

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products With Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

CEDAX (ceftibuten dihydrate) for oral suspension, 90 mg/5 mL and 180 mg/5 mL, are the subject of NDA 050686, held by Pernix Therapeutics LLC, and initially approved on December 20, 1995. CEDAX is indicated for the treatment of individuals with mild-to-moderate infections caused by susceptible strains of *Haemophilus influenzae* (including β -lactamase-producing strains), *Moraxella catarrhalis* (including β -lactamase-producing strains), or *Streptococcus pneumoniae* (penicillin-susceptible strains only) in acute bacterial exacerbations of chronic bronchitis; *H. influenzae* (including β -lactamase-producing strains), *M. catarrhalis* (including β -lactamase-producing strains), or *S. pneumoniae* (penicillin-susceptible strains only) in acute

bacterial otitis media; and *S. pyogenes* in pharyngitis and tonsillitis.

CEDAX (ceftibuten dihydrate) for oral suspension, 90 mg/5 mL and 180 mg/5 mL, are currently listed in the “Discontinued Drug Product List” section of the Orange Book.

Orchid Healthcare (a division of Orchid Pharma, Ltd.) submitted a citizen petition dated October 26, 2016 (Docket No. FDA–2016–P–3560), under 21 CFR 10.30, requesting that the Agency determine whether CEDAX (ceftibuten dihydrate) for oral suspension, 90 mg/5 mL and 180 mg/5 mL, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that CEDAX (ceftibuten dihydrate) for oral suspension, 90 mg/5 mL and 180 mg/5 mL, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of CEDAX (ceftibuten dihydrate) for oral suspension, 90 mg/5 mL and 180 mg/5 mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list CEDAX (ceftibuten dihydrate) for oral suspension, 90 mg/5 mL and 180 mg/5 mL, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to these drug products may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: March 30, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–06701 Filed 4–4–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; 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 Biomedical Imaging and Bioengineering.

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/or 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 grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Biomedical Imaging and Bioengineering.

Date: May 18, 2017.

Open: 8:30 a.m. to 12:00 p.m.

Agenda: Report from the Institute Director, other Institute Staff and scientific presentation.

Place: The William F. Bolger Center, Franklin Building, Classroom 1, 9600 Newbridge Drive, Potomac, MD 20854.

Closed: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: The William F. Bolger Center, Franklin Building, Classroom 1, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: David T. George, Ph.D., Acting Associate Director, Office of Research Administration, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Boulevard, Room 920, Bethesda, MD 20892.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: <http://www.nibib1.nih.gov/about/NACBIB/>

NACBIB.htm, where an agenda and any additional information for the meeting will be posted when available.

Dated: March 30, 2017.

David Clary,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-06666 Filed 4-4-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; 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 materials, 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 Minority Health and Health Disparities Special Emphasis Panel; National Institute on Minority Health and Health Disparities Small Business Review.

Date: May 18–May 19, 2017.

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

Agenda: To review and evaluate grant applications.

Place: Hilton Washington/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Richard C. Palmer, DRPH, Health Scientist Administrator, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20906, (301) 451-2432, *richard.palmer@nih.gov*.

Dated: March 30, 2017.

David Clary,
Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney 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 a meeting of the Board of Scientific Counselors, NIDDK.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Diabetes and Digestive and Kidney Diseases, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIDDK.

Date: April 27–28, 2017.

Time: 8:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, Building 10, 9th Floor South, Room 233, Solarium Conference Room, 10 Center Drive, Bethesda, MD 20892.

Contact Person: Michael W. Krause, Ph.D., Scientific Director, National Institute of Diabetes and Digestive and Kidney Diseases, National Institute of Health, Building 5, Room B104, Bethesda, MD 20892-1818, (301) 402-4633, *mwkrause@helix.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 30, 2017.

David Clary,
Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, through the use of automated collection techniques or other forms of information technology.

Proposed Project: Protection and Advocacy for Individuals With Mental Illness (PAIMI) Annual Program Performance Report (OMB No. 0930-0169)—Extension

The Protection and Advocacy for Individuals with Mental Illness (PAIMI) Act at 42 U.S.C. 10801 *et seq.*, authorized funds to the same protection and advocacy (P&A) systems created under the Developmental Disabilities Assistance and Bill of Rights Act of 1975, known as the DD Act (as amended in 2000, 42 U.S.C. 15001 *et seq.*). The DD Act supports the Protection and Advocacy for Developmental Disabilities (PADD) Program administered by the Administration on Intellectual and Developmental Disabilities (AIDD) within the Administration on Community Living. AIDD is the lead federal P&A agency. The PAIMI Program supports the same governor-designated P&A systems established under the DD Act by providing legal-based individual and systemic advocacy services to individuals with significant (severe) mental illness (adults) and significant