

GAO Finds CTP Fails to Establish Deadlines for Tobacco Product Review

The Government Accountability Office (GAO) released a report today that identifies significant shortcomings in the Food and Drug Administration's Center for Tobacco Products' (CTP) progress towards the review of tobacco products. Senator Richard Burr requested this report because of concerns that the FDA's Center for Tobacco Products is underperforming in its mission to review new tobacco product submissions under the substantially equivalent (SE) pathway.

The Tobacco Control Act of 2009 gave FDA the authority to regulate tobacco products and authorizes the agency to assess and collect user fees from manufacturers for CTP's regulatory activities. The SE review pathway for the two types of submissions – provisional and regular – includes three key steps: jurisdictional review, completeness review and scientific review to determine if the tobacco product is substantially equivalent to a product on the market prior to February 2007.

CTP has Finalized Decisions for Only 17 SE Submissions Out of 3,788 Total

Since 2009, FDA has collected over \$1.1 billion in tobacco user fees – but as of today, has only made final decisions for 17 tobacco products out of the 3,788 total SE submissions in the 3 years since FDA received the first SE submission in June 2010.¹

- CTP took *over a year and a half* on average to complete the initial review steps – jurisdictional and completeness reviews – for the majority of the provisional SE submissions, and 6 months for more than half of the regular SE submissions.
- As of June 2013, CTP started scientific reviews for all of the regular SE submissions, but less than 2 percent of the 2,191 provisional SE submissions that had finished completeness reviews.
- CTP has spent less than half (46%) of the tobacco user fee funds it has collected, leaving \$603 million unspent.

CTP noted several factors impacting review times for new tobacco product submissions including: 1) insufficient information from manufacturers, 2) a shortage of experienced tobacco product review staff, and 3) slow IT systems. While GAO found that agency has taken proactive steps to address these issues and improve review times for SE submissions, *CTP is not held accountable to any time frame for reviewing products.*

CTP Needs to Set Time Frames and Performance Measures to Ensure Regulatory Certainty

CTP needs to establish performance measures to ensure predictability under the regulatory pathway for tobacco product submissions. Since the Tobacco Control Act established CTP four years ago, the agency has received almost 4,000 submissions and collected over a billion dollars in tobacco user fees, yet it has only made final decisions on less than 1% of submissions.

The GAO report noted the potential for CTP to better ensure accountability for reviewers and regulatory certainty for stakeholders, and recommended that CTP establish performance measures including review time frames for final product decisions on SE submissions and Exemption from SE submissions. Additionally, to ensure greater accountability for meeting performance goals, including time frames, CTP should evaluate staff to determine if reviewers are performing efficiently and effectively. Senator Burr welcomes the GAO's analysis of the new tobacco product regulatory pathway and looks forward to working with CTP to ensure greater accountability and regulatory certainty on behalf of stakeholders.

¹ Since GAO completed its analysis, FDA has made final decisions for 11 additional tobacco product submissions under the SE pathway. <http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm339928.htm>