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DEPARTMENT OF AGRICULTURE

Office of the Secretary

7 CFR Part 11

National Appeals Division Rules of Procedure; Correction

AGENCY: Office of the Secretary, National Appeals Division, USDA.

ACTION: Final rule; correction.

SUMMARY: The Department of Agriculture (USDA) published in the **Federal Register** of June 23, 1999, a document promulgating a final rule for the National Appeals Division (NAD) rules of procedure. Inadvertently the rule revised all of 7 CFR part 11 instead of only 7 CFR part 11, subpart A.

DATES: Effective on July 23, 1999.

FOR FURTHER INFORMATION CONTACT: L. Benjamin Young, Jr., General Law Division, Office of the General Counsel, United States Department of Agriculture, STOP 1415, 1400 Independence Avenue SW, Washington, DC 20250-1415; 202/720-4076; e-mail: benjamin.young@usda.gov.

SUPPLEMENTARY INFORMATION: USDA published the final NAD rules of procedure on June 23, 1999, (64 FR 33367), inadvertently revising all of 7 CFR part 11 instead of only 7 CFR part 11, subpart A, which contained the interim final NAD rules of procedure. This correction revises the final rule for the NAD rules of procedure published on June 23, 1999 to revise only 7 CFR part 11, subpart A.

In the final rule for the NAD rules of procedure published on June 23, 1999, (64 FR 33367), make the following corrections. On page 33373, in the first column, revise the amendatory instructions to read as follows:

(1) 1. The heading of part 11 is revised to read "NATIONAL APPEALS DIVISION".

(2) 2. Subpart A of Part 11 is revised to read as follows:

On page 33373, in the first column, make the following editorial corrections:

(1) Add "Subpart A—National Appeals Division Rules of Procedure" following the heading of the part in the table of contents;

(2) Add "Subpart A—National Appeals Division Rules of Procedure" before the authority citation.

Done at Washington, DC, this 30th day of July, 1999.

Dan Glickman,

Secretary of Agriculture.

[FR Doc. 99-20290 Filed 8-6-99; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 101, 102, 105, 112, 113, 116, and 124

[Docket No. 97-117-1]

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

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending our regulations regarding veterinary biological products to reflect the transfer of the Animal and Plant Health Inspection Service's veterinary biologics functions to the Veterinary Services program area and to update the addresses provided for staffs within the Center for Veterinary Biologics. We are also making several nonsubstantive changes to the regulations to correct errors, omissions, or inconsistencies.

EFFECTIVE DATE: August 9, 1999.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Special Assistant to the Deputy Administrator, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737-1231; (301) 734-8245.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 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. We have made several nonsubstantive technical changes to those regulations to update their provisions and correct errors, omissions, or inconsistencies. As part of this rule, we have made the following changes:

1. We have amended the addresses throughout the regulations to reflect the current organizational affiliation of the Center for Veterinary Biologics (CVB) staff within the Animal and Plant Health Inspection Service and the relocation of most of the CVB's Licensing and Policy Development staff to new offices in Ames, IA.

2. In part 101, we have amended the definition of *regulations* to reflect the 1987 addition of part 118 and the definition of *Virus-Serum-Toxin Act* to reflect the 1987 amendments to that act.

3. We have amended § 113.35(f) so that it refers to the labeling requirements that are set forth in § 112.7(g). That paragraph had incorrectly stated that those requirements were in § 112.7(h).

4. In §§ 113.327 and 113.452, information was missing from the tables found in each section. In the table in § 113.327, the words "or less" were not included after each of the numbers provided in the column titled "Failures for satisfactory serials" and the words "or more" were not included after each of the numbers provided in the column titled "Failures for unsatisfactory serials." In § 113.452, the numbers indicating which stage of testing (i.e., 1 or 2) and the number of vaccinates in each stage (40) were missing from the table despite the presence of titled columns for each set of numbers. We have corrected both tables in this rule.

5. In §§ 113.331 and 113.332, we have removed the word "log" from where it appeared incorrectly before the numbers 10^{0.7} and 10^{0.2}.

6. Paragraph (a) of § 113.451 referred to the National Bureau of Standards. We have updated the reference to reflect that agency's current name, the National Institute of Standards and Technology.

7. Paragraph (b) of § 124.1 refers to the Patent and Trademark Office (PTO) regulations concerning patent term extension. We have updated the citation provided for those PTO regulations to

reflect the 1995 addition of two sections to "Subpart F—Extension of Patent Term" (37 CFR 1.710 through 1.791).

8. In §§ 124.32 and 124.43, we have removed outdated references to the "Assistant Secretary for Marketing and Inspection Services" and have replaced them with the current title, "Under Secretary for Marketing and Regulatory Programs."

This rule relates to internal agency management and includes technical amendments. Therefore, pursuant to 5 U.S.C. 553, notice of proposed rulemaking and opportunity to comment thereon are not required, and this rule may be made effective less than 30 days after publication in the **Federal Register**. Further, since this rule relates to internal agency management and includes technical corrections, it is exempt from the provisions of Executive Order 12866 and Executive Order 12988. Finally, this subject is not a rule as defined by Public Law 96-354, the Regulatory Flexibility Act, and thus, is exempt from the provisions of that Act.

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.*).

List of Subjects

9 CFR Part 101

Animal biologics.

9 CFR Part 102

Animal biologics, Reporting and recordkeeping requirements.

9 CFR Part 105

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 116

Animal biologics, Reporting and recordkeeping requirements.

9 CFR Part 124

Animal biologics, Patents.

Accordingly, we are amending 9 CFR parts 101, 102, 105, 112, 113, 116, and 124 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 371.2(d).

2. In § 101.2, the definitions of *Regulations* and *Virus-Serum-Toxin Act* are revised to read as follows:

§ 101.2 Administrative Terminology.

* * * * *

Regulations. The provisions in parts 101 through 118 of this subchapter.

* * * * *

Virus-Serum-Toxin Act. The Act of March 4, 1913, 37 Stat. 832-833; as amended December 23, 1985, Public Law 99-198, 99 Stat. 1654-1655; and as further amended September 28, 1988, Public Law 100-449, 102 Stat. 1868; 21 U.S.C. 151-159.

* * * * *

PART 102—LICENSES FOR BIOLOGICAL PRODUCTS

3. 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 371.2(d).

§ 102.5 [Amended]

4. In § 102.5(e), in the second sentence, remove the words "Animal and Plant Health Inspection Service, Biotechnology, Biologics, and Environmental Protection, Veterinary Biologics, 4700 River Road Unit 148, Riverdale, Maryland 20737-1237" and add, in their place, the words "Director, Center for Veterinary Biologics, Licensing and Policy Development, 510 South 17th Street, Suite 104, Ames, IA 50010-8197".

PART 105—SUSPENSION, REVOCATION, OR TERMINATION OF BIOLOGICAL LICENSES OR PERMITS

5. The authority citation for part 105 continues to read as follows:

Authority: 21 U.S.C. 151-159; 7 CFR 2.22, 2.80, and 371.2(d).

§ 105.1 [Amended]

6. In § 105.1(a)(1), remove the number "117" and add, in its place, the number "118".

PART 112—PACKAGING AND LABELING

7. 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 371.2(d).

§ 112.5 [Amended]

8. In § 112.5(d)(2)(ii), in the first sentence, remove the words "Two-or-three part" and add, in their place, the words "Two-or three-part".

§ 112.6 [Amended]

9. In § 112.6(c), introductory text, in the fourth sentence, remove the words "more then" and add, in their place, the words "more than".

PART 113—STANDARD REQUIREMENTS

10. 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 371.2(d).

§ 113.35 [Amended]

11. In § 113.35(f), remove the citation "§ 112.7(h)" and add, in its place, the citation "§ 112.7(g)".

§ 113.70 [Amended]

12. Section 113.70 is amended as follows:

a. In the introductory text, at the end of the first sentence, remove the words "Pasteurella Multocida" and add, in their place, the words "*Pasteurella multocida*".

b. In paragraph (b)(1) remove the words "Pasteurella Multocida" and add, in their place, the words "*Pasteurella multocida*".

c. In paragraph (b)(3) remove the words "Pasteurella multocida" and add, in their place, the words "*Pasteurella multocida*".

§ 113.113 [Amended]

13. Section 113.113 is amended as follows:

a. In paragraph (a)(2), in the third sentence, remove the words "the Deputy Director, VBFO, 223 South Walnut Avenue, Ames, Iowa 50010" and add, in their place, the words "Director, Center for Veterinary Biologics, Inspection and Compliance, 510 South 17th Street, Suite 104, Ames, IA 50010-8197".

b. In paragraph (a)(3), in the second sentence, remove the words "the Deputy Director, VBFO, 223 South Walnut Avenue, Ames, Iowa 50010" and add, in their place, the words "Director, Center for Veterinary Biologics, Inspection and Compliance, 510 South 17th Street, Suite 104, Ames, IA 50010-8197".

c. In paragraph (c)(2)(iv)(A) in the second sentence, remove the words "Animal and Plant Health Inspection Service, Biotechnology, Biologics, and Environmental Protection, Veterinary Biologics, 4700 River Road Unit 148, Riverdale, Maryland 20737-1237" and add, in their place, the words "Director, Center for Veterinary Biologics,

Licensing and Policy Development, 510 South 17th Street, Suite 104, Ames, IA 50010-8197”.

d. In paragraph (c)(2)(iv)(B), at the beginning of the first sentence, remove

the words “Bulk of” and add, in their place, the words “Bulk or”.

14. In § 113.327(d)(2)(ii), the table is revised to read as follows:

§ 113.327 Bronchitis Vaccine.

* * * * *

(d) * * *

(2) * * *

(ii) * * *

CUMULATIVE TOTALS

Stage	Number of chickens	Failures for satisfactory serials	Failures for unsatisfactory serials
1	25	2 or less	4 or more.
2	50	5 or less	6 or more.

* * * * *

§ 113.331 [Amended]

15. In § 113.331(d)(3), in the second sentence, remove the word “log” both times it appears, and add the word “times” after the number “10^{0.7}”.

§ 113.332 [Amended]

16. In § 113.332(d)(3), in the second sentence, add the word “times” after the number “10^{0.7}” and remove the word “log” before the number “10^{2.0}”.

words “Institute of Standards and Technology” in their place.

18. In § 113.452(b)(4), the table is revised to read as follows:

§ 113.451 [Amended]

17. In § 113.451, in the introductory text of paragraph (a), remove the words “Bureau of Standards” and add the

§ 113.452 Erysipelothrix Rhusiopathiae Antibody.

* * * * *

(b) * * *

(4) * * *

Stage	Number of vaccinates	Cumulative number of vaccinates	Cumulative total number of deaths for a satisfactory test	Cumulative total number of deaths for an unsatisfactory test
1	40	40	6 or less	11 or more.
2	40	80	12 or less	13 or more.

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 371.2(d).

20. In § 116.5, paragraph (b) is revised to read as follows:

§ 116.5 Reports.

* * * * *

(b) If, at any time, there are indications that raise questions regarding the purity, safety, potency, or efficacy of a product, or if it appears that there may be a problem regarding the preparation, testing, or distribution of a product, the licensee, permittee, or foreign manufacturer must immediately notify the Animal and Plant Health Inspection Service concerning the circumstances and the action taken, if any. Notification may be made by mail to Director, Center for Veterinary Biologics, Inspection and Compliance, 510 South 17th Street, Suite 104, Ames, IA 50010-8197; by electronic mail to cvb@usda.gov; by fax to (515) 232-7120; or by telephone to (515) 232-5785.

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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 371.2(m).

§ 124.1 [Amended]

22. In § 124.1(b), remove the number “1.785” and add the number “1.791” in its place.

§ 124.22 [Amended]

23. In § 124.22, in the introductory text of paragraph (a), remove the words “the Animal and Plant Health Inspection Service, Biotechnology, Biologics, and Environmental Protection, Veterinary Biologics, 4700 River Road Unit 148, Riverdale, Maryland 20737-1237” and add, in their place, the words “Director, Center for Veterinary Biologics, Licensing and Policy Development, 510 South 17th Street, Suite 104, Ames, IA 50010-8197”.

§ 124.32 [Amended]

24. In § 124.32(a), in the first sentence, remove the words “Assistant Secretary for Marketing and Inspection Services” and add, in their place, the

words “Under Secretary for Marketing and Regulatory Programs”.

§ 124.40 [Amended]

25. In § 124.40(b)(3), remove the words “Animal and Plant Health Inspection Service, Biotechnology, Biologics, and Environmental Protection, Veterinary Biologics, 4700 River Road Unit 148, Riverdale, Maryland 20737-1237” and add, in their place, the words “Director, Center for Veterinary Biologics, Licensing and Policy Development, 510 South 17th Street, Suite 104, Ames, IA 50010-8197”.

§ 124.43 [Amended]

26. In § 124.43, in the first sentence, remove the words “Assistant Secretary for Marketing and Inspection Services” and add, in their place, the words “Under Secretary for Marketing and Regulatory Programs”.

Done in Washington, DC, this 4th day of August 1999.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 99-20444 Filed 8-6-99; 8:45 am]

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