

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:

Dassault Aviation: Docket 98–NM–325–AD.

Applicability: Model Falcon 10 series airplanes, serial numbers 1 through 152 inclusive, on which Dassault Modification M801 (reference Dassault Service Bulletin F10–280, Revision 1, dated February 10, 1999) has not been accomplished; and Model Mystere-Falcon 50 series airplanes, serial numbers 2 through 250 inclusive and 252, on which Dassault Modification M1850 (reference Dassault Service Bulletin F50–240, Revision 1, dated October 7, 1998) has not been accomplished; 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 (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 take-off with the parking brake engaged, which could result in an extended take-off roll or a rejected take-off, and consequent runway overrun, accomplish the following:

Model Mystere-Falcon 50 Series Airplanes: Modification

(a) For Model Mystere-Falcon 50 series airplanes, within 9 months after the effective date of this AD, modify the aircraft wiring to add the “park brake handle not pushed forward” condition in the illumination conditions of the “T/O CONFIG” red warning light on the cockpit warning panel in accordance with Dassault Service Bulletin F50–240, Revision 1, dated October 7, 1998.

Model Falcon 10 Series Airplanes: Modification and AFM Revision

(b) For Dassault Falcon 10 series airplanes, within 9 months after the effective date of

this AD, accomplish the requirements of paragraphs (b)(1) and (b)(2) of this AD in accordance with Dassault Service Bulletin F10–280, Revision 1, dated February 10, 1999.

(1) Install a “NO TAKEOFF” red light on each pilot’s instrument panel and modify the associated aircraft wiring to activate the lights whenever the aircraft is not in the proper configuration for take-off.

(2) Revise the Normal Procedures Section of the FAA-approved Airplane Flight Manual (AFM) to include the information specified in Falcon 10 AFM DTM722 Temporary Change No. 17, dated March 31, 1995, which introduces procedures for checking that the “NO TAKEOFF” lights are out prior to take-off; and operate the airplane in accordance with those limitations and procedures.

Note 2: This may be accomplished by inserting a copy of Falcon 10 AFM DTM722 Temporary Change No. 17 in the AFM. When these temporary revisions have been incorporated into general revisions of the AFM, the general revisions may be inserted in the AFM, provided the information contained in the general revision is identical to that specified in Temporary Change No. 17.

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, 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

(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.

Note 4: The subject of this AD is addressed in French airworthiness directives 98–300–022(B), dated July 29, 1998, and 98–547–022(B), dated December 30, 1998.

Issued in Renton, Washington, on July 16, 1999.

D.L. Riggins,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.
[FR Doc. 99–18734 Filed 7–21–99; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 99–NM–131–AD]

RIN 2120–AA64

Airworthiness Directives; Saab Model SAAB SF–340 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 Saab Model SAAB SF–340 series airplanes. This proposal would require operators to replace the existing pneumatic de-icing boot pressure indicator switch with a newly designed switch. This proposal is prompted by an occurrence on a similar model airplane in which the pneumatic de-icing boot indication light may have provided the flightcrew with misleading information as to the proper functioning of the de-icing boots. The actions specified by the proposed AD are intended to prevent ice accumulation on the airplane leading edges, which could reduce controllability of the airplane.

DATES: Comments must be received by August 23, 1999.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 99–NM–131–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.

Information concerning this proposal 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 99-NM-131-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. 99-NM-131-AD, 1601 Lind Avenue, SW., Renton, Washington 98055-4056.

Discussion

On December 26, 1989, a British Aerospace Jetstream Model BA-3101 series airplane impacted the ground approximately 400 feet short of the runway while executing an instrument landing system (ILS) approach. The accident occurred at the Tri-Cities Airport, Pasco, Washington. The National Transportation Safety Board (NTSB) determined that the probable cause of the accident was the flightcrew's decision to continue an unstabilized ILS approach that led to a stall, most likely of the horizontal stabilizer, and loss of control at low altitude. Contributing to the stall and loss of control was the accumulation of leading edge ice, which degraded the aerodynamic performance of the airplane.

One result of the NTSB investigation was the determination that the flight deck wing de-icing light illuminated at a lower pressure than the pressure required to fully inflate the de-icing boots. The premature illumination of the wing de-icing light was due to a failure within the wing de-icing boot system, which allowed sufficient air pressure to give the appearance of

normal operation based on the de-icing light, without actually inflating the boots sufficiently to remove ice.

Based on an NTSB Safety Recommendation, the FAA reviewed the pneumatic de-icing boot system designs for airplanes operated under parts 121 and 135 of the Federal Aviation Regulations to ensure that the pneumatic pressure threshold at which each de-icing boot indication light is designed to illuminate is sufficient pressure for effective operation of the pneumatic de-icing boots. The FAA has determined that the flight deck pneumatic de-icing boot pressure indicator switch on certain Model SAAB SF-340 series airplanes may allow the flight deck indication light to illuminate at a lower pressure [10 pounds per square inch gage (psig)] than the pressure required to fully inflate the de-icing boots (15 psig). This condition, if not corrected, could result in ice accumulation on the airplane leading edges, which could reduce controllability of the airplane.

U.S. Type Certification of the Airplane

This airplane model is manufactured in Sweden 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. The FAA has 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 that the existing pneumatic de-icing boot pressure indicator switch be replaced with a switch that activates the indicator light at 15 psig. The action would be required in accordance with a method approved by the FAA.

Cost Impact

The FAA estimates that 117 airplanes of U.S. registry would be affected by this proposed AD. Since the manufacturer has not yet developed one specific modification commensurate with the requirements of this proposal, the FAA is unable at this time to provide specific information as to the number of work hours or cost of parts that would be required to accomplish the proposed modification. As indicated earlier in this preamble, the FAA specifically invites the submission of comments and

other data regarding the economic aspect of this proposal.

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:

SAAB Aircraft AB: Docket 99-NM-131-AD.

Applicability: Model SAAB SF-340 series airplanes, serial numbers 004 through 239 inclusive; 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 (b) 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 ice accumulation on the airplane leading edges, which could result in reduced controllability of the airplane, accomplish the following:

Modification

(a) Within 1 year after the effective date of this AD, replace the flight deck pneumatic de-icing boot pressure indicator switch with a switch that activates the flight deck indicator light at 15 pounds per square inch gage, in accordance with a method approved by the Manager, International Branch, ANM-116, FAA, Transport Airplane Directorate.

Alternative Methods of Compliance

(b) 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. 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

(c) 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.

Issued in Renton, Washington, on July 15, 1999.

D.L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 99-18733 Filed 7-21-99; 8:45 am]

BILLING CODE 4910-13-U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 333

[Docket No. 99N-1819]

RIN 0910-AA01

Topical Antifungal Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that would amend the final monograph for over-the-counter (OTC) topical antifungal drug products. The amendment makes a minor change in the indications for these drug products. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Submit written comments by October 20, 1999; written comments on the agency's economic impact determination by October 20, 1999. See section IV of this document for the proposed effective date of a final rule based on this document.

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: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2307.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 23, 1993 (58 FR 49890), FDA published a final monograph for OTC topical antifungal drug products in part 333 (21 CFR part 333), subpart C. That monograph includes labeling in § 333.250. Section 333.250(b)(1) contains the following introductory language for the indications statement: (Select one of the following: "Treats," "For the treatment of," "For effective treatment of," "Cures," "For the cure of," "Clears up," or "Proven clinically effective in the treatment of"). Section 333.250(b)(2) contains similar language for products labeled for the prevention of athlete's foot.

II. The Panel's Recommendations

The Advisory Review Panel on OTC Antimicrobial (II) Drug Products (the Panel) recommended the above labeling in its report on OTC topical antifungal drug products (47 FR 12480 at 12511, March 23, 1982). The Panel mentioned that there are several less common skin conditions that may affect the feet and the groin, cause symptoms that mimic athlete's foot and jock itch, and may be misdiagnosed as athlete's foot or jock itch. The Panel discussed common examples of such conditions: Candidiasis (a yeast infection), allergic contact dermatitis, bacterial infection of the feet (e.g., erythrasma), psoriasis, and hyperhidrosis (excessive perspiring) that may be associated with maceration of the skin and an inflammatory eruption known as dyshidrotic eczema (47 FR 12480 at 12487). While the Panel discussed these conditions, it did not address appropriate treatment or consequences of misdiagnosis of any of these conditions.

III. The Agency's Tentative Conclusions and Proposal

The agency recognizes that topical antifungal drug products will not cure or treat all conditions commonly thought by consumers to be athlete's foot or jock itch. Also, some of these conditions may have other etiologies. In addition to the conditions discussed by the Panel, consumers may erroneously consider a number of other conditions to be athlete's foot or jock itch. These include: Atopic dermatitis, irritant dermatitis, inverse pityriasis, scabies, and pediculosis pubis. All of these misdiagnosed conditions cannot be treated or cured by a topical antifungal drug product.

Because consumers self select OTC topical antifungal drug products and do not diagnose, the agency believes that the labeling should be revised to more accurately inform them what they can expect from using these products. Therefore, the agency is proposing that the word "most" be inserted in the allowed indications statements between the introductory phrase and the name of the condition(s) for which the product is to be used. This approach is consistent with the current labeling approved for OTC vaginal antifungal drug products under new drug applications (Ref. 1). That labeling states that the product "cures most vaginal yeast infections."

Accordingly, the agency is proposing to revise the indications in § 333.250(b)(1)(i) and (b)(2)(i) to add the word "most" after the introductory parenthetical "Select one of the