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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2012-0022]

Draft Guidelines on Biologics Quality Monitoring: Testing for the Detection of Mycoplasma Contamination

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 "Testing for the Detection of Mycoplasma Contamination." This draft guideline identifies stages of manufacture where products are to be tested and test procedures used to detect 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 [Insert date 60 days after date of publication in the Federal Register].

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 9<sup>th</sup> day of April 2012.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

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