Influenza Vaccine, H1N1 & H3N2, Modified Live Virus

**SUMMARY:** We are advising the public that the Animal and Plant Health Inspection Service has prepared an environmental assessment concerning the field testing of the unlicensed Swine Influenza Vaccine, H1N1 & H3N2, Modified Live Virus. The 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 safety of animals, public health, and the environment. Using the risk analysis with confidential business information removed, APHIS has concluded that the field test data support the issuance of the product for field testing.

**DATES:** We will consider all comments that we receive on or before October 5, 2015.

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

- **Federal eRulemaking Portal:** Go to http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0054 or in our reading room, which 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) 799–7039 before coming.

- **Postal Mail/Commercial Delivery:** Send your comment to Docket No. APHIS–2015–0054, Regulatory Analysis and Development, PPD, APHIS, Station 3A–038, 4700 River Road Unit 118, Riverdale, MD 20737–1236.

Supporting documents and any comments we receive on this docket may be viewed at http://

**www.regulations.gov/#!docketDetail;D=APHIS-2015-0054**

**FOR FURTHER INFORMATION CONTACT:** Dr. Donna Malloy, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737–1231; phone (301) 851–3426, fax (301) 734–4314.

**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 considers the potential effects of this product on the safety of animals, public health, and the environment. Using the risk analysis with confidential business information removed, APHIS has prepared an environmental assessment concerning the field testing of the following unlicensed veterinary biological product:

**Requester:** Boehringer Ingelheim Vetmedica, Inc.

**Product:** Swine Influenza Vaccine, H1N1 & H3N2, Modified Live Virus.

**Possible Field Test Locations:** Iowa, Missouri, North Carolina, and Utah.

The above-mentioned product consists of two live attenuated swine influenza vaccine viruses, subtypes H1N1 and H3N2, each containing a truncated NS1 gene. The attenuated vaccine is intended for vaccination of healthy, susceptible pigs one day of age or older, as an aid in the prevention of clinical disease associated with swine influenza 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 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 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 31st day of August 2015.

**Kevin Shea,**

Administrator, Animal and Plant Health Inspection Service.

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