FoodborneIllnessRiskFactorReduction/ucm224321.htm.

4. FDA National Retail Food Team. ''FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998–2008).'' Available at: *https://wayback.archive-it.org/7993/20170406022950/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm223293.htm.*
5. ''FDA Food Code.'' Available at: *https://www.fda.gov/FoodCode.*

Dated: July 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16189 Filed 7–27–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0007]

Medical Device User Fee Rates for Fiscal Year 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2019. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device User Fee Amendments of 2017 (MDUFA IV), authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. This notice establishes the fee rates for FY 2019, which apply from October 1, 2018, through September 30, 2019. To avoid delay in the review of your application, you should pay the application fee before or at the time you submit your application to FDA. The fee you must pay is the fee that is in effect on the later of the date that your application is received by FDA or the date your fee payment is recognized by the U.S. Treasury. If you want to pay a reduced small business fee, you must qualify as a small business before making your submission to FDA; if you do not qualify as a small business before making your submission to FDA, you will have to pay the higher standard fee. Please note that the establishment registration fee is not eligible for a reduced small business fee. As a result, if the establishment registration fee is the only medical device user fee that you will pay in FY 2019, you should not submit a Small Business Certification Request. This document provides information on how the fees for FY 2019 were determined, the payment procedures you should follow, and how you may qualify for reduced small business fees.

FOR FURTHER INFORMATION CONTACT:

For information on Medical Device User Fees: Visit FDA's website at: *https://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm20081521.htm.*

For questions relating to the MDUFA Small Business Program, please visit CDRH's website: https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/ucm577696.htm.

For questions relating to this notice: David Haas, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd. (COLE–14202I), Silver Spring, MD 20993–0002, 240–402–9845.

SUPPLEMENTARY INFORMATION:

I. Background

Section 738 of the FD&C Act (21 U.S.C. 379j) establishes fees for certain medical device applications, submissions, supplements, notices, and requests (for simplicity, this document refers to these collectively as ''submissions'' or ''applications''); for periodic reporting on class III devices; and for the registration of certain establishments. Under statutorily defined conditions, a qualified applicant may receive a fee waiver or may pay a lower small business fee (see 21 U.S.C. 379j(d) and (e)).

Under the FD&C Act, the fee rate for each type of submission is set at a specified percentage of the standard fee for a premarket application (a premarket application is a premarket approval application (PMA), a product development protocol (PDP), or a biologics license application (BLA)). The FD&C Act specifies the base fee for a premarket application for each year from FY 2018 through FY 2022; the base fee for a premarket application received by FDA during FY 2019 is $300,000. From this starting point, this document establishes FY 2019 fee rates for certain types of submissions, and for periodic reporting, by applying criteria specified in the FD&C Act.

The FD&C Act specifies the base fee for establishment registration for each year from FY 2018 through FY 2022; the base fee for an establishment registration in FY 2019 is $4,548. There is no reduction in the registration fee for small businesses. Each establishment that is registered (or is required to register) with the Secretary of Health and Human Services under section 510 of the FD&C Act (21 U.S.C. 360) because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device is required to pay the annual fee for establishment registration.

II. Revenue Amount for FY 2019

The total revenue amount for FY 2019 is $190,654,875, as set forth in the statute prior to the inflation adjustment (see 21 U.S.C. 379j(b)(3)). MDUFA directs FDA to use the yearly total revenue amount as a starting point to set the standard fee rates for each fee type. The fee calculations for FY 2019 are described in this document.

Inflation Adjustment

MDUFA specifies that the $190,654,875 is to be adjusted for inflation increases for FY 2019 using two separate adjustments—one for payroll costs and one for non-payroll costs (see 21 U.S.C. 379j(c)(2)). The base inflation adjustment for FY 2019 is the sum of one plus these two separate adjustments, and is compounded as specified in the statute (see 21 U.S.C. 379j(c)(2)(C) and 379j(c)(2)(B)).

The component of the inflation adjustment for payroll costs is the average annual percent change in the cost of all personnel compensation and benefits (PC&B) paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding FYs, multiplied by 0.60, or 60 percent (see 21 U.S.C. 379j(c)(2)(C)).

Table 1 summarizes the actual cost and FTE data for the specified FYs, and provides the percent change from the previous FY and the average percent change over the first 3 of the 4 FYs preceding FY 2019. The 3-year average is 2.4152 percent (rounded).

TABLE 1—FDA PC&BS EACH YEAR AND PERCENT CHANGE

Fiscal year	2015	2016	2017	3-Year average
Total PC&B	$2,232,304,000	$2,414,728,159	$2,581,551,000	

TABLE 1—FDA PC&BS EACH YEAR AND PERCENT CHANGE—Continued

Fiscal year	2015	2016	2017	3-Year average
Total FTE	15,484	16,381	17,022	
PC&B per FTE	$144,168	$147,408	$151,660	
Percent change from previous year	2.1136	2.2474	2.8845	2.4152

The payroll adjustment is 2.4152 percent multiplied by 60 percent, or 1.4491 percent.

The statute specifies that the component of the inflation adjustment for non-payroll costs for FY 2019 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 3 of the preceding 4 years of available data multiplied by 0.40, or 40 percent (see 21 U.S.C. 379j(c)(2)(C)).

Table 2 provides the summary data and the 3-year average percent change in the specified CPI for the Baltimore-Washington area. These data are published by the Bureau of Labor Statistics and can be found on their website at: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURA311SA0,CUUSA311SA0.*

TABLE 2—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN BALTIMORE-WASHINGTON AREA CPI

Fiscal year	2015	2016	2017	3-Year average
Annual CPI	155.353	157.180	159.202	
Annual Percent Change	0.3268	1.1760	1.2864	
3-Year Average Percent Change in CPI				0.9297

The non-pay adjustment is 0.9297 percent multiplied by 40 percent, or 0.3719 percent.

Next, the payroll adjustment (1.4491 percent or 0.014491) is added to the non-payroll adjustment (0.3719 percent or 0.003719), for a total of 1.8210 percent (or 0.018210). To complete the inflation adjustment, 1 (100 percent or 1.0) is added for a total base inflation adjustment of 1.018210 for FY 2019.

MDUFA IV provides for this inflation adjustment to be compounded for FY 2019 and each subsequent fiscal year (see 21 U.S.C. 379j(c)(2)(B)(ii)). The base inflation adjustment for FY 2019 (1.018210) is compounded by multiplying it by the compounded applicable inflation factor from FY 2018 (1.054618). To complete the compounded inflation adjustment for FY 2019, the FY 2018 compounded adjustment (1.054618) is multiplied by the FY 2019 base inflation adjustment (1.018210) to reach the applicable inflation adjustment of 1.073823 (rounded) for FY 2019. We then multiply the total revenue amount for FY 2019 ($190,654,875) by 1.073823, yielding an inflation adjusted total revenue amount of $204,730,000 (rounded to the nearest thousand dollars).

III. Fees for FY 2019

Under the FD&C Act, all submission fees and the periodic reporting fee are set as a percent of the standard (full) fee for a premarket application (see 21 U.S.C. 379j(a)(2)(A)).

A. Inflation Adjustment

MDUFA specifies that the base fees of $300,000 (premarket application) and $4,548 (establishment registration) are to be adjusted for FY 2019 using the same methodology as that for the total revenue inflation adjustment in section II (see 21 U.S.C. 379j(c)(2)(D)(i)). Multiplying the base fees by the compounded inflation adjustment of 1.073823 yields inflation adjusted base fees of $322,147 (premarket application) and $4,884 (establishment registration).

B. Further Adjustments

After the applicable inflation adjustment to fees is done, FDA may increase, if necessary to achieve the inflation adjusted total revenue amount, the base fee amounts on a uniform proportionate basis (see 21 U.S.C. 379j(c)(2)(D)(ii)). If necessary after this adjustment, FDA may further increase the base establishment registration fees to generate the inflation adjusted total revenue amount (see 21 U.S.C. 379j(c)(3)).

C. Calculation of Fee Rates

Table 3 provides the last 3 years of fee-paying submission counts and the 3-year average. These numbers are used to project the fee-paying submission counts that FDA will receive in FY 2019. Most of the fee-paying submission counts are published in the MDUFA Financial Report to Congress each year.

TABLE 3—THREE-YEAR AVERAGE OF FEE-PAYING SUBMISSIONS

Application type	FY 2015 actual	FY 2016 actual	FY 2017 actual	3-Year average
Full Fee Applications	42	37	40	40
Small Business	7	10	7	8
Panel-Track Supplement	22	17	27	22
Small Business	3	1	2	2
De Novo Classification Request [1]			24	24
Small Business [1]			31	31
180-Day Supplements	143	116	184	148
Small Business	15	16	36	22
Real-Time Supplements	204	179	195	193
Small Business	28	27	20	25
510(k)s	2,768	2,599	3,141	2,836
Small Business	1,037	1,005	1,125	1,056

TABLE 3—THREE-YEAR AVERAGE OF FEE-PAYING SUBMISSIONS—Continued

Application type	FY 2015 actual	FY 2016 actual	FY 2017 actual	3-Year average
30-Day Notice	920	929	1,080	976
Small Business	71	76	82	76
513(g) (21 U.S.C. 360c(g)) Request for Classification Information	75	68	98	80
Small Business	33	46	41	40
Annual Fee for Periodic Reporting [2]	554	582	429	522
Small Business [2]	73	75	37	62
Establishment Registration	25,363	26,046	27,268	26,226

[1] Three-year average for De Novo is based on estimate for FY 2019.
[2] Includes collection of quarter 4 billing for FY 2017 during FY 2018.

The information in table 3 is necessary to estimate the amount of revenue that will be collected based on the fee amounts. Table 4 displays the FY 2019 base fees set in statute (column one) and the inflation adjusted base fees (per calculations in section III.A.) (column two). Using the inflation adjusted fees and the 3-year averages of fee paying submissions, collections are projected to total $207,708,611, which is $2,978,611 higher than the inflation adjusted total revenue amount. The fees in column two are those we are establishing in FY 2019, which are the standard fees.

TABLE 4—FEES NEEDED TO ACHIEVE NEW FY 2019 REVENUE TARGET

Application type	FY 2019 statutory fees (base fees)	FY 2019 inflation adjusted statutory base fees (standard fees)	FY 2019 revenue from adjusted fees
Full Fee Applications	$300,000	$322,147	$12,885,880
Small Business	75,000	80,537	644,296
Panel-Track Supplement	225,000	241,610	5,315,420
Small Business	56,250	60,403	120,806
De Novo Classification Request	90,000	96,644	2,319,456
Small Business	22,500	24,161	748,991
180-Day Supplements	45,000	48,322	7,151,656
Small Business	11,250	12,081	265,782
Real-Time Supplements	21,000	22,550	4,352,150
Small Business	5,250	5,638	140,950
510(k)s	10,200	10,953	31,062,708
Small Business	2,550	2,738	2,891,328
30-Day Notice	4,800	5,154	5,030,304
Small Business	2,400	2,577	195,852
513(g) Request for Classification Information	4,050	4,349	347,920
Small Business	2,025	2,175	87,000
Annual Fee for Periodic Reporting	10,500	11,275	5,885,550
Small Business	2,625	2,819	174,778
Establishment Registration	4,548	4,884	128,087,784
Total	.....	.....	207,708,611

The standard fee (adjusted base amount) for a premarket application, including a BLA, and for a premarket report and a BLA efficacy supplement, is $322,147 for FY 2019. The fees set by reference to the standard fee for a premarket application are:

- For a panel-track supplement, 75 percent of the standard fee;
- For a de novo classification request, 30 percent of the standard fee;
- For a 180-day supplement, 15 percent of the standard fee;
- For a real-time supplement, 7 percent of the standard fee;
- For an annual fee for periodic reporting concerning a class III device, 3.5 percent of the standard fee;
- For a 510(k) premarket notification, 3.4 percent of the standard fee;
- For a 30-day notice, 1.6 percent of the standard fee; and
- For a 513(g) request for classification information, 1.35 percent of the standard fee.

For all submissions other than a 30-day notice, and a 513(g) request for classification information, the small business fee is 25 percent of the standard (full) fee for the submission (see 21 U.S.C. 379j(d)(2)(C) and (e)(2)(C)). For a 30-day notice, and a 513(g) request for classification information, the small business fee is 50 percent of the standard (full) fee for the submission (see 21 U.S.C. 379j(d)(2)(C)).

The annual fee for establishment registration, after adjustment, is set at $4,884 for FY 2019. There is no small business rate for the annual establishment registration fee; all establishments pay the same fee.

Table 5 summarizes the FY 2019 rates for all medical device fees.

TABLE 5—MEDICAL DEVICE FEES FOR FY 2019

Application fee type	Standard fee (as a percent of the standard fee for a premarket application)	FY 2019 standard fee	FY 2019 small business fee
Premarket application (a PMA submitted under section 515(c)(1) of the FD&C Act (21 U.S.C. 360e(c)(1)), a PDP submitted under section 515(f) of the FD&C Act (21 U.S.C. 360e(f), or a BLA submitted under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262)).	Base fee specified in statute.	$322,147	$80,537
Premarket report (submitted under section 515(c)(2) of the FD&C Act)	100	322,147	80,537
Efficacy supplement (to an approved BLA under section 351 of the PHS Act)	100	322,147	80,537
Panel-track supplement	75	241,610	60,403
De novo classification request	30	96,644	24,161
180-day supplement	15	48,322	12,081
Real-time supplement	7	22,550	5,638
510(k) premarket notification submission	3.40	10,953	2,738
30-day notice	1.60	5,154	2,577
513(g) request for classification information	1.35	4,349	2,175
Annual Fee Type			
Annual fee for periodic reporting on a class III device	3.50	11,275	2,819
Annual establishment registration fee (to be paid by the establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device, as defined by 21 U.S.C. 379i(13)).	Base fee specified in statute.	4,884	4,884

IV. How To Qualify as a Small Business for Purposes of Medical Device Fees

If your business, including your affiliates, has gross receipts or sales of no more than $100 million for the most recent tax year, you may qualify for reduced small business fees. If your business, including your affiliates, has gross sales or receipts of no more than $30 million, you may also qualify for a waiver of the fee for your first premarket application (*i.e.* PMA, PDP, or BLA) or premarket report. If you want to pay the small business fee rate for a submission or you want to receive a waiver of the fee for your first premarket application or premarket report, you should submit the materials showing you qualify as a small business at least 60 days before you send your submission to FDA. FDA will review your information and determine whether you qualify as a small business eligible for the reduced fee and/or fee waiver. If you make a submission before FDA finds that you qualify as a small business, you must pay the standard (full) fee for that submission.

If your business qualified as a small business for FY 2018, your status as a small business will expire at the close of business on September 30, 2018. You must re-qualify for FY 2019 in order to pay small business fees during FY 2019.

If you are a domestic (U.S.) business, and wish to qualify as a small business for FY 2019, you must submit the following to FDA:

1. A completed MDUFA Small Business Certification Request For a Business Headquartered in the U.S. (Form FDA 3602). Form FDA 3602 is provided in the FDA Forms database: *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM573420.pdf.*

2. A signed certified copy of your Federal (U.S.) Income Tax Return for the most recent tax year. The most recent tax year will be 2018, except:

If you submit your MDUFA Small Business Certification Request for FY 2019 before April 15, 2019, and you have not yet filed your return for 2018, you may use tax year 2017.

If you submit your MDUFA Small Business Certification Request for FY 2019 on or after April 15, 2019, and have not yet filed your 2018 return because you obtained an extension, you may submit your most recent return filed prior to the extension.

3. For each of your affiliates, either:

- If the affiliate is a domestic (U.S.) business, a certified copy of the affiliate's Federal (U.S.) Income Tax Return for the most recent tax year, or
- If the affiliate is a foreign business and cannot submit a Federal (U.S.) Income Tax Return, a National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority of the country in which the firm is headquartered. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates of the gross receipts or sales collected. The business must also submit a statement signed by the head of the business's firm or by its chief financial officer that the business has submitted certifications for all of its affiliates, identifying the name of each affiliate, or that the business has no affiliates.

If you are a foreign business, and wish to qualify as a small business for FY 2019, you must submit the following:

1. A completed MDUFA Foreign Small Business Certification Request For a Business Headquartered Outside the United States (Form FDA 3602A). Form FDA 3602A is provided in the FDA Forms database: *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM573423.pdf.*

2. A National Taxing Authority Certification, completed by, and bearing the official seal of, the National Taxing Authority of the country in which the firm is headquartered. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates of the gross receipts or sales collected.

3. For each of your affiliates, either:

- If the affiliate is a domestic (U.S.) business, a certified copy of the affiliate's Federal (U.S.) Income Tax Return for the most recent tax year (2018 or later), or
- If the affiliate is a foreign business and cannot submit a Federal (U.S.) Income Tax Return, a National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority of the

country in which the firm is headquartered. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates for the gross receipts or sales collected. The business must also submit a statement signed by the head of the business's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, identifying the name of each affiliate, or that the business has no affiliates.

V. Procedures for Paying Application Fees

If your application or submission is subject to a fee and your payment is received by FDA between October 1, 2018, and September 30, 2019, you must pay the fee in effect for FY 2019. The later of the date that the application is received in the reviewing center's document room or the date the U.S. Treasury recognizes the payment determines whether the fee rates for FY 2018 or FY 2019 apply. FDA must receive the correct fee at the time that an application is submitted, or the application will not be accepted for filing or review.

FDA requests that you follow the steps below before submitting a medical device application subject to a fee to ensure that FDA links the fee with the correct application. (Note: Do not send your user fee check to FDA with the application.)

A. Secure a Payment Identification Number (PIN) and Medical Device User Fee Cover Sheet From FDA Before Submitting Either the Application or the Payment

Log into the User Fee System at: *https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp.* Complete the Medical Device User Fee cover sheet. Be sure you choose the correct application submission date range. (Two choices will be offered until October 1, 2018. One choice is for applications and fees that will be received on or before September 30, 2018, which are subject to FY 2018 fee rates. A second choice is for applications and fees received on or after October 1, 2018, which are subject to FY 2019 fee rates.) After completing data entry, print a copy of the Medical Device User Fee cover sheet and note the unique PIN located in the upper right-hand corner of the printed cover sheet.

B. Electronically Transmit a Copy of the Printed Cover Sheet With the PIN

When you are satisfied that the data on the cover sheet is accurate, electronically transmit that data to FDA according to instructions on the screen. Applicants are required to set up a user account and password to assure data security in the creation and electronic submission of cover sheets.

C. Submit Payment for the Completed Medical Device User Fee Cover Sheet

1. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize Pay.gov, a web-based payment system, for online electronic payment. You may make a payment via electronic check or credit card after submitting your cover sheet. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* Note: Only full payments are accepted. No partial payments can be made online. Once you search for your invoice, select ''Pay Now'' to be redirected to Pay.gov. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S bank accounts as well as U.S. credit cards.

2. If paying with a paper check:

- All paper checks must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. If needed, FDA's tax identification number is 53–0196965.
- Please write your application's unique PIN (from the upper right-hand corner of your completed Medical Device User Fee cover sheet) on your check.
- *Mail the paper check and a copy of the completed cover sheet to:* Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. (Please note that this address is for payments of application and annual report fees only and is not to be used for payment of annual establishment registration fees.)

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

3. If paying with a wire transfer:

- Please include your application's unique PIN (from the upper right-hand corner of your completed Medical Device User Fee cover sheet) in your wire transfer. Without the PIN, your payment may not be applied to your cover sheet and review of your application may be delayed.
- The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee it is required that you add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a wire transfer: U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33.

FDA records the official application receipt date as the later of the following: (1) The date the application was received by the FDA Document Control Center for the reviewing Center or (2) the date the U.S. Treasury recognizes the payment. It is helpful if the fee arrives at the bank at least 1 day before the application arrives at FDA.

D. Submit Your Application to FDA With a Copy of the Completed Medical Device User Fee Cover Sheet

Please submit your application and a copy of the completed Medical Device User Fee cover sheet to the address located at *https://www.fda.gov/cdrhsubmissionaddress.*

VI. Procedures for Paying the Annual Fee for Periodic Reporting

You will be invoiced at the end of the quarter in which your PMA Periodic Report is due. Invoices will be sent based on the details included on your PMA file. You are responsible for ensuring FDA has your current billing information, and you may update your contact information for the PMA by submitting an amendment to the pending PMA or a supplement to the approved PMA.

1. The preferred payment method is online using electronic check (ACH also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (*Note:* Only full payments are accepted. No partial payments can be made online). Once you search for your invoice, select ''Pay Now'' to be redirected to Pay.gov. Note that electronic payment options are based on the balance due. Payment by

credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

2. If paying with a paper check:

The check must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. If needed, FDA's tax identification number is 53–0196965.

- Please write your invoice number on the check.
- *Mail the paper check and a copy of the invoice to:* Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. (Please note that this address is for payments of application and annual report fees only and is not to be used for payment of annual establishment registration fees.)

To send a check by a courier, the courier must 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 U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery).

3. When paying by a wire transfer it is required that the invoice number is included, without the invoice number the payment may not be applied. If the payment amount is not applied the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee it is required that you add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33.

VII. Procedures for Paying Annual Establishment Registration Fees

To pay the annual establishment registration fee, firms must access the Device Facility User Fee (DFUF) website at *https://userfees.fda.gov/OA_HTML/furls.jsp.* (FDA has verified the website address, but FDA is not responsible for any subsequent changes to the website address after this document publishes in the **Federal Register**.) Create a DFUF order and you will be issued a PIN when you place your order. After payment has been processed, you will be issued a payment confirmation number (PCN). You will not be able to register your establishment if you do not have a PIN and a PCN. An establishment required to pay an annual establishment registration fee is not legally registered in FY 2019 until it has completed the steps below to register and pay any applicable fee (see 21 U.S.C. 379j(g)(2)).

Companies that do not manufacture any product other than a licensed biologic are required to register in the Blood Establishment Registration (BER) system. FDA's Center for Biologics Evaluation and Research (CBER) will send establishment registration fee invoices annually to these companies.

A. Submit a DFUF Order With a PIN From FDA Before Registering or Submitting Payment

To submit a DFUF Order, you must create or have previously created a user account and password for the user fee website listed previously in this section. After creating a user name and password, log into the Establishment Registration User Fee FY 2019 store. Complete the DFUF order by entering the number of establishments you are registering that require payment. When you are satisfied that the information in the order is accurate, electronically transmit that data to FDA according to instructions on the screen. Print a copy of the final DFUF order and note the unique PIN located in the upper right-hand corner of the printed order.

B. Pay For Your DFUF Order

Unless paying by credit card, all payments must be in U. S. currency and drawn on a U.S. bank.

1. If paying by credit card or electronic check (ACH or eCheck):

The DFUF order will include payment information, including details on how you can pay online using a credit card or electronic check. Follow the instructions provided to make an electronic payment.

2. If paying with a paper check:

The check must be in U.S. currency and drawn on a U.S. bank, and mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. (*Note:* This address is different from the address for payments of application and annual report fees and is to be used only for payment of annual establishment registration fees.)

If a check is sent by a courier that requests a street address, the courier can deliver the check to: U.S. Bank, Attn: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery).

Please make sure that both of the following are written on your check: (1) the FDA post office box number (P.O. Box 979108) and (2) the PIN that is printed on your order. Include a copy of your printed order when you mail your check.

3. If paying with a wire transfer:

Wire transfers may also be used to pay annual establishment registration fees. To send a wire transfer, please read and comply with the following information:

Include your order's unique PIN (in the upper right-hand corner of your completed DFUF order) in your wire transfer. Without the PIN, your payment may not be applied to your facility and your registration may be delayed.

The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee it is required that you add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: U.S. Dept. of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

C. Complete the Information Online To Update Your Establishment's Annual Registration for FY 2019, or To Register a New Establishment for FY 2019

Go to the Center for Devices and Radiological Health's website at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm* and click the ''Access Electronic Registration'' link on the left side of the page. This opens up a new page with important information about the FDA Unified Registration and Listing System (FURLS). After reading this information, click on the ''Access Electronic Registration'' link in the middle of the page. This link takes you to an FDA Industry Systems page with tutorials that demonstrate how to create a new FURLS user account if your establishment did not create an account in FY 2018. Manufacturers of licensed biologics should register in the BER system at *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/EstablishmentRegistration/BloodEstablishmentRegistration/default.htm.*

Enter your existing account ID and password to log into FURLS. From the FURLS/FDA Industry Systems menu,

click on the Device Registration and Listing Module (DRLM) of FURLS button. New establishments will need to register and existing establishments will update their annual registration using choices on the DRLM menu. When you choose to register or update your annual registration, the system will prompt you through the entry of information about your establishment and your devices. If you have any problems with this process, email: *reglist@cdrh.fda.gov* or call 301–796–7400 for assistance. (Note: This email address and this telephone number are for assistance with establishment registration only; they are not to be used for questions related to other aspects of medical device user fees.) Problems with the BER system should be directed to *https://www.accessdata.fda.gov/scripts/email/cber/bldregcontact.cfm* or call 240–402–8360.

D. Enter Your DFUF Order PIN and PCN

After completing your annual or initial registration and device listing, you will be prompted to enter your DFUF order PIN and PCN, when applicable. This process does not apply to establishments engaged only in the manufacture, preparation, propagation, compounding, or processing of licensed biologic devices. CBER will send invoices for payment of the establishment registration fee to such establishments.

Dated: July 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16178 Filed 7–27–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0549]

Prescription Polyethylene Glycol 3350; Denial of a Hearing and Order Withdrawing Approval of Abbreviated New Drug Applications; Temporary Stay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice that the effective date of an April 2, 2018, order denying requests for a hearing and withdrawing approval of abbreviated new drug applications (ANDAs) for certain prescription laxatives with the active ingredient polyethylene glycol 3350 (PEG 3350) is stayed until November 2, 2018.

DATES: FDA is staying the effective date of the April 2, 2018, order withdrawing approval of ANDAs for certain prescription laxatives with the active ingredient PEG 3350 until November 2, 2018.

ADDRESSES: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Julie Finegan, Office of Scientific Integrity, Office of the Chief Scientist, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4218, Silver Spring, MD 20993–0002, 301–796–8618.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 2, 2018 (83 FR 13994), FDA denied requests for hearing and issued an order withdrawing approval of ANDAs for certain prescription laxatives with the active ingredient PEG 3350. The effective date of the order was May 2, 2018. Between April 6, 2018, and April 13, 2018, FDA received petitions for stay under § 10.35 (21 CFR 10.35) on behalf of four ANDA holders: Breckenridge Pharmaceutical, Inc. and Nexgen Pharma, Inc. (hereafter Breckenridge/Nexgen) who submitted a joint petition; Lannett Company, Inc.; and Paddock Laboratories, Inc. (collectively the ANDA holders). Breckenridge/Nexgen, Lannett, and Paddock petitioned FDA to stay its order withdrawing the approval of their ANDAs for prescription PEG 3350 and argued that all four criteria for a mandatory stay under § 10.35(e) were met. Bayer Healthcare, LLC, (Bayer) which holds an approved New Drug Application for MiraLAX, an over-the-counter laxative containing PEG 3350, responded. Bayer argued that the petitioners failed to meet any of the factors in § 10.35(e).[1]

By a letter dated April 16, 2018, the Acting Chief Scientist, pursuant to authority delegated by the Commissioner, concluded that the ANDA holders had not met the criteria for a mandatory stay under § 10.35(e). The Acting Chief Scientist granted a temporary, discretionary stay of the effective date of the order until November 2, 2018. As described in the April 16, 2018, letter, based upon information submitted by the ANDA holders and not disputed by Bayer, it would likely be difficult for manufacturers of OTC PEG 3350 products to compensate for the removal of prescription PEG 3350 products within 30 days. The letter explained that public health interests would not be served should the 30-day effective date negatively impact the availability of PEG 3350, particularly given that the basis of the withdrawal of the ANDA products is not an issue of safety or efficacy. The April 16, 2018, letter additionally noted that FDA has provided lengthier time frames to phase out manufacturing and distribution of affected products in other cases. While the Acting Chief Scientist rejected the petitioners' arguments that financial hardship and harm to reputation resulting from the withdrawal order rise to the level of irreparable injury necessary for a mandatory stay under § 10.35(e), she agreed that there may some validity to the petitioner's concerns of harm to their business interests as a result of the 30-day effective date. The Acting Chief Scientist concluded that it is in the public interest and in the interest of justice to stay the effective date of the April 2, 2018, order until November 2, 2018.

The parties' submissions and the Agency's orders are available at *https://www.regulations.gov* and with the Dockets Management Staff (see **ADDRESSES**).

FDA is providing notice of the decision to grant a temporary stay in accordance with § 10.35(f).

Dated: July 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16148 Filed 7–27–18; 8:45 am]

BILLING CODE 4164–01–P

[1] On April 30, 2018, Bayer filed a submission titled ''Request for Clarification of FDA Granting of a Petition for Stay of Action.'' Bayer requested that FDA clarify that the stay allowed new manufacturing only until May 2, 2018, with shipment of product permitted until November 2, 2018. Breckenridge/Nexgen responded to Bayer's request for clarification and argued that Bayer's submission should have been a petition for reconsideration and that it failed to meet the standards required for reconsideration. Regardless of whether Bayer's submission should have been a petition for reconsideration, FDA's letter granting the stay provides that the order is stayed until November 2, 2018, without the limitations Bayer now requests.