Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Engine Certification Office.

(d) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be accomplished.

Issued in Burlington, Massachusetts, on March 8, 1999.

David A. Downey,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 99–6214 Filed 3–12–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–328–AD]

RIN 2120–AA64

Airworthiness Directives; Fokker Model F.28 Mark 0070 and 0100 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to all Fokker Model F.28 Mark 0070 and 0100 series airplanes. This proposal would require modification of the electrical wiring of the flight warning computer (FWC), and installation of upgraded computer software into the FWC. This proposal is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by the proposed AD are intended to prevent certain nuisance alerts generated by the FWC and to ensure annunciation of certain flight alerts by the FWC during initial climb. Such nuisance alerts or failures to annunciate certain alerts could result in an improper response by the flight crew and consequent reduced controllability of the airplane.

DATES: Comments must be received by April 14, 1999.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 98–NM–328–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Fokker Services B.V., Technical Support Department, P.O. Box 75047, 1117 ZN Schiphol Airport, the Netherlands. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; fax (425) 227–1149.

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 shall 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, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice 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 comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 98–NM–328–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, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 98–NM–328–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Rijksluchtvaartdienst (RLD), which is the airworthiness authority for the Netherlands, notified the FAA that an unsafe condition may exist on all Fokker Model F.28 Mark 0070 and 0100 series airplanes. The RLD advises that in-service experience has indicated that certain nuisance flight alerts may be generated by the flight warning computer (FWC) during critical flight phases. Investigation revealed that the nuisance flight alerts are a result of certain conditions established in an earlier version of the computer software of the FWC, which allows a flight-phase transitional delay (in some cases up to 8 seconds) between the moment all relevant input conditions are met and the moment the actual flight-phase switching occurs. Such nuisance flight alerts could prompt the flight crew to unnecessarily abort takeoffs at high speeds.

The RLD also advises that annunciation of the REVERSER ENG 1(2) alerts is suppressed during initial climb between 400 and 1,000 feet off the ground. During this flight phase, there is no warning to the flight crew enabling them to distinguish between a perceived autothrottle malfunction and an actual thrust reverser deployment.

These conditions (nuisance alerts and failures to annunciate flight alerts), if not corrected, could result in an improper response by the flight crew and consequent reduced controllability of the airplane.

Explanation of Relevant Service Information

The manufacturer has issued Fokker Service Bulletin SBF100–31–047, Revision 1, dated March 21, 1997, which describes, among other things, procedures for modification of the electrical wiring of the FWC. The modification involves removing the FWC and installing additional electrical wiring to accommodate the revised configuration of the FWC.

Fokker also has issued Service Bulletin SBF100–31–051, dated August 15, 1998, which describes procedures for installation of an upgraded computer software version (V11.45) into the FWC. (Fokker Service Bulletin SBF100–31–051 refers to AlliedSignal Grimes Aerospace Service Bulletin 80–0610–31–0031, dated May 14, 1998, as an additional source of service information for installation of the upgraded computer software version into the FWC.)

Accomplishment of the actions specified in the Fokker service bulletins described above is intended to

adequately address the identified unsafe condition. The RLD classified these service bulletins as mandatory and issued Dutch airworthiness directive BLA 1998–110, dated August 31, 1998, in order to assure the continued airworthiness of these airplanes in the Netherlands.

FAA's Conclusions

These airplane models are manufactured in the Netherlands and are type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the RLD has kept the FAA informed of the situation described above. The FAA has examined the findings of the RLD, 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.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in the Fokker service bulletins described previously, except as discussed below.

Differences Between Proposed AD and Relevant Service Information

Operators should note that Fokker Service Bulletin SBF100–31–047, Revision 1, recommends, in addition to the procedures described previously, the installation of computer software version V10.40 into the FWC. However, the only procedure of that service bulletin proposed by this AD is modification of the electrical wiring of the FWC. In developing the appropriate requirements for this proposed AD, the FAA has determined that it is not necessary to install computer software version V10.40, since the later version V11.45 is available and is required to be installed by this proposed AD.

Cost Impact

The FAA estimates that 129 airplanes of U.S. registry would be affected by this proposed AD, and that it would take approximately 6 work hours per airplane to accomplish the proposed modification, and that the average labor rate is $60 per work hour. Required parts would cost approximately $93 per airplane. Based on these figures, the cost impact of the modification proposed by this AD on U.S. operators is estimated to be $58,437, or $453 per airplane.

It also would take approximately 1 work hour per airplane to accomplish the proposed installation, at an average labor rate of $60 per work hour. Required parts would cost approximately $1,500 per airplane. Based on these figures, the cost impact of the installation proposed by this AD on U.S. operators is estimated to be $201,240, or $1,560 per airplane.

The cost impact figures discussed above are based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

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 adding the following new airworthiness directive:

Fokker Services B.V.: Docket 98–NM–328–AD.

Applicability: All Model F.28 Mark 0070 and 0100 series airplanes; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes 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 (d) 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.

To prevent certain nuisance alerts generated by the flight warning computer (FWC) and to ensure annunciation of certain flight alerts by the FWC during initial climb, which could result in an improper response by the flight crew and consequent reduced controllability of the airplane, accomplish the following:

(a) Within 18 months after the effective date of this AD, modify the electrical wiring of the FWC in accordance with Part 1 or 2, as applicable, of the Accomplishment Instructions of Fokker Service Bulletin SBF100–31–047, Revision 1, dated March 21, 1997.

Note 2: It is not necessary to install computer software version V10.40 into the FWC, since a later version is available and is required to be installed by this AD.

(b) Concurrent with the accomplishment of the requirements of paragraph (a) of this AD, install upgraded computer software version V11.45 into the FWC in accordance with Fokker Service Bulletin SBF100–31–051, dated August 15, 1998.

Note 3: AlliedSignal Grimes Aerospace has issued Service Bulletin 80–0610–31–0031, dated May 14, 1998, as an additional source of service information for installation of the upgraded computer software version into the FWC.

(c) As of the effective date of this AD, no person shall install on any airplane a flight warning computer, unless it has been modified in accordance with this AD.

(d) 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, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then

send it to the Manager, International Branch, ANM–116.

Note 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Note 5: The subject of this AD is addressed in Dutch airworthiness directive BLA 1998–110, dated August 31, 1998.

Issued in Renton, Washington, on March 9, 1999.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–6210 Filed 3–12–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 864, 866, 868, 870, 872, 874, 876, 878, 884, 886, and 888

[Docket No. 99N–0035]

Medical Devices; Reclassification of 38 Preamendments Class III Devices into Class II

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify 38 preamendments class III devices into class II (special controls). FDA is also identifying the proposed special controls that the agency believes will reasonably ensure the safety and effectiveness of the devices. This reclassification is being proposed on the agency's own initiative based on new information. This action is being taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Safe Medical Devices Act of 1990 (the SMDA) and the FDA Modernization Act of 1997 (FDAMA). The agency is also proposing that the identification of six of the devices subject to this proposal be modified to more accurately reflect the characteristics of devices actually being marketed.

DATES: Written comments by June 14, 1999. See section X of this document for the proposed effective date of a final rule based on this document.

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

FOR FURTHER INFORMATION CONTACT: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850 301–594–1184.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authorities

The act, as amended by the 1976 Medical Device Amendments (the amendments) (Pub. L. 94–295), the SMDA (Pub. L. 101–629), and FDAMA (Pub. L. 105–115), establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) establishes 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 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 postamendment devices, are classified automatically by statute (section 513(f) of the act (21 U.S.C. 360c(f)) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval, or reclassifies the device under 513(f). 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 (510(k)) 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.

The SMDA added section 515(i) (21 U.S.C. 360e(i)) to the act. This section requires FDA to issue an order to manufacturers of preamendment class III devices and substantially equivalent postamendments devices for which no final regulation requiring the submission of PMA's has been issued. This order requires such manufacturers to submit to the agency a summary of, and a citation to, any information known or otherwise available to them respecting such devices, including adverse safety and effectiveness information that has not been submitted under section 519 of the act (21 U.S.C. 360i), which requires manufacturers, importers, distributors, and device user facilities to submit adverse event reports of certain device-related events and reports of certain corrective actions taken. Section 515(i) of the act (21 U.S.C. 360e) also directs FDA to either revise the classification of the device into class I or class II or require the device to remain in class III and establish a schedule for the issuance of a rule requiring the submission of PMA's for those devices remaining in class III.

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA announced the availability of a document setting forth its strategy for implementing section 515(i) of the act. Under this plan, the agency divided preamendment class III devices into the following three groups: Group 1 devices are devices that FDA believes raise significant questions of safety and/or effectiveness, but are no longer used or are in very limited use; Group 2 devices are devices that FDA believes have a high potential for being reclassified; and Group 3 devices are devices that FDA believes are currently in commercial distribution and are not likely candidates for reclassification. FDA also announced its intention to call for submission of PMA's for the 15 highest priority devices in Group 3, and for all Group 1 devices. The agency also announced its intention to issue an order under section 515(i) of the act for the remaining Group 3 devices and for all Group 2 devices.

In the **Federal Register** of August 14, 1995 (60 FR 41984 and 41986), FDA published two orders for certain class III devices, requiring the submission of safety and effectiveness information in accordance with the preamendments class III strategy for implementing