FOR FURTHER INFORMATION CONTACT:
Rachel Sherman, M.D., Deputy Commissioner for Medical Products and Tobacco, Office of Medical Products and Tobacco, Food and Drug Administration, White Oak Bldg. 1, HFD–40, Room 2307, Silver Spring, Maryland, 20993. Phone: 240–402–4474.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970; 60 FR 56606, November 9, 1995; 64 FR 36361, July 6, 1999; 72 FR 50112, August 30, 2007; 74 FR 41713, August 18, 2009; and 76 FR 45270, July 28, 2011) is amended to reflect the reorganization of the Office of Medical Products and Tobacco.

This reorganization establishes the Oncology Center of Excellence (OCE) to optimize an integrated cross-center regulatory approach and enhance the coordination of medical product development in oncology. Located within OMPT, OCE will work closely with the directors of the centers, the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), the Center for Devices and Radiological Health (CDRH), and all FDA staff involved in oncology efforts. The OCE will be responsible, in accordance with an Inter-Center Agreement between OCE, CBER, CDER, and CDRH, for the clinical portion of medical oncology and malignant hematopoietic applications involving drugs, biologics, and devices. Other functions of the OCE include: Harmonization of cancer-specific regulatory approaches; coordination of oncology-specific regulatory science initiatives and outreach; implementation of cross-center oncology-focused meetings; stakeholder engagement to the external community of other government agencies, industry, academia, professional societies, and patient advocacy groups; and communication with international regulatory agencies.

The Food and Drug Administration (FDA), Office of Medical Products and Tobacco (OMPT), has been restructured as follows:

DKK. Organization. The Office of Medical Products and Tobacco is headed by the Deputy Commissioner for Medical Products and Tobacco and includes the following organizational units and FDA Centers that, under the current structure, officially report to OMPT:

Office of Medical Products and Tobacco (DKK)
Office of Special Medical Products (DKKA)
Office of Pediatric Therapeutics (DKKAA)
Office of Orphan Products Development (DKKAB)
Office of Combination Products (DKKAD)

Center for Biologics Evaluation and Research (DKKB)
Center for Tobacco Products (DKKI)
Center for Drug Evaluation and Research (DKKN)
Center for Devices and Radiological Health (DKK)

Oncology Center of Excellence (DKK)

II. Delegations of Authority

Pending further delegation, directives, or orders by the Commissioner of Food and Drugs, all delegations and redelegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further redelegations, provided they are consistent with this reorganization.

III. Electronic Access

This reorganization is reflected in FDA’s Staff Manual Guide (SMG).

III. Electronic Access


Authority: 44 U.S.C. 3101.

Dated: July 17, 2017.

Thomas E. Price, Secretary of Health and Human Services.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.18 of the Department of Health and Human Services’ claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest, which is determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that the Department of Health and Human Services becomes entitled to recovery. The rate cannot be lower than the Department of Treasury’s current value of funds rate or the applicable rate determined from the “Schedule of Certified Interest Rates with Range of Maturities” unless the Secretary waives interest in whole or part, or a different rate is prescribed by statute, contract, or repayment agreement. The Secretary of the Treasury may revise this rate quarterly. The Department of Health and Human Services publishes this rate in the Federal Register.

The current rate of 10⅛%, as fixed by the Secretary of the Treasury, is certified for the quarter ended June 30, 2017. This rate is based on the Interest Rates for Specific Legislation, “National Health Services Corps Scholarship Program (42 U.S.C. 254o(b)(1)(A))” and “National Research Service Award Program (42 U.S.C. 288(c)(4)(B)).” This interest rate will be applied to overdue debt until the Department of Health and Human Services publishes a revision.

Dated: July 13, 2017.

David C. Horn, Director, Office of Financial Policy and Reporting.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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 contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Nonhuman Primate (NHP) Core Functional Genomics Laboratory for AIDS Vaccine Research and Development.

Date: August 31, 2017.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20852 (Telephone Conference Call).
DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Nursing Research.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Advisory Council for Nursing Research.

Date: September 12–13, 2017.

Open: September 12, 2017, 1:00 p.m. to 4:20 p.m.

Agenda: Discussion of Program Policies and Issues.

Place: National Institutes of Health, Building 31, 6th Floor, C Wing, Room 6, 31 Center Drive, Bethesda, MD 20892.


(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)


Natasha M. Copeland,
Program Analyst, Office of Federal Advisory Committee Policy.

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Implementation Cooperative Agreement (U01).

Date: August 8, 2017.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Chelsea D. Boyd, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 5601 Fishers Lane, Room 3F30B, Rockville, MD 20852, 240–669–5029, chelsea.boyd@nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIAID Clinical Trial Planning Grant (R34).

Date: August 8, 2017.

Time: 2:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Jane K. Battles, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 5601 Fishers Lane, Room 3F30B, Rockville, MD 20852, 240–669–5029, battlesja@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)


Natasha M. Copeland,
Program Analyst, Office of Federal Advisory Committee Policy.

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given for the meeting of the Substance Abuse and Mental Health Services Administration’s (SAMHSA) Center for Substance Abuse Prevention National Advisory Council (CSAP NAC) on August 10, 2017.

The Council was established to advise the Secretary, Department of Health and