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.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

Meeting To Discuss Proposed Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) will conduct a public meeting to discuss a proposed direct final rule that would modify 10 CFR 50.54(a). The purpose of the public meeting is to solicit input from interested stakeholders on how best to modify the rule.

DATES: Thursday, October 15, 1998, 1:00 p.m.

ADDRESSES: 11555 Rockville Pike, Rockville, Maryland 20852.

The meeting will be held in room O–3B4 in the NRC One White Flint North Building. The NRC buildings are located across the street from the White Flint Metro Station.

FOR FURTHER INFORMATION CONTACT: Harry Tovmassian or Robert Gramm, Office of Nuclear Reactor Regulation, Mail Stop O–11 F1, U.S. NRC, Washington, DC 20555–0001, telephone (301) 415–3092 or (301) 415–1010, respectively.

SUPPLEMENTARY INFORMATION: The NRC held a public meeting with the Nuclear Energy Institute on this subject on August 27, 1998. A summary of this meeting was issued on September 18, 1998. This summary provides the current NRC staff thinking on this subject and is available from the NRC public document room.

Dated at Rockville, Maryland, this 2nd day of October, 1998.

For the Nuclear Regulatory Commission.

Rajender Auluck,

Acting Chief, Generic Issues and Environmental Projects Branch, Division of Reactor Program Management, Office of Nuclear Reactor Regulation.

[FR Doc. 98–27037 Filed 10–7–98; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 98–NM–198–AD]

RIN 2120–AA64

Airworthiness Directives; Dornier Model 328–100 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 Dornier Model 328–100 series airplanes. This proposal would require one-time visual inspections of the elevator trim system for paint contamination on the actuator pistons and to determine the moisture level of the moisture indicator; verification of the installation and condition of the gasket of the flex drive; and corrective actions, 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 prevent failure of the elevator trim system due to paint/moisture contamination, and consequent reduced controllability of the airplane.

DATES: Comments must be received by November 9, 1998.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 98–NM–198–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 FAIRCHILD DORNIER, DORNIER Luftfahrt GmbH, P.O. Box 1103, D–82230 Wessling, Germany. 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–198–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–198–AD, 1601 Lind Avenue, SW, Renton, Washington 98055–4056.

Discussion

The Luftfahrt-Bundesamt (LBA), which is the airworthiness authority for Germany, notified the FAA that an unsafe condition may exist on all Dornier Model 328–100 series airplanes. The LBA advises that it has received several reports of the elevator trim actuator freezing up during certain phases of flight. Investigation revealed that the moisture indicators of the elevator trim actuators were pink, and in some cases white (blue is normal), which indicates the presence of moisture. Further investigation revealed that paint contamination was present on the actuator pistons of the elevator trim system, which caused wear of the piston seals. Such wear may have allowed moisture to enter the trim system and freeze, which may cause the actuators to bind and the flex drive to become loose. These conditions, if not corrected, could result in failure of the elevator trim system, and consequent reduced controllability of the airplane.

Explanation of Relevant Service Information

Dornier has issued Alert Service Bulletin ASB–328–27–017, Revision 2, dated July 28, 1998. The alert service bulletin describes procedures for one-time visual inspections of the elevator trim system for paint contamination on the actuator pistons and to determine the moisture level of the moisture indicator; and verification of the installation and condition of the gasket of the flex drive; and corrective actions, if necessary. The corrective actions include removal of any paint contamination detected on the piston surface; replacement of the moisture indicator desiccant of the trim actuator; replacement of the gasket with a new gasket; and torquing the nuts of the flex drive to the correct value.

Accomplishment of the actions specified in the Dornier alert service bulletin is intended to adequately address the identified unsafe condition. The LBA classified this alert service bulletin as mandatory and issued German airworthiness directive 97–188, dated July 3, 1997, in order to assure the continued airworthiness of these airplanes in Germany.

Aviac Technologies, the manufacturer of the desiccant, has issued Identification Procedure for Desiccant DAV/AP98–214, Revision 0, dated April 22, 1998, as an additional source of service information to determine the level of saturation of the desiccant.

FAA's Conclusions

This airplane model is manufactured in Germany and is 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 LBA has kept the FAA informed of the situation described above. The FAA has examined the findings of the LBA, 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 alert service bulletin described previously.

Cost Impact

The FAA estimates that 50 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 inspections, 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 $6,000, or $120 per airplane.

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:

Dornier Luftfahrt GMBH: Docket 98–NM–198–AD.

Applicability: All Model 328–100 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 prevent failure of the elevator trim system due to paint/moisture contamination, and consequent reduced controllability of the airplane, accomplish the following:

(a) Within 2 months after the effective date of this AD, perform a one-time visual inspection of the elevator trim system for paint contamination on the actuator pistons and examine the trim actuator moisture indicator to determine the desiccant moisture level, in accordance with the Dornier Alert Service Bulletin ASB–328–27–017, Revision 2, dated July 28, 1998.

(1) If no paint contamination is detected on the actuator pistons, and the moisture indicator of the trim actuator is blue or pale blue, no further action is required by paragraph (a) of this AD.

(2) If no paint contamination is detected on the actuator pistons and the moisture indicator of the trim actuator is pink or white, prior to further flight, replace the trim actuator with a new or serviceable trim actuator and either replace or regenerate the desiccant in accordance with the alert service bulletin.

(3) If any paint contamination is detected on the actuator pistons, prior to further flight, remove the paint in accordance with the alert service bulletin.

Note 2: Aviac Technologies, the manufacturer of the desiccant, has issued Identification Procedure for Desiccant DAV/AP98–214, Revision 0, dated April 22, 1998, as an additional source of service information to determine the level of saturation of the desiccant.

(b) Within 2 months after the effective date of this AD, perform a one-time visual inspection to verify installation of the flat gasket in each end of the flex drive, and to determine if the flat gasket is in good condition (i.e., shows no signs of wear), in accordance with Dornier Alert Service Bulletin ASB–328–27–017, Revision 2, dated July 28, 1998.

(1) If the gasket is installed and in good condition, no further action is required by paragraph (b) of this AD.

(2) If the gasket is missing or is installed and not in good condition, prior to further flight, replace the gasket with a new gasket, and torque the nuts, in accordance with the alert service bulletin.

Note 3: Accomplishment of the actions required by paragraphs (a) and (b) of this AD, prior to the effective date of this AD, in accordance with Dornier Alert Service Bulletin ASB–328–27–017, Revision 1, dated October 1, 1997, is considered acceptable for compliance with the applicable actions specified in paragraphs (a) and (b) of this AD.

(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, 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 4: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

(d) 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 5: The subject of this AD is addressed in German airworthiness directive 97–188, dated July 3, 1997.

Issued in Renton, Washington, on October 1, 1998.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98–26964 Filed 10–7–98; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 216

[Docket No. 98N–0655]

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 include a list of drug products that may not be used for pharmacy compounding pursuant to the exemptions under section 503A of 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. The list has been compiled under the new statutory requirements of the Food and Drug Administration Modernization Act of 1997 (Modernization Act).

DATES: Comments must be received on or before November 23, 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: 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 Modernization Act (Pub. L. 105–115) into law on November 21, 1997. One of the issues addressed in this new 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., 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 127(b) of the Modernization Act provides that section 503A of the act will become effective on November 21, 1998, 1 year from the date of the Modernization Act's enactment.

Section 503A of the act contains several conditions that must be satisfied for pharmacy compounding to qualify for the exemptions under section 503A. 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 accordance with section 503A of the act, FDA has developed a list of drug products that have been withdrawn or removed from the market because they have been found to be unsafe or not effective. Many of the drug products on the list were withdrawn from the market through official proceedings, including publication of a notice in the **Federal Register**. For these drug products, this preamble to the proposed rule includes the reason for the withdrawal and the citation to the official notice of withdrawal. Other products, both approved and unapproved, were removed from the market voluntarily by the manufacturer or application holder, and FDA has information indicating that the reason for the removal was because the product was unsafe or not effective. In such cases, the reason for the removal is provided, and additional sources of information on the drug can be found in the docket identified by the number found in brackets in the heading of this document.

This proposed rule is the first of a series of rulemaking proceedings to establish the list of withdrawn or removed drug products, as the development and issuance of this list will be an ongoing process. The primary focus of this proposed rule is drug products that have been removed or withdrawn for safety reasons. FDA intends that future rulemaking