Notices

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This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

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, USDA.

ACTION: Notice of petition and request for information; reopening of comment period.

SUMMARY: We are reopening the comment period for our notice of receipt of a petition from Zoetis, Inc. requesting approval for the manufacture within the continental United States of a vaccine derived from a leaderless strain of the foot-and-mouth disease (FMD) virus. Although introduction of live FMD virus into the United States is prohibited by law, the petition states that this leaderless strain should not be considered live FMD virus as it is non-infectious, non-transmissible, and incapable of causing FMD. We are taking this action in order to provide commenters with additional scientific information supporting our determination that the leaderless virus strain from which Zoetis, Inc. intends to produce FMD vaccine in the United States poses no risk of causing FMD infection in animals. This action gives interested persons the opportunity to review the additional information and submit comments.

DATES: The comment period for the notice published on July 14, 2020 (85 FR 42346–42347) is reopened. We will consider all comments that we receive on or before January 4, 2021.

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 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: 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: On July 14, 2020, we published in the **Federal Register** (85 FR 42346–42347, Docket No. APHIS–2020–0054) a notice and request for information [1] on a petition submitted by Zoetis, Inc. (Zoetis), a U.S. vaccine manufacturer, seeking approval from the Animal and Plant Health Inspection Service (APHIS) to manufacture within the continental United States a vaccine produced using a leaderless strain [2] of the foot-and-mouth disease (FMD) virus. A leaderless virus lacks part of the genetic code (the leader) critical for determining virulence in a host. Responses to this request for information will help us determine whether to authorize Zoetis to manufacture the vaccine in the United States for commercial distribution.

In the notice, we invited commenters to respond to questions about the risks of manufacturing an FMD vaccine in the United States and what safeguards might be necessary to address risk. We also asked commenters whether the leaderless strain of the virus intended for manufacture of a vaccine should be considered as a live FMD virus based on the Zoetis petition and information we supplied in the notice. This question is important in determining whether the prohibition in 21 U.S.C. 113a on introducing live FMD virus into the United States is applicable to a leaderless virus strain shown to be incapable of causing FMD infection in animals.

We solicited comments concerning our proposal for 60 days ending September 14, 2020. We received a total of 140 comments. While many commenters agreed that the Zoetis leaderless virus poses no FMD risk to U.S. livestock, several others raised safety concerns about using it to manufacture FMD vaccine in the United States. They stated that the notice and petition did not provide enough data to support a determination that the leaderless virus is not a live virus and that it poses no risk of causing FMD infection in animals. To address these concerns, we are providing additional data in this notice supporting the safety of the leaderless FMD virus and its use in manufacturing FMD vaccine and are reopening the comment period for 30 days.

Risk Assessment Summary

In 2017, Zoetis requested from the U.S. Department of Agriculture (USDA) a select agent exclusion for a leaderless strain of FMD virus intended to be used as a platform for producing FMD vaccine. In accordance with the regulations in 9 CFR part 122, USDA issued a permit allowing Zoetis to bring attenuated live FMD virus into the mainland United States for possible vaccine development. Before issuing the permit, USDA reviewed multiple documents and studies related to the request. The review encompassed synthetic virus production, virulence and safety, seroconversion, and concerns related to diagnostic differentiation of vaccinated and naturally infected animals. We concluded from these reviews that the Zoetis leaderless virus is incapable of infecting animals with FMD, and that vaccines produced using the leaderless virus as a platform are safe and efficacious in cattle and swine. Further details of our review findings are included in a risk assessment summary available via the link in footnote 1.

[1] To view the notice, the supporting document, and the comments we have received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0054.*

[2] Referred to in the Zoetis petition as FMD–LL3B3D A24 Cruzeiro vaccine platform virus.

In addition to the risk assessment summary, we wish to provide the following information regarding our evaluation.

Development and Safety of the FMD–LL3B3D Leaderless FMD Virus

The FMD–LL3B3D leaderless vaccine platform virus was created by deleting the leader (L) and one of three 3B genetic sequences of the FMD virus (L is a part of the virus that determines virulence), resulting in an attenuated virus that is innocuous for cattle and pigs but capable of growing in cell culture.[3] As a result, if the FMD–LL3B3D leaderless virus were to escape a manufacturing facility, it would be incapable of causing FMD in any animals exposed to it, nor could such animals spread the virus to other animals. In contrast, the risk of escape from facilities using traditionally virulent FMD viruses to manufacture vaccine is why many countries restrict FMD vaccine production to only local endemic strains. The deletion of L and the relevant 3B genetic sequence was therefore a key consideration in our evaluation.

Of similar importance was our review of available data regarding virulence of FMD–LL3B3D vaccines. Several FMD–LL3B3D vaccine viruses have been derived *in vitro* and characterized for their virulence in cattle and pigs. The cumulative data have shown that these FMD–LL3B3D marker viruses are highly attenuated in their natural hosts. Safety studies involving direct inoculation of live FMD–LL3B3D virus in cattle and pigs (see table 1) showed a high restriction of the novel vaccine virus to replicate and resulted in no clinical disease or transmission.[4]

TABLE 1—LIVE INNOCUITY STUDIES USING A VARIETY OF FMDLL3B3D VACCINE STRAINS IN CATTLE AND SWINE [1]

Construct	Inoculation route	Number of animals	Results
Cattle:			
FMD–LL3B3D–A24 Cruzeiro	Intralingual (7×10^6)	2	• No clinical disease.
FMD–LL3B3D–A24 Cruzeiro	Aerosol (1×10^6 to 3×10^6)	3	• No viral shedding.
FMD–LL3B3D–A24 Cruzeiro	Aerosol and Contact/(1×10^6)	9	• No fever spikes. • No contact transmission. • Very limited if any immune response.
Swine:			
FMD–LL3B3D–A24 Cruzeiro	Heelbulb and Contact (1×10^5)	4	• No clinical disease.
FMD–LL3B3D–Asia1 Shamir	Heelbulb and Contact (1×10^6)	5	• No viral shedding.
FMD–LL3B3D–A Turkey 06	Heelbulb and Contact (1×10^6)	5	• No fever spikes.
FMD–LL3B3D–O1 Campos	Heelbulb and Contact (1×10^6)	4	• No contact transmission.
FMD–LL3B3D–A Argentina	Heelbulb and Contact (2×10^6)	4	• Very limited if any immune response.
FMD–LL3B3D–C3 Indaial	Heelbulb and Contact (2.8×10^6)	4	

[1] Data prepared by Foreign Animal Disease Research Unit, USDA/ARS, Plum Island Animal Disease Center.

We are therefore reopening the comment period on Docket No. APHIS–2020–0054 for an additional 30 days. This action will allow interested persons to prepare and submit comments on the additional information we provided. We will also consider all comments received between September 14, 2020, and the date of this notice.

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 25th day of November 2020.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2020–26560 Filed 12–1–20; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Medicine Bow-Routt National Forests and Thunder Basin National Grassland; Wyoming; 2020 Thunder Basin National Grassland Plan Amendment

AGENCY: Forest Service, USDA.

ACTION: Notice of Grassland Plan amendment approval.

SUMMARY: Russell M. Bacon, Forest Supervisor for the Medicine Bow-Routt National Forests and Thunder Basin National Grassland, Rocky Mountain Region, signed the final Record of Decision (ROD) for the 2020 Thunder Basin National Grassland Land and Resource Management Plan Amendment (Grassland Plan amendment). The Final ROD documents the rationale for approving the Grassland Plan amendment and is consistent with the Reviewing Officer's response to objections and instructions.

DATES: The effective date of the Grassland Plan amendment is 30 days after publication of notice of Grassland Plan amendment approval in the newspaper of record, the *Laramie Boomerang.*

ADDRESSES: To view the final ROD, final environmental impact statement (FEIS), FEIS errata, objection responses, and other related documents, visit the 2020 Thunder Basin National Grassland Plan Amendment website at *https://www.fs.usda.gov/project/?project=55479.*

FOR FURTHER INFORMATION CONTACT: Monique Nelson, plan amendment team leader, by email at *monique.nelson@usda.gov* or by telephone at 307–275–0956.

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339

[3] See the following studies for leaderless FMD virus safety data: Uddowla S., et al. A Safe Foot-and-Mouth Disease Vaccine Platform with Two Negative Markers for Differentiating Infected from Vaccinated Animals. *Journal of Virology* Oct 2012, 86(21) 11675–11685: DOI: 10.1128/JVI.01254–12; Eschbaumer M., et al. Foot-and-mouth disease virus lacking the leader 2 protein and containing two negative DIVA markers 3 (FMDV LL3B3D A24) is fully attenuated in pigs. *Pathogens.* (2020) 17:1–8: DOI: 10.3390/pathogens9020129; Hardham, John M., et al., Novel Foot-and-Mouth Disease Vaccine Platform: Formulations for Safe and DIVA-Compatible FMD Vaccines with Improved Potency. *Frontiers in Veterinary Science,* 25 September 2020; *https://doi.org/10.3389/fvets.2020.554305.*

[4] In a 2018 meeting report drafted by the Global Foot-and-Moth Disease Research Alliance that reviewed FMD vaccine platforms, the FMDLL3B3D platform received the highest score. Global Foot-and-Mouth Disease Research Alliance, Gap Analysis Report. December 2018: *https://go.usa.gov/xdrKh.*