

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control number	Date approval expires
New Animal Drugs for Investigational Use	0910–0117	8/31/2021
Guidance for Industry and FDA Staff, Class II Special Controls: Automated Blood Cell Separator Device Operating by Centrifugal or Filtration Separation Principle	0910–0594	8/31/2021
Petition to Request an Exemption from 100 Percent Identity Testing of Dietary Ingredients: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements ...	0910–0608	8/31/2021
Prescription Drug Advertisements	0910–0686	8/31/2021
Survey of the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types	0910–0744	8/31/2021
Permanent Discontinuation or Interruption in Manufacturing of Certain Drug and Biological Products	0910–0759	8/31/2021
Food and Cosmetic Export Certificate Applications Process	0910–0793	8/31/2021
Guidance for Industry: Medical Product Communications That are Consistent With the Food and Drug Administration Required Labeling—Questions and Answers	0910–0856	8/31/2021
Guidance for Industry: Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities Questions and Answers	0910–0857	8/31/2021
Guidance for Industry: Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities	0910–0858	8/31/2021
Drug Supply Chain Security Act Pilot Program	0910–0859	8/31/2021
Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional and Retail Food Stores and Facility Types (2015–2025)	0910–0799	9/30/2021

Dated: October 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22101 Filed 10–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3323]

Advisory Committee; Antimicrobial Drugs Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Antimicrobial Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Antimicrobial Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until October 7, 2020.

DATES: Authority for the Antimicrobial Drugs Advisory Committee will expire on October 7, 2018, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Lauren Tesh, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring,

MD 20993–0002, 301–796–9001, email: AMDAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Antimicrobial Drugs Advisory Committee. The committee is a discretionary Federal advisory committee established to provide advice to the Commissioner.

The Antimicrobial Drugs Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders and makes appropriate recommendations to the Commissioner of Food and Drugs.

The Committee shall consist of a core of 13 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of infectious disease, internal medicine, microbiology, pediatrics, epidemiology or statistics, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members may include one technically qualified

member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Anti-InfectiveDrugsAdvisoryCommittee/ucm094132.htm> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please check <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: October 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22098 Filed 10–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Charter Renewal of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office of the

Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS) is hereby giving notice that the charter for the Secretary's Advisory Committee on Human Research Protections (SACHRP) has been renewed.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, J.D., Designated Federal Official, Executive Director, SACHRP, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240-453-8141; fax: 240-453-6909; email address: SACHRP@hhs.gov. Additional information is available on the SACHRP website at <https://www.hhs.gov/ohrp/sachrp-committee/index.html>.

SUPPLEMENTARY INFORMATION: SACHRP is a discretionary advisory committee established under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects within the authority of HHS.

SACHRP is authorized to establish subcommittees to provide assistance for accomplishing its mission and currently maintains two subcommittees. The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment. The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

On September 25, 2018, the Secretary approved renewal of the Committee's charter. The new charter was effected and filed with the appropriate Congressional committees and the Library of Congress on October 1, 2018. Renewal of the Committee's charter gives the Committee authorization to operate until October 1, 2020.

A copy of the Committee's charter is available on the Committee's website at <https://www.hhs.gov/ohrp/sachrp-committee/charter/index.html>.

A copy of the charter can also be obtained by accessing the Federal Advisory Committee Act database that is managed by the Committee Management Secretariat under the General Services Administration. The website for the FACA database is <https://facadatabase.gov>.

Dated: September 28, 2018.

Julia G. Gorey,

Executive Director, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. 2018-22167 Filed 10-10-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

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 meeting.

The meeting 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: Heart, Lung, and Blood Initial Review Group; NHLBI Mentored Clinical and Basic Science Review Committee.

Date: October 25-26, 2018.

Time: 10:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Westin Crystal City, 1800 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Keith A Mintzer, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7186, Bethesda, MD 20892-7924, 301-827-7949, mintzerk@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 4, 2018.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-22087 Filed 10-10-18; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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: National Institute on Aging, Special Emphasis Panel; NIA Clinical Trials.

Date: November 13, 2018.

Time: 12:01 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Maurizio Grimaldi, MD, Ph.D., Scientific Review Officer, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Room 2C218, Bethesda, MD 20892, 301-496-9374, grimaldim2@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: October 4, 2018.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018-22085 Filed 10-10-18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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