any area of skin bare metal in the outboard 24 inches of either blade, before further flight, a qualified mechanic must comply with the requirements of paragraph (a) of this AD.

(d) To request a different method of compliance or a different compliance time for this AD, follow the procedures in 14 CFR 39.19. Contact the Manager, Los Angeles Aircraft Certification Office, FAA, *ATTN:* (For R22) Eric Schrieber, Aviation Safety Engineer, Aircraft Certification Office, Airframe Branch, 3960 Paramount Blvd., Lakewood, California 90712, telephone (562) 627–5348, fax (562) 627–5210, or (for R44) Fred Guerin, Aviation Safety Engineer, Airframe Branch, 3960 Paramount Blvd., Lakewood, California 90712, telephone (562) 627–5232, fax (562) 627–5210, for information about previously approved alternative methods of compliance.

(e) Repaint the exposed area of a blade by following Robinson R22 Service Letter SL–56 and R44 Service Letter SL–32, Revision A, dated March 29, 2007. The Director of the Federal Register approved this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Robinson Helicopter Company, 2901 Airport Drive. Torrance, CA 90505, telephone (310) 539–0508, fax (310) 539–5198. Copies may be inspected at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas or 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/code_of_federal_regulations/ibr_locations.html.*

(f) This amendment becomes effective on January 18, 2008.

Issued in Fort Worth, Texas, on December 17, 2007.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. E7–25395 Filed 1–2–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2007–28843 Directorate Identifier 2007–CE–065–AD; Amendment 39–15317; AD 2007–26–25]

RIN 2120–AA64

Airworthiness Directives; DG Flugzeugbau GmbH Model DG–500MB Gliders

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for the products listed above. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

In some cases the electric motor of the spindle drive detached itself from the spindle drive, causing the powerplant to retract itself after engine shutdown. In another case the attachment fork on the spindle drive failed with the same consequences.

We are issuing this AD to require actions to correct the unsafe condition on these products.

DATES: This AD becomes effective February 7, 2008.

On February 7, 2008, the Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov* or in person at Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Greg Davison, Glider Program Manager, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; *telephone:* (816) 329–4130; *fax:* (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to the specified products. That NPRM was published in the **Federal Register** on August 20, 2007 (72 FR 46411). That NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

In some cases the electric motor of the spindle drive detached itself from the spindle drive, causing the powerplant to retract itself after engine shutdown. In another case the attachment fork on the spindle drive failed with the same consequences.

The MCAI requires you to modify the affected parts and exchange pages in the flight, maintenance, and repair manuals.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

The FAA reviewed the proposed requirement of the NPRM to exchange pages in the flight, maintenance, and repair manuals. We have determined that the exchange of certain pages in the flight, maintenance, and repair manuals is outside the scope of what is needed to correct the unsafe condition for aircraft of U.S. registry.

Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting the AD as proposed, except for eliminating the need to exchange manual pages.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use

different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have required different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the AD.

Costs of Compliance

We estimate that this AD will affect 5 products of U.S. registry. We also estimate that it will take about 5 work-hours per product to comply with basic requirements of this AD. The average labor rate is $80 per work-hour. Required parts will cost about $422 per product.

Based on these figures, we estimate the cost of this AD to the U.S. operators to be $4,110 or $822 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 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 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); and

(3) 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 a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD Docket.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* 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 the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

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 AD:

2007–26–25 DG Flugzeugbau GmbH: Amendment 39–15317; Docket No. FAA–2007–28843; Directorate Identifier 2007–CE–065–AD.

Effective Date

(a) This airworthiness directive (AD) becomes effective February 7, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Model DG–500MB gliders, all serial numbers, certificated in any category.

Subject

(d) Air Transport Association of America (ATA) Code 24: Electric Power.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

In some cases the electric motor of the spindle drive detached itself from the spindle drive, causing the powerplant to retract itself after engine shutdown. In another case the attachment fork on the spindle drive failed with the same consequences.

The MCAI requires you to modify the affected parts and exchange pages in the flight, maintenance, and repair manuals.

Actions and Compliance

(f) Unless already done, within 90 days after February 7, 2008 (the effective date of this AD):

(1) Secure the connection between the spindle drive ''Stross BSA10'' and the spindle drive motor following DG Flugzeugbau GmbH Working instruction No. 1, dated January 23, 2006, as referenced in DG Flugzeugbau GmbH Technical Note No. 843–24, dated January 31, 2006.

(2) Replace the fork 8M233/1 from the spindle drive with the strengthened fork 8M233''f''; replace the bearing support with the modified support 8M229''e''; and secure the spindle drive fork between the spindle drive ''Stross BSA10'' and the spindle drive motor following DG Flugzeugbau GmbH Working instruction No. 2, dated January 30, 2006, as referenced in DG Flugzeugbau GmbH Technical Note No. 843–24, dated January 31, 2006; DG Flugzeugbau GmbH Drawing 5M210, Spindle drive Stross BSA 10 assembly, issued: January 22, 2003, revised: May 19, 2006; and DG Flugzeugbau GmbH Drawing 5M211, Spindle drive Stross BSA 10 assembly with strengthened fork 8M233''f'', issued: January 23, 2006.

Note 1: We recommend that you insert and update the new Flight Manual pages 0.1, 0.3, 0.4, 2.8, 3.7, 3.8, 4.1, 4.25, 4.26; the new Maintenance Manual pages 1, 2, 3, 4, 5, 42, 49, 68, 89, 89a, 93, and Enclosure 1; and the new Repair Manual pages 1, 2, 7, and 8 following DG Flugzeugbau GmbH Technical Note No. 843–24, dated January 31, 2006.

FAA AD Differences

Note 2: This AD differs from the MCAI and/or service information as follows:

(1) The service information specifies a one-time inspection of the fork and requires replacement if cracks are found. This AD requires mandatory replacement of these parts with redesigned parts. The FAA believes mandatory replacement rather than inspection will prevent failure of these parts in the future.

(2) The MCAI requires, for gliders certificated for operation in Germany, to have the pages in the flight, maintenance, and repair manuals exchanged.We have determined that the exchange of these pages is outside the scope of what is needed to correct the unsafe condition for gliders certificated for operation in the United States.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, 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: Greg Davison, Glider Program

Manager, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; *telephone:* (816) 329–4130; *fax:* (816) 329–4090. 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) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI Federal Republic of Germany Luftfahrt-Bundesamt AD D–2006–060, dated March 6, 2006; and DG Flugzeugbau GmbH Technical Note No. 843–24, dated January 31, 2006.

Material Incorporated by Reference

(i) You must use DG Flugzeugbau GmbH Technical Note No. 843–24, dated January 31, 2006; DG Flugzeugbau GmbH Working instruction No. 1, dated January 23, 2006; DG Flugzeugbau GmbH Working instruction No. 2, dated January 30, 2006; DG Flugzeugbau GmbH Drawing 5M210, Spindle drive Stross BSA 10 assembly, revised May 19, 2006; and DG Flugzeugbau GmbH Drawing 5M211, Spindle drive Stross BSA 10 assembly with strengthened fork 8M233''f'', dated January 23, 2006, to do the actions required by this AD, unless the AD specifies otherwise.

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

(2) For service information identified in this AD, contact DG Flugzeugbau GmbH, Im Schollengarten 20, D–76646 Bruchsal 4, Federal Republic of Germany.

(3) You may review copies at the FAA, Central Region, Office of the Regional Counsel, 901 Locust, Room 506, Kansas City, Missouri 64106; or 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 Kansas City, Missouri, on December 20, 2007.

John R. Colomy,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–25212 Filed 1–2–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 208, and 209

[Docket No. 2003N–0342]

RIN 0910–AC35

Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim final rule to codify the provisions of the proposed rule entitled ''Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products'' (69 FR 21778, April 22, 2004) (the toll-free number proposed rule or proposed rule) that, under the Food and Drug Administration Amendments Act of 2007 (FDAAA), became effective by operation of law on January 1, 2008. This interim final rule requires the addition of a statement on the labeling of certain human drug products for which an application is approved under the Federal Food, Drug, and Cosmetic Act (the act). The added statement includes a toll-free number and advises that the number is to be used only for reporting side effects and is not intended for medical advice (the side effects statement). As mandated by FDAAA, this interim final rule does not apply to over-the-counter drug products approved as new drugs under the act if the product packaging includes a manufacturer's or distributor's toll-free number for reporting complaints.

DATES: *Effective Date*: This rule is effective January 1, 2008.

Compliance Date: The agency anticipates that affected entities, including manufacturers, authorized dispensers, and pharmacies, will need time to update labeling and systems to comply with the new requirements. Therefore, FDA intends to exercise its enforcement discretion and not take enforcement actions with regard to these regulations until January 1, 2009.

FOR FURTHER INFORMATION CONTACT: Carol Drew, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2007, the President signed into law FDAAA (Public Law 110–85). Among other things, FDAAA reauthorized the Best Pharmaceuticals for Children Act (BPCA). When enacted in 2001, the BPCA (Public Law 107–109) directed FDA to issue a final rule requiring the labeling of each human drug product for which an application is approved under section 505 of the act (21 U.S.C. 355) to include: (1) A toll-free number maintained by FDA for the purpose of receiving reports of adverse events regarding drugs and (2) a statement that the number is to be used for reporting purposes only, not to receive medical advice. Collectively, we refer to the toll-free number and reporting statement as the ''side effects statement.'' The BPCA stated that the final rule must reach the broadest consumer audience and minimize the cost to the pharmacy profession.

As required, FDA issued a proposed rule entitled ''Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products'' (69 FR 21778, April 22, 2004). FDA received 22 comments on this proposed rule and was in the process of analyzing the comments and conducting research on consumer comprehension of the side effects statement when FDAAA was enacted (see section IV of this document).

II. FDAAA Requirements

Section 502(f) of FDAAA states that ''the proposed rule * * * 'Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products' * * * shall take effect on January 1, 2008,'' unless FDA issues a final rule before that date.

FDAAA mandates one change to the proposed rule. As described in section III of this document, section 502(f)(2) of FDAAA states that the toll-free number proposed rule shall not apply to over-the-counter (OTC) drugs marketed with an application approved under section 505 of the act (application OTC drug products) if these application OTC drug products meet certain labeling requirements. (Neither the BPCA, the proposed rule, nor this interim final rule addresses OTC drugs marketed *without* approved applications.)

Because the agency's rulemaking process is ongoing, for the reasons explained in section IV of this document, this interim rule codifies the provisions of the proposed rule as modified by FDAAA. As mandated by FDAAA, these provisions came into effect on January 1, 2008. The agency is publishing this interim final rule to codify the modified toll-free number proposed rule that has now come into effect.