

remarks for this meeting. We also welcome additional comments or presentation materials to be submitted to the docket for consideration.

III. Participating in the Public Meeting

Registration: Please visit the following website for additional information and to register for the public meeting: <https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops>.

The virtual public meeting is free and open to the public, but registration is necessary to attend. General registration will remain open until November 5, 2026. Individuals who want to speak during the public comment period must register by October 26, 2026. Same-day registration is not allowed. Instructions for joining the virtual meeting will be provided upon registration.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the public comment session. We will do our best to accommodate all requests to make public comments. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will notify participants in advance by November 4, 2026. All requests to make oral presentations must be received by the close of speaker registration on October 26, 2026. All presentations must be given orally; we cannot accommodate slides or visuals on the virtual platform. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Notice of this meeting is given pursuant to 21 CFR 10.65.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-20720 Filed 10-8-26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-10396]

Amneal Pharmaceuticals of New York, LLC; Withdrawal of Approval of Abbreviated New Drug Application for Celecoxib Capsules, 50 Milligrams, 100 Milligrams, 200 Milligrams, and 400 Milligrams

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of abbreviated new drug application (ANDA) 208833 for Celecoxib capsules, 50 milligrams (mg), 100 mg, 200 mg, and 400 mg, held by Amneal Pharmaceuticals of New York, LLC, 50 Horseblock Rd., Brookhaven, NY 11719 (Amneal). Amneal requested withdrawal of approval of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of October 9, 2026.

FOR FURTHER INFORMATION CONTACT:

Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: On May 31, 2018, FDA approved ANDA 208833 for Celecoxib capsules, 50 mg, 100 mg, 200 mg, and 400 mg. The reference listed drug (RLD) is Celebrex (celecoxib) capsules, 50 mg, 100 mg, 200 mg, and 400 mg, approved under new drug application (NDA) 020998. According to annual reports filed with the Agency, the drug products approved under ANDA 208833 have not been commercially manufactured since the ANDA's approval in May 2018.

In a letter dated September 16, 2021, FDA notified Amneal that it had significant concerns about the validity and reliability of bioequivalence and bioavailability data generated by a contract research organization that had conducted studies relied on by ANDA 208833 and instructed Amneal to re-conduct bioequivalence studies for ANDA 208833 at an alternate site. The September 16, 2021, letter also informed Amneal that FDA was changing the therapeutic equivalence evaluation code for Amneal's Celecoxib capsules to "BX."¹ In response to multiple inquiries from the Agency, Amneal committed (on October 14, 2021, October 6, 2022, and September 18, 2023) to submitting new bioequivalence studies to enable FDA to make a full evaluation of therapeutic equivalence between Amneal's Celecoxib capsules and the RLD.

¹ The code BX is assigned to specific drug products for which the data that have been reviewed by the Agency are insufficient to determine therapeutic equivalence under the policies stated in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") preface, available at <https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface>. Accessed September 16, 2026.

On February 22, 2024, FDA requested that Amneal describe its efforts to conduct new bioequivalence studies and provide a timeline for completing and submitting these studies and requested that Amneal agree not to distribute the drug products covered by ANDA 208833 until they were shown to be bioequivalent to the RLD based on bioequivalence studies conducted at an alternate site. On March 18, 2024, Amneal submitted a general correspondence communicating its intent to submit new bioequivalence studies by March 2025 and agreeing not to distribute the drug products covered by ANDA 208833 until these studies were completed and were found to demonstrate bioequivalence to the RLD. In November 2024, Amneal's Celecoxib capsules, 50 mg, 100 mg, 200 mg, and 400 mg, approved under ANDA 208833, were moved to the discontinued section of the publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (known generally as the "Orange Book").

In light of the concerns about the validity and reliability of the bioequivalence data on which ANDA 208833 relied for approval, the absence of new bioequivalence studies demonstrating the bioequivalence of Amneal's Celecoxib capsules to the RLD is a potential problem that is sufficiently serious that the drug should be removed from the market.

As of May 28, 2025, Amneal had not submitted new bioequivalence studies demonstrating the bioequivalence of its Celecoxib capsules to the RLD. Accordingly, FDA suggested that Amneal voluntarily seek withdrawal of approval of ANDA 208833 for Celecoxib capsules under § 314.150(d) (21 CFR 314.150(d)) and note that it was waiving its opportunity for a hearing under § 314.150(a).

In a request for withdrawal of approval submitted June 6, 2025, as amended on June 27, 2025, and July 9, 2025, Amneal requested that FDA withdraw approval of ANDA 208833 for Celecoxib capsules under § 314.150(d) and waived its opportunity for a hearing. Amneal stated that its request for withdrawal of approval was based on Amneal's business decision.

For the reasons discussed above, and in accordance with the applicant's request, approval of ANDA 208833 for Celecoxib capsules, 50 mg, 100 mg, 200 mg, and 400 mg, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of Celecoxib capsules, 50 mg, 100 mg, 200 mg, and 400 mg, into interstate commerce without an approved application is illegal and subject to

regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–20758 Filed 10–8–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7426]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Expanded Access to Investigational Drugs for Treatment Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 9, 2026.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0814. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Expanded Access to Investigational Drugs for Treatment Use

OMB Control Number 0910–0814—Revision

This information collection helps support implementation of Food and Drug Administration (FDA, agency, us or we) regulations, as well as agency forms and associated guidance. Provisions in section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) set forth general requirements relating to expanded access to unapproved therapies and diagnostics. Sometimes called “*compassionate use*,” expanded access (EA) is a potential pathway for a patient with an immediately life-threatening condition, or serious disease or condition, to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. To facilitate expanded access to investigational drugs by patients, regulations in 21 CFR part 312, subpart I; *Expanded Access to Investigational Drugs for Treatment Use* (21 CFR 312.300–21 CFR 312.320), establish submission requirements that include demonstrating certain criteria have been met, and that content and format requirements have been satisfied. Information collection associated with all other provisions in 21 CFR 312 are included in OMB control no. 0910–0014 unless specifically noted.

The information collection utilizes Form FDA 3926 entitled, “Individual Patient Expanded Access—Investigational New Drug Application (IND).” Form FDA 3926 requires the completion of data fields that enable us to uniformly collect the minimum information necessary from licensed physicians or industry who want to request expanded access as prescribed in the applicable regulations. We are revising Form FDA 3926 as follows:

- In Field 6, “Treatment Information,” delete the data element “Investigational Drug Name” and replace it with “Planned Date of Treatment Initiation” and revise the data element “FDA Review Division (if known)” to read “FDA Office/Review Division (if known).”
- In Field 9, replace the heading “Contents of Submission” with “Contents of Submission (follow-up/additional submissions only).”

Upon OMB approval of these modifications, we will revise accompanying instructions. Respondents may continue to use either Form FDA 3926 or Form FDA 1571, Investigational New Drug Application

(IND) (approved under OMB control number 0910–0014), for all types of IND submissions to satisfy requirements in 21 CFR 312.23(a). FDA considers a completed Form FDA 3926 signed by the physician and checked in the box in Field 10.a (*Request for Authorization to use Form FDA 3926*) to be a waiver request in accordance with 21 CFR 312.10.

We continue to maintain an expanded access website (www.fda.gov/news-events/public-health-focus/expanded-access), including associated guidance documents. Regulations in 21 CFR 312.145 (approved in control. 0910–0014) provide for the issuance of guidance documents by FDA to assist respondents in complying with applicable regulations in 21 CFR 312. The guidance document “Expanded Access to Investigational Drugs for Treatment Use: Questions and Answers,” (April 2026), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expanded-access-investigational-drugs-treatment-use-questions-and-answers>, supplements reporting instructions applicable to Form FDA 3926.

Description of Respondents:

Respondents to the collection of information are licensed physicians who request patient access to investigational drugs.

In the **Federal Register** of July 28, 2026 (91 FR 47248), we published a 60-day notice requesting public comment on the proposed collection of information. One comment letter was received, containing multiple comments.

One comment was supportive of the proposed revisions to Form FDA 3926, stating that the changes to the form were appropriate and should make it easier to access investigational therapies efficiently. Other comments stated that the information collected through expanded access should not merely satisfy administrative requirements and suggested that the information collection should be used to facilitate the collection of meaningful and standardized information, including safety data, patient-reported outcomes, biomarker information, and other real-world clinical observations. We appreciate the comment and will take the concerns raised into consideration in future evaluations. No changes were made to the information collection or burden estimates as a result of the comment.

We estimate the burden of the collections of information as follows: