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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.

SUMMARY: We are proposing to amend the Virus-Serum-Toxin Act regulations to require that veterinary biologics prepared under the veterinary practitioner exemption must be prepared at the same facility the veterinarian utilizes in conducting the day-to-day activities associated with his or her practice. This exemption applies to veterinary biologics 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. This proposed amendment is necessary to ensure that veterinary biologics are not prepared in unlicensed establishments in violation of the Virus-Serum-Toxin Act. The effect of the proposed amendment would be to clarify the regulations regarding the preparation of product by a veterinary practitioner under a veterinarian-client-patient relationship.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of publication in the Federal Register].

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:

Background

The regulations in Title 9, Code of Federal Regulations (9 CFR), parts 101-118 (referred to below as the regulations) contain provisions implementing the Virus-Serum-Toxin Act (the Act), as amended (21 U.S.C. 151-159). These regulations are administered by the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA). The Act prohibits the preparation, sale, and shipment of veterinary biological products in or from the

United States unless such products have been prepared under and in compliance with USDA regulations at an establishment holding an unsuspended and unrevoked license issued by USDA.

In part 102 of the regulations, §§ 102.1 and 102.2 require that each establishment and every person preparing biological products subject to the Act must hold an unexpired, unsuspended, and unrevoked U.S. Veterinary Biologics Establishment License issued by the Administrator and a U.S. Veterinary Biological Product License for each product prepared in such establishment. Part 107 of the regulations contains exemptions from the requirement for preparation pursuant to unsuspended and unrevoked establishment and product licenses. One of those exemptions, found in § 107.1(a), allows for product to be prepared by a veterinary practitioner solely for administration to animals in the course of his or her State-licensed professional practice of veterinary medicine under a veterinarian-client-patient relationship. The regulations in § 107.1(a)(1) set forth the criteria that must be satisfied in order to establish the existence of a veterinarian-client-patient relationship.

Recently, it has come to APHIS' attention that some veterinary practitioners may be entering into contractual agreements whereby product would be prepared by a commercial laboratory/manufacturing facility (unlicensed vaccine manufacturing establishment) rather than by the practitioner at the facility he or she uses to conduct the day-to-day activities associated with his or her State licensed practice of veterinary medicine. Such arrangements in which an unlicensed establishment, acting as an agent for the practitioner, prepares the product and sells and ships/transports the product directly to the animal owner creates a situation in which product is prepared, sold, and shipped in violation of the Act. Specifically, the Act states that no person, firm, or corporation shall prepare, sell, barter, exchange, or ship any virus, serum, toxin, or analogous product manufactured within the United States and intended for the treatment of

animals, unless and until the said virus, serum, toxin, or analogous product shall have been prepared, under and in compliance with regulations at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture.

While part 107 of the regulations specifies the licensing exemption for product prepared by veterinary practitioners and sets forth the requirements for showing that a veterinarian-client-patient relationship exists, it appears that, given the instances described in the previous paragraph, some clarification is necessary with respect to the issue of the relationship between the veterinary practitioner and the facility where the product is prepared. The purpose of this provision is to allow a veterinarian to prepare veterinary biologics at the location where she or he operates a veterinary practice, which would not be licensed under the Act, and to transport it away from that facility when necessary, for administration to an animal or animals under a veterinarian-client-patient relationship without violating the Act.

However, no provision in the Act or the regulations would allow a veterinary practitioner to take advantage of the licensing exemption while at the same time consigning the actual preparation of the product to a commercial laboratory/manufacturing establishment which would then exchange or deliver the product to a third party. An arrangement such as this is contrary to the statutory requirement that prohibits a person, firm, or corporation from preparing, selling, bartering, exchanging, or shipping a veterinary biologic intended for use in the treatment of animals unless and until such product shall have been prepared in compliance with the regulations in a USDA licensed establishment (see 21 U.S.C. 151).

In order to ensure that product subject to the exemption for products prepared by veterinarians solely for administration to animals in the course of a State licensed professional practice of veterinary medicine under a veterinarian-client-patient relationship is prepared in

accordance with the requirements of the Virus-Serum-Toxin Act, APHIS is proposing to amend its regulations by adding clarifying language to § 107.1 emphasizing the requirement that the exemption from preparation pursuant to unsuspended and unrevoked product and establishment licenses applies only to product prepared by the veterinary practitioner (or by a supervised veterinary assistant) at the facility such veterinarian uses in the day-to-day operation of his/her State-licensed professional practice of veterinary medicine.

The proposed amendment would clarify that the preparation of product prepared by a veterinarian solely for administration to animals in the course of a State-licensed professional practice of veterinary medicine under a veterinarian-client-patient relationship shall only be done at a facility routinely used in the day-to-day operation of a professional practice of veterinary medicine.

We also propose to make minor changes to § 107.1 to replace the term "establishments" with "facilities." As discussed above, § 107.1 exempts product prepared by a veterinary practitioner from preparation pursuant to an unsuspended and unrevoked product and establishment license. However, § 107.1 refers to the sites of such production as "establishments," which is confusing because that term is used elsewhere in the regulations to refer only to production sites that are not exempt from the license requirement. For example, the definitions in § 101.2 define establishment as "One or more premises designated on the establishment license." Therefore, in § 107.1 where we refer to the exemption for the site of day-to-day operation of a veterinarian's State-licensed professional practice, we would use the term "facilities" rather than "establishments."

Executive Order 12866 and Regulatory Flexibility Act

This proposed 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.

This proposed rule would amend the regulations in § 107.1 to clarify that the preparation of biological products pursuant to the exemption in paragraph (a)(1) of that section must take place at the same facility that the veterinarian preparing the product utilizes in conducting the day-to-day activities associated with his/her State-licensed professional practice of veterinary medicine.

As noted previously in this proposed rule, no provision in the Act or the regulations allows a veterinary practitioner to take advantage of the licensing exemption while at the same time consigning the actual preparation of the product to a commercial laboratory or other manufacturing establishment which would then exchange or deliver the product to a third party. An arrangement such as this is contrary to the statutory requirement that prohibits a person, firm, or corporation from preparing, selling, bartering, exchanging, or shipping a veterinary biologic intended for use in the treatment of animals unless and until such product shall have been prepared in compliance with the regulations in a USDA licensed establishment.

Therefore, this proposed amendment to the regulations is simply a clarification of an existing and longstanding prohibition. The proposed amendment would not change the nature of the exemption, the number of veterinary practitioners who are eligible to take advantage of the exemption, or the criteria that must be satisfied in order to establish the existence of a veterinarian-client-patient relationship, nor would it add any reporting or recordkeeping burden. It is possible that there may be one or several veterinary practitioners that currently contract with

an unlicensed commercial laboratory or manufacturing facility to produce veterinary biologics in violation of the Act. These entities could be affected if they become aware of the violation through publication of this proposed rule and discontinue the prohibited activity, but that effect could also occur at any time under the current regulations if APHIS receives specific evidence of such a violation and orders its cessation.

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 where they are necessary to address local disease conditions or eradication programs. However, where safety, efficacy, purity, and potency of biological products are concerned, it is the Agency's intent to occupy the field. Under the Act, Congress clearly intended that there be national uniformity in the regulation of these products, and APHIS will continue to take enforcement action as necessary against practitioners and production facilities with regard to veterinary biologics produced or distributed in contravention of the Act. There are no administrative proceedings which must be exhausted prior to a judicial challenge to the regulations under this rule.

Paperwork Reduction Act

This proposed rule contains no new 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 107

Animal biologics, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR part 107 as follows:

PART 107–EXEMPTIONS FROM PREPARATION PURSUANT TO AN UNSUSPENDED AND UNREVOKED LICENSE

1. The authority citation for part 107 continues to read as follows:

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

2. Section 107.1 is amended as follows:

a. In the introductory text and in paragraph (a)(1), by removing the word "establishments" and adding the word "facilities" in its place.

b. By redesignating paragraph (a)(2) as paragraph (a)(3) and adding a new paragraph (a)(2) to read as follows:

§107.1 Veterinary practitioners and animal owners.

* * * * *

(a) * * *

(2) All steps in the preparation of product being prepared under the exemption in paragraph (a)(1) of this section must be performed at the facilities that the veterinarian utilizes for the day-to-day activities associated with the treatment of animals in the course of his/her State-licensed professional practice of veterinary medicine. A veterinary assistant employed by the veterinary practitioner and working at the veterinary practice's facility under the

veterinarian's direct supervision may perform the steps in the preparation of product. Such preparation may not be consigned to any other party or sub-contracted to a commercial laboratory/manufacturing facility.

* * * * *

Done in Washington, DC, this 12th day of July 2012.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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