

Notices

Federal Register

Vol. 66, No. 45

Wednesday, March 7, 2001

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

Animal and Plant Health Inspection Service

[Docket No. 01-011-1]

Public Meeting; Veterinary Biologics

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of public meeting on biologics for cancer diagnosis, prevention, and immunotherapy.

SUMMARY: We are issuing this notice to inform interested individuals, including producers and users of human and veterinary biological products, that we will be holding a public meeting to discuss regulatory and policy issues related to the manufacture, distribution, and use of biological products for the diagnosis, prevention, and treatment of cancer in humans and animals. The meeting is being organized by the Food and Drug Administration, Center for Biologics Evaluation and Research, and the Animal and Plant Health Inspection Service, Veterinary Services, Center for Veterinary Biologics. The Institute for International Cooperation in Animal Biologics is sponsoring the meeting.

DATES: The public meeting will be held on Thursday and Friday, April 12 and 13, 2001, from 8 a.m. to approximately 5 p.m.

ADDRESSES: The public meeting will be held in the Scheman Building at the Iowa State Center, Iowa State University, Ames, IA.

FOR FURTHER INFORMATION CONTACT: For further information about the meeting, contact Dr. Dave M. Dusek, Center for Veterinary Biologics, Veterinary Services, APHIS, 510 South 17th Street, Suite 104, Ames, IA 50010-8197; phone (515) 232-5785, fax (515) 232-7120, or e-mail Dave.M.Dusek@usda.gov. For registration information, contact Ms. Dawne Buhrow at the Institute for International Cooperation in Animal

Biologics, room 2160, College of Veterinary Medicine, Iowa State University, Ames, IA 50011; phone (515) 294-7632, fax (515) 294-8259, or e-mail iicab@iastate.edu. Information is also available online at <http://www.vetmed.iastate.edu/iicab/cancerbiologics.htm>.

SUPPLEMENTARY INFORMATION: The Animal and Plant Health Inspection Service (APHIS) specifies licensing requirements for veterinary biological products for the treatment of animals in title 9 of the Code of Federal Regulations, parts 101 to 118. Veterinary biological products include, but are not limited to, viruses, serums, toxins (except antibiotics), immunostimulants, cytokines, diagnostic components, and analogous products that are intended for use in the treatment of animals and that act primarily through the direct stimulation, supplementation, enhancement, or modulation of the immune system or immune response. To date, most cancer biologics licensed by APHIS have been conventional in design. However, APHIS anticipates receiving applications for licenses to produce veterinary biological products intended for use in the diagnosis, prevention, or treatment of cancer that are based on advances in biotechnology. The Food and Drug Administration (FDA) regulates the production of biologics for use in humans under its regulations in title 21 of the Code of Federal Regulations. Within the FDA, the Center for Biologics Evaluation and Research has received applications for licensure of biologics for the diagnosis, prevention, or treatment of cancer.

To provide a forum for the discussion of regulatory and policy issues related to the manufacture, distribution, and use of biological products intended for use in the diagnosis, prevention, or treatment of cancer, APHIS and FDA are organizing a public meeting. This public meeting, which is sponsored by the Institute for International Cooperation in Animal Biologics, is scheduled for April 12-13, 2001, will provide an opportunity for the exchange of information and discussion of issues of common concern among APHIS and FDA representatives; producers and users of biological products intended for use in the diagnosis, prevention, or treatment of cancer; and other interested persons. The public meeting will begin

at 8 a.m. and is scheduled to end at 5 p.m. each day.

Information regarding the meeting and registration instructions may be obtained from the persons listed under **FOR FURTHER INFORMATION CONTACT**.

Done in Washington, DC, this 1st day of March 2001.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 01-5591 Filed 3-6-01; 8:45 am]

BILLING CODE 3410-34-U

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 97-093-6]

Commercially Produced Official Identification Eartags and Backtags for Sheep and Goats

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are giving notice that the Animal and Plant Health Inspection Service has established a contact office for companies that wish to produce official identification eartags and backtags for sheep and goats. This office will advise companies on production standards necessary for eartags and backtags to qualify as the official identification that is required for certain sheep and goats under our regulations.

FOR FURTHER INFORMATION CONTACT: Dr. Diane Sutton, National Scrapie Program Coordinator, National Animal Health Programs Staff, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1231; (301) 734-6954.

SUPPLEMENTARY INFORMATION: Scrapie is a degenerative and eventually fatal disease affecting the central nervous systems of sheep and goats. To control the spread of scrapie within the United States, the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), administers regulations at 9 CFR part 79, which restrict the interstate movement of certain sheep and goats. APHIS also has regulations at 9 CFR part 54, which describe a voluntary scrapie control program.

These regulations require that, in some circumstances, certain sheep and

goats must be either individually identified, or identified with their premises of origin. Eartags and backtags are two of the most common devices for accomplishing the required identification. As APHIS continues to revise and expand its scrapie programs, we anticipate that the demand for eartags and backtags for official identification will increase over the next few years. Federal and State agencies, accredited veterinarians, and sheep and goat flock owners will be looking for commercial sources to supply the needed eartags and backtags.

To assist interested companies that wish to produce eartags and backtags for sheep and goats, APHIS has identified the office of the National Scrapie Program Coordinator as the contact point for companies to obtain advice on the production standards eartags and backtags must meet to qualify as official identification in accordance with our regulations. Further details on production standards for eartags and backtags may be obtained from the office identified in the **FOR FURTHER INFORMATION CONTACT** section above. This office will also review sample tags for suitability and approve companies to produce official identification eartags and backtags.

In general, tags may be plastic or metal and must be an appropriate size for use in sheep and goats. Tags must be able to legibly accommodate any required alphanumeric sequences to identify individual animals or their premises. Tags must resist removal and must be difficult to place on another animal once removed, but need not be tamper-proof. Tags must be readily distinguishable as USDA official sheep and goat tags, must carry the alphanumeric sequences, symbols, or logos specified by APHIS, and must have a means of discouraging counterfeiting, such as use of a unique copyrighted logo or trade mark.

Done in Washington, DC, this 1st day of March 2001.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 01-5589 Filed 3-6-01 8:45am]

BILLING CODE 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. 01-009-1]

Control of Rabies in Wildlife; Request for Public Involvement

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The Animal and Plant Health Inspection Service's Wildlife Services program is soliciting public involvement in the planning of a proposed cooperative program to stop the spread of rabies in the States of New York, Ohio, Texas, Vermont, and West Virginia. A small portion of northeastern New Hampshire and the western counties in Pennsylvania that border Ohio could also be included in these control efforts. In addition, Wildlife Services may cooperate in smaller scale oral rabies vaccine projects in the States of Florida, Massachusetts, Maryland, New Jersey, Virginia, and Alabama. The information received in response to this notice will be considered during the planning of the proposed program and development of an environmental assessment that will be prepared in accordance with the National Environmental Policy Act.

DATES: We invite you to comment on this notice. We will consider all comments that we receive by April 6, 2001.

ADDRESSES: Please send four copies of your comment (an original and three copies) to: Docket No. 01-009-1, 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. 01-009-1.

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 dockets, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webpor.html>.

FOR FURTHER INFORMATION CONTACT: Mr. Dennis Slate, Rabies Program Coordinator, Wildlife Services, APHIS, 59 Chennell Drive, Suite 7, Concord, NH 03301-8548; phone (603) 223-6832.

SUPPLEMENTARY INFORMATION: Rabies is an acute, fatal viral disease of mammals most often transmitted through the bite of a rabid animal. The disease can be effectively prevented in humans and domestic animals, but abundant and widely distributed reservoirs among wild mammals complicate rabies control. The vast majority of rabies cases reported to the Centers for Disease Control and Prevention (CDC) each year occur in raccoons, skunks, bats, foxes, and other wild animals. Domestic animals account for less than 10 percent of the reported rabies cases, with cats, dogs, and cattle among those most often reported.

Public health importance of rabies. Over the last 100 years, the rabies situation in the United States has changed dramatically. About 90 percent or greater of all animal cases reported annually to CDC now occur in wildlife, whereas before 1960 the majority of cases were reported in domestic animals. The principal rabies hosts today are wild carnivores and bats. The number of rabies-related human deaths in the United States has declined from more than 100 annually at the beginning of the 20th century to an average of one or two people per year in the 1990's. Modern prophylaxis, which consists of a series of vaccine injections given to people who have been exposed, has proven nearly 100 percent successful in preventing mortality when administered promptly after exposure. In the United States, human fatalities associated with rabies occur in people who fail to seek timely medical assistance, usually because they were unaware of their exposure.

Although human rabies deaths are rare, the estimated public health costs associated with disease detection, prevention, and control have risen, exceeding \$300 million annually. These costs include the vaccination of companion animals, animal control programs, maintenance of rabies laboratories, and medical costs, such as those incurred for exposure case investigations and rabies post-exposure prophylaxis (PEP).

Accurate estimates of these expenditures are not available. Although the number of PEP's given in the United States each year is unknown, it is estimated to be about 40,000. When rabies becomes epizootic (epidemics in animals) or enzootic (i.e., present in an area over time but at low case