Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road, Unit 148, Riverdale, MD 20737–1231; (301) 734–8245.

SUPPLEMENTARY INFORMATION: On October 11, 1994, we published in the **Federal Register** (59 FR 51390–51392, Docket No. 93–039–1) a proposed rule to amend the regulations in 9 CFR part 113 to include a Standard Requirement for *Escherichia coli* bacterins. We solicited comments on the proposed rule for 60 days ending on December 12, 1994. We subsequently reopened the comment period, then extended the comment period again: The first notice, published in the **Federal Register** on May 17, 1995 (60 FR 26384, Docket No. 93–039–2), reopened the comment period until August 15, 1995, and the second notice, published in the **Federal Register** on August 22, 1995 (60 FR 43573–43574, Docket No. 93–039–3), extended the comment period until September 14, 1995.

We received a total of nine comments by the close of the extended comment period. The comments were from veterinary biologics manufacturers and a trade association representing veterinary biologics manufacturers. One commenter supported the concept of a standard test procedure for *E. coli* bacterin, but remarked that the proposed standard lacked sufficient detail concerning the test method. Another commenter identified provisions in the proposed rule that he believed conflicted with the provisions in an interrelated proposed rule concerning *in vitro* testing, and requested an indefinite extension of the comment period pending resolution of the conflicting provisions. The remaining commenters requested clarification of the various technical provisions of the rule and suggested alternative wording for our consideration.

After considering all of the comments that we received, we have concluded that we will withdraw the proposed rule. Therefore, we are withdrawing the October 11, 1994, proposed rule referenced above. The concerns and recommendations of all of the commenters will be considered if any new proposed regulations concerning a Standard Requirement for *E. coli* bacterins are developed.

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

Done in Washington, DC, this 10th day of March 2005.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 05–5155 Filed 3–15–05; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 113

[Docket No. 03–054–2]

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; withdrawal.

SUMMARY: We are withdrawing a proposed rule to amend the Virus-Serum-Toxin Act regulations concerning Standard Requirements for Bovine Virus Diarrhea Vaccine, Killed Virus, and Bovine Rhinotracheitis Vaccine, Killed Virus. The proposed rule would have required vaccines to 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 taking this action after considering the comments we received following the publication of the proposed rule.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Section Leader, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, 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. On October 6, 2003, we published in the **Federal Register** (68 FR 57638–57639, Docket No. 03–054–1) a proposed rule to amend the 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. The proposed action would have established potency test requirements for these vaccines that were based on the host animal protection study performed by the licensee.

We solicited comments concerning our proposal for 60 days ending on December 5, 2003. We received nine comments by that date. The comments were from veterinary biologics manufacturers, trade associations representing veterinary biologics manufacturers, a microbiologist, and a veterinary association. One commenter supported the proposed rule. Another commenter expressed support for the proposal in principle, but urged delay in its implementation pending the completion of additional studies. The remaining commenters were opposed to the proposed rule. Some of those commenters stated that the proposed rule was scientifically flawed, and suggested that it be withdrawn lest it have a negative impact on the industry and future availability of vaccine. Other commenters stated that the proposed rule was inconsistent with the requirements for vaccine evaluated by other test methods and suggested that the Agency address the disparity in requirements.

After considering all of the comments that we received, we have concluded that we will withdraw the proposed rule. Therefore, we are withdrawing the October 6, 2003, proposed rule referenced above. The concerns and recommendations of all of the commenters will be considered if any new proposed regulations concerning Standard Requirements for Bovine Virus Diarrhea Vaccine, Killed Virus, and Bovine Rhinotracheitis Vaccine, Killed Virus, are developed.

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

Done in Washington, DC, this 10th day of March 2005.

Elizabeth E. Gaston,

Acting Administrator, Animal and Plant Health Inspection Service.

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