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 title Electronic User Fee Payment Request Forms. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, 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--

(OMB Control Number 0910-NEW)

The Government Paperwork Elimination Act (GPEA) (Pub. L. 105-277, title XVII), was signed into law on October 21, 1998. GPEA requires Federal Agencies to allow individuals or entities that deal with the Agencies the option to submit information or transact business with the Agency electronically, when practicable, and to maintain records electronically, when practicable. Its goal is to encourage Agencies to incorporate technologically improved respondent reporting, as this process typically lowers the burden on the respondent. GPEA allows FDA to collect information relating to a user fee payment refund request and transfer request.

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 the user fee payment refund request.

In fiscal year 2014, approximately 1,741 user fee refunds were processed for cover sheets and invoices including 27 for Animal Drug User Fee Act, 5 for Animal Generic Drug User Fee Act, 3 for Biosimilar Drug User Fee Act, 1 for a Center for Tobacco Products Civil Money Penalties, 216 for Export Certificate Program, 79 for Freedom of Information Act requests, 523 for Generic Drug User Fee Amendments, 539 for Medical Device User Fee Amendments, 266 for Mammography inspection fee, 81 for Prescription Drug User Fee Act, and 1 for a Tobacco product fee.

Form FDA 3914, User Fee Payment Transfer Request, is designed to provide the minimum necessary information 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 the user fee payment transfer request.

In fiscal year 2014, approximately 1,291 user fee payment transfers were processed for cover sheets and invoices including 21 for Animal Drug User Fee Act, 2 for Animal Generic Drug User Fee Act, 544 for Generic Drug User Fee Amendments, 627 for Medical Device User Fee Amendments, and 97 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 re-applied 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 http://www.fda.gov/forindustry/userfees/default.htm. This electronic submission is intended to reduce the burden for customers to submit a user fee payment refund and transfer request.

In the Federal Register of June 26, 2015 (80 FR 36822), 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]

21 CFR Section	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	1,700	1	1,700	0.40 (24 minutes)	680
User Fee Payment Transfer Request--Form FDA 3914	1,700	1	1,700	0.25 (15 minutes)	425
Total					1105

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

Dated: September 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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