

representing manufacturers who have previously submitted an ENDS PMTA, including those with a PMTA currently pending with FDA. Final eligibility for attendance will be determined by FDA. Participants should be at a sufficiently senior level with significant scientific and/or regulatory responsibility to be knowledgeable about their company's PMTA.

**Registration:** Registration is free. For information on how to register for the roundtable as a panelist, please visit the following website: <https://www.fda.gov/tobacco-products/ctp-newsroom/february-10-2026-roundtable-premarket-tobacco-application-submissions-electronic-nicotine-delivery>, by January 27, 2026, 11:59 p.m. Eastern Time. Registrants should include the following information for the attendee in their request to participate in the roundtable:

- Name of proposed attendee, job title, address, email, and telephone number
- Name of company and brief company description
- How many people the company employs (including subsidiaries)
- Indicate which of the 5 topics you wish to discuss as a panel member (you may select multiple topics):
  - A. Product Characterization
  - B. Manufacturing Controls
  - C. Pharmacological Profile
  - D. Studies of Adult Benefit
  - E. Toxicological Profile

Registration for panelists is on a rolling basis determined by space availability, with priority given to early registrants. FDA will evaluate registrations based on the submitted information until a maximum of 30 participants have been selected for the roundtable and will then inform applicants of selection decisions. Due to time and space constraints, there is a limit of one person to represent and speak on behalf of each company. Panel registrants will receive confirmation as to whether they have been accepted. If panelist registration closes prior to the submission deadline, we will update the website to reflect that change. For persons interested in viewing the roundtable virtually, information will be provided on our website: <https://www.fda.gov/tobacco-products/ctp-newsroom/february-10-2026-roundtable-premarket-tobacco-application-submissions-electronic-nicotine-delivery>.

If you need special accommodations due to a disability, please email: [CTP-OS-ACS@fda.hhs.gov](mailto:CTP-OS-ACS@fda.hhs.gov) no later than February 3, 2026.

**Virtual Participation and Live Streaming of the Roundtable:** This roundtable will also be available for

virtual attendance. If you have been accepted to participate in the roundtable meeting as a panelist but will attend virtually, you will receive details prior to the roundtable. For non-panelist attendees interested in viewing the roundtable virtually, information will be provided on our website: <https://www.fda.gov/tobacco-products/ctp-newsroom/february-10-2026-roundtable-premarket-tobacco-application-submissions-electronic-nicotine-delivery>.

**Transcripts:** Please be advised that as soon as a transcript of the roundtable is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://www.fda.gov/tobacco-products/ctp-newsroom/february-10-2026-roundtable-premarket-tobacco-application-submissions-electronic-nicotine-delivery>.

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

**Lowell M. Zeta,**

*Acting Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025-23851 Filed 12-23-25; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2023-E-3236]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; LEQEMBI

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for LEQEMBI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

**DATES:** Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by February 27, 2026. Furthermore, any interested person may

petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by June 29, 2026. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

**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 February 27, 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–E–3236 for “Determination of Regulatory Review Period for Purposes of Patent Extension; LEQEMBI.” 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 § 10.20 (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:** Jack Dan, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6200, Silver Spring, MD 20993, 240–402–6940.

**SUPPLEMENTARY INFORMATION:**

## I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA’s determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product LEQEMBI (lecanemab- irmb). LEQEMBI is indicated for the treatment of Alzheimer’s disease. Subsequent to this approval, the USPTO received a patent term restoration application for LEQEMBI (U.S. Patent No. 8,025,878) from BioArctic AB, and the USPTO requested FDA’s assistance in determining this patent’s eligibility for patent term restoration. In a letter dated January 30, 2024, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of LEQEMBI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product’s regulatory review period.

## II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for LEQEMBI is 4,546 days. Of this time, 4,300 days occurred during the testing phase of the regulatory review period, while 246 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* July 29, 2010. FDA has verified the applicant’s claim that the date the investigational new drug application became effective was on July 29, 2010.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* May 6, 2022. FDA has verified the applicant’s claim that the biologics license application (BLA) for LEQEMBI (BLA 761269) was initially submitted on May 6, 2022.

3. *The date the application was approved:* January 6, 2023. FDA has verified the applicant’s claim that BLA 761269 was approved on January 6, 2023.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

## III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket

No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**Brian Fahey,**

*Associate Commissioner for Legislation.*

[FR Doc. 2025–23865 Filed 12–23–25; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2025–N–6896]

#### Over-the-Counter Monograph Drug User Fee Amendments—OTC Monograph Order Request Fee Rates for Fiscal Year 2026

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

**ACTION:** Notice.

**SUMMARY:** The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Over-the-Counter Monograph Drug User Fee Amendments (herein referred to as “OMUFA II”), authorizes the Food and Drug Administration (FDA, the Agency, or we) to assess and collect user fees from qualifying manufacturers of over-the-counter (OTC) monograph drugs and submitters of OTC monograph order requests (OMOR)s for fiscal years 2026 through 2030. In this notice, FDA is announcing the OMOR fee rates for fiscal year (FY) 2026. FDA plans to announce the FY 2026 OMUFA facility fee rates, *i.e.*, monograph drug facility (MDF) and contract manufacturing organization (CMO) facility fee rates, in a subsequent **Federal Register** notice (and anticipates its issuance will generally align with the timing of the OMUFA facility fee rate publication for prior FYs).

**DATES:** These OMOR fees are effective on October 1, 2025, and will remain in effect through September 30, 2026.

**FOR FURTHER INFORMATION CONTACT:** Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–4989; or the User Fees Support Staff at *OO-OFBA-OFM-UFSS-Government@fda.hhs.gov*.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 744M of the FD&C Act (21 U.S.C. 379j–72), as amended by OMUFA

II,<sup>1</sup> authorizes FDA to assess and collect, for each of fiscal years 2026 through 2030: (1) facility fees from qualifying owners of OTC MDFs and (2) fees from submitters of qualifying OTC OMORs. These fees are to support FDA’s OTC monograph drug activities, which are detailed in section 744L(6) of the FD&C Act (21 U.S.C. 379j–71(6)) and include specified FDA activities associated with regulating OTC monograph drugs.<sup>2</sup>

For OMUFA purposes, an OMOR is a request for an administrative order, with respect to an OTC monograph drug, which is submitted under section 505G(b)(5) of the FD&C Act (see section 744L(7) of the FD&C Act).

Under section 744M(a)(2)(A) of the FD&C Act, the Agency is authorized to assess and collect fees from submitters of OMORs, except for OMORs that request certain safety-related changes (as discussed below). There are two levels of OMOR fees, based on whether the OMOR at issue is a Tier 1 or Tier 2 OMOR.<sup>2</sup>

For FY 2026, the OMUFA fee rates for OMORs are: Tier 1 OMOR fees (\$587,529) and Tier 2 OMOR fees (\$117,505). These fees are effective for the period from October 1, 2025, through September 30, 2026. This document is issued pursuant to section 744M(a)(2) and (c)(5) of the FD&C Act and describes the calculations used to set the OMUFA OMOR fees for FY 2026 in accordance with the directives in the statute.

##### II. Determination of FY 2026 OMOR Fees

For FY 2026, the Tier 1 OMOR fee is \$587,529 and the Tier 2 OMOR fee is \$117,505, including an adjustment for inflation (see sections 744M(a)(2)(A)(i) and (ii) of the FD&C Act, respectively). OMOR fees are not included in the OMUFA target revenue calculation, which is based on the facility fees (see section 744M(b) of the FD&C Act).

An OMOR fee is generally assessed to each person who submits an OMOR (see section 744M(a)(2)(A) of the FD&C Act). OMOR fees are due on the date of the

<sup>1</sup> Over-the-Counter Monograph Drug User Fee Amendments, title V of Division F of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (Pub. L. 119–37).

<sup>2</sup> For OMUFA purposes, an OTC monograph drug is a nonprescription drug without an approved new drug application that is governed by the provisions of section 505G of the FD&C Act (21 U.S.C. 355h) (see section 744L(5) of the FD&C Act).

<sup>2</sup> Under OMUFA, a Tier 1 OMOR is defined as any OMOR that is not a Tier 2 OMOR (see section 744L(8) of the FD&C Act). Tier 2 OMORs are detailed in section 744L(9) of the FD&C Act.

submission of the OMOR (see section 744M(a)(2)(B) of the FD&C Act). The payor should submit the OMOR fee that applies to the type of OMOR they are submitting (*i.e.*, Tier 1 or Tier 2). FDA will determine whether the appropriate OMOR fee has been submitted following receipt of the OMOR and the fee.

An OMOR fee will not be assessed if the OMOR seeks to make certain safety changes with respect to an OTC monograph drug. Specifically, no fee will be assessed if FDA finds that the OMOR seeks to change the drug facts labeling of an OTC monograph drug in a way that would add to or strengthen: (1) a contraindication, warning, or precaution; (2) a statement about risk associated with misuse or abuse; or (3) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug (see section 744M(a)(2)(C) of the FD&C Act).

##### III. OMOR Fee Adjustment for Inflation

The dollar amount of the inflation adjustment to the fee for OMORs for FY 2026 is equal to the product of the applicable fee for FY 2025 and the inflation adjustment percentage.<sup>3</sup> For FY 2026, the inflation adjustment percentage is equal to the sum of:

- The average annual percent change in the cost, per full-time equivalent (FTE) position at FDA, of all personnel compensation and benefits (PC&B) paid with respect to such positions for the first 3 years of the preceding 4 FYs, multiplied by the proportion of PC&B costs to total FDA costs of OTC monograph drug activities for the first 3 years of the preceding 4 FYs (see section 744M(c)(1)(C)(i) of the FD&C Act); and
- The average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Arlington-Alexandria, DC-VA-MD-WV; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 FYs (see section 744M(c)(1)(C)(ii) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified FYs, provides the percent changes from the

<sup>3</sup> See section 744M(c)(1)(B) of the FD&C Act.