

the presence of Mycoplasma contamination. Because the guidelines apply to final product and master seed/cell testing in 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 June 12, 2012.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#documentDetail;D=APHIS-2012-0022-0001>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2012-0022, 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-2012-0022> 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: Dr. Donna L. Malloy, Section Leader, Operational Support, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale Maryland 20737-1231; (301) 851-3426.

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 "Testing for the Detection of Mycoplasma Contamination" (VICH Topic GL34) has been made available by the VICH Steering Committee for comments by interested parties. Mycoplasma contaminants may be introduced into cell culture and *in ovo* origin biological products through the master seeds, the master cell seed (stock), starting materials of animal origin, and in processing of biological materials during passage and product assembly. Therefore, it is necessary to demonstrate through testing that Mycoplasmas are not present, within the limits of the test, in the final product, working seeds and cells and harvests, and starting materials such as the master seed, master cell seed, and ingredients of animal origin. The draft guideline establishes stages of manufacture to be tested and test procedures to detect the presence of Mycoplasma contamination and would provide a unified standard to facilitate the mutual acceptance of test data by the relevant regulatory authorities. Because the draft guideline would apply to final product and master seed/cell testing in veterinary vaccines regulated by the APHIS under the Virus-Serum-Toxin Act (VSTA), 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.

In accordance with the VICH process, once a final draft of the 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 version of "Testing for the Detection of Mycoplasma Contamination" 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 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 9th day of April 2012.

Kevin Shea,
Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2012-8908 Filed 4-12-12; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2012-0017]

Availability of an Environmental Assessment for Field Testing Feline Interleukin-2 Immunomodulator, Live Canarypox Vector

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared an environmental assessment concerning authorization to ship for the purpose of field testing, and then to field test, an unlicensed Feline Interleukin-2

Immunomodulator, Live Canarypox Vector. The environmental assessment, which is based on a risk analysis prepared to assess the risks associated with the field testing of this vaccine, examines the potential effects that field testing this veterinary vaccine could have on the quality of the human environment. Based on the risk analysis, we have reached a preliminary determination that field testing this veterinary vaccine will not have a significant impact on the quality of the human environment, and that an environmental impact statement need not be prepared. We intend to authorize shipment of this vaccine for field testing following the close of the comment period for this notice unless new substantial issues bearing on the effects of this action are brought to our attention. We also intend to issue a U.S. Veterinary Biological Product license for this vaccine, provided the field test data support the conclusions of the environmental assessment and the issuance of a finding of no significant impact and the product meets all other requirements for licensing.

DATES: We will consider all comments that we receive on or before May 14, 2012.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0017-0001>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2012-0017, 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-2012-0017> 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: 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 removed), 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.*), a veterinary biological product must be shown to be pure, safe, potent, and efficacious before a veterinary biological product license may be issued. 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 the Animal and Plant Health Inspection Service (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 conducted a risk analysis to assess the potential effects of this product on the safety of animals, public health, and the environment. Based on the risk analysis, APHIS has prepared an environmental assessment (EA) concerning the field testing of the following unlicensed veterinary biological product:

Requester: Merial, Inc.

Product: Feline Interleukin-2 Immunomodulator, Live Canarypox Vector.

Field Test Locations: Georgia, North Carolina, New York, Tennessee, Florida, and Arizona.

The product consists of a live recombinant canarypox virus vector expressing the feline interleukin-2 cytokine. The vaccine is for subcutaneous vaccination of adult cats diagnosed with Stage I fibrosarcoma as an aid in delaying post-surgical recurrence following excision of the tumor.

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).

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 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 product license, and would determine that an environmental impact statement need not be prepared. APHIS intends to issue a veterinary biological product license for this vaccine following 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 9th day of April 2012.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2012-8912 Filed 4-12-12; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2012-0013]

Notice of Establishment of a Veterinary Services Stakeholder Registry

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: This notice announces the availability of a new Veterinary Services email subscription service.

FOR FURTHER INFORMATION CONTACT: Mrs. R.J. Cabrera, Writing, Editing, and Regulatory Coordination, VS, APHIS, 4700 River Road Unit 35, Riverdale, MD 20737-1231; (301) 851-3478.

SUPPLEMENTARY INFORMATION: The Animal and Plant Health Inspection Service (APHIS) has established a Veterinary Services (VS) Stakeholder Registry, an email subscription service for individuals and organizations interested in receiving updates regarding APHIS and VS issues. Subscribers will be able to choose from an array of topics such as VS spotlights