August 2019

GENERIC DRUG APPLICATIONS

FDA Should Take Additional Steps to Address Factors That May Affect Approval Rates in the First Review Cycle

GAO Highlights

Highlights of GAO-19-565, a report to congressional committees

Why GAO Did This Study

Generic drugs—copies of brand-name drugs—lead to significant cost savings. Before a generic drug can be marketed, FDA must approve the generic drug application. According to FDA, applications go through an average of three cycles of review before being approved, which may take years.

The FDA Reauthorization Act of 2017 included a provision for GAO to study issues regarding the approval of generic drug applications in the first review cycle. This report examines 1) the first review cycle approval rate of generic drug applications in recent years and factors that may have contributed to whether applications were approved; and 2) changes FDA has made to increase the first review cycle approval rate. GAO reviewed FDA data on all generic drug applications reviewed from fiscal years 2015 through 2017 and documentation from the first review cycle for a judgmental selection of 35 applications from fiscal years 2017 and 2018. GAO also interviewed a non-generalizable selection of stakeholders. Applications and stakeholders were chosen to ensure variation in experience with the approval process.

What GAO Recommends

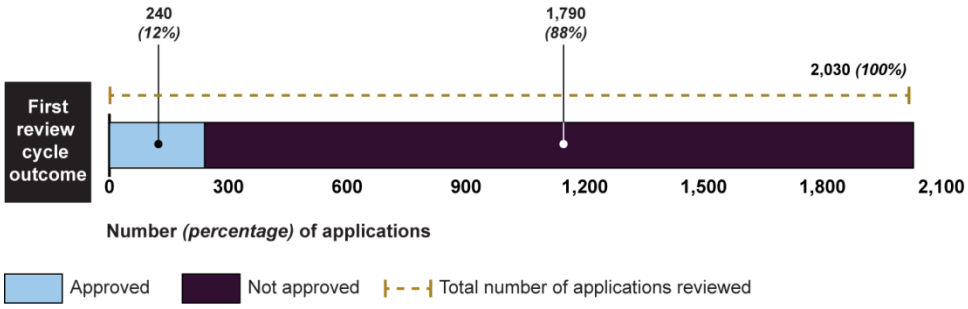
GAO recommends that FDA 1) take additional steps to address inconsistency in its written comments to generic drug application sponsors and 2) assess the extent to which the timing of brand-name drug companies' drug labeling changes affects the approval of generic drugs and take steps, as appropriate, to limit the effect. HHS concurred with GAO's recommendations.

View GAO-19-565. For more information, contact John Dicken at (202) 512-7114 or dickenj@gao.gov.

What GAO Found

GAO found that 12 percent of the 2,030 generic drug applications reviewed by the Food and Drug Administration (FDA) from fiscal years 2015 through 2017 were approved in the first review cycle. The first review cycle begins when FDA accepts a generic drug application for review and ends when FDA makes its first decision about whether the drug should be approved for marketing and sale. For applications that were not approved in that first cycle, the application must undergo one or more subsequent review cycles to obtain approval, delaying the generic drug's arrival to market.

Number and Percentage of Generic Drug Applications Approved in the First Review Cycle, Fiscal Years 2015–2017



Source: GAO analysis of Food and Drug Administration data. | GAO-19-565

GAO identified several factors that may have contributed to whether a generic drug was approved during the first review cycle. For example, certain types of complex drugs were less likely to receive approval in the first review cycle, such as eye drops or other drugs administered through the eye.

FDA has taken steps to increase the rate of generic drug approvals in the first review cycle. For example, FDA has increased communication with applicants and introduced templates for reviewers to improve the consistency and clarity of their comments. However, GAO's review of a judgmental selection of 35 applications found examples of variation in the clarity and content of FDA's comments to applicants. Such variation may have contributed to whether applicants could adequately address deficiencies within the first cycle, and therefore whether the applications were approved. In addition, stakeholders GAO interviewed expressed concern that changes to the brand-name drug's labeling mid-cycle could delay or prevent generic drugs' approval in the first review cycle, and some stakeholders said they believe that the labeling changes may be strategically timed to delay approvals. Although FDA officials noted that it would be difficult for brand-name companies to time labeling changes in this way, they said that the agency has not conducted analysis that would enable it to assess the validity of these concerns. Therefore, FDA lacks the information needed to respond to these concerns or address problems should they exist.