''Pay Now'' to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available only for balances 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. When paying by check, bank draft, or U.S. postal money order, please include the invoice number. Also write the FDA post office box number (P.O. Box 979108) on the enclosed check, bank draft, or money order. Mail the payment including the invoice number on the check stub to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000.

When paying by wire transfer, it is required that the invoice number is included; without the invoice number the payment may not be applied. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. For international wire transfers, please inquire with the financial institutions prior to submitting the payment. Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check to: U.S. Bank, Attn: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This phone number is only for questions about courier delivery.) The tax identification number of FDA is 53–0196965. (Note: Invoice copies do not need to be submitted to FDA with the payments.)

### V. What are the consequences of not paying this fee?

The consequences of not paying these fees are outlined in Section J of ''FDA's Voluntary Qualified Importer Program; Guidance for Industry'' document (available at *https://www.fda.gov/media/92196/download*). If the user fee is not paid before October 1, a VQIP importer will not be eligible to participate in VQIP. For the first year a VQIP application is approved, if the user fee is not paid before October 1, 2022, you are not eligible to participate in VQIP. If you subsequently pay the user fee, FDA will begin your benefits after we receive the full payment. The user fee may not be paid after December 31, 2022. For a subsequent year, if you do not pay the user fee before October 1, FDA will send a Notice of Intent to Revoke your participation in VQIP. If you do not pay the user fee within 30 days of the date of the Notice of Intent to Revoke, we will revoke your participation in VQIP.

Dated: July 22, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–16175 Filed 7–27–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–N–1591]**

## Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2023

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the fiscal year (FY) 2023 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).

**DATES:** These fees are effective on October 1, 2022, and will remain in effect through September 30, 2023.

**FOR FURTHER INFORMATION CONTACT:** Jimmy Carlton, Office of Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–888–1556, *jimmy.carlton@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Background

Section 107 of the 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 (sections 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 (sections 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, 2022, and will remain in effect through September 30, 2023. 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,'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-implementation-fee-provisions-section-107-fda-food-safety-modernization-act*), 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 2023.

### II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2023

FDA is required to estimate 100 percent of its costs for each activity in order to establish fee rates for FY 2023. In each year, the costs of salary (or

[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)).

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 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 2023*

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, nonpayroll, and rent.

We have used an average of past year cost elements to predict the FY 2023 cost. The FY 2023 FDA-wide average cost for payroll (salaries and benefits) is $173,393; nonpayroll (including equipment, supplies, IT, and general and administrative overhead) is $103,078; and rent, including cost allocation analysis and adjustments for other rent and rent-related costs, is $23,944 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, nonpayroll, and rent, brings the FY 2023 average fully supported cost to $300,416 [2] 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 2023 prior to including domestic or foreign travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2023 average fully supported cost of $300,416 per FTE by the average number of supported direct FDA work hours in FY 2021 (the last fiscal year for which data are available). See table 1.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2021

| | |
|---|---|
| Total number of hours in a paid staff year | 2,080 |
| Less: | |
| 11 paid holidays | −88 |
| 20 days of annual leave | −160 |
| 10 days of sick leave | −80 |
| 12.5 days of training | −100 |
| 22 days of general administration | −176 |
| 26.5 days of travel | −212 |
| 2 hours of meetings per week | −104 |
| Net Supported Direct FDA Work Hours Available for Assignments | 1,160 |

[2] Total includes rounding.

Dividing the average fully supported FTE cost in FY 2023 ($300,416) by the total number of supported direct work hours available for assignment in FY 2023 (1,160) results in an average fully supported cost of $259 (rounded to the nearest dollar), excluding inspection travel costs, per supported direct work hour in FY 2023.

*B. Adjusting FY 2021 Travel Costs for Inflation To Estimate FY 2023 Travel Costs*

To adjust the hourly rate for FY 2023, FDA must estimate the cost of inflation in each year for FY 2022 and FY 2023. 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 2022 inflation rate to be 2.2013 percent; this rate was published in the FY 2022 PDUFA user fee rates notice in the **Federal Register** (August 16, 2021, 86 FR 45732). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 2.2013 percent for FY 2022 and 1.6404 percent for FY 2023, and FDA intends to use these inflation rates to make inflation adjustments for FY 2023 for several of its user fee programs; the derivation of this rate will be published in the **Federal Register** in the FY 2023 notice for the PDUFA user fee rates.

The average fully supported cost per supported direct FDA work hour, excluding travel costs, of $259 already takes into account inflation as the calculation above is based on FY 2023 predicted costs. FDA will use this base unit fee in determining the hourly fee rate for reinspection and recall order fees for FY 2023 prior to including domestic or foreign travel costs as applicable for the activity. In FY 2021, FDA's Office of Regulatory Affairs (ORA) spent a total of $4,920,033 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 4,965 CFSAN and CVM domestic inspections, which averages a total of $991 per inspection. These inspections average 46.43 hours per inspection. Dividing $991 per inspection by 46.43 hours per inspection results in a total and an additional cost of $21 (rounded to the nearest dollar) per hour spent for domestic inspection travel costs in FY 2021. To adjust for the $21 per hour additional domestic cost inflation increases for FY 2022 and FY 2023, FDA must multiply the FY 2022 PDUFA inflation rate adjustor (1.022013) times the FY 2023 PDUFA inflation rate adjustor (1.016404) times the $21 additional domestic cost, which results in an estimated cost of $22 (rounded to the nearest dollar) per paid hour in addition to $259 for a total of $281 per paid hour ($259 plus $22) for each direct hour of work requiring domestic inspection travel. FDA will use these rates in charging fees in FY 2023 when domestic travel is required.

In FY 2020,[3] ORA spent a total of $1,449,058 on 171 foreign inspection trips related to FDA's CFSAN and CVM field activities programs, which averaged a total of $8,474 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $8,474 per trip by 120 hours per trip results in a total and an additional cost of $71 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2020. To adjust $71 for inflationary increases in FY 2021, FY 2022, and FY 2023, FDA must multiply it by the same inflation factors mentioned previously in this document (1.022013 and 1.016404) and the inflation factor for FY 2021 [4] (1.013493), which results in an estimated cost of $75 (rounded to the nearest dollar) per paid hour in addition to $259 for a total of $334 per paid hour ($259 plus $75) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2023 when foreign travel is required.

[3] We use FY 2020 numbers for the foreign inspection travel costs due to the limited number of inspections done in FY 2021 due to travel restrictions caused by the COVID–19 Pandemic.

[4] FDA previously determined the FY 2021 inflation rate to be 1.3493 percent; this rate was published in the FY 2021 PDUFA user fee rates notice in the **Federal Register** (August 3, 2020, 85 FR 46651).

TABLE 2—FSMA FEE SCHEDULE FOR FY 2023

| Fee category | Fee rates for FY 2023 |
|---|---|
| Hourly rate if domestic travel is required | $281 |
| Hourly rate if foreign travel is required | 334 |

**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 noncompliance was materially related to food safety requirements of the FD&C Act. FDA considers such noncompliance to include noncompliance 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 noncompliance that is materially related to a food safety requirement to include circumstances where the noncompliance 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 noncompliance, 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 noncompliance 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 U.S. 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 noncompliance 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 noncompliance 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 noncompliance 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 noncompliance 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 Noncompliance 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). Noncompliance 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.

*D. 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 30 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.

**V. 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 22, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–16169 Filed 7–27–22; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2022–D–1253]**

### Laser-Assisted In Situ Keratomileusis Lasers—Patient Labeling Recommendations; 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 ''Laser-Assisted In Situ Keratomileusis (LASIK) Lasers—Patient Labeling Recommendations.'' This draft guidance recommends content and formatting for patient labeling information for LASIK devices. FDA is issuing this guidance to help ensure that physicians can share and patients can understand information on the benefits and risks of these devices. The recommendations are being made based on concerns that some patients are not receiving and/or understanding information regarding the benefits and risks of LASIK devices. 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 October 26, 2022 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 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–2022–D–1253 for ''Laser-Assisted In Situ Keratomileusis (LASIK) Lasers—Patient Labeling Recommendations.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

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 ''Laser-Assisted In Situ Keratomileusis (LASIK) Lasers—Patient Labeling Recommendations'' to the Office of Policy, 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-