Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of April 29, 2024. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products listed in the table without an approved new drug application or ANDA violates sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)). Drug products that are listed in the table that are in inventory on April 29, 2024 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: March 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06730 Filed 3–28–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–1298]

Over-the-Counter Monograph Drug User Fee Program—Facility 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 drug facility (MDF) 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 OTC monograph order requests (OMORs). This notice publishes the OMUFA facility fee rates for FY 2024.

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

FOR FURTHER INFORMATION CONTACT: Olufunmilayo (Funmi) 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 OMORs. The OTC OMOR fee rates for FY 2024 were published on September 12, 2023.[1] 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. 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);
- An OTC MDF is a foreign or domestic business or other entity that, in addition to meeting other criteria, is engaged in manufacturing or processing the finished dosage form of an OTC monograph drug (see section 744L(10) of the FD&C Act); and
- A contract manufacturing organization (CMO) facility is an OTC monograph drug facility where neither the owner nor any affiliate of the owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States (see section 744L(2) of the FD&C Act).

Under section 744M(a)(1)(A) of the FD&C Act, a facility fee for FY 2024 shall be assessed with respect to each facility that is identified as an OTC monograph drug facility during the fee-liable period from January 1, 2023, through December 31, 2023.[2] Consistent with the statute, FDA will assess and collect facility fees with respect to the two types of OTC monograph drug facilities—MDF and CMO facilities. A full facility fee will be assessed to each qualifying person that owns a facility identified as an MDF (see section 744M(a)(1)(A) of the FD&C Act), and a reduced facility fee of two-thirds will be assessed to each qualifying person that owns a facility identified as a CMO facility (see section 744M(a)(1)(B)(ii) of the FD&C Act). The facility fees for FY 2024 are due on June 3, 2024 (see section 744M(a)(1)(D)(ii) of the FD&C Act).[3]

As discussed in greater detail below:

- OTC monograph drug facilities are exempt from FY 2024 facility fees if they had ceased OTC monograph drug activities, and updated their registration with FDA to that effect, prior to December 31, 2022 (see section 744M(a)(1)(B)(i) of the FD&C Act).
- Entities that registered with FDA during the Coronavirus Disease 2019 (COVID–19) pandemic whose sole activity with respect to OTC monograph drugs during the pandemic consists (or had consisted) of manufacturing OTC hand sanitizer products[4] are not identified as OTC monograph drug facilities subject to OMUFA facility fees for FY 2024.[5]

For FY 2024, the OMUFA facility fee rates are: MDF facility fees ($34,166) and CMO facility fees ($22,777). These fees are effective for the period from October 1, 2023, through September 30, 2024.[6] This document is issued pursuant to section 744M(a)(4) and 744M(c)(4)(B) of the FD&C Act and describes the calculations used to set the OMUFA facility fees for FY 2024 in accordance with the directives in the statute.

II. Facility Fee Revenue Amount for FY 2024

A. Base Fee Revenue Amount

Under OMUFA, FDA sets annual facility fees to generate the total facility fee revenues for each fiscal year

[1] *https://www.federalregister.gov/documents/2023/09/12/2023-19609/over-the-counter-monograph-drug-user-fee-program-otc-monograph-order-requests-fee-rates-for-fiscal.*

[2] Under section 744M(a)(1) of the FD&C Act, ''Each person that owns a facility identified as an OTC monograph drug facility on December 31 of the fiscal year or at any time during the preceding 12-month period shall be assessed an annual fee for each such facility.'' For purposes of FY 2024 facility fees, that time period is January 1, 2023, through December 31, 2023.

[3] Assuming that, as we anticipate, the FY 2024 fee appropriation will occur prior to June 3, 2024. Under section 744M(a)(1)(D)(ii), the FY 2024 facility fees are due on the later of: (1) the first business day of June 2024 (*i.e.,* June 3, 2024) or (2) the first business day after the enactment of an appropriations Act providing for the collection and obligation of FY 2024 OMUFA fees.

[4] The term ''hand sanitizer'' commonly refers to consumer antiseptic rubs. However, because the Department of Health and Human Services (HHS) notice published January 12, 2021, referred to ''persons that entered the over-the-counter drug market to supply hand sanitizer products in response to the COVID–19 Public Health Emergency'' (86 FR 2420 *https://www.federalregister.gov/documents/2021/01/12/2021-00237/notice-that-persons-that-entered-the-over-the-counter-drug-market-to-supply-hand-sanitizer-during*), we are using the same terminology—''hand sanitizer products''—to refer to OTC monograph drug products intended for use (without water) as antiseptic hand rubs or antiseptic hand wipes by consumers or healthcare personnel.

[5] See HHS **Federal Register** notice of January 12, 2021, 86 FR 2420, *https://www.federalregister.gov/documents/2021/01/12/2021-00237/notice-that-persons-that-entered-the-over-the-counter-drug-market-to-supply-hand-sanitizer-during.*

[6] These OMUFA fees are for FY 2024, per section 744M(a) of the FD&C Act.

established by section 744M(b) of the FD&C Act. The yearly base revenue amount is the starting point for setting annual facility fee rates. The base revenue for FY 2024 is the dollar amount of the total revenue amount for the previous fiscal year, without certain adjustments made for that previous year, and is $21,421,133 (see section 744M(b)(3)(B) of the FD&C Act).

B. Fee Revenue Adjustment for Inflation

Under OMUFA, the annual base revenue amount for facility fees is adjusted for inflation for FY 2024 and each subsequent fiscal year (see section 744M(c)(1) of the FD&C Act). That provision states that the dollar amount of the inflation adjustment is equal to the product of the annual base revenue for the fiscal year and the inflation adjustment percentage. For FY 2024 the inflation adjustment percentage is the sum of:

- (I) the average annual percent change in cost, per full-time equivalent (FTE) position of 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 (PC&B) costs to total costs of the 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
- (II) the average annual percent change that occurred in the Consumer Price Index (CPI) 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 other than personnel compensation and benefits costs to total costs of OTC monograph dug activities for the first 3 years of the preceding 4 fiscal years (see section 744M(c)(1)(C)(ii)(II) of the FD&C Act).

As a result of a geographical revision made by the Bureau of Labor and Statistics in January 2018, the ''Washington, DC-Baltimore'' index was discontinued and replaced with two separate indices (*i.e.,* the ''Washington-Arlington-Alexandria'' and ''Baltimore-Columbia-Towson'' indices). To continue applying a CPI that best reflects the geographic region in which FDA is located and that provides the most current data available, the ''Washington-Arlington-Alexandria'' index is used in calculating the inflation adjustment percentage.

Table 1 summarizes the actual cost and FTE data for the specified fiscal years, provides the percent changes from the previous fiscal years, and provides the average percent changes over the first 3 of the 4 fiscal years preceding FY 2024. The 3-year average is 3.9280 percent.

TABLE 1—FDA PC&B EACH YEAR AND PERCENT CHANGES

Year	2020	2021	2022	3-Year average
Total PC&B	2,875,592,000	3,039,513,000	3,165,477,000	.....
Total FTE	17,535	18,501	18,474	.....
PC&B per FTE	163,992	164,289	171,348	.....
Percent Change From Previous Year	7.3063%	0.1811%	4.2967%	3.9280%

Under the statute, this 3.9280 percent would be multiplied by the proportion of PC&B costs to the total FDA costs of OTC Monograph drug activities for the first 3 years of the preceding 4 fiscal years (see section 744M(c)(1)(C)(ii) of the FD&C Act). Because OMUFA was first authorized beginning with FY 2021, FDA used cost data of OTC monograph drug activities for the preceding three fiscal years (*i.e.,* FYs 2021–2023) to align with OMUFA's authorization.[7]

Table 2 shows the PC&B and the total obligations for OTC monograph drug activities for the last 3 fiscal years.

TABLE 2—PC&B AS A PERCENT OF TOTAL COST OF THE PROCESS FOR OTC MONOGRAPH DRUG ACTIVITIES

Year	2021	2022	2023	3-Year average
Total PC&B	23,133,775	25,415,237	39,133,075	.....
Total Costs	35,030,659	49,644,273	68,480,052	.....
PC&B Percent	66.0387%	51.1947%	57.1452%	58.1262%

The payroll adjustment is 3.9280 percent from table 1 multiplied by 58.1262 percent resulting in 2.2832 percent.

Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Arlington-Alexandria, DC-VA-MD-WV. The data are published by the Bureau of Labor Statistics on its website: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0.*

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA, DC-VA-MD-WV AREA

Year	2020	2021	2022	3-Year average
Annual CPI	267.16	277.728	296.117	.....

[7] We note that in preparing this FY 2024 facility fee rate notice, the Agency had final cost data for FY 2023 OTC monograph drug activities, while in preparing the preceding FY 2024 OMOR fee rate notice (referenced above), the Agency used estimated final FY 2023 cost data, as described therein.

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA, DC-VA-MD-WV AREA—Continued

Year	2020	2021	2022	3-Year average
Annual Percent Change	0.8989%	3.9568%	6.6212%	3.8256%

The statute specifies that this 3.8256 percent be multiplied by the proportion of all costs other than PC&B to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 fiscal years (and again, FDA is using cost data of OTC monograph drug activities for the preceding 3 fiscal years, *i.e.,* FYs 2021–2023, to align with OMUFA's authorization). Because 58.12624 percent was obligated for PC&B (as shown in table 2), 41.8738 percent is the portion of costs other than PC&B (100 percent minus 58.1262 percent equals 41.8738 percent). The non-payroll adjustment is 3.8256 percent times 41.8738 percent, or 1.6019 percent.

Next, we add the payroll adjustment (2.2832 percent) to the non-payroll adjustment (1.6019 percent), for a total inflation adjustment of 3.8851 percent for FY 2024.

Pursuant to the statute, the FY 2024 base revenue of $21,421,133 is increased by the total inflation adjustment of 3.8851 percent, yielding an inflation adjusted base revenue amount of $22,253,365 for FY 2024 (see section 744M(c)(1)(A)).

C. Additional Dollar Amounts

For FY 2024, the inflation adjusted revenue amount of $22,253,365 is increased by an additional dollar amount of $7 million as specified in the statute (see section 744M(b)(2)(E) of the FD&C Act). This yields an adjusted fee revenue subtotal of $29,253,365.

D. Fee Revenue Adjustment for Additional Direct Cost

Fee revenue is further adjusted for additional direct costs as specified in the statute. In FY 2024, $3 million is added to the facility fee revenues to account for additional direct costs (see section 744M(c)(3)(B) of the FD&C Act). Adding the additional direct costs amount of $3 million to $29,253,365 yields an additional direct cost adjusted fee revenue of $32,253,365.

E. Fee Revenue Adjustment for Operating Reserve

Under OMUFA, FDA may further increase the FY 2024 facility fee revenue and fees if such an adjustment is necessary to provide up to 10 weeks of operating reserves of carryover user fees for OTC monograph drug activities (see section 744M(c)(2)(B) of the FD&C Act). Accordingly, in setting fees for FY 2024, the Agency must estimate its carryover for FY 2024 to ensure the Agency has sufficient carryover to continue its OTC monograph drug activities, as required under the statute, including an operating reserve to mitigate certain financial risks, such as under collections, unanticipated surges in program costs, or a lapse in appropriations. Under the statute, if FDA has carryover for OTC monograph drug activities that would exceed 10 weeks of such operating reserves, FDA is required to decrease FY 2024 fee revenues and fees to provide for not more than 10 weeks of operating reserves of carryover user fees (see section 744M(c)(2)(C) of the FD&C Act).

Per the statute, OMUFA facility fees are not due until the third quarter of each fiscal year (*i.e.,* the first business day in June). To address this timing of facility fee collections for late in the fiscal year, the Agency must set aside additional carryover, beyond that for an operating reserve, to sustain the Agency's OTC monograph drug activities until the facility fees for the subsequent fiscal year are due and payable on the first business day in June (*i.e.,* June 2, 2025). Thus, the Agency will require FY 2024 carryover sufficient to cover payroll and operating expenses for the first 8 months (*i.e.,* 35 weeks rounded) of the following fiscal year (*i.e.,* October 1, 2024, to May 31, 2025). We refer to the amount of carryover needed to cover this 35-week period as the ''continuity set-aside'', consistent with the Agency's use of this term in the annual OMUFA Financial Reports.[8]

To determine the amount of this continuity set-aside, the Agency starts with the additional direct cost adjusted fee revenue of $32,253,365 (calculated in section D), divides it by 52 to yield a weekly operating amount of $620,257, and then multiplies the weekly operating amount by 35. Based on this calculation, FDA requires $21,708,995 to support the program until the FY 2025 facility fees are due. After running analyses on the projected collections and obligations for FY 2024, including accounting for possible financial risks described above, FDA estimates the FY 2024 carryover to be $24,578,371, which is $2,869,361 above the continuity set-aside amount needed to support the program through the 35-week period until the FY 2025 facility fees are due.

To determine whether the carryover above this continuity set-aside is within the 10-week limit for the operating reserve, FDA multiplies the weekly operating amount ($620,257) by 10, resulting in an operating reserve limit of $6,202,570. Because the estimated FY 2024 carryover above the continuity set-aside is below the 10-week threshold, FDA will not increase or reduce the FY 2024 fees or fee revenue under the statutory provision for an operating reserve adjustment. The final FY 2024 OMUFA target facility fee revenue is $32,253,000 (rounded to the nearest thousand dollars).

III. Facility Fee Calculations

A. Facility Fee Revenues and Fees

For FY 2024, facility fee rates are being established to generate a total target revenue amount, as determined under the statute, equal to $32,253,000 (rounded to the nearest thousand dollars). FDA used the methodology described below to determine the appropriate number of MDF and CMO facilities to be used in setting the OMUFA facility fees for FY 2024. FDA took into consideration that the CMO facility fee is equal to two-thirds of the amount of the MDF facility fee (see section 744M(a)(1)(B)(ii) of the FD&C Act).

B. Calculating the Number of Qualifying Facilities and Setting the Facility Fees

For FY 2024, FDA utilized data consisting of the number of facilities that were registered in FDA's electronic Drug Registration and Listing System (eDRLS) to manufacture human OTC products produced under a monograph [9]

[8] *https://www.fda.gov/about-fda/user-fee-financial-reports/omufa-financial-reports.*

[9] See section 744M(d) of the FD&C Act. OTC monograph drug facilities had selected in the eDRLS the business operation qualifiers of ''manufactures human over-the-counter drug products produced under a monograph'' or ''contract manufacturing for human over-the-counter drug products produced under a monograph'' and indicated at least one of the following business operations: finished dosage form

during the FY 2023 fee-liable period (*i.e.,* January 1, 2022, through December 31, 2022, and that paid FY 2023 OMUFA facility fees, as the primary sources for estimating the number of each facility fee type (*i.e.,* MDF and CMO). In addition, the Agency considered data provided by firms regarding their operation as MDFs and CMOs during FY 2023 (*i.e.,* October 1, 2022, through September 30, 2023) when they were submitting OTC Monograph User Fee Cover Sheets to pay the FY 2023 fee. These data helped FDA estimate the number of firms operating as MDF and CMO facilities during the FY 2024 fee-liable period (*i.e.,* January 1, 2023, through December 31, 2023) [9] [10] and thus informed FDA's calculation of the number and ratio of MDF and CMO facilities used in determining the FY 2024 fee rates. FDA's review of data also reflected input received during the FY 2024 fee-liable period from facilities whose manufacturing or processing practices meet the definition of fee-eligible OTC monograph drug facilities, to help capture those facilities that are in the market and intend to remain in the market for FY 2024.

Those facilities that only manufacture the active pharmaceutical ingredient of an OTC monograph drug do not meet the definition of an OTC monograph drug facility (see section 744L(10)(A)(i)(II)) of the FD&C Act). Likewise, a facility is not an OTC monograph drug facility if its only manufacturing or processing activities are one or more of the following: (1) production of clinical research supplies; (2) testing; or (3) placement of outer packaging on packages containing multiple products, for such purposes as creating multipacks, when each monograph drug product contained within the overpackaging is already in a final packaged form prior to placement in the outer overpackaging (see section 744L(10)(A)(iii) of the FD&C Act).

Consistent with the January 12, 2021 HHS **Federal Register** notice [11] (HHS FRN) and FDA's subsequent **Federal Register** notices published on March 26, 2021, March 16, 2022, and March 27, 2023, announcing the FY 2021, FY 2022, and FY 2023 OMUFA fees (respectively),[12] [13] [14] facilities are not identified as an ''OTC monograph drug facility'' and will not be assessed a FY 2024 OMUFA facility fee if they: (1) were not registered with FDA as OTC drug manufacturers prior to the HHS declaration of the COVID–19 public health emergency (PHE) on January 27, 2020; [15] (2) registered with FDA on or after the declaration of the COVID–19 PHE; and (3) registered for the sole purpose of producing hand sanitizer products during the COVID–19 PHE. We note, however, that under the FD&C Act, whether an entity is subject to OMUFA fees has no bearing on whether the entity or the entity's products are subject to other requirements under the FD&C Act. FDA will continue to use its regulatory compliance and enforcement tools to protect consumers, including from hand sanitizers or other drugs that are potentially dangerous or subpotent.

Although this notice addresses FY 2024 OMUFA facility fees, the Agency is highlighting the following information for interested parties in the interest of transparency regarding the Agency's planning for assessment of OMUFA facility fees for FY 2025: the January 12, 2021 HHS FRN explains that ''[t]he Department's conclusion [that certain hand sanitizer manufacturers are not identified as OTC monograph drug facilities] does not apply to such persons which (1) manufacture, distribute, and sell over-the-counter drugs in addition to hand sanitizer or (2) *continue to manufacture* (as opposed to hold, distribute, or sell existing inventories) *hand sanitizer products as of December 31 of the year immediately following the year during which the COVID–19 Public Health Emergency is terminated. In those cases, the Department may identify such persons as OTC drug manufacturing facilities*'' [16] (emphasis added). Accordingly, as the PHE expired on May 11, 2023, those facilities which ''continue to manufacture'' solely hand sanitizer products as of December 31, 2024, will be identified as OTC monograph drug facilities and be subject to an OMUFA facility fee for FY 2025. Conversely, if such facilities cease manufacturing hand sanitizer products and delist and deregister to reflect that before 12 a.m. EST on December 31, 2024, they will not be identified as an OTC monograph drug facility [17] and will not be considered fee liable for purposes of FY 2025 OMUFA facility fees.[18] In other words if facilities described in the January 12, 2021 HHS FRN, *i.e.,* those that first registered with FDA on or after the declaration of the COVID–19 PHE for the sole purpose of producing hand sanitizer products during the COVID–19 PHE, seek to avoid being identified as OTC monograph drug facilities subject to OMUFA facility fees for FY 2025 and beyond, they will need to cease production of hand sanitizer products and update their registration and listing accordingly, before 12 a.m. on December 31, 2024.

In undertaking the statutorily directed fee calculations for FY 2024 fees, the Agency also made certain assumptions, including that: (1) facilities using expired Structured Product Labeling codes in eDRLS, that have not reregistered, were no longer manufacturing and marketing OTC monograph drugs; (2) facilities that have deregistered in eDRLS have exited the market; (3) facilities that FDA believes registered incorrectly as OTC monograph drug facilities (for example, because the associated drug listings for these facilities did not include OTC monograph drugs but instead indicated such products as OTC drug products under an approved drug application or OTC animal drug products) were not engaged in manufacturing or processing the 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

manufacture, label, manufacture, pack, relabel, or repack.

[10] FDA considers relabelers and repackagers to be a category of OTC monograph drug facilities subject to OMUFA facility fees. See section 744L(10)(A); see also section 744L(10)(A)(iii) of the FD&C Act, excluding from the definition of ''OTC monograph drug facility'' those facilities whose manufacturing or processing consists solely of a narrow range of specified activities (*e.g.,* placement of outer overpackaging on products already in final packaged form); *cf* section 744A(6)(A)(ii) of the FD&C Act (which expressly excludes from the definition of ''facility'', for purposes of Generic Drug User Fee Amendments facility fees, a business or other entity whose only manufacturing or processing activities are repackaging, relabeling, or testing). See also 21 CFR 207.1 (addressing drug establishment registration), stating that ''[m]anufacture means each step in the manufacture, preparation, propagation, compounding, or processing of a drug,'' and indicating that ''the term 'manufacture, preparation, propagation, compounding, or processing,' as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes relabeling, repackaging, and salvaging activities.''

[11] See 86 FR 2420, *https://www.federalregister.gov/documents/2021/01/12/2021-00237/notice-that-persons-that-entered-the-over-the-counter-drug-market-to-supply-hand-sanitizer-during.*

[12] See 86 FR 16223, *https://www.federalregister.gov/documents/2021/03/26/2021-06361/fee-rates-under-the-over-the-counter-monograph-drug-user-fee-program-for-fiscal-year-2021.*

[13] See 87 FR 14888, *https://www.federalregister.gov/documents/2022/03/16/2022-05542/over-the-counter-monograph-drug-user-fee-rates-for-fiscal-year-2022.*

[14] See 88 FR 18156, *https://www.federalregister.gov/documents/2023/03/27/2023-06299/over-the-counter-monograph-drug-user-fee-rates-for-fiscal-year-2023.*

[15] See *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[16] See *https://www.federalregister.gov/documents/2021/01/12/2021-00237/notice-that-persons-that-entered-the-over-the-counter-drug-market-to-supply-hand-sanitizer-during.*

[17] Id.

[18] Id.

were not manufacturing or processing such drug products; and (5) facilities that, at the close of FY 2023, remain on the arrears list for failure to satisfy the FY 2021, FY 2022, or FY 2023 facility fee are likely to be placed on the FY 2024 arrears list as well.

Based on the above-referenced factors and assumptions, FDA estimates there will be 1,102 OMUFA fee-paying units. The Agency estimates that 57 percent ($1{,}102 \times 0.57 = 628$, rounded) will incur the MDF fee and 43 percent ($1{,}102 \times 0.43 = 474$, 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 (628) and a value of ⅔ to each CMO ($474 \times ⅔ = 316$) for a full facility equivalent of 944 (rounded). The target fee revenue of $32,253,000 is then divided by 944 for an MDF fee of $34,166 and a CMO fee of $22,777.

V. Fee Schedule for FY 2024

The fee rates for FY 2024 are displayed in table 4.

TABLE 4—FEE SCHEDULE FOR FY 2024

Fee category	FY 2024 Fee rates
Facility Fees:	
MDF	$34,166
CMO	22,777

VI. Fee Payment Options and Procedures

The new facility fee rates are for the period from October 1, 2023, through September 30, 2024. 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.*

A user fee identification (ID) number will be generated. Payment must be made in U.S. currency by electronic check or wire transfer, payable to the order of the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card for payments under $25,000 (Discover, VISA, MasterCard, American Express).

FDA has partnered with the U.S. Department of the Treasury to use *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after completing the OTC Monograph User Fee Cover Sheet and generating the user fee ID number. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* (*Note:* Only full payments are accepted through *https://userfees.fda.gov/pay.* No partial payments can be made online). Once an invoice 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 that are 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 number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied, which could result in consequences of nonpayment per section 744M(e)(1) of the FD&C Act. The originating financial institution may charge a wire transfer fee. Applicable wire transfer fees must be included with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

If you are assessed an FY 2024 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.*

Dated: March 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–06723 Filed 3–28–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–1242]

Animal Studies for Dental Bone Grafting Material Devices—Premarket Notification (510(k)) Submissions; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Animal Studies for Dental Bone Grafting Material Devices—Premarket Notification (510(k)) Submissions.'' This draft guidance document provides animal study design recommendations and animal study information to include to support a 510(k) submission for dental bone grafting material devices. This draft guidance may help manufacturers comply with some special controls for dental bone grafting material devices. The recommendations reflect current review practices and are intended to promote consistency and facilitate efficient review of these submissions. This draft guidance is not final nor is it for implementation at this time.

DATES: Submit either electronic or written comments on the draft guidance by May 28, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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