TABLE 2—FY 2016 FEE RATES—Continued

| Generic new animal drug user fee category | Fee rate for FY 2016 |
|---|---|
| Abbreviated Application Fee for Generic New Animal Drug subject to the criteria in section 512(d)(4) | 116,650 |
| Generic New Animal Drug Product Fee | 8,705 |
| 100 Percent Generic New Animal Drug Sponsor Fee [1] | 83,800 |
| 75 Percent Generic New Animal Drug Sponsor Fee [1] | 62,850 |
| 50 Percent Generic New Animal Drug Sponsor Fee [1] | 41,900 |

[1] An animal drug sponsor is subject to only one fee each fiscal year.

## VII. Procedures for Paying FY 2016 Generic New Animal Drug User Fees

### *A. Abbreviated Application Fees and Payment Instructions*

The FY 2016 fee established in the new fee schedule must be paid for an abbreviated new animal drug application subject to fees under AGDUFA that is submitted on or after October 1, 2015. Payment must be made in U.S. currency from a U.S. bank by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration, by wire transfer, or by automatic clearing house using Pay.gov. (The Pay.gov payment option is available to you after you submit a cover sheet. Click the ''Pay Now'' button). On your check, bank draft, U.S. or postal money order, please write your application's unique Payment Identification Number, beginning with the letters ''AG'', from the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write the FDA post office box number (P.O. Box 953877) on the enclosed check, bank draft, or money order. Your payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet can be mailed to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000.

If payment is made via wire transfer, send payment to U. S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., Silver Spring, MD 20993–0002. You are responsible for any administrative costs associated with the processing of a wire transfer. Contact your bank or financial institution about the fee and add it to your payment to ensure that your fee is fully paid.

If you prefer to send a check by a courier, the courier may deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery contact the U.S. Bank at 314–418–4013. This phone number is only for questions about courier delivery.)

The tax identification number of FDA is 53–0196965. (Note: In no case should the payment for the fee be submitted to FDA with the application.)

It is helpful if the fee arrives at the bank at least a day or two before the abbreviated application arrives at FDA's Center for Veterinary Medicine (CVM). FDA records the official abbreviated application receipt date as the later of the following: The date the application was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Department of the Treasury notifies FDA of payment. U.S. Bank and the United States Treasury are required to notify FDA within 1 working day, using the Payment Identification Number described previously.

### *B. Application Cover Sheet Procedures*

Step One—Create a user account and password. Log onto the AGDUFA Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm* and scroll down the page until you find the link ''Create AGDUFA User Fee Cover Sheet.'' Click on that link and follow the directions. For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated animal drug application. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique Payment Identification Number.

Step Three—Send the payment for your application as described in Section VII.A of this document.

Step Four—Please submit your application and a copy of the completed Animal Generic Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

### *C. Product and Sponsor Fees*

By December 31, 2015, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2016 using this fee schedule. Fees will be due by January 31, 2016. FDA will issue invoices in November 2016 for any products and sponsors subject to fees for FY 2016 that qualify for fees after the December 2015 billing.

Dated: July 28, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–18909 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]**

## Generic Drug User Fee—Abbreviated New Drug Application, Prior Approval Supplement, Drug Master File, Final Dosage Form Facility, and Active Pharmaceutical Ingredient Facility Fee Rates for Fiscal Year 2016

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the rates for abbreviated new drug applications (ANDAs), prior approval supplements to an approved ANDA (PASs), drug master files (DMFs),

generic drug active pharmaceutical ingredient (API) facilities, and finished dosage form (FDF) facilities user fees related to the Generic Drug User Fee Program for fiscal year (FY) 2016. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Generic Drug User Fee Amendments of 2012 (GDUFA), authorizes FDA to assess and collect user fees for certain applications and supplements for human generic drug products, on applications in the backlog as of October 1, 2012 (only applicable to FY 2013), on FDF and API facilities, and on type II active pharmaceutical ingredient DMFs to be made available for reference. This document establishes the fee rates for FY 2016.

**FOR FURTHER INFORMATION CONTACT:** Rachel Richter, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14216, Silver Spring, MD 20993–0002, 301–796–7111.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Sections 744A and 744B of the FD&C Act (21 U.S.C. 379j–41 and 379j–42) establish fees associated with human generic drug products. Fees are assessed on: (1) Certain applications in the backlog as of October 1, 2012 (only applicable to FY 2013); (2) certain types of applications and supplements for human generic drug products; (3) certain facilities where APIs and FDFs are produced; and (4) certain DMFs associated with human generic drug products (see section 744B(a)(1)–(4) of the FD&C Act).

For FY 2016, the generic drug fee rates are: ANDA ($76,030), PAS ($38,020), DMF ($42,170), domestic API facility ($40,867), foreign API facility ($55,867), domestic FDF facility ($243,905), and foreign FDF facility ($258,905). These fees are effective on October 1, 2015, and will remain in effect through September 30, 2016.

Fees for ANDA, PAS, and DMF will increase in FY 2016 over the corresponding fees in FY 2015 due to a drop in the number of submissions in each of those three categories over the course of FY 2015. The fees for all types of facilities will decrease in FY 2016 over the corresponding fees in FY 2015 due to an increase in the number of facilities that self-identified for FY 2016.

## II. Fee Revenue Amount for FY 2016

The base revenue amount for FY 2016 is $299 million, as set in the statute prior to the inflation adjustment. GDUFA directs FDA to use the yearly revenue amount as a starting point to set the fee rates for each fee type. For more information about GDUFA, please refer to the FDA Web site (*http://www.fda.gov/gdufa*). The ANDA, PAS, DMF, API facility, and FDF facility fee calculations for FY 2016 are described in this document.

### *Inflation Adjustment*

GDUFA specifies that the $299 million is to be adjusted for inflation increases for FY 2016 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 744B(c)(1) of the FD&C Act).

The component of the inflation adjustment for PC&B costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position (FTE) at FDA for the first three of the four preceding fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of the review of human generic drug activities for the first three of the preceding four fiscal years (see section 744B(c)(1)(A)–(B) of the FD&C Act).

Table 1 summarizes the actual cost and total FTE for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first three of the four fiscal years preceding FY 2016. The 3-year average is 2.2328 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE

| Fiscal year | 2012 | 2013 | 2014 | 3-Year average |
|---|---|---|---|---|
| Total PC&B | $1,824,703,000 | $1,927,703,000 | $2,054,937,000 | |
| Total FTE | 13,382 | 13,974 | 14,555 | |
| PC&B per FTE | $136,355 | $137,949 | $141,184 | |
| % Change from Previous Year | 3.1843% | 1.1690% | 2.3451% | 2.2328% |

The statute specifies that this 2.2328 percent should be multiplied by the proportion of PC&B expended for human generic drug activities for the first three of the preceding four fiscal years. When FDA set fees in FY 2014, the 3-year average of PC&B costs for the entire Agency was used because information for GDUFA was not available. Now that the first 2 years of GDUFA have been completed, FDA will use the data from FY 2013 and FY 2014 to calculate the PC&B and non-PC&B proportions. Table 2 shows the amount of PC&B and the total amount obligated for human generic drug activities in FY 2013 and FY 2014.

TABLE 2—PC&B AS A PERCENT OF FEE REVENUES SPENT ON THE PROCESS OF HUMAN GENERIC DRUG APPLICATIONS OVER THE LAST 3 YEARS

| Fiscal year | 2012 | 2013 | 2014 | 3-Year Average |
|---|---|---|---|---|
| PC&B | NA | $117,576,760 | $171,612,147 | |
| Non-PC&B | NA | $149,307,336 | $215,469,133 | |
| Total Costs | NA | $266,884,096 | $387,081,279 | |
| PC&B percent | | 44.0554% | 44.3349% | 44.1952% |
| Non-PC&B percent | | 55.9446% | 55.6651% | 55.8048% |

The payroll adjustment is 2.2328 percent multiplied by 44.1952 percent (or 0.9868 percent).

The statute specifies that the portion of the inflation adjustment for non-PC&B costs for FY 2016 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC–MD–VA–WV; not seasonally adjusted; all items; annual

index) for the first three of the preceding four years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of human generic drug activities (see section 744B(c)(1)(C) of the FD&C Act). Table 3 provides the summary data for the percent change in the specified CPI for the Baltimore-Washington area. The data are published by the Bureau of Labor Statistics and can be found on their Web site at *http://data.bls.gov/cgi-bin/surveymost?cu* by checking the box marked ''Washington-Baltimore All Items, November 1996=100—CUURA311SA0'' and then clicking on the ''Retrieve Data'' button.

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR BALTIMORE-WASHINGTON AREA

| Year | 2012 | 2013 | 2014 | 3-Year average |
|---|---|---|---|---|
| Annual CPI | 150.212 | 152.500 | 154.847 | |
| Annual Percent Change | 2.2024% | 1.5232% | 1.5390% | 1.754867% |

To calculate the inflation adjustment for non-pay costs, we multiply the 3-year average percent change in the CPI (1.7549 percent) by the proportion of all costs other than PC&B to total costs of human generic drug activities obligated. Since 44.1952 percent was obligated for PC&B as shown in table 2, 55.8048 percent is the portion of costs other than PC&B. The non-pay adjustment is 1.7549 percent times 55.8048 percent, or 0.9793 percent.

To complete the inflation adjustment for FY 2016, we add the PC&B component (0.9868 percent) to the non-PC&B component (0.9793 percent) for a total inflation adjustment of 1.9661 percent (rounded) for FY 2016.

GDUFA provides for this inflation adjustment to be compounded after FY 2013 (see section 744B(c)(1) of the FD&C Act). This factor for FY 2016 (1.9661 percent) is compounded by adding one to it, and then multiplying it by the compounded inflation adjustment factor for FY 2015 (1.044228), as published in the **Federal Register** of August 1, 2014 (79 FR 44797). The result of this multiplication of the inflation factors for the 3 years since FY 2013 (1.019661 times 1.044228 percent) becomes the inflation adjustment for FY 2016. For FY 2016, the inflation adjustment is 6.4759 percent (rounded). We then add one, making 1.064759. Finally, we multiply the FY 2016 base revenue amount ($299 million) by 1.064759, yielding inflation-adjusted target revenue of $318,363,000 (rounded to the nearest thousand dollars).

## III. ANDA and PAS Fees

Under GDUFA, the FY 2016 ANDA and PAS fees are owed by each applicant that submits an ANDA or a PAS, on or after October 1, 2015. These fees are due on the receipt date of the ANDA or PAS. Section 744B(b)(2)(B) specifies that the ANDA and PAS fees will make up 24 percent of the $318,363,000, which is $76,407,000 (rounded to the nearest thousand dollars), and further specifies that the PAS fee is equal to half the ANDA fee.

In order to calculate the ANDA fee, FDA estimated the number of full application equivalents (FAEs) that will be submitted in FY 2016. This is done by assuming ANDAs count as one FAE and PASs (supplements) count as one-half an FAE since the fee for a PAS is one half of the fee for an ANDA. GDUFA also requires, however, that 75 percent of the fee paid for an ANDA or PAS filing fee be refunded if the ANDA or PAS is refused due to issues other than failure to pay fees (section 744B(a)(3)(D) of the FD&C Act). Therefore, an ANDA or PAS that is considered not to have been received by the Secretary due to reasons other than failure to pay fees counts as one-fourth of an FAE if the applicant initially paid a full application fee, or one-eighth of an FAE if the applicant paid the supplement fee (one half of the full application fee amount).

FDA utilized data from ANDAs and PASs submitted from October 1, 2012, to May 31, 2015, to estimate the number of new original ANDAs and PASs that will incur filing fees in FY 2016. For FY 2016, the Agency estimates that approximately 801 new original ANDAs and 421 PASs will be submitted and incur filing fees. Not all of the new original ANDAs and PASs will be received by the Agency, and some of those not received will be resubmitted in the same fiscal year. Therefore, the Agency expects that the FAE count for ANDAs and PASs will be 1,005 for FY 2016.

The FY 2016 application fee is estimated by dividing the number of FAEs that will pay the fee in FY 2016 (1,005) into the fee revenue amount to be derived from application fees in FY 2016 ($76,407,000). The result, rounded to the nearest $10, is a fee of $76,030 per ANDA. The PAS fee is one-half that amount, or $38,020, rounded to the nearest $10.

The statute provides that those ANDAs that include information about the production of active pharmaceutical ingredients other than by reference to a DMF will pay an additional fee that is based on the number of such active pharmaceutical ingredients and the number of facilities proposed to produce those ingredients (see section 744B(a)(3)(F) of the FD&C Act). FDA considers that this additional fee is unlikely to be assessed often; therefore, FDA has not included projections concerning the amount of this fee in calculating the fees for ANDAs and PASs.

## IV. DMF Fee

Under GDUFA, the DMF fee is owed by each person that owns a type II active pharmaceutical ingredient DMF that is referenced, on or after October 1, 2012, in a generic drug submission by an initial letter of authorization. This is a one-time fee for each individual DMF. This fee is due no later than the date on which the first generic drug submission is submitted that references the associated DMF. Under section 744B(a)(2)(D)(iii) of the FD&C Act, if a DMF has successfully undergone an initial completeness assessment and the fee is paid, the DMF will be placed on a publicly available list documenting DMFs available for reference. Thus, some DMF holders may choose to pay the fee prior to the date that it would otherwise be due in order to have the DMF placed on that list.

In order to calculate the DMF fee, FDA assessed the volume of DMF submissions over time. The statistical forecasting methodology of power regression analysis was selected because this model showed a very good fit to the distribution of DMF submissions over time. Based on data representing the total paid DMFs from October 2012 to May 2015 and projecting a 5-year timeline (October 2012 to September 2017), FDA is estimating 453 fee-paying DMFs for FY 2016.

The FY 2016 DMF fee is determined by dividing the DMF target revenue by the estimated number of fee-paying DMFs in FY 2016. Section 744B(b)(2)(A) specifies that the DMF fees will make up 6 percent of the $318,363,000, which is $19,102,000 (rounded up to the

nearest thousand dollars). Dividing the DMF revenue amount ($19,102,000) by the estimated fee-paying DMFs (453), and rounding to the nearest $10, yields a DMF fee of $42,170 for FY 2016.

**V. Foreign Facility Fee Differential**

Under GDUFA, the fee for a facility located outside the United States and its territories and possessions shall be not less than $15,000 and not more than $30,000 higher than the amount of the fee for a facility located in the United States and its territories and possessions, as determined by the Secretary. The basis for this differential is the extra cost incurred by conducting an inspection outside the United States and its territories and possessions. For FY 2016, FDA has determined that the differential for foreign facilities will be $15,000. The differential may be adjusted in future years.

**VI. FDF Facility Fee**

Under GDUFA, the annual FDF facility fee is owed by each person that owns a facility which is identified, or intended to be identified, in at least one generic drug submission that is pending or approved to produce one or more finished dosage forms of a human generic drug. These fees are due no later than the first business day on or after October 1 of each such year. Section 744B(b)(2)(C) of the FD&C Act specifies that the FDF facility fee revenue will make up 56 percent of $318,363,000, which is $178,283,000 (rounded to the nearest thousand dollars).

In order to calculate the FDF fee, FDA used 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 (77 FR 60125). The total number of FDF facilities identified through self-identification was 705. Of the total facilities identified as FDF, there were 283 domestic facilities and 422 foreign facilities. The foreign facility fee 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 (422) 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 $6,330,000 of the total FDF fee revenue. Subtracting the foreign facility differential fee revenue ($6,330,000), from the total FDF facility target revenue ($178,283,000) results in a remaining fee revenue balance of $171,953,000. To determine the domestic FDF facility fee, we divide the $171,953,000 by the total number of facilities (705) which gives us a domestic FDF facility fee of $243,905. The foreign FDF facility fee is $15,000 more than the domestic FDF facility fee, or $258,905.

**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 $318,363,000 in fee revenue, which is $44,571,000 (rounded to the nearest thousand dollars).

In order to calculate the API fee, FDA used 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 826. Of the total facilities identified as API facilities, there were 105 domestic facilities and 721 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 (721) 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 $10,815,000 of the total API fee revenue. Subtracting the foreign facility differential fee revenue ($10,815,000) from the total API facility target revenue ($44,571,000) results in a remaining balance of $33,756,000. To determine the domestic API facility fee, we divide the $33,756,000 by the total number of facilities (826) which gives us a domestic API facility fee of $40,867. The foreign API facility fee is $15,000 more than the domestic API facility fee, or $55,867.

**VIII. Fee Schedule for FY 2016**

The fee rates for FY 2016 are set out in table 4.

TABLE 4—FEE SCHEDULE FOR FY 2016

| Fee category | Fee rates for FY 2016 |
|---|---|
| Applications: | |
| Abbreviated New Drug Application (ANDA) | $76,030 |
| Prior Approval Supplement (PAS) to an ANDA | 38,020 |
| Drug Master File (DMF) | 42,170 |
| Facilities: | |
| Active Pharmaceutical Ingredient (API)—Domestic | 40,867 |
| API—Foreign | 55,867 |
| Finished Dosage Form (FDF)—Domestic | 243,905 |
| FDF—Foreign | 258,905 |

**IX. Fee Payment Options and Procedures**

The new fee rates are effective October 1, 2015. 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 Pay.gov, a Web-based payment application, for online electronic

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]

**BILLING CODE 4164–01–P**

## 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.