

costs for those components throughout the cost statement. The A series of schedules collects the HO/CO trial balance of expenses, reclassifications, and adjustments, for allocation of the HO/CO costs to its components. On the B series of schedules, the home office directly allocates costs directly attributable to specific components. On the C and D series of schedules, the HO/CO functionally allocates costs to components in a manner that reasonably relates to the services provided to the components. On the E series of schedules, the HO/CO allocates pooled costs (costs not directly assigned or functionally allocated) to the components. On the F series of schedule, the HO/CO summarizes the cost allocations by component. On the G series of schedules, the HO/CO reports financial data from their balance sheet and income statement. *Form Number:* CMS-287-21 (OMB control number 0938-0202); *Frequency:* Annually; *Affected Public:* Private Sector, State, Business, and Not-for Profits; *Number of Respondents:* 1,626; *Number of Responses:* 1,626; *Total Annual Hours:* 757,716. (For questions regarding this collection, contact Gail Duncan at 410-786-7278.)

Dated: November 20, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020-26156 Filed 11-25-20; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1736]

Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine: A Risk Management Tool for Antimicrobial New Animal Drugs; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and request for comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice announcing a public meeting and requesting comments that appeared in the **Federal Register** of October 13, 2020. In that notice, FDA announced a public meeting, held on November 16, 2020, and requested public input on a

potential revised approach for considering the human medical importance of antimicrobial new animal drugs when assessing and managing the antimicrobial resistance risks associated with the use of antimicrobial drugs in animals. Specifically, the Agency requested comments on the potential revised process for ranking antimicrobials according to their relative importance in human medicine, on the potential criteria for their ranking, and on the resulting ranked list of antimicrobial drugs. FDA is taking this action in response to several requests for extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period announced in the notice of public meeting and request for comments published October 13, 2020 (85 FR 64481). Submit either electronic or written comments by March 16, 2021, to ensure that the Agency considers your comments regarding this public meeting and request for comments.

ADDRESSES: 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 and 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-1736 for "Potential Approach for Ranking of Antimicrobial Drugs According to Their Importance in Human Medicine: A Risk Management Tool for Antimicrobial New Animal Drugs." 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." The Agency 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 to 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 this 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 56469, 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

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.

Dated: November 20, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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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/d75d80a3eb6e419986181c1a881fe2671d>.

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 and 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.