

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2023-D-1954]

**Classification Categories for Certain Supplements Under the Biosimilar User Fee Amendments of 2022; Draft Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Classification Categories for Certain Supplements Under BsUFA III.” This draft guidance provides recommendations for applicants and FDA review staff on classification categories A, B, C, D, E, and F for original and resubmitted prior approval supplements submitted to approved applications under the Public Health Service Act (PHS Act). The commitment letter associated with the Biosimilar User Fee Amendments of 2022 (BsUFA III) sets forth these supplement classification categories and their associated review performance goals. This draft guidance is intended to help applicants identify the appropriate classification category and review goal date of the supplement being submitted.

**DATES:** Submit either electronic or written comments on the draft guidance by October 10, 2023 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your

comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2023-D-1954 for “Classification Categories for Certain Supplements Under BsUFA III.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80

FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 1132, Silver Spring, MD 20993, 301-796-1042, [sandra.benton@fda.hhs.gov](mailto:sandra.benton@fda.hhs.gov); or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Classification Categories for Certain Supplements Under BsUFA III.” This draft guidance provides recommendations for applicants and FDA review staff on classification categories A, B, C, D, E, and F for original and resubmitted prior approval supplements (hereafter “supplements”) submitted to approved applications under section 351(k) of the PHS Act (42 U.S.C. 262(k)).

These classification categories pertain to supplements for biosimilar and interchangeable biosimilar products seeking the following:

- 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.*

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**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](mailto: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-steroidal 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