

end of FY 2016, FDA estimates that 523 establishments will have been billed for establishment fees, before all decisions on requests for waivers or reductions are made. FDA estimates that a total of 16 establishment fee waivers or reductions will be made for FY 2016. In addition, FDA estimates that another 16 full establishment fees will be exempted this year based on the orphan drug exemption in section 736(k) of the FD&C Act. Subtracting 32 establishments (16 waivers, plus the estimated 16 establishments under the orphan exemption) from 523 leaves a net of 491 fee-paying establishments. FDA will use 491 to estimate the FY 2017 establishments paying fees. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments (\$251,508,000) by the estimated 491 establishments, for an establishment fee rate for FY 2017 of \$512,200 (rounded to the nearest hundred dollars).

B. Product Fees

At the beginning of FY 2016, the product fee was based on an estimate that 2,480 products would be subject to and would pay product fees. By the end of FY 2016, FDA estimates that 2,646 products will have been billed for product fees, before all decisions on requests for waivers, reductions, or exemptions are made. FDA assumes that there will be 41 waivers and reductions granted. In addition, FDA estimates that another 32 product fees will be exempted this year based on the orphan drug exemption in section 736(k) of the FD&C Act. FDA estimates that 2,573 products will qualify for and pay product fees in FY 2016, after allowing for an estimated 73 waivers and reductions, including the orphan drug products, and will use this number for its FY 2017 estimate. The FY 2017 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees (\$251,508,000) by the estimated 2,573 products for a FY 2017 product fee of \$97,750 (rounded to the nearest ten dollars).

VII. Fee Schedule for FY 2017

The fee rates for FY 2017 are displayed in table 8:

TABLE 8—FEE SCHEDULE FOR FY 2017

Fee category	Fee rates for FY 2017 (\$)
Applications: Requiring clinical data	2,038,100

TABLE 8—FEE SCHEDULE FOR FY 2017—Continued

Fee category	Fee rates for FY 2017 (\$)
Not requiring clinical data	1,019,050
Supplements requiring clinical data	1,019,050
Establishments	512,200
Products	97,750

VIII. Fee Payment Options and Procedures

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application or supplement subject to fees under PDUFA that is received on or after October 1, 2016. Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, or U.S. postal money order payable to the order of the Food and Drug Administration. 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). Secure electronic payments can be submitted using the User Fees Payment Portal at <https://userfees.fda.gov/pay>. Once you search for your invoice, click “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 less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S. bank accounts as well as U.S. credit cards.

FDA has partnered with the U.S. Department of the Treasury to use Pay.gov, a Web-based payment application, for online electronic payment. The Pay.gov feature is available on the FDA Web site after the user fee ID number is generated.

Please include the user fee identification (ID) number on your check, bank draft, or postal money order. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197-9000.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: U.S. Bank, Attention: Government Lockbox 979107, 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 the U.S. Bank at 314-418-4013. This telephone number

is only for questions about courier delivery).

Please make sure that the FDA post office box number (P.O. Box 979107) 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 fee and add it to your payment to ensure that your fee is fully paid. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993-0002.

The tax identification number of FDA is 53-0196965.

B. Establishment and Product Fees

FDA will issue invoices for establishment and product fees for FY 2017 under the new fee schedule in August 2016. Payment will be due on October 1, 2016. FDA will issue invoices in November 2017 for any products and establishments subject to fees for FY 2017 that qualify for fee assessments after the August 2016 billing.

Dated: July 25, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0530]

Agency Information Collection Activities; Proposed Collection; Comment Request; Pre-Submission Program for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of

information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requests for feedback submitted under the Pre-Submission program for medical devices.

DATES: Submit either electronic or written comments on the collection of information by September 26, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2012-D-0530 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Pre-Submission Program for Medical Devices." Received comments will be placed in the docket and, except for

those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20851, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR

1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Pre-Submission Program for Medical Devices—OMB Control Number 0910–0756—Extension

The guidance entitled "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" describes the Pre-Submission program for medical devices reviewed in the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The guidance provides recommendations regarding the information that should be submitted in a Pre-Submission package and procedures that should be followed for meetings between CDRH and CBER staff and industry representatives or application sponsors. In addition to Pre-Submissions, the guidance addresses other feedback mechanisms including Informational Meetings, Study Risk Determinations, Formal Early Collaboration Meetings, and Submission Issue Meetings and the procedures to request feedback using these mechanisms.

A Pre-Submission is defined as a formal written request from an applicant for feedback from FDA to be provided in the form of a formal written response

or, if the manufacturer chooses, a meeting or teleconference in which the feedback is documented in meeting minutes. A Pre-Submission is appropriate when FDA's feedback on specific questions is necessary to guide product development and/or

application preparation. The proposed collections of information are necessary to allow the Agency to receive Pre-Submission packages in order to implement this voluntary submission program.

For clarity, we are requesting that the title of the information collection request, OMB control number 0910-0756, be changed to "Pre-Submission Program for Medical Devices."

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

FDA Center	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
CDRH	2,465	1	2,465	137	337,705
CBER	79	1	79	137	10,823
Total					348,528

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents are medical device manufacturers subject to FDA's laws and regulations. FDA's annual estimate of 2,544 submissions is based on experienced trends over the past several years. FDA's administrative and technical staffs, who are familiar with the requirements for current Pre-Submissions, estimate that an average of 137 hours is required to prepare a Pre-Submission.

Dated: July 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Psychopharmacologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee. The general function of the committees is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on September 14, 2016, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT:

Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: PDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committees will discuss a completed postmarketing-requirement randomized, placebo controlled trial of the neuropsychiatric effects of CHANTIX (varenicline), ZYBAN (bupropion), and nicotine replacement therapy, along with relevant published observational studies to determine whether the findings support changes to product labeling.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committees. Written submissions may be made to the contact person on or before August 30, 2016. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 22, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 23, 2016.

Persons attending FDA's advisory committee meetings are advised that the