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 USC 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Fokker: Docket 95–NM–151–AD.

Applicability: Model F28 series airplanes (excluding Model F28 Mark 0100 series airplanes); serial numbers 11003 through 11151 inclusive, 11991, and 11992; 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 stress corrosion cracking of the junction fitting lug of the horizontal stabilizer, which could result in failure of the lug and uncommanded movement of the horizontal stabilizer, and subsequent reduced controllability of the airplane; accomplish the following:

(a) Within 18 months after the effective date of this AD, replace the aluminum 7079 junction fittings (left and right) of the horizontal stabilizer with improved fittings made from aluminum 7075, in accordance with Part 1 of the Accomplishment Instructions of Fokker Service Bulletin F28/55–029, Revision 1, dated January 23, 1993.

(b) For airplanes on which the drive-fitting bushings and bolts of the horizontal stabilizer have not been replaced in accordance with Fokker Service Bulletin F28/55–24: Within 18 months after the effective date of this AD, replace the drive-fitting bushings and bolts of the horizontal stabilizer with new bushings and bolts, in accordance with Part 2 of the Accomplishment Instructions of Fokker Service Bulletin F28/55–029, Revision 1, dated January 23, 1993.

(c) Accomplishment of the replacements required by paragraphs (a) and (b) of this AD constitute terminating action for the inspections identified as item 55–50–05 in the Fokker Structural Integrity Program (SIP) Document 28438, Part 1, revised up through October 15, 1992, which are required by AD 93–13–04, amendment 39–8617 (58 FR 38513, July 19, 1993). Once these replacements are accomplished, the life limits of the fitting lugs (identified as items 55–50–01 and 55–50–02 in the SIP Document) no longer apply.

(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, Standardization Branch, ANM–113, 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, Standardization Branch, ANM–113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(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.

Issued in Renton, Washington, on March 26, 1996.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–7854 Filed 3–29–96; 8:45 am]

BILLING CODE 4910–13–U

14 CFR Part 39

[Docket No. 95–NM–170–AD]

Airworthiness Directives; Fokker Model F28 Series Airplanes (Excluding Model F28 Mark 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 certain Fokker Model F28 series airplanes. This proposal would require a one-time detailed visual inspection to detect cracking of the elevator gust lock housing and the gust lock support structure, and repair or replacement of cracked parts. This proposal is prompted by a report of failure of an elevator gust lock housing due to fatigue cracking. The actions specified by the proposed AD are intended to prevent fatigue cracking of the elevator gust lock housing and the gust lock support structure, which could result in loss of the elevator and the support structure, and subsequent possible loss of primary pitch control.

DATES: Comments must be received by May 9, 1996.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 95–NM–170–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 Aircraft USA, Inc., 1199 North Fairfax Street, Alexandria, Virginia 22314. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Connie Beane, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington 98055–4056; telephone (206) 227–2796; fax (206) 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 95–NM–170–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–103, Attention: Rules Docket No. 95–NM–170–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Rijksluchtvaartdienst (RLD), which is the airworthiness authority for the Netherlands, recently notified the FAA that an unsafe condition may exist on certain Fokker Model F28 series airplanes. The RLD advises that it received a report indicating that the elevator gust lock housing on a Model F28 series airplane failed during maintenance. This failure occurred after the cockpit control column was moved with the gust lock in the ''ON'' position and the hydraulic system activated. After the gust lock was disengaged, the elevator appeared to be obstructed. Results of a subsequent investigation revealed that the two upper legs of the gust lock housing had broken off, while the housing was bent towards the tension regulator quadrant. The gust lock support structure on which the two lower legs were mounted also was damaged. The cause of breakage of the gust lock housing and damage to the support structure has been attributed to fatigue cracking. Fatigue cracking of the elevator gust lock housing and the gust lock support structure, if not detected and corrected in a timely manner, could result in loss of the elevator and the support structure, and subsequent possible loss of primary pitch control.

Fokker has issued Service Bulletin F28/55–30, Revision 1, dated January 4, 1993, which describes procedures for a one-time detailed visual inspection to detect cracking of the elevator gust lock housing and the gust lock support structure, and repair or replacement of cracked parts with new or serviceable parts. The service bulletin permits further flight with cracking of the gust lock support structure, provided that cracking is within certain limits, until the structure is replaced or repaired. However, the service bulletin specifies that inspections to detect further cracking should be accomplished in the interim. The service bulletin also specifies that, if any cracking is found, use of the gust lock system is prohibited until the cracked part is replaced. The RLD classified this service bulletin as mandatory and issued Dutch airworthiness directive BLA 92–101/4 (A), dated January 28, 1994, in order to assure the continued airworthiness of these airplanes in the Netherlands.

These airplane models are manufactured in the Netherlands and are type certificated for operation in the United States under the provisions of section 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.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design, the proposed AD would require a one-time detailed visual inspection to detect cracking of the elevator gust lock housing and the gust lock support structure, and repair or replacement of cracked parts with new or serviceable parts. For airplanes on which cracking is found, the proposed AD also would prohibit use of the gust lock system until cracked parts are replaced. The actions would be required to be accomplished in accordance with the service bulletin described previously.

Operators should note that, unlike the procedures described in the referenced service bulletin, this proposed AD would not permit further flight with cracking detected in the gust lock support structure. The FAA has determined that, due to the safety implications and consequences associated with such cracking, all structure that is found to be cracked must be replaced or repaired prior to further flight.

The FAA estimates that 43 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 2 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $5,160, or $120 per airplane.

The cost impact figure discussed above is 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.

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 USC 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Fokker: Docket 95–NM–170–AD.

Applicability: Model F28 series airplanes, excluding Model F28 Mark 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 (c) 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 fatigue cracking of the elevator gust lock housing and the gust lock support structure, which could result in loss of the elevator and the support structure, and subsequent possible loss of primary pitch control, accomplish the following:

(a) Within 30 days after the effective date of this AD, perform a one-time detailed visual inspection to detect cracking of the elevator gust lock housing and the gust lock support structure, in accordance with Fokker Service Bulletin F28/55–30, Revision 1, dated January 4, 1993.

(b) If any cracking is found, prior to further flight, repair or replace the cracked elevator gust lock housing or gust lock support structure with a new or serviceable part in accordance with Fokker Service Bulletin F28/55–30, Revision 1, dated January 4, 1993. Use of the elevator gust lock system is prohibited until cracked parts are replaced with new or serviceable parts.

(c) 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, Standardization Branch, ANM–113, 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, Standardization Branch, ANM–113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(d) 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.

Issued in Renton, Washington, on March 26, 1996.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–7853 Filed 3–29–96; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. 95N–0400]

RIN 0910–AA09

Medical Devices; Reclassification and Codification of Rigid Gas Permeable Contact Lens Solution; Soft (Hydrophilic) Contact Lens Solution; and Contact Lens Heat Disinfecting Unit

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) rigid gas permeable contact lens solution, soft (hydrophilic) contact lens solution, and the contact lens heat disinfection unit. Collectively, these devices are referred to as transitional contact lens care products, which include saline solutions, in-eye lubricating/rewetting drops, disinfecting and conditioning products, contact lens cleaners, and heat disinfecting units. This reclassification is in response to provisions in the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) and the Safe Medical Devices Act of 1990 (the SMDA). FDA is also amending the regulations for transitional contact lens care products to more accurately reflect the intent of the original regulation. Under the SMDA, FDA is implementing a special control that the agency has determined is necessary to provide reasonable assurance of the safety and effectiveness of the proposed reclassified contact lens care products. That special control is the availability of guidance for premarket notification submissions for these products. Elsewhere in this issue of the Federal Register, FDA is announcing the availability of a draft guidance describing the evidence that demonstrates the substantial equivalence of new contact lens care products to contact lens care products already marketed.

DATES: Written comments by June 17, 1996. The agency proposes that any final rule that may issue based on this proposal become effective 30 days after date of publication of the final rule in the Federal Register.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: David M. Whipple, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2205.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 321 *et seq.*), as amended by the 1976 amendments (Pub. L. 94–295) and the SMDA (Pub. L. 101–629), 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 classes of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: Class I, general controls; class II, special controls; and class III, premarket approval.

The 1976 amendments broadened the definition of ''device'' in section 201(h) of the act (21 U.S.C. 321(h)) to include certain articles that were once regulated as drugs. Under the 1976 amendments, Congress classified all transitional devices (i.e., those devices previously regulated as new drugs), including: Rigid gas permeable contact lens solutions; soft (hydrophilic) contact lens solutions; and contact lens heat disinfecting units, into class III (premarket approval). The legislative history of the SMDA reflects congressional concern that many transitional devices were being over regulated in class III. H. Rept. 808, 101st Cong., 2d sess. 26–27 (1990); S. Rept. 513, 101st Cong., 2d sess. 26–27 (1990). Congress amended section 520(l) of the act, (21 U.S.C. 360j(l)) to direct FDA to collect certain safety and effectiveness information from the manufacturers of transitional devices and review the classification of those still remaining in class III to determine if the device could be reclassified into class II (special controls) or class I (general controls).