meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For more information on parking and security procedures, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the agenda approximately 5 days before the meeting at: *http://www.fda.gov/Drugs/NewsEvents/ucm459342.htm.*

FOR FURTHER INFORMATION CONTACT: Christine Le, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3196, Silver Spring, MD 20993, 301–796–2398, email: *Christine.Le@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In general, HCs are highly effective in preventing pregnancy when used correctly. However, concomitant use of other drugs may affect the safety and/or efficacy of HCs due to drug interactions affecting either blood levels (PK) and/or physiologic effects (PD) of HC components (*e.g.,* estrogen and progestins). Understanding drug interaction potential of HCs and other drugs is important when investigating HC-related issues, and in the design and conduct of clinical trials. Evolving knowledge on drug interaction mechanisms has led to new insights and increased interest in the clinical investigation of drug interactions with HCs.

Historically, most drug interaction studies conducted during drug development with HCs have not had a clearly stated rationale for the choice of HCs being studied. Questions remain as to whether the study results of specific contraceptive steroids can be extrapolated to other progestins or estrogens or other dose strengths. The choice of HC is important because different progestins may have different metabolic and/or transporter pathways and safety profiles. Without a mechanistic understanding of the underlying drug-drug interaction (DDI) mechanism, it is difficult to interpret and extrapolate study results from one HC to another.

II. Discussion Topics for the Meeting and for Public Comments

The public meeting on November 9, 2015, will include a discussion of the following topics on which FDA is also seeking public comment:

- Public health concerns associated with use of HCs and interacting drugs that might affect efficacy and safety.
- PK and PD considerations in designing drug interaction studies with HCs during drug development. Key elements in designing a study include a mechanistic understanding of potential DDI mechanisms, the choice of contraceptive products and their dose, study population/duration, and proper selection of a PK alone or PK–PD-based drug interaction study approach.
- Drug interaction study result interpretation and its potential impact on guidance of HC use in women of childbearing potential who are enrolled in clinical trials for other therapeutic agents during drug development.
- The current approach of translating the results from drug interaction studies into labeling recommendations and opportunities to improve the communication to healthcare providers.
- Research opportunities and tools for investigating the safe use of HCs in the presence of other drugs.

The input received may be used to refine FDA's thinking on the drug interaction study design with HCs and labeling communication of drug interaction risks with HCs.

III. Meeting Attendance and Participation

If you wish to attend these meetings, register online at *https://www.surveymonkey.com/r/HC-DDIMeeting.* Please register by October 9, 2015. Those who are unable to attend the meetings in person can register to view a live Web cast of the meetings. You will be asked to indicate in your registration whether you plan to attend in person or via the Web cast. Your registration should also contain your complete contact information, including name, title, affiliation, address, email address, and phone number.

Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meetings will be based on space availability. If you need special accommodations because of disability, please contact Christine Le (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

FDA will hold an open public comment period during the November 9, 2015, public meeting to give the public an opportunity to comment. Registration for open public comment will occur at the registration desk on the day of the meeting on a first-come, first-served basis.

IV. Comments

Regardless of whether you attend this meeting, you can submit electronic or written comments, including responses to the public docket (see **ADDRESS** above), by December 15, 2015. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

V. Transcripts

Transcripts for the November 9, 2015, meeting will be posted, when available, at *http://www.fda.gov/Drugs/NewsEvents/ucm459342.htm.*

Dated: September 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–22949 Filed 9–10–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria

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 Department of Health and Human Services (HHS) is hereby giving notice that a meeting of the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (the Advisory Council) is scheduled for September 29, 2015, from 9:00 a.m. to 5:00 p.m. ET. The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is required 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 email *CARB@hhs.gov.* Registration information is available on the Web site *http://www.hhs.gov/ash/*

carb/ and must be completed by September 21, 2015; all in-person attendees must pre-register by this date. Additional information about registering for the meeting and providing public comment can be obtained at *http://www.hhs.gov/ash/carb/.*

DATES: The meeting is scheduled to be held on September 29, 2015, from 9:00 a.m. to 5:00 p.m. ET. Pre-registration for attending the meeting in person is required to be completed no later than September 21, 2015; public attendance at the meeting is limited to the available space.

ADDRESSES: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Great Hall, 200 Independence Avenue SW., Washington, DC 20201.

The meeting also can be accessed through a live webcast the day of the meeting. For more information, visit *http://www.hhs.gov/ash/carb/.*

FOR FURTHER INFORMATION CONTACT: Bruce Gellin, Designated Federal Official, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Phone: (202) 260–6638; email: *CARB@hhs.gov.*

SUPPLEMENTARY INFORMATION:

Under Executive Order 13676, dated September 18, 2014, authority was given to the Secretary of Health and Human Services to establish the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (Advisory Council), in consultation with the Secretaries of Defense and Agriculture. Activities of the Advisory Council are governed by the provisions of Public Law 92–463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of federal advisory committees.

The Advisory Council will provide advice, information, and recommendations to the Secretary of HHS regarding programs and policies intended to support and evaluate the implementation of Executive Order 13676, including the National Strategy for Combating Antibiotic-Resistant Bacteria and the National Action Plan for Combating Antibiotic-Resistant Bacteria. The Advisory Council shall function solely for advisory purposes.

In carrying out its mission, the Advisory Council will provide advice, information, and recommendations to the Secretary regarding programs and policies intended to preserve the effectiveness of antibiotics by optimizing their use; advance research to develop improved methods for combating antibiotic resistance and conducting antibiotic stewardship; strengthen surveillance of antibiotic-resistant bacterial infections; prevent the transmission of antibiotic-resistant bacterial infections; advance the development of rapid point-of-care and agricultural diagnostics; further research on new treatments for bacterial infections; develop alternatives to antibiotics for agricultural purposes; maximize the dissemination of up-to-date information on the appropriate and proper use of antibiotics to the general public and human and animal healthcare providers; and improve international coordination of efforts to combat antibiotic resistance.

The September public meeting will be the inaugural meeting for the Advisory Council. The Advisory Council members will be sworn in and presented with an overview of different topics surrounding antibiotic resistance, including an overview of the National Strategy for Combating Antibiotic-Resistant Bacteria and Action Plan for Combating Antibiotic-Resistant Bacteria. The meeting agenda will be posted on the Advisory Council Web site at *http://www.hhs.gov/ash/carb/* when it has been finalized.

Public attendance at the meeting is limited to the available space. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the National Vaccine Program Office at the address/telephone number listed above at least one week prior to the meeting. For those unable to attend in person, a live webcast will be available. More information on registration and accessing the webcast can be found at *http://www.hhs.gov/ash/carb/.*

Members of the public will have the opportunity to provide comments prior to the Advisory Council meeting by emailing *CARB@hhs.gov.* Public comments should be sent in by midnight September 28, 2015, and should be limited to no more than one page. All public comments will be read during the public comment period designated on the agenda; limited to two minutes per comment.

Dated: August 19, 2015.

Bruce Gellin,

Deputy Assistant Secretary for Health, Designated Federal Official, Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria.

[FR Doc. 2015–22920 Filed 9–10–15; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Molecular Targets for Cancer Intervention.

Date: October 5–6, 2015.

Time: 7:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: The Westin St. Francis, 335 Powell Street, San Francisco, CA 94102.

Contact Person: Careen K. Tang-Toth, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, (301) 435–3504, *tothct@csr.nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Nursing and Related Clinical Sciences Study Section.

Date: October 8–9, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Dupont Hotel, 1500 New Hampshire Avenue NW., Washington, DC 20036.

Contact Person: Martha L. Hare, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3154, MSC 7770, Bethesda, MD 20892, (301) 451–8504, *harem@mail.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function B Study Section.

Date: October 15–16, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Pier 2620 Hotel at Fisherman's Wharf, 2620 Jones St, San Francisco, CA 94133.

Contact Person: C-L Albert Wang, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7806, Bethesda, MD 20892, 301–435–1016, *wangca@csr.nih.gov.*