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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 102, 103, 104, 108, 112, 113, 114, 116, and 124

[Docket No. APHIS-2009-0069]

Viruses, Serums, Toxins, and Analogous Products and Patent Term Restoration; Nonsubstantive Amendments

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Direct final rule.

SUMMARY: We are amending the Virus-Serum-Toxin Act regulations concerning veterinary biological products to update the addresses provided for units within the Center for Veterinary Biologics. We are also making several nonsubstantive technical changes to the regulations to update information concerning the number of copies of Outlines of Production and labeling to submit, and to provide information concerning using the Internet to obtain forms and apply for veterinary biologics permits.

DATES: This rule will be effective on June 21, 2010, unless we receive written adverse comments or written notice of intent to submit adverse comments on or before May 21, 2010. If we receive written adverse comments or written notice of intent to submit adverse comments, we will publish a document in the **Federal Register** withdrawing this rule before the effective date.

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

- Federal eRulemaking Portal: Go to (*http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2009-0069*) to submit or view comments and to view supporting and related materials available electronically.
- Postal Mail/Commercial Delivery: Please send one copy of your comment to Docket No. APHIS-2009-0069, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. APHIS-2009-0069.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room 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) 690-2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at (*http://www.aphis.usda.gov*).

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief of Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737-1231; (301) 734-8245.

SUPPLEMENTARY INFORMATION:

Background

The regulations in Title 9, Code of Federal Regulations (9 CFR), parts 101 through 118 (referred to below as the regulations), contain provisions implementing the Virus-Serum-Toxin Act, as amended (21 U.S.C. 151–159). The regulations in 9 CFR part 124 contain procedural requirements for patent extensions for veterinary biologics under 35 U.S.C. 156. In accordance with the procedures explained below under "Dates," this final rule makes several nonsubstantive technical changes to those regulations to update their provisions. Specifically:

- We will amend the addresses throughout the regulations to reflect the relocation of the Center for Veterinary Biologics to new facilities in Ames, IA.
- We will amend 9 CFR part 102, § 102.3(b)(2)(i), 9 CFR part 104, § 104.5(a)(4), and 9 CFR part 114, §§ 114.8(c) and 114.9(a)(1), (a)(5), and (a)(7) regarding the number of copies of the Outline of Production or revised pages of an Outline of Production, or special outline that are required to be submitted in support of an application for veterinary biological product license or permit.
- We will amend 9 CFR part 103, § 103.3(d), and 9 CFR part 112, § 112.5(d)(1)(iii) and (d)(1)(iv) regarding the number of copies of finished labels that are required to be submitted for review and filing.
- We will amend 9 CFR part 103, § 104.3(a), and 9 CFR part 112, § 112.5(a), to indicate that the Internet may be used to obtain forms and apply for certain veterinary biologics permits.
- We will amend 9 CFR part 104, § 104.5(a)(1), and 9 CFR part 108, § 108.7, regarding the number of copies of all plot plans, blueprints, and legends required to be submitted for review and filing.

Dates

We are publishing this rule without a prior proposal because we view this action as noncontroversial and anticipate no adverse public comment. This rule will be effective, as published in this document, on June 21, 2010, unless we receive written adverse comments or written notice of intent to submit adverse comments on or before May 21, 2010.

Adverse comments are comments that suggest the rule should not be adopted or that suggest the rule should be changed.

If we receive written adverse comments or written notice of intent to submit adverse comments, we will publish a document in the **Federal Register** withdrawing this rule before the effective date. We will then publish a proposed rule for public comment.

As discussed above, if we receive no written adverse comments or written notice of intent to submit adverse comments within 30 days of publication of this direct final rule, this direct final rule will become effective 60 days following its publication. We will publish a document in the **Federal Register**, before the effective date of this direct final rule, confirming that it is effective on the date indicated in this document.

Executive Order 12866 and Regulatory Flexibility Act

This rule is subject to Executive Order 12866. However, for this action, the Office of Management and Budget has waived its review under Executive Order 12866.

This direct final rule will affect all licensed manufacturers of veterinary biologics. Currently, there are approximately 125 veterinary biologics manufacturers, including permittees. According to the standards of the Small Business Administration, most veterinary biologics establishments are small entities.

The provisions of this direct final rule that update addresses and indicate the availability of forms on the Internet will have no economic effect on any entities, large or small. The provisions that reduce from three to two the number of copies of certain forms, labels, plot plans, blueprints, and legends that regulated entities are required to submit in specific cases may result in some cost savings to those entities, but those savings will be inconsequential.

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 direct final 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. 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 rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Further, this rule will reduce information collection or recordkeeping requirements in 9 CFR parts 102, 103, 104, 108, 112, and 114.

List of Subjects

9 CFR Parts 102, 103, 114, and 116

Animal biologics, Reporting and recordkeeping requirements.

9 CFR Part 104

Animal biologics, Imports, Reporting and recordkeeping requirements, Transportation.

9 CFR Part 108

Animal biologics

9 CFR Part 112

Animal biologics, Exports, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

9 CFR Part 113

Animal biologics, Exports, Imports, Reporting and recordkeeping requirements.

9 CFR Part 124

Animal biologics, Patents.

■ Accordingly, we are amending 9 CFR parts 102, 103, 104, 108, 112, 113, 114, 116, and 124 as follows:

PART 102—LICENSES FOR BIOLOGICAL PRODUCTS

■ 1. The authority citation for part 102 continues to read as follows:

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

§ 102.3 [Amended]

■ 2. In § 102.3, paragraph (b)(2)(i) is amended by removing the words "four copies" and adding the word "two copies" in their place.

§ 102.5 [Amended]

■ 3. In § 102.5, paragraph (e), the second sentence is amended by removing the words "Licensing and Policy Development, 510 South 17th Street, Suite 104, Ames, IA 50010-8197" and adding the words "Policy, Evaluation, and Licensing, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010" in their place.

PART 103—EXPERIMENTAL PRODUCTION, DISTRIBUTION, AND EVALUATION OF BIOLOGICAL PRODUCTS PRIOR TO LICENSING

■ 4. The authority citation for part 103 continues to read as follows:

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

§ 103.3 [Amended]

■ 5. In § 103.3, paragraph (d), the first sentence is amended by removing the words "Three copies" and adding the words "Two copies" in their place.

PART 104—PERMITS FOR BIOLOGICAL PRODUCTS

■ 6. The authority citation for part 104 continues to read as follows:

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

■ 7. In § 104.3, paragraph (a) is amended by revising the second sentence to read as follows:

§ 104.3 Permit application.

(a) * * * Application forms are available on the Internet at (*http://www.aphis.usda.gov/animal_health/vet_biologics/vb_forms.shtml*) and application for a permit to import a veterinary biologic for research and evaluation or transit shipment may be made on the Internet at (*http://www.aphis.usda.gov/animal_health/permits/vet_bio_permits.shtml*).

* * * * *

§ 104.5 [Amended]

■ 8. Section 104.5 is amended as follows:

■ a. In paragraph (a)(1), in the first sentence, by removing the words "Three copies" and adding the words "Two copies" in their place.

■ b. In paragraph (a)(4), in the second sentence, by removing the words "Four copies" and adding the words "Two copies" in their place.

PART 108—FACILITY REQUIREMENTS FOR LICENSED ESTABLISHMENTS

■ 9. The authority citation for part 108 continues to read as follows:

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

§ 108.7 [Amended]

■ 10. In § 108.7, the first sentence is amended by removing the words "Three copies" and adding the words "Two copies" in their place.

PART 112—PACKAGING AND LABELING

■ 11. The authority citation for part 112 continues to read as follows:

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

§ 112.5 [Amended]

■ 12. Section 112.5 is amended as follows:

■ a. In paragraph (a), in the first sentence, by removing the words "furnished by Animal and Plant Health inspection Service upon request" and adding the words "available on the

Internet at (*http://www.aphis.usda.gov/animal_health/vet_biologics/vb_forms.shtml*)" in their place.

■ b. In paragraph (d)(1)(iii), in the first sentence, by removing the words "three copies" and adding the words "two copies" in their place and, in the second sentence, by removing the words "Two copies" and adding the words "One copy" in their place.

■ c. In paragraph (d)(1)(iv), in the first sentence, by removing the words "three copies" and adding the words "two copies" in their place and, in the fifth sentence, by removing the words "Two copies" and adding the words "One copy" in their place.

PART 113—STANDARD REQUIREMENTS

■ 13. The authority citation for part 113 continues to read as follows:

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

§ 113.113 [Amended]

■ 14. Section 113.113 is amended as follows:

■ a. In paragraph (a)(2), in the third sentence, by removing the words "510 South 17th Street, Suite 104, Ames, IA 50010-8197" and adding the words "1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010" in their place.

■ b. In paragraph (a)(3), in the second sentence, by removing the words "510 South 17th Street, Suite 104, Ames, IA 50010-8197" and adding the words "1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010" in their place.

■ c. In paragraph (c)(1)(iv), in the first sentence, by removing the words "510 South 17th Street, Suite 104, Ames, IA 50010-8197" and adding the words "1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010" in their place.

■ d. In paragraph (c)(2)(iv)(A), in the second sentence, by removing the words "Licensing and Policy Development, 510 South 17th Street, Suite, 104, Ames, IA 50010-8197" and adding the words "Policy, Evaluation, and Licensing, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010" in their place.

§ 113.209 [Amended]

■ 15. In § 113.209, paragraph (b)(1), the fifth sentence is amended by removing the words "1800 Dayton Avenue, P.O. Box 844, Ames, IA 50010; phone (515) 239-8331; fax (515) 239-8673" and adding the words "1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010; phone (515) 337-6100; fax (515) 337-6120" in their place and, in the seventh sentence, by removing the words "Licensing, and Policy Development, 4700 River Road, Riverdale, MD" and adding the words "Policy, Evaluation, and Licensing, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010" in their place.

PART 114—PRODUCTION REQUIREMENTS FOR BIOLOGICAL PRODUCTS

■ 16. The authority citation for part 114 continues to read as follows:

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

■ 17. In § 114.8, paragraph (c) is revised to read as follows:

§ 114.8 Outline of Production required.

* * * * *

(c) One copy of the Outline of Production shall be retained by the Animal and Plant Health Inspection Service and one copy returned to the licensee or permittee.

* * * * *

§ 114.9 [Amended]

■ 18. Section 114.9 is amended as follows:

■ a. In paragraph (a)(1), in the first sentence, by removing the words "The original and not more than four" and adding the word "All" in their place.

■ b. In paragraph (a)(5), in the first sentence, by removing the words "the original and one copy" and adding the words "both copies" in their place.

■ c. In paragraph (a)(7), by removing the second sentence and adding the sentence "Transmittal forms are available on the Internet at (*http://www.aphis.usda.gov/animal_health/vet_biologics/vb_forms.shtml*)." in its place.

PART 116—RECORDS AND REPORTS

■ 19. The authority citation for part 116 continues to read as follows:

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

§ 116.5 [Amended]

■ 20. In § 116.5, paragraph (b), the second sentence is amended by removing the words "510 South 17th Street, Suite 104, Ames, IA 50010-8197; by electronic mail to (*cvb@aphis.usda.gov*); by fax to (515) 232-7120; or by telephone to (515) 232-5785" and adding the words "1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010; by electronic mail to (*cvb@aphis.usda.gov*); by fax to (515) 337-6120; or by telephone to (515) 337-6100" in their place.

PART 124—PATENT TERM RESTORATION

■ 21. The authority citation for part 124 continues to read as follows:

Authority: 35 U.S.C. 156; 7 CFR 2.22, 2.80, and 371.4.

§ 124.22 [Amended]

■ 22. In § 124.22, paragraph (a), the second sentence is amended by removing the words "Licensing, and Policy Development, 510 South 17th Street, Suite 104, Ames, IA 50010-8197" and adding the words "Policy, Evaluation, and Licensing, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010" in their place.

§ 124.40 [Amended]

■ 23. In § 124.40, paragraph (b)(3) is amended by removing the words "Licensing and Policy Development, 510 South 17th Street, Suite 104, Ames, IA 50010-8197" and adding the words "Policy, Evaluation, and Licensing, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010" in their place.

Done in Washington, DC, this 14th day of April 2010.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2010–9072 Filed 4–20–10; 10:24 am]

BILLING CODE 3410–34–S

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2009–0937; Airspace Docket No. 09–ASO–27]

Establishment of Class E Airspace; Jackson, AL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: This action confirms the effective date of a direct final rule published in the **Federal Register** December 7, 2009 that establishes Class E airspace at Jackson Muni, Jackson, AL.

DATES: Effective Date: 0901 UTC, April 21, 2010.

FOR FURTHER INFORMATION CONTACT: Melinda Giddens, Operations Support Group, Eastern Service Center, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone (404) 305–5610.

SUPPLEMENTARY INFORMATION:

Confirmation of Effective Date

The FAA published this direct final rule with a request for comments in the **Federal Register** on December 7, 2009 (74 FR 63973), Docket No. FAA–2009–