

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](mailto: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

statement that would convey clinically useful information to veterinary practitioners and other consumers of veterinary biologics. At that meeting, the American Veterinary Medical Association, which represents the single largest group of consumers of veterinary biologics, informed APHIS that its members consider labeling indications statements that are based on the guidance provided in VSM 800.202 to be confusing and expressed a desire for indications statements that provide insight into the actual performance of the product, including summaries of safety and efficacy data. On the other hand, representatives of the trade associations representing veterinary biologics manufacturers have remarked that their members expend significant resources on studies to provide data to support labeling that includes indications statements that emphasize the unique properties of their product versus that of a competitor. They expressed concern about any change to the labeling regulations that would deemphasize product differences or require public disclosure of proprietary information that could compromise manufacturers' competitive positions in the marketplace.

In response to the concerns expressed by these stakeholders, APHIS has developed a draft policy guideline (concept paper) concerning the wording of indications statements used in veterinary biologics labeling. The draft guideline differs from current guidance regarding label claims in VSM 800.202 in that a single indications statement (e.g., "This product has been shown to be effective for the vaccination of healthy animals X weeks of age or older against \* \* \*") would replace current indications statements that may reflect any of four different levels of effectiveness. In addition to a standardized indications statement, the draft guideline also provides for the public disclosure of a summary (with confidential business information removed) of the efficacy and safety data submitted to APHIS in support of the issuance of the product license. The draft guideline may be viewed on the *Regulations.gov* Web site (see **ADDRESSES** above) or obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**.

We are holding a public meeting to solicit input and discussion of any issues that are pertinent to this concept. This meeting is scheduled for Thursday, June 16, 2011. Registration information and copies of the agenda for the meeting may be obtained from the person listed under **FOR FURTHER INFORMATION CONTACT**. The public meeting will begin

at 9 a.m. and is scheduled to end at 3 p.m. but may end earlier if all persons wishing to comment have been heard. The meeting will be recorded, and information about obtaining a transcript will be provided at the meeting. If you require special accommodations, such as a sign language interpreter, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

You may also submit comments regarding the concept paper using one of the methods described under **ADDRESSES** above.

Done in Washington, DC, this 18th day of May 2011.

**Kevin Shea,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2011-12762 Filed 5-23-11; 8:45 am]

**BILLING CODE 3410-34-P**

## DEPARTMENT OF AGRICULTURE

### Forest Service

#### Central Montana Resource Advisory Committee

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice of meeting.

**SUMMARY:** The Central Montana Resource Advisory Committee will meet in Stanford, MT. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (Pub. L. 110-343) (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with the title II of the Act. The meeting is open to the public. This will be the second official meeting of the Central Montana Resource Advisory Committee.

**DATES:** The meeting will be held June 1, 2011, 7 p.m.

**ADDRESSES:** The meeting will be held at the Judith Ranger District, 109 Central Ave. Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**.

All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Judith Ranger District. Please call ahead to (406) 566-2292 to facilitate entry into the building to view comments.

**FOR FURTHER INFORMATION CONTACT:** Ron Wiseman, District Ranger, Lewis and Clark National Forest, (406) 566-2292, *rwiseman@fs.fed.us*.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday. Requests for reasonable accommodation for access to the facility or proceedings may be made by contacting the person listed **FOR FURTHER INFORMATION**.

**SUPPLEMENTARY INFORMATION:** The following business will be conducted: (1) Discussion and approval of RAC operating guidelines. (2) Discussion of project development and recommendation process. (3) Review and vote on projects. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by May 18 to be scheduled on the agenda. Written comments and requests for time for oral comments must be sent to 109 Central Ave., Stanford, MT 59479, or by e-mail to *rwiseman@fs.fed.us*, or via facsimile to (406) 566-2408.

Dated: May 9, 2011.

**Ron B. Wiseman,**

*District Ranger.*

[FR Doc. 2011-12569 Filed 5-23-11; 8:45 am]

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## DEPARTMENT OF AGRICULTURE

### Rural Utilities Service

#### Announcement of Grant and Loan Application Deadlines and Funding Levels

**AGENCY:** Rural Utilities Service, USDA.

**ACTION:** Notice of funding availability and solicitation of applications.

**SUMMARY:** The Rural Utilities Service (RUS) announces its Revolving Fund Program (RFP) application window for Fiscal Year (FY) 2011. In addition to announcing the application window, RUS announces the available funding of \$496,000 for RFP competitive grants for the fiscal year.

The RFP is authorized under section 306(a)(2)(B) of the Consolidated Farm and Rural Development Act (Con Act), 7 U.S.C. 1926(a)(2)(B). Under the RFP, qualified private, non-profit organizations receive RFP grant funds to establish a lending program for eligible entities. Eligible entities for the revolving loan fund will be the same entities eligible, under paragraph 1 or 2