compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(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 1998–042/2, dated February 29, 2000.

Issued in Renton, Washington, on January 9, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1236 Filed 1–12–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–303–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 777–200 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 Model 777–200 series airplanes. This proposal would require repetitive detailed visual and ultrasonic inspections of the lower flange of the flaperon inboard support to find cracking, and corrective actions, if necessary. This proposal also would require a modification, which would terminate the repetitive inspections. This action is necessary to prevent fracture of the inboard support structure, which could result in an in-flight loss of the inboard flaperon, structural damage, and consequent reduced controllability of the airplane. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by March 2, 2001.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2000–NM–303–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. 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–303–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 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: Stan Wood, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2772; 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 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 2000–NM–303–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–303–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

Flight testing of certain Boeing Model 777–200 series airplanes showed that high engine thrust conditions during takeoff cause tremendous cyclic loads on the support structure of the inboard flaperon. Based on engineering analysis, fatigue cracks of the support structure could develop at approximately 4,000 flight cycles. Such fatigue cracking could result in fracture of the inboard support structure, in-flight loss of the inboard flaperon, significant damage to the surrounding structure, and consequent reduced controllability of the airplane.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Alert Service Bulletin 777–57A0036, dated June 24, 1999, which describes procedures for detailed visual and ultrasonic inspections of the lower flange of the flaperon inboard support to find cracking, and corrective actions if cracking is found. The corrective actions consist of accomplishment of the terminating action in Part 2 of the service bulletin. The terminating action includes, but is not limited to, a high frequency eddy current inspection to find cracks of the aft holes that attach the failsafe strap to the lower flange, oversizing of the holes if cracks are found, and installation of a failsafe strap. Accomplishment of the actions specified in the service bulletin 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 service bulletin described previously, except as discussed below.

Differences Between Service Bulletin and This Proposed AD

While the effectivity listing of the service bulletin includes airplanes having line numbers (L/N) 2 through 9 inclusive; this proposed AD would apply to airplanes having L/N's 1 through 9 inclusive. The FAA has determined that the subject area on the airplane with L/N 1 is identical to the subject areas on the Model 777–200 series airplanes listed in the service bulletin; so the airplane with L/N 1 is also subject to the identified unsafe condition.

Although the service bulletin specifies that the manufacturer may be contacted for instructions on repair of certain conditions, this proposed AD would require the repair of those conditions to be accomplished per a method approved by the FAA, or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative who has been authorized by the FAA to make such findings.

Cost Impact

There are approximately 9 airplanes of the affected design in the worldwide fleet.

The FAA estimates that 1 airplane of U.S. registry would be affected by this proposed AD.

It would take approximately 3 work hours per airplane to accomplish the proposed inspections, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the inspections proposed by this AD on U.S. operators is estimated to be $180 per airplane, per inspection cycle.

It would take approximately 6 work hours per airplane to accomplish the proposed terminating action, at an average labor rate of $60 per work hour. Required parts would cost approximately $2,932 per airplane. Based on these figures, the cost impact of the terminating action proposed by this AD on U.S. operators is estimated to be $3,292 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:

Boeing: Docket 2000–NM–303–AD.

Applicability: Model 777–200 series airplanes, line numbers (L/N) 1 through 9 inclusive, 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 per 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 fracture of the inboard support structure of the flaperon, which could result in an in-flight loss of the inboard flaperon, structural damage, and consequent reduced controllability of the airplane, accomplish the following:

Repetitive Inspections

(a) Before the accumulation of 4,000 total flight cycles, or within 90 days after the effective date of this AD, whichever occurs later: Do a detailed visual and an ultrasonic inspection of the lower flange of the flaperon inboard support to find cracks per Part 1 of the Accomplishment Instructions of Boeing Alert Service Bulletin 777–57A0036, dated June 24, 1999.

(1) If no cracking is found: Repeat the applicable inspections thereafter at intervals not to exceed 300 flight cycles until accomplishment of the terminating action specified in paragraph (b) of this AD.

(2) If any cracking is found, before further flight, do the terminating action required by paragraph (b) of this AD, except, where the service bulletin specifies to contact Boeing for instructions, before further flight, repair per a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative (DER) who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved by the Manager, Seattle ACO, as required by this paragraph, the approval letter must specifically reference this AD.

Terminating Action

(b) On or before the accumulation of 8,000 total flight cycles, or within 1,200 flight cycles after the effective date of this AD, whichever occurs later: Do the terminating action (a high frequency eddy current inspection to find cracks of the aft holes that attach the failsafe strap to the lower flange, oversizing of the holes if cracks are found, and installation of a failsafe strap), per Part 2 of the Accomplishment Instructions of Boeing Alert Service Bulletin 777–57A0036, dated June 24, 1999. Accomplishment of this paragraph terminates the repetitive inspections required by paragraph (a) 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 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, 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 Permit

(d) Special flight permits may be issued per 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 January 9, 2001.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 01–1235 Filed 1–12–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 807

[Docket No. 00N–1625]

Medical Devices; Rescission of Substantially Equivalent Decisions and Rescission Appeal Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing regulations under which FDA may rescind a decision issued under the Federal Food, Drug, and Cosmetic Act (the act) that a device is substantially equivalent to a legally marketed device, and, therefore, may be marketed. In addition, under this proposal, a premarket notification (commonly known as a ''510(k)'') holder may request administrative review of a proposed rescission action. This proposed rule is being issued in order to standardize the procedures for considering rescissions.

DATES: Submit written comments by April 16, 2001.

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

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

The Medical Device Amendments (Public Law 94–295) (the amendments) to the act (21 U.S.C. 301 *et seq.*) were enacted on May 28, 1976. Among other things, the amendments directed FDA to issue regulations classifying all medical devices into one of three regulatory control categories. The classification depends upon the degree of regulation necessary to provide reasonable assurance of the safety and effectiveness of the device.

Under section 513(a)(1)(A) of the act (21 U.S.C. 360c(a)(1)(A)), class I devices are subject to a comprehensive set of regulatory provisions applicable to all classes of devices, e.g., registration and listing, prohibitions against adulteration and misbranding, and good manufacturing practice requirements. A class I device is exempt from the premarket notification requirements of the act unless it is intended for a use which is of substantial importance in preventing impairment of human health, or the device presents a potential unreasonable risk of illness or injury under section 510(l) of the act (21 U.S.C. 360(l)). Class II devices are subject to special controls as well as general controls. These special controls may consist of performance standards, postmarket surveillance, patient registries, FDA guidelines, or other appropriate controls under section 513(a)(1)(B) of the act. Class III devices require premarket approval (PMA) or a completed product development protocol by FDA before they may be marketed, unless they are class III devices for which we have not called for PMA's under section 515(b) of the act (21 U.S.C. 360e(b)).

II. Premarket Notification Requirements

Section 510(k) of the act requires each person who is required to register and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use to submit a 510(k).

Throughout this proposal, we use the following terms:

1. The ''510(k) submitter.''—the person who submitted the 510(k) to the FDA.

2. The ''510(k) holder''—the person who possesses the rights to market the device that is the subject of a 510(k) substantial equivalence order. (The 510(k) submitter and the 510(k) holder may or may not be the same person.)

3. The ''510(k) holder of record''—the person whom FDA has on file as being the 510(k) holder.

The proposed rule adds these definitions to 21 CFR 807.3.

There may be instances when 510(k) ownership has changed without FDA's knowledge. In the event of a proposed rescission, FDA would provide notice to the 510(k) holder of record. FDA would attempt to notify the holder of record by registered letter. FDA would also post notice of a proposed rescission on FDA's Center for Devices and Radiological Health's (CDRH) home page on the Internet at http://www.fda.gov/cdrh/index.html. To protect the privacy of the 510(k) holder, only the proposed rescission would be listed; the factual basis and reasons for the rescission would not be posted on CDRH's home page on the Internet.

Under the 510(k) process, the 510(k) submitter may claim that its new device is substantially equivalent to a legally marketed class I or class II device or to a preamendments class III device that is not yet required to be the subject of an approved premarket approval application. If, after reviewing the 510(k), the agency determines that the device is substantially equivalent to the legally marketed device (as defined in 21 CFR 807.92(a)(3)), the agency will issue an order permitting the 510(k) submitter to market its device without the need for the more rigorous premarket approval under section 515 of the act.

The criteria the agency must use to determine substantial equivalence are in section 513(i) of the act. Section 513(i) of the act defines substantial equivalence to mean that the device has the same intended use as the predicate device and that FDA, by order, has found that the device—(i) has the same technological characteristics as the predicate device, or (ii)—(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including clinical data if deemed necessary by FDA, that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the legally marketed device.

The statute allows 510(k) marketing clearance only for devices that FDA determines are comparable in safety and effectiveness to a legally marketed device. New devices that are not substantially equivalent must remain in class III and meet the premarket approval requirements under section 515 of the act before they can be marketed, unless the device is reclassified under section 513(f) of the act.