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. 98–NM–132–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Model A300, A310, and A300–600 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 A300, A310, and A300–600 series airplanes. This proposal would require a one-time operational test and repetitive functional tests of the free fall control mechanism of the landing gear, to ensure proper release of the main landing gear (MLG), and corrective action, if necessary. This proposal also would require eventual modification of the free fall control mechanism of landing gear, which constitutes terminating action for the repetitive functional tests. This proposal is prompted by issuance of mandatory continuing airworthiness information by a foreign civil airworthiness authority. The actions specified by the proposed AD are intended to prevent malfunction of the free fall control mechanism of the landing gear, which could result in the inability to extend the MLG in the event of failure of the hydraulic extension system.

DATES: Comments must be received by June 15, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 98–NM–132–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 Airbus Industrie, 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: Norman B. Martenson, Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2110; 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 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–13–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–132–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, recently notified the FAA that an unsafe condition may exist on certain Airbus Model A300, A310, and A300–600 series airplanes. The DGAC advises that during training flights on two Airbus Model A300 series airplanes, the flight crew reported difficulty in extending the main landing gear (MLG) by means of the free fall control mechanism of the landing gear. The free fall control mechanism allows the flight crew to extend the landing gear in the event of failure of the hydraulic system that normally is used to extend the landing gear. A functional test of the free fall control mechanism on both airplanes revealed that this mechanism was rigged incorrectly, which caused the cockpit control handle of the free fall control mechanism to reach its mechanical stop before the MLG was released for extension by free fall. Malfunction of the free fall control mechanism, if not corrected, could result in the inability to extend the MLG in the event of failure of the hydraulic extension system.

Explanation of Relevant Service Information

The manufacturer has issued Airbus Industrie All operator Telex (AOT) 32–14, dated February 3, 1997, and Revision 01, dated March 13, 1997, which describe procedures or a one-time operational test and repetitive functional tests of the free fall control mechanism of the landing gear, and corrective action, if necessary. Procedures for the one-time operational test of the free fall control mechanism include inspecting the free fall control mechanism of the MLG with the landing gear extended and the weight of the airplane on the landing gear. Procedures for the repetitive functional test of the free fall control mechanism of the landing gear while the airplane is on jacks. Corrective actions, if necessary, including readjusting the telescopic rods of the MLG uplock of the free fall control mechanism, or completely rerigging the free fall control mechanism by adjusting specified components of the mechanism. The AOT also recommends that operators of airplanes

on which installation of Airbus Modification 04443 is pending need not accomplish the scheduled operational test of the free fall control mechanism of he landing gear.

The manufacturer also has issued Airbus Industrie Service Bulletins A300–32–0425, Revision 01; A310–32–2111, Revision 01; and A300–32–6072, Revision 01; all dated October 10, 1997. These service bulletins describe procedures for modification of the free fall control mechanism of the landing gear on Airbus Model A300, A310, and A300–600 series airplanes. The Modification includes removing telescope rods and cranks or crank assemblies from the MLG part of the free fall control mechanism of the landing gear, replacing the telescopic rods with new parts, and replacing the cranks or crank assemblies with improved parts. Accomplishment of the modification eliminates the need for the repetitive inspections described previsously.

Accomplishment of the actions specified in the AOT's and service bulletins described previously is intended to adequately address the identified unsafe condition. The DGAC classified the AOT's and service bulletins as mandatory and issued French airworthiness directive 97–113–322(B)R1, dated December 3, 1997, in order to assure 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 AOT's and the service bulletins described previously.

Cost Impact

The FAA estimates that 24 Model A300 series airplanes, 41 Model, A310 series airplanes, and 61 Model A300–600 series airplanes of U.S. registry would be affected by this proposed AD.

It would take approximately 3 work hours per airplane to accomplish the proposed operational test, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the proposed operational test on U.S. operators is estimated to be $22,680, or $180 per airplane.

It would take approximately 2 work hours per airplane to accomplish the proposed functional test, at an average labor rate of $60 per work hour. Based on these figures, the cost impact of the proposed functional test on U.S. operators is estimated to be $15,120, or $120 per airplane, per test cycle.

It would take approximately 26 work hours per airplane to accomplish the proposed modification on the Model A300 and A300–600 series airplanes, at an average labor rate of $60 per work hour. Required parts would cost approximately $2,630 per airplane. Based on these figures, the cost impact of the proposed modification on U.S. operators of Model A300 or A300–600 series airplanes is estimated to be $356,150, or $4,190 per airplane.

It would take approximately 28 work hours per airplane to accomplish the proposed modification on the Model A310 series airplanes, at an average labor rate of $60 per work hour. Required parts would cost approximately $3,710 per airplane. Based on these figures, the cost impact of the proposed modification on U.S. operators of Model A310 series airplanes is estimated to be $220,990, or $5,390 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:

Airbus Industrie: Docket 98–NM–132–AD.

Applicability: Model A300, A310, and A300–600 series airplanes; on which Airbus Industrie Modification 02781 has been accomplished, and on which Airbus Industrie Modification 03433 or 04443 has not been accomplished; certificated in any category.

Note: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise 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 malfunction of the free fall control mechanism of the landing gear, which could result in the inability to extend the main landing gear (MLG) in the event of

failure of the hydraulic extension system, accomplish the following:

(a) Within 600 flight hours after the effective date of this AD, perform a one-time operational test of the free fall control mechanism of the landing gear to ensure proper release of the MLG for extension by free fall, in accordance with Airbus Industrie All Operator Telex (AOT) 32–14, dated February 3, 1997, or Revision 01, dated March 13, 1997. If any discrepancy is detected in the functioning of the free fall control mechanism of the landing gear, prior to further flight, readjust the mechanism, and repeat the operational test in accordance with the AOT. If any discrepancy is detected in the second operational test, prior to further flight, rerig the free fall control mechanism in accordance with the AOT, and accomplish the actions required by paragraph (b) of this AD.

(b) Within 10 months after the effective date of this AD, perform a functional test of the free fall control mechanism of the landing gear to ensure proper release of the MLG for extension by free fall, in accordance with AOT 32–14, dated February 3, 1997, or Revision 01, dated March 13, 1997. Thereafter, repeat the functional test of the free fall control mechanism of the landing gear at intervals not to exceed 12 months, until the modification required by paragraph (c) of the AD has been accomplished. During any test performed in accordance with paragraph (b) of this AD, if the free fall control mechanism of the landing gear fails to fully extend the MLG, prior to further flight, readjust or rerig the mechanism in accordance with the AOT.

(c) Within 66 months after the effective date of this AD, modify the free fall control mechanism of the landing gear in accordance with Airbus Industrie Service bulletin A300–32–0425, Revision 01 (for Model A300 series airplanes); A310–32–2111, Revision 01 (for Model A310 series airplanes): or A300–32–6072, Revision 01 (for Model A300–600 series airplanes); all dated October 10, 1997; as applicable. Accomplishment of the modification constitutes terminating action for the repetitive functional tests required by paragraph (b) of this AD.

(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, International Branch, ANM–116, 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, 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.

(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 3: The subject of this AD is addressed in French airworthiness directive 97–113–221(B)R1, dated December 3, 1997.

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

John J. Hickey,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–12807 Filed 5–13–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 207, 807, and 1271

[Docket No. 97N–484R]

RIN 0910–AB05

Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require manufacturers of certain human cellular and tissue-based products to register with the agency and list their products. In addition, the agency is proposing to amend the registration and listing regulations that currently apply to human cellular and tissue-based products regulated as drugs, devices, and/or biological products. This action is being taken to establish a unified registration and listing program for human cellular and tissue-based products.

DATES: Submit written comments on the proposed rule by August 12, 1998. Submit written comments on the information collection provisions by June 15, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Dano B. Murphy or Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is putting in place a comprehensive new system of regulation for human cellular and tissue-based products. As a first step toward accomplishing this goal, the agency is proposing regulations that will require establishments that manufacture those products to register and list their products with the agency.

A. Background

The term ''human cellular and tissue-based products'' encompasses an array of medical products derived from the human body and used for replacement, reproductive, or therapeutic purposes. Skin, tendons, bone, heart valves, and corneas have long been used as replacements for damaged or diseased tissues. Semen, ova, and embryos are transferred for reproductive purposes. Currently, some human cellular and tissue-based products are being developed for new therapeutic uses. For example, scientists are studying the use of manipulated human cells to treat viral infections, Parkinson's disease, and diabetes, among other diseases.

Human cellular and tissue-based products serve a crucial role in medicine, and they have the potential for providing important new therapies. Yet they also raise public health concerns. With the development of new products, and new uses for existing products, come questions about safety and effectiveness that need to be answered through clinical investigation. Furthermore, all human cellular and tissue-based products, because they contain components of the human body, pose some risk of carrying pathogens that could cause disease in health-care personnel, other handlers of tissue, recipients, and family members or other close contacts of recipients.

FDA has never had a single regulatory program for human cellular and tissue-based products. Instead, it has regulated these products on a case-by-case basis responding as it determined appropriate to the particular characteristics of and concerns raised by each type of product. Some tissues have been regulated as medical devices under section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*). Corneal lenticules, dura mater, heart valve allografts, and umbilical cord vein grafts fall into this category. Other products have been considered biological products under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262) and drugs under the act (hereinafter referred to as biological drugs). Somatic cell therapy products and some gene therapy products fall