Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2001–NM–30–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 777 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 all Boeing Model 777 series airplanes. This proposal would require repetitive inspections for cracking of the floor beam structure located at body station 246; and repair, if necessary. This action is necessary to find and fix such cracking, which could extend and sever the floor beam, resulting in rapid depressurization of the airplane and consequent collapse of the floor structure. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by August 5, 2002.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2001–NM–30–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. 2001–NM–30–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: Suzanne Masterson, 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 2001–NM–30–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. 2001–NM–30–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received numerous reports of fatigue cracking of the floor beam structure located at body station (BS) 246 on several Boeing Model 777 series airplanes. Investigation revealed that the fatigue is caused by high bending stresses in the forward and aft directions of the BS 246 floor beam during flight. The high stress is due to the temperature difference between the fuselage skin and the floor structure, which results in contraction of the fuselage skin and subsequent cracking of the floor structure. Additionally, cracked stiffeners and mid-chord cracking of the left and/or right body line (BL) 38.5 were found. Several web cracks were also found at left and right BL 32.5. Such cracking could extend and sever the floor beam, resulting in rapid depressurization of the airplane and consequent collapse of the floor structure.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Service Bulletin 777–53–0031, dated October 26, 2000, which describes procedures for a detailed inspection for cracking of the floor beam structure located at BS 246. The inspection includes the floor beam clips, stiffeners, webs, and chords. The service bulletin also describes procedures for a low frequency eddy current (LFEC) inspection for cracking of the upper flange of the mid-chord at left and right BL 38.5. As an alternative to the LFEC inspection, the service bulletin allows for a detailed inspection of those areas. The alternative inspection necessitates removal of certain equipment and floor panels installed on the aft side of the BS 246 floor beam for access. If cracking is found, the service bulletin describes procedures for repair, as specified in the Boeing Model 777 Structural Repair

Manual. The service bulletin also specifies obtaining repair data from Boeing for certain cracking. 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.

Difference Between This Proposed AD and the Service Bulletin

Although the service bulletin specifies that the manufacturer may be contacted for disposition of certain repairs/inspection procedures, this proposed AD would require such repairs/inspection procedures 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 Manager, Seattle Aircraft Certification Office, to make such findings.

Interim Action

This is considered to be interim action. The manufacturer has advised that it currently is developing a modification to address the unsafe condition that will reduce or eliminate the need for the requirement imposed by this proposed AD. Once this modification is developed, approved, and available, the FAA may consider additional rulemaking.

Cost Impact

There are approximately 184 airplanes of the affected design in the worldwide fleet. The FAA estimates that 81 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour per airplane to accomplish the proposed inspections, and that the average labor rate is $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 $4,860, or $60 per airplane, per inspection cycle.

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 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 2001–NM–30–AD.

Applicability: All Model 777 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 find and fix cracking of the floor beam structure located at body station (BS) 246, which could extend and sever the floor beam, resulting in rapid depressurization of the airplane and consequent collapse of the floor structure, accomplish the following:

Repetitive Inspections

(a) Within 2,500 flight cycles or 5,000 flight hours after the effective date of this AD, whichever is first: Do the inspections for cracking of the floor beam structure located at BS 246 as specified in paragraphs (a)(1) and (a)(2) of this AD, per Boeing Service Bulletin 777–53–0031, dated October 26, 2000. Repeat the inspections every 2,500 flight cycles or 5,000 flight hours, whichever is first.

(1) Do a detailed inspection for cracking of the floor beam structure (including floor beam clips, stiffeners, webs, and chords) located at BS 246.

(2) Do a low frequency eddy current (LFEC) inspection for cracking of the upper flange of the mid-chord at left and right body lines 38.5: As an alternative to the LFEC inspection a detailed inspection of this area may be done, provided that removal of certain equipment and floor panels installed on the aft side of the BS 246 floor beam is done to obtain access.

Note 2: For the purposes of this AD, a detailed inspection is defined as: ''An intensive visual examination 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 good lighting at intensity deemed appropriate by the inspector. Inspection aids such as mirror, magnifying lenses, etc., may be used. Surface cleaning and elaborate access procedures may be required.''

Repair

(b) If any crack is found during any inspection per paragraph (a) of this AD: Before further flight, repair per Boeing Service Bulletin 777–53–0031, dated October 26, 2000; except where the service bulletin specifies to contact Boeing for disposition of certain repairs, 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 who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved as required by this paragraph,

the approval must specifically reference this AD.

Note 3: There is no terminating action currently available for the repetitive inspections required by 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. 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 4: 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 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 June 12, 2002.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 02–15368 Filed 6–18–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 312

[Docket No. 00N–1663]

RIN 0910–AA61

Investigational New Drugs: Export Requirements for Unapproved New Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations on the exportation of investigational new drugs, including biological products. The proposed rule would provide four different mechanisms for exporting an investigational new drug product. These provisions would implement changes in FDA's export authority resulting from the FDA Export Reform and Enhancement Act of 1996, and they would also simplify the existing requirements for exports of investigational new drugs.

DATES: Submit written or electronic comments by September 17, 2002. Submit written comments on the information collection requirements by July 19, 2002.

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.* Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20502, Attn: Stuart Shapiro.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy, Planning, and Legislation (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Background

Current FDA regulations at § 312.110 (21 CFR 312.110) require any person who intends to export an unapproved new drug product for use in a clinical investigation either to have an investigational new drug application (IND) or to submit a written request to FDA. The written request must provide sufficient information about the drug to satisfy FDA that the drug is appropriate for investigational use in humans, that the drug will be used for investigational purposes only, and that the drug may be legally used by the consignee in the importing country for the proposed investigational use (see § 312.110(b)(2)(i)). The request must also specify the quantity of the drug to be shipped and the frequency of expected shipments (§ 312.110(b)(2)(i)). If FDA authorizes exportation of the drug, it notifies the government of the importing country (§ 312.110(b)(2)(i)). Similar procedures exist for export requests made by foreign governments (see § 312.110(b)(2)(ii)). Section 312.110(b)(3) states that the requirements in paragraph (b) apply only where the drug is to be used for the purpose of a clinical investigation. Section 312.110(b)(4) states that the requirements in paragraph (b) do not apply to the exports of new drugs approved or authorized for export under section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) or section 351(h)(1)(A) of the Public Health Service Act.

The program for exporting investigational new drugs is commonly known as the ''312 program'' because the regulation pertaining to the program is located in part 312 (21 CFR part 312). Between fiscal years 1994 and 1997, FDA received nearly 1,800 export requests under the 312 program. Very few requests (less than 1 percent) presented any safety, quality, or other public health concerns.

In 1996, the President signed into law amendments to the act that changed the export requirements for certain drugs, biologics, and devices that may not be marketed or sold in the United States. These amendments, known as the FDA Export Reform and Enhancement Act of 1996 (Public Law 104–134, amended by Public Law 104–180), created, among other things, two new provisions that affect the exportation of investigational drug products. One provision, now section 802(b)(1)(A) of the act, authorizes exportation of an unapproved new drug to any country if that drug has valid marketing authorization by the appropriate authority in Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, the European Union (EU), or a country in the European Economic Area (EEA) and certain other requirements are met. These countries are listed in section 802(b)(1)(A)(i) and (b)(1)(A)(ii) of the act and are sometimes referred to as the ''listed countries.'' Currently, the EU countries are Austria, Belgium, Denmark, Germany, Greece, Finland, France, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom. The EEA countries are the EU countries, and Iceland, Liechtenstein, and Norway. The list of countries in section 802(b)(1)(A)(i) of the act will expand automatically if any country accedes to the EU or becomes a member of the EEA. Exports under section 802(b)(1)(A) of the act can encompass exportation of an unapproved new drug product for investigational use in a foreign country if the exported drug product has marketing authorization in any listed country and the relevant statutory requirements are met. Exports under section 802(b)(1)(A) of the act do not require prior FDA authorization.

The second provision, now section 802(c) of the act, permits exportation of unapproved new drugs (including biological products) intended for investigational use to any listed country in accordance with the laws of that country. Exports of drugs to the listed countries under section 802(c) of the act do not require prior FDA authorization and are exempt from regulation under section 505(i) of the act (21 U.S.C. 355(i)).