

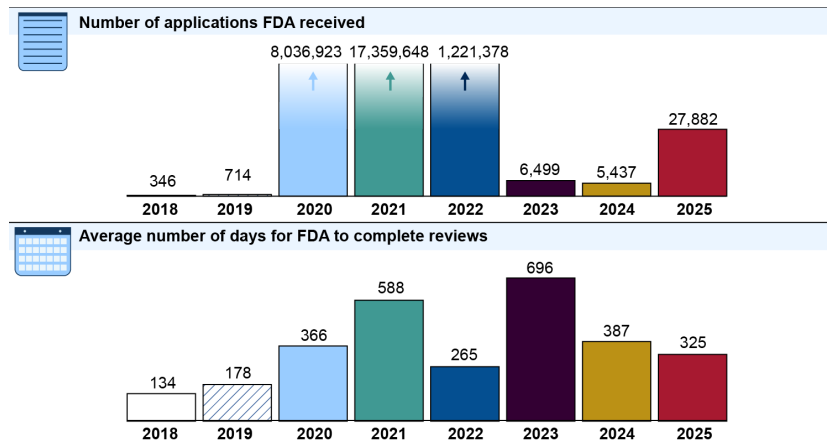
A report to congressional requesters

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What GAO Found

In 2016, the Food and Drug Administration (FDA) expanded its authority to oversee all tobacco products, including millions of e-cigarettes that were already on the market. In response, it received a surge of applications from manufacturers in 2020 for products seeking authorization to remain on the market legally. Specifically, it received over 25 million applications in 2020 and 2021, compared to just over 1 thousand applications in 2018 and 2019. This led to a backlog of applications. While FDA has since reviewed most of the applications submitted during this period, almost 132 thousand remained without a completed review as of December 31, 2025. (See figure.)

Figure: FDA Tobacco Product Application Reviews, Calendar Year (CY) 2018-2025



Source: GAO analysis of Food and Drug Administration (FDA) data (data); GAO (icons). | GAO-26-108195

From CY2018 to CY2025, FDA took an average of 507 days to complete its review of tobacco product applications. FDA has goals for each phase of the review process, ranging from 7 to 180 days. For the screening phase, FDA did not meet its goals, although it has made progress toward them. FDA also has goals for the last phase of review, when it must review an application's scientific information. However, FDA's data system was not designed to track steps in this part of the review process. Thus, it does not collect the data necessary to monitor whether it is meeting these goals. According to practices identified in prior GAO work, collecting performance information and using it to monitor performance are needed to assess if programs and activities are achieving intended goals. Meeting these goals will help FDA ensure a more predictably timed application process, and more completed reviews will help clarify which products are legally marketed, thus allowing FDA to take action against unauthorized products.

FDA has taken steps to improve review timeliness. For example, since the surge of applications, it issued multiple guidance documents for manufacturers to improve application quality, as it found that poor quality applications slowed the review process. In September 2025, the agency also created a pilot program aimed at streamlining the review process for nicotine pouches and plans to apply lessons learned from that pilot to other product types. However, the changes are too recent to know whether they will increase the timeliness of reviews.

Why GAO Did This Study

FDA has regulated certain tobacco products, such as cigarettes, since 2009. A surge of new product applications soon after led to an application backlog and significant delays, as GAO reported in 2013. FDA took steps to address these challenges and implemented performance measures for review timeliness. However, the 2016 expansion of FDA's authority to oversee all tobacco products once again raised questions about timeliness.

GAO was asked to provide an update on FDA's efforts to review applications and provide timely responses. This report examines (1) the status of FDA's reviews of tobacco product applications submitted 2018 through 2025, (2) the extent to which it met its timeliness goals for reviewing these applications, and (3) the steps FDA took to improve the timeliness of these reviews, among other topics.

GAO analyzed FDA tobacco product application data for submissions FDA received in 2018 through 2025, reviewed agency documents, and interviewed FDA officials and tobacco representatives.

What GAO Recommends

GAO recommends FDA collect the data necessary to monitor whether it is meeting its timeliness goals for reviewing scientific information in all tobacco product applications. HHS agreed with the recommendation.