(3) *Crediting service.* An employee's creditable service must total at least 3 years, under the following conditions:

(i) *Work schedule.* (A) Full-time service, and part-time service on or after July 1, 1962, are counted as calendar time from the date of appointment to date of separation.

(B) Intermittent service on or after July 1, 1962, is counted as 1 day for each day an employee is in pay status, regardless of the number of hours for which the employee is actually paid on a given day. Agencies should consult the ''260-Day Work Year Chart'' in OPM's *Guide to Processing Personnel Actions* to convert intermittent days worked to calendar time. The service requirement may not be satisfied in less than 3 years of calendar time.

(ii) *Nonpay status on the rolls and time off the rolls.* An agency may not credit periods of nonpay status and time off the rolls except as follows:

(A) Credit the first 30 calendar days of each period of nonpay status on the rolls during full-time employment, or during part-time employment on or after July 1, 1962. On this same basis, a seasonal employee receives credit for the first 30 calendar days of each period of nonduty/nonpay status. Nonpay status in excess of 30 days is not creditable.

(B) Credit periods of nonpay status and time off the rolls incident to entry into and return from military service and return from defense transfer, provided the person is reemployed in Federal service during the period of his or her statutory or regulatory restoration or reemployment rights.

(C) Credit periods of nonpay status and time off the rolls incident to transfer to and return from an international organization, provided the person is reemployed in Federal service under subpart C of part 352 of this chapter.

(D) Credit periods of nonpay status during which an employee was eligible to receive continuation of pay or injury compensation from the Office of Workers' Compensation Programs. Also credit periods of time off the rolls during which an employee was eligible to receive injury compensation from the Office of Workers' Compensation Programs, provided the person is reemployed under part 353 of this chapter.

(E) Credit up to 30 calendar days for time off the rolls that follows separation by reduction in force of employees who are eligible for entry on the reemployment priority list under subpart B of part 330 of this chapter, provided the person is reemployed in Federal service during the period of his or her reemployment priority.

(F) Credit up to 30 calendar days for time off the rolls that follow involuntary separation without personal cause of employees who are eligible for a noncompetitive appointment based on an interchange agreement with another merit system under § 6.7 of this chapter, provided the person is employed in the competitive service under the agreement during the period of his or her eligibility.

(G) Credit periods of nonpay status incident to an assignment to a State, local, or Indian tribal government, institution of higher education, or other eligible organization provided the employee returns to a creditable appointment pursuant to an agreement established under subchapter VI of chapter 33, title 5, U.S.C., and part 334 of this chapter.

(iii) *Restoration based on unwarranted or improper actions.* Based on a finding made on or after March 30, 1966, that a furlough, suspension, or separation was unwarranted or improper, an employee restored to duty receives full calendar time credit for the period of furlough, suspension, or separation for which he or she is eligible to receive back pay. If the employee is restored to duty at a date later than the original adverse action, credit for intervening periods of nonpay status is given in accordance with other provisions of this subsection. If the employee had been properly separated from the rolls of the agency before a finding was made that the adverse action was unwarranted or improper, the correction and additional service credit given the employee may not extend beyond the date of the proper separation.

(iv) *Intervening service.* Certain types of service that ordinarily are not creditable are counted when they intervene between two periods of creditable service. Under these conditions, credit each period of service:

(A) In the excepted service of the Federal executive branch, including employment in nonappropriated fund positions in or under any Federal agency;

(B) Under temporary, term, or other nonpermanent employment in the Federal competitive service;

(C) In the Senior Executive Service;

(D) In the Federal legislative branch;

(E) In the Federal judicial branch;

(F) In the armed forces;

(G) In the District of Columbia Government through December 31, 1979. For an employee on the District rolls on December 31, 1979, who converted on January 1, 1980, to the District independent personnel system, credit is also given for service between January 1, 1980, and September 25, 1980. Otherwise, service in the District of Columbia Government on or after January 1, 1980, is not creditable as intervening service; and

(H) Performed overseas by family members, as defined by § 315.608 of this chapter.

* * * * *

[FR Doc. 2016–26888 Filed 11–7–16; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 112

[Docket No. APHIS–2008–0008]

RIN 0579–AD19

Viruses, Serums, Toxins, and Analogous Products; Packaging and Labeling

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule; technical amendment.

SUMMARY: In a final rule published in the **Federal Register** on August 30, 2016, and effective on October 31, 2016, we amended the Virus-Serum-Toxin Act regulations to make veterinary biologics labeling requirements more consistent with current science and veterinary practice. However, we inadvertently removed a requirement for an indications statement that should appear on final container labels, carton labels, and enclosures. This document corrects that error.

DATES: Effective November 8, 2016.

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; (301) 851–2352.

SUPPLEMENTARY INFORMATION: In a final rule [1] that was published in the **Federal Register** on August 30, 2016 (81 FR 59427, Docket No. APHIS–2008–0008), and effective on October 31, 2016, we amended the Virus-Serum-Toxin Act regulations to make veterinary biologics labeling requirements more consistent with current science and veterinary practice. Among other things, in 9 CFR part 112, we amended § 112.2(a)(5) to clarify that ''full instructions for the

[1] To view the final rule and supporting documents, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0008.*

proper use of the product'' refers to vaccination schedules, revaccination schedules (if necessary), indications for use, target species, recommended age for vaccination, vaccination route(s), and product license restrictions prescribed by the Animal and Plant Health Inspection Service that have a bearing on product use. However, when we made that change, we inadvertently removed a requirement for an indications statement to appear on final container labels, carton labels, and enclosures. Therefore, we are amending § 112.2(a) to re-establish the requirement for an indications statement.

List of Subjects in 9 CFR Part 112

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

Accordingly, we are amending 9 CFR part 112 as follows:

PART 112—PACKAGING AND LABELING

■ 1. 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.

■ 2. Section 112.2 is amended by adding paragraph (a)(12) to read as follows:

§ 112.2 Final container label, carton label, and enclosure.

(a) * * *

(12) An indications statement to read, ''This product has been shown to be effective for the vaccination of healthy (insert name of species) __ weeks of age or older against __.'' *Provided,* That in the case of very small final container labels or carton, a statement as to where such information is to be found, such as ''See enclosure for complete directions,'' ''Full directions on carton,'' or comparable statement.

* * * * *

Done in Washington, DC, this 2nd day of November 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–26936 Filed 11–7–16; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 10

[Docket No. FDA–2011–N–0697]

RIN 0910–AG26

Amendments to Regulations on Citizen Petitions, Petitions for Stay of Action, and Submission of Documents to Dockets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending certain regulations relating to citizen petitions, petitions for stay of action (PSAs), and the submission of documents to the Agency. In particular, the final rule establishes new regulations to implement certain provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), which concern certain citizen petitions and PSAs that involve a request for FDA to take any form of action relating to a pending abbreviated new drug application (ANDA), 505(b)(2) application, or certain applications submitted under the Public Health Service Act (PHS Act). We are making these changes to implement provisions of the Food and Drug Administration Amendments Act of 2007 (FDAAA) and the Food and Drug Administration Safety and Innovation Act (FDASIA).

DATES: This rule is effective January 9, 2017.

ADDRESSES: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number (FDA–2011–N–0697) into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Darren Eicken, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6206, Silver Spring, MD, 20993–0002, 240–402–0978.

SUPPLEMENTARY INFORMATION:

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Executive Summary

Purpose of the Rule

This rule establishes new regulations implementing section 505(q) of the FD&C Act (21 U.S.C. 355(q)) as enacted by FDAAA (Pub. L. 110–85) and amended by FDASIA (Pub. L. 112–144). Section 505(q) of the FD&C Act governs the manner in which FDA handles certain citizen petitions and PSAs that ask the Agency to take any form of action related to an ANDA, a 505(b)(2) application, or an application submitted under section 351(k) of the PHS Act (351(k) application) (42 U.S.C. 262(k)). Section 505(q) of the FD&C Act specifies that FDA must not delay approval of a pending application because of any request to take any form of action relating to the application, unless the request is in writing and in a citizen petition or a PSA, and the Agency determines, upon reviewing the petition, that a delay is necessary to protect the public health. Section 505(q) of the FD&C Act also requires that all submitters of a petition (or PSA) include with their submission a verbatim certification statement specifying the date on which the information relied on in the petition first became known. Similarly, section 505(q) of the FD&C Act requires that the submitters of a supplement or a comment to a petition include with their submission a verbatim verification statement specifying the date on which the information relied on in their submission first became known. By enacting section 505(q) of the FD&C Act, Congress indicated a desire to ensure that petitions not be used to improperly delay approval of ANDAs, 505(b)(2) applications, or 351(k) applications. This rule clarifies the requirements of section 505(q) of the FD&C Act.

Summary of the Major Provisions of the Rule

This rule amends FDA's regulations on general administrative procedures in part 10 (21 CFR part 10).