

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>, select "Animal and Plant Health Inspection Service" from the agency drop-down menu, then click "Submit." In the Docket ID column, select APHIS-2007-0057 to submit or view public comments and to view supporting and related materials available electronically. Information on using Regulations.gov, including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's "User Tips" link.

- *Postal Mail/Commercial Delivery:* Please send four copies of your comment (an original and three copies) to Docket No. APHIS-2007-0057, 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-2007-0057.

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: For information on an information collection associated with the importation of animals and poultry, animal and poultry products, and animal germplasm, contact Dr. James Davis, Senior Staff Veterinarian, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737-1231; (301) 734-0694. For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

SUPPLEMENTARY INFORMATION: *Title:* Importation of Animals and Poultry, Animal and Poultry Products, Certain Animal Embryos, Semen, and Zoological Animals.

OMB Number: 0579-0040.

Type of Request: Extension of approval of an information collection.

Abstract: 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 of animals, animal products, and other articles into the United States to prevent the introduction of animal diseases and pests. In connection with this mission, APHIS collects pertinent information from persons who import animals or poultry, animal or poultry products, or animal germplasm into the United States.

This information includes data such as the origins of the animals or animal products to be imported, the health status of the animals or the processing methods used to produce animal products to be imported, and whether the animals or animal products were temporarily offloaded in another country during their transit to the United States. We need this information to help ensure that these imports do not introduce exotic animal diseases into the United States.

We use a variety of information collection procedures, devices, and forms including, but not limited to: Health certificates, import permits, ear tags, leg bands, specimen submission forms, inspection reports, cooperative and trust fund agreements, and certification statements.

We are asking the Office of Management and Budget (OMB) to approve our use of these 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 0.41688779 hours per response.

Respondents: Entities that import animals or poultry, animal or poultry products, and animal embryos, germplasm, and semen.

Estimated annual number of respondents: 77,976.

Estimated annual number of responses per respondent: 162.4330306.

Estimated annual number of responses: 12,665,878.

Estimated total annual burden on respondents: 528,025 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 11th day of May 2007.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E7-9551 Filed 5-17-07; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2007-0056]

Draft Guidelines on Pharmacovigilance of Veterinary Medicinal Products: Controlled Lists of Terms

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: Controlled Lists of Terms." This draft guideline provides guidance for the development and maintenance of the controlled lists of terms required to complete the controlled data fields contained in adverse event reports concerning the use of veterinary medicinal products. 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 July 17, 2007.

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

Federal eRulemaking Portal: Go to <http://www.regulations.gov>, select "Animal and Plant Health Inspection Service" from the agency drop-down menu, then click "Submit." In the Docket ID column, select APHIS-2007-0056 to submit or view public comments and to view supporting and related materials available electronically. After the close of the comment period, the docket can be viewed using the "Advanced Search" function in Regulations.gov.

Postal Mail/Commercial Delivery: Please send four copies of your comment (an original and three copies) to Docket No. APHIS-2007-0056, 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-2007-0056.

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: Controlled Lists of Terms" (VICH Topic GL30) has been made available by the VICH Steering Committee for comments by interested parties. The guideline is intended to provide guidance for the development and maintenance of the controlled lists of terms required to complete the controlled data fields contained in adverse event reports concerning the use of marketed veterinary medicinal products. Because the draft guideline applies to some veterinary biological products regulated by APHIS under the Virus-Serum-Toxin Act—particularly with regard to development and maintenance of the controlled lists of terms—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 development and maintenance of the controlled lists of terms required to complete the controlled data fields used for the submission and exchange of spontaneous adverse events reports between marketing authorization holders (licensees/permittees) and regulatory authorities concerning the clinical effects of marketed veterinary medicinal products. 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: Controlled Lists of Terms" 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 11th day of May 2007.

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

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DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

Crop Insurance Education in Targeted States (Targeted States Program)

Announcement Type: Modification—Competitive Cooperative Agreements.

This announcement modifies the Request for Application Notice published in the **Federal Register**, March 14, 2007 (Vol. 72, No. 49, Pages 11839-11846). The Dates and Summary portions have been modified.

CFDA Number: 10.458.

DATES: Applications are due 5 p.m. EDT, June 4, 2007.

SUMMARY: The following paragraph has been added to the beginning of the