- To update prescribing information and, if applicable, FDA-approved patient labeling (*e.g.,* Patient Package Insert, Medication Guide, Instructions for Use) with safety information that has been updated in the reference product labeling and is applicable to one or more indications for which the biosimilar or interchangeable biosimilar product is licensed
- To receive licensure for an additional indication
- To remove an approved indication
- To receive an initial determination of interchangeability

This draft guidance is intended to help applicants identify the appropriate classification category and review goal date of the supplement being submitted. Section I.A. of the commitment letter associated with the BsUFA III sets forth these supplement classification categories and their associated review performance goals. The full text of the proposed BsUFA III Commitment Letter can be found on the Agency's web page ''BsUFA III: Fiscal Years 2023–2027,'' available at *https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-iii-fiscal-years-2023-2027*.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Classification Categories for Certain Supplements Under BsUFA III.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information pertaining to the Biosimilar User Fee Program and for the submission of biologics license applications under section 351(k) of the PHS Act regarding biosimilar product applications, interchangeable biosimilar product applications, and supplemental applications have been approved under OMB control number 0910–0718. The collections of information in 21 CFR 201.56 and 201.57 for the submission of labeling have been approved under OMB control number 0910–0572. The collections of information pertaining to Medication Guides for prescription human drug and biological products have been approved under OMB control number 0910–0393. The collections of information in 21 CFR part 601 for the submission of biologics license applications, supplemental applications, and Form FDA 356h have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: August 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–17262 Filed 8–10–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–0915]

Determination That ANJESO (Meloxicam) Solution, 30 Milligrams/Milliliter, Was 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 or Agency) has determined that ANJESO (meloxicam) solution, 30 milligrams (mg)/milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for meloxicam solution, 30 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Donna Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6213, Silver Spring, MD 20993–0002, 301–796–3600, *Donna.Tran@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act 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 known generally as the ''Orange Book.'' Under FDA regulations, drugs are 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

ANJESO (meloxicam) solution, 30 mg/mL, is the subject of NDA 210583, held by Baudax Bio, Inc., and initially approved on February 20, 2020. ANJESO is indicated for use in adults for the management of moderate-to-severe pain, alone or in combination with non-nonsteroidal anti-inflammatory drug analgesics. ANJESO (meloxicam) solution, 30 mg/mL, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book.

Emprise Pharma, LLC submitted a citizen petition dated March 11, 2023 (Docket No. FDA–2023–P–0915), under 21 CFR 10.30, requesting that the Agency determine whether ANJESO (meloxicam) solution, 30 mg/mL, was 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 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, programmatical, 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.