September 2013

NEW TOBACCO PRODUCTS

FDA Needs to Set Time Frames for Its Review Process

GAO Highlights

Highlights of GAO-13-723, a report to the Ranking Member, Subcommittee on Primary Health and Aging, Committee on Health, Education, Labor, and Pensions, U.S. Senate

Why GAO Did This Study

In 2009, the Family Smoking Prevention and Tobacco Control Act granted FDA, an agency within the Department of Health and Human Services (HHS), authority to regulate tobacco products such as cigarettes. The act requires that tobacco manufacturers submit information to be reviewed by FDA in order to market new tobacco products and established tobacco user fees to fund FDA's tobacco-related activities. The act represents the first time that FDA has had the authority to regulate tobacco products.

Manufacturers have raised concerns about the progress of CTP, the FDA center established by the act to implement its provisions. GAO was asked to examine CTP's review of new tobacco product submissions, responses to meeting requests, and use of funds. This report examines (1) the status of CTP's reviews of new tobacco product submissions; (2) how CTP responded to manufacturers' and other entities' meeting requests, and the length of time CTP took to hold the meetings; and (3) the extent to which FDA has spent its tobacco user fee funds. GAO analyzed data regarding submissions received by FDA as of January 7, 2013; reviewed data on meeting requests, spending plans, and amounts obligated; and interviewed CTP and tobacco industry officials.

What GAO Recommends

GAO recommends that FDA establish performance measures that include time frames for making decisions on new tobacco product submissions and that the agency monitor performance relative to those time frames. HHS agreed with GAO's recommendations.

View GAO-13-723. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

As of January 7, 2013, the Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) had finished initial, but not final, review steps for most of about 3,800 submissions for new tobacco products (those not on the market on February 15, 2007). Ninety-nine percent of the submissions received by FDA were made under the substantial equivalence (SE) pathway. CTP determines whether the new tobacco product in an SE submission has the same characteristics as a predicate tobacco product (a product commercially marketed in the United States on February 15, 2007, or previously found by FDA to be substantially equivalent) or has different characteristics that do not raise different questions of public health. Initial review steps include CTP's determination of whether the new product is a type regulated by FDA and whether the submission is missing information. For most SE submissions, CTP took more than a year and a half from the date a submission was received to the date these initial steps were completed. Of the 3,788 SE submissions, 3,165 were received by FDA prior to a statutory deadline (March 22, 2011) allowing the product to be marketed unless CTP finds that they are not substantially equivalent. SE submissions received after that date cannot be marketed until CTP determines they are substantially equivalent. In late June 2013, CTP made a final decision on 6 of the 3,788 SE submissions, finding that 2 of the products were substantially equivalent and that 4 were not; the remaining submissions were still undergoing CTP review. CTP officials and manufacturers told GAO that several factors (such as CTP requests for additional information from manufacturers for submissions and having to hire and train new staff) impacted the time it took CTP to review SE submissions. While CTP is working to address these factors by, for example, disseminating information to manufacturers to improve submission quality and developing training for staff, CTP does not have performance measures that include time frames for making final decisions on submissions by which to assess its progress. Without time frames, CTP is limited in its ability to evaluate policies, procedures, and staffing resources in relation to its review process and, in turn, is limited in its ability to reasonably assure efficiency and effectiveness.

A variety of outside entities (such as manufacturers) have requested meetings with CTP to discuss new tobacco product submissions, public health activities, and other issues, and four CTP offices have received meeting requests. Those offices granted more meetings (72) than they denied (22) of all the meeting requests they received through January 7, 2013. The number of calendar days from the date a meeting was requested to the date it was held ranged from 1 to 262 days, and the averages among the four offices ranged from 51 to 97 days.

FDA spent (obligated) less than half of the nearly $1.1 billion in tobacco user fees it collected from manufacturers and others through the end of fiscal year 2012; $603 million of these user fees remained unspent and, thus, remained available to CTP. CTP spent substantially less than planned in fiscal years 2011 and 2012. CTP had planned on spending a total of $611 million for fiscal year 2012; instead, the center spent $272 million for that year. CTP officials told GAO that the time it took to award contracts contributed to the center spending less than planned. For example, CTP planned to award a $145 million contract in fiscal year 2012 for a public health education campaign, but most of that amount was not awarded until the first quarter of fiscal year 2013.