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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0284]

Over-the-Counter Monograph Drug User Fee Rates for Fiscal Year 2022

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the fee rates under the over-the-counter (OTC) monograph drug user fee program (OMUFA) for fiscal year (FY) 2022. 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. This notice publishes the OMUFA fee rates for FY 2022.

FOR FURTHER INFORMATION CONTACT: David Haas, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 240–402–9845.

SUPPLEMENTARY INFORMATION:

I. Background

Section 744M of the FD&C Act (21 U.S.C. 379j–72), as added by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), 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 and inspection of facilities associated with such products.

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 monograph drug facility (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);
- 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); and
- 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).

Under section 744M(a)(1)(A) of the FD&C Act, a facility fee for FY 2022 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, 2021, through December 31, 2021.[1] 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 2022 are due on June 1, 2022 (see section 744M(a)(1)(D)(ii) of the FD&C Act).[2]

As discussed in greater detail below:

- OTC monograph drug facilities are exempt from FY 2022 facility fees if they had ceased OTC monograph drug activities, and updated their registration with FDA to that effect, prior to December 31, 2020 (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[3] are not identified as OTC monograph drug facilities subject to OMUFA facility fees.[4]

In addition to facility fees, 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.[5]

For FY 2022, the OMUFA fee rates are: Tier 1 OMOR fees ($507,021), Tier 2 OMOR fees ($101,404), MDF facility fees ($24,178), and CMO facility fees ($16,119). These fees are effective for the period from October 1, 2021, through September 30, 2022.[6] 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 facility fees and OMOR fees for FY 2022 in accordance with the directives in the statute.

II. Facility Fee Revenue Amount for FY 2022

A. Base Fee Revenue Amount

Under OMUFA, FDA sets annual facility fees to generate the total facility fee revenues for each fiscal year 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 2022 is the dollar amount of the total revenue amount for the previous fiscal year, without certain adjustments made for that previous year, and is $8,000,000 (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

[1] 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 2022 facility fees, that time period is January 1, 2021, through December 31, 2021.

[2] Assuming that, as we anticipate, the FY 2022 fee appropriation will occur prior to June 1, 2022. Under section 744M(a)(1)(D)(ii), the FY 2022 facility fees are due on the later of (1) the first business day of June 2022 (*i.e.,* June 1, 2022) or (2) the first business day after the enactment of an appropriations Act providing for the collection and obligation of FY 2022 OMUFA fees.

[3] The term ''hand sanitizer'' commonly refers to consumer antiseptic rubs. However, because the 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.

[4] 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.*

[5] 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.

[6] These OMUFA fees are for FY 2022, per section 744M(a) of the FD&C Act.

adjusted for inflation for FY 2022 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 each of FYs 2022 and 2023, the inflation adjustment percentage is equal to 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 (section 744M(c)(1)(C) 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 provides the summary data for the percent changes in the specified CPI for the Washington-Arlington-Alexandria area. The data are published by the Bureau of Labor Statistics and can be found on its website at: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0.*

TABLE 1—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

Year	2018	2019	2020	3-year average
Annual CPI	261.445	264.777	267.157	.....
Annual Percent Change	2.0389%	1.2745%	0.8989%	1.4041%

Pursuant to the statute, the FY 2022 base revenue of $8,000,000 is increased by 1.4041 percent, yielding an inflation adjusted base revenue amount of $8,112,328 for FY 2022 (see section 744M(c)(1)(A)).

C. Additional Dollar Amounts

The inflation adjusted revenue amount of $8,112,328 is increased by an additional dollar amount of $7,000,000 as specified in the statute (see section 744M(b)(2)(E) of the FD&C Act). This yields an adjusted fee revenue subtotal of $15,112,328.

D. Fee Revenue Adjustment for Additional Direct Cost

Fee revenue is further adjusted for additional direct costs as specified in the statute. In FY 2022, $7,000,000 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 $7,000,000 to $15,112,328 yields an additional direct cost adjusted fee revenue of $22,112,328.

E. Fee Revenue Adjustment for Operating Reserve

Under OMUFA, FDA may further increase the FY 2022 facility fee revenue and fees if such an adjustment is necessary to provide up to 7 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 2022, the Agency must estimate its carryover for FY 2022, 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 2022 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). As described below, a fee revenue adjustment for the FY 2022 operating reserve is necessary to ensure that FDA has sufficient resources to maintain its authorized OTC monograph drug activities.

Per the statute, OMUFA facility fees are not due until the third quarter of each fiscal year (*i.e.,* June 1). 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 June 1, 2023. Thus, the Agency will require FY 2022 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, 2022, to May 31, 2023). To determine the carryover needed, the Agency starts with the additional direct cost adjusted fee revenue of $22,112,328 (calculated in section D), divides it by 52 to yield a weekly operating amount of $425,237, and then multiplies the weekly operating amount by 35. Based on this calculation, FDA requires $14,883,298 to support the program until the FY 2023 fees are due. After running analyses on the projected collections and obligations for FY 2022, FDA estimates the FY 2022 carryover to be $13,107,260 which is $1,776,038 lower than the total required to support the program through the 35-week period (*i.e.,* $14,883,298).

Therefore, FDA is applying an operating reserve adjustment for FY 2022 in the amount of $1,776,038, equating to approximately 4 weeks of program costs, to increase the FY 2022 facility fee revenue and fees to enable the Agency to sustain program operations through the 35-week period of FY 2023. As a result of the above calculations, the final FY 2022 OMUFA target facility fee revenue is $23,888,000 (rounded to the nearest thousand dollars).

III. Determination of FY 2022 OMOR Fees

Under OMUFA, the FY 2022 Tier 1 OMOR fee is $507,021 and the Tier 2 OMOR fee is $101,404 (see section 744M(a)(2)(A)(i) and (ii) of the FD&C Act, respectively) including an adjustment for inflation. OMOR fees are not included in the OMUFA target revenue calculation, which is based on the facility fees (see section 744M(b)(1) 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).

IV. Facility Fee Calculations

A. Facility Fee Revenues and Fees

For FY 2022, facility fee rates are being established to generate a total target revenue amount, as determined under the statute, equal to $23,888,000 (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 2022. 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 2022, 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 [7] during the FY 2021 fee-liable period (*i.e.,* January 1, 2020, through December 31, 2020) and the number of facilities that paid FY 2021 OMUFA 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 2021—*i.e.,* October 1, 2020, through September 30, 2021—when they were submitting OTC Monograph User Fee Cover Sheets to pay the FY 2021 fee. These data helped FDA estimate the number of firms operating as MDF and CMO facilities during the FY 2022 fee-liable period (*i.e.,* January 1, 2021, through December 31, 2021) [8] and thus informed FDA's calculation of the number and ratio of MDF and CMO facilities used in determining the FY 2022 fee rates. FDA's review of data also reflected input received during the first three quarters of the FY 2022 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 2022.

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 [9] and FDA's subsequent March 26, 2021, **Federal Register** Notice publishing FY 2021 OMUFA fees,[10] facilities are not identified as an ''OTC monograph drug facility'' and will not be assessed a FY 2022 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 on January 27, 2020 [11]; (2) registered with FDA on or after the declaration of the COVID–19 public health emergency; and (3) registered for the sole purpose of producing hand sanitizer products during the COVID–19 public health emergency. 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 potentially dangerous or subpotent hand sanitizers.

In undertaking the statutorily directed fee calculations, the Agency also made certain assumptions, including that: (1) Facilities using expired Structured Product Labeling (SPL) codes in eDRLS, that did not reregister for calendar year (CY) 2022, 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 were not manufacturing or processing such drug products; and (5) facilities that, at the close of FY 2021, remain on the arrears list for failure to satisfy the FY 2021 facility fee are likely to be placed on the FY 2022 arrears list as well.

Based on the above-referenced factors and assumptions, FDA estimates there will be 1,118 OMUFA fee-paying units. The Agency estimates that 65 percent ($1{,}118 \times 0.65 = 727$, rounded) will incur the MDF fee and 35 percent ($1{,}118 \times 0.35 = 391$, 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 (727) and a value of ⅔ to each CMO ($391 \times ⅔ = 261$) for a full facility equivalent of 988 (rounded). The target fee revenue of $23,888,000 is then divided by 988 for an MDF fee of $24,178 and a CMO fee of $16,119.

V. Fee Schedule for FY 2022

The fee rates for FY 2022 are displayed in table 1.

[7] 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 manufacture, label, manufacture, pack, relabel, or repack.

[8] 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'' (emphasis added).

[9] 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.*

[10] 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.*

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

TABLE 1—FEE SCHEDULE FOR FY 2022

Fee category	FY 2022 fee rates
OMOR:	
Tier 1	$507,021
Tier 2	101,404
Facility Fees:	
MDF	24,178
CMO	16,119

VI. Fee Payment Options and Procedures

The new fee rates are for the period from October 1, 2021, through September 30, 2022. To pay the OMOR, 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. 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 FDA not filing an OMOR request, for example, and other penalties. 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 2022 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 9, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1593]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Accessories

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on medical device accessory requests.

DATES: Submit either electronic or written comments on the collection of information by May 16, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before May 16, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 16, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–2016–N–1593 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device Accessories.'' 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