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

Animal and Plant Health Inspection Service

[Docket No. 98–050–1]

Availability of an Environmental Assessment and Finding of No Significant Impact for Field Testing Edwardsiella Ictaluri Vaccine

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 and finding of no significant impact concerning authorization to ship for the purpose of field testing and the field testing of an unlicensed live bacterial vaccine for use in catfish. A risk analysis, which forms the basis for the environmental assessment, has led us to conclude that field testing this veterinary vaccine will not have a significant impact on the quality of the human environment. Based on our finding of no significant impact, we have determined that an environmental impact statement need not be prepared. With this notice, we state our intention to authorize shipment of this vaccine for field testing 14 days after the date of this notice, unless new substantial issues bearing on the effects of the action contemplated here are brought to our attention. We also state our intention to issue a veterinary biological product license for this vaccine, provided the field test data support the conclusions of the environmental assessment and finding of no significant impact and the product meets all other requirements for licensure.

ADDRESSES: Copies of the environmental assessment and finding of no significant impact 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. Copies of the environmental assessment and finding of no significant impact (as well as the risk analysis with confidential business information removed) are available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect those documents are requested to call ahead on (202) 690-2817 to facilitate entry into the reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Jeanette Greenberg, Technical Writer-Editor, Center for Veterinary Biologics, Licensing and Policy Development, VS, APHIS, USDA, 4700 River Road Unit 148, Riverdale, MD 20737-1231; telephone (301) 734–5338; fax (301) 734–4314; e-mail jgreenberg@aphis.usda.gov.

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 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.

In determining 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). APHIS has concluded that field testing the unlicensed veterinary biological product will not significantly affect the quality of the human environment. Based on this finding of no significant impact (FONSI), we have determined that there is no need to prepare an environmental impact statement.

An EA and FONSI have been prepared by APHIS concerning the field testing of the following unlicensed veterinary biological product:

Requester: Alpharma NW Inc.

Product: Edwardsiella Ictaluri Vaccine, Avirulent Live Culture, Code 1531.R0.

Field test locations: Arkansas, Louisiana, and Mississippi.

The above-mentioned product is an *aro*A gene-deleted bacterial vaccine for use as an aid in preventing enteric septicemia in channel catfish.

The EA and FONSI have been prepared in accordance with: (1) The National Environmental Policy Act of 1969, as amended (NEPA) (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 authorize shipment of the above product for the initiation of field tests 14 days from the date of this notice.

Because the issues raised by field testing and by issuance of a license are identical, APHIS has concluded that the EA and FONSI that were 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 FONSI, APHIS does not intend to issue a separate EA 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 licensure.

Authority: 21 U.S.C. 151–159.

Done in Washington, DC, this 15th day of May 1998.

Charles P. Schwalbe,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 98–13571 Filed 5–20–98; 8:45 am]

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