

were repaired using repair procedures TV5415R or HRS3491, within 900 FH after the effective date of this AD, inspect for the condition of the ice-impact panels and blue fillers on the engine. Use 3.B.(1) through 3.D.(1)(a) of the Accomplishment Instructions of RRD SB No. TAY-72-1631, dated February 6, 2004.

**Installing Engines That Are Not Inspected**

(k) After the effective date of this AD, do not install any TAY 620-15, TAY 650-15, or TAY 651-54 engine with ice-impact panels, if those ice-impact panels incorporate RR SB No. TAY-72-1326 or were repaired using repair procedures TV5415R or HRS3491, unless the panels and blue fillers are inspected for condition using 3.B.(1) through 3.D.(2) (in-service) or 3.H.(1) through 3.K.(1)(b) (at overhaul or shop visit) of the Accomplishment Instructions of RRD SB No.

TAY-72-1627, Revision 2, dated February 5, 2004.

(l) After the effective date of this AD, do not install any TAY 611-8 engine with ice-impact panels, if those ice-impact panels incorporate RR SB No. TAY-72-1326 or were repaired using repair procedures TV5415R or HRS3491, unless the panels are inspected for condition using 3.B.(1) through 3.D.(1)(a) (in-service) or 3.H.(1) through 3.K.(1) (at overhaul or shop visit) of the Accomplishment Instructions of RRD SB No. TAY-72-1631, dated February 6, 2004.

**Alternative Methods of Compliance**

(m) The Manager, Engine Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

**Material Incorporated by Reference**

(n) You must use the service information specified in Table 1 to perform the inspections required by this AD. The Director of the Federal Register approved the incorporation by reference of the documents listed in Table 1 of this AD in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You can get a copy from Rolls-Royce Deutschland Ltd & Co KG, Eschenweg 11, D-15827 Dahlewitz, Germany; telephone 49 (0) 33-7086-1768; fax 49 (0) 33-7086-3356. You may review copies at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. Table 1 follows:

TABLE 1.—INCORPORATION BY REFERENCE

Service bulletin No.	Page	Revision	Date
TAY-72-1627, Total Pages—22 .....	All .....	2 .....	February 5, 2004.
TAY-72-1631, Total Pages—19 .....	All .....	Original .....	February 6, 2004.

**Related Information**

(o) Luffahrt-Bundesamt airworthiness directive (AD) D-2004-055R1, dated January 24, 2004; and AD D-2004-090, dated February 12, 2004; also address the subject of this AD.

Issued in Burlington, Massachusetts, on March 3, 2004.

**Francis A. Favara,**

*Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.*

[FR Doc. 04-5263 Filed 3-9-04; 8:45 am]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION**

**Federal Aviation Administration**

**14 CFR Part 39**

[Docket No. 2002-SW-44-AD; Amendment 39-13518; AD 2004-05-23]

RIN 2120-AA64

**Airworthiness Directives; Eurocopter France Model AS350B, AS350BA, AS350B1, AS350B2, AS350B3, AS350C, AS350D, AS350D1, AS355E, AS355F, AS355F1, AS355F2, and AS355N Helicopters**

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment supersedes an existing airworthiness directive (AD) for the specified Eurocopter France (ECF) model helicopters that currently requires certain inspections of the main rotor swashplate bearing (bearing) and

plugging the nonrotating swashplate vent holes and barrel nut orifices. This amendment eliminates most of those AD actions, which are now included in the Airworthiness Limitations section of the maintenance manual, but retains the requirements for the inspections and lubrication of the main rotor swashplate. This amendment also clarifies that repetitive maintenance of the main rotor swashplate and bearing is required at intervals not to exceed 100 hours time-in-service (TIS). This amendment is prompted by the need to clarify the AD wording to avoid any misinterpretation of the required interval for inspecting and lubricating the main rotor swashplate and bearing. The actions specified by this AD are intended to prevent failure of the bearing and subsequent loss of control of the helicopter.

**DATES:** Effective April 14, 2004.

**FOR FURTHER INFORMATION CONTACT:** Gary Roach, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Regulations and Guidance Group, Fort Worth, Texas 76193-0111, telephone (817) 222-5130, fax (817) 222-5961.

**SUPPLEMENTARY INFORMATION:** A proposal to amend 14 CFR part 39 by superseding AD 89-21-01, Docket No. 89-ASW-53, Amendment 39-6562 (55 FR 12332, April 3, 1990), for the specified ECF model helicopters was published in the **Federal Register** on May 16, 2003 (68 FR 26552). AD 89-21-01 requires inspecting the bearing for play or binding, proper assembly and lubrication, and measuring the swashplate rotational torque. In

addition, that AD requires plugging the nonrotating swashplate vent holes and barrel nut orifices at specified hours TIS. The requirements of that AD are intended to prevent failure of the bearing, which could result in loss of control of the helicopter.

Since issuing that AD, an FAA inspector reports that the repetitive lubrication requirement in paragraph (c) of AD 89-21-01 requiring lubrication “within every 100 hours” additional time-in-service” is being misinterpreted by a certain operator to only require lubrication every 199 hours rather than the intended 100-hour interval. Therefore, the inspector recommends that AD 89-21-01 be rewritten to clearly state that lubrication of the bearings be required at intervals not to exceed 100 hours TIS. To remove any doubt as to the intended lubrication interval, we have made the suggested changes. The additional requirements contained in AD 89-21-01 for inspecting and servicing the main rotor swashplate are no longer necessary because they are contained currently in the mandatory Airworthiness Limitations section of the Eurocopter Master Servicing Recommendations (maintenance manual) for the Model AS 350, dated April 26, 2001, and for the Model AS 355, dated May 31, 2001.

Interested persons have been afforded an opportunity to participate in the making of this amendment. Due consideration has been given to the one comment received. The commenter suggests that current maintenance instructions are adequate and that no

change to the AD is necessary. The FAA concurs with the comment; however, this change to the AD is necessary to clarify the correct maintenance action.

After careful review of the available data, including the comment noted above, the FAA has determined that air safety and the public interest require adopting the rule as proposed except the labor rate is now estimated to be \$65 per work hour rather than \$60 as stated in the proposal. The FAA has determined that this change will only minimally increase the economic burden on any operator (\$60 per year per helicopter) and will not increase the scope of the AD.

The FAA estimates that this AD will affect 587 helicopters of U.S. registry and that it will take approximately 2 work hours per helicopter to accomplish at an average labor rate of \$65 per work hour. Based on these figures, we estimate the total cost impact of the AD on U.S. operators to be \$457,860.

The regulations adopted herein 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that this action (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. A final evaluation has been prepared for this action, and it is contained in the Rules Docket at the FAA, Office of the Regional Counsel, Southwest Region, 2601 Meacham Blvd., Room 663, Fort Worth, Texas.

#### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

#### Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration 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. Section 39.13 is amended by removing Amendment 39-6562 (55 FR 12332, April 3, 1990) and by adding a new airworthiness directive (AD), to read as follows:

#### 2004-05-23 Eurocopter France:

Amendment 39-13518, Docket No. 2002-SW-44-AD. Supersedes AD 89-21-01, Amendment 39-6562, Docket No. 89-ASW-53.

*Applicability:* Model AS350B, AS350BA, AS350B1, AS350B2, AS350B3, AS350C, AS350D, AS350D1, AS355E, AS355F, AS355F1, AS355F2, and AS355N helicopters, certificated in any category.

**Note 1:** This AD applies to each helicopter identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For helicopters that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

*Compliance:* Required as indicated, unless accomplished previously.

**Note 2:** The current Airworthiness Limitations sections of the Eurocopter AS 350 and AS 355 maintenance manuals contain requirements for inspecting and lubricating the main rotor swashplate at intervals not to exceed 100 hours time-in-service (TIS).

To prevent failure of the main rotor swashplate bearing and subsequent loss of control of the helicopter, accomplish the following:

(a) Within 10 hours time-in-service (TIS) and thereafter at intervals not to exceed 100 hours TIS, inspect and lubricate the main rotor swashplate.

**Note 3:** Eurocopter Master Servicing Recommendations, Airworthiness Limitations section, AS 350, dated April 26, 2001, and AS 355, dated May 31, 2001, pertain to the subject of this AD.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Safety Management Group, Rotorcraft Directorate, FAA. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, Safety Management Group.

**Note 4:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Safety Management Group.

(c) Special flight permits will not be issued.

(d) This amendment becomes effective on April 14, 2004.

Issued in Fort Worth, Texas, on March 2, 2004.

Scott A. Horn,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 04-5333 Filed 3-9-04; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 314

[Docket No. 2003N-0417]

#### Application of 30-Month Stays on Approval of Abbreviated New Drug Applications and Certain New Drug Applications Containing a Certification That a Patent Claiming the Drug Is Invalid or Will Not Be Infringed; Technical Amendment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule, technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is revoking certain sections of its regulation concerning 30-month stays of approval of abbreviated new drug applications (ANDAs) and certain new drug applications (NDAs) that contain a certification that a patent claiming the drug is invalid or will not be infringed. This action is taken in response to the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 signed December 8, 2003. Title XI, Access to Affordable Pharmaceuticals, contains provisions that supersede sections of the regulation. This action will result in the revocation of 21 CFR 314.52(a)(3) and 21 CFR 314.95(a)(3).

**DATES:** This rule is effective March 10, 2004.

**FOR FURTHER INFORMATION CONTACT:** Jarilyn Dupont, Office of Policy and Planning (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360.

#### SUPPLEMENTARY INFORMATION:

##### 1. Background

In the *Federal Register* of June 18, 2003 (68 FR 36676), we (FDA) issued a final rule that amended our patent submission and listing requirements. The final rule revised the regulations regarding the effective date of approval for ANDAs and certain other NDAs,