4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2015-N-1837]**

# Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic User Fee Payment Request Forms

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0805. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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.

In the *Federal Register* of May 15, 2018 (83 FR 22493), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1.--Estimated Annual Reporting Burden[1]

| FDA Form | No. of Respondents | No. 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: October 1, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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