

percent of the swine must not exceed 104.6 °F on 2 or more consecutive days.

(6) The allowable dating of the master reference previously qualified as specified in paragraph (a)(2) of this section is the same as the dating of a serial of product or as approved by APHIS. The expiration date and the lot number of the master reference must be specified in the filed outline of production. The dating of the master reference may be extended by confirming its stability in accordance with § 113.8 prior to the expiration date specified in the filed outline of production.

(7) The master reference may be requalified by one of the following methods:

(i) Performing an immunogenicity test as specified in paragraph (a)(1) through (a)(5) of this section, except that the number of test animals may be reduced to 10 vaccinates and 5 controls, provided that 8 of 10 vaccinates and 4 of 5 controls meet the criteria specified in paragraphs (a)(3), (a)(4), and (a)(5) of this section.

(ii) Immunologic methods not requiring vaccination and challenge (e.g., serology) may be used to demonstrate the stability of a reference if the immunologic response was initially correlated to protection during the immunogenicity test. For a satisfactory test, 5 of 5 controls must remain seronegative at a 1:2 dilution, and 80 percent of the vaccinates must demonstrate bioequivalent serologic titers when compared to the protective titers established during the immunogenicity test. The length of the serologic study need not be the same as the immunogenicity test if adequate data acceptable to APHIS exist to correlate the serologic response earlier after vaccination than the immunogenicity test with protection at market weight.

(iii) A purified protein from *Erysipelothrix rhusiopathiae* that has been shown to elicit a protective response to challenge with virulent *Erysipelothrix rhusiopathiae* in swine may be used to requalify a working reference or qualify a new working reference. Such protein must be prepared by immunoaffinity purification methods using monospecific antisera or by other purification methods acceptable to APHIS. The purity and potency of a purified protein master reference must be well-characterized by in vitro methods such as high-performance liquid chromatography, protein quantification methods, immunoblot analyses, and/or other methods acceptable to APHIS. The

immunogenicity of a purified protein master reference must be directly established or indirectly established using a qualifying serial of product as provided in § 113.8 and paragraphs (a)(3), (a)(4), and (a)(5) of this section.

(8) An outline of production and data acceptable to APHIS must be approved for filing before authorization for the use of a new lot of master reference, a new lot of working reference, or a requalified master reference is granted.

(b) *Test requirements for release.* Each serial of *Erysipelothrix Rhusiopathiae* Bacterin must meet the applicable requirements of § 113.100 and must be tested for purity, safety, and potency as prescribed in this section. A serial found unsatisfactory by any prescribed test is not eligible for release.

(1) *Purity test.* Final container samples of completed product from each serial must be tested for viable bacteria and fungi as prescribed in § 113.26.

(2) *Safety test.* Bulk or final container samples of completed product from each serial must be tested for safety as provided in § 113.33(b).

(3) *Potency test.* In accordance with § 113.8(c), bulk or final container samples of completed product from each serial derived from an approved master seed must be evaluated for relative antigen content (potency) by the procedure specified in the filed outline of production as compared with an unexpired reference (which has been shown directly or indirectly to elicit acceptable duration of immunity) by a direct or indirect parallel line immunoassay. Potency may also be evaluated by measuring serologic response in animals that has been correlated to protection provided by a protective protein or other procedure acceptable to APHIS. The immunoassay must use a monoclonal antibody or monospecific antibody that has been shown to impart passive protection in animals following challenge with virulent *Erysipelothrix rhusiopathiae*.

(i) For a valid potency assay, at least two replications of at least six dilutions of the reference must be compared to at least two replications of at least six dilutions of each test serial on the same microtitration plate.

(ii) When comparing the test serial to the master reference by a relative potency method, a satisfactory test must have a minimum relative potency greater than or equal to 1.0. A relative potency of 1.0 is based on the antigen concentration of the master reference or qualifying serial of vaccine used in the host animal duration of immunity efficacy trial specified in paragraphs (a)(3), (a)(4), and (a)(5) of this section or

on the serologic response to a protective immunogen elicited by the master reference or qualifying serial.

(iii) On the basis of the results of such tests, each serial that meets the required minimum relative potency of greater than or equal to 1.0 will be released for marketing. Each serial that does not meet the required minimum potency must be withheld from the market.

(c) *Products without the required duration of immunity.* This section's requirement that an *Erysipelothrix Rhusiopathiae* Bacterin provide 22 weeks' duration of immunity in swine and 14 weeks' duration of immunity in turkeys will become effective 1 year after the publication of the final rule. Producers of *Erysipelothrix Rhusiopathiae* Bacterin may use the 1-year interval between the date of publication of the final rule and its effective date to update their products to provide the required duration of immunity. During this 1-year period, *Erysipelothrix Rhusiopathiae* Bacterins that do not protect vaccinates to market age (22 weeks for swine and 14 weeks for turkeys) may continue to be marketed if the labels for such products specify the duration of immunity demonstrated in the host animal protection study required for licensing. At the end of this 1-year period, *Erysipelothrix Rhusiopathiae* Bacterins that do not provide the minimum specified protection must be withheld from the market until they comply with the requirements of this section.

Done in Washington D.C., this 11th day of July 2001.

**Bobby R. Acord,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

[Docket No. 2000-NM-27-AD]

RIN 2120-AA64

#### Airworthiness Directives; Boeing Model 727-100 Series Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Proposed rule; withdrawal.

**SUMMARY:** This action withdraws a notice of proposed rulemaking (NPRM) that proposed a new airworthiness directive (AD), applicable to certain Boeing Model 727-100 series airplanes.

That action would have required repetitive inspections to detect corrosion of the lower surface of the wing center section and the surrounding area, and follow-on actions. Since the issuance of the NPRM, the Federal Aviation Administration (FAA) has received new information that indicates that the unsafe condition does not exist on the airplanes identified in the proposed rule. Accordingly, the NPRM is withdrawn.

**FOR FURTHER INFORMATION CONTACT:** Stan Wood, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055-4056; telephone (425) 227-2772; fax (425) 227-1181.

**SUPPLEMENTARY INFORMATION:** A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to add a new airworthiness directive (AD), applicable to certain Boeing Model 727-100 series airplanes, was published in the **Federal Register** as a Notice of Proposed Rulemaking (NPRM) on April 5, 2000 (65 FR 17827). The NPRM would have required repetitive inspections to detect corrosion of the lower surface of the wing center section and the surrounding area, and follow-on actions. The NPRM was prompted by a report from the manufacturer indicating that the affected airplanes were subject to corrosion progression through the lower surface of the wing center section into the center wing fuel tank, and subsequent fuel leakage into the ram air duct. The proposed actions were intended to detect and correct such conditions, which, if combined with a leak in the primary or secondary heat exchanger, could result in the release of fuel vapors into the cabin and consequent adverse effects on flight crew and passengers.

#### Actions Since the NPRM Was Issued

Since the issuance of the NPRM, the FAA has received new information concerning the configuration of Model 727-100 series airplanes, which are identified in the applicability of the NPRM. The NPRM was based on configuration similarities between those airplanes and Model 727-200 series airplanes, which are identified in the applicability of AD 85-24-02, amendment 39-5170 (50 FR 47356, November 18, 1985). That AD addresses a corrosion problem in the area of the lower surface of the wing center section, which forms the upper wall of the ram air plenum chambers. As a result of the corrosion problem, fuel leaked into the plenum chambers and fuel vapors were circulated into the airplane air

conditioning system and cockpit. The FAA has verified that the configuration of the subject area on Model 727-100 series airplanes is not the same as that on Model 727-200 series airplanes. Therefore, the three Model 727-100 series airplanes affected by the NPRM are not susceptible to the unsafe condition.

#### FAA's Conclusions

Upon further consideration, the FAA has determined that the identified unsafe condition does not exist on the airplanes identified in the NPRM. Accordingly, the proposed rule is hereby withdrawn.

Withdrawal of this notice of proposed rulemaking constitutes only such action, and does not preclude the agency from issuing another notice in the future, nor does it commit the agency to any course of action in the future.

#### Regulatory Impact

Since this action only withdraws a notice of proposed rulemaking, it is neither a proposed nor a final rule and therefore is not covered under Executive Order 12866, the Regulatory Flexibility Act, or DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979).

#### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

#### The Withdrawal

Accordingly, the notice of proposed rulemaking, Docket 2000-NM-27-AD, published in the **Federal Register** on April 5, 2000 (65 FR 17827), is withdrawn.

Issued in Renton, Washington, on July 10, 2001.

**Donald L. Riggan,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

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**BILLING CODE 4910-13-U**

## DEPARTMENT OF THE TREASURY

### Bureau of Alcohol, Tobacco and Firearms

#### 27 CFR Part 20

[Notice No. 923]

**RIN 1512-AB57**

#### Distribution and Use of Denatured Alcohol and Rum (2000R-291P)

**AGENCY:** Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Bureau of Alcohol, Tobacco and Firearms (ATF) proposes to amend the regulations in 27 CFR part 20 by eliminating the requirement for users of specially denatured spirits (SDS) to file a bond. ATF believes that elimination of the requirement to file a bond will greatly reduce and simplify the qualification process for industrial alcohol user permits. ATF also proposes to liberalize certain qualification requirements relating to industrial alcohol user permits.

**DATES:** Written comments must be received on or before September 17, 2001.

**ADDRESSES:** Send written comments to: Chief, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 50221, Washington, DC 20091-0221, (Attention: Notice No. 923). See "Public Participation" section of this notice if you want to comment by facsimile or e-mail.

**FOR FURTHER INFORMATION CONTACT:** Lisa M. Gesser, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW, Washington, DC 20226, (202-927-9347) or e-mail at [LMGesser@atfhq.atf.treas.gov](mailto:LMGesser@atfhq.atf.treas.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

##### *Background on SDS*

Specially denatured spirits (SDS) are alcohol or rum that have been treated with denaturants to make them unfit for beverage use. SDS include specially denatured alcohol (SDA) and specially denatured rum (SDR). A user purchases SDS to use in a process or in the manufacture of a substance, preparation, or product requiring SDS. SDS have many uses, such as:

- In laboratories as a solvent, for cleansing purposes, or in the preparation of indicator solutions and reagents.

- In the manufacture of such articles as perfumes, proprietary solvents, tobacco flavors, lotions, and sprays.

- In conversion processes to produce other substances, such as vinegar or ethyl acetate.

An industrial alcohol user permit is needed to procure, use, recover, or deal in SDS. To obtain an industrial alcohol user permit, certain registration requirements must be met. These requirements may include the submission of a detailed application with supporting data, the payment of special (occupational) tax (SOT), and the acquisition of bond coverage. Once