6. Section 104.14 would be amended by revising paragraph (a) to read as follows:

§ 104.14 Formal requirements regarding reports and statements.

(a) Each individual having the responsibility to file a designation, report or statement required under this subchapter shall sign the original designation, report or statement except that:

(1) Reports or statements of independent expenditures filed by facsimile machine or electronic mail under 11 CFR 104.4(b) or 11 CFR 109.2 must be verified in accordance with those sections; and

(2) Reports, designations, or statements filed electronically under 11 CFR 104.18 must follow the signature requirements of 11 CFR 104.18(g).

* * * * *

7. Section 104.18 would be amended by revising paragraph (h) to read as follows:

§ 104.18 Electronic filing of reports (2 U.S.C. 432(d) and 434(a)(11)).

* * * * *

(h) *Schedules and forms with special requirements.* (1) The following are schedules and forms that require the filing of additional documents and that have special signature requirements:

(i) Schedules C–1 and C–P–1, Loans and Lines of Credit From Lending Institutions (see 11 CFR 104.3(d)); and

(ii) Form 8, Debt Settlement Plan (see 11 CFR 116.7(e)).

(2) If a person files a report electronically by submitting a diskette to the Commission and is required to file any of the schedules or forms listed in paragraph (h)(1) of this section, the person shall file a paper copy of the required schedule or form with the electronic submission, or a digitized version as a separate file in the electronic submission, by the close of business on the prescribed filing date.

(3) If a person files a report electronically by uploading the data to the Commission's electronic filing system and is required to file any schedules or forms listed in paragraph (h)(1) of this section, the person shall file a paper copy or a digitized version of the required schedule or form by the close of business on the prescribed filing date.

* * * * *

PART 109—INDEPENDENT EXPENDITURES (2 U.S.C. 431(17), 434(c))

8. The authority citation for part 109 would continue to read as follows:

Authority: 2 U.S.C. 431(17), 434(a)(11) and (c), 438(a)(8), and 441d.

9. Section 109.1 would be amended by adding new paragraph (f) to read as follows:

§ 109.1 Definitions (2 U.S.C. 431(17)).

* * * * *

(f) An independent expenditure is made on the earliest of—

(1) The date on which a written contract, including a media contract, promise or agreement to make an independent expenditure is executed;

(2) The first date on which the communication is printed, broadcast or otherwise publicly disseminated; or

(3) The date on which the person making the independent expenditure pays for it.

10. Section 109.2 would be amended by revising the introductory text in paragraphs (a) and (a)(1) by revising paragraphs (a)(1)(v), (a)(2), and (b) by redesignating paragraph (a)(1)(vi) as paragraph (a)(1)(vii) and adding new paragraphs (a)(1)(vi) and (c) to read as follows:

§ 109.2 Reporting of independent expenditures by persons other than a political committee (2 U.S.C. 434(c)).

(a) Every person other than a political committee, who makes independent expenditures aggregating in excess of $250 in a calendar year shall file a verified statement or report on FEC Form 5 with the Commission or Secretary of the Senate in accordance with 11 CFR 104.4(c).

(1) If a verified statement is submitted, the statement shall include:

* * * * *

(v) A verified certification under penalty of perjury as to whether such expenditure was made in cooperation, consultation or concert with, or at the request or suggestion of any candidate or any authorized committee or agent thereof;

(vi) A verified certification under penalty of perjury as to whether the expenditure involved the financing, dissemination, distribution or republication of any campaign materials prepared by a candidate or a candidate's agent or authorized committee; and

* * * * *

(2) Reports or statements filed under this section shall be filed at the end of the reporting period (quarterly, pre-election, post-election, semi-annual or annual) (See 11 CFR 104.5)) during which any independent expenditure which aggregates in excess of $250 is made and in any reporting period thereafter in which additional independent expenditures are made.

(b) Reports of independent expenditures aggregating $1,000 or more made by any person after the twentieth day, but more than 24 hours before 12:01 a.m of the day of an election must be received by the appropriate officers as listed in paragraph (c) of this section within 24 hours after such independent expenditure is made. Such report or statement shall contain the information required by paragraph (a) of this section indicating whether the independent expenditure is made in support of, or in opposition to, a particular candidate.

(c) Verification of independent expenditure statements and reports: For reports filed on paper (e.g., by hand delivery, U.S. Mail or facsimile machine), the certification required by paragraphs (a)(1)(v) and (a)(1)(vi) of this section must be immediately followed by the handwritten signature of the person who made the independent expenditure and who certifies, under penalty of perjury, its independence. For reports filed by electronic mail, the certification required by paragraphs (a)(1)(v) and (a)(1)(vi) of this section must be immediately followed by the typewritten name of the person who made the independent expenditure and who certifies, under penalty of perjury, its independence.

Dated: May 3, 2001.

Danny L. McDonald,

Chairman, Federal Election Commission.

[FR Doc. 01–11587 Filed 5–8–01; 8:45 am]

BILLING CODE 6715–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–SW–03–AD]

RIN 2120–AA64

Airworthiness Directives; Eurocopter France Model AS–365N3 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes adopting a new airworthiness directive (AD) for Eurocopter France Model AS–365N3 helicopters. This proposal would require modifying the Full Authority Digital Engine Control (FADEC) software within 90 days after the effective date of this AD. This proposal is prompted by a design problem in the FADEC ''power loss printed circuit board'' software found during laboratory

testing. The actions specified by the proposed AD are intended to prevent loss of the FADEC one-engine-inoperative (OEI) power and subsequent loss of control of the helicopter.

DATES: The FAA must receive any comments on this proposal by July 9, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 2001–SW–03–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. You may also send comments electronically to the Rules Docket at the following address: 9-asw-adcomments@faa.gov. Comments may be inspected at the Office of the Regional Counsel between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Carroll Wright, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Regulations Group, Fort Worth, Texas 76193–0111, telephone (817) 222–5120, fax (817) 222–5961.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments will be considered before taking action on the proposed rule. The proposals contained in this document may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their mailed comments submitted in response to this proposal must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 2001–SW–03–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 2001–SW–03–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137.

Discussion

The Direction Generale De L'Aviation Civile (DGAC), the airworthiness authority for France, notified us that an unsafe condition may exist on Eurocopter France Model AS–365N3 helicopters. The DGAC advises that the engine FADEC software and the associated existing wiring for the engine indicating system for the FADEC should be modified. The main purpose of these modifications is to transfer the ''OEI torque limit setting'' and the ''NG difference indicating'' function from the ''power loss'' card to the main computer. This modification should eliminate hung starts and loss of access to the maximum allowable emergency OEI power from the remaining engine after one engine has failed.

Eurocopter France has issued Eurocopter France Service Bulletin (SB) 71.00.13, Revision 1, dated October 17, 2000. This SB specifies modifying the engine FADEC computer software and the associated existing wiring. The DGAC classified this SB as mandatory and issued AD No. 2000–517–051(A), dated December 13, 2000, to ensure the continued airworthiness of these helicopters in France. Incorporation of the SB provides terminating action for DGAC AD Nos. 1998–517–048(A) R2, dated December 13, 2000; 1998–517–048(A) R1, dated April 5, 2000; and 1998–517–048(A), dated January 13, 1999.

This helicopter model is manufactured in France and is type certificated for operation in the United States under the provisions 14 CFR 21.29 and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

We have identified an unsafe condition that is likely to exist or develop on other Eurocopter France Model AS–365N helicopters of this same type design registered in the United States. The proposed AD would require modifying the FADEC software and wiring within 90 days after the effective date of this AD. The actions would be required to be accomplished in accordance with the SB's described previously.

Regulatory Impact

We estimate that 1 helicopter of U.S. registry would be affected by this proposed AD and that it would take approximately 17 work hours per helicopter to modify the wiring. The average labor rate is $60 per work hour. The FADEC software modification will have an estimated turbomeca labor charge of $1200. The manufacturer has stated that the wiring kits will be furnished at no cost. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $2220.

The regulations proposed herein 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. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

For the reasons discussed above, I certify that 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); and (3) if promulgated, 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. You can get a copy of the draft regulatory evaluation prepared for this action from the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the mailing address listed under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 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. The FAA amends § 39.13 by adding the following new airworthiness directive:

Eurocopter France: Docket No. 2001–SW–03–AD.

Applicability: Model AS–365N3 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: Within 90 days after the effective date of this AD, unless previously accomplished.

To prevent loss of the Full Authority Digital Engine Control (FADEC) one-engine-inoperative power and subsequent loss of control of the helicopter, accomplish the following:

(a) Modify the FADEC software in accordance with the Accomplishment Instructions of Eurocopter France Service Bulletin 71.00.13, Revision 1, dated October 17, 2000 (except this AD does not require contact with the manufacturer as specified in the caution statement in paragraph 2.B. and the Note I in paragraph 2.B.2.).

(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, Regulations 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, Regulations Group.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Regulations Group.

(c) Special flight permits may be issued in accordance with 14 CFR 21.197 and 21.199 to operate the helicopter to a location where the requirements of this AD can be accomplished.

Note 3: The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD Nos. 2000–517–051(A) and 1998–517–048(A) R2, both dated December 13, 2000; 1998–517–048(A) R1, dated April 5, 2000; and 1998–517–048(A), dated January 13, 1999.

Issued in Fort Worth, Texas, on April 26, 2001.

Mark R. Schilling,

Acting Manager, Rotorcraft Directorate,, Aircraft Certification Service.

[FR Doc. 01–11585 Filed 5–8–01; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. 95P–0351]

Hematology and Pathology Devices; Reclassification of Automated Differential Cell Counters

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify from class III (premarket approval) to class II (special controls) the automated differential cell counter (ADCC). The ADCC is a device intended to identify and classify one or more of the formed elements of the blood, or to flag, count, or classify immature or abnormal hematopoietic cells of the blood, bone marrow, or other body fluids. FDA is basing this reclassification on new information submitted in a reclassification petition from the International Society for Laboratory Hematology (ISLH). The agency is taking this action under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written comments by August 7, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Larry J. Brindza, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1293.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The act, as amended by the 1976 amendments (Public Law 94–295), the SMDA (Public Law 101–629), and FDAMA (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not