

treatment of Attention Deficit Hyperactivity Disorder (ADHD).

In a letter dated March 23, 2016, Novartis notified FDA that RITALIN LA (methylphenidate hydrochloride) extended-release capsules, 60 mg, were being discontinued, and FDA moved the drug product to the “Discontinued Drug Product List” section of the Orange Book.

Abhai, LLC, submitted a citizen petition dated April 19, 2017 (Docket No. FDA-2017-P-2496), under 21 CFR 10.30, requesting that the Agency determine whether RITALIN LA (methylphenidate hydrochloride) extended-release capsules, 60 mg, were withdrawn from sale for reasons of safety or effectiveness.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determined under § 314.161 that RITALIN LA (methylphenidate hydrochloride) extended-release capsules, 60 mg, were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that RITALIN LA (methylphenidate hydrochloride) extended-release capsules, 60 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of RITALIN LA (methylphenidate hydrochloride) extended-release capsules, 60 mg, 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 We have reviewed the available evidence and determined that this drug product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list RITALIN LA (methylphenidate hydrochloride) extended-release capsules, 60 mg, 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 RITALIN LA (methylphenidate hydrochloride) extended-release capsules, 60 mg, 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 this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 28, 2017.

Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017-18817 Filed 9-5-17; 8:45 am]

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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 Initial Review Group; Clinical Aging Review Committee.

Date: October 5–6, 2017.

Time: 3:30 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Alicja L. Markowska, Ph.D., DSC, National Institute on Aging, National Institutes of Health, Gateway Building 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301-496-9666, markowska@nia.nih.gov.

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

Dated: August 30, 2017.

Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-18805 Filed 9-5-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, September 12, 2017, 1:00 p.m. to September 12, 2017, 4:00

p.m., National Cancer Institute—Shady Grove, 9609 Medical Center Drive, Conference Room TE406 and TE408, Rockville, MD, 20850 (Virtual Meeting) which was published in the **Federal Register** on August 14, 2017, 82 FR 37885.

The meeting notice is amended to change the times of the open and closed sessions. The open session will end at 2:15 p.m. The closed session will begin at 2:30 p.m. and end at 3:30 p.m. The meeting is partially closed to the public.

Dated: August 30, 2017.

Melanie J. Pantoja,
Program Analyst Office of Federal Advisory Committee Policy.

[FR Doc. 2017-18804 Filed 9-5-17; 8:45 am]

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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 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 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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR-15-067: NIDDK Multi-Center Clinical Study Cooperative Agreement (U01): CKD and Bone Mineral Disorders in Children.

Date: October 2, 2017.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Najma S. Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7349, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 594-8894, begumn@nidk.nih.gov.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, PAR-16-126: High Impact, Interdisciplinary Science in NIDDK