### **DEPARTMENT OF TRANSPORTATION**

### **Federal Aviation Administration**

14 CFR Part 39

[Docket No. 96-NM-229-AD]

RIN 2120-AA64

# Airworthiness Directives; Saab Model SAAB 2000 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 2000 series airplanes. This proposal would require replacement of the ignition exciter in the auxiliary power unit with a part that is designed to operate better in cold weather. This proposal is prompted by two occurrences of the auxiliary power unit (APU) failing to start after flight in cold soak conditions. The actions specified by the proposed AD are intended to prevent such APU failure, which could result in the inability of the APU to restart the engines in the event both engines quit operating during flight.

**DATES:** Comments must be received by June 19, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 96-NM–229-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 SAAB Aircraft AB, SAAB Aircraft Product Support, S–581.88, Linköping, Sweden. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Ruth Harder, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone

## SUPPLEMENTARY INFORMATION:

### **Comments Invited**

Interested persons are invited to participate in the making of the proposed rule by submitting such

(206) 227-1721; fax (206) 227-1149.

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 96-NM-229-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–103, Attention: Rules Docket No. 96-NM–229-AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

#### **Discussion**

The Luftfartsverket (LFV), which is the airworthiness authority for Sweden, recently notified the FAA that an unsafe condition may exist on certain Saab Model SAAB 2000 series airplanes. The LFV advises that the auxiliary power unit (APU), part number 4500090 (serial numbers SP-E941224, and SP-E941228 through SP-E951259 inclusive), could fail to start in temperatures below -4degrees F (-20 degrees C) after flight of two hours or more in cold soak conditions. At these temperatures, the electrical current to the ignition exciter in the auxiliary power unit is too high. This causes the over-current protection circuit in the Electronic Sequence Unit (ESU) to release, thus causing failure of the APU to start (ESU BITE-EXTERNAL SHORT). This condition, if not corrected in a timely manner, could result in the inability of the APU to restart the engines in the event both engines quit operating during flight.

## **Explanation of Relevant Service Information**

Saab has issued Service Bulletin 2000–49–005, dated December 19, 1995, which describes procedures for replacing the ignition exciter, part number 4950787, with an ignition exciter having part number 179420–2, which is designed to operate better in cold weather. The LFV classified this service bulletin as mandatory and issued Swedish airworthiness directive (SAD) No 1–082, dated December 20, 1995, in order to assure the continued airworthiness of these airplanes in Sweden.

### **FAA's Conclusions**

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. Pursuant to this bilateral airworthiness agreement, the LFV has kept the FAA informed of the situation described above. The FAA has examined the findings of the LFV, 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 replacement of the ignition exciter in the auxiliary power unit with a part that is designed to operate better in cold weather. The proposed action would be required to be accomplished in accordance with the service bulletin described previously.

### **Cost Impact**

The FAA estimates that 3 Saab Model SAAB 2000 series airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour per airplane to accomplish the proposed replacement, and that the average labor rate is \$60 per work hour. Required parts would be provided by the manufacturer at no cost to operators. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be \$180, or \$60 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished the modification proposed by this AD action, and that no operator would accomplish this modification 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:

SAAB Aircraft AB: Docket 96-NM-229-AD.

Applicability: Model SAAB 2000 series airplanes, equipped with an auxiliary power unit (APU) having part number 4500090, serial numbers SP-E941224, and SP-E941228 through SP-E951259 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 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 auxiliary power unit (APU) failure, which could result in the inability of the APU to restart the engines in the event both engines quit operating during flight, accomplish the following:

(a) Within 60 days after the effective date of this AD: Replace the ignition exciter, part number 4950787, with an ignition exciter having part number 179420–2, in accordance with Saab Service Bulletin 2000–49–005, dated December 19, 1995.

(b) As of the effective date of this AD, no person shall install an ignition exciter having part number 4950787 on any airplane.

(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, Standardization Branch, ANM–113, 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, Standardization Branch, ANM–113.

**Note 2:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM-113

(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.

Issued in Renton, Washington, on May 2, 1997.

## Neil D. Schalekamp,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service. [FR Doc. 97–12040 Filed 5–7–97; 8:45 am] BILLING CODE 4910–13–U

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 511 and 514 [Docket No. 96N-0411]

New Animal Drugs for Investigational Use and New Animal Drug Applications; Reopening of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Advance notice of proposed rulemaking; reopening of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is reopening to June 9, 1997 the comment period for the advance notice of proposed rulemaking (ANPRM) for investigational use new animal drug (INAD) regulations and the new animal drug applications (NADA) regulations that published in the Federal Register of November 21, 1996. The comment period is being reopened for the sole purpose of inviting interested persons to submit comments that will give FDA guidance in developing proposed regulations defining "good study practices." Elsewhere in this issue of the Federal Register, FDA is publishing a related document, a proposed rule further defining adequate and well-controlled studies. The definition of adequate and well-controlled studies requires that such a study, when conducted in the target animal, be conducted in compliance with good study practices. **DATES:** Written comments by June 9.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Herman M. Schoenemann, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1638.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 21, 1996 (61 FR 59209), FDA published an advance notice of proposed rulemaking announcing the agency's intention to propose revisions to the INAD regulations and the NADA regulations. The purpose of these revisions is to: (1) Implement the Animal Drug Availability Act of 1996 (ADAA) (Pub. L. 104–250) and (2) fulfill FDA's commitment as announced in the President's National