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GENERIC DRUG USER FEES

Application Review Times Declined, but FDA Should Develop a Plan for Administering Its Unobligated User Fees

GAO Highlights

Highlights of GAO-17-452, Report to the Chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate

Why GAO Did This Study

Nearly 90 percent of prescription drugs dispensed in the United States are generic drugs. According to FDA, an increasing volume of generic drug applications over the past decades stressed its ability to review applications efficiently. GDUFA granted FDA the authority to collect user fees from the generic drug industry to supplement resources for the generic drug program. In return, FDA committed to meeting certain performance goals related to the timely review of generic drug applications and to implementing review process improvements.

GAO was asked to examine FDA's implementation of GDUFA. In this report, GAO (1) examines how user fees supported the generic drug program, (2) describes FDA's improvements to the generic drug application review process, and (3) analyzes changes in generic drug application review times. GAO reviewed laws and regulations; FDA policy, guidance, the GDUFA Commitment Letter, and GDUFA financial reports from fiscal years 2013 through 2016; FDA data on application review times from fiscal years 2012 through 2015; and interviewed officials from FDA, generic drug manufacturers, and trade associations.

What GAO Recommends

GAO recommends that FDA develop a plan for administering user fee carryover that includes analyses of program costs and risks and reflects operational needs and contingencies. HHS agreed with GAO's recommendation.

View GAO-17-452. For more information, contact John E. Dicken at (202) 512-7114 or dickenj@gao.gov.

What GAO Found

Since the enactment of the Generic Drug User Fee Amendments of 2012 (GDUFA), the Food and Drug Administration's (FDA) reliance on user fees has increased from $121 million in fiscal year 2013 to $373 million in fiscal year 2016, or 45 percent of total program obligations in fiscal year 2013 to 76 percent in fiscal year 2016. FDA carried over $174 million in unobligated user fees at the end of the fourth year of the GDUFA 5-year period. GAO found that although FDA uses an internal management report to track user fee cash flows for internal purposes, it lacks a plan for administering its carryover—one that includes a fully-documented analysis of program costs and risks to ensure that program operations can be sustained in case of unexpected changes in collections or costs. GAO previously found that it is important for entities with carryover to establish appropriate target amounts based on program needs, risks, and contingencies. FDA's approach is inconsistent with best practices for managing federal user fees. Without a carryover plan, FDA lacks reasonable assurance that the size of its carryover is appropriate to ensure the efficient and responsible use of resources.

Generic Drug User Fee Collections, Obligations, and the Carryover, Fiscal Years 2013 through 2016

Dollars in millions

Fiscal year	Beginning user fee carryover	User fee collections	User fee obligations	Year-end user fee carryover
2013	n/a	$298	$121	$176
2014	$176	$327	$226	$278
2015	$278	$285	$332	$231
2016	$231	$315	$373	$174

Legend: n/a = not applicable

Source: GAO analysis of Food and Drug Administration data. | GAO-17-452.

FDA took steps to improve the timeliness and predictability of generic drug application reviews. FDA restructured the generic drug program by building a more robust organizational infrastructure, upgrading information technology systems, and implementing communication reforms. As FDA implemented these changes, it made additional refinements in response to applicants' feedback.

Generic drug application review times have improved under GDUFA. FDA's review time for a new generic drug application (known as an Abbreviated New Drug Application (ANDA)) decreased from 28 months for applications submitted in fiscal year to 2012 to about 14 months for those submitted in fiscal year 2015. FDA also surpassed multiple GDUFA performance goals. For example, FDA committed to reviewing 60 percent of ANDAs submitted in fiscal year 2015 within 15 months of their receipt. GAO found that FDA had taken action on 89 percent of such ANDAs for which it committed to conducting a substantive review by December 31, 2016, thereby surpassing this goal.