their participants, the contexts in which they are operated, and their promising practices. The implementation study will also assess whether the PJAC interventions are implemented as intended (implementation fidelity) as well as how the treatment implemented differed from the status quo (treatment contrast). The detailed descriptions will assist in interpreting program impacts and identifying program features and conditions necessary for effective program replication or improvement. Key activities of the implementation study will include: (1) A Management Information System (MIS) for collection and analysis of program participation data to track participant engagement in PJAC activities; (2) semi-structured interviews with program staff and staff from selected community partner organizations; (3) semi-structured interviews with program participants to learn about their experiences in PJAC; and (4) a staff questionnaire to gather broader quantitative information on program implementation and staff experiences.

2. *Impact Study:* The goal of the impact study is to provide rigorous estimates of the effectiveness of the six programs using an experimental research design. Program applicants who are eligible for PJAC services will be randomly assigned to either a program group that is offered program services or to a control group that is not offered those services. The random assignment process will require child support program staff to complete a brief data entry protocol. The impact study will rely on administrative data from state and county child support systems, court records, criminal justice records, and data from the National Directory of New Hires. Administrative records data will be used to estimate impacts on child support payments, enforcement actions, contempt proceedings, jail stays, and employment and earnings. The impact study will also include a follow-up survey of participants that will be administered approximately 12 months after random assignment to a subset of the sample. The survey will gather information on participant experiences with the child support program and family court, family relationships, parenting and co-parenting, informal child support payments, and job characteristics. In an effort to enhance response rates, the PJAC survey firm will attempt to track survey sample members at a few points over the 12-month follow-up period in order to stay in touch with them and gather updated contact information from them.

3. *Benefit-Cost Study:* The benefit-cost study will estimate the costs and benefits associated with the implementation and impact of the PJAC interventions. The study will examine the costs and benefits from the perspective of the government, noncustodial parents, custodial parents and their children, and society. Once measured, particular impacts or expenditures will constitute benefits or costs, depending on which analytical perspective is considered. For each of the perspectives, pertinent benefits and costs will be added together to determine the net value of the program. Key hypothesized benefits and costs to be assessed include increased PJAC intervention costs, reduced costs for contempt actions, increased payments from non-custodial parents, reduced court costs, and reduced jail time, among others. The benefit-cost study will rely on the results of the impact study, analysis of participation data from the MIS, and results of a staff time study in order to quantify various PJAC-related costs and benefits.

This 30-Day Notice covers the following data collection activities: (1) Staff data entry for random assignment; (2) Study MIS to track program participation; (3) Staff and community partner interview topic guide; (4) Participant interview topic guide; and (5) Participant survey tracking letter.

Respondents: Respondents for the first information collection phase include study participants and grantee staff and community partners. Specific respondents per instrument are noted in the burden table below.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Total annual burden hours
Staff data entry for random assignment	120	150	0.05	900	300
Study MIS to track program participation	120	150	1.00	18,000	6,000
Staff and community partner interview topic guide	150	2	1.00	300	100
Participant interview topic guide	180	1	1.00	180	60
Participant survey tracking letter	3,000	3	0.10	900	300

Estimated Total Annual Burden Hours: 6,760.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201. Attention: Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2017–16254 Filed 8–1–17; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4281]

Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2018

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2018 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 (the FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). These fees are effective on October 1, 2017, and will remain in effect through September 30, 2018.

FOR FURTHER INFORMATION CONTACT: Jason Lewis, Office of Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rm. 2046, 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 (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, 2017, and will remain in effect through September 30, 2018. 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/GuidanceDocuments RegulatoryInformation/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 2018.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2018

FDA is required to estimate 100 percent of its costs for each activity in order to establish fee rates for FY 2018. 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 2018

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.

The FY 2018 FDA-wide average cost for payroll (salaries and benefits) is $154,638; non-payroll—including equipment, supplies, IT, general and administrative overhead—is $89,224; and rent, including cost allocation analysis and adjustments for other rent and rent-related costs, is $23,922 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2018 average fully supported cost to $267,783 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 2018 prior to including domestic or foreign travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2018 average fully supported cost of $267,783 per FTE by the average number of supported direct FDA work hours in FY 2016—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 2016

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 full-time equivalent in FY 2018 ($267,783) by the total number of supported direct work hours available for assignment in FY 2016 (1,160) results in an average fully supported cost of $231 (rounded to the nearest dollar), excluding inspection travel costs, per supported direct work hour in FY 2016.

B. Adjusting FY 2016 Travel Costs for Inflation To Estimate FY 2018 Travel Costs

To adjust the hourly rate for FY 2018, FDA must estimate the cost of inflation in each year for FY 2017 and FY 2018. 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 2017 inflation rate to be 1.5468 percent; this rate was published in the FY 2017 PDUFA user fee rates notice in the **Federal Register**

[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)).

(July 28, 2016, 81 FR 49674). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 1.5468 percent for 2017 and 1.6868 percent for 2018, and FDA intends to use these inflation rates to make inflation adjustments for FY 2018 for several of its user fee programs; the derivation of this rate will be published in the **Federal Register** in the FY 2018 notice for the PDUFA user fee rates.

In FY 2016, FDA's Office of Regulatory Affairs (ORA) spent a total of $5,185,331 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 9,755 CFSAN and CVM domestic inspections, which averages a total of $532 per inspection. These inspections average 33.61 hours per inspection. Dividing $532 per inspection by 33.61 hours per inspection results in a total and an additional cost of $16 (rounded to the nearest dollar) per hour spent for domestic inspection travel costs in FY 2016. To adjust for the $16 per hour additional domestic cost inflation increases for FY 2017 and FY 2018, FDA must multiply the FY 2017 PDUFA inflation rate adjustor (1.015468) times the FY 2018 PDUFA inflation rate adjustor (1.016868) times the $16 additional domestic cost, which results in an estimated cost of $17 (rounded to the nearest dollar) per paid hour in addition to $231 for a total of $248 per paid hour ($231 plus $17) for each direct hour of work requiring domestic inspection travel. FDA will use these rates in charging fees in FY 2018 when domestic travel is required.

In FY 2016, ORA spent a total of $2,166,592 on 344.31 foreign inspection trips related to FDA's CFSAN and CVM field activities programs, which averaged a total of $6,293 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $6,293 per trip by 120 hours per trip results in a total and an additional cost of $52 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2016. To adjust $52 for inflationary increases in FY 2017 and FY 2018, FDA must multiply it by the same inflation factors mentioned previously in this document (1.015468, 1.016868), which results in an estimated cost of $54 (rounded to the nearest dollar) per paid hour in addition to $231 for a total of $285 per paid hour ($231 plus $54) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2018 when foreign travel is required.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2018

Fee category	Fee rates for FY 2018 ($)
Hourly rate if domestic travel is required	$248
Hourly rate if foreign travel is required	285

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.

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.

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 25, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–16184 Filed 8–1–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0007]

Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2018

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for fiscal year (FY) 2018 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2013 (AGDUFA II), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. This notice establishes the fee rates for FY 2018.

FOR FURTHER INFORMATION CONTACT: Visit FDA's Web site at *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm,* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6888. For general questions, you may also email the Center for Veterinary Medicine (CVM) at *cvmagdufa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 741 of the FD&C Act (21 U.S.C. 379j–21) establishes three different types of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j–21(a)). When certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication (21 U.S.C. 379j–21(d)).

For FY 2014 through FY 2018, the FD&C Act establishes aggregate yearly base revenue amounts for each of these fee categories (21 U.S.C. 379j–21(b)). Base revenue amounts established for fiscal years after FY 2014 are subject to adjustment for workload (21 U.S.C. 379j–21(c)). The target revenue amounts for each fee category for FY 2018, after the adjustment for workload, are as follows: For application fees, the target revenue amount is $2,355,000; for product fees, the target revenue amount is $3,532,000; and for sponsor fees, the target revenue amount is $3,532,000.

For FY 2018, the generic new animal drug user fee rates are: $193,000 for each abbreviated application for a generic new animal drug other than those subject to the criteria in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $96,500 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4); $8,195 for each generic new animal drug product; $76,250 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $57,188 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $38,125 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for