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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) 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 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 [**INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: 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 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-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.

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: June 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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