through the night, daily hygiene, participation in sports or social activities, intimacy with a spouse or partner, etc.)

4. How has your chronic pain changed over time? (Considerations include severity and frequency of your chronic pain and the effects of chronic pain on your daily activities.)

Topic 2: Patients' Perspectives on Current Approaches to Treatment of Chronic Pain

1. What are you currently doing to help treat your chronic pain? (Examples may include prescription medicines, over-the-counter products, and non-drug therapies.)

a. How has your treatment regimen changed over time, and why? (Examples may include change in your condition, change in dose, or treatment side effects.)

b. What factors do you take into account when making decisions about selecting a course of treatment?

2. How well does your current treatment regimen manage your chronic pain? (Considerations include severity and frequency of your chronic pain and the effects of chronic pain on your daily activities.)

3. What are the most significant downsides to your current treatments, and how do they affect your daily life?

4. What challenges or barriers to accessing or using medical treatments for chronic pain have you or do you encounter?

5. What specific things would you look for in an ideal treatment for your chronic pain?

III. Participating in the Public Meeting

Registration: To register for the public meeting, visit *https://chronicpain-pfdd.eventbrite.com.* Please register by July 2, 2018. Persons without access to the internet can call 240–402–6525 to register. If you are unable to attend the meeting in person, you can register to view a live webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the webcast.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by July 2, 2018. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation once they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 9 a.m. If you need special accommodations because of a disability, please contact Meghana Chalasani (see **FOR FURTHER INFORMATION CONTACT**) no later than July 2, 2018.

Panelist Selection: Patients or patient representatives who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients or patient representatives also will be asked to send *PatientFocused@fda.hhs.gov* a brief summary of responses to the topic questions by June 25, 2018. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Open Public Comment: There will be time allotted during the meeting for open public comment. Signup for this session will be on a first-come, first-serve basis on the day of the workshop. Individuals and organizations with common interests are urged to consolidate or coordinate and request time for a joint presentation. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Please register for the webcast by visiting *https://chronicpain-pfdd.eventbrite.com.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/Drugs/NewsEvents/ucm603093.htm.*

Dated: May 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10284 Filed 5–14–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1837]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic User Fee Payment Request Forms

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 electronic user fee payment request forms.

DATES: Submit either electronic or written comments on the collection of information by July 16, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 16, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of July 16, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, 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–2015–N–1837 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic User Fee Payment Request Forms.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, 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.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Electronic User Fee Payment Request Forms—Form FDA 3913 and Form FDA 3914

OMB Control Number 0910–0805—Extension

Form FDA 3913, User Fee Payment Refund Request, is designed to provide the minimum necessary information for FDA to review and process a user fee payment refund. The information collected includes the organization, contact, and payment information. The information is used to determine the reason for the refund, the refund amount, and who to contact if there are any questions regarding the refund request. A submission of the User Fee Payment Refund Request form does not guarantee that a refund will be issued. FDA estimates an average of 0.40 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. The estimated hours are based on past FDA experience with user fee payment refund requests.

In fiscal year 2017, approximately 1,657 user fee refunds were processed for cover sheets and invoices including 12 for Animal Drug User Fee Act, 2 for Animal Generic Drug User Fee Act, 13 for Biosimilar Drug User Fee Act, 68 for Export Certificate Program, 14 for Freedom of Information Act requests, 227 for Generic Drug User Fee Amendments, 1,021 for Medical Device User Fee Amendments, 227 for mammography inspection fees, 67 for Prescription Drug User Fee Act, and 6 for tobacco product fees.

Form FDA 3914, User Fee Payment Transfer Request, is designed to provide the minimum information necessary for FDA to review and process a user fee payment transfer request. The information collected includes payment and organization information. The information is used to determine the reason for the transfer, how the transfer should be performed, and who to contact if there are any questions regarding the transfer request. A submission of the User Fee Payment Transfer Request form does not guarantee that a transfer will be performed. FDA estimates an average of 0.25 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. FDA estimated hours are

based on past FDA experience with user fee payment transfer requests.

In fiscal year 2017, approximately 871 user fee payment transfers were processed for cover sheets and invoices including 8 for Animal Drug User Fee Act, 1 for Animal Generic Drug User Fee Act, 1 for Biosimilar Drug User Fee Act, 163 for Generic Drug User Fee Amendments, 692 for Medical Device User Fee Amendments, and 6 for Prescription Drug User Fee Act.

Respondents for the electronic request forms include domestic and foreign firms (including pharmaceutical, medical device, etc.). Specifically, refund request forms target respondents who submitted a duplicate payment or overpayment for a user fee cover sheet or invoice. Respondents may also include firms that withdrew an application or submission. Transfer request forms target respondents who submitted payment for a user fee cover sheet or invoice and need that payment to be reapplied to another cover sheet or invoice (transfer of funds).

The electronic user fee payment request forms will streamline the refund and transfer processes, facilitate processing, and improve the tracking of requests. The burden for this collection of information is the same for all customers (small and large organizations). The information being requested or required has been held to the absolute minimum required for the intended use of the data. Customers will be able to request a user fee payment refund and transfer online at *https://www.fda.gov/forindustry/userfees/default.htm.* This electronic submission is intended to reduce the burden for customers to submit user fee payment refund and transfer requests.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
User Fee Payment Refund Request—Form FDA 3913.	1,657	1	1,657	0.40 (24 minutes)	663
User Fee Payment Transfer Request—Form FDA 3914.	871	1	871	0.25 (15 minutes)	218
Total					881

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

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. New information technology applications have more accurately calculated the number of registrants of drug facilities/food facilities/medical device facilities/medicated feed facilities, and we have therefore revised the number of respondents to the information collection.

Dated: May 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10329 Filed 5–14–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–N–4951; FDA–2017–N–5569; FDA–2017–N–6145; FDA–2011–N–0275; FDA–2017–N–7012; and FDA–2017–N–6175]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control number	Date approval expires
Medical Devices; Humanitarian Use Devices	0910–0332	3/31/2021
Medical Devices; Device Tracking	0910–0442	3/31/2021
Dispute Resolution Procedures for Science-Based Decisions on Products Regulated by the Center for Veterinary Medicine	0910–0566	3/31/2021
Certification to Accompany Drug, Biological Product, and Device Applications or Submissions (Form FDA 3674)	0910–0616	3/31/2021
Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics	0910–0850	3/31/2021