This draft guidance establishes standard dissolution methodology and specifications that are appropriate for BCS class 1 and class 3 drugs. The availability of these standards will facilitate the rapid development of dissolution methodology and related specifications for these classes during drug development and application review.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on Dissolution Testing and Specification Criteria for Immediate-Release Solid Oral Dosage Forms Containing Biopharmaceutics Classification System Class 1 and 3 Drugs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: July 29, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18968 Filed 7–31–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0007]

Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2016

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2016 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, 2015, and will remain in effect through September 30, 2016.

FOR FURTHER INFORMATION CONTACT: Jason Lewis, Office of Resource 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, 2015, and will remain in effect through September 30, 2016. Section 743(b)(2)(B)(iii) of the FD&C Act directs FDA to develop a proposed set of guidelines in consideration of the burden of fee amounts on small businesses. As a first step in developing these guidelines, FDA invited public comment on the potential impact of the fees authorized by section 743 of the FD&C Act on small businesses (76 FR 45818, August 1, 2011). The comment period for this request ended November 30, 2011. As stated in FDA's September 2011 ''Guidance for Industry: Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act,'' (*http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm274176.htm*), because FDA recognizes that for small businesses the full cost recovery of FDA reinspection or recall oversight could impose severe economic hardship, FDA intends to consider reducing certain fees for those firms. FDA does not intend to issue invoices for reinspection or recall order fees until FDA publishes a guidance document outlining the process through which firms may request a reduction in fees.

In addition, as stated in the September 2011 Guidance, FDA is in the process of considering various issues associated with the assessment and collection of importer reinspection fees. The fee rates set forth in this notice will be used to determine any importer reinspection fees assessed in FY 2016.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2016

FDA is required to estimate 100 percent of its costs for each activity in order to establish fee rates for FY 2016. 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.

[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)).

A. Estimating the Full Cost per Direct Work Hour in FY 2014

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 2014. In that year, FDA obligated a total of $669,055,119 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 3,016 FTEs or paid staff years. Dividing $669,055,119 by 3,016 FTEs results in an average cost of $221,835 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) 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 2014, the average cost of an FTE was $221,835. Multiplying this amount by 1.43 results in an average fully supported cost of $317,224 per FTE, excluding the cost of inspection travel.

To calculate an hourly rate, FDA must divide the average fully supported cost of $317,224 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 2014 ($317,224) by the total number of supported direct work hours available for assignment (1,600) results in an average fully supported cost of $198 (rounded to the nearest dollar), excluding inspection travel costs, per supported direct work hour in FY 2014—the last FY for which data are available.

B. Adjusting FY 2014 Costs for Inflation To Estimate FY 2016 Costs

To adjust the hourly rate for FY 2016, FDA must estimate the cost of inflation in each year for FY 2015 and FY 2016. 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 FDA has used consistently. FDA previously determined the FY 2015 inflation rate to be 2.0813; this rate was published in the FY 2015 PDUFA user fee rates notice in the **Federal Register** of August 1, 2014 (79 FR 44807). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 2.0266 percent for FY 2016, and FDA intends to use this inflation rate to make inflation adjustments for FY 2016 for several of its user fee programs; the derivation of this rate is published in the **Federal Register** in the FY 2016 notice for the PDUFA user fee rates. The compounded inflation rate for FYs 2015 and 2016, therefore, is 4.150 percent (1 plus 2.0813 percent times 1 plus 2.0266 percent).

Increasing the FY 2014 average fully supported cost per supported direct FDA work hour of $198 (excluding inspection travel costs) by 4.150 percent yields an inflationary adjusted estimated cost of $206 per a supported direct work hour in FY 2016, 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 2016 prior to including domestic or foreign travel costs as applicable for the activity.

In FY 2014, ORA spent a total of $4,536,206 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 10,392 CFSAN and CVM domestic inspections, which averages a total of $437 per inspection. These inspections average 31.64 hours per inspection. Dividing $437 per inspection by 31.64 hours per inspection results in a total and an additional cost of $14 per hour spent for domestic inspection travel costs in FY 2014. To adjust $14 for inflationary increases in FY 2015 and FY 2016, FDA must multiply it by the same inflation factor mentioned previously in this document (1.04150), which results in an estimated cost of $15 dollars per paid hour in addition to $206 for a total of $221 per paid hour ($206 plus $15) for each direct hour of work requiring domestic inspection travel. FDA will use these rates in charging fees in FY 2016 when domestic travel is required.

In FY 2014, ORA spent a total of $3,209,009 on 255 foreign inspection trips related to FDA's CFSAN and CVM field activities programs, which averaged a total of $12,584 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $12,584 per trip by 120 hours per trip results in a total and an additional cost of $105 per paid hour spent for foreign inspection travel costs in FY 2014. To adjust $105 for inflationary increases in FY 2015 and FY 2016, FDA must multiply it by the same inflation factor mentioned previously in this document (1.04150), which results in an estimated cost of $109 dollars per paid hour in addition to $206 for a total of $315 per paid hour ($206 plus $109) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2016 when foreign travel is required.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2016

Fee category	Fee rates for FY 2016
Hourly rate if domestic travel is required	$221
Hourly rate if foreign travel is required	315

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

A. What will cause this fee to be assessed?

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

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

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

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

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

B. Who will be responsible for paying this fee?

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

C. How much will this fee be?

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

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

A. What will cause this fee to be assessed?

The fee will be assessed for not complying with a recall order under section 423(d) (21 U.S.C. 350*l*(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 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2596]

Understanding Potential Intervention Measures To Reduce the Risk of Foodborne Illness From Consumption of Cheese Manufactured From Unpasteurized Milk

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information.

SUMMARY: The Food and Drug Administration (FDA or we) is requesting comments and scientific data and information that would assist us in identifying and evaluating intervention measures that might have an effect on the presence of bacterial pathogens in cheeses manufactured from unpasteurized milk. We are taking this action in light of scientific data on potential health risks associated with consumption of cheese made from unpasteurized milk.

DATES: Submit either electronic or written comments and scientific data and information by November 2, 2015.

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

FOR FURTHER INFORMATION CONTACT: Andrew Yeung, Center for Food Safety and Applied Nutrition (HFS–316), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1541, *andrew.yeung@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

A 2012 review of outbreaks of foodborne illness that occurred in the United States between 1993 and 2006 that were attributed to dairy products determined that more than 50 percent of the outbreaks reviewed in the study involved cheese, with the remaining outbreaks being attributable to fluid milk (Ref. 1). Forty-two percent of the 65 cheese-associated outbreaks (*i.e.,* 27 outbreaks) were attributable to products manufactured from unpasteurized milk, even though the contribution of unpasteurized dairy products to all dairy product consumption in the United States during the time period under study was estimated at below 1 percent (on a weight or volume base) (Ref. 1). The 65 analyzed outbreaks due to cheese made from unpasteurized milk resulted in 641 associated illnesses with 131 hospitalizations (*i.e.,* a hospitalization rate of more than 20 percent). Pathogens associated with these outbreaks included *Listeria monocytogenes, Escherichia coli* (*E. coli*) O157, *Salmonella,* and others (Ref. 1). All of these pathogens can cause significant illness and even death.

FDA and Health Canada recently collaborated on the development of a model to evaluate the impact of factors, such as the microbiological status of milk used in cheese production, various cheese manufacturing steps, conditions during distribution and storage, and cross-contamination during processing and handling, on the public health risk of listeriosis from consumption of soft-ripened cheese. Elsewhere in this issue of the **Federal Register,** we are announcing the release of the ''Joint Food and Drug Administration/Health Canada—Santé Canada Quantitative Assessment of the Risk of Listeriosis From Soft-Ripened Cheese Consumption in the United States and Canada'' (the FDA/Health Canada QRA) (Ref. 2).

FDA establishes food standards of identity, to promote honesty and fair dealing in the interest of consumers, under the authority set forth in section 401 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 341). Some of these standards of identity (*e.g.,* the standard of identity for soft-ripened cheese in § 133.182 (21 CFR 133.182)) permit the manufacture of cheese from unpasteurized milk. These standards of identity specify that the process for cheese manufactured from unpasteurized milk include an aging period. A typical aging period is not less than 60 days at not less than 35 °F (see § 133.182(a) in the standard of identity for soft-ripened cheese).

The aging period for cheese manufactured from unpasteurized milk was presumed to act as a control measure to reduce the risk that pathogens would be present when the cheese was consumed. However, the available data and information raise questions about the safety of cheese manufactured from unpasteurized milk, even when aged. For example, research has demonstrated that pathogens such as *E. coli* O157:H7 can survive a 60-day aging period in a hard cheese such as Cheddar cheese (Refs. 3 and 4). In addition, a 1997 memorandum from a subcommittee of the National Advisory Committee on Microbiological Criteria for Foods stated that the scientific literature confirms that pathogens can survive the 60-day aging process for cheeses manufactured using unpasteurized milk (Ref. 5). More recently, the results of the FDA/Health Canada QRA suggest that the 60-day aging period for soft-ripened cheese may increase the risk of listeriosis from consumption of soft-ripened cheese by allowing more time for *L. monocytogenes,* if present, to multiply (rather than decrease) as the soft-ripened cheese ages (Ref. 6).

FDA recognizes that there is broad diversity in cheese manufacturing operations and approaches and that many factors go into ensuring the safety of the food. Many types of raw milk cheeses are made using traditional methods that require a successful balance involving the quality of the milk, the equipment, and the environment, including ensuring the presence of bacteria critical to the nature of the cheese while preventing the introduction or growth of pathogens. In issuing this call for data and information, we are particularly interested in learning more about the standards and practices in use by the growing artisanal cheese manufacturing community.