domestic FDF facility fee of $247,717. The foreign FDF facility fee is $15,000 more than the domestic FDF facility fee, or $262,717.

VII. API Facility Fee

Under GDUFA, the annual API facility fee is owed by each person that owns a facility which produces, or which is pending review to produce, one or more active pharmaceutical ingredients identified, or intended to be identified, in at least one generic drug submission that is pending or approved or in a Type II active pharmaceutical ingredient drug master file referenced in such generic drug submission. These fees are due no later than the first business day on or after October 1 of each such year. Section 744B(b)(2)(D) of the FD&C Act specifies that the API facility fee will make up 14 percent of $312,224,000 in fee revenue, which is $43,711,000 (rounded to the nearest thousand dollars).

In order to calculate the API fee, FDA has used the data submitted by generic drug facilities through the self-identification process mandated in the GDUFA statute and specified in a Notice of Requirement published on October 2, 2012. The total number of API facilities identified through self-identification was 795. Of the total facilities identified as API facilities, there were 103 domestic facilities and 692 foreign facilities. The foreign facility differential is $15,000. In order to calculate the fee for domestic facilities, we must first subtract the fee revenue that will result from the foreign facility fee differential. We take the foreign facility differential ($15,000) and multiply it by the number of foreign facilities (692) to determine the total fees that will result from the foreign facility differential. As a result of that calculation the foreign fee differential will make up $10,380,000 of the total API fee revenue. Subtracting the foreign facility differential fee revenue ($10,380,000) from the total API facility target revenue ($43,711,000) results in a remaining balance of $33,331,000. To determine the domestic API facility fee, we divide the $33,331,000 by the total number of facilities (795) which gives us a domestic API facility fee of $41,926. The foreign API facility fee is $15,000 more than the domestic API facility fee, or $56,926.

VIII. Fee Payment Options and Procedures

The new fee rates are effective October 1, 2014. To pay the ANDA, PAS, DMF, API facility, and FDF facility fee, you must complete a Generic Drug User Fee cover sheet, available at *http://www.fda.gov/gdufa,* and generate a user fee identification (ID) number. Payment must be made in U.S. currency drawn on a U.S. bank by electronic check, check, bank draft, U.S. postal money order, or wire transfer.

FDA has partnered with the U.S. Department of the Treasury to utilize *https://www.pay.gov,* a Web-based payment application, for online electronic payment. The *https://www.pay.gov* feature is available on the FDA Web site after completing the generic drug user fee cover sheet and generating the user fee ID number.

Please include the user fee ID number on your check, bank draft, or postal money order and make payable to the order of the Food and Drug Administration. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. If checks are to be sent by a courier that requests a street address, the courier can deliver checks to: U.S. Bank, Attention: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (**Note:** This U.S. Bank address is for courier delivery only.) Please make sure that the FDA post office box number (P.O. Box 979108) is written on the check, bank draft, or postal money order.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the wire transfer fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: New York Federal Reserve Bank, U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, account number: 75060099, routing number: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., Silver Spring, MD 20993–0002. The tax identification number of FDA is 53–0196965.

Dated: July 28, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18108 Filed 7–31–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0007]

Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2015

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2015 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, 2014, and will remain in effect through September 30, 2015.

FOR FURTHER INFORMATION CONTACT: Hunter Herrman, Office of Resource Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rm. 2049, Rockville, MD 20857, 240–402–3102, email: *Hunter.Herrman@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), (B), and (D)), 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, 2014, and

[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)).

will remain in effect through September 30, 2015. 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 is currently developing a guidance document to outline the process through which firms may request such a reduction of fees. FDA does not intend to issue invoices for reinspection or recall order fees until this guidance document has been published.

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. FDA is currently developing a guidance document that will provide information regarding fees that the Agency may assess and collect from importers to cover reinspection-related costs. The fee rates set forth in this notice will be used to determine any importer reinspection fees assessed in FY 2015.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2015

FDA is required to estimate 100 percent of its costs for each activity in order to establish fee rates for FY 2015. 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, and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2013

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of a full-time equivalent (FTE) or paid staff year for the relevant activity. This is done by dividing the total funds allocated to the elements of FDA primarily responsible for carrying out the activities for which fees are being collected by the total FTEs allocated to those activities. For the purposes of the reinspection and recall order fees authorized by section 743 of the FD&C Act (the fees that are the subject of this notice), primary responsibility for the activities for which fees will be collected rests with FDA's Office of Regulatory Affairs (ORA). ORA carries out inspections and other field-based activities on behalf of FDA's product centers, including the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM). Thus, as the starting point for estimating the full cost per direct work hour, FDA will use the total funds allocated to ORA for CFSAN and CVM related field activities. The most recent FY with available data was FY 2013. In that year, FDA obligated a total of $642,483,679 for ORA in carrying out the CFSAN and CVM related field activities work, excluding the cost of inspection travel. In that same year, the number of ORA staff primarily conducting the CFSAN and CVM related field activities was 2,967 FTEs or paid staff years. Dividing $642,483,679 by 2,967 FTEs results in an average cost of $216,543 per paid staff year, excluding travel costs.

Not all of the FTEs required to support the activities for which fees will be collected are conducting direct work such as inspecting or reinspecting facilities, examining imports, or monitoring recalls. Data collected over a number of years and used consistently in other FDA user fee programs (e.g., under the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee and Modernization Act (MDUFA)) show that every seven FTEs who perform direct FDA work require three indirect and supporting FTEs. These indirect and supporting FTEs function in budget, facility, human resource, information technology, planning, security, administrative support, legislative liaison, legal counsel, program management, and other essential program areas. On average, two of these indirect and supporting FTEs are located in ORA or the FDA center where the direct work is being conducted, and one of them is located in the Office of the Commissioner. To get the fully supported cost of an FTE, FDA needs to multiply the average cost of an FTE by 1.43, to take into account the indirect and supporting functions. The 1.43 factor is derived by dividing the 10 fully supported FTEs by 7 direct FTEs. In FY 2013, the average cost of an FTE was $216,543. Multiplying this amount by 1.43 results in an average fully supported cost of $309,657 per FTE, excluding the cost of inspection travel.

To calculate an hourly rate, FDA must divide the average fully supported cost of $309,657 per FTE by the average number of supported direct FDA work hours. See table 1.

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

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
10 days of training	80
2 hours of meetings per week	80
Net supported direct FDA work hours available for assignments	1,600

Dividing the average fully supported cost of an FTE in FY 2013 ($309,657) by the total number of supported direct work hours available for assignment (1,600) results in an average fully supported cost of $194 (rounded to the nearest dollar), excluding inspection travel costs, per supported direct work hour in FY 2013—the last FY for which data are available.

B. Adjusting FY 2013 Costs for Inflation To Estimate FY 2015 Costs

To adjust the hourly rate for FY 2015, FDA must estimate the cost of inflation in each year for FY 2014 and FY 2015. FDA uses the method prescribed for estimating inflationary costs under the 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 we have used consistently. FDA previously determined the FY 2014 inflation rate to be 2.20; this rate was published in the FY 2014 PDUFA user fee rates notice in the **Federal Register** of August 2, 2013 (78 FR 46980). Using the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 2.0813 percent for FY 2015, and FDA intends to use this inflation rate to make inflation adjustments for FY 2015 for several of its user fee programs; the derivation of this rate is published in the **Federal Register** in the FY 2015

notice for the PDUFA user fee rates. The compounded inflation rate for FYs 2014 and 2015, therefore, is 4.325 percent (1 plus 2.20 percent times 1 plus 2.0813 percent).

Increasing the FY 2013 average fully supported cost per supported direct FDA work hour of $194 (excluding inspection travel costs) by 4.325 percent yields an inflationary adjusted estimated cost of $202 per a supported direct work hour in FY 2015, excluding inspection travel costs. FDA will use this base unit fee in determining the hourly fee rate for reinspection and recall order fees for FY 2015, prior to including domestic or foreign travel costs as applicable for the activity.

In FY 2013, ORA spent a total of $4,687,907 for domestic regulatory inspection travel costs and General Services Administration Vehicle costs related to FDA's CFSAN and CVM field activities programs. The total ORA domestic travel costs spent is then divided by the 11,779 CFSAN and CVM domestic inspections, which averages a total of $398 per inspection. These inspections average 27.91 hours per inspection. Dividing $398 per inspection by 27.91 hours per inspection results in a total and an additional cost of $14 per hour spent for domestic inspection travel costs in FY 2013. To adjust $14 for inflationary increases in FY 2014 and FY 2015, FDA must multiply it by the same inflation factor mentioned previously in this document (1.04325), which results in an estimated cost of $15 dollars per paid hour in addition to $202 for a total of $217 per paid hour ($202 plus $15) for each direct hour of work requiring domestic inspection travel. FDA will use these rates in charging fees in FY 2015 when domestic travel is required.

In FY 2013, ORA spent a total of $2,797,656 on 235 foreign inspection trips related to FDA's CFSAN and CVM field activities programs, which averaged a total of $11,905 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $11,905 per trip by 120 hours per trip results in a total and an additional cost of $99 per paid hour spent for foreign inspection travel costs in FY 2013. To adjust $99 for inflationary increases in FY 2014 and FY 2015, FDA must multiply it by the same inflation factor mentioned previously in this document (1.04325) which results in an estimated cost of $103 dollars per paid hour in addition to $202 for a total of $305 per paid hour ($202 plus $103) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2015 when foreign travel is required.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2015

Fee category	Fee rates for FY 2015
Hourly rate if domestic travel is required	$217
Hourly rate if foreign travel is required	305

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)) 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 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18172 Filed 7–31–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0634]

Draft Guidance for Industry on Cell-Based Products for Animal Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry #218 entitled ''Cell-Based Products for Animal Use.'' This draft guidance describes FDA's Center for Veterinary Medicine's (CVM) current thinking on cell-based products for animal use that meet the definition of a new animal drug. This draft guidance is for firms and individuals developing cell-based products, including animal stem cell-based products (ASCPs).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 30, 2014.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Lynne Boxer, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0611, *lynne.boxer@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry #218 entitled ''Cell-Based Products for Animal Use.'' CVM is aware that many veterinary therapies may be produced using cell-based products. Developers of such products for veterinary use have approached CVM for clarification regarding the regulation of these products. This draft guidance for industry describes CVM's current thinking on cell-based products for animal use that meet the definition of a new animal drug.

Cell-based products meeting the definition of a new animal drug are subject to the same statutory and regulatory requirements as other new animal drugs. Although this draft guidance relates to other cell-based products, this draft guidance focuses on ASCPs meeting the definition of a new animal drug.

This draft guidance addresses the following topics:

- How existing regulations apply to cell-based products for veterinary use;
- A common vocabulary for ASCPs;
- A risk-based category structure for ASCPs; and
- Industry interaction with CVM early in product development.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR