

• *Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0070>.*

• *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2016-0070, 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-2016-0070> 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) 7997039 before coming.

**FOR FURTHER INFORMATION CONTACT:** Dr. Donna Malloy, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road, Unit 148, Riverdale, MD 20737-1231; phone (301) 851-3426, fax (301) 734-4314.

For information regarding the environmental assessment or the risk analysis, or to request a copy of the environmental assessment (as well as the risk analysis with confidential business information redacted), contact Dr. Patricia L. Foley, Risk Manager, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010; phone (515) 337-6100, fax (515) 337-6120.

**SUPPLEMENTARY INFORMATION:** Under the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) is authorized to promulgate regulations designed to ensure that veterinary biological products are pure, safe, potent, and efficacious before a veterinary biological product license may be issued. 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. Regulations concerning

veterinary biological products are contained in 9 CFR parts 101 to 124.

A field test is generally necessary to satisfy preclicensing requirements for veterinary biological products. Prior to conducting a field test on an unlicensed product, an applicant must obtain approval from APHIS, as well as obtain APHIS' authorization to ship the product for field testing.

To determine whether to authorize shipment and grant approval for the field testing of the unlicensed product referenced in this notice, APHIS considers the potential effects of this product on the safety of animals, public health, and the environment. Based upon a risk analysis and other relevant data, APHIS has prepared an environmental assessment (EA) concerning the field testing of the following unlicensed veterinary biological product:

*Requester:* Biomune Company.

*Product:* Bursal Disease-Marek's Disease-Newcastle Disease Vaccine, Serotype 3, Live Marek's Disease Vector.

*Possible Field Test Locations:* Alabama, Delaware, Georgia, Maryland, North Carolina, Pennsylvania, and Virginia.

The above-mentioned product is a live Marek's Disease serotype 3 vaccine virus containing a gene from the Newcastle disease virus and a gene from the infectious bursal disease virus. This vaccine would be the recombinant fraction used in combination with a conventional live Marek's disease vaccine virus, either a serotype 1 or serotype 2 strain, during the field safety tests. The attenuated vaccine is intended for use in healthy 18-day-old or older embryonated eggs or day-old chickens, as an aid in the prevention of infectious bursal disease, Marek's disease, and Newcastle disease.

The EA has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

We are publishing this notice to inform the public that we will accept written comments regarding the EA from interested or affected persons for a period of 30 days from the date of this notice. Unless substantial issues with adverse environmental impacts are raised in response to this notice, APHIS intends to issue a finding of no significant impact (FONSI) based on the

EA and authorize shipment of the above product and the two products with a conventional live Marek's disease vaccine virus, either a serotype 1 or serotype 2 strain, that incorporate it as a recombinant fraction, for the initiation of field tests following the close of the comment period for this notice.

Because the issues raised by field testing and by issuance of a license are identical, APHIS has concluded that the EA that is generated for field testing would also be applicable to the proposed licensing action. Provided that the field test data support the conclusions of the original EA and the issuance of a FONSI, APHIS does not intend to issue a separate EA and FONSI to support the issuance of the associated product licenses, and would determine that an environmental impact statement need not be prepared. APHIS intends to issue a veterinary biological product license for this vaccine and the two associated products containing it following satisfactory completion of the field test, provided no adverse impacts on the human environment are identified and provided the product meets all other requirements for licensing.

**Authority:** 21 U.S.C. 151-159.

Done in Washington, DC, this 11th day of January 2017.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2017-01010 Filed 1-17-17; 8:45 am]

**BILLING CODE 3410-34-P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS-2016-0079]

#### Updates to the Biotechnology Regulatory Services BQMS Program

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

**ACTION:** Notice.

**SUMMARY:** We are advising the public that Biotechnology Regulatory Services of the Animal and Plant Health Inspection Service (APHIS) is updating its Biotechnology Quality Management System Program and renaming it the Biotechnology Quality Management Support Program to offer a more flexible, more customizable, and less costly program that is easily accessible to a wider universe of researchers and developers conducting biotechnology activities under APHIS' regulations. These updates represent the next step in

the continual improvement to this voluntary quality management program. **FOR FURTHER INFORMATION CONTACT:** Ms. Rochelle Langley, Quality Management Specialist, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 146, Riverdale, MD 20737-1228; 301-851-3906, *Rochelle.A.Langley@aphis.usda.gov*.

**SUPPLEMENTARY INFORMATION:** The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), regulates the importation, interstate movement, and environmental release of genetically engineered (GE) organisms that are, or may be, plant pests. In September 2007, APHIS' Biotechnology Regulatory Services (BRS) announced a voluntary, audit-based compliance assistance program known as the Biotechnology Quality Management System (BQMS) Program to assist the regulated community in achieving and maintaining compliance with requirements for field trials and movements of GE organisms under its regulations in 7 CFR part 340.

Under the BQMS Program, APHIS-BRS has provided support for the voluntary adoption by participants of a quality management system to improve their management of domestic research and development of regulated GE organisms in order to fully comply with regulations. The BQMS Program included a mandatory audit standard that provided extensive criteria for the development, implementation, and an objective evaluation of the participant's quality management system.

We are notifying the public that BRS is updating its BQMS Program and renaming it the Biotechnology Quality Management Support Program, which will use the same BQMS acronym, in order to reach a broader audience. After engaging with current and prospective BQMS participants, APHIS-BRS determined a modularized, more flexible, Web-based approach reaches a wider universe of researchers and developers conducting biotechnology activities. Small organizations, academics, and first-time users now have access to a program that previously was only within the means of a select few with considerable resources. The new BQMS Program is no longer audit-based, and no longer requires an "all or nothing" quality management system that relies on a BRS-developed audit standard, a required 3-day BRS-led training session for all participants, and a third-party audit cycle to maintain Program recognition. The new BQMS Program remains a voluntary compliance assistance program but with fewer impediments to users—no

required multi-day training, no cost-prohibitive third-party audits and associated travel expenses, and no exhaustive resource commitments.

The new BQMS Program is a flexible, Web-based, modular approach designed to enhance compliance by enabling organizations large and small to develop sound quality management practices. Users can select any or all critical control points applicable to their organizations' compliance assistance needs such as: Site selection planning, procedures for storage, transportation (interstate movement and importation), environmental release planning and monitoring, post-harvest handling and transfer, devitalization and final disposition, potential regulatory compliance incidents, and a reporting form for regulatory compliance incidents. User costs should decrease with the ability to easily choose only the modules they need to meet their unique compliance assistance needs.

The new BQMS Program offers a comprehensive repository of user-friendly, Web-based templates, guidelines, and checklists to assist users in the implementation of processes, procedures, and the foundation for a quality management system. No matter how big or small their organization, BQMS users will continue to have the option of requesting one-on-one tailored assistance from BRS staff, as in the past.

Organizations participating in the voluntary program will be encouraged to use BQMS resources as a foundation to ensure all personnel are properly trained regarding the requirements for working with GE organisms; identify and develop control measures to minimize the risk or occurrence of unauthorized releases; and monitor quality management practices and procedures.

These updates are the next step in the continual improvement of the voluntary BQMS Program.

Done in Washington, DC, this 11th day of January 2017.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2017-01017 Filed 1-17-17; 8:45 am]

**BILLING CODE 3410-34-P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS-2016-0113]

#### Notice of Request for Extension of Approval of an Information Collection; Interstate Movement of Fruit From Hawaii

**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 an extension of approval of an information collection associated with the regulations for the interstate movement of fruit from Hawaii.

**DATES:** We will consider all comments that we receive on or before March 20, 2017.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov#!docketDetail;D=APHIS-2016-0113>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2016-0113, 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-2016-0113> 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 the regulations for the interstate movement of fruit from Hawaii, contact Dr. Robert Baca, Assistant Director, Permitting and Compliance Coordination, Compliance and Environmental Coordination Branch, PPQ, APHIS, 4700 River Road, Unit 150, Riverdale, MD 20737; (301) 851-2292. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2483.

**SUPPLEMENTARY INFORMATION:**