

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,

known as 505(b)(2) applications, submitted under the Federal Food, Drug, and Cosmetic Act (the act). In certain situations, Federal law bars FDA from making the approval of certain ANDAs and 505(b)(2) applications effective for 30 months if the applicant has certified that a patent claiming the drug is invalid or will not be infringed and the patent owner or NDA holder then sues the applicant for patent infringement. The final rule stated that there was only one opportunity for a 30-month stay of the approval date of each ANDA and 505(b)(2) application. The final rule also clarified the types of patents that must and must not be submitted to FDA and revised the declaration that NDA applicants must submit to FDA regarding patents to help ensure that NDA applicants submit only appropriate patents. The final rule became effective on August 18, 2003.

On December 8, 2003, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) was signed into law. Title XI, Access to Affordable Pharmaceuticals, subtitle A, section 1101 (Public Law 108-173) contains provisions that supersede sections of the regulation issued in the June 18, 2003, final rule (68 FR 36676). The new statutory provisions address the effective date of approval for certain ANDAs and 505(b)(2) applications and prohibit approval for 30 months if the applicant has certified that a patent claiming the drug is invalid or will not be infringed, and the patent owner or NDA holder then sues the applicant for patent infringement. The effective date of these provisions was made retroactive to August 18, 2003. The new statutory provisions address the applicability of 30-month stays in approval of certain ANDAs and 505(b)(2) applications in a different manner than our final rule, which was issued under statutory language now superseded.

Therefore, certain regulations issued in the final rule published on June 18, 2003 (68 FR 36676) are superseded by the new statutory provisions. The affected sections of the regulation are 21 CFR 314.52(a)(3) and 21 CFR 314.95(a)(3) that stay the effective date of approval for certain ANDAs and 505(b)(2) applications for 30 months in certain situations.

In accordance with the new statutory provisions, we are revoking the applicable sections of the regulation. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)).

List of Subjects in 21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR 314 is amended as follows:

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 1. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 356, 356a, 356b, 356c, 371, 374, 379e.

§ 314.52 [Amended]

■ 2. Section 314.52 is amended by removing paragraph (a)(3) and redesignating paragraph (a)(4) as paragraph (a)(3).

§ 314.95 [Amended]

■ 3. Section 314.95 is amended by removing paragraph (a)(3) and redesignating paragraph (a)(4) as paragraph (a)(3).

Dated: March 1, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-5407 Filed 3-9-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 803, 806, 807, 814, 820, and 1005

Medical Device Reports; Reports of Corrections and Removals; Establishment Registration and Device Listing; Premarket Approval Supplements; Quality System Regulation; Importation of Electronic Products; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is correcting certain regulations in 21 CFR parts 803, 806, 807, 814, 820, and 1005. This rule corrects some inadvertent typographical errors and some technical errors, and it is intended to improve the accuracy of the agency's regulations.

EFFECTIVE DATE: March 10, 2004.

FOR FURTHER INFORMATION CONTACT:

Joseph M. Sheehan, Center for Devices and Radiological Health, Food and Drug Administration, HFZ-215, Piccard Dr., Rockville, MD 20850, 301-827-2974.

SUPPLEMENTARY INFORMATION:

I. Highlights of Final Rule

FDA is making the following changes in several regulations concerning medical devices and radiological health to correct errors, and update addresses and form numbers:

1. FDA is revising 21 CFR 803.18(e) to eliminate a reference to 21 CFR 820.162, a section which no longer exists.

2. FDA is amending §§ 806.10(f), 820.198(d), and 820.200(c) to eliminate references to 21 CFR part 804, a part which no longer exists.

3. FDA is revising the FDA forms numbers listed in certain sections of part 807 (21 CFR part 807), specifically §§ 807.22, 807.25, 807.26, 807.30, 807.35, and 807.37, to identify the forms correctly.

4. FDA is updating the address in § 807.22 (a).

5. FDA is amending § 807.26 to conform to FDA's existing procedure. Changes made between annual registration periods are now done by submitting a letter and need not be submitted on a specific form.

6. FDA is updating the address in § 807.37 (a) and (b)(2).

7. FDA is amending § 807.30 by removing references to block numbers for FDA forms. FDA has changed these forms from time to time and, therefore, the numbers are no longer accurate.

8. FDA is amending § 814.39 by moving part of § 814.39(f) to § 814.39(e). This paragraph was inadvertently placed in paragraph (f) after an amendment published on October 8 1998 (63 FR 54043).

9. FDA is amending § 1005.3 by replacing the references to section 358 of the act with section "534 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360kk)." This correction conforms to the redesignation of this section by the Safe Medical Devices Act of 1990.

II. Environmental Impact

The agency has determined under 21 CFR 25.30(i) that this final rule 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 was required. The changes in these amendments do not alter this conclusion.