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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2020-0054]

Petition to Manufacture Foot-and-Mouth Disease Vaccine in the United States

AGENCY: Animal and Plant Health Inspection Service, Agriculture (USDA).

ACTION: Notice of petition and request for information.

SUMMARY: We are notifying the public that the Animal and Plant Health Inspection Service has received a petition from Zoetis, Inc. to approve the manufacture within the continental United States of a vaccine derived from a leaderless strain of the foot-and-mouth disease (FMD) virus. While introduction of live FMD virus into the United States is prohibited by law, the petition states that this attenuated strain of the virus is incapable of causing FMD symptoms or infection in animals. We are soliciting comments from the public regarding the petition and requesting information that will aid us in determining how best to respond to the petition.

DATES: We will consider all comments that we receive on or before [Insert date 60 days after date of 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-2020-0054.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2020-0054, 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-2020-0054 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.

FOR FURTHER INFORMATION CONTACT: Dr. Byron Rippke, Director, Center for Veterinary Biologics, APHIS, Veterinary Services, Diagnostics and Biologics, 1920 Dayton Ave., Ames, IA 50010; (515) 337-6101; Byron.e.rippke@usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Foot-and-mouth disease, or FMD, is a severe, highly contagious viral illness of cows, pigs, sheep, goats, deer, and other animals with divided hooves. The virus weakens affected animals and permanently reduces their ability to produce meat and milk. While FMD has been eradicated from the United States since 1929, the disease is currently found in parts of Africa, Asia, Europe, and South America.

Federal regulations restrict or prohibit the importation of live ruminants and swine, or fresh meat and certain products of ruminants or swine, from any region where FMD exists. In addition, the Federal Select Agent Program, managed jointly by the U.S. Department of Health and Human Services and the U.S. Department of Agriculture (USDA), oversees the possession, use, and transfer of biological select agents and toxins. Within USDA, APHIS regulates those agents that can cause disease in animals under 9 CFR part 121. As FMD has the potential to

pose a severe threat to animal health and animal products, it is listed in § 121.3 of the regulations as a Tier 1 select agent.

Under 21 U.S.C. 113a, the Secretary of Agriculture is authorized to establish laboratories and make contracts for research and study, in the United States or elsewhere, of FMD or other diseases that constitute a threat to the livestock industry of the United States. No live virus of FMD may be introduced for any purpose into any part of the mainland of the United States unless the Secretary determines that it is necessary and in the public interest for the conduct of research and study in the United States and issues a permit under such rules so as to protect animal health.

APHIS has received a petition from Zoetis, Inc. to approve the manufacture of a vaccine derived from an attenuated, leaderless strain of the FMD virus. In accordance with the regulations in 9 CFR part 122, USDA issued a permit to the petitioner to bring attenuated live FMD virus into the mainland United States for the purpose of developing a vaccine.

The FMD virus strain brought into the United States under permit was genetically modified by removing the leader protease gene, rendering the strain incapable of becoming infectious, pathogenic, contagious, or of producing clinical or subclinical signs of FMD. This modification makes the virus unable to reacquire its infectious abilities through mutation. The petitioner also introduced unique restriction enzyme sites into the genome for emerging vaccine strain development, as well as markers that allow for differentiation of infected from vaccinated animals.

Based on these modifications, the petitioner asserts that manufacturing FMD vaccine using the modified FMD virus as the master seed should not be considered within the scope of

prohibitions in 21 U.S.C. 113a on the grounds that their virus strain is no longer a live virus of FMD.

This request for information (RFI) seeks public comment on this interpretation, as well as whether public support exists for the development of an FMD vaccine within the United States. Comments received on this RFI will inform our determination whether to authorize the petitioner to manufacture the vaccine for possible commercial distribution.[1]

As we review the petition, we are soliciting public comments on the following questions:

- Are there possible risks to livestock associated with the commercial manufacture of FMD vaccine in the United States? If so, are these offset by possible benefits associated with such development, assuming appropriate safeguarding?
- If there are possible risks, do these risks differ depending on the location and method of development? If so, how?
- What safeguards should surround the commercial manufacture of FMD vaccine, if authorized?
- How should the overall language of 21 U.S.C 113a be interpreted in light of significant technical developments in the field of virology since its enactment?

[1] To view the petition, go to http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0054.

- APHIS notes that “introduced” is not defined within 21 U.S.C. 113a. How should “introduced…into the mainland United States” be interpreted?
- Based on the information supplied, should the modified virus (master seed) be considered a “live virus of foot-and-mouth disease”? Specifically, should its inability to express as FMD be considered to place it outside the scope of 21 U.S.C. 113a?

We welcome all comments on the petition and the issues outlined above.

Authority: 7 U.S.C. 1633, 7701-7772, 7781-7786, and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 8th day of July 2020.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

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