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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 101 and 113

[Docket No. APHIS-2013-0034]

RIN 0579-AD86

Viruses, Serums, Toxins, and Analogous Products; Standard Requirements; Addition of Terminology to Define Veterinary Biologics Test Results

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the veterinary biological product regulations by defining the terms used for reporting the results of tests performed on veterinary biological products. Licensees and permittees of veterinary biological products must conduct these tests and report the results to the Animal and Plant Health Inspection Service so that the Agency can determine if the products are eligible for release. Defining these terms will clarify the circumstances under which the results of a prescribed test can be reported as satisfactory, unsatisfactory, inconclusive, or a No Test. We are also removing several obsolete testing standard requirements from the regulations. These changes will update our regulations and improve communication between regulators and product licensees and permittees with respect to reporting test results.

EFFECTIVE DATE: [Insert date 30 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; (301) 851-3426.

SUPPLEMENTARY INFORMATION:

Background

The Animal and Plant Health Inspection Service (APHIS) administers and enforces the Virus-Serum-Toxin Act (21 U.S.C. 151 et seq.). Under the Virus-Serum-Toxin Act, a veterinary biological product must be shown to be pure, safe, potent, and efficacious before a veterinary biological product license may be issued. The regulations in 9 CFR part 113, "Standard Requirements" (referred to below as the regulations), prohibit the release of biological products prior to the completion of tests identified in the regulations and in the Outline of Production, a document submitted by the licensee that explains how a serial of product is formulated, tested, packaged, dated, and recommended for use.

On May 30, 2014, we published in the Federal Register (79 FR 31054-31056, Docket No. APHIS-2013-0034) a proposal[1] to amend the regulations by defining the terms used for reporting the results of tests performed on veterinary biological products. We proposed to add definitions of the terms used to designate test results, "satisfactory," "unsatisfactory," and "inconclusive," to § 101.5(l) and to revise the definition of "No Test" currently in that section in order to align the regulations in 9 CFR part 113 with current industry standards and practices. We also proposed to remove §§ 113.201, 113.202, 113.203, 113.211, 113.213, and 113.214 from the regulations. These standards, which involve testing on live animals, are no longer used by the industry because newer testing methods are available.

[1] To view the proposed rule and supporting documentation, go to http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0034.

We solicited comments concerning our proposal for 60 days ending July 29, 2014. We did not receive any comments. Therefore, for the reasons given in the proposed rule, 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.

APHIS is amending the regulations in order to better define the terminology used when reporting the results of tests performed on veterinary biological products, thereby bringing the regulations up to date with current industry standards.

The changes will clarify when the results of a prescribed test can be reported as satisfactory, unsatisfactory, inconclusive, or can be designated as a No Test. The definitional changes will improve communication between APHIS and the regulated industry, and enable APHIS to more efficiently process the release of a tested product using current industry standards for reporting of test results.

There are about 330 firms in the United States that manufacture biological products. It is not known how many of these firms are engaged in manufacturing biologic products specifically for veterinary purposes. The Small Business Administration (SBA) standard for a small business in this industry is a firm with not more than 500 employees; the average firm in this industry has

93 employees. While most firms that would be affected by this rule are small, the changes will not impose a financial burden on them, but rather help make the product approval process timelier.

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

9 CFR Part 101

Animal biologics.

9 CFR Part 113

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

Accordingly, we are amending 9 CFR parts 101 and 113 as follows:

PART 101--DEFINITIONS

1. The authority citation for part 101 continues to read as follows:

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

2. In §101.5, paragraph (l) is revised to read as follows:

§ 101.5 Testing terminology.

* * * * *

(l) Test results. Terms used to designate testing results are as follows:

(1) No Test. Designation used when a deficiency in the test system has rendered a test unsuitable for drawing a valid conclusion.

(2) Satisfactory. Designation is a final conclusion given to a valid test with results that meet the release criteria stated in the filed Outline of Production or Standard Requirement.

(3) Unsatisfactory. Designation is a final conclusion given to a valid test with results that do not meet the release criteria stated in the filed Outline of Production or Standard Requirement.

(4) Inconclusive. Designation used for an initial test when a sequential test design established in the filed Outline of Production or Standard Requirement allows further testing if a valid initial test is not satisfactory.

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PART 113--STANDARD REQUIREMENTS

3. 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.

4. In § 113.5, paragraph (d) is revised to read as follows:

§113.5 General testing.

* * * * *

(d) When the initial or any subsequent test is declared a No Test, the reasons shall be reported in the test records, the results shall not be considered as final, and the test may be repeated. When a test is declared satisfactory, the test designation is considered to be a final conclusion. When a test is declared unsatisfactory, the test designation is considered to be a final conclusion. When the initial or any subsequent test is declared inconclusive, the reasons shall be reported in the test records, the result shall not be considered as final, and the test may be repeated as established in the filed Outline of Production or Standard Requirement. If a test is designated inconclusive or No Test and the biological product is not further tested, the test designation of unsatisfactory is the final conclusion.

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§§ 113.33, 113.36, 113.38, 113.39, 113.40, 113.41, 113.44, 113.45, 113.47, 113.67, 113.70, 113.71, 113.108, 113.109, 113.111, 113.112, 113.116, 113.117, 113.118, 113.204, 113.205, 113.207, 113.208, 113.215, 113.216, 113.301, 113.302, 113.303, 113.304, 113.305, 113.306, 113.310, 113.311, 113.313, 113.314, 113.315, 113.316, 113.317, 113.318, 113.326, 113.327, 113.328, 113.329, 113.330, 113.331, 113.332, 113.406, 113.450, 113.454, and 113.455 [Amended]

5. Sections 113.33, 113.36, 113.38, 113.39, 113.40, 113.41, 113.44, 113.45, 113.47, 113.67, 113.70, 113.71, 113.108, 113.109, 113.111, 113.112, 113.116, 113.117, 113.118, 113.204, 113.205, 113.207, 113.208, 113.210, 113.215, 113.216, 113.301, 113.302, 113.303, 113.304, 113.305, 113.306, 113.310, 113.311, 113.313, 113.314, 113.315, 113.316, 113.317, 113.318, 113.326, 113.327, 113.328, 113.329, 113.330, 113.331, 113.332, 113.406, 113.450, 113.454, and 113.455 are amended by removing the word "inconclusive" each time it occurs and by adding the words "a No Test" in its place.

§§ 113.109, 113.111, and 113.112 [Amended]

6. Sections 113.109, 113.111, and 113.112 are amended by removing the word "invalid" each time it occurs and adding the words "a No Test" in its place.

§§ 113.201, 113.202, 113.203, and 113.211 [Removed and Reserved]

7. Sections 113.201, 113.202, 113.203, and 113.211 are removed and reserved.

§ 113.212 [Amended]

8. In §113.212, paragraphs (b) and (d)(1) are amended by removing the word "inconclusive" each time it occurs and replacing it with the words "a No Test".

§§ 113.213 and 113.214 [Removed and Reserved]

9. Sections 113.213 and 113.214 are removed and reserved.

10. Section 113.325 is amended as follows:

a. By revising paragraph (b); and

b. In paragraphs (c)(4), (d)(1), and (d)(2)(ii), by removing the word "inconclusive" each time it occurs and replacing it with the words "a No Test".

The revision reads as follows:

§ 113.325 Avian Encephalomyelitis Vaccine.

* * * * *

(b) Each lot of Master Seed Virus shall be tested for pathogens by the chicken embryo inoculation test prescribed in §113.37, except that, if the test is a No Test because of a vaccine virus override, the test may be repeated and if the repeat test is inconclusive for the same reason, the chicken inoculation test prescribed in §113.36 may be conducted and the virus judged accordingly.

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Done in Washington, DC, this 12th day of September 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2014-22294 Filed 09/17/2014 at 8:45 am; Publication Date: 09/18/2014]