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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 107

[Docket No. APHIS-2011-0048]

RIN 0579-AD66

Viruses, Serums, Toxins, and Analogous Products; Exemptions from Preparation Pursuant to an Unsuspended and Unrevoked License

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We are reopening the comment period for our proposed rule that clarified our interpretation of the veterinary practitioner exemption provided by the Virus-Serum-Toxin Act.

This action will allow interested persons additional time to prepare and submit comments.

DATES: We will consider all comments that we receive on or before November 16, 2012.

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2011-0048-0001>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2011-0048, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0048> or in our reading room, which 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) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Donna Malloy, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737-1231; phone (301) 851-3426, fax (301) 734-4314.

SUPPLEMENTARY INFORMATION:

The Virus-Serum-Toxin Act, as amended (21 U.S.C. 151–159) includes an exemption that allows veterinary biologics to be prepared by a veterinary practitioner solely for administration to animals in the course of a State-licensed professional practice of veterinary medicine under a veterinarian-client-patient relationship. On July 18, 2012, we published in the Federal Register (77 FR 42195-42197, Docket No. APHIS-2011-0048) a proposal that clarified our interpretation of this exemption.

Comments on the proposed rule were required to be received on or before September 17, 2012. We are reopening the comment period on Docket No. APHIS-2011-0048 for an additional 60 days. This action will allow interested persons additional time to prepare and submit comments. We will also consider all comments received between September 18, 2012, (the day after the close of the original comment period) and the date of this notice.

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

Done in Washington, DC, this 14<sup>th</sup> day of September 2012.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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