General Visual, Contour, and Clearance Inspections of Ground Spoilers, and Related Investigative/Corrective Actions

(a) Within 400 flight cycles after the effective date of this AD: Do one-time general visual, contour, and clearance inspections for discrepancies of the ground spoiler assemblies and the wing flaps by doing all the actions per the Accomplishment Instructions of Dornier Service Bulletin SB–328J–57–180, Revision 1, dated March 10, 2003. Any applicable related investigative and corrective actions must be done before further flight per the service bulletin.

Note 1: 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 from within touching distance unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight 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.''

Submission of Inspection Results Not Required

(b) Although the service bulletin referenced in this AD specifies to submit information to the manufacturer, this AD does not include such a requirement.

Alternative Methods of Compliance

(c) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, is authorized to approve alternative methods of compliance for this AD.

Note 2: The subject of this AD is addressed in German airworthiness directive 2003–120/2, dated July 24, 2003.

Issued in Renton, Washington, on March 11, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–5967 Filed 3–16–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–224–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A320–211, –212, –214, –232 and –233 Series Airplanes and Model A321–211, –231 and –232 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 Airbus Model A320–211, –212, –214, –232 and –233 series airplanes and Model A321–211, –231 and –232 series airplanes. This proposal would require a one-time ultrasonic inspection of certain floor crossbeams to determine if they are of nominal thickness; and a structural modification to reinforce any crossbeam that is not of nominal thickness. This action is necessary to prevent reduced structural integrity of the floor in the event of rapid depressurization or rapid vertical acceleration. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by April 16, 2004.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2002–NM–224–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. 2002–NM–224–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 or 2000 or ASCII text.

The service information referenced in the proposed rule may be obtained from Airbus, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer; International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

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 2002–NM–224–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. 2002–NM–224–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, notified the FAA that an unsafe condition may exist on certain Airbus Model A320–211, –212, –214, –232 and –233 series airplanes and Model A321–211, –231 and –232 series airplanes. The DGAC advises that an Airbus quality check revealed that, due to a process discrepancy during production, certain floor structural crossbeams were manufactured that were not of nominal thickness and were installed in certain airplanes before the discrepancy was discovered. This condition, if not corrected, could result in reduced

structural integrity of the floor in the event of rapid depressurization or rapid vertical acceleration.

Explanation of Relevant Service Information

Airbus has issued Service Bulletin A320–53A1162, including Appendix 01 and Appendix 02, dated June 25, 2002, which describes procedures for a one-time ultrasonic inspection of certain floor crossbeams for nominal thickness. Airbus has also issued Service Bulletin A320–53A1163, dated June 25, 2002, which describes procedures for reinforcement of crossbeams found not at nominal thickness. Accomplishment of the actions specified in the service bulletins is intended to adequately address the identified unsafe condition. The DGAC classified these service bulletins as mandatory and issued French airworthiness directive 2002–418(B), on August 7, 2002, to ensure the continued airworthiness of these airplanes in France.

FAA's Conclusions

These airplane models are manufactured in France and are type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require accomplishment of the actions specified in the applicable service bulletins described previously, except as described below.

Difference Between Proposed Rule and Referenced Service Bulletins

Operators should note that, although Airbus Service Bulletin A320–53A1162, including Appendix 01 and Appendix 02, dated June 25, 2002, describes procedures for submitting inspection results to the manufacturer, this proposed AD would not require that action.

Cost Impact

The FAA estimates that 25 airplanes of U.S. registry would be affected by this proposed AD.

The ultrasonic inspection required by this proposed AD would take approximately 1 work hour per airplane to accomplish at an average labor rate of $65 per work hour. Based on these figures, the cost impact of this AD on U.S. operators is estimated to be $1,625, or $65 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. 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:

Airbus: Docket 2002–NM–224–AD.

Applicability: This AD applies to the airplanes specified in Table 1 of this AD; certificated in any category.

TABLE 1

For model	Manufacturer's Serial Number (MSN)	Except for MSN
A320–211, –212, –214, –232, and –233 series airplanes	1516 to 1754 inclusive	1624, 1655, 1665, 1676, 1694, 1697, 1708, 1730, 1732 and 1736
A321–211, –231 and –232 series airplanes	1572 to 1711 inclusive	1675 and 1681

Compliance: Required as indicated, unless accomplished previously.

To prevent reduced structural integrity of the floor in the event of rapid depressurization or rapid vertical acceleration, accomplish the following:

Inspection

(a) Within 450 flight hours from the effective date of this AD, perform a one-time ultrasonic inspection of the specified floor crossbeams for nominal thickness, as defined in Airbus Service Bulletin A320–53A1162, including Appendix 01 and Appendix 02, as applicable, dated June 25, 2002. Do the inspection per the Accomplishment Instructions of the Service Bulletin.

(1) If both floor crossbeams are found to be at the nominal thickness, no further action is required by this AD.

(2) If any floor crossbeam is found to not be at the nominal thickness, within 50 flight hours after the inspection required by paragraph (a) of this AD, reinforce the crossbeam in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–53A1163, dated June 25, 2002, as applicable.

Difference Between Proposed Rule and Referenced Service Bulletins

(b) Although the service bulletins referenced in this AD specify to submit certain information to the manufacturer, this AD does not include such a requirement.

Alternative Methods of Compliance

(c) In accordance with 14 CFR 39.19, the Manager, International Branch, ANM–116, FAA, is authorized to approve alternative methods of compliance for this AD.

Note 1: The subject of this AD is addressed in French airworthiness directive 2002–418(B), dated August 7, 2002.

Issued in Renton, Washington, on March 10, 2004.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 04–5968 Filed 3–16–04; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 1998N–1111]

Gastroenterology-Urology Devices; Classification for External Penile Rigidity Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify external penile rigidity devices intended to create or maintain sufficient penile rigidity for sexual intercourse into class II (special controls). Also, FDA is giving notice of its intent to exempt this type of device from the premarket notification (510(k)) requirements of the Federal Food, Drug, and Cosmetic Act. 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 this device. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of a draft guidance document that would serve as the special control for the devices if this proposal becomes final.

DATES: Submit written or electronic comments by June 15, 2004. *See* section IX of this document for the proposed effective date of a final rule based on this document.

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

FOR FURTHER INFORMATION CONTACT: Janine Morris, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, (301) 594–2194.

SUPPLEMENTARY INFORMATION:

I. Background

A. Regulatory Authorities

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 (SMDA) (Public Law 101–629), the Food and Drug Administration Modernization Act (FDAMA) (Public Law 105–115), and the Medical Devices User Fee and Modernization Act (MDUFMA) (Public Law 107–250) established a comprehensive system for regulating 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 amendments), generally referred to as preamendments devices, are classified after FDA has taken the following steps: (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 before 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 until FDA performs the following tasks: (1) Reclassifies the device into class I or II; (2) 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 the FDAMA; or (3) issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a legally marketed device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed 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.

FDAMA added a new section 510(m) to the act (21 U.S.C. 360(m)). New section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if the agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of external penile rigidity devices.

B. Regulatory History

External penile rigidity devices are preamendments devices. These devices were not classified with the gastroenterology and urology devices that were classified in 1983. FDA has reviewed marketing submissions for these devices through the 510(k) process. Based on the premarket notifications (510(k)) reviews, the agency believes that the labeling of these devices adequately informs users and practitioners about the safe and effective use of the devices.

Consistent with the act and the regulations, FDA consulted with the Gastroenterology-Urology Advisory Panel (the Panel), an FDA advisory committee, regarding the classification of these devices. During a public meeting on August 7, 1997, the Panel discussed the history, composition, and usage of external penile rigidity devices. The Panel recommended classifying