

ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
606.171 Reporting of product deviations by licensed manufacturers, unlicensed registered blood establishments and transfusion services	3486	2,455	6.630	16,277	2.0	32,554
1271.350(b) Reporting requirements (human cells tissues and cellular and tissue-based products)	3486	86	2.465	212	2.0	424
1271.350(b) CBER addendum report	² 3486A	127	6.50	826	0.25	207
Total				17,818		34,191

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² Five percent of the number of respondents ((2,455 + 86) × 0.05 = 127).

Following publication of the 60-day notice, the Agency identified a multiplication and rounding error in the burden calculations. The corrected estimates are reflected in this 30-day notice. This revision does not reflect a substantive or programmatic change to the information collection. Our estimated burden for the information collection reflects an overall increase of approximately 4,612 hours and a corresponding increase of 2,642 responses. We attribute this adjustment to an increase in the number of product deviations we received in FY 2024 from licensed manufacturers, unlicensed registered blood establishments and transfusion services under § 606.171. This is likely due to the issuance of the revised guidance document titled, “Biological Product Deviation Reporting for Blood and Plasma Establishments” (85 FR 14682; March 13, 2020), which provided blood and plasma establishments with revised recommendations related to BPD reporting.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0053]

Challenges and Solutions in Lot-Level Food Traceability; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting titled “Challenges and Solutions in Lot-Level Food Traceability.” The purpose of the meeting is to provide a forum for

the public to share information on continued implementation of the “Requirements for Additional Traceability Records for Certain Foods” final rule and areas of concern, especially as they relate to lot-level tracking, and identify potential flexibilities to support compliance.

DATES: The public meeting will be held on November 6, 2026, from 12:00 p.m. to 3:30 p.m. Eastern Time. Either electronic or written comments on this public meeting must be submitted by December 6, 2026. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held virtually, and login instructions will be provided at registration.

You may submit comments as follows. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 6, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2014–N–0053 for “Challenges and Solutions in Lot-Level Food Traceability: Public Meeting.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Katherine Vierk, Office of Surveillance Strategy and Risk Prioritization, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2122, Katherine.Vierk@fda.hhs.gov; or Alissa Van Wie, Office of Regulations and International Programs, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378, Alissa.vanwie@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA final rule, “Requirements for Additional Traceability Records for Certain Foods” (87 FR 70910, November 21, 2022) (Food Traceability Rule), establishes enhanced recordkeeping requirements for those who manufacture, process, pack, or hold foods on FDA’s Food Traceability List (FTL). The Food Traceability Rule requires lot-level tracking for foods on the FTL. Businesses that perform specific activities are required to assign unique codes, known as Traceability Lot Codes (TLCs), that must be passed along unchanged (unless the food is transformed) as the food moves through the supply chain. Entities that handle foods on the FTL are required to record Key Data Elements (KDEs), such as the TLC, when they perform specific

Critical Tracking Events (CTEs), such as initial packing, transformation, and shipping. Lot-level tracking enables rapid tracing of contaminated foods during recall events, allowing FDA to identify the source of the food faster, narrowing the scope of recalls and removing affected product from the supply chain more quickly, resulting in fewer foodborne illnesses and deaths.

The original compliance date for all persons subject to the recordkeeping requirements of the Food Traceability Rule was January 20, 2026. FDA proposed to extend the compliance date for the rule by 30 months to July 20, 2028 (90 FR 38084, August 7, 2025). Subsequently, the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act of 2026 (Pub. L. 119-37) (Continuing Appropriations Act) directed FDA not to enforce the Food Traceability Rule prior to that same date of July 20, 2028. FDA intends to comply with this Congressional directive.

Section 780 of the Continuing Appropriations Act also directed FDA to engage quarterly with regulated entities to identify and implement, as appropriate, additional flexibilities for satisfying the Food Traceability Rule’s lot-level tracking requirement. The public meeting announced in this notice is part of a series of engagements being held to fulfill that directive. As part of the same series of engagements, we previously held a public meeting on June 15, 2026. Prior to that public meeting, we published a discussion paper titled “Identifying Additional Flexibilities for Satisfying the Food Traceability Rule’s Lot-Level Tracking Requirement” (<https://www.regulations.gov/document/FDA-2014-N-0053-1371>). We provided an opportunity for stakeholders to submit feedback on the ideas presented in the discussion paper. We received 26 comments on the discussion paper from industry, trade associations, and technology partners. We have provided a high-level summary of those comments below. All comments can be accessed by searching Docket No. FDA-2014-N-0053 on <https://www.regulations.gov>.

TLC Flexibilities: Many commenters supported flexibility for identification of TLCs by allowing for a reasonable range of TLCs or inferred TLCs to be used when shipping FTL foods from distribution to retail. With both options, several stakeholders noted the need for these flexibilities to be accompanied by guardrails, including documented operational practices, validation exercises, and an understanding that the

reasonable range of TLCs or inferred TLCs be limited to the fewest TLCs possible. However, some commenters expressed concern that a flexibility for TLCs could reduce product-specific traceability and unnecessarily broaden the scope of a recall.

Flexibility for Eatches, Returns, Reclamations, and Food Waste Recovery: There was broad support from stakeholders to provide flexibilities for eatches, returns, and reclamations as these account for a relatively small amount of product that has often been separated from the original case. There was also support for additional clarity on the exemption for donated food to ensure that food waste recovery is not discouraged due to the requirements of the rule.

Intracompany Shipments: Some stakeholders noted continued confusion around the required records for intracompany shipments and requested clarification on these requirements. Some stakeholders also requested flexibility to track incoming and outgoing TLCs with records of internal movements of FTL foods that would be available upon request.

Retail Transformer Shipments: There was broad support from commenters for a simplified, modified recordkeeping framework for retail-kitchen-to-affiliated-store shipments.

Data Standardization: There was strong support among stakeholders for FDA to recognize GS1 as an acceptable data standard for use in identifying shipments of FTL foods. FDA recently posted a FAQ on data standards, which is available at <https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma-food-traceability-rule#TPTS3>.

II. Topics for Discussion at the Public Meeting

The goal of this public meeting is for FDA to hear stakeholder perspectives on lot-level food traceability efforts and implementation challenges facing industry. FDA is interested in learning more about the challenges and potential solutions for satisfying the Food Traceability Rule’s lot-level tracking requirements.

Specifically, we are interested in feedback on the potential flexibilities in achieving compliance with the rule that have been identified to date and on the feedback received on the discussion paper in the docket. We encourage those participating in this public meeting to consider the questions posed in the discussion paper, stakeholder responses to these questions submitted to the docket, and any new ideas regarding flexibilities as you develop your

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.

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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