

failures, if not corrected, could lead to the loss of main battery power and result in the loss of all electrical power, except the emergency battery supply, during flight.

#### Actions Since Issuance of Previous Rule

Since the issuance of that AD, the Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, has advised the FAA that the unsafe condition identified in French airworthiness directives AD T98-148-076(B) and AD T98-149-038(B), both dated March 20, 1998, was an isolated case. The DGAC advised that further investigation, a design review of the DC electrical system, and bench testing results indicate that the reset of the first failed generator did not contribute to the loss of the second generator. The DGAC concludes that there is no reason to prohibit reset of a failed generator, and concludes that the incident that prompted need for mandatory action was an isolated case. Consequently, the DGAC has issued French airworthiness directives 98-148-076(B) R1 and 98-149-038(B) R1, both dated July 15, 1998, which provide cancellation notice of the French airworthiness directives that required the AFM revision.

#### FAA's Conclusions

Since receipt and review of the DGAC information, the FAA has determined that it is unnecessary to require the AFM revisions required by AD 98-09-16.

This proposed action would rescind AD 98-09-16. Rescission of AD 98-09-16 would constitute only such action, and, if this proposal is followed by a final action, it would not preclude the agency from issuing another notice in the future, nor would it commit the agency to any course of action in the future.

#### Cost Impact

The FAA estimates that 145 airplanes of U.S. registry are affected by AD 98-09-16. The actions that are currently required by that AD take approximately 1 work hour per airplane to accomplish, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of the currently required actions on U.S. operators is estimated to be \$8,700, or \$60 per airplane. However, the adoption of this proposed rescission would eliminate those costs.

Removal of the AFM revision required by AD 98-09-16 would take approximately 1 work hour per airplane to accomplish, at an average labor rate of \$60 per work hour. Based on these figures, the cost impact of removal of

the AFM revision is estimated to be \$8,700, or \$60 per airplane.

#### Regulatory Impact

The regulations proposed herein would not have substantial direct effects 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, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

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. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption ADDRESSES.

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

Air transportation, Aircraft, Aviation safety, Safety.

#### The Proposed Amendment

Accordingly, pursuant to 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. Section 39.13 is amended by removing amendment 39-10497.

**AEROSPATIALE:** Docket 98-NM-259-AD. Rescinds AD 98-09-16, Amendment 39-10497.

**Applicability:** All Model ATR-42 and ATR-72 series airplanes; certificated in any category.

Issued in Renton, Washington, on November 3, 1999.

**D.L. Riggins,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 99-29331 Filed 11-8-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 600, 606, 607, 610, 630, 640, and 660

[Docket Nos. 98N-0581, 98N-0607, and 98N-0815]

#### Blood Safety Initiative: Extension of Comment Period on Proposed Rules and Announcement of Public Meeting

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

**ACTION:** Proposed rule; announcement of public meeting.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public meeting and is extending to December 22, 1999, the comment period on two proposed rules entitled "Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents," and "General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors." FDA is also extending to December 22, 1999, the comment period on the advance notice of proposed rulemaking (ANPRM) entitled "Plasma Derivatives and other Blood-Derived Products; Requirements for Tracking and Notification." The purpose of the meeting is to provide a public forum for gathering information and views regarding the proposed rules and the ANPRM. The comment periods are being extended to provide time for the submission of comments that may result from the issues discussed at the public meeting.

**DATES:** The public meeting will be held on Monday, November 22, 1999, from 8:30 a.m. to 12 noon. Submit written comments for "Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents," "General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors," and "Plasma Derivatives and other Blood-Derived Products; Requirements for Tracking and Notification" by December 22, 1999.

**ADDRESSES:** The public meeting will be held at the National Institutes of Health

(NIH), NIH Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD.

Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the appropriate docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

For registration and meeting information: Kathy Eberhart, Center for Biologics Evaluation and Research (HFM-49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-1317, FAX 301-827-3079, e-mail: eberhart@cber.fda.gov.

For information about this document: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the *Federal Register* of August 19, 1999 (64 FR 45340 and 45355), FDA published two proposed rules that were intended to help protect the safety and ensure the quality of the nation's blood supply and to promote consistency in the industry. The document entitled "Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents" (64 FR 45340) [Docket No. 98N-0581] proposed to revise the general biological product standards by updating the hepatitis B virus (HBV) and human immunodeficiency virus (HIV) testing requirements, by adding testing requirements for hepatitis C virus (HCV), human T-lymphotropic virus (HTLV), and by adding requirements for licensed supplemental (i.e., additional, more specific) testing when a donation is found to be repeatedly reactive for any of the required screening tests for evidence of infection due to communicable disease agents.

The document entitled "General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors" (64 FR 45355) [Docket No. 98N-0607] proposed to require blood and plasma establishments to notify donors of their deferral due to test results for communicable disease agents or failure to satisfy suitability requirements with the intent of reducing the risk of transmission of communicable disease

through the use of blood, blood components, and blood derivatives. Blood and plasma establishments would notify donors that they have been deferred and the reason for the deferral; provide information concerning appropriate medical follow up and counseling; describe the types of donations the donors should not make in the future; and discuss the possibility that the donor may be found suitable in the future, where appropriate. FDA provided until November 17, 1999, to submit comments on these proposed rules.

The ANPRM entitled "Plasma Derivatives and other Blood-Derived Products; Requirements for Tracking and Notification" (64 FR 45383, August 19, 1999) [Docket No. 98N-0815] announced FDA's intention to propose regulations to require certain blood-derived products, including certain plasma derivatives, be tracked from a U.S. licensed manufacturer, through the distribution network, to any patient having custody of the product. FDA also announced its intention to propose to require notification of consignees and patients having custody of a blood-derived product or an analogous recombinant product in the event the product is associated with a potential increased risk of transmitting a communicable disease, as determined by FDA or by a U.S. licensed manufacturer. FDA provided until November 17, 1999, to submit comments on the ANPRM.

**II. Comments**

Interested persons may submit written comments on these proposed rules and the ANPRM to the Dockets Management Branch (address above) by the date listed above. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the appropriate docket number found in brackets in the heading of this document. If time permits, comments may be taken from the floor. FDA is requesting that those persons making oral presentations at the public meeting also submit their statements in writing by December 22, 1999, as described above, to ensure their adequate consideration. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

**III. Registration and Requests for Oral Presentations**

Mail or fax registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to

make oral presentations, to Kathy Eberhart (address above) by Monday, November 15, 1999. If you do not intend to make a presentation, registration is not required. However, all interested persons are encouraged to pre-register.

If you need special accommodations due to a disability, please contact Kathy Eberhart at least 7 days in advance.

**IV. Transcripts**

Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript will also be available on CBER's website at <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Dated: November 2, 1999.

**William K. Hubbard,**

*Senior Associate Commissioner for Policy, Planning, and Legislation.*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[MI23-01-6258; FRL-6472-6]

**Approval and Promulgation of State Implementation Plans; Michigan**

**AGENCY:** Environmental Protection Agency.

**ACTION:** Proposed rule.

**SUMMARY:** The United States Environmental Protection Agency (USEPA) is proposing to disapprove revisions to the State of Michigan's New Source Review (NSR) State Implementation Plan (SIP). The Michigan Department of Environmental Quality (MDEQ) submitted these revisions on November 11, 1993; May 16, 1996; April 3, 1998; and August 20, 1998. MDEQ submitted some of these revisions to meet the requirements of the Clean Air Act (CAA) amendments of 1990. Because these revisions are required under the CAA, a final disapproval would constitute a disapproval under section 179(a)(2) of the CAA. Pursuant to section 179(a) of the CAA, the State of Michigan has up to 18 months after a final disapproval to correct the deficiencies that are the subject of the disapproval before USEPA must impose sanctions.

**DATES:** Comments on this proposed rule must be received before December 9, 1999.