Notices

Federal Register
Vol. 73, No. 182
Thursday, September 18, 2008

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. APHIS–2008–0099]

Availability of an Environmental Assessment for Field Testing Rabies Vaccine, Live Raccoon Poxvirus 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 an environmental assessment concerning authorization to ship for the purpose of field testing, and then to field test, an unlicensed Rabies Vaccine, Live Raccoon Poxvirus Vector. 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, and that an environmental impact statement need not be prepared. 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. We also intend to issue a U.S. Veterinary Biological Product license for this vaccine, provided the field test data support the conclusions of the environmental assessment and the issuance of a finding of no significant impact and the product meets all other requirements for licensing.

DATES: We will consider all comments that we receive on or before October 20, 2008.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2008-0099* to submit or view comments and to view supporting and related materials available electronically.
- *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS–2008–0099, 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–2008–0099.

Reading Room: You may read any comments that we receive on the environmental assessment 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, Section Leader, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; phone (301) 734–8245, fax (301) 734–4314.

For information regarding the environmental assessment or the risk analysis, or to request a copy of the environmental assessment (as well as the risk analysis with confidential business information removed), contact Dr. Patricia L. Foley, Risk Manager, Center for Veterinary Biologics, Policy, Evaluation, and Licensing VS, APHIS, 510 South 17th Street, Suite 104, Ames, IA 50010; phone (515) 232–5785, fax (515) 232–7120.

SUPPLEMENTARY INFORMATION:

Background

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 efficacious before a veterinary biological product license may be issued. A field test is generally necessary to satisfy prelicensing requirements for veterinary biological products. Prior to conducting a field test on an unlicensed product, 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 product 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 an environmental assessment (EA) concerning the field testing of the following unlicensed veterinary biological product:

Requester: Fort Dodge Animal Health, Division of Wyeth Corporation.

Product: Rabies Vaccine, Live Raccoon Poxvirus Vector.

Field Test Locations: Iowa, Indiana, Texas, North Carolina, Oklahoma, Wisconsin, New York, Illinois, Minnesota, and Kansas.

The above-mentioned product consists of a live recombinant raccoon poxvirus vector expressing rabies glycoprotein. The vaccine is for use in cats and dogs as an aid in the prevention of rabies virus infection.

The 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 1), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Unless substantial issues with adverse environmental impacts are raised in response to this notice, APHIS intends to issue a finding of no significant impact (FONSI) based on the EA and authorize shipment of the above product for the initiation of field tests following

the close of the comment period for this notice.

Because the issues raised by field testing and by issuance of a license are identical, APHIS has concluded that the EA that is generated for field testing would also be applicable to the proposed licensing action. Provided that the field test data support the conclusions of the original EA and the issuance of a FONSI, APHIS does not intend to issue a separate EA and FONSI to support the issuance of the product license, and would determine that an environmental impact statement need not be prepared. APHIS intends to issue a veterinary biological product license for this vaccine following completion of the field test provided no adverse impacts on the human environment are identified and provided the product meets all other requirements for licensing.

Authority: 21 U.S.C. 151–159.

Done in Washington, DC, this 12th day of September 2008.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. E8–21820 Filed 9–17–08; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2008–0019]

Codex Alimentarius Commission: Meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses

AGENCY: Office of the Under Secretary for Food Safety, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The Office of the Under Secretary for Food Safety, U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA), U.S. Department of Health and Human Services (HHS), are sponsoring a public meeting on September 24, 2008. The objective of the public meeting is to provide information and receive public comments on agenda items and draft United States positions that will be discussed at the 30th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) of the Codex Alimentarius Commission (Codex), which will be held in Capetown, South Africa, on November 3–November 7, 2008. In addition, a working group will meet on November 1, 2008, to discuss agenda items on the Scientific Basis of Health Claims and Nutrient Reference Values for food labeling purposes, and any other matters related to the World Health Organization's (WHO) Global Strategy on Diet, Physical Activity and Health which are under consideration by the CCNFSDU. The Under Secretary for Food Safety and FDA recognize the importance of providing interested parties the opportunity to obtain background information on the 30th Session of CCNFSDU and to address items on the agenda.

DATES: The public meeting is scheduled for Wednesday, September 24, 2008, from 1 p.m. to 4 p.m.

ADDRESSES: The public meeting will be held in the Auditorium (1A003), Food and Drug Administration, Harvey Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD 20740. Parking is adjacent to this building and will be available at no charge to individuals who pre-register by the date below (See Pre-Registration). In addition, the College Park metro station is across the street. Codex documents related to the 30th Session of the CCNFSDU will be accessible via the World Wide Web at the following address: *http://www.codexalimentarius.net/current.asp*.

Pre-Registration: To gain admittance to this meeting, individuals must present a photo ID for identification and also *are required to pre-register*. In addition, no cameras or videotaping equipment will be permitted in the meeting room. To pre-register, please send the following information to e-mail address *nancy.crane@fda.hhs.gov* by *September 17, 2008:*

—Your Name
—Organization
—Mailing Address
—Phone number
—E-mail address

FOR FURTHER INFORMATION ABOUT THE 30TH SESSION OF THE CCNFSDU CONTACT: Nancy Crane, Assistant to the U.S. Delegate to the CCNFSDU, Office of Nutrition, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, FDA, 5100 Paint Branch Parkway (HFS–830), College Park, MD 20740, Phone: (301) 436–1450, Fax: (301) 436–2636, E-mail: *nancy.crane@fda.hhs.gov*.

FOR FURTHER INFORMATION ABOUT THE PUBLIC MEETING CONTACT: Edith Kennard, Staff Officer, U.S. Codex Office, Food Safety and Inspection Service (FSIS), Room 4861, South Building, 1400 Independence Avenue, SW., Washington, DC 20250, Phone: (202) 720–5261, Fax: (202) 720–3157, E-mail: *edith.kennard@fsis.usda.gov*.

SUPPLEMENTARY INFORMATION:

Background

The Codex Alimentarius (Codex) was established in 1963 by two United Nations organizations, the Food and Agriculture Organization and the WHO. Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers and ensure that fair practices are used in trade.

The CCNFSDU was established to study specific nutritional problems assigned to it by the Commission and advise the Commission on general nutritional issues; to draft general provisions as appropriate concerning the nutritional aspects of all foods; to develop standards, guidelines, or related texts for foods for special dietary uses in cooperation with other committees when necessary; and to consider, amend if necessary, and endorse provisions on nutritional aspects proposed for inclusion in Codex standards, guidelines, and related texts. The Committee is hosted by the Federal Republic of Germany.

Issues To Be Discussed at the Public Meeting

The following items on the agenda for the 30th Session of the CCNFSDU will be discussed during the public meeting:

- Matters Referred to the Committee from Other Codex Bodies (including the Global Strategy on Diet, Physical Activity and Health and Infant Formula Methods of Analysis);
- Guidelines for Use of Nutrition Claims: Draft Table of Conditions for Nutrient Contents: Part B, Containing Provisions on Dietary Fibre
- Draft Advisory List of Nutrient Compounds for Use in Foods for Special Dietary Uses for Infants and Young Children: Part D Advisory List of Food Additives for Special Nutrient Forms: Provisions on Gum Arabic;
- Draft Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses;
- Proposed Draft Recommendations on the Scientific Basis of Health Claims;
- Proposal for New Work to Amend the Codex General Principles for the Addition of Essential Nutrients to Foods;
- Proposal for New Work to Establish a Standard for Processed Cereal-Based