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.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 113

[Docket No. 03–054–1]

Viruses, Serums, Toxins, and Analogous Products; Standard Requirements for Bovine Virus Diarrhea and Bovine Rhinotracheitis Vaccines

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the Virus-Serum-Toxin Act regulations concerning Standard Requirements for Bovine Virus Diarrhea Vaccine, Killed Virus, and Bovine Rhinotracheitis Vaccine, Killed Virus, to require that those vaccines elicit specific antibody titer that is at least 80 percent of the geometric mean antibody titer obtained in the vaccinates in the host animal protection study to pass the potency test. We are proposing these changes based on data showing that the 1:8 minimum antibody titer for vaccinates specified in the current standard requirement potency tests may not be adequate to protect animals challenged with virulent virus. The effect of the proposed changes would be to establish potency test requirements for these vaccines that are based on the host animal protection study performed by the licensee.

DATES: We will consider all comments that we receive on or before December 5, 2003.

ADDRESSES: You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 03–054–1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. 03–054–1. If you use e-mail, address your comment to *regulations@aphis.usda.gov*. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and ''Docket No. 03–054–1'' on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at *http://www.aphis.usda.gov/ppd/rad/webrepor.html*.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief of Operational Support, Center for Veterinary Biologics, Licensing and Policy Development, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

The Virus-Serum-Toxin Act regulations in 9 CFR part 113 (referred to below as the regulations) prescribe standard requirements for the preparation and testing of veterinary biological products. A standard requirement consists of test methods, procedures, and criteria established by the Animal and Plant Health Inspection Service (APHIS) to help ensure that veterinary biological products are pure, safe, potent, and efficacious. The requirements in § 113.215 for Bovine Virus Diarrhea Vaccine, Killed Virus, and in § 113.216 for Bovine Rhinotracheitis Vaccine, Killed Virus, specify minimum potency requirements for those products. Under those regulations, a serial of vaccine must induce antibody titers of at least 1:8 in calves.

The current standard requirements state that four of the five calves vaccinated with bovine virus diarrhea vaccine or bovine rhinotracheitis vaccine in a valid potency test must respond with minimum antibody titers of at least 1:8 or greater for a satisfactory serial, but do not specify that the titers must have been shown to be protective in a host animal protection study. Post-vaccinal antibody titers of 1:8 were once considered to be the minimal index of protection for bovine virus diarrhea vaccines and bovine rhinotracheitis vaccines, but more recent data suggest that while some bovine virus diarrhea vaccines and bovine rhinotracheitis vaccines may induce antibody titers of 1:8, those titers may not be indicative of protection in all cases.

We are proposing to amend the standard requirements in §§ 113.215 and 113.216 by changing the minimum specific antibody titers that must be obtained in calves in a satisfactory potency test from at least 1:8 to at least 80 percent of the geometric mean antibody titer elicited in vaccinates challenged successfully in the manufacturer's host animal protection study. We believe that a minimum antibody titer that is based on the protective titer determined in the host animal protection study will be more indicative of an efficacious product than the 1:8 titer currently specified in the standard requirements.

We are proposing to establish minimum potency requirements for Bovine Virus Diarrhea Vaccine, Killed Virus, and Bovine Rhinotracheitis Vaccine, Killed Virus, that are specific to the products that each manufacturer has shown to be efficacious in a host animal protection study. We would set 80 percent of the geometric mean antibody titer elicited in vaccinates used in the host animal protection study as the minimum specific antibody titer that each vaccine must induce to pass the potency test. We have determined that vaccines that induce titers similar to the titers elicited in the efficacy study are more likely to protect cattle against disease.

Potency

Under this proposed rule, vaccinates in a valid potency test would have to develop minimum antibody titers that are at least 80 percent of the geometric mean antibody titer developed by vaccinates that were protected against challenge in the manufacturer's host animal protection study.

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.

* * * * *

(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.

[FR Doc. 03–25252 Filed 10–3–03; 8:45 am]

BILLING CODE 3410–34–P

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