

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**THE FOOD AND DRUG
ADMINISTRATION GENERALLY
SPENT PRESCRIPTION DRUG
USER FEE COLLECTIONS
APPROPRIATELY**

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Office of Inspector General

<https://oig.hhs.gov>

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: September 2017
Report No. A-05-16-00040

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Review

The Prescription Drug User Fee Act of 1992, P.L. No. 102-571, authorized the Food and Drug Administration (FDA) to collect user fees from pharmaceutical and biotechnology companies seeking FDA approval of certain human drug and biological products to expedite the review of human drug applications. Congress must reauthorize the PDUFA every 5 years; it was renewed in 1997, 2002, 2007, 2012, and 2017. FDA expects to use the user fees it collects under the PDUFA to meet its goals for the timely review of human drug applications. We performed this audit to determine whether FDA appropriately expended prescription drug user fee collections.

Our objective was to determine whether FDA appropriately expended prescription drug user fee collections.

How OIG Did This Review

We obtained and reviewed documentation from the FDA to determine whether FDA appropriately spent prescription drug user fees.

We limited our review to \$796,065,980 in prescription drug user fees reported for October 1, 2014, through September 30, 2015.

The Food and Drug Administration Generally Spent Prescription Drug User Fee Collections Appropriately

What OIG Found

FDA generally spent prescription drug user fee collections appropriately. However, FDA did not have adequate supporting documentation for \$6,403 in travel expenses, made a duplicate payment for airfare of \$1,213, and overpaid a traveler \$587. FDA recovered the duplicate payment and overpayment from the travelers during our review. The lack of supporting documentation appeared to be an oversight by FDA staff and not a systemic issue. Accordingly, this report contains no recommendations.

INTRODUCTION

WHY WE DID THIS REVIEW

The Prescription Drug User Fee Act (PDUFA) of 1992, P.L. No. 102-571, authorized the Food and Drug Administration (FDA) to collect user fees from pharmaceutical and biotechnology companies seeking FDA approval of certain human drug and biological products to expedite the review of human drug applications. Congress must reauthorize the PDUFA every 5 years; it was renewed in 1997, 2002, 2007, 2012, and 2017. FDA expects to use the user fees it collects under the PDUFA to meet its goals for the timely review of human drug applications. We performed this audit to determine whether FDA appropriately expended prescription drug user fee collections.

OBJECTIVE

Our objective was to determine whether FDA spent prescription drug user fee collections appropriately.

BACKGROUND

Prescription drug user fees provide FDA with resources, including the ability to hire more reviewers and support staff and to upgrade information technology systems. FDA intended that the additional staffing and upgraded information technology would expedite the review of drug and supplement applications.

Since passage of the PDUFA, user fees have played an important role in expediting the drug approval process and eliminating backlogs of pending applications. Before the PDUFA, the average approval time for an application was 2 years. As a result, patients, particularly HIV/AIDS patients, were unable to access new medicines in a timely manner.

HOW WE CONDUCTED THIS REVIEW

We obtained and reviewed documentation from FDA to determine whether it appropriately spent prescription drug user fees. We limited our review to \$796,065,980 in prescription drug user fees reported for October 1, 2014, through September 30, 2015.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology and Appendix B contains the details on Federal requirements related to travel reimbursement.

RESULTS OF REVIEW

FDA generally spent prescription drug user fee collections appropriately. However, FDA did not have adequate supporting documentation for \$6,403 in travel expenses, made a duplicate payment for airfare of \$1,213, and overpaid a traveler \$587. FDA recovered the duplicate payment and overpayment from the travelers during our review. The lack of supporting documentation appeared to be an oversight by FDA staff and not a systemic issue.

Accordingly, this report contains no recommendations.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed FDA policies and procedures and financial records related to prescription drug user fees to determine whether FDA appropriately spent prescription drug user fees. We limited our review of FDA's internal controls to those controls that related to our audit objective.

We limited our review to \$796,065,980 in prescription drug user fees reported for October 1, 2014, through September 30, 2015.

We conducted our fieldwork at the FDA offices in Silver Spring, MD.

Methodology

To accomplish our audit objective, we:

- reviewed applicable Federal regulations;
- interviewed key FDA personnel to obtain an understanding of FDA's accounting policies and procedures;
- reviewed the annual PDUFA financial report and compared reported financial information to information from FDA's accounting system;
- reviewed the PDUFA program budget to identify any irregularities;
- reviewed FDA's chart of accounts to determine whether PDUFA funds were segregated from other funds;
- verified that FDA tracked and reported PDUFA spending separately from other user fee sources;
- reviewed FDA's accounting policies and procedures to determine whether
 - internal controls were adequate to protect PDUFA funds,
 - costs charged to the PDUFA program were allowable and allocable, and
 - invoices and payments were authorized by the appropriate manager and supported with adequate documentation; and

- compared actual PDUFA obligations with budgeted amounts.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: FEDERAL REGULATIONS FOR TRAVEL REIMBURSEMENT

Federal Travel Regulations, § 301-52.4, state that travelers must provide receipts for any expense over \$75. If it is impractical to furnish receipts in any instance as required by this subtitle, the failure to do so must be fully explained on the travel voucher. Receipts must be retained for 6 years and 3 months, as prescribed by the National Archives and Records Administration.