BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2015-0066]

Notice of Request for Approval of an Information Collection; Viruses, Serums, Toxins, and Analogous Products; Packaging and Labeling

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: New 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 approval of a new information collection concerning packaging and labeling for products approved in accordance with the Virus-Serum-Toxin Act.

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-2015-0066.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2015-0066, 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-2015-0066 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 on packaging and labeling requirements for products approved under the Virus-Serum-Toxin Act, contact Dr. Donna L. Malloy, Section Leader, Operational Support, Center for Veterinary Biologics Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737-1231; (301) 851-3426. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2727.

SUPPLEMENTARY INFORMATION:

Title: Viruses, Serums, Toxins, and Analogous Products; Packaging and Labeling.

OMB Control Number: 0579-XXXX.

Type of Request: Approval of a new information collection.

Abstract: Under the Virus-Serum-Toxin Act (the Act, 21 U.S.C. 151-159) and regulations issued under the Act, the Animal and Plant Health Inspection Service (APHIS) grants licenses or permits for biological products which are pure, safe, potent, and efficacious when used according to label instructions.

The regulations in 9 CFR part 112, "Packaging and Labeling" (referred to below as the regulations), prescribe requirements for the packaging and labeling of veterinary biological products including requirements applicable to final container labels, carton labels, and enclosures. The main purpose of the regulations in part 112 is to regulate the packaging and labeling of veterinary biologics in a comprehensive manner, which includes ensuring that labeling provides adequate instructions for the proper use of the product, including vaccination schedules, warnings, and cautions. Complete labeling (either on the product or accompanying the product) must be reviewed and approved by APHIS in accordance with the regulations in part 112 prior to their use.

On January 13, 2011, we published in the Federal Register (76 FR 2268-2277, Docket No. APHIS-2008-0008) a proposal[1] to amend the regulations to make veterinary biologics labeling requirements more consistent with current science and veterinary practice. Among other things, for labels for export, we proposed to require licensees and permitees to complete, and submit to APHIS, the Transmittal of Labels and Circulars or Outlines form (APHIS Form 2015), maintain label records, and for labels that do not comply with APHIS regulations for packaging and labeling, to provide written authorization statements from foreign veterinary officials of the importing country stating that the labels for export comply with the requirements of their country (importing country).

When we listed the above information collection activities in the proposed rule, we inadvertently did not obtain approval from the Office of Management and Budget (OMB). By this notice, we are asking OMB to approve our use of this information collection for 3 years and to assign an OMB control number.

---

[1] To view the proposed rule and the comments we received, go to http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0008.

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 0.1058 hours per response.

Respondents: Foreign veterinary authorities and U.S. importers and exporters of veterinary biological products.

Estimated annual number of respondents: 200.

Estimated annual number of responses per respondent: 8.5.

Estimated annual number of responses: 1,700.

Estimated total annual burden on respondents: 180 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 28th day of September 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015-25078 Filed: 10/1/2015 08:45 am; Publication Date: 10/2/2015]