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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: Final rule.

SUMMARY: We are amending 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 rule is necessary to ensure that veterinary biologics are not prepared in unlicensed establishments in violation of the Virus-Serum-Toxin Act and to clarify the regulations regarding the preparation of product by a veterinary practitioner under a veterinarian-client-patient relationship.

DATES: Effective [Insert date 60 days after date of publication in the Federal Register].

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)(1), 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) also set forth the criteria that must be satisfied in order to establish the existence of 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 proposal¹ to amend the regulations to require that veterinary biologics prepared under the veterinary practitioner exemption be prepared at the same facility the veterinarian utilizes in conducting the day-to-day activities associated with his or her practice. The proposal was intended to ensure that veterinary biologics are not prepared in unlicensed establishments in violation of the Virus-Serum-Toxin Act and to clarify the regulations regarding the preparation of product by a veterinary practitioner under a veterinarian-client-patient relationship.

We solicited comments concerning our proposal for 60 days ending September 17, 2012. We reopened and extended the deadline for comments until November 16, 2012, in a document published in the Federal Register on September 20, 2012 (77 FR 58323, Docket No. APHIS-2011-0048). We received 55 comments by that date. They were from veterinarians and veterinary associations, several State universities, pork producers' associations, trade organizations, veterinary biologics companies, private laboratories, aquaculture companies, officials from the State of Iowa, and individuals. These comments are discussed below by topic.

Some commenters not only supported the proposal but recommended that we speed the implementation process along.

We are finalizing this rule as expeditiously as possible. Given the number of comments we received on the proposed rule and the substantive nature of most of them, however, we

¹ To view the proposed rule and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0048>.

determined that we needed to carefully review and evaluate those comments before implementing any regulatory changes.

Several organizations and a number of veterinary practitioners raised concerns about what they termed the “forced relocation” of preparation sites for veterinary biologics to the same facility in which the veterinarian conducts day-to-day activities connected with his or her practice. Commenters stated that a veterinary practice is an environment poorly suited to the aseptic conditions required for biologics production and that personnel working in these facilities are trained in animal care rather than in specialized laboratory work. Several commenters recommended that APHIS revise the rule to require that, regardless of the location of the production facility, veterinarians that use the facility must document regular involvement in the management of the facility, provide such documentation on request, and allow regular on-site inspections, presumably by APHIS.

APHIS disagrees with the commenters’ recommendation. As noted in the preamble to the July 2012 proposed rule, the intent of the veterinary practitioner exemption in § 107.1(a)(1) is to allow a practitioner to prepare exempt biological products at a location not licensed under the Act, where the practitioner operates a veterinary practice, and to transport such products away from that facility when necessary for administration to an animal or animals under a veterinarian-client-patient relationship without violating the Act. The intention behind the proposed rule was to clarify the relationship between the veterinary practitioner and the facility where exempt veterinary biological product is prepared. No provision in the Act or the regulations allows an unlicensed commercial laboratory, acting as the agent for the practitioner, to prepare, produce, sell, and ship the veterinary biological product under the exemption in § 107.1(a)(1). Such an arrangement would violate the Act. Nothing in this rule or in the Act,

however, prevents veterinarians from working with establishments with a license to produce autogenous products , i.e., limited use biologics.

Commenters expressed concern about how this rule would affect practitioners who have offices in multiple locations in which there are multiple practitioners. It was stated that changes within the swine industry have led many veterinarians to practice in this manner. According to the commenters, this rule would potentially require that a “brick and mortar” location for vaccine production would have to be the same as the physical location of the veterinarian. In the commenters’ view, such a requirement could prove problematic for a multi-location veterinary practice in which there may only be one location suitable for the preparation of exempt veterinary biological product. Commenters questioned how we would address the issue of multiple locations managed by the same veterinarian or practice even though the prescribing veterinarian may not routinely work out of the office where the exempt biological product is prepared.

APHIS acknowledges that it has become a common occurrence in the swine industry for swine practitioners to work in multi-veterinarian, multi-location corporate practices. Nothing in this rule, however, prohibits a veterinarian from producing an exempt biological product in any of the locations routinely used in his or her day-to-day practice, provided that the other conditions in § 107.1 are met.

Noting that § 107.1(a)(2) of the proposed rule stated that a biological product may be prepared by a veterinary assistant under the veterinarian’s “direct supervision,” some commenters, while generally supportive of the rule, requested that we clarify how we define that term.

APHIS interprets “direct supervision” to mean that the licensed veterinarian is readily available on the premises where the product is being prepared and has the responsibility for its preparation by the assistant working under his or her direction.

Some commenters suggested that the emphasis of the rule should be redirected away from location of the exempt facilities and toward the quality and management of the facilities where the products are prepared. It was stated that the rule focuses too much on location and not enough on animal health.

As noted above, the purpose of this rule is to clarify who may prepare exempted biological products and where those exempted products may be prepared under the regulations. Requirements pertaining to the quality and management of veterinary biologics establishments are already addressed in 9 CFR part 108.

Some commenters maintained that unlicensed laboratories should be allowed to prepare and ship exempt veterinary biological products on behalf of veterinary practitioners, that the rule may hinder innovative practices, and that the relationship between the veterinarian and the facility should be legal rather than location-based. The commenters expressed concern that the rule will restrict veterinarians’ access to certain customized vaccines that are prepared in specialized settings and thus prevent practitioners from responding rapidly to mutating viruses. Several commenters cited the case of an Iowa manufacturer, which they viewed as an innovative company with expertise in new technologies that enabled it to prepare vaccines quickly and effectively. The commenters stated that that company’s activities may be restricted under this rule.

The purpose of this rule is to clarify the relationship between the veterinary practitioner and the facility where exempt veterinary biological products are prepared. We do not intend to

hinder innovation and the development of valuable new technologies, nor do we anticipate that this rule will have such an effect. Any manufacturing establishment wishing to provide its technology and expertise to veterinarians has several licensing options that will allow it to market its product. To cite one example, in 2012, APHIS published guidelines for obtaining a conditional veterinary biologics license using production platform technology. These guidelines, which describe the policies and procedures regarding the licensure of product platforms based on recombinant technology, can be viewed at http://www.aphis.usda.gov/animal_health/vet_biologics/publications/memo_800_213.pdf.

Some commenters expressed concerns about how this rule may affect minor species, in particular, the aquaculture industry. It was stated that the language contained in the proposed rule was too restrictive, as it was based on an erroneous assumption of a homogenous type of veterinary practice involving mainly major species where there is only in-patient or on-the-farm care. Veterinary practitioners in the aquaculture industry routinely prepare autogenous vaccines, which may be isolated from a particular school of fish. A commenter stated that for minor species and minor indications, it is not cost-effective to have separate facilities for the preparation of existing exempt vaccines and autogenous vaccines. The commenter recommended that, for minor species applications, we add a provision to the final rule allowing the production of exempt biological products in a veterinary establishment that has either full or autogenous licensure to produce biologics, provided that the practitioner can demonstrate temporal and sanitary separation between exempt and non-exempt products.

We do not agree that adding such a provision to the regulations is necessary. This rule does not affect the preparation of exempt veterinary biological product for minor species, such as farmed fish; it merely clarifies where such products can be prepared. Veterinarians who service

minor species will continue to have the options currently available to them of preparing an exempt product or working with a licensed establishment to produce an autogenous vaccine.

The July 2012 proposed rule included some additional changes to § 107.1. Specifically, we proposed to replace the term “establishments” with “facilities” in the introductory text and in paragraph (a)(1). One commenter favored retaining the original terminology. The commenter stated that “facilities” is too narrow a term and that, conversely, “establishments” correctly reflects many of the types of operations that licensed veterinarians are associated with (ambulatory, zoos, aquarium, fish culture facilities, feedlots, etc.).

We do not agree with this comment. The reason for the proposed change in terminology was to distinguish between manufacturers that produce licensed biological products in licensed establishments and those that produce exempt veterinary biological products under the conditions described in § 107.1. The introductory text of § 107.1 contains a reference to establishment licenses. Elsewhere in the regulations, including § 107.2, only production sites that are not exempt from licensing requirements are referred to as establishments. Drawing a clear distinction between establishments, where vaccines are prepared in accordance with our licensing requirements, and facilities, where exempt products are produced, helps to clarify the regulations and eliminate possible confusion.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, without change.

Executive Order 12866 and Regulatory Flexibility Act

This final 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.

In accordance with the Regulatory Flexibility Act, we have analyzed the potential economic effects of this action on small entities. The analysis is summarized below. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

This final rule amends 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.

The 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. 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.

The Regulatory Flexibility Act requires agencies to consider whether a rule will have a significant economic impact on a substantial number of small entities.

Some commenters on the July 2012 proposed rule expressed concerns that the rule would adversely affect how veterinary practitioners conduct day-to-day activities connected with their practices, prevent veterinarians from working with commercial labs or manufacturing facilities in preparing vaccines, and hinder the development of innovative practices.

For the most part, there should be little or no effect on veterinary practitioners.

Veterinary practitioners who are in compliance with the regulations do not need to alter the way they conduct their veterinarian-client-patient relationships. This final rule will not change the nature of the exemption, the number of veterinary practitioners 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. Also, this final rule will not add any additional reporting or recordkeeping burden.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog 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 final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule will 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. This includes, but is not limited to, the regulation of labeling. Under the Act, Congress clearly intended that there be national uniformity in the regulation of these products. There are no administrative proceedings which must be exhausted prior to a judicial challenge to the regulations under this rule.

Paperwork Reduction Act

This final 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 are amending 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 of the section and in paragraph (a)(1), introductory text, by removing the word “establishments” both times it appears and adding the word “facilities” in its place; and
 - b. By redesignating paragraph (a)(2) as paragraph (a)(3) and adding a new paragraph (a)(2).

The addition reads 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 6th day of May 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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