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DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Parts 204, 211, 235, 251, 252, 274a, 299, 316 and 334

[INS No. 1703–95]

RIN 1115–AD81

Delay of Effective Date for Establishment of Form I–551, Alien Registration Receipt Card, as the Exclusive Form of Registration for Lawful Permanent Resident Aliens

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule; delay of effective dates.

SUMMARY: The Immigration and Naturalization Service (''the Service'') is delaying the effective date of a final rule previously published in the **Federal Register** on September 20, 1993, at 58 FR 48775–48780, which provided, *inter alia*, for the termination of the validity of the Form I–151, Alien Registration Receipt Card.

EFFECTIVE DATE: Effective March 17, 1995, the effective date for the regulation published on September 20, 1993, amending 8 CFR Parts 204, 211, 235, 251, 252, 274a, 299, 316, and 334, is delayed until March 20, 1996.

FOR FURTHER INFORMATION CONTACT: Gerard Casale, Senior Adjudications Officer, Immigration and Naturalization Service, Room 3214, 425 I Street NW., Washington, DC 20536, telephone (202) 514–5014.

SUPPLEMENTARY INFORMATION:

Background

On September 20, 1993, the Service published a final rule in the **Federal Register** at 58 FR 48775–48780, establishing the Form I–551, Alien Registration Receipt Card, as the exclusive form of registration for lawful permanent residence, and terminating the validity of the old Form I–151, Alien Registration Receipt Card. In addition, the final rule provided procedures by which a lawful permanent resident alien in possession of a Form I–151 or a prior alien registration document, such as the Form AR–3 or AR–103, could replace these documents with the current Form I–551. The effective date of the amendments to 8 CFR part 264 concerning application procedures became effective on October 20, 1993. The final rule also provided that the effective date for the removal of references to the Form I–151 from 8 CFR parts 204, 211, 223, 235, 251, 252, 274a, 299, 316, and 334 would be September 20, 1994, on which date the validity of the Form I–151 would officially terminate. On September 14, 1994, the Service published a final rule in the **Federal Register** at 59 FR 47063, which extended the validity of the I–151 by delaying the effective date of the amendments to 8 CFR parts 204, 211, 223, 235, 251, 252, 274a, 299, 316, and 334, until March 20, 1995. This rule further extends the validity of the I–151 by delaying the effective date of the amendments to 8 CFR parts 204, 211, 235, 251, 252, 274a, 299, 316, and 334, until March 20, 1996. Delaying the effective date of the amendment to 8 CFR 223 is not necessary since, pursuant to a final rule published on January 11, 1994, at 59 FR 1455–1466, that part no longer contains a reference to Form I–151.

This delay in the effective date is necessary in order to minimize the possibility that lawful permanent resident aliens who apply for either a replacement Form I–551 card or for naturalization prior to March 20, 1995, as a result of the I–151 replacement program, will not have had their applications adjudicated before their old registration cards expire. The I–151 replacement program will terminate on March 20, 1995. Any application for a replacement I–551 card or for naturalization filed by the bearer of a Form I–151 or prior alien registration document after that date will not be considered as having been filed pursuant to the I–151 replacement program. Applicants who wait until after March 20, 1995, to replace their cards or to apply for naturalization assume a much greater risk of being inconvenienced in the event that their applications are not adjudicated prior to the expiration of the Form I–151 on March 20, 1996. Accordingly, lawful permanent resident aliens in possession of a Form I–151 or prior alien registration document issued before 1979 who have not already applied to replace that card with a Form I–551 or for naturalization are urged to apply without delay. For the convenience of the public, these application forms may be ordered by telephone, toll-free, by calling: 1–800–755–0777.

The implementation of this rule as a final rule is based upon the ''good cause'' exception found at 5 U.S.C. 553(b)(B) and (d)(3). The reason for the immediate implementation of this final rule is as follows: A notice and comment period for a proposed rule is impracticable and contrary to the public interest. Absent an extension of the validity of the Form I–151, several aliens who have applied for replacement I–551 cards or for naturalization pursuant to the I–151 replacement program would no longer have valid evidence of their status after March 20, 1995. Accordingly, this regulation affords a benefit rather than a burden or penalty of any kind on affected persons.

Dated: March 10, 1995.

Doris Meissner,

Commissioner, Immigration and Naturalization Service.

[FR Doc. 95–6711 Filed 3–16–95; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 101 and 113

[Docket No. 92–201–2]

Viruses, Serums, Toxins, and Analogous Products; General Requirements for Inactivated Bacterial Products

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations to include a general standard requirement for inactivated bacterial products that is consistent with the general standard requirements

for live bacterial products, killed virus vaccines, and live virus vaccines. We are also including criteria and test concerning the identity of master seed. Finally, the amendment provides a choice of the most appropriate test methods, including identity tests, for the broad range of inactivated bacterial products available today. The final rule is necessary to update the current standards and provide uniform, relevant criteria for inactivated bacterial products.

EFFECTIVE DATE: April 17, 1995.

FOR FURTHER INFORMATION CONTACT: Dr. Richard E. Pacer, Senior Staff Veterinarian, Animal and Plant Health Inspection Service, Biotechnology, Biologics, and Environmental Protection, Veterinary Biologics, 4700 River Road Unit 148, Riverdale, MD 20737–1228, (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

In accordance with the regulations in 9 CFR part 113, standard requirements are prescribed for the licensing of veterinary biological products. A standard requirement consists of specifications, procedures, and test methods which define the standards of purity, safety, potency, and efficacy for a given type of veterinary biological product.

On March 1, 1994, we published in the **Federal Register** (59 FR 9681–9682, Docket No. 92–201–1) a proposal to amend the regulations by revising § 113.100 to include the relevant criteria for evaluation of the purity, safety, and identity of inactivated bacterial products. In addition, we proposed to define the master seed concept as it applies to inactivated bacterial products. This action was intended to provide specific criteria for these inactivated bacterial products. We also proposed to move certain definitions from § 113.100 to part 101.

We solicited comments on our proposal for a 60-day period ending May 2, 1994. We received one comment by that date. This comment was from a licensed manufacturer of veterinary biological products. The commenter's only concern was about the manufacture of inactivated bacterial products for fish.

The commenter sought clarification of our requirement for safety tests as proposed in § 113.100(b). This requirement states that each bacterial product shall be evaluated in mice and/or guinea pigs with the exception that, if the product is specific for poultry, then the safety test will be performed in poultry. The commenter suggested that an exception similar to that for poultry should be considered for products specifically intended for fish. We agree with the rationale of the commenter because it would be more appropriate to evaluate the safety of a biological product intended for fish in an aquatic species than in a mammalian species. In response to the commenter, we have amended the proposal by adding a new paragraph (b)(3) in § 113.100 concerning fish and including other aquatic species or reptiles which states: ''The product is recommended for fish, other aquatic species or reptiles. In such instances, the product shall be safety tested in fish or other aquatic species or reptiles as required by specific Standard Requirement or Outline of Production for the product.'' We have also made a slight change to the definitions to clarify the fact that the defined products are inactivated bacterial products.

Therefore, with the exception of the above changes, we are adopting the provisions of the proposal as a final rule.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for purposes of Executive Order 12866, and, therefore, has not been reviewed by the Office of Management and Budget.

There are currently no general requirements for inactivated bacterial products in the regulations. However, approximately 30 percent of the 114 currently licensed veterinary biologics companies manufacture inactivated bacterial products. Many of these companies are considered small entities and will benefit from the adoption of this rule. The benefits of the rule include increased efficiency and reduced time and expense in accomplishing the steps toward licensure of an inactivated bacterial product. These benefits will be realized because of ready access to clear requirements, uniformity and consistency in product development, and the alleviation of unnecessary steps in production of these type of products. These companies should not experience any additional costs above those which they currently incur to license an inactivated bacterial product as a result of adoption of this rule.

Under these circumstances, the Administrator for 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 12778

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

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.)

List of Subjects

9 CFR Part 101

Animal biologics.

9 CFR Part 113

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

Accordingly, 9 CFR parts 101 ad 113 are amended 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 2.17, 2.51, and 371.2(d).

2. Section 101.3, is amended by adding, at the end of the section, the following definitions to read as follows:

§ 101.3 Biological products and related terms.

* * * * *

(m) *Bacterin.* An inactivated bacterial product consisting of an antigenic suspension of organisms or particulate parts of organisms, representing a whole culture or a concentrate thereof, with or without the unevaluated growth products, which has been inactivated as demonstrated by acceptable tests written into the filed Outline of Production for the product.

(n) *Toxoid.* An inactivated bacterial product which consists of a sterile, antigenic toxin or toxic growth product, which has resulted from the growth of bacterial organisms in a culture medium from which the bacterial cells have been removed, which has been inactivated

without appreciable loss of antigenicity as measured by suitable tests, and which is nontoxic as demonstrated by acceptable tests written into the filed Outline of Production.

(o) *Bacterin-toxoid.* An inactivated bacterial product which is either:

(1) A suspension of organisms, representing a whole culture or a concentrate thereof, with the toxic growth products from the culture which has been inactivated without appreciable loss of antigenicity as measured by suitable tests, the inactivation of organisms and toxins being demonstrated by acceptable tests written into the filed Outline of Production: *Provided,* That it shall contain cellular antigens and shall stimulate the development of antitoxin; or

(2) A combination product in which one or more toxoids or bacterin-toxoids is combined with one or more bacterins or one or more bacterin-toxoids.

(p) *Bacterial extract.* An inactivated bacterial product which consists of the sterile, nontoxic, antigenic derivatives extracted from bacterial organisms or from culture medium in which bacterial organisms have grown.

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 217, 2.51, and 371.2(d).

4. In § 113.100, the heading, introductory paragraph, and paragraphs (a) through (d) are revised to read as follows:

§ 113.100 General requirements for inactivated bacterial products.

Unless otherwise prescribed in an applicable Standard Requirement or in the filed Outline of Production, an inactivated bacterial product shall meet the applicable requirements in this section.

(a) *Purity tests.* (1) Final container samples of completed product from each serial and each subserial shall be tested for viable bacteria and fungi as provided in § 113.26.

(2) Each lot of Master Seed Bacteria shall be tested for the presence of extraneous viable bacteria and fungi in accordance with the test provided in § 113.27(d).

(b) *Safety tests.* Bulk or final container samples of completed product from each serial shall be tested for safety in young adult mice in accordance with the test provided in § 113.33(b) unless:

(1) The product contains material which is inherently lethal for mice.

In such instances, the guinea pig safety test provided in § 113.38 shall be conducted in place of the mouse safety test.

(2) The product is recommended for poultry. In such instances, the product shall be safety tested in poultry as defined in the specific Standard Requirement or Outline of Production for the product.

(3) The product is recommended for fish, other aquatic species, or reptiles. In such instances, the product shall be safety tested in fish, other aquatic species, or reptiles as required by specific Standard Requirement or Outline of Production for the product.

(c) *Identity test.* Methods of identification of Master Seed Bacteria to the genus and species level by laboratory tests shall be sufficient to distinguish the bacteria from other similar bacteria according to criteria described in the most recent edition of ''Bergey's Manual of Systematic Bacteriology'' or the American Society for Microbiology ''Manual of Clinical Microbiology''. If Master Seed Bacteria are referred to by serotype, serovar, subtype, pilus type, strain or other taxonomic subdivision below the species level, adequate testing must be used to identify the bacteria to that level. Tests which may be used to identify Master Seed Bacteria include, but are not limited to:

(1) Cultural characteristics,

(2) Staining reaction,

(3) Biochemical reactivity,

(4) Fluorescent antibody tests,

(5) Serologic tests,

(6) Toxin typing,

(7) Somatic or flagellar antigen characterization, and

(8) Restriction endonuclease analysis.

(d) *Ingredient requirements.* Ingredients used for the growth and preparation of Master Seed Bacteria and of final product shall meet the requirements provided in § 113.50. Ingredients of animal origin shall meet the applicable requirements provided in § 113.53.

* * * * *

Done in Washington, DC, this 13th day of March 1995.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 95–6648 Filed 3–16–95; 8:45 am]

BILLING CODE 3410–34–M

9 CFR Part 113

[Docket No. 93–057–2]

Viruses, Serums, Toxins, and Analogous Products; Sampling of Biological Products

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations concerning the number of representative samples of product that a firm is required to submit to the Animal and Plant Health Inspection Service for testing at the National Veterinary Services Laboratories, Ames, Iowa. The amendment is applicable to diagnostic test kits and Master Seeds and Cells, and will codify provisions which are not currently in the regulations.

EFFECTIVE DATE: April 17, 1995.

FOR FURTHER INFORMATION CONTACT: Dr. Richard E. Pacer, Senior Staff Veterinarian, Animal and Plant Health Inspection Service, Biotechnology, Biologics, and Environmental Protection, Veterinary Biologics, 4700 River Road, Unit 148, Riverdale, MD 20737–1228, (301) 734–8245.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR Part 113 contain standard requirements for evaluating veterinary biological products that are licensed by the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, under the Virus-Serum-Toxin Act of 1913, as amended by the Food Security Act of 1985. Licenses are required to show that biological products are pure, safe, potent, and efficacious.

Purity and identify tests are performed by the licensee and the National Veterinary Services Laboratories (NVSL) on master seed(s) and master cell stock(s) used in the production of veterinary biological products. The licensee is also required to perform tests on the completed veterinary biological product for purity, safety, and potency as prescribed in a filed outline of production or applicable standard requirements for the product in accordance with § 113.5. The licensee's test results may be confirmed by NVSL personnel using representative biological product samples that the manufacturer is required to submit to APHIS in accordance with § 113.3.

Section 113.3 currently provides licensees and permittees with criteria for selection and submission of veterinary biological products, such as