



## Testimony

Before the Subcommittee on Health,  
Committee on Energy and Commerce,  
House of Representatives

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# TOBACCO PRODUCTS

## FDA Spending and New Product Review Time Frames

Statement of Marcia Crosse  
Director, Health Care

# GAO Highlights

Highlights of [GAO-14-508T](#), a testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

## Why GAO Did This Study

In 2009, the Tobacco Control Act granted FDA authority to regulate tobacco products such as cigarettes. The act authorizes FDA to assess and collect user fees from each tobacco manufacturer and importer for FDA activities related to tobacco product regulation. The act also requires that manufacturers submit information—for example, a statement of the tobacco product’s ingredients—to be reviewed by FDA in order to market new tobacco products. FDA reviews the products using a public health standard, taking into account the risks and benefits of tobacco products on the population as a whole, including users and nonusers. The act represents the first time that FDA has had the authority to regulate tobacco products.

This testimony highlights and provides selected updates to key findings from our September 2013 report, entitled, *New Tobacco Products: FDA Needs to Set Time Frames for Its Review Process* ([GAO-13-723](#)). This report examined (1) the extent to which FDA spent its tobacco user fee funds, and (2) the status of CTP’s reviews of new tobacco product submissions. GAO reviewed FDA data on tobacco user fees collected by FDA and spent by all of CTP’s offices. GAO also analyzed CTP data on product submissions, including whether specific steps in the review process had been completed.

## What GAO Recommends

In its September 2013 report, GAO recommended FDA establish time frames for making decisions on submissions. FDA plans to identify time frames in spring 2014 and implement them by October 2014.

View [GAO-14-508T](#). For more information, contact Marcia Crosse at (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov).

April 8, 2014

## TOBACCO PRODUCTS

### FDA Spending and New Product Review Time Frames

## What GAO Found

The Food and Drug Administration (FDA) spent (obligated) less than half of the \$1.1 billion in tobacco user fees it collected from manufacturers and others from fiscal year 2009 through the end of fiscal year 2012; however, FDA’s spending increased substantially in fiscal year 2013. Through December 31, 2013, FDA spent nearly 81 percent of the approximately \$1.75 billion in fees collected by that time. According to officials in FDA’s Center for Tobacco Products (CTP), the center established by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) to implement the act’s provisions, the time it took to award contracts contributed to the center spending less than it had planned to spend. In fiscal year 2013, FDA was able to carry out a number of activities that were originally planned for fiscal years 2011 and 2012, such as efforts to educate youth on the dangers of tobacco use. About 79 percent (\$1.12 billion) of user fees spent as of December 31, 2013, was spent by three CTP offices: Office of Health Communication and Education, Office of Science, and Office of Compliance and Enforcement.

As of January 7, 2013, CTP had finished initial, but not final, review steps for most of about 3,800 submissions it had received for new tobacco products (those not on the market on February 15, 2007). Ninety-nine percent of the submissions received were made under the substantial equivalence (SE) pathway, through which CTP determines whether the product has the same characteristics as a predicate tobacco product (a product commercially marketed in the United States on February 15, 2007, or previously found to be substantially equivalent) or has different characteristics that do not raise different questions of public health. For most SE submissions received by January 7, 2013, CTP took more than a year and a half from the date a submission was received to the date CTP’s initial review steps were completed; initial review steps precede a scientific review step during which CTP determines whether the product is substantially equivalent to a predicate product. CTP made its first decisions on SE submissions in late June 2013—about 3 years after FDA’s receipt of the first SE submission—and as of December 31, 2013, had made final decisions for 30 of the 4,490 SE submissions the agency had received. CTP officials stated that CTP requests for additional information from manufacturers for submissions and having to hire and train new staff impacted the time it took to review submissions. GAO also found that CTP has not had performance measures that include time frames for making final decisions on SE submissions by which to assess its progress. Time frames would allow CTP to evaluate its efficiency and effectiveness and help it make appropriate adjustments.

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Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee,

I am pleased to be here today to discuss the Food and Drug Administration's (FDA) implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). Tobacco use is the leading cause of preventable death, disease, and disability, and it is a significant contributor to health care costs in the United States. In June 2009, the Tobacco Control Act granted the FDA, an agency within the Department of Health and Human Services (HHS), authority to regulate tobacco products such as cigarettes.<sup>1</sup> The act requires that tobacco manufacturers submit information—for example, a statement of the product's ingredients and a description of the methods used for manufacturing the product—to be reviewed by FDA in order to market new tobacco products. FDA reviews the products using a public health standard, taking into account the risks and benefits of tobacco products on the population as a whole, including users and nonusers. The act represents the first time that FDA has had the authority to regulate tobacco products.

The Tobacco Control Act also established the Center for Tobacco Products (CTP) within FDA to be responsible for implementing the act.<sup>2</sup> CTP was formed in 2009—the first new center within FDA in 21 years—and it implements the act by reviewing submissions for marketing new tobacco products, enforcing prohibitions on the sale of certain tobacco products, developing and issuing regulations and guidance, engaging in public education about the risks associated with tobacco product use, and performing other activities.<sup>3</sup> The act also authorizes FDA to assess and

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<sup>1</sup>Pub. L. No. 111-3, div. A, 123 Stat. 1776 (2009). Tobacco products that FDA currently regulates include cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco products. The Tobacco Control Act enables FDA to assert jurisdiction over other tobacco products—for example, cigars, pipe tobacco, hookah, and e-cigarettes that do not make drug claims—through rulemaking. In October 2013, FDA submitted to the White House Office of Management and Budget (OMB) a proposed rule to regulate other tobacco products that are not currently regulated. As of April 2, 2014, the proposed rule was still under review by the OMB and had not been issued by FDA.

<sup>2</sup>Tobacco Control Act, § 101(b), 123 Stat. at 1787 (codified at 21 U.S.C. § 387a(e)).

<sup>3</sup>In addition to the term submission, CTP uses the terms report, request, and application (depending on the new tobacco product) to refer to the package of information that manufacturers provide to FDA for review in order to legally market a new tobacco product.

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collect user fees from each tobacco manufacturer and importer and specifies that the tobacco user fees may only be applied towards FDA activities that relate to the regulation of tobacco products.<sup>4</sup> All of CTP's activities are funded exclusively through tobacco user fees.

My statement will highlight key findings from our September 2013 report on FDA's review process for new tobacco products, and includes selected updates to the report.<sup>5</sup> Among other things, our report examined (1) the extent to which FDA spent its tobacco user fee funds, and (2) the status of CTP's reviews of new tobacco product submissions.

To examine the extent to which FDA has spent its tobacco user fee funds, we reviewed FDA's data, including information from CTP on tobacco user fees from the fourth quarter of fiscal year 2009 through the fourth quarter of fiscal year 2012, such as the amounts collected by FDA, and the amount spent by all of CTP's offices.<sup>6</sup> We also reviewed FDA and CTP documents, such as FDA budget justification documents. In addition, we obtained and reviewed updated information from CTP on tobacco user fees collected and spent, including spending by each CTP office, through December 31, 2013.

To examine the status of CTP's reviews of new tobacco product submissions, we analyzed data maintained by CTP's Office of Science (OS)—the CTP office primarily responsible for conducting reviews of new tobacco product submissions—regarding all submissions received by FDA as of January 7, 2013. This included data on whether specific steps of the review process were completed for each submission, and key

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<sup>4</sup>User fees are a fee assessed to users for goods or services provided by the federal government. The Tobacco Control Act specified the total amount of user fees authorized to be collected for each fiscal year beginning with fiscal year 2009, and authorized user fees to remain available until expended (which means that FDA may carry over user fees to subsequent fiscal years if they are not obligated by the end of the fiscal year in which they were collected). Fees are collected and available for obligation only to the extent and in the amount provided in advance in appropriations acts. For fiscal year 2014, Congress appropriated \$534 million in tobacco user fees for collection and obligation—the total amount authorized under the Tobacco Control Act.

<sup>5</sup>GAO, *New Tobacco Products: FDA Needs to Set Time Frames for Its Review Process*, [GAO-13-723](#) (Washington, D.C.: Sept. 6, 2013).

<sup>6</sup>For the purposes of this testimony, spending means obligations, including those for which expenditures have been made. The term obligation refers to a definite commitment by a federal agency that creates a legal liability to make payments immediately or in the future.

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dates for each submission. We also reviewed relevant laws, regulations, and agency documents (such as guidance documents and draft standard operating procedures); we interviewed OS officials to learn about the process for tracking and reviewing submissions, and to identify factors that contributed to the time CTP took to review new tobacco product submissions. We compared CTP's review processes against internal control standards, which specify that performance measures such as time frames and the monitoring of actual performance against measures are an integral part of operating efficiently, achieving effective results, and planning appropriately.<sup>7</sup> We also interviewed industry representatives from manufacturers and tobacco trade associations to learn about factors that may have contributed to the time taken by CTP to review submissions. In addition, we obtained and examined updated data on the number of new tobacco product submissions received by FDA as of December 31, 2013. We also discussed factors affecting timeframes with CTP officials.

We assessed the reliability of FDA data we received by reviewing related documentation, performing data reliability checks (such as examining the data for missing values), and interviewing CTP officials. After taking these steps, we determined that the data we used were sufficiently reliable for our purposes.

We conducted the work for the report on which this statement is based from November 2012 to September 2013, and updated selected information in April 2014, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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<sup>7</sup>See GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: Nov. 1999) and its supplemental guide, *Internal Control Management and Evaluation Tool*, [GAO-01-1008G](#) (Washington, D.C.: Aug. 2001).

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## FDA Spent Less Than Half of the User Fees Collected by the End of Fiscal Year 2012; Spending Increased Substantially in Fiscal Year 2013

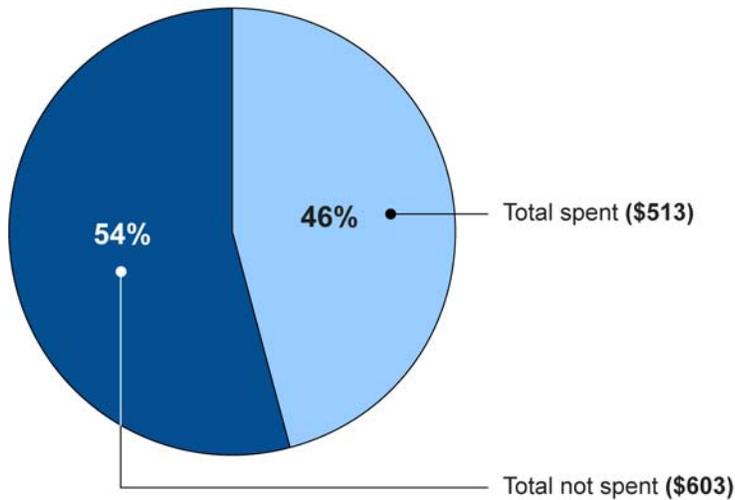
FDA spent (obligated) less than half of the tobacco user fees it collected from manufacturers and others through the end of fiscal year 2012; however, FDA's spending increased substantially in fiscal year 2013. From fiscal year 2009 through the end of fiscal year 2012, FDA had collected about \$1.1 billion in tobacco user fees; \$603 million of these user fees remained unspent at the end of fiscal year 2012 and, thus, remained available to CTP (see fig. 1). The \$513 million CTP did spend was substantially less than it had planned to spend. For example, in fiscal years 2011 and 2012, CTP spent about 45 percent of what it had planned to spend. CTP officials told us 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. Spending for other contracts for both fiscal years 2011 and 2012 was lower than expected for a number of reasons, according to CTP officials: fewer contracts than expected were awarded, the scope of a contract changed, or CTP was short of staff to support the work of the contract.<sup>8</sup>

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<sup>8</sup>CTP officials told us that fewer than expected contracts were awarded in those fiscal years because, for example, CTP and FDA spent significant amounts of time to determine the structure of public education campaign contracts.

**Figure 1: Total Tobacco User Fees Spent and Not Spent by FDA through Fiscal Year 2012**

Dollars (in millions)



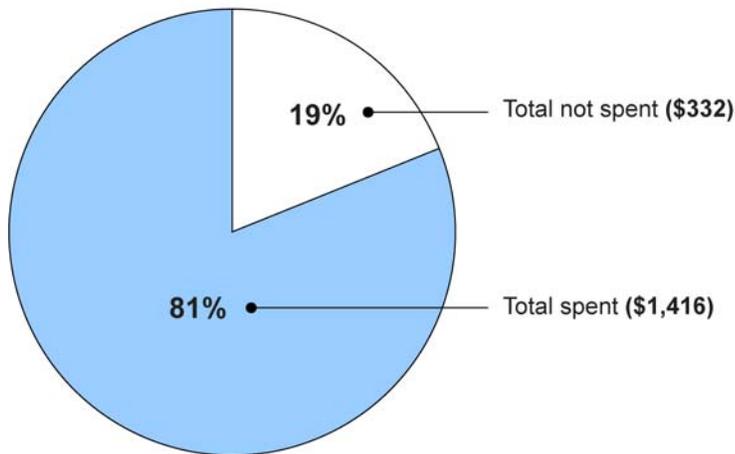
Source: GAO analysis of FDA data.

Note: This figure shows the tobacco user fees collected from fiscal year 2009 through fiscal year 2012 (which totaled about \$1.1 billion), the percentage and amount of these fees spent during this period, and the percentage and amount of these fees remaining unspent at the end of this period. The total amount collected is the amount received through fiscal year 2012. The figure does not include about \$62 million that was billed in fiscal year 2012 but collected in fiscal year 2013. Of the almost \$513 million spent by FDA, the Center for Tobacco Products spent almost \$468 million. The remaining funds were spent by other FDA entities (including the Office of Regulatory Affairs, Headquarters, and the Office of the Commissioner) and include funds spent on U.S. General Services Administration rent, other rent, and rent-related activities.

The proportion of collected tobacco user fees that FDA spent increased substantially in fiscal year 2013. Through December 31, 2013, FDA had collected nearly \$1.75 billion in tobacco user fees and spent nearly \$1.42 billion; \$332 million of these fees remained unspent (see fig. 2).

**Figure 2: Total Tobacco User Fees Spent and Not Spent by FDA as of December 31, 2013**

Dollars (in millions)

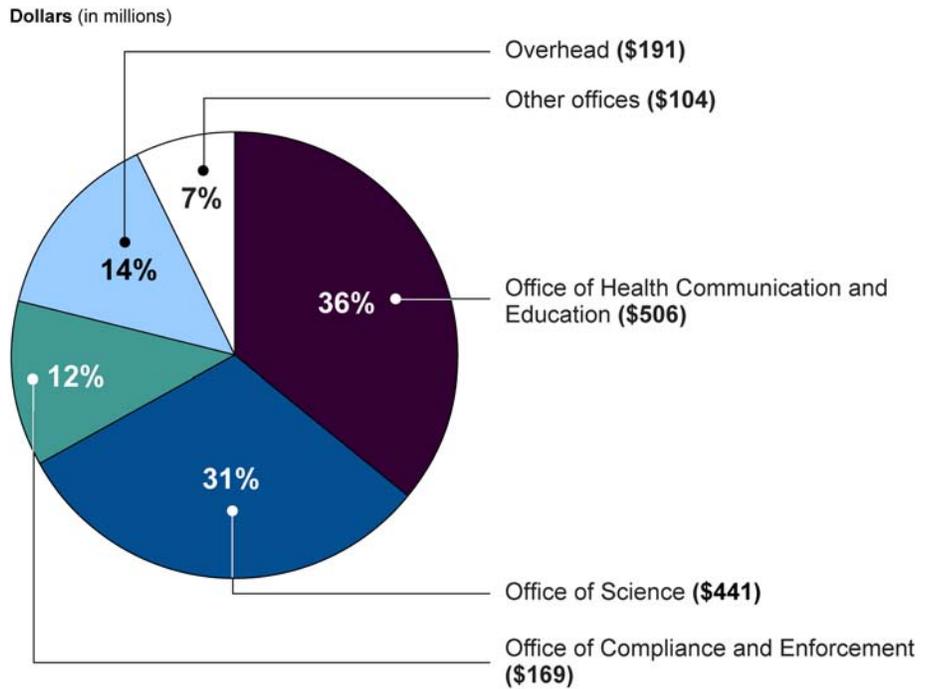


Source: GAO analysis of FDA data.

Note: This figure shows the tobacco user fees collected from fiscal year 2009 through December 31, 2013 (which totaled about \$1.75 billion), the percentage and amount of these fees spent during this period, and the percentage and amount of these fees remaining unspent at the end of this period. Of the \$1.42 billion spent by FDA, the Center for Tobacco Products and FDA's Office of Regulatory Affairs spent about \$1.36 billion. The remaining funds were spent by other FDA entities (including headquarters and the Office of the Commissioner) and spent on U.S. General Services Administration rent, other rent, and rent-related activities.

More than half of FDA's spending on tobacco-related activities through December 31, 2013, (61 percent) occurred in fiscal year 2013. FDA spent \$868 million that fiscal year. As the contracting issues the agency encountered in the initial years of the center were addressed, FDA was able to carry out a number of activities in fiscal year 2013 that were originally planned for fiscal years 2011 and 2012 such as public health education campaigns. About 79 percent (\$1.12 billion) of user fees spent as of December 31, 2013, was spent by three CTP offices: Office of Health Communication and Education, OS, and Office of Compliance and Enforcement (see fig. 3). In fiscal year 2013, CTP's Office of Health Communication and Education was responsible for the majority of the spending, which supported, in large part, its efforts to educate youth on the dangers of tobacco use.

**Figure 3: FDA Spending by Center for Tobacco Products Office as of December 31, 2013**



Source: GAO analysis of FDA data.

Note: This figure excludes FDA spending on tobacco-related activities in fiscal year 2009. Overhead includes U.S. General Services Administration rent and rent-related activities; Center for Tobacco Products and FDA overhead (information technology infrastructure and centralized funding for, among other things, furniture, office equipment, and center-wide training); and the tobacco-related spending of FDA headquarters and the Office of the Commissioner. Other offices include CTP's Office of the Center Director, Office of Management, Office of Policy, and Office of Regulation. Spending for the Office of Compliance and Enforcement includes spending for FDA's Office of Regulatory Affairs, which conducts inspections.

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## CTP Finished Initial, but Not Final, Review Steps for Most Submissions, and Lacks Time Frames for Its Review Processes

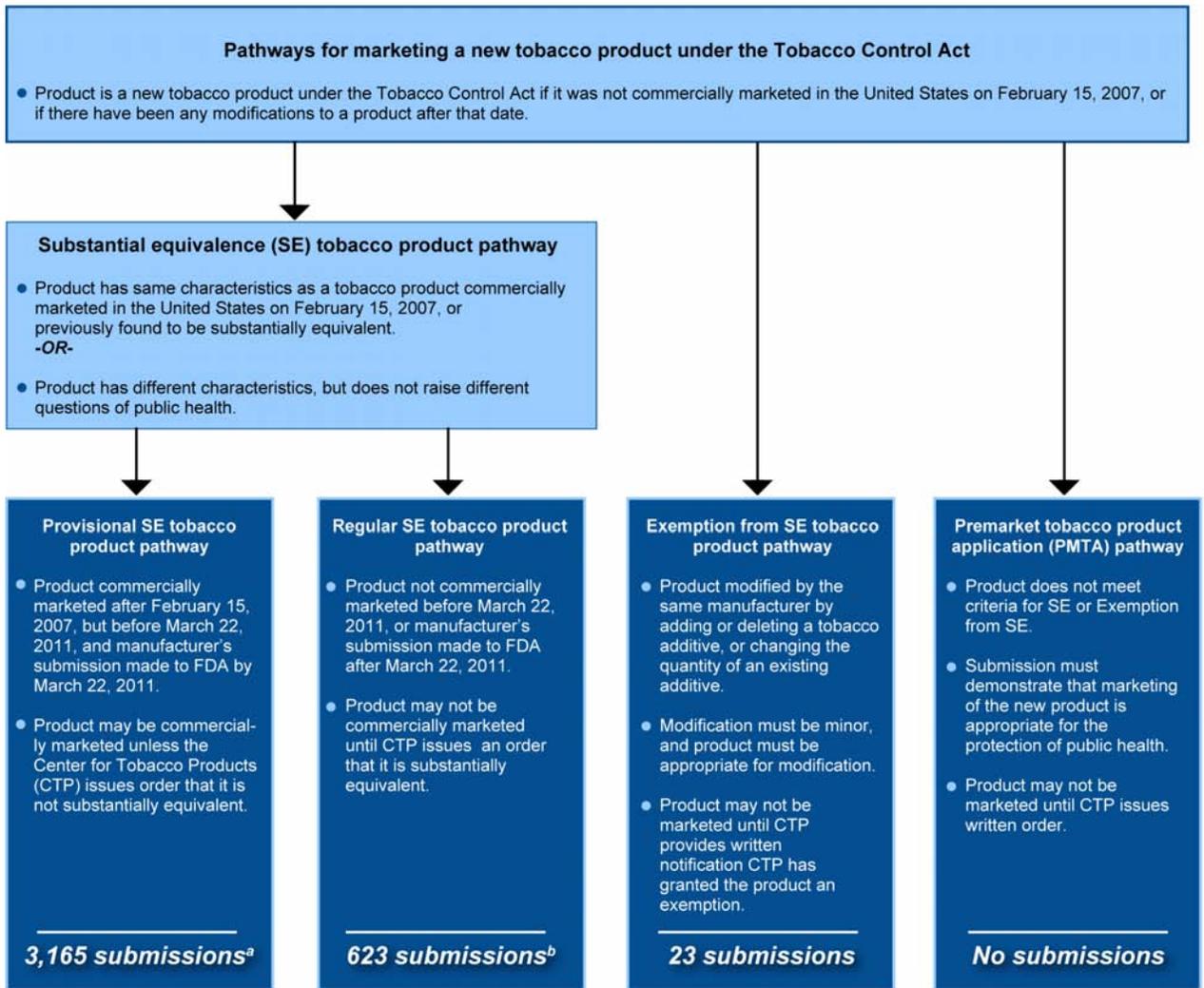
As of January 7, 2013, CTP had finished initial, but not final, review steps for most of about 3,800 submissions for new tobacco products (those not on the market on February 15, 2007). Ninety-nine percent of the submissions received by FDA were made under the substantial equivalence (SE) pathway. Under this pathway for new tobacco products, CTP determines whether the 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. About 84 percent (3,165) of the 3,788 SE submissions received as of January 7, 2013, were provisional SE submissions—that is, they were received by FDA prior to a statutory deadline allowing the product to be marketed unless CTP finds that they are not substantially equivalent.<sup>9</sup> SE submissions received after that statutory deadline—called regular SE submissions—cannot be marketed until CTP determines they are substantially equivalent. In addition to submissions under the SE pathway, FDA had received 23 submissions under the Exemption from SE pathway and had not received any submissions under the Premarket Tobacco Product Application (PMTA) pathway.<sup>10</sup> See figure 4 for information on each new tobacco product submission pathway and the number of submissions FDA received under each as of January 7, 2013.

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<sup>9</sup>Almost all of the provisional SE submissions were received in the second quarter of fiscal year 2011—3,115 of the provisional SE submissions were received within the 3 weeks prior to the statutory deadline of March 22, 2011.

<sup>10</sup>Eligibility for the Exemption from SE pathway is limited to new tobacco products that are minor modifications of an existing tobacco product (adding, deleting, or changing the quantity of an additive) already marketed by the same manufacturer. New tobacco products that are not substantially equivalent or are not minor modifications of an existing tobacco product are subject to the PMTA pathway, which, among other things, requires submission of full reports of investigations of health risks. According to CTP officials and industry representatives, one reason for the lack of submissions under the PMTA pathway may be the challenge in demonstrating that a manufacturer has met the public health standard (appropriate for the protection of public health) for the PMTA pathway.

**Figure 4: Number of Submissions Received by FDA for Each New Tobacco Product Pathway as of January 7, 2013**



Source: GAO summary of FDA information.

<sup>a</sup>Of the 3,165 provisional SE submissions, 44 were withdrawn by the manufacturer as of January 7, 2013.

<sup>b</sup>Of the 623 regular SE submissions, 20 were withdrawn by the manufacturer as of January 7, 2013.

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As of January 7, 2013, CTP finished initial, but not final, review steps for over two-thirds of the SE submissions the agency received since June 2010.<sup>11</sup> For most SE submissions, CTP took more than a year and a half from the date a submission was received to the date CTP's initial review steps were completed. 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.<sup>12</sup> These initial review steps are followed by a scientific review, which involves an assessment of the new product by scientists in different disciplines (such as chemistry and toxicology) to determine whether it is substantially equivalent to a predicate tobacco product. As of January 7, 2013, CTP had not finished scientific review for any SE submissions—that is, had not made any decisions on SE submissions.

CTP made its first decisions on SE submissions in late June 2013—about 3 years after FDA's receipt of the first SE submission—and as of December 31, 2013, CTP had made a final decision on a total of 30 of the 4,490 SE submissions it had received. All 30 final decisions were for regular SE submissions—FDA found 17 submissions to be substantially equivalent and 13 submissions to be not substantially equivalent to a predicate tobacco product. In addition, CTP had refused to accept 22 of the 59 Exemption from SE submissions because the submissions did not meet statutory requirements, and had made no decisions for the 4 PMTA submissions. Of the 4,490 SE submissions FDA received as of December 31, 2013, 201 submissions had been withdrawn by manufacturers; of the 63 non-SE submissions FDA received, none were withdrawn. (See table 1.)

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<sup>11</sup>FDA received the first SE submission on June 11, 2010.

<sup>12</sup>Our analysis of data provided by CTP found that the length of time to determine whether regular SE submissions were missing information improved over time.

**Table 1: Number of New Tobacco Product Submissions and Status of FDA Review, as of December 31, 2013**

Submission type		Submissions received	Initial review completed	Closed review without decision (withdrawal)	Decisions		
					Product meets criteria for marketing	Product does not meet criteria for marketing	Refuse to accept or refuse to file
Substantial Equivalence (SE) <sup>a</sup>	Provisional <sup>b</sup>	3,557	3,230	117	0	0	0
	Regular <sup>c</sup>	933	862	84	17	13	0
	Total SE	4,490	4,092	201	17	13	0
Exemption from SE <sup>d</sup>		59	30	0	0	0	22
Premarket tobacco product application (PMTA) <sup>e</sup>		4	0	0	0	0	0

Source: GAO summary of FDA information.

Notes: The Tobacco Control Act requires that manufacturers of tobacco products submit information—for example, a statement of the product's ingredients—to be reviewed by FDA using the public health standard in order to legally market tobacco products in the United States.

<sup>a</sup>Manufacturers use the SE pathway if a new tobacco product 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, but does not raise different questions of public health.

<sup>b</sup>Provisional SE submissions are for new tobacco products commercially marketed after February 15, 2007, but before March 22, 2011. Provisional SE submissions were received by FDA by March 22, 2011. The tobacco products represented in these submissions may be commercially marketed unless the Center for Tobacco Products (CTP) issues an order that they are not substantially equivalent.

<sup>c</sup>Regular SE submissions are for new tobacco products not yet commercially marketed. Regular SE submissions were received by FDA after March 22, 2011. The tobacco products represented in these submissions may not be marketed until CTP issues an order that they are substantially equivalent.

<sup>d</sup>Manufacturers use the Exemption from SE pathway for new tobacco products with minor modifications (adding, deleting, or changing the quantity of an additive) of another product marketed by the same manufacturer.

<sup>e</sup>Manufacturers use the PMTA pathway for new tobacco products that do not meet the criteria for the other two pathways. Products included in PMTA submissions can only be legally marketed after FDA issues an order permitting their marketing.

In February 2014, CTP made its first decisions on provisional SE submissions, finding products in four provisional SE submissions to be not substantially equivalent to predicate products. The agency issued orders on February 21, 2014, to stop the further sale and distribution of four tobacco products currently on the market.<sup>13</sup> According to FDA, the

<sup>13</sup>FDA publishes its final decisions—including the four orders for its decisions to stop the further sale and distribution of tobacco products on the market that were issued on February 21, 2014—on its website: <http://www.fda.gov/tobaccoproducts/labeling/marketingandadvertising/ucm339928.htm> (accessed Apr. 3, 2014).

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company making the SE submissions did not provide sufficient information to support a finding of substantial equivalence—for example, the company did not fully identify eligible predicate tobacco products as required for CTP to perform an SE review.

CTP officials and manufacturers told us 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. Another factor affecting review time frames was CTP's decision to place a higher priority on its review of regular SE submissions than on its review of provisional SE submissions, which contributed to longer review times for provisional SE submissions when compared to regular SE submissions. Specifically, according to OS officials, in the summer of 2011 CTP prioritized reviews for regular SE submissions over provisional SE submissions, so resources were shifted away from provisional SE submissions. CTP officials said that there were three reasons for placing a higher priority on its review of regular SE submissions over provisional SE submissions: (1) tobacco products in provisional SE submissions could remain on the market legally (unless and until CTP issued an order of not substantially equivalent), (2) FDA received a large number of provisional SE submissions on March 21, 2011 (the day before the statutory deadline for submitting provisional SE submissions), making it impractical to prioritize reviews by the date the submission was received, and (3) CTP required time to assess which approach to reviewing provisional submissions would be the most effective at addressing the public health burden of tobacco use.

While CTP has been working to address these factors by, for example, disseminating information to manufacturers to improve submission quality and developing training for staff, CTP has not had performance measures that include time frames for making final decisions on SE submissions by which to assess its progress.<sup>14</sup> Time frames would allow CTP to evaluate its efficiency and effectiveness and help it make appropriate adjustments. Under federal standards for internal control, control activities that establish performance measures, such as time frames, and the

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<sup>14</sup>The Tobacco Control Act does not mandate a time frame for CTP's review of new tobacco product submissions with the exception of PMTA submissions. For PMTA submissions, the act requires CTP to issue an order stating whether the product may be marketed as promptly as possible, but not later than 180 days after FDA's receipt of a submission.

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monitoring of actual performance against measures are an integral part of operating efficiently, achieving effective results, and planning appropriately.<sup>15</sup> We reported that the lack of performance measures like time frames for reviews of SE submissions will limit CTP's ability to evaluate policies, procedures, and staffing resources in relation to CTP's submission review process and, in turn, limit CTP's ability to reasonably assure efficient operations and effective results. We recommended 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.<sup>16</sup> HHS agreed with our recommendation, and as of April 2, 2014, FDA officials said that they expect to identify performance measures that include time frames for the regular SE and Exemption from SE review processes in spring 2014, and to implement these performance measures by October 2014.<sup>17</sup>

In addition, although FDA has increased its staff and training for staff, tobacco industry stakeholders expressed concerns about whether CTP will have a sufficient number of qualified staff to review the backlog of the more than 4,000 new tobacco product submissions received as of December 31, 2013 and also review new submissions that may be made in the future, particularly if FDA asserts jurisdiction over new types of tobacco products that are not currently subject to FDA's regulatory authority. CTP officials reported that many additional staff have been and will continue to be hired and trained, and the center does not expect hiring qualified staff to be a continuing challenge for the purpose of conducting product reviews.

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<sup>15</sup>While we focused on the timeliness of the reviews in our work, other dimensions of an organization's performance—such as the outcomes to be achieved, quality, and cost—are equally important for evaluating overall efficiency and effectiveness.

<sup>16</sup>[GAO-13-723](#), 39.

<sup>17</sup>In response to our recommendation, FDA stated that the agency will take a phased approach to implementing these performance measures and time frames, starting with regular SE submissions and Exemption from SE submissions. FDA stated that as the agency gains more experience with reviewing provisional SE submissions, it will begin to implement performance measures and time frames with respect to those submissions.

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Chairman Pitts, Ranking Member Pallone, and Members of the Subcommittee, this completes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

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## GAO Contact and Staff Acknowledgments

If you or your staff have any questions about this testimony, please contact me at (202) 512-7114 or [crosssem@gao.gov](mailto:crosssem@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. GAO staff who made key contributions to this testimony are listed in appendix I.

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# Appendix I: GAO Contact and Staff Acknowledgments

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## GAO Contact

Marcia Crosse, (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov)

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## Staff Acknowledgments

In addition to the contact named above, Kim Yamane, Assistant Director; Danielle Bernstein; Hernán Bozzolo; Britt Carlson; Sandra George; Cathleen Hamann; Erin Henderson; Mariel Lifshitz; Richard Lipinski; and Lisa Motley made key contributions to this statement.

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