Installations and AFM Revision (Mark 200, 500, 600 Airplanes)

(c) For Model F27 Mark 200, 500, and 600 series airplanes: Within 18 months after the effective date of this AD, accomplish the requirements of paragraphs (c)(1) and (c)(2) of this AD.

(1) Install a monitoring system for the horizontal and vertical stabilizer de-icing system in accordance with Fokker Service Bulletin F27/30–44, dated February 20, 1998. Prior to further flight thereafter, revise the FAA-approved AFM to incorporate the flight manual changes described in Fokker MCNO F27–004, dated February 10, 1998.

(2) Install a modified pressure switch in the monitoring system in accordance with Fokker Service Bulletin F27/30–45, dated August 11, 1999.

Alternative Methods of Compliance

(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.

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 3: The subject of this AD is addressed in Dutch airworthiness directives 1998–019/2, and 1997–113/3, both dated June 18, 1999.

Issued in Renton, Washington, on December 28, 1999.

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–47 Filed 1–3–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–211–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 repetitive eddy current inspections to detect cracking on the door edge frames of the fuselage bulk cargo compartment, and repair, if necessary. 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 detect and correct cracks in the door edge frames of the fuselage bulk cargo compartment, which could result in reduced structural integrity of the airframe.

DATES: Comments must be received by February 3, 2000.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 98–NM–211–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.

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–211–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–211–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Direction Generale 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 A300, A310, and A300–600 series airplanes. The DGAC advises that, during routine maintenance on a Model A300 series airplane, stress corrosion induced cracks were found in door edge frames FR67 and FR69 of the bulk cargo compartment between stringers 33 and 48 (right-hand side). This condition, if not corrected, could result in reduced structural integrity of the airframe.

The subject door edge frames on Airbus Model A310 and A300–600 series airplanes are identical to those on the affected Airbus Model A300 series airplanes. Therefore, all of these airplanes may be subject to the same unsafe condition.

Explanation of Relevant Service Information

Airbus has issued Service Bulletins A300–53–0339, Revision 1, dated July 28, 1998, including Appendix 01 (for Model A300 series airplanes); A310–53–2106 (for Model A310 series airplanes), dated October 2, 1997, including Appendix 01; and A300–53–6114, dated October 2, 1997, including Appendix 01 (for Model A300–600 series airplanes). These service bulletins describe procedures for a one-time eddy current inspection to detect cracks in the door edge frames of the bulk cargo compartment, and repair of the door edge frame, if necessary. The service bulletins also describe procedures for reporting the results of the inspection to

Airbus. The DGAC classified these service bulletins as mandatory and issued French airworthiness directive 98–123–245(B), dated March 11, 1998, 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 service bulletins described previously, except as discussed below. This proposed AD also would provide for optional terminating action for the repetitive inspections.

The FAA has determined that the repetitive inspections proposed by this AD can be allowed to continue in lieu of accomplishment of a terminating action. In making this determination, the FAA considers that, in the case of this proposed AD, long-term continued operational safety will be adequately assured by accomplishing the repetitive inspections to detect cracking before it represents a hazard to the airplane.

Differences Between Proposed Rule and Foreign Airworthiness Directive

The proposed AD would differ from the parallel French airworthiness directive in that it would require the eddy current inspection to be repeated at intervals not to exceed 5 years. The FAA has determined that, because of the unpredictable nature of stress corrosion induced crack propagation, repetitive inspections are necessary. In addition, the DGAC has informed the FAA that it may consider revising its airworthiness directive to also require repetitive eddy current inspections.

Operators also should note that, unlike the parallel French airworthiness directive, this proposed AD would not permit further flight if cracks are detected in the door edge frames. The FAA has determined that, because of the safety implications and consequences associated with such cracking, any subject door edge frame that is found to be cracked must be repaired prior to further flight.

Interim Action

This is considered to be interim action. The inspection reports that are required by this proposed AD will enable the manufacturer to obtain better insight into the nature, cause, and extent of the cracking, and eventually to develop final action to address the unsafe condition. Once final action has been identified, the FAA may consider further rulemaking.

Cost Impact

The FAA estimates that 126 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 2 work hours per airplane to accomplish the proposed inspection, and that the average labor rate is $60 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $15,120, or $120 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 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–211–AD.

Applicability: Model A300 series airplanes on which Airbus Modification 2140 (reference Airbus Service Bulletin A300–53–109) has been accomplished; and Model A310 and A300–600 series airplanes, except those airplanes on which Airbus Modification 5438 was accomplished during production; certificated in any category.

Note 1: 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 detect and correct cracks in the door edge frames of the bulk cargo compartment, which could result in reduced structural integrity of the airframe, accomplish the following:

Repetitive Inspections

(a) Perform an eddy current inspection to detect cracking in the inner and outer flanges on the door edge frames of the fuselage bulk cargo compartment, in accordance with Airbus Service Bulletins A300–53–0339, Revision 1, dated July 28, 1998, including Appendix 01 (for Model A300 series airplanes); A310–53–2106, dated October 2, 1997, including Appendix 01 (for Model A310 series airplanes); or A300–53–6114,

dated October 2, 1997, including Appendix 01 (for Model A300–600 series airplanes); as applicable; at the applicable time specified in paragraph (a)(1) or (a)(2) of this AD. Thereafter, repeat the inspection at intervals not to exceed 5 years.

(1) For airplanes with less than 15 years since date of manufacture as of the effective date of this AD: Inspect within 10 years since date of manufacture, or within 12 months after the effective date of this AD, whichever occurs later.

(2) For airplanes with 15 or more years since date of manufacture as of the effective date of this AD: Inspect within 6 months after the effective date of this AD.

Note 2: For Model A300 series airplanes, accomplishment of an eddy current inspection prior to the effective date of this AD in accordance with Airbus Service Bulletin A300–53–0339, dated October 2, 1997, is considered acceptable for compliance with the initial eddy current inspection required by paragraph (a) of this AD.

Corrective Actions

(b) If any crack is detected during any inspection required by paragraph (a) of this AD, prior to further flight, repair the door edge frame in accordance with Airbus Service Bulletins A300–53–0339, Revision 1, dated July 28, 1998 (for Model A300 series airplanes); A310–53–2106 (for Model A310 series airplanes), dated October 2, 1997; or A300–53–6114 (for Model A300–600 series airplanes), dated October 2, 1997; as applicable. Complete replacement of a door edge frame with a new door frame in accordance with the service bulletin constitutes terminating action for the repetitive inspections required by this AD for that door frame only.

Report Requirements

(c) Submit a report of the inspection results (both positive and negative findings) to Airbus Industrie, Customer Services Directorate, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France, at the applicable time specified in paragraph (e)(1) or (e)(2) of this AD. Information collection requirements contained in this regulation have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) and have been assigned OMB Control Number 2120–0056.

(1) For airplanes on which any inspection is accomplished after the effective date of this AD: Submit the report within 30 days after performing any inspection required by paragraph (a) or (b) of this AD.

(2) For airplanes on which the inspection has been accomplished prior to the effective date of this AD: Submit the report within 10 days after the effective date of this AD.

Alternative Methods of Compliance

(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 3: Information concerning the existence of approved alternative methods of 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 4: The subject of this AD is addressed in French airworthiness directive 98–123–245(B), dated March 11, 1998.

Issued in Renton, Washington, on December 28, 1999.

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–48 Filed 1–3–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 216

[Docket No. 99N–4490]

Additions to the List of Drug Products That Have Been Withdrawn or Removed From the Market for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to add two drug products to the list of drug products that may not be used for pharmacy compounding under the exemptions provided by the Federal Food, Drug, and Cosmetic Act (the act) because they have had their approval withdrawn or were removed from the market because the drug product or its components have been found to be unsafe or not effective.

DATES: Written comments must be received on or before March 20, 2000.

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: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

President Clinton signed the Food and Drug Administration Modernization Act (Public Law 105–115) into law on November 21, 1997. One of the issues addressed in the legislation is the applicability of the act to the practice of pharmacy compounding. Compounding involves a process whereby a pharmacist or physician combines, mixes, or alters ingredients to create a customized medication for an individual patient. Section 127 of the Modernization Act, which adds section 503A to the act (21 U.S.C. 353a), describes the circumstances under which compounded drugs qualify for exemptions from certain adulteration, misbranding, and new drug provisions of the act (i.e., sections 501(a)(2)(B), 502(f)(1), and 505 of the act (21 U.S.C. 351(a)(2)(B), 352(f)(1), and 355)).

Section 503A of the act contains several conditions that must be satisfied for pharmacy compounding to qualify for the exemptions. One of the conditions is that the licensed pharmacist or licensed physician does not ''compound a drug product that appears on a list published by the Secretary in the **Federal Register** of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective.''

II. Rulemaking to Establish the List

In the **Federal Register** of October 8, 1998 (63 FR 54082), we proposed the original list of drug products that have had their approval withdrawn or were removed from the market because the drug product or its components have been found to be unsafe or not effective. We published the original list as a final rule in the **Federal Register** of March 8, 1999 (64 FR 10944). You may wish to read these documents for additional information about the list. The two **Federal Register** documents may be found on the Center for Drug Evaluation and Research's website at http://www.fda.gov/cder/pharmcomp/default.htm or the Government Printing Office's website at http://www.access.gpo.gov/su docs/aces/aces140.html.

The list was codified as § 216.24 of Title 21 in the Code of Federal Regulations (CFR) (21 CFR 216.24). This is the first time we have proposed to amend the list.

III. Description of this Proposed Rule

We are proposing that the drug products described below be added to