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.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Cindy Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0817, email: *cindy.burnsteel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft GFI #263 entitled ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter.'' This draft guidance, when finalized, will provide information to sponsors of certain new animal drug products who are interested in changing the approved marketing status of these products from OTC to Rx consistent with FDA's recommendation that the use of such drugs in animals be limited to uses that include veterinary oversight in order to mitigate development of antimicrobial resistance and thereby preserve the effectiveness of these drugs for use as therapies to treat infections in humans and animals. The draft guidance, when finalized, also will recommend timeframes for stakeholders wishing to comply voluntarily with this guidance.

In 2016, in response to recommendations made by FDA as part of a strategy to address antimicrobial resistance associated with the use of antimicrobial drugs in animal agriculture, sponsors of all medically important antimicrobial drugs approved for use in or on the feed or drinking water of food-producing animals worked with FDA to voluntarily withdraw approval of indications that were not considered necessary for assuring animal health (production indications), and voluntarily change all remaining approved uses of such new animal drugs from OTC to either Veterinary Feed Directive or Rx marketing status, as applicable.[1]

Although all medically important antimicrobials used in feed or water for food-producing animals are currently under veterinary oversight, some other dosage form products (*e.g.,* injectable, tablet, intramammary infusion) intended for use in food-producing and non-food-producing animals remain available OTC. This draft guidance, when finalized, will provide sponsors with specific recommendations on how to facilitate voluntary changes to the approved conditions of use of these drugs to prescription marketing status. The voluntary process outlined in this draft guidance will help to ensure new animal drugs containing antimicrobials of human medical importance are administered only under veterinary oversight and only for therapeutic uses.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on veterinary oversight of medically important antimicrobial drugs administered to animals. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This draft guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(n)(1)) have been approved under OMB control number 0910–0669. The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

IV. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov*.

Dated: September 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–20688 Filed 9–23–19; 11:15 am]

BILLING CODE 4164–01–P

[1] See GFI #213, ''New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-213-new-animal-drugs-and-new-animal-drug-combination-products-administered-or-medicated-feed*)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Assistant Secretary for Administration; Delegation of Authority

Notice is hereby given that I have delegated to the Assistant Secretary for Preparedness and Response (ASPR); the Director, Centers for Disease Control and Prevention (CDC); the Administrator, Health Resources and Services Administration (HRSA); the Director, National Institutes for Health (NIH); the Director, Office of Global Affairs (OGA); and the Administrator, Substance Abuse and Mental Health Services Administration (SAMHSA) the authority vested in the Secretary by section 212(l) of the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019 (FY 19 HHS Appropriations Act) Public Law 115–245, division B, title II, (September 28, 2018), or substantially similar authorities vested in me in the future by Congress, in order to carry out international health activities, including HIV/AIDS and other infectious disease, chronic and environmental disease, and other health activities abroad. Section 212(l) of the FY19 HHS Appropriations

Act permits the Secretary of HHS to exercise authority equivalent to that available to the Secretary of State under 22 U.S.C. 2669(c) to award personal services contracts for work performed in foreign countries.

The authority delegated herein includes the authority to determine the necessity of negotiating, executing, and performing such contracts without regard to statutory provisions as relate to the negotiation, making, and performance of contracts and performance of work in the United States. This authority is immediately revoked in the event that any subsequent fiscal year HHS appropriations act does not contain the provision currently in section 212(1) or substantially similar authority.

The Director, CDC may redelegate this authority to the Chief Operating Officer, CDC for a period of one (1) year from the effective date of this delegation to respond to the current Ebola outbreak. This authority may not be further redelegated except as noted above.

The delegatees shall consult with the Secretary of State and relevant Chief of Mission to ensure that this authority is exercised in a manner consistent with section 207 of the Foreign Service Act of 1980 and other applicable statutes administered by the Department of State.

This delegation became effective upon date of signature. In addition, I hereby affirm and ratify any actions taken by the delegatees or their subordinates which involved the exercise of the authorities delegated herein, or substantially similar authorities vested in me by prior annual HHS appropriations acts, prior to the effective date of the delegation.

Dated: September 19, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2019–20840 Filed 9–24–19; 8:45 am]

BILLING CODE 4151–17–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.

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 65th full Council meeting in Miami, Florida. Miami-Dade County is one of the counties indicated in *Ending the HIV Epidemic: A Plan for America.* Agenda items will include an update on HIV and the Latinx Community, Ending the HIV Epidemic in Florida and Puerto Rico, addressing the unique needs in Florida and Puerto Rico, a federal panel to discuss federal efforts and mechanisms to ensure continued community engagement, and a presentation on performance indicators for tracking the Initiative. The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is encouraged for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or send in their public comment via email should send an email to Caroline Talev, MPA, at *Caroline.Talev@hhs.gov.* Pre-Registration must be complete by Tuesday, October 15, 2019.

DATES: The Council meeting is scheduled to convene on Monday, October 21, 2019 from approximately 1:30 p.m. to 5:30 p.m. ET and Tuesday, October 22, 2019 from approximately 9:00 a.m. to 5:00 p.m. ET (times are tentative and subject to change). The meeting agenda will be posted on the PACHA web page at *https://www.hiv.gov/federal-response/pacha/about-pacha.* Public attendance is limited to available space.

ADDRESSES: Miami Marriott Biscayne Bay, 1633 N Bayshore Drive, Miami, Florida 33132.

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, MPA, Public Health Analyst, Presidential Advisory Council on HIV/AIDS, 330 C Street SW, Room L106B, Washington, DC 20024; (202) 795–7622 or *Caroline.Talev@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 13811, dated September 29, 2017. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective prevention and care of HIV infection and AIDS. The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 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, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House. The agenda for will be posted on HIV.gov at *https://www.hiv.gov/federal-response/pacha/about-pacha.*

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Caroline Talev at *Caroline.Talev@hhs.gov.* Due to space constraints, pre-registration for public attendance is advisable and can be accomplished by contacting Caroline Talev at *Caroline.Talev@hhs.gov* by close of business Tuesday, October 15, 2019. Members of the public will have the opportunity to provide comments during the meeting. Comments will be limited to no more than three minutes per speaker. Any individual who wishes to participate in the public comment session must register with Caroline Talev at *Caroline.Talev@hhs.gov* by close of business Tuesday, October 15, 2019; registration for public comment will not be accepted by telephone. Individuals are encouraged to provide a written statement of any public comment(s) for accurate minute taking purposes. Any members of the public who wish to have printed material distributed to PACHA members at the meeting are asked to submit, at a minimum, 1 copy of the material(s) to Caroline Talev, no later than close of business on Tuesday, October 15, 2019.

Dated: September 16, 2019.

B. Kaye Hayes,

Principal Deputy Director, Office of Infectious Disease and HIV/AIDS Policy, Executive Director, Presidential Advisory Council on HIV/AIDS, Office of the Assistant Secretary for Health, Department of Health and Human Services.

[FR Doc. 2019–20783 Filed 9–24–19; 8:45 am]

BILLING CODE 4150–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.