

Miscellaneous

The regulations in §§ 113.215(c)(2)(vii) and 113.216(c)(2)(vii) provide that prevaccination and postvaccination sera from a satisfactory potency test shall be submitted to the National Veterinary Services Laboratories (NVSL) for testing by APHIS. The testing referred to in those paragraphs is now performed by APHIS' Center for Veterinary Biologics-Laboratory, and not by NVSL, so we would amend §§ 113.215(c)(2)(vii) and 113.216(c)(2)(vii) to reflect that change.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

Currently, only 7 of the approximately 135 licensed veterinary biologics manufacturers produce Bovine Virus Diarrhea Vaccine, Killed Virus, and Bovine Rhinotracheitis Vaccine, Killed Virus, and would thus be affected by this proposal. According to the standards of the Small Business Administration, most veterinary biologics establishments would be classified as small entities.

This proposed rule would amend the standard requirements in § 113.215 for Bovine Virus Diarrhea Vaccine, Killed Virus, and in § 113.216 for Bovine Rhinotracheitis Vaccine, Killed Virus, by specifying that the effectiveness of the antibody titers based on host animal studies is the basis for determining the potency of the vaccine. We believe that the antibody titer elicited in the manufacturer's host animal protection study would be more indicative of the efficacy of the vaccine than the titer currently specified in the regulations. This change would affect all licensed manufacturers of veterinary biologics producing Bovine Virus Diarrhea Vaccine, Killed Virus, and Bovine Rhinotracheitis Vaccine, Killed Virus. However, we do not expect that there would be any increase in costs for the biologics manufacturers affected by this proposed rule. The changes should actually be cost neutral for most affected manufacturers because those manufacturers would not be required to change the way that their products are manufactured or tested.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not

have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the category of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies unless they present an irreconcilable conflict with this rule. The Virus-Serum-Toxin Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

This proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 113

Animal biologics, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR part 113 as follows:

PART 113—STANDARD REQUIREMENTS

1. The authority citation for part 113 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

2. In § 113.215, paragraphs (c)(2)(v) and (c)(2)(vii) would be revised to read as follows.

§ 113.215 Bovine Virus Diarrhea Vaccine, Killed Virus.

* * * * *

(c) * * *

(2) * * *

(v) *Test interpretation.* If the controls have not remained seronegative at 1:2, the test is a No Test (NT) and may be repeated. If at least four of the five vaccinates in a valid test have not developed 50 percent endpoint titers that are at least 80 percent of the geometric mean antibody titer developed in the vaccinates in the host animal protection study provided for in paragraph (b) of this section, the serial

is unsatisfactory except as provided in paragraph (c)(2)(vi) of this section.

* * * * *

(vii) The prevaccination and postvaccination sera from a satisfactory potency test shall be submitted to the Center for Veterinary Biologics-Laboratory for confirmatory testing.

3. In § 113.216, paragraphs (c)(2)(v) and (c)(2)(vii) would be revised to read as follows.

§ 113.216 Bovine Rhinotracheitis Vaccine, Killed Virus.

* * * * *

(c) * * *

(2) * * *

(v) *Test interpretation.* If the three controls have not remained seronegative at 1:2, the test is a No Test (NT), and may be repeated. If at least four of the five vaccinates in a valid test have not developed 50 percent endpoint titers that are at least 80 percent of the geometric mean antibody titer developed in the vaccinates in the host animal protection study provided for in paragraph (b) of this section, the serial is unsatisfactory, except as provided in paragraph (c)(2)(vi) of this section.

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(vii) The prevaccination and postvaccination sera from a satisfactory potency test shall be submitted to the Center for Veterinary Biologics-Laboratory for testing by the Animal and Plant Health Inspection Service.

Done in Washington, DC, this 30th day of September 2003.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NM–49–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767–200, –300, and –300F 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 Boeing Model 767–200, –300, and –300F series airplanes. This proposal