BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2015-0062]

Availability of an Environmental Assessment and Finding of No Significant Impact for Field Use of Vaccines Against Avian Influenza H5 Virus Strains

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability and request for comments.

SUMMARY: We are advising the public that an environmental assessment has been prepared by the Animal and Plant Health Inspection Service relative to the use of one or more veterinary biological products as a treatment for and as an aid in the reduction of highly pathogenic avian influenza (HPAI) incidence caused by strains such as Eurasian H5 viruses of clade 2.3.4.4 lineage. Any biological products would become part of the measures to reduce the incidence of HPAI in the nation's commercial poultry flocks. Based on the environmental assessment, we have concluded that the use of vaccines as described in the environmental assessment will not have a significant impact on the human environment. We are making this environmental assessment and finding of no significant impact available to the public for review and comment.

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 http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0062.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2015-0062, 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 http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0062 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.

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; (301) 851-3426, fax (301) 734-4314.

SUPPLEMENTARY INFORMATION:

Under the Virus-Serum-Toxin Act (21 U.S.C. 151 et seq.), the Animal and Plant Health Inspection Service (APHIS) is authorized to promulgate regulations designed to ensure that veterinary biological products are pure, safe, potent, and efficacious. Veterinary biological products include viruses, serums, toxins, and analogous products of natural or synthetic origin, such as vaccines, antitoxins, or the immunizing components of microorganisms intended for the diagnosis, treatment, or prevention of diseases in domestic animals.

APHIS issues licenses to qualified establishments that produce veterinary biological products and issues permits to importers of such products. APHIS also enforces requirements

concerning production, packaging, labeling, and shipping of these products and sets standards for the testing of these products. Regulations concerning veterinary biological products are contained in 9 CFR parts 101 to 124.

Veterinary biological products meeting the requirements of the regulations may be considered for addition to the U.S. National Veterinary Stockpile (NVS). The NVS is the nation's repository of vaccines and other critical veterinary supplies and equipment. It exists to augment State and local resources in responding to high-consequence livestock diseases that could potentially devastate U.S. agriculture, seriously affect the economy, and threaten public health. NVS vaccines would be used in APHIS programs or under department control or supervision. The addition of vaccines to the stockpile would not preclude private development and use of other poultry vaccines meeting the requirements of the Virus-Serum-Toxin Act.

The arrival in December 2014 of Eurasian H5 strains of highly pathogenic avian influenza (HPAI) and their subsequent dissemination in North America caused a catastrophic outbreak in both domestic poultry and avian wildlife. It is thought that wild, migratory waterfowl carried an H5 virus into North America, which generated reassortants (genetic variants resulting from crosses among AI strains) that spilled over into the domestic poultry population. The H5 viruses are likely to persist within the endemic wild, migratory waterfowl population, which is the primary reservoir of the virus. This viral reservoir will continue to pose a significant threat to U.S. poultry and avian collections.

Two poultry production sectors, commercial meat turkeys and laying chickens, were heavily impacted by these H5 viruses, resulting in the loss or destruction of over 48 million birds between December 2014 and June 2015. Response by regulatory agencies combined with migration of wild waterfowl and the natural disinfectant action of the summer heat temporarily

halted new disease outbreaks. The return of potentially infected migratory waterfowl in autumn, however, may precipitate a new round of outbreaks on an expanded national scale.

Therefore, we are advising the public that we have prepared an environmental assessment (EA) entitled "For Field Use of Avian Influenza Vaccines Against Avian Influenza H5 Virus Strains (August 2015)" to analyze the potential use of one or more veterinary biological products as a treatment for and as an aid in the reduction of HPAI incidence caused by H5 strain viruses. We are publishing this notice to inform the public that we will accept written comments regarding the EA from interested or affected persons for a period of 30 days from the date of this notice. Based on an individual vaccine's risk analysis and the findings in this EA, APHIS would authorize deployment (including shipment, field testing, addition to the NVS, and use in commercial poultry production) of safe, well-characterized biological products upon making a finding of no significant impact (FONSI).

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. If APHIS receives substantive comments that were not previously considered, the Agency would consider issuing a supplement to the EA and FONSI. Because timeliness is essential, it is imperative that APHIS authorize shipment and field use of safe, well-characterized vaccines as soon as possible, and possibly prior to the close of the comment period of this notice.

Possible Field Use Locations: Where Federal and State authorities agree on use.

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).

Authority: 21 U.S.C. 151-159.

Done in Washington, DC, this 1st day of October 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015-25445 Filed: 10/6/2015 08:45 am; Publication Date: 10/7/2015]