U.S. Food and Drug Administration
Electronic User Fee Payment Form Requests
OMB Control No. 0910-0805

SUPPORTING STATEMENT **Part A: Justification**

Terms of Clearance: None

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA or we) user fee programs. 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 theFDA to collect information relating to user fee payment refunds 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.

To assist respondents with the reporting requirements associated with the information collection, we have developed two forms: Form FDA 3913 entitled, "User Fee Payment Refund Request," and Form FDA 3914 entitled, "User Fee Payment Transfer Request." We therefore request OMB approval of the information collection found in Forms FDA 3913 and 3914, and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

FormsFDA 3913 facilitate our review and processing of user fee payment refunds. The Form FDA 3913 intendsto collect information from respondents who wish to electronically submit a user fee refund request for a duplicate payment, overpayment or for a withdrawn application or submission.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. 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.

Form FDA 3914 collects information from respondents who wish to electronically submit a request to transfer a user fee payment from one user fee cover sheet or invoice to another cover sheet or invoice. The information is used to determine the reason for the transfer, how the transfer should be performed and who to contact if we have questions regarding the transfer request. A submission of the User Fee Payment Transfer Request form does not guarantee that a transfer will be performed. Respondents to the collection are

individuals and entitites from the private sector, state, local, tribal or Federal Government.

3. Use of Improved Information Technology and Burden Reduction

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

We estimate that approximately 95 percent of all respondents will submit the information in electronic format.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative informmation collection. While we have established information collections currently approved by OMB to support FDA cover sheets, as associated with respective user fee programs (OMB 0910-0297, OMB 0910-0511, 0910-0539, 0910-0613, 0910-0632, 0910-0659, and 0910-0718), this collection supports requests for refunds and transfers exclusively.

5. Impact on Small Businesses or Other Small Entities

The information collection does not impose undue burden on small entitites. User Fee schedules are established by statute and provide for small business determinations. FDA provides guidance to respondents on User Fee schedules and small business determinations on our website at https://www.fda.gov/ForIndustry/UserFees/default.htm

6. Consequences of Collecting the Information Less Frequently

The information collection occurs occasionally. The collection of information is dependent on the respondent and ncessary for providing refunds and transfers associated with user fee payments submitted to the agency..

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

There are no special circumstances for this collection of information.

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 May 15, 2018 (83 FR 22493). 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.

    In developing this information collection, FDA staff have also consulted with the FDA Privacy Officer to assure appropriate handling of information collected that may require privacy protection under the Privacy Act.

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.

    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. CDER submitted a privacy impact assessment which is under review with the FDA privacy office.

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

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

	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.

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 request. FDA estimates an average of 0.40 hours per response for user fee payment refund requests under Form FDA 3913, 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 fiscal year 2017, approximately 1,657 user fee refunds were processed via Form FDA 3913 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 fee, 67 for Prescription Drug User Fee Act, and 6 for 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. 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 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.

12b. Annualized Cost Burden Estimate

FDA assumes that an accountant/bookkeeper 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 accountant/bookkeeper position 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

The information collection is funded through existing resource allocations under FDA's user fee programs.

15. Explanation for Program Changes or Adjustments

The estimated annual hourly burden, formerly estimated as 1,105 hours, has decreased by 224 hours to a total estimated annual hourly burden of 881 hours. These are determined by the number of refund/transfer requests received from industry. As the user fee programs mature, processes and procedures utilized by industry also mature, leading to fewer requests for transfers of fees or refunds.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.