TABLE 1

Average flight time (AFT): flight hours/flight cycles	Threshold (flight cycles)	Visual inspection interval (flight cycles)	Eddy current/liquid penetrant inspection interval (flight cycles)
2.10–2.49	5,900	4,700	5,300
2.50–2.99	5,600	4,400	4,900
3.00–3.49	5,200	4,100	4,600
3.50–3.99	4,800	3,800	4,200
4.00–4.49	4,400	3,500	3,900
4.50–4.99	4,000	3,200	3,500
5.00–5.49	3,600	2,800	3,200
5.50–5.99	3,200	2,500	2,800
6.00–6.50	2,800	2,200	2,500

(b) Except as provided by paragraph (d) of this AD, if any crack is found during an inspection required by paragraph (a) of this AD, prior to further flight, accomplish follow-on corrective actions in accordance with the procedures specified in Airbus Service Bulletin A300–57–6052, Revision 1, dated July 22, 1996.

(c) Within 4 years after the effective date of this AD, modify the angle fitting at frame 40 (both left and right) in accordance with Airbus Service Bulletin A300–57–6053, Revision 1, dated October 31, 1995. Accomplishment of the modification constitutes terminating action for the repetitive inspections required by paragraph (a) of this AD.

(d) If any crack is found during an inspection required by paragraph (a) of this AD, and the applicable service bulletin specifies to contact the manufacturer for an appropriate action: Prior to further flight, repair in accordance with a method approved by the Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate.

(e) 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. 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.

(f) 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.

Note 3: The subject of this AD is addressed in French airworthiness directive (CN) 95–111–181(B) R1, dated October 23, 1996.

Issued in Renton, Washington, on October 7, 1998.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–27477 Filed 10–13–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–243–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 inspections to verify correct installation of certain fasteners located on the trailing edges of the horizontal and vertical stabilizer; replacement of the existing fasteners with new fasteners installed with wet sealant; and follow-on actions, if necessary. This proposal is prompted by reports indicating that, during manufacture of the horizontal and vertical stabilizers, certain fasteners attaching the aluminum ribs and brackets to the trailing edges on the empennage were not correctly installed with wet sealant. The actions specified by the proposed AD are intended to prevent corrosion and possible cracking of those aluminum parts, which could result in loss of the attachment of the elevator and rudder to the empennage and consequent reduced controllability of the airplane.

DATES: Comments must be received by November 30, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 98–NM–243–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 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, Transport Airplane Directorate, 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 notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice

must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 98–NM–243–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 98–NM–243–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received reports indicating that, during manufacture of the horizontal and vertical stabilizers, which are made primarily of graphite composite, certain fasteners attaching the aluminum ribs and brackets to the trailing edges on the empennage were not correctly installed with wet sealant. If moisture is present this lack of sealant results in an electrolytic path between the aluminum components and composite structure that could cause corrosion of the aluminum components. Such corrosion could lead to the initiation of fatigue cracks. This condition, if not corrected, could result in loss of the attachment of the elevator and rudder to the empennage and consequent reduced controllability of the airplane.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Alert Service Bulletin 777–55A0005, Revision 1, dated June 4, 1998, which describes procedures for visual inspections to verify correct installation of certain fasteners located on the trailing edges of the horizontal and vertical stabilizer, and replacement of the existing fasteners with new fasteners installed with wet sealant, if necessary. The alert service bulletin also describes follow-on procedures for oversizing the fastener holes and applying primer prior to installation of fasteners. Accomplishment of the actions specified in the alert 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 alert service bulletin described previously.

Cost Impact

There are approximately 18 airplanes of the affected design in the worldwide fleet. The FAA estimates that 2 airplanes of U.S. registry would be affected by this proposed AD.

It would take approximately 331 work hours per airplane to accomplish the proposed inspection of the horizontal stabilizer, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $39,720, or $19,860 per airplane.

It would take approximately 206 work hours per airplane to accomplish the proposed inspection of the vertical stabilizer, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $24,720, or $12,360 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–243–AD.

Applicability: Model 777–200 series airplanes, line numbers 15 through 33, excluding line number 18; 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 (b) 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 corrosion and possible cracking of the aluminum ribs and brackets of the trailing edges on the empennage, which could result in loss of the attachment of the elevator and rudder to the empennage and consequent reduced controllability of the airplane, accomplish the following:

(a) Within five years since the date of manufacture of the airplane, perform visual inspections of the specified number of fasteners installed in each zone on the aluminum ribs and brackets located on the trailing edges of the horizontal and vertical stabilizer to verify correct installation of fasteners with wet sealant, in accordance with Boeing Alert Service Bulletin 777–55A0005, Revision 1, dated June 4, 1998. Following the inspection, oversize the holes for all removed fasteners, apply primer, and install new, oversize fasteners with wet sealant, in accordance with the alert service bulletin.

(1) If the fasteners are correctly installed with wet sealant, no further action is required for that zone.

(2) If the fasteners are not correctly installed with wet sealant in any zone, remove the remaining fasteners in that zone, oversize the holes, apply primer, and install new, oversize fasteners with wet sealant, in accordance with the alert service bulletin.

(3) If it cannot be determined that the fasteners are correctly installed with wet sealant, remove and inspect the specified number of additional fasteners in that zone, oversize the holes, apply primer, and install new, oversize fasteners with wet sealant, in accordance with the alert service bulletin.

(i) If, after removal, all additional fasteners inspected in that zone are found to be correctly installed with wet sealant, no further action is required for that zone.

(ii) If, after removal, the fasteners in that zone are found to be incorrectly installed, remove all other fasteners in the zone, oversize the holes, apply primer, and install new, oversize fasteners with wet sealant, in accordance with the alert service bulletin.

(b) 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.

(c) 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 October 7, 1998.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–27481 Filed 10–13–98; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 315 and 601

[Docket No. 98N–0040]

Regulations for In Vivo Radiopharmaceuticals Used for Diagnosis and Monitoring; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to November 16, 1998, the comment period on a proposed rule that was published in the **Federal Register** of May 22, 1998 (63 FR 28301). The document proposed to amend the drug and biologics regulations by adding provisions that would clarify the evaluation and approval of in vivo radiopharmaceuticals used for diagnosis and monitoring. The agency is taking this action to provide interested persons additional time to submit comments to FDA on the proposed rule.

DATES: Written comments by November 16, 1998.

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

FOR FURTHER INFORMATION CONTACT:

Dano B. Murphy, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210, or

Brian L. Pendleton, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5649.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 22, 1998 (63 FR 28301), FDA published a proposed rule to amend the drug and biologics regulations by adding provisions that would clarify the evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis and monitoring of diseases. The proposed regulations would describe certain types of indications for which FDA may approve diagnostic radiopharmaceuticals. The proposed rule would also include criteria that the agency would use to evaluate the safety and effectiveness of a diagnostic radiopharmaceutical under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. FDA provided until August 5, 1998, to submit comments on the proposed rule.

In the **Federal Register** of August 3, 1998 (63 FR 41219), FDA extended the comment period on the proposed rule until October 15, 1998, to allow interested persons additional time to submit comments on the proposed rule. FDA finds it appropriate to further extend the comment period to November 16, 1998, to permit interested persons the opportunity to consider the proposed rule in light of the agency's draft guidance for industry entitled ''Developing Medical Imaging Drugs and Biologics.'' Notice of the availability of this draft guidance is published elsewhere in this issue of the **Federal Register**.

Interested persons may, on or before November 16, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 2, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–27494 Filed 10–13–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 315 and 601

[Docket No. 98D–0785]

Draft Guidance for Industry on Developing Medical Imaging Drugs and Biologics; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Availability of guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Developing Medical Imaging Drugs and Biologics.'' This draft guidance is intended to assist developers of drug and biological products used for medical imaging, as well as radiopharmaceutical drugs used in disease diagnosis, in planning and coordinating the clinical investigations of, and submitting various types of applications for, such products. The draft guidance also provides information on how the agency will interpret and apply provisions in the proposed regulations for in vivo radiopharmaceuticals used for diagnosis and monitoring, which published in the **Federal Register** of May 22, 1998 (63 FR 28301).

DATES: Written comments on the draft guidance may be submitted by December 14, 1998. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401