E 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2022-0029]

Availability of an Environmental Assessment for Field Testing of Bursal Disease-Infectious Laryngotracheitis-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

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 Bursal Disease-Infectious Laryngotracheitis-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease 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 are making the environmental assessment and risk analysis available for public review and comment. 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 [INSERT DATE 30 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

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

- Federal eRulemaking Portal: Go to www.regulations.gov. Enter APHIS-2022-0029 in the Search Field. Select the Documents tab, then select the Comment button in the list of documents.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2022-0029, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at www.regulations.gov or in our reading room, which is located in room 1620 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) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information regarding the environmental assessment or the risk analysis, or to request a copy of the environmental assessment or risk analysis with confidential business information removed, contact Dr. Barbara J. Sheppard, Senior Staff Veterinary Medical Officer, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 1920 Dayton Avenue, Ames, IA; phone: (515) 337-6100; email: barbara.j.sheppard@usda.gov.

The alternative contact is Dr. Matthew Erdman, Science Advisor, Diagnostics and Biologics, Associate Deputy Administrator's Office, VS, APHIS, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010; phone: (515) 337-6100; email: matthew.m.erdman@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.

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: Intervet Inc.

Product: Bursal Disease-Infectious Laryngotracheitis-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector.

Possible Field Test Locations: Arkansas, Georgia, and South Carolina, among others.

The vaccine has been shown to be effective for the vaccination of 18- to 19-day-old embryonated chicken eggs (E18) or healthy 1-day-old chickens against Marek's disease, infectious bursal disease, and infectious laryngotracheitis. This vaccine consists of a live Marek's Disease, Serotype 3, Turkey Herpesvirus (HVT) vector expressing proteins encoded by genes from an Infectious Bursal Disease Virus (IBDV) and an Infectious Laryngotracheitis Virus (ILTV). In the proposed study, the vaccine will be administered *in ovo* at E18 or older or subcutaneously at 1-day-old.

APHIS' review and analysis of the potential environmental impacts associated with the proposed field tests are documented in detail in an EA titled "Environmental Assessment for Field Testing of a Bursal Disease – Infectious Laryngotracheitis-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector." We are making this EA and the risk analysis with confidential business information removed available to the public for review and comment. We will consider all comments that we receive on or before the date listed under the DATES section at the beginning of this notice.

The EA and the risk analysis may be viewed on the Regulations.gov website or in our reading room (see ADDRESSES above for a link to Regulations.gov and information on the location and hours of the reading room). You may request paper copies of the EA by calling or writing to the person listed under FOR FURTHER INFORMATION CONTACT. Please refer to the title of the EA when requesting copies.

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 1b), 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 APHIS 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; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 24th day of August 2022 .

Anthony Shea,
Administrator,
Animal and Plant Health Inspection Service.

[FR Doc. 2022-18727 Filed: 8/29/2022 8:45 am; Publication Date: 8/30/2022]