Electronic User Fee Payment Form Requests

0910- NEW
SUPPORTING STATEMENT

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Government Paperwork Elimination Act (GPEA), Public Law 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 burden to the respondent.

GPEA allows FDA to collect information relating to a user fee payment refund and transfer requests. The information contained in the forms is the minimum amount of information required to review and process a refund or transfer request. This electronic submission is intended to reduce the burden for customers to submit a user fee payment refund or transfer request.

2. Purpose and Use of the Information Collection

ICR collects information from customers who wish to electronically submit a user fee refund request for a duplicate payment, overpayment or for a withdrawn application or submission. Respondents submit organization, contact and payment information. Food and Drug Administration (FDA) has developed Form 3913 to facilitate its review and processing of user fee payment refunds. 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.

Additionally, this ICR collects information from customers who wish to electronically submit a request to transfer a user fee payment from one cover sheet or invoice to another cover sheet or invoice. Respondents submit payment and organization information. FDA has developed Form 3914 to facilitate its review and processing of user fee payment transfer requests. 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.

Forms 3913 and 3914 may be submitted by various types of customers including individuals, private sector, state, local, tribal or Federal Government.

3. Use of Improved Information Technology and Burden Reduction

Forms 3913 and 3914 leverage existing information technology resources and reduce burden on the submitter. The forms capture all of the required information FDA would need to review and if applicable, perform either the refund or the transfer. Without the electronic form, submitters provide information via other methods that are more time consuming including email, phone and fax.

FDA estimates that approximately 95 percent of all respondents will submit the information in electronic format.

4. Efforts to Identify Duplication and Use of Similar Information

This information collection is not duplicative. User fee payment refund and transfer request information are not already available to FDA. A customer must contact FDA to request a user fee payment refund or transfer.

5. Impact on Small Businesses or Other Small Entities

The burden for this collection of information is the same for all customers (small and large organizations). The information being requested has been held to the absolute minimum required for the intended use of the data.

6. Consequences of Collecting the Information Less Frequently

Respondents will respond to the information collection occasionally. The collection of information is dependent on the respondent. If the information is not collected, the FDA would not be able to accomplish refunds and transfers to the respondent.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

In some circumstances, respondents may be asked to submit proof of payment in the form of a copy of a cancelled check, etc. if a payment cannot be found by FDA. This will be done subsequent to the submission of a user fee payment refund or transfer request. For a refund request, the proof of payment is needed in order to locate the payment, research what happened to the payment and refund the payment. For a transfer request, the proof of payment is needed in order to locate the payment, research what happened to the payment and to apply the payment to the appropriate cover sheet or invoice.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

   In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of June 26, 2015 (80 FR 36822). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

   This information collection does not provide for any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

    In some circumstances, FDA may receive sensitive documents and information. If a cancelled check or other sensitive documents and information are provided to FDA for purposes of researching a payment for a refund or transfer, these documents will be handled by FDA employees (not contractors). Record keeping will comply with FDA's policies and procedures for records management. Documents are securely maintained in locked file cabinets and/or offices.

11. Justification for Sensitive Questions

    FDA collects Employer Identification Numbers (EINs) (also known as a Federal Tax Identification Numbers) for uniquely identifying a business entity. All U.S. organizations must have an EIN to conduct business with the Federal Government. EINs collected may contain social security numbers (SSNs) because some customers are individuals. FDA cannot determine which EINs are SSNs. EINs are required by FDA in order to process payment refunds. A refund cannot be processed by the U.S. Department of the Treasury for a customer without an EIN. As payment refund and transfer requests are voluntary, a customer is providing his/her consent when the customer provides the EIN.

12. Estimates of Annualized Burden Hours and Costs

    12 a. Annualized Hour Burden Estimate

    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	680
User Fee Payment Transfer Request-- Form FDA 3914	1,700	1	1,700	0.25	425
Total					1105

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

In fiscal year (FY) 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.

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 for payment refunds. The estimated hours are based on past FDA experience with the user fee payment refund request.

In FY 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.

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 for payment transfers. FDA estimated hours are based on past FDA experience with the user fee payment transfer request.

12b. Annualized Cost Burden Estimate

FDA assumes that an accountant at the firm that is requesting the refund or transfer will perform the activities associated with completing Form 3913 and 3914. According to the Department of Labor, Bureau of Labor and Statistics, the average hourly salary for an

account is approximately $35.00, FDA has used this estimate to formulate the cost burden for a firm requesting a refund or transfer. FDA estimates that a firm would make only one refund or transfer request per year.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent
Accountant - refund request	0.4	$35.00	$14
Accountant - transfer request	0.25	$35.00	$9
Total			$23

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no additional capital costs associated with this collection of information.

14. Annualized Cost to the Federal Government

There is no cost to the federal government other than staff time. We approximate that 680 hours of staff time is spent reviewing documents and managing the refund process and 425 hours of staff time is spent reviewing documents and managing the transfer process (an estimate of staff time at the GS 12 ($35) level to manage the processes annually. These expenses include form review, processing and data management and result in a total of $23,800 per year for refund processing and $14,875 for transfer processing to the Federal Government, which totals $38,675.

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

A three-year clearance is requested. The user fee payment refund and transfer data may be used by FDA staff to analyze submission trends (e.g. number of user fee payment refund and transfer requests). The data may help FDA identify improvement areas in order to optimize services to customers and enhance the current user fee payment refund and transfer process.

17. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.