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 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 September 17, 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:

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.

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

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2012–17533 Filed 7–17–12; 8:45 am]

BILLING CODE 3410–34–P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 121

RIN 3245–AG37

Small Business Size Standards: Construction

AGENCY: U.S. Small Business Administration.

ACTION: Proposed rule.

SUMMARY: The U.S. Small Business Administration (SBA) proposes to increase small business size standards for one industry and one sub-industry in North American Industry Classification System (NAICS) Sector 23, Construction. SBA proposes to increase the size standard for NAICS 237210, Land Subdivision, from $7 million to $25 million and the size standard for Dredging and Surface Cleanup Activities, a sub-industry category (or an ''exception'') under NAICS 237990, Other Heavy and Civil Engineering Construction, from $20 million to $30 million in average annual receipts. As part of its ongoing comprehensive size standards review, SBA has evaluated all size standards in NAICS Sector 23 to determine whether they should be retained or revised. This proposed rule is one of a series of proposed rules that will review size standards of industries grouped by NAICS Sector. SBA issued a White Paper entitled ''Size Standards Methodology'' and published a notice in the October 21, 2009 issue of the **Federal Register** to advise the public that the document is available on its Web site at *www.sba.gov/size* for public review and comments. The ''Size Standards Methodology'' White Paper explains how SBA establishes, reviews, and modifies its receipts based and employee based small business size standards. In this proposed rule, SBA has applied its methodology that pertains to establishing, reviewing, and modifying a receipts based size standard.

DATES: SBA must receive comments to this proposed rule on or before September 17, 2012.

ADDRESSES: Identify your comments by RIN 3245–AG37 and submit them by one of the following methods: (1) *Federal eRulemaking Portal: www.regulations.gov,* following the instructions for submitting comments; or (2) Mail/*Hand Delivery/Courier:* Khem R. Sharma, Ph.D., Chief, Size Standards Division, 409 Third Street SW., Mail Code 6530, Washington, DC 20416. SBA will not accept comments to this proposed rule submitted by email.

SBA will post all comments to this proposed rule on *www.regulations.gov*. If you wish to submit confidential business information (CBI) as defined in the User Notice at *www.regulations.gov,* you must submit such information to U.S. Small Business Administration, Khem R. Sharma, Ph.D., Chief, Size Standards Division, 409 Third Street SW., Mail Code 6530, Washington, DC 20416, or send an email to *sizestandards@sba.gov*. Highlight the information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review your information and determine whether it will make the information public.

FOR FURTHER INFORMATION CONTACT: Jorge Laboy-Bruno, Ph.D., Economist, Size Standards Division, (202) 205–6618 or *sizestandards@sba.gov*.

SUPPLEMENTARY INFORMATION: To determine eligibility for Federal small business assistance, SBA establishes small business size definitions (referred to as size standards) for private sector industries in the United States. SBA uses two primary measures of business size: Average annual receipts and average number of employees. SBA uses financial assets, electric output, and refining capacity to measure the size of a few specialized industries. In addition, SBA's Small Business Investment Company (SBIC), Certified Development Company (504), and 7(a) Loan Programs use either the industry based size standards or net worth and net income based alternative size standards to determine eligibility for those programs. At the beginning of the current comprehensive size standards review, there were 41 different size standards covering 1,141 NAICS industries and 18 sub-industry activities (''exceptions'' in SBA's table of size standards). Thirty-one of these size levels were based on average annual receipts, seven were based on average number of employees, and three were based on other measures.

Over the years, SBA has received comments that its size standards have not kept up with changes in the economy, in particular the changes in the Federal contracting marketplace and industry structure. The last time SBA conducted a comprehensive review of all size standards was during the late 1970s and early 1980s. Since then, most reviews of size standards were limited to a few specific industries in response to requests from the public and Federal agencies. SBA also adjusts its monetary based size standards for inflation at least once every five years. SBA's latest inflation adjustment to size standards was published in the **Federal Register** on July 18, 2008 (73 FR 41237).

Given its importance in the Federal Procurement market, SBA has studied and reviewed the construction industry over time. In 1985, SBA adopted a new size standard for the Dredging sub-industry (an exception within NAICS industry 237990). The new size standard was based on a 1984 study of the industry structure, conducted in cooperation with the Corps of Engineers and members of the industry. The final rule was published in the **Federal Register** on November 8, 1985 (50 FR 46418). Finally, the industry's