

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.

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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. Mizrahi, Office of Operations, Food

and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@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 |

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB—Continued

| Title of collection | OMB control number | Date approval expires |
|---|--------------------|-----------------------|
| Food and Drug Administration Recall Regulations | 0910-0249 | 4/30/2021 |

Dated: May 9, 2018.
Leslie Kux,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1577]

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on June 20, 2018, from 8 a.m. to 4:30 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: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2018-N-1577. The docket will close on June 19, 2018. Submit either electronic or written comments on this public meeting by June 19, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 19, 2018.

The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of June 19, 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.

Comments received on or before June 5, 2018, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

You may submit comments as follows:

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-2018-N-1577 for “Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.” 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.” FDA 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 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 the 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