payment. The 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, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18915 Filed 7–31–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1997–D–0187]

Dissolution Testing and Specification Criteria for Immediate-Release Solid Oral Dosage Forms Containing Biopharmaceutics Classification System Class 1 and 3 Drugs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Dissolution Testing and Specification Criteria for Immediate-Release Solid Oral Dosage Forms Containing Biopharmaceutics Classification System Class 1 and 3 Drugs.'' This draft guidance has been developed to provide manufacturers with recommendations for submission of new drug applications (NDAs), investigational new drug applications (INDs), and/or abbreviated new drug applications (ANDAs), as appropriate, for immediate-release (IR) tablets and capsules that contain highly soluble drug substances. The draft guidance is intended to define when a standard release test and criteria may be used in lieu of extensive method development and specification-setting exercises. When final, this guidance will supersede the guidance for industry on ''Dissolution Testing of Immediate Release Solid Oral Dosage Forms'' (August 1997) for biopharmaceutics classification system (BCS) class 1 and 3 drug substances that meet the criteria in this draft guidance. For class 2 and 4 drug substances, applicants should still refer to the August 1997 guidance mentioned previously.

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 October 2, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. 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: Richard Lostritto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, 301–796–1667.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Dissolution Testing and Specification Criteria for Immediate-Release Solid Oral Dosage Forms Containing Biopharmaceutics Classification System Class 1 and 3 Drugs.'' Drug absorption from a solid dosage form after oral administration depends on the release of the drug substance from the drug product, the dissolution or solubilization of the drug under physiological conditions, and the permeation across the gastrointestinal membrane. NDAs and ANDAs submitted to FDA contain bioavailability (BA) or bioequivalence (BE) data and in vitro dissolution data that, together with chemistry, manufacturing, and controls (CMC) data, characterize the quality and performance of the drug product. In vitro dissolution data are generally obtained from batches that have been used in pivotal clinical and/or bioavailability studies and from other human studies conducted during product development. Knowledge about the solubility, permeability, dissolution, and pharmacokinetics of a drug product is considered when defining dissolution test specifications for the drug approval process.

The BCS is a scientific framework for classifying drug substances based on their aqueous solubility and intestinal permeability. The definitions of high and low solubility and high and low permeability are used as described in FDA's Biopharmaceutics Classification System (BCS) Guidance. The different classifications are:

Class 1: High Solubility—High Permeability Drugs
Class 2: Low Solubility—High Permeability Drugs
Class 3: High Solubility—Low Permeability Drugs
Class 4: Low Solubility—Low Permeability Drugs

This classification can be used as a basis for determining when in vivo bioavailability and bioequivalence studies are needed and can be used to determine when a successful in vivo-in vitro correlation (IVIVC) is likely. The BCS suggests that, for certain high solubility drugs, dissolution testing can be standardized or may not be needed. Owing to their high solubility, BCS class 1 and 3 drugs are considered to be relatively low risk regarding the impact of dissolution on performance, provided the in vitro performance meets or exceeds the recommendations discussed in the guidance.

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]

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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)).