Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.
Office of Inspector General
https://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

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The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG’s internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.
NOTICES

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Section 8M of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG website.

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.
Why OIG 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 prescription drug 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 prescription drug 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 accurately computed prescription drug user fee rates.

Our objective was to determine whether FDA accurately computed prescription drug user fee rates.

How OIG Did This Review
We obtained and reviewed documentation from FDA, such as policies and procedures and financial records, to determine whether it accurately computed prescription drug user fee rates. We also analyzed prescription drug user fee collection amounts. We limited our review to $821.9 million in prescription drug user fee collections reported for October 1, 2014, through September 30, 2015.

The Food and Drug Administration Computed Prescription Drug User Fee Rates Accurately

What OIG Found
FDA computed prescription drug user fee rates accurately. We determined that the human drug review workload computation was appropriate. We also determined that the inflation adjustment for personnel compensation and benefits and nonpersonnel compensation and benefit costs were correctly computed.

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 prescription drug 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 prescription drug 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 accurately computed prescription drug user fee rates.

OBJECTIVE

Our objective was to determine whether FDA accurately computed prescription drug user fee rates.

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, prescription drug 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.

Under PDUFA V (fiscal years 2013-2017), application fees, establishment fees, and product fees were each set to contribute one-third of the total revenue amount in a fiscal year, though actual collections may have varied from this formula. An application fee must be collected when certain new drug applications or biologics license applications are submitted. Product fees are assessed for marketed products, with certain exceptions. An establishment fee is assessed for each prescription drug establishment. Product and establishment fees are due annually. The total annual fee revenue amount is set in section 736 of the Federal Food, Drug, and Cosmetic Act and is adjusted for annual changes in the inflation rate and FDA’s human drug review workload. FDA may obligate only prescription drug user fee revenues that are apportioned for use.

In fiscal year 2015, FDA reported a cumulative carryover balance of $362,345,905 in PDUFA fees for use in future fiscal years. This balance includes amounts carried over from 1992 through
2010, totaling $78,850,995,¹ in PDUFA fees that were in excess of FDA’s annual appropriation and have not been apportioned to FDA for obligation. Cumulative carryover amounts are summarized in the Table below.

Table: Prescription Drug User Fee Carryover Balances by Fiscal Year

<table>
<thead>
<tr>
<th>Program</th>
<th>Fiscal Years</th>
<th>Beginning Carryover</th>
<th>Year-End Carryover</th>
</tr>
</thead>
<tbody>
<tr>
<td>PDUFA</td>
<td>1993-1997</td>
<td>$0</td>
<td>$36,462,154</td>
</tr>
<tr>
<td>PDUFA II</td>
<td>1998-2002</td>
<td>36,462,154</td>
<td>22,683,224</td>
</tr>
<tr>
<td>PDUFA III</td>
<td>2003-2007</td>
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<td>130,816,093</td>
</tr>
<tr>
<td>PDUFA IV</td>
<td>2008-2012</td>
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<td>178,468,707</td>
</tr>
<tr>
<td>PDUFA V</td>
<td>2013</td>
<td>178,468,707</td>
<td>240,162,879</td>
</tr>
<tr>
<td>2014</td>
<td>240,162,879</td>
<td>303,099,604</td>
<td></td>
</tr>
<tr>
<td>2015</td>
<td>303,099,604</td>
<td>362,345,905</td>
<td></td>
</tr>
</tbody>
</table>

HOW WE CONDUCTED THIS REVIEW

We obtained and reviewed documentation from FDA, such as policies and procedures and financial records, to determine whether it accurately computed prescription drug user fee rates. We also analyzed prescription drug user fee collection amounts. We limited our review to $821,927,421 in prescription drug user fee collections 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.

The Appendix contains the details of our audit scope and methodology.

RESULTS OF REVIEW

FDA computed prescription drug user fee rates accurately. We determined that the human drug review workload computation was appropriate. We also determined that the inflation adjustment for personnel compensation and benefits and nonpersonnel compensation and benefit costs were correctly computed.

Accordingly, this report contains no recommendations.

¹ According to FDA’s Five-Year Financial Plan for PDUFA fiscal years 2018 through 2022, FDA’s ability to access and obligate these collections remains uncertain.
APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

We reviewed FDA policies and procedures and financial records submitted to HHS related to prescription drug user fees in an effort to determine whether FDA accurately computed prescription drug user fee rates in accordance with Federal regulations. We limited our review of FDA’s internal controls to those that relate to our audit objective.

We limited our review to $821,927,421 in prescription drug user fee collections reported for October 1, 2014, through September 30, 2015.

We conducted our fieldwork at the FDA offices in Silver Spring, Maryland from August 2017 through April 2018.

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 PDUFA annual financial reports,
- reviewed FDA’s organizational structure and internal departments’ responsibilities and authority,
- analyzed prescription drug user fee collection amounts to obtain an understanding of the amount collected annually,
- verified that the number of applications used to calculate the application fee tied to FDA financial records, and
- reviewed the components of the inflation adjustment for payroll costs and nonpersonnel compensation and benefits costs and tied them to supporting accounting records.

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.