labor rate of $60 per work hour. Required parts would cost approximately $549 per airplane. Based on these figures, the cost impact of the proposed replacement on U.S. operators is estimated to be $775,371, or $669 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:

Boeing: Docket 98–NM–253–AD.

Applicability: Model 737–100, –200, –300, –400, and –500 series airplanes; that are not equipped with a Grimes Aerospace taxi light assembly having part number (P/N) 50–0199–9, 50–0199–11, 50–0128–1A, 50–0128–1MA, 50–0128–3A, or 50–0128–3MA; 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 damage to the taxi light assembly, which could result in detachment of the taxi light from the airplane, ingestion of taxi light debris into an engine, and consequent loss of thrust from one or both engines; accomplish the following:

Initial and Repetitive Inspections

(a) Within 60 days after the effective date of this AD, perform a detailed visual inspection to detect damage (including cracking, corrosion, deformation, or evidence of impact) of the taxi light assembly mounted on the nose landing gear of the airplane. Repeat the inspection thereafter at intervals not to exceed 1 day, until the requirements of paragraph (c) have been accomplished.

Note 2: For the purposes of this AD, a detailed visual inspection is defined as an intensive visual inspection of a specific structural area, system, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of lighting at an intensity deemed appropriate by the inspector. Inspection aids such as mirrors, magnifying glasses, etc., may be used. Surface cleaning and elaborate access procedures may be necessary.

Replacement

(b) If any damage of the taxi light assembly is detected during any inspection performed in accordance with paragraph (a) of this AD, prior to further flight, replace the existing taxi light assembly with a new or serviceable taxi light assembly in accordance with the applicable maintenance manual. If the existing taxi light assembly is replaced with a Grimes Aerospace taxi light assembly having P/N 50–0199–9, 50–0199–11, 50–0128–1A, 50–0128–1MA, 50–0128–3A, or 50–0128–3MA: no further action is required by this AD.

Terminating Action

(c) Within 2 years after the effective date of this AD: Replace the existing taxi light assembly with a Grimes Aerospace taxi light assembly having P/N 50–0199–9, 50–0199–11, 50–0128–1A, 50–0128–1MA, 50–0128–3A, or 50–0128–3MA; in accordance with the applicable maintenance manual. Such replacement constitutes terminating action for the repetitive inspection requirement of paragraph (a) of this AD.

Alternative Methods of Compliance

(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, Seattle Aircraft Certification Office (ACO), 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, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(e) 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 airplane to a location where the requirements of this AD can be accomplished.

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

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–11617 Filed 5–7–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–NM–18–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Models 737–100, –200, –300, –400, and –500 Series Airplanes; and Model 727–100 and –200 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 Boeing Models 737–100, –200, –300, –400, and –500 series airplanes, and all Models 727–100 and –200 series airplanes. This proposal would require a one-time inspection to determine the presence and condition of the breather plug in each fuel tank boost pump; and

either installation of a new plug or replacement of the boost pump with a new pump, if necessary. This proposal is prompted by a report that breather plugs were missing from fuel tank boost pumps. The actions specified by the proposed AD are intended to prevent possible ignition of fuel vapor in the fuel boost pump, which could result in a fuel tank explosion in the event of a boost pump internal failure.

DATES: Comments must be received by June 24, 1999.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 99–NM–18–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Dorr Anderson, Aerospace Engineer, Propulsion Branch, ANM–140S, FAA, Transport Airplane Directorate, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2684; fax (425) 227–1181.

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 99–NM–18–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. 99–NM–18–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received reports indicating that breather plugs were missing from the Argo-Tech/TRW fuel tank boost pumps of two Boeing Model 727 series airplanes. One fuel pump on each airplane was missing its associated breather plug. At another facility, an operator reported finding 2 breather plugs in a test stand filter, which suggests that those plugs may have been removed from boost pumps but not reinstalled.

A breather plug serves as a flame arrestor in the return line from the boost pump to the fuel tank. The purpose of the flame arrestor is to quench a flame front initiated inside the fuel pump and prevent it from propagating back to the fuel tank.

The breather plug on an Argo-Tech/TRW boost pump is retained within the boost pump return line by an adhesive bond. When a boost pump is installed in an airplane, the breather plug is also mechanically retained within the pump return line by a mating surface on the airplane side of the installation. If the pump is removed from the airplane, the plug is secured within the pump by only the adhesive bond. Any failure of that adhesive could result in loss of the breather plug. A loose, damaged, or missing breather plug, if not detected and corrected, could result in possible ignition of fuel vapor in the fuel boost pump and a consequent fuel tank explosion in the event of a boost pump internal failure.

Other Affected Models

Certain Boeing Model 737 series airplanes also are equipped with Argo-Tech/TRW boost pumps, which incorporate the breather plugs; therefore, those airplanes also may be subject to the unsafe condition identified in this proposed AD.

Explanation of Relevant Service Information

The FAA has reviewed Boeing Telex M–7200–98–03173, dated October 21, 1998, which describes procedures for a one-time inspection of each fuel tank boost pump to determine the presence and condition of its breather plug. For any plug that is loose, damaged, or missing, the telex provides procedures for either installation of a new breather plug or replacement of the boost pump with a new pump.

Temporary Revision (TR) No. 28–1 to the Argo Overhaul Manual (''Plug-in Booster Pump''), dated November 13, 1998, provides procedures for the installation of breather plugs into fuel tank boost pumps.

Accomplishment of the actions specified in the telex and the TR is intended to adequately address the identified unsafe condition.

Explanation of Requirements of Proposed Rule

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 telex and the TR described previously, except as discussed below.

Differences Between Proposed AD and Telex: Compliance Times

The compliance times recommended in the telex differ from those proposed by this AD. The telex recommends a longer compliance time for inspection of the boost pumps of the main fuel tanks, and the proposed AD would allow a longer compliance time for inspection of the boost pumps of the center and auxiliary fuel tanks.

For the inspections of the boost pumps in the main fuel tanks, the proposed AD would require a 12-month compliance time, whereas the telex recommends accomplishment at the next ''C'' check or within 6,000 flight hours for Model 737 series airplanes. (The telex does not specify a compliance time for inspection of affected Model 727 series airplanes.) The FAA has determined that 12 months would allow operators sufficient time to complete the required inspections of all affected airplanes during regular maintenance, without compromising safety. Further, the FAA has determined that an adequate supply of parts is expected to be available within this compliance time.

For the inspections of the boost pumps of Model 737 center fuel tanks and Model 727 center and auxiliary fuel

tanks, the proposed AD would allow a compliance time longer than that recommended by the telex. (The telex does not specify a compliance time for inspection of Model 727 center fuel tanks.) While the FAA recognizes the unsafe condition identified in this proposed AD, the FAA also finds that the burden that would be imposed on operators by specifying a 30-day compliance time is unjustified. The 6-month compliance time proposed by this AD was determined to be appropriate in consideration of the safety implications, the average utilization rate of the affected fleet, and the practical aspects of an orderly inspection of the fleet during regular maintenance periods.

In consideration of all of these factors, the FAA has determined that the proposed compliance times would represent an appropriate interval in which the proposed actions could be accomplished within the fleet in a timely manner, and still maintain an adequate level of safety.

Difference Between Proposed AD and Telex: Approved Installation Method

In addition, operators should note that, although the telex recommends that the manufacturer be contacted for instructions regarding installation of breather plugs, if necessary, this proposal would require such installation to be accomplished in accordance with Argo Overhaul Manual TR 28–1. (The proposed AD would optionally require replacement of the pump with a new pump, in accordance with Boeing maintenance manual procedures.)

Cost Impact

There are approximately 2,477 airplanes of the affected design in the worldwide fleet. The FAA estimates that 1,345 airplanes of U.S. registry would be affected by this proposed AD. It would take approximately 2 work hours per boost pump to accomplish the proposed inspection at an average labor rate of $60 per work hour. (There are 6 boost pumps in the center and main fuel tanks on Model 737 series airplanes, 8 boost pumps in the center and main fuel tanks on Model 727 series airplanes, and 2 boost pumps in each auxiliary fuel tank, which may be installed on some affected airplanes of both models.) Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $120 per boost pump.

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.

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:

Boeing: Docket 99–NM–18–AD.

Applicability: Model 737–100, –200, –300, –400, and –500 series airplanes that are equipped with Argo-Tech/TRW fuel boost pumps; and all Model 727–100 and –200 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 possible ignition of fuel tank vapor in the fuel boost pump, which could result in a fuel tank explosion, accomplish the following:

Inspection and Corrective Actions

(a) Perform a one-time detailed inspection to detect discrepant breather plugs (including loose, damaged, and missing plugs) in the fuel tank boost pumps, at the time specified in paragraph (a)(1) or (a)(2), as applicable, of this AD; in accordance with Boeing Telex M–7200–98–03173, dated October 21, 1998. If any discrepancy is detected, prior to further flight, either install a new breather plug in accordance with Temporary Revision (TR) No. 28–1 of the Argo Overhaul Component Maintenance Manual, dated November 13, 1998; or replace the boost pump with a new pump, in accordance with procedures specified in section 28–22–41 of the Boeing 737 Airplane Maintenance Manual (AMM) or Section 28–22–21 of the Boeing 727 AMM, as applicable.

(1) For center fuel tanks installed on Model 737 series airplanes, and for auxiliary fuel tanks installed on Model 727 and 737 series airplanes: Inspect within 6 months after the effective date of this AD.

(2) For main fuel tanks installed on Model 737 series airplanes, and for center and main fuel tanks installed on Model 727 series airplanes: Inspect within 12 months after the effective date of this AD.

Spares

(b) As of the effective date of this AD, no person shall install on any airplane an Argo-Tech/TRW fuel boost pump, unless that pump has been inspected and applicable corrective actions have been performed in accordance with the requirements 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, Seattle Aircraft Certification Office (ACO), 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, Seattle ACO.

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

Special Flight Permits

(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 airplane to a location where the requirements of this AD can be accomplished.

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

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99–11615 Filed 5–7–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. 99N–0922]

Obstetrics and Gynecology Devices; Proposed Requirement for Premarket Approval and Change in Classification of Glans Sheath Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the glans sheath medical device. The agency is also summarizing its proposed findings regarding the degree of risk of illness or injury intended to be eliminated or reduced by requiring the device to meet the statute's approval requirements as well as the benefits to the public from the use of the device. In addition, FDA is announcing the opportunity for interested persons to request the agency to change the classification of the device based on new information. This action is being taken to establish that there is sufficient information to provide reasonable assurance of the safety and effectiveness of this type of device.

DATES: Written comments by August 9, 1999; requests for a change in classification by May 26, 1999.

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

FOR FURTHER INFORMATION CONTACT: Colin M. Pollard, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1180.

SUPPLEMENTARY INFORMATION:

I. Background

Section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), and devices marketed on or after that date that are substantially equivalent to such devices have been, or are being, classified by FDA. For convenience, this preamble refers to both the devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date as ''preamendments devices.''

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or a notice of completion of a PDP until 90 days after the effective date of the final rule FDA issues requiring premarket approval for the device, or 30 months after final classification of the device, whichever is later. Also, a preamendments device subject to the rulemaking procedure under section 515(b) of the act is not required to have an approved investigational device exemption (IDE) (part 812 (21 CFR part 812)) contemporaneous with its interstate distribution until the date identified by FDA in the final rule requiring the submission of a PMA or PDP for the device. At that time, an IDE must be submitted only if a PMA has not been submitted or a PDP has not been declared completed.

Section 515(b)(2)(A) of the act provides that a proceeding to issue a final rule to require premarket approval shall be initiated by publication of a notice of proposed rulemaking containing: (1) The proposed rule, (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device, (3) an opportunity to submit comments on the proposed rule and the proposed findings, and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(2)(B) of the act provides that if FDA receives a request for a change in the classification of the device within 15 days of the publication of the notice, FDA shall, within 60 days of the publication of the notice, consult with the appropriate FDA advisory committee and publish a notice denying the request for change of classification or announcing its intent to initiate a proceeding to reclassify the device under section 513(e) of the act. If FDA does not initiate such a proceeding, section 513(b)(3) of the act provides that FDA shall, after the close of the comment period on the proposed rule and consideration of any comments received, issue a final rule to require premarket approval, or publish a notice terminating the proceeding. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the act, unless the reason for termination is that the device is a banned device under section 516 of the act (21 U.S.C. 360f).

If a proposed rule to require premarket approval for a preamendments device is made final, section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)) requires that a PMA or a notice of completion of a PDP for any such device be filed within 90 days after the effective date of the final rule or 30 months after FDA's final classification of the device under section 513 of the act, whichever is later. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease. The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, and no IDE is in effect, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the act, and subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334) if its distribution continues. Shipment of the device in interstate commerce will be subject to injunction under section 302 of the act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the act (21 U.S.C. 333). In the past, FDA has requested that manufacturers take action to prevent the further use of devices for which no PMA has been filed and may determine that such a request is appropriate for the glans sheath device.

The act does not permit an extension of the 90-day period after the effective date of the final rule, within which an