

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0002]

Determination That BIAVIN XL Oral Tablets Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug

Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6207, Silver Spring, MD 20993-0002, 301-796-8363.

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 approved under an ANDA procedure. ANDA sponsors 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. Sponsors of ANDAs 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 generally known as the

“Orange Book.” Under FDA regulations, a drug is 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of the drug’s NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

Application No.	Drug	Applicant
NDA 050775	BIAVIN XL Tablet; Oral 500 mg	AbbVie Inc., 1 North Waukegan Road, North Chicago, IL 60064

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. 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: August 21, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-21236 Filed 8-26-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; 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 Board of Scientific Counselors, NIA.

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 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 ON AGING, 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, NIA.

Date: October 13, 2015.

Closed: 7:30 a.m. to 7:45 a.m.

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

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room, 251 Bayview Boulevard, Baltimore, MD 21224.

Open: 7:45 a.m. to 11:30 a.m.

Agenda: Committee discussion, individual presentations, laboratory overview.

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room, 251 Bayview Boulevard, Baltimore, MD 21224.

Closed: 11:30 a.m. to 1:00 p.m.

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

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room, 251 Bayview Boulevard, Baltimore, MD 21224.

Open: 1:00 p.m. to 5:00 p.m.

Agenda: Committee discussion, individual presentations, laboratory overview.

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room, 251 Bayview Boulevard, Baltimore, MD 21224.

Closed: 5:00 p.m. to 6:00 p.m.

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

Place: National Institute on Aging, Biomedical Research Center, 3rd Floor Conference Room, 251 Bayview Boulevard, Baltimore, MD 21224.

Contact: Luigi Ferrucci, Ph.D., MD, Scientific Director, National Institute on Aging, 251 Bayview Boulevard, Suite 100, Room 4C225, Baltimore, MD 21224, 410-558-8110, LF27Z@NIH.GOV.

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

Dated: August 21, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-21221 Filed 8-26-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary & Integrative Health 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: National Center for Complementary and Integrative Health Special Emphasis Panel "Clinical Research on Mind-Body Interventions (R34)".

Date: November 6, 2015.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Democracy Two, Suite 401, 6707 Democracy Boulevard, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Hungyi Shau, Ph.D., Scientific Review Officer, National Center for Complementary and Integrative Health, National Institutes of Health, 6707 Democracy Boulevard, Suite 401, Bethesda, MD 20892, 301-480-9504, Hungyi.Shau@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Alternative Medicine, National Institutes of Health, HHS)

Dated: August 21, 2015.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-21223 Filed 8-26-15; 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 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 on Aging Special Emphasis Panel; Sedentary Behavior and Aging.

Date: September 24, 2015.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute on Aging, Gateway Building, 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Isis S. Mikhail, DRPH, MD, MPH, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301-402-7704, MIKHAILI@MAIL.NIH.GOV.

Name of Committee: National Institute on Aging Special Emphasis Panel; CVD Disease in Aging.

Date: September 30, 2015.

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

Agenda: To review and evaluate contract proposals.

Place: National Institute on Aging, Gateway Building, 2C212, 7201 Wisconsin

Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Alicja L. Markowska, DSC, Ph.D., Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Suite 2C212, 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 24, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-21241 Filed 8-26-15; 8:45 am]

BILLING CODE 4140-01-P

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 16, 2015, 01:00 p.m. to September 16, 2015, 03:00 p.m., National Cancer Institute Shady Grove, 9609 Medical Center Drive, Rockville, MD, 20850 which was published in the **Federal Register** on August 18, 2015, 80FR50016.

This meeting is being amended to change the end time of the Open Session on September 16, 2015 from 2:00 p.m. to 1:30 p.m. and the Closed Session time from 2:00 p.m. to 3:30 p.m. to 1:30 p.m. to 3:00 p.m. The meeting is partially Closed to the public.

Dated: August 21, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-21225 Filed 8-26-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Integrative Health; 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