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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2013-0011]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Virus-Serum-Toxin Act and Regulations

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the Virus-Serum-Toxin Act and regulations.

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/#!documentDetail;D=APHIS-2013-0011-0001.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2013-0011, 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-2013-0011 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: For information regarding the Virus-Serum-Toxin Act and regulations, contact Dr. Donna Malloy, Section Leader, Policy, Evaluation and Licensing, CVB, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737; (301) 851-3426. For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

SUPPLEMENTARY INFORMATION:

Title: Virus-Serum-Toxin Act and Regulations.

OMB Number: 0579-0013.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: Under the Virus-Serum-Toxin Act (21 U.S.C. 151–159), the Animal and Plant Health Inspection Service (APHIS) is authorized to promulgate regulations designed to prevent the importation, preparation, sale, or shipment of harmful veterinary biological products. These regulations are contained in 9 CFR parts 102 to 124.

Veterinary biological products include viruses, serums, toxins, and analogous products of natural or synthetic origin, such as vaccines, antitoxins, or the immunizing components of

microorganisms intended for the diagnosis, treatment, or prevention of diseases in domestic animals.

APHIS issues licenses to qualified establishments that produce veterinary biological products and issues permits to importers of such products. APHIS also enforces requirements concerning production, packaging, labeling, and shipping of these products and sets standards for the testing of these products.

To help ensure that veterinary biological products used in the United States are pure, safe, potent, and effective, APHIS requires certain information collection activities, including, among other things, establishment license applications, product license applications, product import permit applications, product and test report forms, field study summaries, and recordkeeping. These information activities have been approved by the Office of Management and Budget (OMB) under control number 0579-0013.

In addition, in accordance with the regulations in 9 CFR 105.3 and 115.2, APHIS may notify a veterinary biologics licensee or permittee to stop the preparation, importation, and/or distribution and sale of a serial or a subserial of a veterinary biological product if, at any time, it appears that such product may be worthless, contaminated, dangerous, or harmful in the treatment of animals. This notification triggers two information collection activities: (1) After being contacted by APHIS, veterinary biologics licensees or permittees must immediately, but no later than 2 days, send stop distribution and sale notifications to any wholesalers, jobbers, dealers, foreign consignees, or other persons known to have such veterinary biological product in their possession; and (2) veterinary biologics licensees and permittees must account for the remaining quantity of each serial or subserial of any such veterinary biological product at each

location in the distribution channel known to the licensee or permittee. These information collection activities have been approved by OMB under control number 0579-0318.

This notice includes a description of the information collection activities currently approved by OMB under numbers 0579-0013 and 0579-0318. After OMB approves and combines the burden for both collections under one collection (number 0579-0013), the Department will retire number 0579-0318.

We are asking OMB to approve our use of these information activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; e.g., permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 1.963 hours per response.

Respondents: U.S. importers, exporters, and shippers of veterinary biological products; State veterinary authorities; and operators of establishments that produce or test veterinary biological products or that engage in product research and development and their wholesalers, dealers, jobbers, foreign consignees, or other persons known to have any such worthless, contaminated, dangerous, or harmful veterinary biological product in their possession.

Estimated annual number of respondents: 220.

Estimated annual number of responses per respondent: 181.413.

Estimated annual number of responses: 39,911.

Estimated total annual burden on respondents: 78,349 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 22nd day of May 2013.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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