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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Peripheral Vascular Atherectomy Devices—Premarket Notification [510(k)] Submissions'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Misti Malone, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 120, Silver Spring, MD 20993–0002, 301–796–2520.

SUPPLEMENTARY INFORMATION:

I. Background

Atherectomy is an interventional procedure performed to debulk atherosclerotic plaque from diseased arteries. Atherectomy has been used in treatment of both coronary and peripheral arterial disease. FDA has developed this draft guidance for members of industry who submit and FDA staff who review premarket submissions for atherectomy devices used in the peripheral vasculature. When finalized, this guidance is intended to provide recommendations for information to include in premarket notifications (510(k)) for peripheral vascular atherectomy devices (*e.g.,* descriptive characteristics, labeling, biocompatibility, sterility, non-clinical, animal, and clinical performance testing).

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Peripheral Vascular Atherectomy Devices—Premarket Notification [510(k)] Submissions.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Peripheral Vascular Atherectomy Devices—Premarket Notification [510(k)] Submissions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 16013 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB Control No.
807, subpart E	Premarket Notification	0910–0120
812	Investigational Device Exemption	0910–0078
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073
807, subparts A through D	Electronic Submission of Medical Device Registration and Listing	0910–0625
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards	0910–0755
56	Institutional Review Boards	0910–0130
58	Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies	0910–0119
801.150(a)(2) and (e)	Agreement for Shipments of Devices for Sterilization	0910–0131

Dated: July 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16029 Filed 7–26–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2775]

Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2019 fee rates for certain domestic and foreign facility reinspections, failures to comply with a recall order, and importer reinspections that are authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). These fees are effective on October 1, 2018, and will remain in effect through September 30, 2019.

FOR FURTHER INFORMATION CONTACT: Jason Lewis, Office of Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rm. 2406, Rockville, MD 20857,

301–796–5957, email: *Jason.Lewis@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 107 of FSMA (Pub. L. 111–353) added section 743 to the FD&C Act (21 U.S.C. 379j–31) to provide FDA with the authority to assess and collect fees from, in part: (1) The responsible party for each domestic facility and the U.S. agent for each foreign facility subject to a reinspection, to cover reinspection-related costs; (2) the responsible party for a domestic facility and an importer who does not comply with a recall order, to cover food [1] recall activities associated with such order; and (3) each importer subject to a reinspection to cover reinspection-related costs (section 743(a)(1)(A), (B), and (D) of the FD&C Act). Section 743 of the FD&C Act directs FDA to establish fees for each of these activities based on an estimate of 100 percent of the costs of each activity for each year (section 743(b)(2)(A)(i), (ii), and (iv)), and these fees must be made available solely to pay for the costs of each activity for which the fee was incurred (section 743(b)(3)). These fees are effective on October 1, 2018, and will remain in effect through September 30, 2019. Section 743(b)(2)(B)(iii) of the FD&C Act directs FDA to develop a proposed set of guidelines in consideration of the burden of fee amounts on small businesses. As a first step in developing these guidelines, FDA invited public comment on the potential impact of the fees authorized by section 743 of the FD&C Act on small businesses (76 FR 45818, August 1, 2011). The comment period for this request ended November 30, 2011. As stated in FDA's September 2011 ''Guidance for Industry: Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act,'' (*http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm274176.htm*), because FDA recognizes that for small businesses the full cost recovery of FDA reinspection or recall oversight could impose severe economic hardship, FDA intends to consider reducing certain fees for those firms. FDA does not intend to issue invoices for reinspection or recall order fees until FDA publishes a guidance document outlining the process through which firms may request a reduction in fees.

In addition, as stated in the September 2011 Guidance, FDA is in the process of considering various issues associated with the assessment and collection of importer reinspection fees. The fee rates set forth in this notice will be used to determine any importer reinspection fees assessed in FY 2019.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2019

FDA is required to estimate 100 percent of its costs for each activity to establish fee rates for FY 2019. In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all of the remaining funds (operating funds) available to FDA are used to support FDA employees for paying rent, travel, utility, information technology (IT), and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2019

Full-time equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered ''hours worked'' for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an Agency-wide total cost per FTE requires three primary cost elements: Payroll, non-payroll, and rent.

We have used an average of past year cost elements to predict the FY 2019 cost. The FY 2019 FDA-wide average cost for payroll (salaries and benefits) is $157,731; non-payroll—including equipment, supplies, IT, general and administrative overhead—is $91,008; and rent, including cost allocation analysis and adjustments for other rent and rent-related costs, is $24,400 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2019 average fully supported cost to $273,139 per FTE, excluding travel costs. FDA will use this base unit fee in determining the hourly fee rate for reinspection and recall order fees for FY 2019 prior to including domestic or foreign travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2019 average fully supported cost of $273,139 per FTE by the average number of supported direct FDA work hours in FY 2017—the last FY for which data are available. See table 1.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2017

Total number of hours in a paid staff year	2,080
Less:	
10 paid holidays	−80
20 days of annual leave	−160
10 days of sick leave	−80
12.5 days of training	−100
26.5 days of general administration	−184
26.5 days of travel	−212
2 hours of meetings per week	−104
Net Supported Direct FDA Work Hours Available for Assignments	1,160

Dividing the average fully supported FTE cost in FY 2019 ($273,139) by the total number of supported direct work hours available for assignment in FY 2017 (1,160) results in an average fully supported cost of $235 (rounded to the nearest dollar), excluding inspection travel costs, per supported direct work hour in FY 2019.

B. Adjusting FY 2017 Travel Costs for Inflation To Estimate FY 2019 Travel Costs

To adjust the hourly rate for FY 2019, FDA must estimate the cost of inflation in each year for FY 2018 and FY 2019. FDA uses the method prescribed for estimating inflationary costs under the Prescription Drug User Fee Act (PDUFA) provisions of the FD&C Act (section 736(c)(1) (21 U.S.C. 379h(c)(1)), the statutory method for inflation adjustment in the FD&C Act that FDA has used consistently. FDA previously determined the FY 2018 inflation rate to be 1.6868 percent; this rate was published in the FY 2018 PDUFA user fee rates notice in the **Federal Register** (September 14, 2017, 82 FR 43244). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 1.6868 percent for 2018 and 1.7708 percent for 2019, and FDA intends to use these inflation rates to make inflation adjustments for FY 2019 for several of its user fee programs; the derivation of this rate will be published in the **Federal Register** in the FY 2019 notice for the PDUFA user fee rates.

The average fully supported cost per supported direct FDA work hour, excluding travel costs of $235 already takes into account inflation as the calculation above is based on FY 2019

[1] The term ''food'' for purposes of this document has the same meaning as such term in section 201(f) of the FD&C Act (21 U.S.C. 321(f)).

predicted costs. FDA will use this base unit fee in determining the hourly fee rate for reinspection and recall order fees for FY 2019 prior to including domestic or foreign travel costs as applicable for the activity. In FY 2017, FDA's Office of Regulatory Affairs (ORA) spent a total of $5,846,091 for domestic regulatory inspection travel costs and General Services Administration Vehicle costs related to FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) field activities programs. The total ORA domestic travel costs spent is then divided by the 10,289 CFSAN and CVM domestic inspections, which averages a total of $568 per inspection. These inspections average 34.05 hours per inspection. Dividing $568 per inspection by 34.05 hours per inspection results in a total and an additional cost of $17 (rounded to the nearest dollar) per hour spent for domestic inspection travel costs in FY 2017. To adjust for the $17 per hour additional domestic cost inflation increases for FY 2018 and FY 2019, FDA must multiply the FY 2018 PDUFA inflation rate adjustor (1.016868) times the FY 2019 PDUFA inflation rate adjustor (1.017708) times the $17 additional domestic cost, which results in an estimated cost of $18 (rounded to the nearest dollar) per paid hour in addition to $235 for a total of $253 per paid hour ($235 plus $18) for each direct hour of work requiring domestic inspection travel. FDA will use these rates in charging fees in FY 2019 when domestic travel is required.

In FY 2017, ORA spent a total of $2,566,050 on 480 foreign inspection trips related to FDA's CFSAN and CVM field activities programs, which averaged a total of $5,346 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $5,346 per trip by 120 hours per trip results in a total and an additional cost of $45 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2017. To adjust $45 for inflationary increases in FY 2018 and FY 2019, FDA must multiply it by the same inflation factors mentioned previously in this document (1.016868 and 1.107708), which results in an estimated cost of $47 (rounded to the nearest dollar) per paid hour in addition to $235 for a total of $282 per paid hour ($235 plus $47) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2019 when foreign travel is required.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2019

Fee category	Fee rates for FY 2019
Hourly rate if domestic travel is required	$253
Hourly rate if foreign travel is required	282

III. Fees for Reinspections of Domestic or Foreign Facilities Under Section 743(a)(1)(A)

A. What will cause this fee to be assessed?

The fee will be assessed for a reinspection conducted under section 704 of the FD&C Act (21 U.S.C. 374) to determine whether corrective actions have been implemented and are effective and compliance has been achieved to the Secretary of Health and Human Services' (the Secretary) (and, by delegation, FDA's) satisfaction at a facility that manufactures, processes, packs, or holds food for consumption necessitated as a result of a previous inspection (also conducted under section 704) of this facility, which had a final classification of Official Action Indicated (OAI) conducted by or on behalf of FDA, when FDA determined the non-compliance was materially related to food safety requirements of the FD&C Act. FDA considers such non-compliance to include non-compliance with a statutory or regulatory requirement under section 402 of the FD&C Act (21 U.S.C. 342) and section 403(w) of the FD&C Act (21 U.S.C. 343(w)). However, FDA does not consider non-compliance that is materially related to a food safety requirement to include circumstances where the non-compliance is of a technical nature and not food safety related (*e.g.,* failure to comply with a food standard or incorrect font size on a food label). Determining when non-compliance, other than under sections 402 and 403(w) of the FD&C Act, is materially related to a food safety requirement of the FD&C Act may depend on the facts of a particular situation. FDA intends to issue guidance to provide additional information about the circumstances under which FDA would consider non-compliance to be materially related to a food safety requirement of the FD&C Act.

Under section 743(a)(1)(A) of the FD&C Act, FDA is directed to assess and collect fees from ''the responsible party for each domestic facility (as defined in section 415(b) (21 U.S.C. 350d(b))) and the United States agent for each foreign facility subject to a reinspection'' to cover reinspection-related costs.

Section 743(a)(2)(A)(i) of the FD&C Act defines the term ''reinspection'' with respect to domestic facilities as ''1 or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified non-compliance materially related to a food safety requirement of th[e] Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction.''

The FD&C Act does not contain a definition of ''reinspection'' specific to foreign facilities. In order to give meaning to the language in section 743(a)(1)(A) of the FD&C Act to collect fees from the U.S. agent of a foreign facility subject to a reinspection, the Agency is using the following definition of ''reinspection'' for purposes of assessing and collecting fees under section 743(a)(1)(A), with respect to a foreign facility, ''1 or more inspections conducted by officers or employees duly designated by the Secretary subsequent to such an inspection which identified non-compliance materially related to a food safety requirement of the FD&C Act, specifically to determine whether compliance has been achieved to the Secretary's (and, by delegation, FDA's) satisfaction.''

This definition allows FDA to fulfill the mandate to assess and collect fees from the U.S. agent of a foreign facility in the event that an inspection reveals non-compliance materially related to a food safety requirement of the FD&C Act, causing one or more subsequent inspections to determine whether compliance has been achieved to the Secretary's (and, by delegation, FDA's) satisfaction. By requiring the initial inspection to be conducted by officers or employees duly designated by the Secretary, the definition ensures that a foreign facility would be subject to fees only in the event that FDA, or an entity designated to act on its behalf, has made the requisite identification at an initial inspection of non-compliance materially related to a food safety requirement of the FD&C Act. The definition of ''reinspection-related costs'' in section 743(a)(2)(B) of the FD&C Act relates to both a domestic facility reinspection and a foreign facility reinspection, as described in section 743(a)(1)(A).

B. Who will be responsible for paying this fee?

The FD&C Act states that this fee is to be paid by the responsible party for each domestic facility (as defined in section 415(b) of the FD&C Act) and by the U.S. agent for each foreign facility (section 743(a)(1)(A) of the FD&C Act). This is

the party to whom FDA will send the invoice for any fees that are assessed under this section.

C. How much will this fee be?

The fee is based on the number of direct hours spent on such reinspections, including time spent conducting the physical surveillance and/or compliance reinspection at the facility, or whatever components of such an inspection are deemed necessary, making preparations and arrangements for the reinspection, traveling to and from the facility, preparing any reports, analyzing any samples or examining any labels if required, and performing other activities as part of the OAI reinspection until the facility is again determined to be in compliance. The direct hours spent on each such reinspection will be billed at the appropriate hourly rate shown in table 2 of this document.

IV. Fees for Non-Compliance With a Recall Order Under Section 743(a)(1)(B)

A. What will cause this fee to be assessed?

The fee will be assessed for not complying with a recall order under section 423(d) (21 U.S.C. 350l(d)) or section 412(f) of the FD&C Act (21 U.S.C. 350a(f)) to cover food recall activities associated with such order performed by the Secretary (and by delegation, FDA) (section 743(a)(1)(B) of the FD&C Act). Non-compliance may include the following: (1) Not initiating a recall as ordered by FDA; (2) not conducting the recall in the manner specified by FDA in the recall order; or (3) not providing FDA with requested information regarding the recall, as ordered by FDA.

B. Who will be responsible for paying this fee?

Section 743(a)(1)(B) of the FD&C Act states that the fee is to be paid by the responsible party for a domestic facility (as defined in section 415(b) of the FD&C Act) and an importer who does not comply with a recall order under section 423 or under section 412(f) of the FD&C Act. In other words, the party paying the fee would be the party that received the recall order.

C. How much will this fee be?

The fee is based on the number of direct hours spent on taking action in response to the firm's failure to comply with a recall order. Types of activities could include conducting recall audit checks, reviewing periodic status reports, analyzing the status reports and the results of the audit checks, conducting inspections, traveling to and from locations, and monitoring product disposition. The direct hours spent on each such recall will be billed at the appropriate hourly rate shown in table 2 of this document.

V. How must the fees be paid?

An invoice will be sent to the responsible party for paying the fee after FDA completes the work on which the invoice is based. Payment must be made within 90 days of the invoice date in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Detailed payment information will be included with the invoice when it is issued.

VI. What are the consequences of not paying these fees?

Under section 743(e)(2) of the FD&C Act, any fee that is not paid within 30 days after it is due shall be treated as a claim of the U.S. Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

Dated: July 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16069 Filed 7–26–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the President's Council on Sports, Fitness, and Nutrition

AGENCY: President's Council on Sports, Fitness, and Nutrition, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the President's Council on Sports, Fitness, and Nutrition (PCSFN) will hold its annual meeting. The meeting will be open to the public.

DATES: The meeting will be held on September 21, 2018, from 9:30 a.m. to 12:30 p.m.

ADDRESSES: Newseum, Knight Conference Center 7th Floor, 555 Pennsylvania Ave. NW, Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Ms. Holli M. Richmond, Executive Director, Office of the President's Council on Sports, Fitness, and Nutrition, Tower Building, 1101 Wootton Parkway, Suite 560, Rockville, MD 20852, (240) 276–9567. Information about PCSFN, including details about the upcoming meeting, can be obtained at *www.fitness.gov.*

SUPPLEMENTARY INFORMATION: The primary functions of the PCSFN include (1) advising the President, through the Secretary, concerning progress made in carrying out the provisions of Executive Order 13265, as amended by Executive Order 13824, and recommending to the President, through the Secretary, actions to accelerate such progress; (2) recommending to the Secretary a national strategy to expand children's participation in youth sports, encourage regular physical activity, including active play and promote good nutrition for all Americans. Recommendations may address, but are not necessarily limited to, increasing awareness of the benefits of participation in sports and regular physical activity, as well as the importance of good nutrition; promoting private and public sector strategies to increase participation in sports, encourage regular physical activity, and improve nutrition; developing metrics that gauge youth sports participation and physical activity to inform efforts that will improve participation in sports and regular physical activity among young Americans; and establishing a national and local strategy to recruit volunteers who will encourage and support youth participation in sports and regular physical activity, through coaching, mentoring, teaching, or administering athletic and nutritional programs. The Council's performance of these functions shall take into account the Department of Health and Human Services' Physical Activity Guidelines for Americans, including consideration for youth with disabilities.

The Council shall meet, at a minimum, one time per fiscal year. The meeting will be held to (1) assess ongoing Council activities; and, (2) discuss and plan future projects and programs. The agenda for the planned meeting is being developed and will be posted at *www.fitness.gov* when it has been finalized.

The meeting that is scheduled to be held on September 21, 2018, is open to the public and the media. Every effort will be made to provide reasonable accommodations for persons with disabilities and/or special needs who wish to attend the meeting. Persons with disabilities and/or special needs should call (240) 276–9567 no later than close of business Monday, September 10, 2018, to request accommodations. Members of the public who wish to attend the meeting are asked to pre-register by sending an email to