

consistent with section 911(e) of the FD&C Act, FDA is making the redacted MRTPAs that are the subject of this notice available electronically (see section II).

**II. Electronic Access**

Persons with access to the internet may obtain the documents at <https://www.fda.gov/tobacco-products/advertising-and-promotion/22nd-century-group-inc-modified-risk-tobacco-product-mrtp-applications>.

Dated: July 19, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-15831 Filed 7-24-19; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2008-D-0031]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Clinical Laboratory Improvement Amendments Waiver Applications**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by August 26, 2019.

**ADDRESSES:** To ensure that comments on the information collection are received,

OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0598. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Clinical Laboratory Improvement Amendments Waiver Applications**

*OMB Control Number 0910-0598—Extension*

Congress passed the Clinical Laboratory Improvement Amendments (CLIA) (Pub. L. 100-578) in 1988 to establish quality standards for all laboratory testing. The purpose was to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test took place. CLIA requires that clinical laboratories obtain a certificate from the Secretary of Health and Human Services (the Secretary), before accepting materials derived from the human body for laboratory tests (42 U.S.C. 263a(b)). Laboratories that perform only tests that are “simple” and that have an “insignificant risk of an erroneous result” may obtain a certificate of waiver (42 U.S.C. 263a(d)(2)). The Secretary has delegated to FDA the

authority to determine whether particular tests (waived tests) are “simple” and have “an insignificant risk of an erroneous result” under CLIA (69 FR 22849).

On January 30, 2008, FDA published a guidance document entitled “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices—Guidance for Industry and FDA Staff” (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm079632.htm>). This guidance describes recommendations for device manufacturers submitting to FDA an application for determination that a cleared or approved device meets this CLIA standard (CLIA waiver application). The guidance recommends that CLIA waiver applications include a description of the features of the device that make it “simple”; a report describing a hazard analysis that identifies potential sources of error, including a summary of the design and results of flex studies and conclusions drawn from the flex studies; a description of fail-safe and failure alert mechanisms and a description of the studies validating these mechanisms; a description of clinical tests that demonstrate the accuracy of the test in the hands of intended operators; and statistical analyses of clinical study results.

In the **Federal Register** of March 26, 2019 (84 FR 11307), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
CLIA Waiver Application .....	13	1	13	1,200	15,600	\$350,000

<sup>1</sup> There are no capital costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN <sup>1</sup>

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
CLIA Waiver Records .....	13	1	13	2,800	36,400

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

The total number of reporting and recordkeeping hours is 52,000 hours. FDA bases the burden on an Agency analysis of premarket submissions with clinical trials similar to the waived laboratory tests. Based on previous years' experience with CLIA waiver applications, FDA expects 13 manufacturers to submit one CLIA waiver application per year. The time required to prepare and submit a waiver application, including the time needed to assemble supporting data, averages 1,200 hours per waiver application for a total of 15,600 hours for reporting. Based on previous years' experience with CLIA waiver applications, FDA expects that each manufacturer will spend 2,800 hours creating and maintaining the record for a total of 36,400 hours.

The total operating and maintenance cost associated with the waiver application is estimated at \$350,000. This cost is largely attributed to clinical study costs incurred, which include site selection and qualification, protocol review, and study execution (initiation, monitoring, closeout, and clinical site/subject compensation—including specimen collection for study as well as shipping and supplies).

Our estimated burden for the information collection reflects a decrease of 27 responses and 27 records, and a corresponding overall decrease of 108,000 hours. We attribute this adjustment to a decrease in the average number of submissions we received over the last few years.

Dated: July 19, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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## 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 2020

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2020 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, 2019, and will remain in effect through September 30, 2020.

#### FOR FURTHER INFORMATION CONTACT:

Tierra Ramsey, Office of Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, email: [oraomdfobudgetformbranch@fda.hhs.gov](mailto:oraomdfobudgetformbranch@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<sup>1</sup> 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, 2019, and will remain in effect through September 30, 2020. 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->

<sup>1</sup> 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)).

*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, 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 2020.

##### II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2020

FDA is required to estimate 100 percent of its costs for each activity in order to establish fee rates for FY 2020. 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 2020

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 2020 cost. The FY 2020 FDA-wide average cost for payroll (salaries and benefits) is \$160,885; non-payroll—including equipment, supplies, IT, general and administrative overhead—is \$92,828; and rent, including cost allocation analysis and adjustments for other rent and rent-related costs, is \$24,888 per paid staff year, excluding travel costs.