objective to engage with our stakeholders to develop and implement a strategy for promoting antimicrobial stewardship in companion animals.[5] One of the actions related to this objective (Action 1.2.1 under Phase 1 Actions [6]) is to obtain public input regarding antimicrobial use practices in companion animals and the impact of such use practices on the development of resistance.

II. Questions for Consideration

CVM seeks input on the following questions and information requests:

1. Please describe if antimicrobial use practices in companion animals have impacted the development of antimicrobial resistance in bacterial pathogens of companion animals. Please provide information, data, and/or references to support your response.

2. Please describe if antimicrobial use practices in companion animals, including extralabel use, have impacted the development of antimicrobial resistance in human bacterial pathogens. If possible, please describe whether the impact was the result of direct or indirect contact between humans and the treated companion animals. Are there specific concerns about the development of antimicrobial resistance in human bacterial pathogens when particular antimicrobial drugs or drug classes are used in companion animals? Please provide information, data, and/or references to support your response.

3. How should the human medical importance of particular antimicrobial drugs or drug classes be considered when deciding whether, or under what conditions, to use such drugs in companion animals?

4. How can CVM best engage with our stakeholders on promoting antimicrobial stewardship for companion animals? Examples of stakeholders include other government agencies, the pharmaceutical industry, public health organizations (both public and private entities), veterinary professional organizations, veterinary schools, veterinarians, pet owners, and veterinary diagnostic laboratories.

5. How can CVM encourage the development of antimicrobial drugs consistent with the principles of antimicrobial stewardship for the treatment of infectious diseases in companion animals for which there are no FDA-approved animal drugs?

a. What bacterial diseases affecting companion animals are most in need of an FDA-approved animal antimicrobial drug?

b. What safety and effectiveness study design considerations present challenges for developing antimicrobial drugs to address specific infectious diseases in companion animals (*e.g.,* Lyme disease, sepsis, or osteomyelitis)? Are there alternative study designs that would address these challenges? If not, what role(s) could the stakeholder groups identified in question 4 play in developing such alternative study designs?

c. Are there specific infectious diseases in companion animals for which topical formulations of antimicrobial drugs (*e.g.,* medicated shampoos, rinses, or ointments) may be a better alternative than using systemic antimicrobial drugs from the perspective of antimicrobial stewardship? If so, what role(s) could the stakeholder groups identified in question 4 play toward fostering the use of such topical antimicrobial formulations?

6. Labeling:

a. What information on currently approved animal drug labeling helps the veterinarian prescribe or use an antimicrobial drug in a manner consistent with the principles of antimicrobial stewardship?

b. What additional information could be added to the approved animal drug labeling to improve the veterinarian's ability to prescribe or use an antimicrobial drug in a manner consistent with the principles of antimicrobial stewardship?

c. Is there a need for materials containing labeling information and/or information about antimicrobial stewardship that veterinarians could provide to the client when they prescribe an antimicrobial drug (*e.g.,* client information sheets or other educational handouts)?

7. With respect to the use of antimicrobial drugs in companion animals, what other actions should CVM consider taking to foster greater antimicrobial stewardship?

Dated: February 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03245 Filed 2–15–22; 8:45 am]

BILLING CODE 4164–01–P

[5] As a part of the plan, CVM established three goals, which include: (1) Align antimicrobial drug product use with the principles of antimicrobial stewardship; (2) foster stewardship of antimicrobials in veterinary settings; and (3) enhance monitoring of antimicrobial resistance and antimicrobial drug use in animals. See the five-year action plan at p. 5.

[6] CVM intends to initiate the actions outlined in the plan in two phases, with Phase 1 activities being initiated between FY 2019 and FY 2021 and Phase 2 activities being initiated between FY 2022 and FY 2023. See the five-year action plan at pp. 5–6.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0008]

Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held virtually on March 10, 2022, from 10 a.m. to 1:30 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.* The online web conference meeting will be available at the following link on the day of the meeting: *https://youtu.be/silb2C_Ro8I.*

FOR FURTHER INFORMATION CONTACT: Christina Vert or Tonica Burke, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 1244, Silver Spring, MD 20993–0002, 240–402–8054, *ctgtac@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before joining the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On March 10,

2022, for Topic I, the committee will meet in open session to hear an overview of the research programs in the Gene Transfer and Immunogencity Branch, Division of Cellular and Gene Therapies, Office of Tissues and Advanced Therapies, Center for Biologics Research. After the Topic I open session, the meeting will be closed to the public for committee deliberations.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: On March 10, 2022, from 10 a.m. to 12:40 p.m. Eastern Time, the meeting is open to the public for Topic I. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 3, 2022. Oral presentations from the public will be scheduled between approximately 11:40 a.m. and 12:40 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 23, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 24, 2022.

Closed Committee Deliberations: On March 10, 2022, from 12:40 p.m. to 1:30 p.m. Eastern Time for Topic I, the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The recommendations of the advisory committee regarding the progress of the individual investigators' research programs, along with other information, will be discussed during this session. We believe that public discussion of these recommendations on individual scientists would constitute an unwarranted invasion of personal privacy.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Christina Vert at *ctgtac@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 10, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–03366 Filed 2–15–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of a virtual meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will be holding the 73rd full Council meeting utilizing virtual technology on Monday, March 14 and Tuesday, March 15, 2022 from approximately 10:00–4:30 p.m. (ET) on both days. The meeting will be open to the public and there will be an interactive community engagement session during the first day of the meeting. Additionally, there will be a public comment session during the meeting; pre-registration is required to provide public comment. To pre-register to provide public comment, please send an email to *PACHA@hhs.gov* and include your name, organization, and title by close of business Monday, March 7, 2022. If you decide you would like to provide public comment but do not pre-register, you may submit your written statement by emailing *PACHA@hhs.gov* by close of business Tuesday, March, 22, 2022. The meeting agenda will be posted on the PACHA page on *HIV.gov* at *https://www.hiv.gov/federal-response/pacha/about-pacha* prior to the meeting.

DATES: The meeting will be held on Monday, March 14 and Tuesday March 15, 2022 from approximately 10:00–4:30 p.m. (ET) on both days. This meeting will be conducted utilizing virtual technology.

ADDRESSES: Instructions on attending this meeting virtually will be posted prior to the meeting at: *https://www.hiv.gov/federal-response/pacha/about-pacha.*

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, MPA, Management Analyst, Presidential Advisory Council on HIV/AIDS, 330 C Street SW, Room L609A, Washington, DC 20024; (202) 795–7622 or *PACHA@hhs.gov.* Additional information can be obtained by accessing the Council's page on the *HIV.gov* site at *www.hiv.gov/pacha.*

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996 and is currently operating under the authority given in Executive Order 14048, dated September 30, 2021. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective HIV diagnosis, treatment, prevention, and quality care services. The functions of the Council are solely advisory in nature.

The Council consists of not more than 35 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, population health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. PACHA selections also include persons with lived HIV experience and racial/ethnic and sexual and gender minority persons disproportionately affected by HIV.