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 2001–NM–290–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 (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 detect and correct incorrect an insufficient over-center force in the corresponding thrust reverser operating lever and incorrect setting of the thrust reverser selector switch (S9), which could result in uncommanded deployment of the thrust reversers during flight and consequent reduced controllability of the airplane, accomplish the following:

Over-Center Force Measurement and Readjustment

(a) Within 6 months after the effective date of this AD, measure the over-center force of the left- and right-hand thrust reverser operating levers, per paragraph 2.A. of the Accomplishment Instructions of Fokker Service Bulletin SBF100–76–015, dated January 15, 2001, including Manual Change Notification MCNM F100–060, dated January 1, 2001.

(1) If the over-center force is equal to or higher than 4.5 pounds, but not higher than 5.5 pounds, no further action is required by this paragraph.

(2) If the over-center force is less than 4.5 pounds or higher than 5.5 pounds, before further flight, readjust the over-center force and accomplish the corrective actions (including measuring and readjusting the minimum stop of the reverse-thrust lever and over-center force of the thrust reverser), per the service bulletin.

Functional Test and Corrective Actions

(b) Within 6 months after the effective date of this AD, perform a functional test to verify proper energizing of the secondary lock solenoid of the left- and right-hand thrust reversers, per paragraph 2.B. of the Accomplishment Instructions of Fokker Service Bulletin SBF100–76–015, dated January 15, 2001, including Manual Change Notification MCNM F100–060, dated January 1, 2001.

(1) If the secondary lock solenoid does NOT (momentarily or continuously) energize with movement of the thrust reverser operating lever as described in paragraph 2.B.(9) of the service bulletin, no further action is required by this paragraph.

(2) If the secondary lock solenoid (momentarily or continuously) energizes with movement of the thrust reverser operating lever as described in paragraph 2.B.(9) of the service bulletin, before further flight, perform a rigging test of the thrust reverser switchbox and repeat the functional test to verify proper energizing of the secondary lock solenoid one more time, per paragraph 2.B.(9) of the service bulletin.

(i) If the solenoid does NOT (momentarily or continuously) energize with movement of the thrust reverser operating lever as described in paragraph 2.B.(9) of the service bulletin, no further action is required by this paragraph.

(ii) If the secondary lock solenoid still (momentarily or continuously) energizes with movement of the thrust reverser operating lever as described in paragraph 2.B.(9) of the service bulletin, before further flight, replace the thrust reverser switchbox with a new or serviceable switchbox, per the service bulletin.

Alternative Methods of Compliance

(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, International Branch, ANM–116, Transport Airplane Directorate, FAA. 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 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(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.

Note 3: The subject of this AD is addressed in Dutch airworthiness directive 2001–040, dated March 30, 2001.

Issued in Renton, Washington, on March 28, 2002.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02–8284 Filed 4–4–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–197–AD]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model MD–90–30 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 McDonnell Douglas Model MD–90–30 airplanes. This proposal would require an inspection of the galley power feeder cable above the main cabin ceiling supports for damage caused by chafing. The proposal would also require repairing any damage on the outer cable jacket or primary insulation, installing a splice on the power feeder cable to remove damage, installing sleeving along a portion of the cable, installing standoffs for the cable, re-routing the galley power feeder cable, and testing the galley equipment, as applicable. This action is necessary to prevent future damage to the galley power feeder cable as well as to detect and correct existing damage to the galley power feeder cable, which could result in electrical arcing, possibly leading to damage to adjacent structures and to fire in the airplane. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by May 20, 2002.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–197–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. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9–anm–nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2000–NM–197–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 for Windows or ASCII text.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Aircraft Group, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024). This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California.

FOR FURTHER INFORMATION CONTACT: George Y. Mabuni, Aerospace Engineer, Systems and Equipment Branch, ANM–130L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5341; fax (562) 627–5210.

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 action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.,* reasons or data) for each request.

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 action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2001–NM–197–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. 2000–NM–197–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received reports indicating that the aft galley power feeder wires are chafing on the main cabin ceiling supports located in the overwing area. This condition, if not corrected, could result in damage to the galley power feeder cable, which could result in electrical arcing, possibly leading to damage to adjacent structures and to fire in the airplane.

Related Proposed Rulemaking

On August 24, 2001, the FAA issued a Notice of Proposed Rulemaking (NPRM), Docket Number 2001–NM–149–AD (66 FR 45948, August 31, 2001), which proposed to require an inspection of the aft galley power feeder cables for riding, chafing, and damage, and follow-on actions. The follow-on actions include repair of any damage on the outer cable jacket or primary insulation, installation of a splice on the power feeder cables to remove damage, installation of sleeving over the affected area, and a functional test of the galley equipment, as applicable. The actions are proposed to be taken in accordance with McDonnell Douglas Alert Service Bulletin MD90–24A046, Revision 02, dated March 26, 2001. No comments regarding the proposed AD were received.

Since the Issuance of that NPRM

The FAA has reviewed and approved McDonnell Douglas Alert Service Bulletin MD90–24A047, Revision 01, dated July 31, 2000, which describes procedures for modification of the installation of the galley power feeder cable. That service bulletin recommends that Alert Service Bulletin MD90–24A046, Revision 02 (the applicable service information specified in NPRM Docket No. 2001–NM–149–AD), be accomplished prior to or concurrent with modification of the installation of the power feeder cable.

Explanation of Relevant Service Information

The FAA has reviewed and approved two service bulletins pertaining to chafing of the galley power feeder cable against the main cabin ceiling supports located in the overwing area on the left side. One, McDonnell Douglas Alert Service Bulletin MD90–24A046, Revision 02, dated March 26, 2001, was specified in NPRM Docket Number 2000–NM–149–AD as the relevant service information. That alert service bulletin describes procedures for a one-time general visual inspection of the power feeder cable for damage caused by chafing. That alert service bulletin also describes procedures for follow-on actions, including repair of any damage on the outer cable jacket or primary insulation, installation of a splice on the power feeder cable to remove damage, installation of sleeving along a portion of the cable, and a functional test of the galley equipment, as applicable.

The second service bulletin—McDonnell Douglas Alert Service Bulletin MD90–24A047, Revision 01, dated July 31, 2000—describes procedures for installing standoffs for the power feeder cable and re-routing of the power feeder cable to provide additional clearance between the cable and the main ceiling supports. Accomplishment of the actions specified in these alert service bulletin is intended to adequately address the identified unsafe condition.

Explanation of Requirements of Proposed Rule

The FAA has determined that, rather than proposing to require inspection, follow-on actions, and repair, if necessary, and modification of the galley power feeder cable in two separate ADs, it is technically reasonable to combine the requirements into a single AD. Combining these

actions would also provide a convenience for the operators and would not adversely affect safety. Therefore, this NPRM proposes the accomplishment of the actions specified in both McDonnell Douglas Alert Service Bulletin MD90–24A046, Revision 02, dated March 26, 2001, and Alert Service Bulletin MD90–24A047, Revision 01, dated July 31, 2000. The FAA is considering action to withdraw NPRM Docket Number 2001–NM–149–AD.

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require accomplishment of the actions specified in the alert service bulletins described previously.

Cost Impact

The FAA estimates that 17 airplanes of U.S. registry would be affected by the proposed requirement to accomplish McDonnell Douglas Alert Service Bulletin MD90–24A046, Revision 02, dated March 26, 2001. We estimate that 22 airplanes of U.S. registry would be affected by the proposed requirement to accomplish McDonnell Douglas Alert Service Bulletin MD90–24A047, Revision 01, dated July 31, 2000.

It would take approximately 1 work hour per airplane to accomplish the proposed inspection, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the proposed inspection on U.S. operators is estimated to be $1,020, or $60 per airplane.

It would take approximately 2 work hours per airplane to accomplish the proposed installation of sleeving along a portion of the cable, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the proposed installation of sleeving on U.S. operators is estimated to be $2,040, or $120 per airplane.

It would take approximately 5 work hours per airplane to accomplish the proposed modification of the installation of the galley power feeder cables and re-routing of the cables, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the proposed modification and re-routing of the cable on U.S. operators is estimated to be $6,600, or $300 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 proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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. 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:

McDonnell Douglas: Docket 2001–NM–149–AD.

Applicability: Model MD–90–30 airplanes, as listed in McDonnell Douglas Alert Service Bulletins MD90–24A046, Revision 02, dated March 26, 2001, and MD90–24A047, Revision 01, dated July 31, 2000; 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 future damage to the galley power feeder cable as well as to detect and correct existing damage to the galley power feeder cable, which could result in electrical arcing, possibly leading to damage to adjacent structures and to fire in the airplane, accomplish the following:

Inspection and Follow-On Actions

(a) For McDonnell Douglas Model MD–90–30 airplanes as identified in McDonnell Douglas Alert Service Bulletin MD90–24A046, Revision 02, dated March 26, 2001: Within 90 days after the effective date of this AD, do a one-time general visual inspection of the galley power feeder cable located above the main cabin ceiling supports in the overwing area on the left side for damage caused by chafing—particularly near the ends of the ceiling supports—in accordance with the Accomplishment Instructions of McDonnell Douglas Alert Service Bulletin MD90–24A046, Revision 02, dated March 26, 2001.

Note 2: For the purposes of this AD, a general visual inspection is defined as ''A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or drop-light, and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked.''

Condition 1: Damage to Outer Cable Jacket or Primary Insulation

(1) If any damage to the outer cable jacket or the primary insulation is found, prior to further flight, repair the scuffed jacket or insulation and modify the galley power feeder cable installation by installing sleeving over the wire assembly per the alert service bulletin.

Condition 2: Damage to Power Feeder Cable Conductor

(2) If any damage to the power feeder cable conductor is found, prior to further flight, repair the damaged cable by installing a splice at the damaged location, modify the galley power feeder cable installation by installing sleeving over the cable assembly, and do a functional test of the galley equipment per the alert service bulletin.

Condition 3: No Damage

(3) If no damage is found, prior to further flight, modify the galley power feeder cable installation by installing sleeving over the cable assembly per the alert service bulletin.

Note 3: Accomplishment of the applicable actions prior to the effective date of this AD per McDonnell Douglas Alert Service Bulletin MD90–24A046, dated July 31, 1997; or Revision 01, dated February 16, 1998; is acceptable for compliance with the requirements of paragraph (a) of this AD.

Modification of Installation and Re-routing of Power Feeder Cable

(b) For McDonnell Douglas Model MD–90–30 airplanes, as identified in McDonnell Douglas Alert Service Bulletin MD90–24A047, Revision 01, dated July 31, 2000: Within one year after the effective date of this AD, modify the installation of the galley power feeder cables by installing standoffs and re-route the galley power feeder cable, as shown in Figure 1 of McDonnell Douglas Alert Service Bulletin MD90–24A047, Revision 01, dated July 31, 2000, in accordance with the service bulletin.

Note 4: Accomplishment of the applicable actions prior to the effective date of this AD per McDonnell Douglas Alert Service Bulletin MD90–24–047, dated September 15, 1997, is acceptable for compliance with the requirements of paragraph (b) of this AD.

Alternative Methods of Compliance

(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, Manager, Los Angeles Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Los Angeles ACO.

Note 5: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Los Angeles ACO.

Special Flight Permit

(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 28, 2002.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02–8283 Filed 4–4–02; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 02N–0010]

Dental Devices; Classification for Intraoral Devices for Snoring and/or Obstructive Sleep Apnea

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify the intraoral devices for snoring and/or obstructive sleep apnea, used to control or treat simple snoring and/or obstructive sleep apnea. Under the proposal, the intraoral devices for snoring and/or obstructive sleep apnea would be classified into class II (special controls). The agency is publishing in this document the recommendations of the Dental Devices Panel (the Panel) regarding the classification of these devices. After considering public comments on the proposed classification, FDA will publish a final regulation classifying these devices. This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance document that would serve as the special control if this proposal becomes final.

DATES: Submit written or electronic comments by July 5, 2002. See section VII of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Susan Runner, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (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 new 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 21 CFR part 807 of the regulations.

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.

Consistent with the act and the regulations, FDA consulted with the Panel, an FDA advisory committee,