

§ 314.161 that ANJESO (meloxicam) solution, 30 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ANJESO (meloxicam) solution, 30 mg/mL, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of ANJESO (meloxicam) solution, 30 mg/mL, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list ANJESO (meloxicam) solution, 30 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 ANJESO (meloxicam) solution, 30 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: August 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17263 Filed 8–10–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Mental Health Council.

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 open session will be videocast and can be accessed from the NIH Videocasting and

Podcasting website (<http://videocast.nih.gov/>).

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 Mental Health Council.

Date: September 7–8, 2023.

Closed: September 7, 2023, 12:00 p.m. to 4:30 p.m.

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

Place: National Institutes of Health, NSC Building, Rooms 1255 & 1265, 6001 Executive Blvd., Rockville, MD 20852.

Open: September 8, 2023, 12:00 p.m. to 4:00 p.m.

Agenda: Presentation of the NIMH Director's Report and discussion of NIMH programs.

Place: National Institutes of Health, Neuroscience Center, Rooms 1145 & 1155, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Tracy L. Waldeck, Ph.D., Director, Division of Extramural Activities, National Institute of Mental Health, NIH, DHHS Neuroscience Center, 6001 Executive Boulevard, Bethesda, MD 20892, (301) 480–6833, tracy.waldeck@nih.gov

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their 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: www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/index.shtml, where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: August 8, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–17255 Filed 8–10–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Deafness and Other Communication Disorders Advisory Council.

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 open session will be videocast and can be accessed from the NIH Videocasting website (<http://videocast.nih.gov/>).

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 Deafness and Other Communication Disorders Advisory Council.

Date: September 14–15, 2023.

Closed: September 14, 2023, 9:00 a.m. to 11:00 a.m.

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

Place: Porter Neuroscience Research Center, Building 35A, Room 620/630, 35 Convent Drive, Bethesda, MD 20892.

Open: September 14, 2023, 1:00 p.m. to 4:35 p.m.

Agenda: Staff reports on divisional, programmatic, and special activities.

Place: Porter Neuroscience Research Center, Building 35A, Room 620/630, 35 Convent Drive, Bethesda, MD 20892.

Closed: September 15, 2023, 9:00 a.m. to 9:40 a.m.

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