to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10769 Satisfaction of Nursing Homes, Hospitals, and Outpatient Clinicians Working with the CMS Network of Quality Improvement and Innovation Contractors Program (NQIIC)

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Satisfaction of Nursing Homes, Hospitals, and Outpatient Clinicians Working with the CMS Network of Quality Improvement and Innovation Contractors Program (NQIIC); *Use:* The purpose of this Information Collection Request (ICR) is to collect data to inform the program evaluation of the Centers for Medicare & Medicaid Services (CMS) Quality Innovation Network-Quality Improvement Organization (QIN–QIO) and Hospital Quality Improvement Contractors (HQIC) programs under the Network of Quality Improvement and Innovation Contractors (NQIIC) contract vehicle. This is a revision package. First, we updated the Nursing Home and Hospital Surveys to cover all the quality improvement focus areas targeted by NQIIC awardees, removed some but not all COVID–19 Public Health Emergency (PHE) related questions to reflect the progress of federal health program (*e.g.,* Agency for Healthcare Research and Quality Project Echo program was officially ended in August 2021), and made minor refinements based on the first round of survey fielding. Second, we added the Outpatient Clinician Survey in the same revision package since all three surveys are conducted under the same NQIIC contract.

This revision package supports evaluation of the technical assistance provided by the QINQIO Program to nursing homes and outpatient clinicians in community settings, and Hospital Quality Improvement Contractors (HQIC) Program activities to support hospitals. This ICR is part of a larger evaluation of the overall impact of the NQIIC Program. *Form Number:* CMS–10769 (OMB control number: 0938–1424); *Frequency:* Yearly; *Affected Public:* State and Private Sector (Business or other for-profits); *Number of Respondents:* 1,900; *Total Annual Responses:* 1,900; *Total Annual Hours:* 559. (For policy questions regarding this collection, contact Jeff Mokry at 214–767–4021.)

Dated: September 7, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–19603 Filed 9–11–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0579]

Mayya Tatsene: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Mayya Tatsene from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Ms. Tatsene was convicted of a felony under Federal law for conduct that relates to the regulation of any drug product under the FD&C Act. Ms. Tatsene was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of July 8, 2023 (more than 30 days after receipt of the notice, as prescribed by regulation), Ms. Tatsene has not responded to the notice. Ms. Tatsene's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is applicable September 12, 2023.

ADDRESSES: Any application by Ms. Tatsene for special termination of debarment under section 306(d)(4) of the FD&C Act (21 U.S.C. 335a(d)(4)) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application 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 an application with confidential

information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

- *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 a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2023–N–0579. Received applications 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 an application with confidential information that you do not wish to be made publicly available, submit your application 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 your application. 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. 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, 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 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, at 240–402–8743, or *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(B) of the FD&C Act requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act.

On January 10, 2023, Mayya Tatsene was convicted in the U. S. District Court for the Southern District of New York when the court entered judgment of conviction against her, after her plea of guilty, to one count of Conspiracy to Commit Wire Fraud in violation of 18 U.S.C. 1349 and one count of Wire Fraud in violation of 18 U.S.C. 1343.

The underlying facts supporting the conviction are contained in the Information, entered into the docket on May 29, 2019, and from the transcript of Ms. Tatsene's guilty plea hearing which occurred on May 29, 2019. Ms. Tatsene was an employee of AMA Laboratories (AMA), a consumer product testing company in Rockland County, New York. At AMA, Ms. Tatsene was employed as the clinical laboratory director and, between 2005 and 2017, was in charge of the Repeat Insult Patch Test laboratory at AMA. AMA purported to test the safety and efficacy of cosmetics, sunscreens, and other products on specified numbers of volunteer panelists in exchange for fees paid by consumer products companies. The customers who engaged AMA to run these tests on their products used the results to determine whether those products were safe and effective. From at least in or about 2005, through in or about April 2017, Ms. Tatsene and AMA personnel defrauded AMA's customers in excess of $25 million by testing products on materially lower numbers of panelists than the numbers specified and paid for by AMA's customers. Ms. Tatsene and other AMA employees made materially false and misleading statements about the results of the tests to AMA's customers. Specifically, Ms. Tatsene and other AMA employees falsely represented to AMA's customers that AMA had tested the products on the number of panelists specified by the laboratory's customers. Ms. Tatsene and other AMA employees sent its customers laboratory results containing false information via interstate email and facsimile communications.

Based on this conviction, FDA sent Ms. Tatsene by certified mail on May 25, 2023, a notice proposing to permanently debar her from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Ms. Tatsene was convicted, as set forth in section 306(l)(1) of the FD&C Act, of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Ms. Tatsene an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to file a timely request for a hearing would constitute an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Ms. Tatsene received the proposal on June 8, 2023. She did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Tatsene has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Ms. Tatsene is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see section 306(a)(2)(B) and (c)(2)(A)(ii) of the FD&C Act. Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses in any capacity the services of Ms. Tatsene during her debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Ms. Tatsene provides services in any capacity to a person with an approved or pending drug product application during her period of debarment, she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not

accept or review any abbreviated new drug application from Ms. Tatsene during her period of debarment, other than in connection with an audit under section 306 of the FD&C Act. Note that, for purposes of sections 306 and 307 of the FD&C Act, a ''drug product'' is defined as a ''drug subject to regulation under section 505, 512, or 802 of this Act [(21 U.S.C. 355, 360b, 382)] or under section 351 of the Public Health Service Act [(42 U.S.C. 262)]'' (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Dated: September 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–19672 Filed 9–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3573]

Over-the-Counter Monograph Drug User Fee Program—OTC Monograph Order Requests Fee Rates for Fiscal Year 2024

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the over-the-counter (OTC) monograph order request (OMOR) fee rates under the OTC monograph drug user fee program (OMUFA) for fiscal year (FY) 2024. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to assess and collect user fees from qualifying manufacturers of OTC monograph drugs and submitters of OMORs. This notice publishes the OMOR fee rates under OMUFA for FY 2024. FDA plans to publish the FY 2024 OMUFA facility fee rates in a subsequent **Federal Register** notice (and anticipates its issuance will generally align with the timing of OMUFA facility fee rate publication for prior fiscal years).

DATES: These fees are effective on October 1, 2023, and will remain in effect through September 30, 2024.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., 6th Floor, Beltsville, MD 20705–4304, 240–402–4989; or the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 744M of the FD&C Act (21 U.S.C. 379j–72), authorizes FDA to assess and collect: (1) facility fees from qualifying owners of OTC monograph drug facilities and (2) fees from submitters of qualifying OTC monograph order requests. 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 various FDA activities associated with OTC monograph drugs.[1]

For OMUFA purposes, an OTC monograph order request (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). Given that OMOR fees are due on the date of submission of the OMOR,[2] the Agency is publishing the OMOR fee rates for FY 2024 in advance of the fiscal year to ensure that applicable OMOR fee rates are available in the event that OMORs are submitted early in the fiscal year.[3]

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.[4]

For FY 2024, the OMUFA fee rates are: Tier 1 OMOR fees ($537,471), Tier 2 OMOR fees ($107,494). These fees are effective for the period from October 1, 2023, through September 30, 2024. This document is issued pursuant to sections 744M(a)(4) and 744M(c)(4)(B) of the FD&C Act and describes the calculations used to set the OMUFA OMOR fees for FY 2024 in accordance with the directives in the statute.

II. Determination of FY 2024 OMOR Fees

Under OMUFA, the FY 2024 Tier 1 OMOR fee is $537,471 and the Tier 2 OMOR fee is $107,494, 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 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

Under OMUFA, the OMOR fee is adjusted for inflation for FY 2022 and each subsequent fiscal year (see section 744M(c)(1)(B) of the FD&C Act). That provision states that the dollar amount of the inflation adjustment to the fee for OMORs is equal to the product of the applicable fee for the preceding fiscal year and the inflation adjustment percentage.[5] For FY 2024, the inflation adjustment percentage is equal to the sum of

- (1) the average annual percent change in the cost, per full-time equivalent position of the FDA, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 fiscal years (see section 744M(c)(1)(C)(ii)(I) of the FD&C Act); and
- (2) the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–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

[1] 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);

[2] Section 744M(a)(2)(B) of the FD&C Act.

[3] The Agency anticipates a greater likelihood of OMOR submissions in FY 2024 compared to prior fiscal years.

[4] 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.

[5] See section 744M(c)(1)(C) of the FD&C Act.