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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: Proposed rule

SUMMARY: We are proposing to amend 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 would 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 proposing to remove several obsolete testing standard requirements from part 113. These changes would update our regulations and improve communication between regulators and product licensees and permittees with respect to reporting test results.

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/#!docketDetail;D=APHIS-2013-0034.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2013-0034, 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-2013-0034 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; (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.

The results of these tests must be reported in accordance with 9 CFR part 116. Specifically, § 116.7 requires veterinary biologics licensees to submit summaries of all tests conducted on each serial and subserial of product using APHIS Form 2008 or an acceptable equivalent form prior to release of each serial or subserial. This form lists four terms to designate test results: "Satisfactory," "unsatisfactory," "inconclusive," and "No Test." The terms "satisfactory," "unsatisfactory," and "inconclusive" are not defined in the regulations. Section 101.5(l) of the regulations currently defines the term "No Test" as a test that produces inconclusive or invalid results and, therefore, cannot be used to evaluate a biological product. Section 113.5(d) of the regulations indicates that when an initial or subsequent test is declared a No Test, the reasons must be reported in the test records, the results will not be considered as final, and the test may be repeated.

We are proposing 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. Defining these testing terms will align the regulations in 9 CFR part 113 with current industry standards and practices.

We propose to revise paragraph (l) in section 101.5 to define the testing terms in new subparagraphs (1) through (4). Paragraph (l)(1) will provide a revised definition of "No Test." The term "No Test" would now be defined as the test designation used when a deficiency in the test system has rendered a test unsuitable for drawing a valid conclusion. For example, the deficiency can be the result of a failure to meet the test's internal validity requirements established in the filed Outline of Production or standard requirements, or be caused by an

uncontrollable occurrence such as a power outage affecting incubators or other equipment. A No Test is considered an intermediate designation and cannot be used to evaluate a biological product. A further process is then required to determine a final test conclusion of satisfactory or unsatisfactory, which will be based on the filed Outline of Production or standard requirements.

Paragraph (l)(2) would define the term "satisfactory" as the final, conclusive designation given to a valid test with results that meet the release criteria stated in the filed Outline of Production or Standard Requirement.

Paragraph (l)(3) would define the term "unsatisfactory" as the final, conclusive designation given to a valid test with results that do not meet the release criteria stated in the filed Outline of Production or Standard Requirement.

Paragraph (l)(4) would define the term "inconclusive" as the test 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.

We are also proposing to revise § 113.5(d), which indicates that, when the initial or any subsequent test is declared a No Test, the reasons must be reported in the test records, the results will not be considered as final, and the test may be repeated. We would explain to licensees and permittees what the status of the product serial or subserial would be when the result of the test is designated as satisfactory, unsatisfactory, or inconclusive. When a test is declared satisfactory or unsatisfactory, the test designation would be considered a final conclusion. When the initial or any subsequent test is declared inconclusive, the reasons would have to be reported in the test records, the result would not be considered as a final conclusion, and the test could be repeated. If a test designated inconclusive is not performed again, it would be considered concluded and the final result reported as unsatisfactory.

The definitions we propose are intended to clarify the circumstances under which the results of prescribed tests can be reported as satisfactory, unsatisfactory, inconclusive, or No Test. In some cases, the proposed definitions would change how the test results are reported by licensees and permittees on APHIS Form 2008. We have identified more than 50 specific instances of tests in the regulations in which results designated as inconclusive would be redesignated as No Test based on the proposed definition. As one example, § 113.44(b) outlines the swine safety test procedure and interpretation of the test results:

(b) Interpretation. If unfavorable reactions attributable to the product occur in either of the swine during the observation period, the serial or subserial is unsatisfactory. If unfavorable reactions which are not attributable to the product occur, the test shall be declared inconclusive and may be repeated; Provided, That, if the test is not repeated, the serial or subserial shall be declared unsatisfactory.

As a result of our proposed changes to this and other tests in part 113, the term "inconclusive" in the paragraph above would be replaced by the term "No Test." The procedural steps in many part 113 tests differ depending on whether the test is initially reported as a No Test or is inconclusive. A No Test indicates an invalid test that can be repeated without regard to the initial test. On the other hand, an inconclusive initial test result cannot be disregarded. The interpretation of any subsequent testing outcomes takes into account the initial inconclusive test result, for example by averaging its results with subsequent tests and using the average to complete subsequent tests.

For a list of instances where we are proposing to redesignate test outcomes from inconclusive to No Test, please see the proposed amendatory text below.

We are also proposing 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.

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.

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 by contacting the person listed under FOR FURTHER INFORMATION CONTACT or on the Regulations.gov Web site (see ADDRESSES above for instructions for accessing Regulations.gov).

APHIS is proposing to amend 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 proposed changes would 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 would 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 proposed changes would 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 would 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 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. 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 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

9 CFR Part 101

Animal biologics.

9 CFR Part 113

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

Accordingly, we propose to amend 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.

* * * * *

§§ 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, 113.215, 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. Section 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, 113.210, 113.211, 113.213, and 113.214 [Removed and Reserved]

7. Sections 113.201, 113.202, 113.203, 113.211, 113.213, and 113.214 are removed and reserved.

§ 113.210 [Amended]

8. In § 113.210, paragraphs (d)(1) and (d)(2) are amended by removing the word "inconclusive" each time it occurs and replacing it with the words "a No Test".

§ 113.212 [Amended]

9. Section 113.212 is amended as follows:

a. In paragraph (b), by removing the word "inconclusive" and replacing it with the words "a No Test"; and

b. In paragraph (d)(1), by removing the word "inconclusive" and replacing it with the words "a No Test".

§ 113.325 [Amended]

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 23rd day of May 2014.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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