

Notices

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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Notice of Government Owned Invention Available for Licensing

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of government owned invention available for licensing.

SUMMARY: The invention listed below is owned by the U.S. Government as represented by the Department of Agriculture and is available for licensing. U.S. Patent Application Serial No. 09/637,031 entitled "Magnetostrictive Precipitation Gage" is available for licensing in accordance with 35 U.S.C. 207 and 37 CFR 404 to achieve expeditious commercialization of results of Federally funded research and development. Foreign patents are filed on selected inventions to extend market coverage for U.S. companies and may also be available for licensing.

DATES: (Federal Register) Comments must be received on or before January 30, 2001.

FOR FURTHER INFORMATION CONTACT: Technical and licensing information on this invention may be obtained by writing to: Janet I. Stockhausen of the USDA Forest Service, One Gifford Pinchot Drive, Madison, Wisconsin 53705-2398; telephone 608-231-9502; fax: 608-231-9508; or e-mail jstockh@facstaff.wisc.edu. Issued patents may be obtained from the Commissioner of Patents, U.S. Patent and Trademark Office, Washington, DC 20231.

June Blalock,

Technology Licensing Coordinator.

[FR Doc. 00-30660 Filed 11-30-00; 8:45 am]

BILLING CODE 3410-03-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 00-114-1]

General Conference Committee of the National Poultry Improvement Plan; Meeting

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of meeting.

SUMMARY: We are giving notice of a meeting of the General Conference Committee of the National Poultry Improvement Plan.

DATES: The General Conference Committee will meet on December 12, 2000, from 9:00 a.m. to 4 p.m. and on December 13, 2000, from 8:00 a.m. to noon.

ADDRESSES: On December 12, 2000, the meeting will be held at the USDA South Building, 14th Street and Independence Avenue SW., Room 3501, Washington, DC; and on December 13, 2000, at the USDA Center at Riverside, 4700 River Road, Room 2D02CN, Riverdale, MD.

FOR FURTHER INFORMATION CONTACT: Mr. Andrew R. Rhorer, Senior Coordinator, National Poultry Improvement Plan, VS, APHIS, 1498 Klondike Road, Suite 200, Conyers, GA 30094-1231; (770) 922-3496.

SUPPLEMENTARY INFORMATION: The General Conference Committee (the Committee) of the National Poultry Improvement Plan, representing cooperating State agencies and poultry industry members, serves an essential function by acting as liaison between the poultry industry and the Department in matters pertaining to poultry health.

Topics for discussion at the upcoming meeting include:

1. U.S. Salmonella Clean program for meat-type chicken breeding flocks.
2. *Mycoplasma gallisepticum* epidemiology update.
3. Proposed changes to the provisions of the National Poultry Improvement Plan.
4. *Salmonella enteritidis* in egg-type chicken breeding flocks.

The meeting will be open to the public. However, due to time constraints, the public will not be allowed to participate in the discussions during the meeting. Written statements

on meeting topics may be filed with the Committee before or after the meeting by sending them to the person listed under **FOR FURTHER INFORMATION**

CONTACT. Written statements may also be filed at the meeting. Please refer to Docket No. 00-114-1 when submitting your statements.

This notice of meeting is given pursuant to section 10 of the Federal Advisory Committee Act.

Done in Washington, DC, this 21st day of November 2000.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00-30598 Filed 11-30-00; 8:45 am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 00-116-1]

Draft Guideline on Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports, VICH Topic GL24

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: A draft guideline titled "Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports" has been developed by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). The draft guideline deals with the spontaneous reporting system for identification of possible adverse events following the use of marketed veterinary medicinal products. Because the draft guideline applies, in part, to veterinary biological products regulated by the Animal and Plant Health Inspection Service under the Virus-Serum-Toxin Act, 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.

DATES: We invite you to comment on the draft guidelines. We will consider all comments that we receive by January 30, 2001.

ADDRESSES: Please send four copies of your comment (an original and three copies) to: Docket No. 00-116-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Please state that your comment refers to Docket No. 00-116-1.

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.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS rules, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

You may request a copy of the draft guideline "Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports" by writing to or calling the person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Center for Veterinary Biologics-Licensing and Policy Development, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737-1231; phone (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 International Office of Epizootics (OIE, the Office International des Epizooties) 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 regarding 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 document that is the subject of this notice, "Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports" (VICH Topic GL24), has been made available by the VICH Steering Committee for comments by interested parties. The draft guideline, which defines pharmacovigilance of veterinary medicinal products as the detection and investigation of the effects of veterinary medicinal products, mainly aimed at safety and efficacy in animals and safety in people exposed to these products, deals with the spontaneous reporting system for identification of possible adverse events following 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 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 document reflects current APHIS thinking on the generation and submission of adverse event reports concerning veterinary biological products. (The draft guideline refers to such products as "veterinary medicinal products.") In accordance with the VICH process, once a final draft of "Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports" 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, the 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 guidance document for use by U.S. veterinary biologics licensees, permittees, and applicants. In addition, APHIS will consider its use as a basis for the investigation of adverse event reports that raise questions regarding the purity, safety, potency, or efficacy of veterinary biological products under 9 CFR 116.5. APHIS may also use the final guidance document as the basis for proposed additions or amendments to its 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 "Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports" may be introduced into APHIS' veterinary biologics regulatory program in the future, we encourage your comments on the draft version.

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

Done in Washington, DC, this 22nd day of November 2000.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00-30599 Filed 11-30-00; 8:45 am]

BILLING CODE 3410-34-U

DEPARTMENT OF AGRICULTURE

Forest Service

Helena National Forest Travel Plan, Helena National Forest, Broadwater, Lewis and Clark, Meagher and Powell Counties, Montana

AGENCY: Forest Service, USDA.

ACTION: Notice; intent to prepare Environmental Impact Statement.

SUMMARY: The Forest Service will prepare an Environmental Impact Statement on a proposal to update travel management and approximately 390,000 acres of National Forest lands on the Townsend, Helena and Lincoln Ranger Districts. These 390,000 acres are the remaining lands that have not been subject to recent motorized travel management decisions or have decisions pending. The project covers three separate areas in the Blackfoot, Divide/Little Blackfoot and the South Belts areas. Motorized travel activities in these areas are presently subject to the June 30, 1994 Helena National Forest Travel Plan.

DATES: Comments concerning the proposal and scope of the analysis