

§ 314.161 that ANJESO (meloxicam) solution, 30 mg/mL, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that ANJESO (meloxicam) solution, 30 mg/mL, was withdrawn for reasons of safety or effectiveness.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 We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.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]

BILLING CODE 4164–01–P

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]

BILLING CODE 4140–01–P

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.

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

Open: September 15, 2023, 10:00 a.m. to 11:50 a.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.

Contact Person: Rebecca Wagenaar-Miller, Ph.D., Director, Division of Extramural Activities, NIDCD/NIH, 6001 Executive Boulevard, Bethesda, MD 20892, (301) 496-8693, rebecca.wagenaar-miller@nih.gov.

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.

In the interest of security, NIH has procedures at <https://www.nih.gov/about-nih/visitor-information/campus-access-security> for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. Information is also available on the Institute's/Center's home page: <https://www.nidcd.nih.gov/about/advisory-council>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: August 8, 2023.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-17252 Filed 8-10-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; 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 Council for Nursing Research.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below.

Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should

notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: <https://videocast.nih.gov/watch=51158>.

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 Advisory Council for Nursing Research.

Date: September 12, 2023.

Open: 9:00 a.m. to 10:30 a.m.

Agenda: Call to Order and Opening Remarks, NINR Director's Report, NCATS Updates, Priorities, and Opportunities for Collaboration.

Place: National Institutes of Health, Building 31, C-Wing, Sixth Floor, Rooms A&B, 31 Center Drive, Bethesda, MD 20892 (Hybrid Meeting).

Open: 10:45 a.m. to 12:30 p.m.

Agenda: Community Partnerships to Advance Science for Society (CompPASS) Initiative, Artificial Intelligence/Machine Learning Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD) Program.

Place: National Institutes of Health, Building 31, C-Wing, Sixth Floor, Rooms A&B, 31 Center Drive, Bethesda, MD 20892 (Hybrid Meeting).

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

Agenda: CSR Initiatives Related to Strengthening Review Panel Diversity, Addressing Bias, and Evaluating Panel Quality, Implementing a Maternal health and Pregnancy Outcomes Vision for Everyone (IMPROVE) Initiative, Concepts, Council Open Discussion, Adjournment.

Place: National Institutes of Health, Building 31, C-Wing, Sixth Floor, Rooms A&B, 31 Center Drive, Bethesda, MD 20892 (Hybrid Meeting).

Closed: 3:00 p.m. to 3:20 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, C-Wing, Sixth Floor, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Elizabeth Tarlov, Ph.D., RN, Director, Division of Extramural Science Programs (DESP), National Institute of Nursing Research, Bethesda, MD 20892, (301) 594-1580, elizabeth.tarlov@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 an organization 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 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 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.

In the interest of security, NIH has procedures at <https://www.nih.gov/about-nih/visitor-information/campus-access-security> for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: <https://www.ninr.nih.gov/aboutninr/nacnr>, where an agenda and any additional information for the meeting will be posted when available. (Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: August 8, 2023.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023-17253 Filed 8-10-23; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Manufacture, Distribution, Sale and Use of T-Cell-Based Immunotherapies for Solid Tumors

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and the National Cancer Institute, both institutes of the National Institutes of Health, Department of Health and Human Services, are contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to EnZeta Immunotherapies, Inc. of the State of Delaware.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center