Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

THE FOOD AND DRUG ADMINISTRATION COMPUTED PRESCRIPTION DRUG USER FEE RATES ACCURATELY

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Office of Inspector General

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

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

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.

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

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

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.