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-2016-0028* 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) 7997039 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; phone (301) 851–3426, 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, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010; phone (515) 337–6100, fax (515) 337–6120.

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 before a veterinary biological product license may be issued. 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.

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 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. Based upon a risk analysis provided by the requester and other relevant data, APHIS has prepared an environmental assessment (EA) concerning the field testing of the following unlicensed veterinary biological product:

Requester: Merck Animal Health, Intervet Inc.

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

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

The above-mentioned product is a live Marek's Disease serotype 3 vaccine virus containing a gene from the Newcastle disease virus and two genes from the infectious laryngotracheitis virus. The attenuated vaccine is intended for use in healthy 18-day-old or older embryonated eggs or day-old chickens, as an aid in the prevention of infectious laryngotracheitis, Marek's disease, and Newcastle disease.

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).

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. 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 6th day of May 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–11148 Filed 5–11–16; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2016–0020]

Availability of an Environmental Assessment for Issuance of a Permit for Distribution and Sale for Emergency Use of a Classical Swine Fever Virus Vaccine, Live Pestivirus 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 import under permit, for distribution and sale for emergency use, a Classical Swine Fever Virus Vaccine, Live Pestivirus Vector. The environmental assessment, which is based on a risk analysis prepared to assess the risks associated with the use of this vaccine, examines the potential effects that this veterinary vaccine could have on the quality of the human environment. Based on the risk analysis and other relevant data, we have reached a preliminary determination that use of 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 under permit for distribution and sale for emergency use in the United States 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 and provided the product meets all requirements for approval.

DATES: We will consider all comments that we receive on or before June 13, 2016.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2016-0020.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2016–0020, 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-2016-0020* 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; phone (301) 851–3426, 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, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010; phone (515) 337–6100, fax (515) 337–6120.

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. The NVS vaccines would be used in APHIS programs or under U.S. Department of Agriculture control or supervision. The manufacturer of Classical Swine Fever Virus Vaccine, Live Pestivirus Vector, has been awarded a contract to supply the vaccine to the NVS for emergency use in the United States. The addition of this vaccine to the stockpile would not preclude private development and use of other vaccines meeting the requirements of the Virus-Serum-Toxin Act.

To determine whether to authorize shipment and grant approval for the use of the imported product referenced in this notice, APHIS has considered the potential effects of this product on the safety of animals, public health, and the environment. Using a risk analysis and other relevant data, APHIS has prepared an environmental assessment (EA) concerning the safety testing of the following unlicensed veterinary biological product:

Requester: Zoetis, Inc.

Product: Classical Swine Fever Virus Vaccine, Live Pestivirus Vector.

The above-mentioned product is a single-dose 1-mL modified live product for emergency vaccination in an outbreak situation. The proposed indication is intramuscular administration to healthy swine 6 weeks of age or older as an aid in preventing mortality and viremia caused by classical swine fever virus.

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).

Unless substantial issues with adverse environmental impacts are raised in response to this notice, APHIS intends to issue a finding of no significant impact based on the EA and authorize the importation under permit of the above product for distribution and sale for emergency use following the close of the comment period for this notice, provided the product meets all other requirements for approval.

Authority: 21 U.S.C. 151–159.

Done in Washington, DC, this 6th day of May 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2016–11149 Filed 5–11–16; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2015–0042]

Notice of Availability of an Evaluation of the Fever Tick Status of the State of Chihuahua, Excluding the Municipalities of Guadalupe y Calvo and Morelos

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are notifying the public that we have prepared an evaluation of the State of Chihuahua, excluding the municipalities of Guadalupe y Calvo and Morelos, for fever ticks. The evaluation concludes that this region is free from fever ticks, and that ruminants imported from the area pose a low risk of exposing ruminants within the United States to fever ticks. We are making the evaluation available for review and comment.

DATES: We will consider all comments that we receive on or before July 11, 2016.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0042.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2015–0042, Regulatory Analysis