Notices

Federal Register
Vol. 65, No. 112
Friday, June 9, 2000

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. 00–046–1]

Availability of a Draft Environmental Assessment for Field Testing Rinderpest Vaccine, Vaccinia 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 a draft environmental assessment concerning authorization to ship to Kenya for the purpose of field testing, and then to field test in Kenya, an unlicensed, genetically engineered, vaccinia-vectored rinderpest vaccine for use in cattle. 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. 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.

DATES: We invite you to comment on this docket. We will consider all comments that we receive by July 10, 2000.

ADDRESSES: Please send your comments and three copies to: Docket No. 00–046–1, 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. 00–046–1.

Copies of the draft environmental assessment may be obtained by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the docket number, date, and complete title of this notice when requesting copies. A copy of the draft environmental assessment (as well as the risk analysis with confidential business information removed) and any comments that we receive on this docket are available for public inspection 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/webrepor.html.

FOR FURTHER INFORMATION CONTACT: Dr. Albert P. Morgan, Chief Staff Officer, Center for Veterinary Biologics, Licensing and Policy Development, VS, APHIS, USDA, 4700 River Road Unit 148, Riverdale, MD 20737–1231; (301) 734–8245.

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 have a reasonable expectation of efficacy before a field trial may be authorized. The purpose of a field trial is to gather additional information concerning the safety and efficacy of a vaccine when used under field conditions that are similar to those in the area(s) where the vaccine will be distributed and used. Prior to conducting a field test on an experimental vaccine, 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 vaccine 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 a draft environmental assessment (EA) concerning the field testing of the following unlicensed veterinary biological product:

Requester: Dr. Tilahun Yilma, Director, International Laboratory of Molecular Biology for Tropical Disease Agents, School of Veterinary Medicine, University of California, Davis.

Product: A live, genetically engineered, vaccinia-vectored rinderpest vaccine.

Field test location: Kikuyu, Kenya.

The above-mentioned vaccine is for use as an aid in the prevention of rinderpest in cattle. The vaccine was constructed with the Wyeth vaccine strain of the vaccinia virus and further attenuated by insertional inactivation of the thymidine kinase and hemagglutinin genes of the vaccinia virus.

The draft 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 environmental issues are raised in response to this notice, APHIS intends to issue a final EA and finding of no significant impact and authorize shipment of the above product for the initiation of field tests following the close of the comment period for this notice.

Authority: 21 U.S.C. 151–159.

Done in Washington, DC, this 5th day of June 2000.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00–14615 Filed 6–8–00; 8:45 am]

BILLING CODE 3410–34–P