laboratories and private inspection services) to be accredited by APHIS to perform specific laboratory testing or phytosanitary inspections that could serve as the basis for issuing Federal phytosanitary certificates, phytosanitary certificates for reexport, or export certificates for processed plant products.

The accreditation process requires the use of several information collection activities to ensure that nongovernment facilities applying for accreditation possess the necessary qualifications.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities 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 3.4482758 hours per response.

Respondents: Operators of nongovernment facilities who wish to be accredited to perform laboratory testing or phyosanitary inspection services in connection with APHIS' export certification program and certain employees of such nongovernment facilities.

Estimated annual number of respondents: 15.

Estimated annual number of responses per respondent: 5.8.

Estimated annual number of responses: 87.

Estimated total annual burden on respondents: 300 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 18th day of May 2011.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2011–12751 Filed 5–23–11; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2011–0024]

Notice of Request for Extension of Approval of an Information Collection; Select Agent Registration

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: 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 extension of approval of an information collection associated with regulations for the possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to human and animal health, to animal health, to plant health, or to animal products and plant products.

DATES: We will consider all comments that we receive on or before July 25, 2011.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2011&-0024* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send one copy of your comment to Docket No. APHIS–2011–0024, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2011–0024.

Reading Room: You may read any comments that we receive on this docket in our reading room. The reading room 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) 690–2817 before coming.

Other Information: Additional information about APHIS and its programs is available on the Internet at *http://www.aphis.usda.gov.*

FOR FURTHER INFORMATION CONTACT: For information regarding the select agent registration process associated with the possession, use, or transfer of biological agents and toxins in 7 CFR part 331, contact Dr. Charles Divan, Branch Chief, Agriculture Select Agent Program, RIPPS, PPQ, APHIS, 4700 River Road, Unit 2, Riverdale, MD 20737; (301) 734–8758.

For information regarding the select agent registration process associated with the possession, use, or transfer of biological agents and toxins in 9 CFR part 121, contact Mr. Robert Rice, Security Manager, Agriculture Select Agent Program, Technical Trade Services Team, NCIE, VS, APHIS, 4700 River Road, Unit 2, Riverdale, MD 20737; (301) 734–5557.

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: Select Agent Registration.

OMB Number: 0579–0213.

Type of Request: Extension of approval of an information collection.

Abstract: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 provides for the regulation of certain biological agents and toxins by the Department of Agriculture (USDA) and the Department of Health and Human Services (HHS). Under section 212 of the Act, USDA regulates biological agents and toxins that have the potential to pose a severe threat to both human and animal health, to animal health, to plant health, or to animal and plant products. The Animal and Plant Health Inspection Service (APHIS) has the primary responsibility for implementing the provisions of the Act within USDA. Select agents and toxins that have been determined to pose a severe threat to both human and animal health or animal products are subject to regulation by both APHIS and the Centers for Disease Control and Prevention (CDC), HHS, which has the primary responsibility for implementing the provisions of the Act within HHS.

APHIS regulations are contained in 7 CFR part 331 (plant) and 9 CFR part 121 (animal and overlap). They require an individual or entity (unless specifically

exempted under the regulations) to register with APHIS or, for overlap agents or toxins, APHIS or CDC, in order to possess, use, or transfer biological agents or toxins.

The registration process is designed to obtain critical information concerning individuals or entities in possession of certain agents or toxins, as well as the specific characteristics of the agents or toxins, including name, strain, and genetic information. These data are needed, in part, to allow APHIS to determine the biosafety and biocontainment level of an entity as well as the entity's security situation. This, in turn, helps APHIS to ensure that appropriate safeguard, containment, and disposal requirements commensurate with the risk of the agent or toxin are present at the entity, thus preventing access to such agents and toxins for use in domestic or international terrorism. APHIS will also request information to determine that individuals seeking to register have a lawful purpose to possess, use, or transfer agents or toxins. Forms PPQ 526, VS 16–3, and VS 16–7 are approved under this collection for use in the registration process.

We are asking the Office of Management and Budget (OMB) to approve our use of the information collection activities 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 information collection, 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 information collection 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 1.9544673 hours per response.

Respondents: Researchers, universities, research and development organizations, diagnostic laboratories, and other interested parties who possess, use, or transfer select agents or toxins.

Estimated annual number of respondents: 1,163.

Estimated annual number of responses per respondent: 1.0008598.

Estimated annual number of responses: 1,164.

Estimated total annual burden on respondents: 2,275 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 18th day of May 2011.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2011–12753 Filed 5–23–11; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2011–0049]

Effectiveness Indications Statements in Veterinary Biologics Labeling; Notice of Public Meeting and Request for Comments

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are issuing this notice to inform producers and users of veterinary biological products, as well as other interested individuals, that we will be holding a public meeting to discuss a draft guideline (concept paper) concerning effectiveness indications statements in veterinary biologics labeling. We are also making the concept paper available for review and comment.

DATES: The public meeting will be held on Thursday, June 16, 2011, from 9 a.m. to 3 p.m. We will consider all comments that we receive on or before July 25, 2011.

ADDRESSES: The public meeting will be held at the National Centers for Animal Health, 1920 Dayton Avenue, Ames, IA. *You may submit comments on the concept paper by either of the following methods:*

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2011-0049* to submit or view comments and to view the concept paper.
- *Postal Mail/Commercial Delivery:* Please send one copy of your comment to Docket No. APHIS–2011–0049, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2011–0049.

Reading Room: You may view the concept paper and any comments we receive on the *Regulations.gov* Web site (see link above) or in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. 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) 690–2817 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Dee McVey, Center for Veterinary Biologics, VS, APHIS, 1920 Dayton Avenue, Ames, IA 50010; phone (515) 337–6100, fax (515) 337–6120, or e-mail: *dee.mcvey@aphis.usda.gov.*

SUPPLEMENTARY INFORMATION: The Animal and Plant Health Inspection Service (APHIS) administers and enforces the Virus-Serum-Toxin Act (the Act), as amended (21 U.S.C. 151–159). The regulations issued pursuant to the Act are intended to ensure that veterinary biological products are pure, safe, potent, and effective when used according to label instructions. The regulations in 9 CFR part 112 prescribe requirements for packaging and labeling veterinary biologics. The regulations in part 112 ensure that labeling provides adequate information concerning the expected effectiveness and safety of the product. Current APHIS guidelines (Veterinary Services Memorandum [VSM] No. 800.202—General Licensing Considerations: Efficacy Studies) provide examples of statements that may be used in labeling to describe the indications for use of a product, provided that the product has demonstrated a specified level of performance in an efficacy study that was the basis for issuance of the product license. VSM 800.202 specifies performance requirements and allowable indications statements for four different levels (tiers) of effectiveness.

In July 2009, representatives of veterinary biologics manufacturers and the American Veterinary Medical Association met with APHIS to discuss the Agency's current labeling guidance and to explore the possibility of developing a single indications