

neurological condition (*i.e.*, Hunt and Hess Grades I through V).

In a letter dated May 4, 2020, Arbor notified FDA that NYMALIZE (nimodipine), oral solution, 3 mg/mL was being discontinued, and FDA moved the drug product to the “Discontinued Drug Product List” section of the Orange Book. As indicated in the Orange Book, Arbor markets a 6 mg/mL strength of NYMALIZE (nimodipine) oral solution, which was approved through NDA 203340/S-011 on April 8, 2020.

Annora Pharma Private Limited submitted a citizen petition dated June 6, 2020 (Docket No. FDA-2020-P-1511) and Windels Marx Lane & Mittendorf, LLC submitted a citizen petition dated June 10, 2020 (Docket No. FDA-2020-P-1549), both under 21 CFR 10.30, requesting that the Agency determine whether NYMALIZE (nimodipine), oral solution, 3 mg/mL was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petitions and comments submitted to the dockets and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that NYMALIZE (nimodipine), oral solution, 3 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that NYMALIZE (nimodipine), oral solution, 3 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NYMALIZE (nimodipine), oral solution, 3 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events.

A comment submitted by Arbor suggests that it was necessary to discontinue marketing the 3 mg/mL strength to mitigate potential confusion between the 3 mg/mL and 6 mg/mL strengths of NYMALIZE (nimodipine), oral solution. FDA disagrees. While discontinuation of the 3 mg/mL strength is one way to reduce the risk of confusion between the two strengths, there are other (often-used) mitigation strategies that may be employed to reduce the risk of confusion among multiple marketed strengths of a drug that could have been used by Arbor. Arbor’s comment also states that FDA should find that the 3 mg/mL strength was discontinued for safety reasons because the Agency made similar determinations for BREVIBLOC (esmolol hydrochloride) injection, 250 mg/mL, 10-mL ampule, and the original

formulation of PROTONIX I.V. (pantoprazole sodium) for injection. Our finding that the 3 mg/mL strength for NYMALIZE was not withdrawn from sale for reasons of safety is factually distinguishable from BREVIBLOC and PROTONIX I.V.

Based on a thorough evaluation of the information we have available to us and the latest version of the approved labeling for NYMALIZE (nimodipine), oral solution, 3 mg/mL, we have determined that this drug product would be considered safe and effective if it were reintroduced to the market today. Certain labeling changes should be considered to prevent future medication errors due to the presence of two different strengths of NYMALIZE (nimodipine), oral solution, on the market (*i.e.*, NYMALIZE (nimodipine), oral solution, 3 mg/mL and NYMALIZE (nimodipine), oral solution, 6 mg/mL), but no existing safety signals or efficacy concerns make labeling changes necessary.

Accordingly, the Agency will continue to list NYMALIZE (nimodipine), oral solution, 3 mg/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 NYMALIZE (nimodipine), oral solution, 3 mg/mL, 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: February 10, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-03083 Filed 2-16-21; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Fellowships: Surgical Sciences, Biomedical Imaging and Bioengineering.

Date: March 16, 2021.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Yuanna Cheng, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, MSC 7814, Bethesda, MD 20892, (301) 435-1195, Chengy5@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR20-117: Maximizing Investigators’ Research Award (MIRA) for Early Stage Investigators (R35—Clinical Trial Optional).

Date: March 17–18, 2021.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Guoqin Yu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 435-1276, guoqin.yu@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Immune Responses and Vaccines to Microbial Infections.

Date: March 17–18, 2021.

Time: 9:30 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Barna Dey, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3184, Bethesda, MD 20892, 301-451-2796, bdey@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Healthcare Delivery and Methodologies.

Date: March 17, 2021.

Time: 9:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karen Nieves Lugo, MPH, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, Bethesda, MD 20892, 301-594-9088, karen.nieveslugo@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR-20-131: Mammalian Models for Translational Research.

Date: March 17, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Malaya Chatterjee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6192, MSC 7804, Bethesda, MD 20892, 301-806-2515, chatterm@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Biomedical Data Repositories and Knowledgebases.

Date: March 17-18, 2021.

Time: 10:00 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joseph Thomas Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301-408-9694, petersonjt@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Digestive system inflammatory disease.

Date: March 17, 2021.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ganesan Ramesh, Ph.D., Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 827-5467, ganesan.ramesh@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Cancer Prevention.

Date: March 17, 2021.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Mehrdad Mohseni, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5211, MSC 7854, Bethesda, MD 20892, 301-435-0484, mohsenim@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 20-153: NIH Science Education Partnership Award (SEPA) (R25—Clinical Trial Not Allowed).

Date: March 17, 2021.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jonathan Arias, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5170, MSC 7840, Bethesda, MD 20892, 301-435-2406, ariasj@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: February 10, 2021.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-03098 Filed 2-16-21; 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 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 Mental Health Special Emphasis Panel; NIMH Pilot Effectiveness Trials for Treatment, Preventive, and Services Interventions (R34).

Date: March 10, 2021.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Serena Chu, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6000, MSC 9606, Bethesda, MD 20852, 301-500-5829, serena.chu@nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Computational Psychiatry Review Meeting (R01, R21).

Date: March 11, 2021.

Time: 11:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6149, MSC 9608, Bethesda, MD 20892-9608, 301-443-4525, steinerr@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Pharmacologic or Device-based Interventions for the Treatment of Mental Disorders.

Date: March 12, 2021.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Serena Chu, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6000, MSC 9606, Bethesda, MD 20852, 301-500-5829, serena.chu@nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: February 10, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021-03113 Filed 2-16-21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; 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