

importation of beef from Uruguay, contact Dr. Lynette Williams-McDuffie, Staff Veterinarian, Technical Trade Services—Products, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale MD 20737; (301) 734–3277. 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:* Importation of Beef from Uruguay.

*OMB Number:* 0579–xxxx.

*Type of Request:* Approval of an information collection.

*Abstract:* Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture is authorized, among other things, to prohibit or restrict the importation and interstate movement of animals and animal products to prevent the introduction into and dissemination within the United States of livestock diseases and pests. To carry out this mission, APHIS regulates the importation of animals and animal products into the United States. The regulations are contained in title 9, parts 92 through 98, of the Code of Federal Regulations.

Part 94, § 94.22, allows the importation, subject to certain conditions, of beef from Uruguay. Among the conditions is a requirement for a certificate that must be completed by an authorized official of the Government of Uruguay with a statement that specific conditions have been met to protect the United States against the introduction of foot-and-mouth disease.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for 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 1.5004034 hours per response.

*Respondents:* Federal animal health officials of the Government of Uruguay.

*Estimated annual number of respondents:* 21.

*Estimated annual number of responses per respondent:* 59.

*Estimated annual number of responses:* 1,239.

*Estimated total annual burden on respondents:* 1,859 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 October 2010.

**Kevin Shea,**

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

[FR Doc. 2010–26749 Filed 10–21–10; 8:45 am]

**BILLING CODE 3410–34–P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS–2010–0098]

#### Draft Guidelines on Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice of availability and request for comments.

**SUMMARY:** The International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) has developed a draft guideline titled “Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data.” This draft guideline provides information concerning the development of a single electronic message to transmit adverse event reports concerning veterinary biologics between regulatory authorities in the European Union, Japan, and the United States and marketing authorization holders (veterinary biologics licensees and permittees) in

those regions. Because the draft guideline applies to pharmacovigilance and adverse event reporting on veterinary vaccines regulated by the Animal and Plant Health Inspection Service under the Virus-Serum-Toxin Act, we are requesting comments on the scope of the guideline and its provisions so that we may include any relevant public input on the draft in the Agency's comments to the VICH Steering Committee.

**DATES:** We will consider all comments that we receive on or before December 21, 2010.

**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-2010-0098> 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–2010–0098, 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–2010–0098.

*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:** Dr. Albert P. Morgan, Center for Veterinary Biologics—Policy Evaluation and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; (301) 734–8245.

**SUPPLEMENTARY INFORMATION:** The International Cooperation on Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) is a unique project conducted under the auspices of the World Organization for Animal Health that brings together the regulatory authorities of the European Union, Japan, and the United States and representatives from the animal health industry in the three regions. The purpose of VICH is to harmonize

technical requirements for veterinary products (both drugs and biologics). Regulatory authorities and industry experts from Australia and New Zealand participate in an observer capacity. The World Federation of the Animal Health Industry (COMISA, the Confederation Mondiale de L'Industrie de la Sante Animale) provides the secretarial and administrative support for VICH activities.

The United States Government is represented in VICH by the Food and Drug Administration (FDA) and the Animal and Plant Health Inspection Service (APHIS). The FDA provides expertise on veterinary drugs, while APHIS fills a corresponding role for veterinary biological products. As VICH members, APHIS and FDA participate in efforts to enhance harmonization and have expressed their commitment to seeking scientifically based, harmonized technical requirements for the development of veterinary drugs and biological products. One of the goals of harmonization is to identify and reduce the differences in technical requirements for veterinary drugs and biologics among regulatory agencies in different countries.

The draft guideline "Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data" (VICH Topic GL35) has been made available by the VICH Steering Committee for comments by interested parties. The guideline is intended to provide standards to construct a single electronic message to transmit the contents of adverse event reports concerning the use of veterinary medicinal products to all regions. Because the draft guideline applies to some veterinary biological products regulated by APHIS under the Virus-Serum-Toxin Act—particularly with regard to electronic messages to transmit adverse event reports—we are requesting comments on its provisions so that we may include any relevant public input on the draft in the Agency's comments to the VICH Steering Committee.

The draft guideline reflects current APHIS thinking on the use of electronic messages to transmit adverse event reports concerning the use of veterinary medicinal products between marketing authorization holders (licensees/ permittees) and regulatory authorities in the three regions. In accordance with the VICH process, once a final draft of each document has been approved, the guideline will be recommended for adoption by the regulatory bodies of the European Union, Japan, and the United States. As with all VICH documents,

each final guideline will not create or confer any rights for or on any person and will not operate to bind APHIS or the public. Further, the VICH guidelines specifically provide for the use of alternative approaches if those approaches satisfy applicable regulatory requirements.

Ultimately, APHIS intends to consider the VICH Steering Committee's final guideline for use by U.S. veterinary biologics licensees, permittees, and applicants. In addition, we may consider using the final guideline as the basis for proposed amendments to the regulations in 9 CFR chapter I, subchapter E (Viruses, Serums, Toxins, and Analogous Products; Organisms and Vectors). Because we anticipate that applicable provisions of the final versions of "Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data" may be introduced into APHIS' veterinary biologics regulatory program in the future, we encourage your comments on the draft guideline.

The draft guideline may be viewed on the Regulations.gov Web site or in our reading room (*see ADDRESSES* above for instructions for accessing Regulations.gov and information on the location and hours of the reading room). You may request paper copies of the draft guideline by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**.

**Authority:** 21 U.S.C. 151 *et seq.*

Done in Washington, DC, this 18th day of October 2010.

**Kevin Shea,**

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

[FR Doc. 2010-26748 Filed 10-21-10; 8:45 am]

**BILLING CODE 3410-34-P**

## DEPARTMENT OF AGRICULTURE

### Rural Utilities Service

#### **Southern Maryland Electric Cooperative: Notice of Finding of No Significant Impact**

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

**ACTION:** Notice of Finding of No Significant Impact.

**SUMMARY:** The Rural Utilities Service (RUS) has issued a Finding of No Significant Impact (FONSI) for the Environmental Assessment (EA) associated with the Holland Cliff to Hewitt Road 230 kV Transmission proposal in Calvert and St. Mary's Counties, Maryland. The EA was prepared pursuant to the National Environmental Policy Act of 1969

(NEPA) (U.S.C. 4231 *et seq.*) and in accordance with the Council on Environmental Quality's (CEQ's) regulations for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508) and RUS's NEPA implementing regulations (7 CFR part 1794, Environmental Policies and Procedures). The purpose of the EA was to evaluate the potential environmental impacts of and alternatives to a Southern Maryland Electric Cooperative (SMECO) application for a RUS loan for the proposal. The proposal includes construction of a 30-mile 230 kilovolt (kV) transmission line, a new 230/69 kV switching station, and a 230/69 kV switching station expansion.

**ADDRESSES:** To obtain copies of the FONSI or EA, or for further information, contact: Ms. Lauren McGee, Environmental Scientist, USDA, Rural Utilities Service, 1400 Independence Avenue, SW., Stop 1571, Room 2239-S, Washington, DC 20250-1571, telephone: (202) 720-1482, fax: (202) 690-0649, or e-mail: [lauren.mcgee@wdc.usda.gov](mailto:lauren.mcgee@wdc.usda.gov). A copy of the FONSI and EA can be viewed online at: <http://www.usda.gov/rus/water/ees/ea.htm>.

**SUPPLEMENTARY INFORMATION:** SMECO proposes to construct a 230 kV transmission line between the existing Holland Cliff Switching Station in Calvert County to the existing Hewitt Road Switching Station in St. Mary's County, Maryland. The proposal has five segments and includes: (1) The installation of approximately 20 miles of new 230 kV single pole, double-circuit transmission line from the Holland Cliff switching station to a new switching station located in Southern Calvert; (2) the installation of the new Sollers Wharf 230/69 kV switching station; (3) the installation of approximately 8 miles of new 230 kV single pole, double-circuit transmission line from the new Southern Calvert switching station to the existing Hewitt Road switching station; (4) the installation of approximately 2 miles of 230 kV underground transmission cable circuit across the lower Patuxent River; and (5) the expansion of the existing 230 kV ring bus at the Hewitt Road switching station to accommodate the new 230 kV transmission line from Southern Calvert. Throughout the right-of-way, the existing 69 kV poles would be removed, and new 230 kV poles would be installed. The existing 69 kV and new 230 kV lines would be installed on the new poles. This configuration would allow for the use of the existing 69 kV transmission line right-of-way and preclude the need for additional easement acquisition. The preferred site