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

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respondents who wish to electronically submit a user fee refund request for a duplicate payment, overpayment or for a withdrawn application or submission.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

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.

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 April 29, 2021 (86 FR 22669). 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 developing this information collection, FDA staff have also consulted with the FDA Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII) or other data of a personal nature. PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form 3913, User Fee Payment Transfer Request is contact name, contact title/position, work address, work email address, work telephone numbers, and work fax telephone number for the primary contact at a business. The PII submitted via Form 3914, User Fee Payment Transfer Request is contact name, contact title/position, work address, work email address, work telephone numbers, and work fax telephone number for the primary contact at a business. Once received by FDA, the forms can also capture the name of FDA personnel serving as contacts for their office as relevant to internal processes.

FDA further determined that this collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply.

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.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

The confidentiality of the information received by FDA is maintained consistent with the Freedom of Information Act and regulations under 21 CFR Part 20. Manufacturers seeking to market a diagnostic radio pharmaceutical or a new indication for use for an approved diagnostic radiopharmaceutical may be required to reveal proprietary information or trade secrets to gain FDA approval of the product or new indication. However, such information is deleted from the application before it is released under the Freedom of Information Act and FDA

Under 21 U.S.C. 350b(a) and 21 CFR 190.6(e), FDA must keep NDI notifications private to the extent provided for by law for 90 days after receipt. After the 90th day, we place the notification on public display at FDA's Division of Dockets Management, except for any trade secrets or other private commercial information. Trade secrets and private commercial information are redacted from the notification and not otherwise disclosed to the public, as required by 21 U.S.C. 413(a) and 21 CFR 190.6(e).

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.

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	474	1	474	0.40 (24 minutes)	190
User Fee Payment Transfer Request- Form FDA 3914	194	1	194	0.25 (15 minutes)	49
Total					239

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

FDA estimates an average of 24 minutes (0.40) 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 2020, approximately 474 user fee refunds were processed via Form FDA 3913 for cover sheets and invoices including 0 for Animal Drug User Fee Act, 0 for Animal Generic Drug User Fee Act, 1 for Biosimilar Drug User Fee Act, 0 for Export Certificate Program, 0 for Freedom of Information Act requests, 31 for Generic Drug User Fee Amendments, 200 for Medical Device User Fee Amendments, 0 for

Mammography inspection fee, 1 for Prescription Drug User Fee Act, and 0 for Tobacco product fee.

FDA estimates an average of 15 minutes (0.25) per response for user fee payment transfer requests under Form FDA 3914, 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 2020, approximately 194 user fee payment transfers were processed for cover sheets and invoices including 0 for Animal Drug User Fee Act, 0 for Animal Generic Drug User Fee Act, 1 for Biosimilar Drug User Fee Act, 34 for Generic Drug User Fee Amendments, 78 for Medical Device User Fee Amendments, 1 for Prescription Drug User Fee Act, and 0 for Tobacco product fees

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 $25.00, 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 Costs
Accountant – refund request	190	$25.00	$4,750
Accountant – transfer request	49	$25.00	$1,225
Total			$5,975

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 881 hours, has decreased by 642 hours to a total estimated annual hourly burden of 239 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.