and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:
Kelly Covington, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5661, Kelly.Covington@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 13, 2020, FDA published a notice announcing a public meeting and requesting comments on a concept paper entitled “Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine: A Risk Management Tool for Antimicrobial New Animal Drugs” with a 94-day comment period.

Interested persons were originally given until January 15, 2021, to comment on the public meeting and request for comments. The Agency received several requests to allow interested persons additional time to comment. The requests conveyed concern that the initial 94-day comment period did not allow sufficient time to develop a comprehensive response. FDA believes that an extension of 60 days allows adequate time for interested persons to submit comments.


Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26182 Filed 11–25–20; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1898]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA’s regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document. Consistent with FDA’s regulations, this notice is being published with less than 15 days prior to the date of the meeting based on a determination that convening a meeting of the Vaccines and Related Biological Products Advisory Committee as soon as possible is warranted. This Federal Register notice could not be published 15 days prior to the date of the meeting due to a recent submission of a request for Emergency Use Authorization (EUA) for an investigational vaccine to prevent Coronavirus Disease 2019 (COVID–19) and the need for prompt discussion of such submission, given the COVID–19 pandemic.

DATES: The meeting will be held on December 10, 2020, from 9 a.m. Eastern Time to 6 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions including information regarding special accommodations due to a disability may be accessed at: https://www.fda.gov/advisory-committees/about-advisory-committees/common-questions-and-answers-about-fda-advisory-committee-meetings. The online web conference meeting will be available at the following link on the day of the meeting: https://fda.yorkcast.com/webcast/Play/d75db0a3ebb641996681c1a881fe2671d.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2020–N–1898. The docket will close on December 9, 2020. Submit either electronic or written comments on this public meeting by December 9, 2020. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 9, 2020. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 9, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before December 4, 2020 will be provided to the committee. Comments received after December 4, 2020, and by December 9, 2020, will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications, submissions, or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions
Submit electronic comments in the following way:
• Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions
Submit written/paper submissions as follows:
• Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2020–N–1898 for “Vaccines and Related Biological Products; Notice of Meeting; Establishment of a Public Docket; Request for Comments.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.
• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56409, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts.

FOR FURTHER INFORMATION CONTACT:
Prabhakara Atreya or Kathleen Hayes, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Room 3017, Silver Spring, MD 20993, or 301–796–4540, or 301–796–4540.

If you require accommodations due to a disability, please contact the Office of Disability Affairs at fdaoma@fda.hhs.gov or 301–796–4540.

SUPPLEMENTARY INFORMATION: Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The Committee will meet in open session to discuss EUA of the Pfizer-BioNTech COVID–19 Vaccine for the prevention of COVID–19 in individuals 16 years of age and older. This EUA authority allows FDA to help strengthen the nation’s public health protections against chemical, biological, radiological, nuclear (CBRN) threats by facilitating the availability and use of Medical Countermeasures (MCMs) needed during public health emergencies.

Pfizer-BioNTech COVID–19 Vaccine for Emergency Use Authorization


Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26229 Filed 11–25–20; 8:45 am]

BILLING CODE 4164–01–P