finished dosage form of an OTC monograph drug; (4) facilities that registered but did not have an active OTC monograph drug product listing associated in their registration profile were not manufacturing or processing such drug products; (5) a portion of facilities that newly registered during the fee liable period are estimated to be in arrears based on a review of the prior 3-year average of newly registered facilities in arrears; and (6) facilities that, at the close of FY 2025, remain on the arrears list for failure to satisfy the FY 2023, FY 2024, or FY 2025 facility fee are likely to be placed on the FY 2026 arrears list as well.

Based on the above-referenced factors and assumptions, FDA estimates there will be 1,039 OMUFA fee-paying units. The Agency estimates that 54 percent ($1{,}039 \times 0.54 = 561$, rounded) will incur the MDF fee and 46 percent ($1{,}039 \times 0.46 = 478$, rounded) will incur the CMO fee.

To determine the number of full fee-paying equivalents (the denominator) to be used in setting the OMUFA fees, FDA assigns a value of 1 to each MDF (561) and a value of ⅔ to each CMO ($478 \times ⅔ = 319$) for a full facility equivalent of 880 (rounded). The target fee revenue of $16,885,000 is then divided by 880 for an MDF fee of $19,188 and a CMO fee of $12,792.

IV. Fee Schedule for FY 2026

The fee rates for FY 2026 are displayed in table 4.

TABLE 4—FEE SCHEDULE FOR FY 2026

Fee category	FY 2026 fee rates
MDF	$19,188
CMO	12,792

V. Electronic Federal Payment Methods

The new facility fee rates are for the period from October 1, 2025, through September 30, 2026. To pay the MDF and CMO fees, complete an OTC Monograph User Fee Cover Sheet, available at: *https://userfees.fda.gov/OA_HTML/omufaCAcdLogin.jsp,* and generate a unique user fee identification (ID) number or use the OMUFA FY 2026 Facility Fee Invoice that is issued by the Agency in April 2026.[11]

Payments made to FDA must be made in U.S. currency drawn on a U.S. bank by electronic check, credit card, or wire transfer. The preferred method for payments to FDA is online using electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov,* a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website upon receipt of an invoice or after completing the User Fee Cover Sheet and generating the user fee ID number. Secure electronic payments to FDA can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* (*Note:* Only full payments are accepted; no partial payments can be made online). Once an invoice or cover sheet is located, ''Pay Now'' should be selected to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID or invoice number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID or invoice number, the payment may not be applied. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfers: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33.

FDA's tax identification number is 53–0196965. If a fee is not paid in full, the fee will be treated as a claim of the U.S. Government (see section 744M(g) of the FD&C Act and 45 CFR part 30), meaning the invoice balance due amount is referred to collection.

If you are assessed an FY 2026 OMUFA facility fee and believe your facility is not an OTC monograph drug facility as described in this notice, please contact *CDERCollections@fda.hhs.gov.*

Grace Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–05276 Filed 3–17–26; 8:45 am]

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[11] The unique user fee identification (ID) number is also referred to as Payment Identification Number (PIN) in OMUFA coversheet creation instructions; these terms are used interchangeably. See *https://userfees.fda.gov/OA_HTML/OMUFAFacilityFeeCoverSheetCreationProcess.pdf.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–P–3942]

Labeling and Preventing Cross-Contact of Gluten for Packaged Foods; Request for Information; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Petition for rulemaking; request for information; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the notice that appeared in the **Federal Register** on January 22, 2026. In the notice, FDA requested data and information on the issues raised in and specific questions related to a citizen petition from Celiac Journey related to labeling and preventing cross-contact of gluten for packaged foods. We are taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice published on January 22, 2026 (91 FR 2781). Electronic or written comments must be submitted by April 22, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 22, 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–2023–P–3942 for ''Labeling and Preventing Cross-Contact of Gluten for Packaged Foods; Request for Information.'' 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: Carol D'Lima, Office of Nutrition and Food Labeling (HFS–800), Nutrition Center of Excellence, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371; Meridith L. Kelsch, Office of Policy and International Engagement, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 22, 2026, FDA published a notice requesting data and information on the issues raised in a citizen petition from Celiac Journey requesting that FDA act to protect consumers with celiac disease by requiring that all ingredients with gluten be listed by name in the ingredient list and by requiring cross-contact controls with gluten-containing grains, as well as specific questions related to those issues (91 FR 2781). The notice requested comments by March 23, 2026.

We have received a request to extend the comment period for this notice. Pointing to the complexity of the issues and information requested and the need to collect responsive information, the request asserts that additional time would allow stakeholders to provide FDA with more thorough and useful responses. We have considered the request and are extending the comment period for the notice by 30 days, until April 22, 2026. We believe that the extension will allow adequate time for interested persons to submit comments.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–05259 Filed 3–17–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[FDA–2025–P–6392]

Determination That METHERGINE (Methylergonovine Maleate) Injection, 0.2 Milligram/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 METHERGINE (methylergonovine maleate) injection, 0.2 milligram (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 methylergonovine maleate injection, 0.2 mg/mL, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Sungjoon Chi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6216, Silver Spring, MD 20993–0002, 240–402–9674, *Sungjoon.Chi@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