



Report to the Ranking Member,  
Subcommittee on Primary Health and  
Aging, Committee on Health,  
Education, Labor, and Pensions,  
U.S. Senate

---

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 [crosse@m@gao.gov](mailto:crosse@m@gao.gov).

September 2013

## NEW TOBACCO PRODUCTS

### FDA Needs to Set Time Frames for Its Review Process

## 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.

---

# Contents

---

Letter		1
	Background	5
	CTP Finished Initial, but Not Final, Review Steps for Most Submissions, and Lacks Time Frames for its Review Process	14
	CTP Granted Most Meeting Requests, but the Time from Request to Date Held Varied Widely	29
	FDA Spent Less than Half of the \$1.1 Billion in User Fees Collected	33
	Conclusions	39
	Recommendations for Executive Action	39
	Agency Comments	40
Appendix I	Staffing Resources for Conducting Reviews of New Tobacco Product Submissions	42
Appendix II	Comments from the Department of Health and Human Services	45
Appendix III	GAO Contact and Staff Acknowledgments	51
Tables		
	Table 1: Description of FDA Center for Tobacco Product (CTP) Offices	6
	Table 2: Types of Submissions under the Substantial Equivalence (SE) Pathway	7
	Table 3: Tobacco Control Act Authorization of Tobacco User Fees, Fiscal Years 2009 through 2019	13
	Table 4: Meeting Requests Received by FDA Center for Tobacco Products (CTP) through January 7, 2013	30
	Table 5: Calendar Days from Date Meeting Request Received to Date Meeting Held, by Center for Tobacco Products (CTP) Office	32
	Table 6: Center for Tobacco Products (CTP) Planned and Actual Spending, Fiscal Years 2011 and 2012	36
	Table 7: Time Spent on Review of New Tobacco Product Submissions for the Center for Tobacco Products (CTP) Office of Science by Job Title	44

---

---

## Figures

Figure 1: Key Review Steps Performed by FDA’s Center for Tobacco Products (CTP) for Substantial Equivalence (SE) Submissions as of January 7, 2013	9
Figure 2: Number of Submissions Received by FDA for Each New Tobacco Product Pathway as of January 7, 2013	15
Figure 3: Provisional and Regular Substantial Equivalence (SE) Submissions Received by FDA as of January 7, 2013, by Fiscal Year Quarter	17
Figure 4: Finished Review Steps for Provisional and Regular Substantial Equivalence (SE) Submissions Received by FDA, as of January 7, 2013	20
Figure 5: Time Taken for Initial Review Steps for Provisional Substantial Equivalence (SE) Submissions	23
Figure 6: Time Taken for Initial Review Steps for Regular Substantial Equivalence (SE) Submissions	24
Figure 7: Meeting Requests Received by FDA Center for Tobacco Products (CTP) Offices, by Type of Entity	31
Figure 8: Total Tobacco User Fees Spent and Not Spent by FDA through Fiscal Year 2012	34
Figure 9: Center for Tobacco Products (CTP) Planned and Actual Spending, by Office, Fiscal Years 2011 and 2012	37
Figure 10: Center for Tobacco Products (CTP) Office of Science (OS) Staff Time Spent Conducting Reviews of New Tobacco Products	43

---

---

## Abbreviations

AI	Advice and information
CTP	Center for Tobacco Products
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
OCD	Office of the Center Director
OCE	Office of Compliance and Enforcement
OP	Office of Policy
OS	Office of Science
PMTA	Premarket tobacco product application
SE	Substantial equivalence

This is a work of the U.S. government and is not subject to copyright protection in the United States. The published product may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.



September 6, 2013

The Honorable Richard Burr  
Ranking Member  
Subcommittee on Primary Health and Aging  
Committee on Health, Education, Labor, and Pensions  
United States Senate

Dear Senator Burr:

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. The Centers for Disease Control and Prevention reports that smoking and exposure to secondhand smoke account for over 440,000 premature deaths per year. In June 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) granted the Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), authority to address the concern of tobacco use by young people and to regulate the manufacturing, marketing, and distribution of tobacco products using a public health standard.<sup>1</sup> Under this standard, FDA regulates tobacco products as appropriate for the protection of public health while taking into account the risks and benefits of tobacco products on the population as a whole, including users and nonusers. The Tobacco Control Act requires that manufacturers of tobacco products 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 using this public health standard in order to introduce new tobacco products into the

---

<sup>1</sup>Pub. L. No. 111-31, div. A, 123 Stat. 1776 (2009) (hereafter, "Tobacco Control Act"). 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 April 2011, FDA announced its plans to issue a proposed rule to regulate other tobacco products, such as e-cigarettes, that are not currently regulated, but as of July 2, 2013, the agency had not issued a proposed rule or specified which other products it planned to propose to regulate.

---

market after February 15, 2007.<sup>2</sup> The Tobacco Control 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>3</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>4</sup> The act also authorizes FDA to assess and collect user fees from each tobacco manufacturer and importer to be spent on only FDA's tobacco regulation activities.<sup>5</sup> All of CTP's activities are funded exclusively through tobacco user fees.

Tobacco manufacturers have raised concerns about CTP's progress in implementing the provisions of the Tobacco Control Act. You asked us to look at CTP's review of new tobacco product submissions, responses to meeting requests, and use of resources. This report examines (1) the status of CTP's reviews of new tobacco product submissions; (2) how CTP has responded to requests for meetings from manufacturers and other entities, and the length of time CTP has taken to hold the meetings; and (3) the extent to which FDA has spent its tobacco user fee funds. We also provide information on staffing resources for conducting reviews of new tobacco product submissions. (See app. I.)

To examine the status of CTP's review 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

---

<sup>2</sup>Tobacco Control Act, § 101(b), 123 Stat. at 1808 (codified at 21 U.S.C. § 387j(b)(1)).

<sup>3</sup>Tobacco Control Act, § 101(b), 123 Stat. at 1787 (codified at 21 U.S.C. § 387a(e)).

<sup>4</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.

<sup>5</sup>Tobacco Control Act, § 101(b), 123 Stat. at 1826 (codified at 21 U.S.C. § 387s). User fees are a fee assessed to users for goods or services provided by the federal government.

---

of the review process were completed for each submission, and key dates for each submission. We calculated the number of calendar days to complete key steps in the review process and the number of days a submission was pending in a particular step in the process. In addition, we reviewed relevant laws, regulations, and agency documents (such as guidance documents and draft standard operating procedures) and we viewed CTP webinars on new tobacco product submissions. We also 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>6</sup> Finally, we 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.

To examine on how CTP responded to requests for meetings and the length of time CTP has taken to hold the meetings, we reviewed and analyzed data from the four CTP offices that received meeting requests from manufacturers and other entities: OS, the Office of the Center Director (OCD), the Office of Compliance and Enforcement (OCE), and the Office of Policy (OP). For each of the four offices, we analyzed data provided by officials from the office on meeting requests received as of January 7, 2013, including the date requests were received and the date meetings were held. We analyzed the data from each of the four offices separately because the data maintained by each office varied. For example, OS officials only maintain data on the date the meeting request was received by FDA while OP officials maintain data on the date the meeting request was received by FDA and by OP. We analyzed the number of meeting requests granted, denied, transferred, withdrawn, and pending. We also analyzed the number of calendar days from the date the request was received by FDA or a specific CTP office, depending on

---

<sup>6</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).



---

available data, to the date the meeting was held.<sup>7</sup> Finally, we reviewed a relevant FDA guidance document, and interviewed officials from each of the four CTP offices to learn about the processes for scheduling and holding meetings.

To examine on 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 amounts spent by all seven CTP offices:<sup>8</sup> OS, OCD, OCE, OP, Office of Management, Office of Regulations, and Office of Health Communication and Education. We analyzed these data to determine how collection related to spending over time. Further, we reviewed FDA and CTP documents, such as FDA budget justification documents, CTP's spend plan (which is used by CTP to identify its plans for spending user fee funds on staffing, acquisitions, and operational needs), and CTP quarterly reports to Congress (which describe CTP's implementation of the Tobacco Control Act provisions).<sup>9</sup>

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 this performance audit from November 2012 to September 2013 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

---

<sup>7</sup>We did not analyze calendar days from the date a meeting request was received to the date a response was communicated because not all of the offices maintained data on the date a response to a meeting request was communicated with outside entities.

<sup>8</sup>For the purposes of this report, 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.

<sup>9</sup>We also reviewed CTP's data on the number of staff members employed in each CTP office at the beginning and end of each fiscal year, and we interviewed officials from OS about the responsibilities and activities of the staff in their office. OS officials provided self-reported data on how OS staff spend their time.

---

that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

---

## Background

FDA's authority to regulate tobacco products under a public health standard is unique among its regulatory responsibilities. CTP is the FDA center with primary responsibility for executing this regulatory responsibility, and its offices conduct work in several areas, including reviewing submissions for new tobacco products to determine if such products can be legally marketed in the United States, and responding to meeting requests from manufacturers and other entities. All of CTP's activities are funded through tobacco manufacturer user fees, as required by the Tobacco Control Act.<sup>10</sup>

---

## FDA Oversight of Tobacco Products

FDA—primarily through CTP—undertakes four broad categories of activities in carrying out its responsibilities and authorities under the Tobacco Control Act:<sup>11</sup> (1) reviewing submissions for marketing new tobacco products and setting scientific standards for tobacco products; (2) enforcing statutory and regulatory requirements prohibiting the sale, marketing, and distribution of certain tobacco products; (3) developing and issuing regulations and guidance, conducting compliance checks, and removing violative products from the market pursuant to the Tobacco Control Act; and (4) engaging in public education and outreach activities about the risks associated with tobacco product use, and promoting awareness of and compliance with the Tobacco Control Act. CTP is organized into seven offices. (See table 1.) Within CTP, OS is the office primarily responsible for conducting reviews of new tobacco product submissions; however, OS staff duties are not limited to reviewing new tobacco product submissions.

---

<sup>10</sup>Tobacco Control Act, § 101(b), 123 Stat. at 1826 (codified at 21 U.S.C. § 387s(c)(2)(B)(i)).

<sup>11</sup>CTP may work with other FDA offices such as the Office of Regulatory Affairs, which conducts inspections, and other HHS agencies such as the National Institutes of Health, which conducts research, to implement the Tobacco Control Act.

**Table 1: Description of FDA Center for Tobacco Product (CTP) Offices**

Office	Description
Office of the Center Director	<ul style="list-style-type: none"> <li>Provides scientific, policy, and managerial leadership and direction to the other six offices that constitute the center.</li> <li>Communicates agency initiatives and guidance to consumers and industry in support of public health.</li> </ul>
Office of Compliance and Enforcement	<ul style="list-style-type: none"> <li>Advises center officials on compliance and enforcement issues, policies, and procedures relating to regulated tobacco products and industry.</li> <li>Ensures that regulated tobacco products and the manufacturers, distributors, retailers and importers of those products are in compliance with the law.</li> </ul>
Office of Health Communication and Education	<ul style="list-style-type: none"> <li>Leads CTP's public education and communication activities.</li> </ul>
Office of Management	<ul style="list-style-type: none"> <li>Provides administrative services to support CTP's business operations in the following areas: financial management, information technology, human resources, acquisitions, management analysis, and logistics.</li> </ul>
Office of Policy	<ul style="list-style-type: none"> <li>Develops and analyzes policies to implement the Tobacco Control Act.</li> </ul>
Office of Regulations	<ul style="list-style-type: none"> <li>Leads and coordinates the development and issuance of regulatory and policy documents.</li> </ul>
Office of Science	<ul style="list-style-type: none"> <li>Develops and implements CTP's regulatory science framework and policies in tobacco regulatory development and tobacco product review.</li> <li>Implements a research agenda to meet regulatory science needs and to evaluate population and public health impact of tobacco products.</li> </ul>

Source: GAO summary of FDA information.

## New Tobacco Product Submissions and CTP's Review Process

Under the Tobacco Control Act, a manufacturer may make a submission to FDA for CTP's determination of whether the manufacturer may introduce a new tobacco product to the market in the United States. CTP reviews submissions made by manufacturers through one of three pathways:

- Substantial Equivalence (SE) pathway:** Manufacturers make a submission under the SE pathway if either (1) a new tobacco product has the same characteristics as a predicate tobacco product—that is, a product commercially marketed in the United States on February 15, 2007, or a product previously found by CTP to be substantially equivalent; or (2) the new tobacco product has different characteristics from a predicate tobacco product, but does not raise different questions of public health. There are two types of submissions made under the SE pathway—provisional and regular—that are defined by the date that the product came on the market and when the manufacturer made the submission. For provisional SE submissions, a manufacturer may market the new product that is the subject of the submission while CTP conducts its review of the submission, but for regular SE submissions, a manufacturer may not

market the new product until CTP completes its review and determines that the product meets the SE requirements. (See table 2.)

**Table 2: Types of Submissions under the Substantial Equivalence (SE) Pathway**

SE submission type	Statutory criteria for SE submission type	When manufacturer may legally market the new tobacco product in the United States
Provisional	<ul style="list-style-type: none"> <li>New tobacco product commercially marketed after February 15, 2007, but before March 22, 2011, and</li> <li>SE submission made to FDA by March 22, 2011.</li> </ul>	May be commercially marketed unless the FDA Center for Tobacco Products (CTP) issues an order that the new tobacco product is not substantially equivalent.
Regular	<ul style="list-style-type: none"> <li>Does not meet the statutory criteria for a provisional SE submission.</li> </ul>	Cannot be marketed until CTP issues an order that the new tobacco product is substantially equivalent.

Source: GAO summary of FDA information.

Note: A substantially equivalent tobacco product is one that CTP has found to either have 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.

- Exemption from SE pathway:** Manufacturers make a submission under the Exemption from SE pathway if (1) the new product is a minor modification (adding, deleting, or changing the quantity of an additive) of another tobacco product marketed by the same manufacturer; (2) an SE submission is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health; and (3) an Exemption from SE is otherwise appropriate.
- Premarket Tobacco Product Application (PMTA) pathway:** Manufacturers make a submission under the PMTA pathway if the new tobacco product does not meet the criteria of the SE or Exemption from SE pathways—that is, the new tobacco product is not substantially equivalent to a predicate product or is not a minor modification of an appropriate product for modification. The PMTA submission must include, among other things, full reports of investigations of health risks, and must meet the public health

---

standard described under the Tobacco Control Act (that is, would be appropriate for the protection of public health).<sup>12</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.<sup>13</sup>

CTP reviews of SE submissions—primarily conducted by OS—include three key steps:<sup>14</sup> (1) jurisdiction review to determine if the product is regulated by FDA, (2) completeness review to determine if the submission is missing information, and (3) scientific review to determine if the product is substantially equivalent or not (see fig.1).

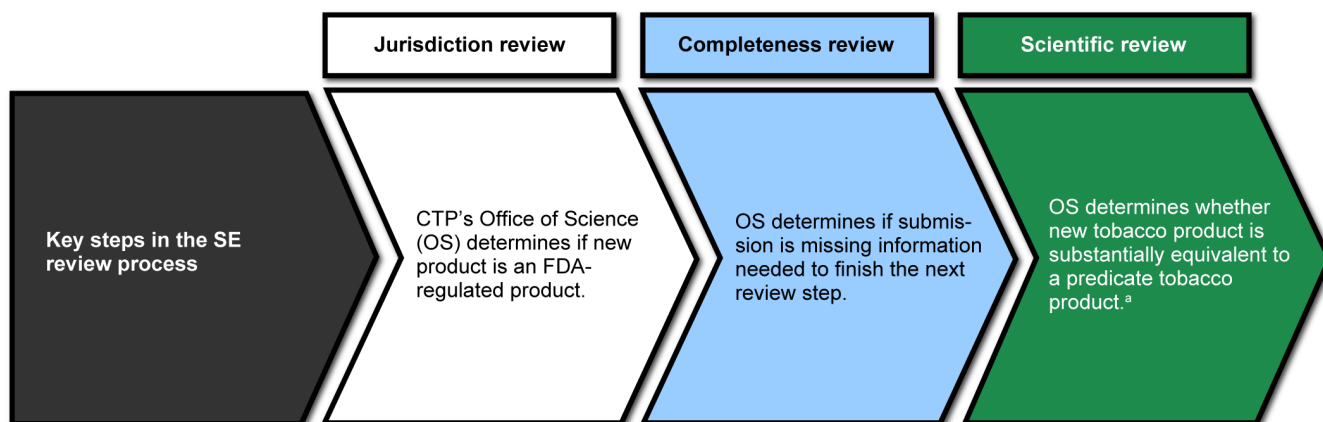
---

<sup>12</sup>Tobacco Control Act, § 101(b), 123 Stat. at 1807 (codified at 21 U.S.C. § 387j). To determine whether marketing of a new tobacco product would be appropriate for the protection of public health, CTP applies standards that take into account the risks and benefits to the population as a whole, including users and nonusers of tobacco products; increased or decreased likelihood that existing users of tobacco products will stop using such products; and increased or decreased likelihood that those who do not use tobacco products will start using such products.

<sup>13</sup>Tobacco Control Act, § 101(b), 123 Stat. at 1809 (codified at 21 U.S.C. § 387j(c)(1)).

<sup>14</sup>In addition to OS, CTP officials told us that OCE participates in the SE review process by confirming that the tobacco product to which the new tobacco product in the submission is being compared meets the statutory requirements for a predicate tobacco product. A predicate product is a tobacco product commercially marketed in the United States on February 15, 2007, or previously found by FDA to be substantially equivalent, in each case, provided the product has not been removed from the market at FDA's request or has not been determined by a judicial order to be misbranded or adulterated.

**Figure 1: Key Review Steps Performed by FDA’s Center for Tobacco Products (CTP) for Substantial Equivalence (SE) Submissions as of January 7, 2013**



Source: GAO summary of FDA information.

Note: The steps in this figure represent key steps in CTP’s review process for SE submissions. There are other steps in the review process that are not represented in this figure.

<sup>a</sup>A substantially equivalent tobacco product is one that CTP has found to either have 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.

The jurisdiction and completeness review steps are facilitated by OS’s project managers. During jurisdiction review, project managers use a checklist to determine whether the new tobacco product is an FDA-regulated tobacco product (that is, whether it is a cigarette, cigarette tobacco, roll-your-own tobacco, or smokeless tobacco).<sup>15</sup> During completeness review, project managers use another checklist to determine whether the submission is missing information that OS will need for scientific review, such as the product’s full brand name and a rationale for why a comparison between the new and the predicate tobacco products’ characteristics should find that the new product is substantially equivalent. When project managers determine that additional information is needed to make SE determinations, OS issues administrative advice and information (AI) letters to manufacturers. Initially, CTP officials said they had given manufacturers 60 days to

<sup>15</sup>According to CTP officials, project managers determine whether the product (including any component, part, or accessory of the product) is made or derived from tobacco; whether it is a drug or medical device; and whether it meets established definitions for any type of FDA-regulated tobacco product.

---

respond to administrative AI letters, but in April 2012, CTP began giving manufacturers 30 days to respond to an administrative AI letter.

After OS finishes these initial two steps in the SE review process, the next step is a scientific review, which involves an assessment of the product by scientists in different disciplines (such as chemistry and toxicology).<sup>16</sup> These scientists work to determine whether the product is substantially equivalent to a product already on the market—that is, has the same characteristics as a predicate tobacco product, or has different characteristics but does not raise different questions of public health. During scientific review, OS may issue scientific AI letters to request additional information that the scientists determine is needed to make a final determination (such as clarification of ingredients and additional testing results). In these letters, CTP officials told us that OS requests that manufacturers respond within 60 days. If OS determines that the SE criteria have been met, then CTP will issue an SE order, and the product may continue being marketed by the manufacturer (if it was a provisional SE submission) or may be legally introduced into the U.S. market (if it was a regular SE submission). If neither of these criteria is met, then CTP will issue an order that the product is not substantially equivalent and the manufacturer must remove the product from the market (if it was a provisional SE submission) or cannot introduce the product into the market under the SE pathway (if it was a regular SE submission).

---

<sup>16</sup>According to CTP officials, in late 2012, CTP began issuing notices to each manufacturer about the manufacturer's submission after finishing completeness review and before beginning scientific review. According to CTP officials, the notice informs the manufacturer that its submission will be undergoing scientific review and that the manufacturer has 45 days to make any amendments to the submission. In addition, in late 2012, CTP began segmenting the review process into three phases. The first phase includes FDA's receipt of a submission, jurisdiction review, and completeness review. The second phase includes the notice sent to manufacturers 45 days prior to beginning scientific review and OCE's review to determine whether the tobacco product to which the new tobacco product in the submission is being compared meets the statutory requirements for a predicate tobacco product. The third phase includes scientific review. In this phase, CTP may issue a preliminary finding letter if the manufacturer has not provided the information needed to make a final decision. CTP issued its first preliminary finding letter in April 2013. The preliminary finding letter provides the manufacturer with 30 days to provide the missing information, and OS then makes a decision on whether the product is substantially equivalent or not substantially equivalent. In this report, we present information about jurisdiction and completeness review steps (which are in the first phase) and scientific review (which is in the third phase).

---

According to CTP officials, reviews of Exemption from SE and PMTA submissions also include jurisdiction, completeness, and scientific review steps. However, the specific activities within each review step for those pathways may differ from the specific activities involved in review steps for SE submissions.

---

### Requests for Meetings with CTP Offices

The Tobacco Control Act does not require CTP to conduct meetings with outside entities, but CTP officials reported that they are valuable because they increase knowledge of tobacco regulation among public health groups, promote compliance among manufacturers, and clarify information needed for new tobacco product submissions. However, each CTP office follows different processes for receiving and processing meeting requests. In the event that an outside entity—for instance, a manufacturer or a public health advocacy organization—wants to meet with CTP officials, it can request a meeting in various ways. For example, manufacturers can submit written requests to the Director of OS by mail, courier, or electronically to FDA’s document center. Manufacturers have requested meetings with OS to discuss their new tobacco product submissions, as well as study protocols and other scientific issues. Manufacturers, tobacco trade associations, and other entities have also proposed meetings with OS, OCD, OCE, and OP to educate CTP on tobacco industry operations (for example, current practices in tobacco product manufacturing), and to discuss industry’s views on FDA’s approaches to tobacco regulation (for example, industry feedback on published guidance documents). State, local, and tribal governments, as well as academic and scientific organizations, have requested meetings in order to coordinate public health efforts or share relevant knowledge. CTP officials told us that CTP follows FDA’s practice not to grant meetings for which the topic of discussion is in draft guidance. Additionally, according to officials, one office within CTP may transfer a meeting request to another office within CTP in order to provide the most knowledgeable and appropriate agency officials at the meeting. However, a request may not result in a scheduled meeting.



---

## Tobacco User Fees

The Tobacco Control Act requires FDA to assess user fees on manufacturers of FDA-regulated tobacco products based on their market share and specifies that the tobacco user fees can only be applied toward FDA activities that relate to the regulation of tobacco products.<sup>17</sup> FDA bills and collects tobacco user fees from manufacturers on a quarterly basis and fees are generally collected the quarter after they are billed. For example, fees billed in the fourth quarter of fiscal year 2011 were collected in the first quarter of fiscal year 2012. 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).<sup>18</sup> (See table 3.)

---

<sup>17</sup>Tobacco Control Act, § 101(b), 123 Stat. at 1826-28 (codified at 21 U.S.C. § 387s(b)-(c)). In addition to manufacturers, the Tobacco Control Act authorizes FDA to assess user fees on tobacco product importers. FDA currently relies on the U.S. Department of Agriculture to determine the manufacturer's market share for assessing the user fees. However, in May 2013, FDA issued a proposed rule that would require manufacturers and importers to submit information needed to calculate the amount of user fees assessed under the Tobacco Control Act. 78 Fed. Reg. 32,581 (May 31, 2013).

<sup>18</sup>Fees are collected and available for obligation only to the extent and in the amount provided in advance in appropriations acts, with the exception of user fees assessed for fiscal year 2009, which were appropriated by the Tobacco Control Act. For each of fiscal years 2009 through 2013, Congress appropriated the total amounts of tobacco user fees authorized to be assessed and collected under the Tobacco Control Act to FDA. The fiscal year 2013 appropriation amount of \$505 million, however, was subject to a five percent reduction, as a result of the sequestration order issued by the President on March 1, 2013. Therefore, the maximum amount of fiscal year 2013 tobacco user fee collections available to FDA for obligation was reduced by approximately \$25 million, to \$480 million. In general, actual collections may be less than the amounts authorized and, therefore, the amounts credited to the agency's account may be less than the authorized amount.

**Table 3: Tobacco Control Act Authorization of Tobacco User Fees, Fiscal Years 2009 through 2019**

Dollars in millions

Fiscal year	User fee amount
2009	85 <sup>a</sup>
2010	235
2011	450
2012	477
2013	505
2014	534
2015	566
2016	599
2017	635
2018	672
2019 and each subsequent year	712

Source: GAO analysis of the Tobacco Control Act.

Note: The amounts shown are the total user fee amounts authorized to be collected by FDA for its regulation of tobacco products. Fees are collected and available for obligation only to the extent and in the amount provided in advance in appropriations acts, with the exception of user fees assessed for fiscal year 2009, which were appropriated by the Tobacco Control Act. Tobacco Control Act, § 101(b), 123 Stat. at 1826-28 (codified at 21 U.S.C. § 387s(b)-(c)).

<sup>a</sup>Because the Tobacco Control Act was enacted during fiscal year 2009, the \$85 million authorization for fiscal year 2009 was reduced by a pro-rata amount.

All of CTP's activities, other FDA activities related to tobacco regulation (such as the tobacco-related work of FDA's Office of Regulatory Affairs and FDA Headquarters and Office of the Commissioner), and other activities such as rent are funded only through tobacco user fees.<sup>19</sup>

According to CTP officials, 426 full-time equivalent staff in FDA were supported by the tobacco user fees in fiscal year 2012, 346 (81 percent) of which were in CTP.

<sup>19</sup>Tobacco user fees are assessed differently than FDA user fees for medical devices and human drugs. FDA assesses both application and annual fees against medical device and human drug manufacturers for certain types of applications, including premarket review, and products. Such user fees, which are standard and do not vary based on market share, pay for a portion of FDA activities related to oversight of medical devices and drugs. In contrast, tobacco manufacturers do not pay user fees with their submissions for new tobacco products; instead, they pay a quarterly fee based on their market share of FDA-regulated tobacco products. FDA relies exclusively on tobacco user fee funds to support its activities related to tobacco oversight.

---

**CTP Finished Initial, but Not Final, Review Steps for Most Submissions, and Lacks Time Frames for its Review Process**

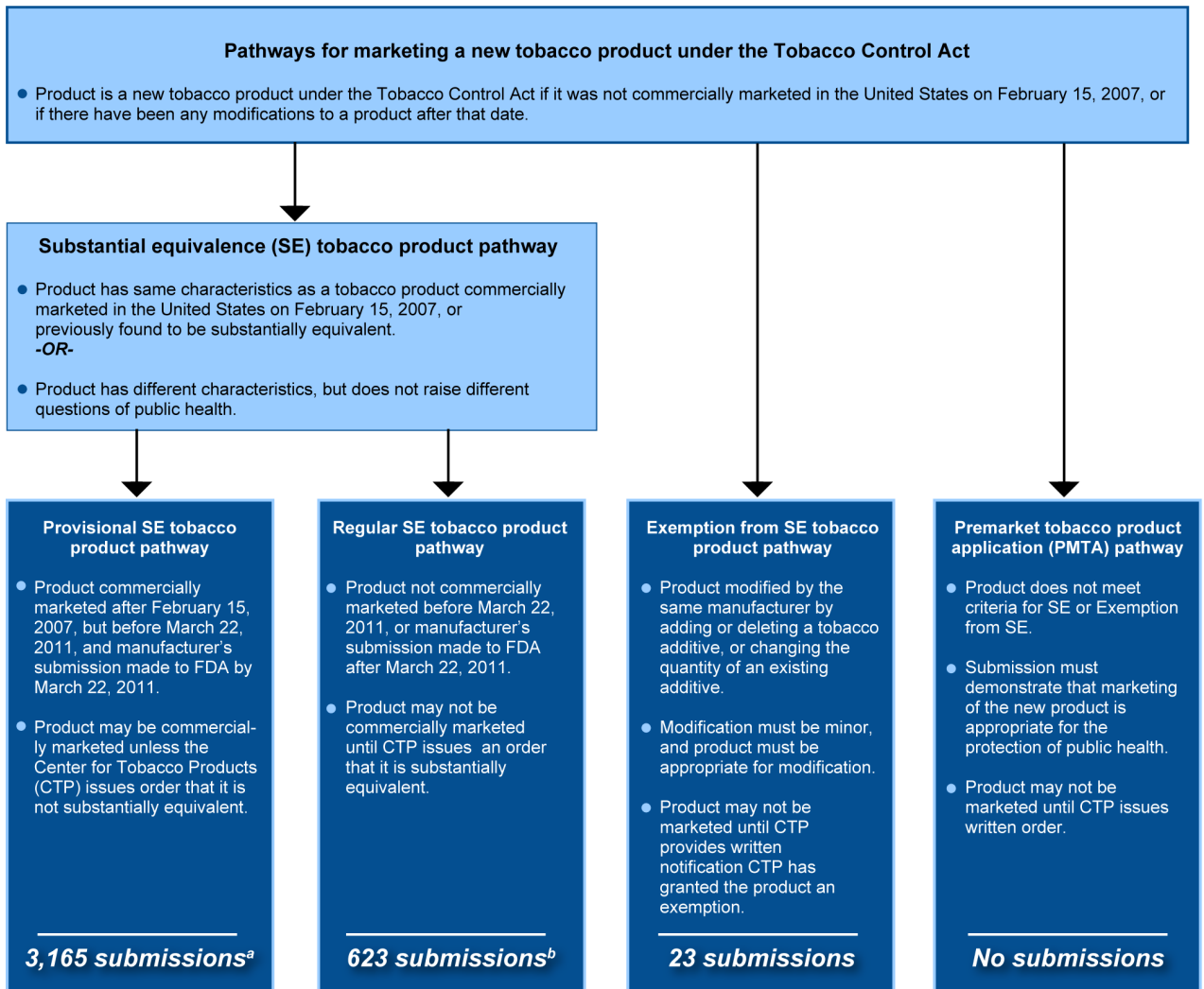
As of January 7, 2013, the vast majority of new tobacco product submissions FDA received from manufacturers were made under the SE pathway. CTP has finished initial review steps (jurisdiction and completeness reviews) for most SE submissions, but CTP has not made final decisions for most submissions. For the majority of provisional SE submissions, CTP took over a year and a half to complete these initial review steps. 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. Several factors contributed to the significant amount of time it took for review of new tobacco product submissions, according to officials from CTP and tobacco manufacturers. CTP officials reported taking steps to address factors that contributed to the length of time the center has taken to review submissions, but the center has not established review time frames by which to assess progress.

---

**Almost All New Tobacco Product Submissions Have Been under the SE Pathway**

As of January 7, 2013, nearly all new tobacco product submissions FDA received from manufacturers (99 percent) were SE submissions, most of which were provisional SE submissions. FDA received a total of 3,788 SE submissions and 23 Exemption from SE submissions from manufacturers. FDA did not receive any PMTA submissions. (See fig. 2.)

**Figure 2: Number of Submissions Received by FDA for Each New Tobacco Product Pathway as of January 7, 2013**



Source: GAO summary of FDA information.

Note: This figure represents new tobacco product submissions received by FDA as of January 7, 2013.

<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.

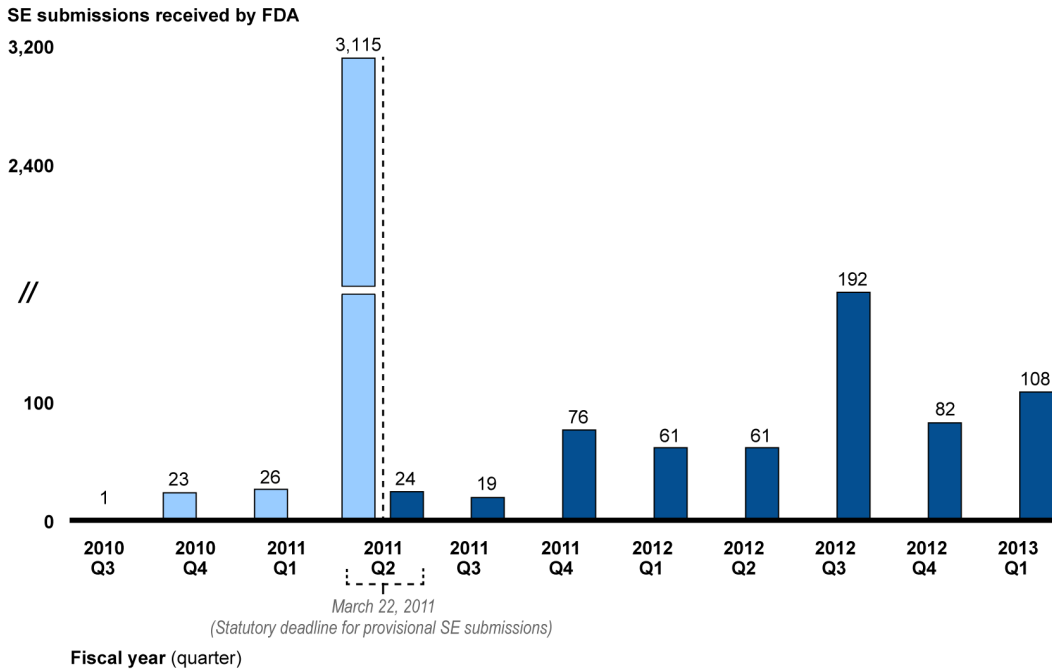
---

As shown in figure 2, of the 3,788 SE submissions received by FDA as of January 7, 2013, 3,165 (84 percent) were provisional SE submissions and 623 (16 percent) were regular SE submissions.<sup>20</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. The number of regular SE submissions received in a quarter ranged from 19 (in the third quarter of fiscal year 2011) to 192 (in the third quarter of fiscal year 2012). (See fig. 3.)

---

<sup>20</sup>Of the 3,788 SE submissions, 64 (44 provisional and 20 regular) were withdrawn by the manufacturer as of January 7, 2013. According to FDA officials, manufacturers are not required to provide reasons for withdrawing submissions, and FDA does not track such information.

**Figure 3: Provisional and Regular Substantial Equivalence (SE) Submissions Received by FDA as of January 7, 2013, by Fiscal Year Quarter**



Provisional SE submissions<sup>a</sup>  
 Regular SE submissions<sup>b</sup>

Source: GAO analysis of FDA data.

Note: This figure represents 3,788 SE submissions (3,165 provisional and 623 regular) received by FDA as of January 7, 2013. FDA did not receive any SE submission from January 1, 2013, through January 7, 2013.

<sup>a</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>b</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.

---

In addition to the 3,788 SE submissions, FDA received 23 Exemption from SE submissions from manufacturers as of January 7, 2013.<sup>21</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. According to CTP officials, a key factor contributing to the relatively small number of submissions is that it is not common for a manufacturer to change only additives when making a change to an existing tobacco product. According to industry representatives, a key reason for the relatively small number of submissions under this pathway is insufficient guidance from CTP about what exactly constitutes a minor modification of another commercially marketed tobacco product. FDA did not include a definition of the term “minor modification” in its final rule to establish procedures for the Exemption from SE pathway because the agency did not have the experience needed to provide a useful definition.<sup>22</sup> In the rule, FDA stated that as it gains experience in evaluating Exemption from SE submissions, it will consider establishing a definition for minor modifications.

CTP had not received any PMTA submissions as of January 7, 2013.<sup>23</sup> CTP’s guidance document for the PMTA pathway states that PMTA submissions should include data from well-controlled studies demonstrating that the tobacco product is appropriate for the protection of the public health. According to CTP officials and industry representatives, one reason for the lack of submissions under this 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. Data from such studies must address, for example, the health risks associated with the product in comparison to the health risks of other products on the market and the product’s effect on the likelihood

---

<sup>21</sup>On June 25, 2013, CTP determined that the new tobacco products in 20 of these submissions—which were received by FDA in late September 2011 through late December 2012—did not meet the requirements for the Exemption from SE pathway. CTP officials reported that they anticipate receiving new SE submissions or PMTA submissions for the products identified in these 20 submissions. In addition, from January 8, 2013, through June 25, 2013, FDA received an additional seven Exemption from SE submissions.

<sup>22</sup>76 Fed. Reg. 38,961 (July 5, 2011) (codified at 21 C.F.R. §1107.1).

<sup>23</sup>CTP officials also reported that no submissions were received by FDA from January 8, 2013, through June 25, 2013.

---

that current tobacco users will stop using tobacco products. According to industry representatives, meeting the standards under the PMTA pathway may not be feasible for some manufacturers—in particular, for small manufacturers (which are manufacturers that have fewer than 350 employees). Industry representatives reported that small manufacturers do not have the research and development resources to design or initiate clinical trials that would be needed to support a PMTA submission.

---

### CTP Finished Initial Review Steps for Most SE Submissions

As of January 7, 2013, CTP finished jurisdiction and completeness reviews for over two thirds of the provisional and regular SE submissions received since June 2010, but had not made a final decision on any of the 3,788 SE submissions.<sup>24</sup> CTP finished both jurisdiction and completeness reviews for about 69 percent of provisional SE submissions (2,191 out of 3,165), and about 67 percent of regular SE submissions (415 out of 623). Almost all of the remaining 974 provisional SE submissions and about half of the remaining 208 regular SE submissions were through jurisdiction review but not completeness review. (See fig. 4.) Provisional SE submissions and regular SE submissions were pending in completeness review for as long about 1.5 years and 1 year, respectively.<sup>25</sup> As of January 7, 2013, CTP had not finished scientific review for any of the SE submissions.

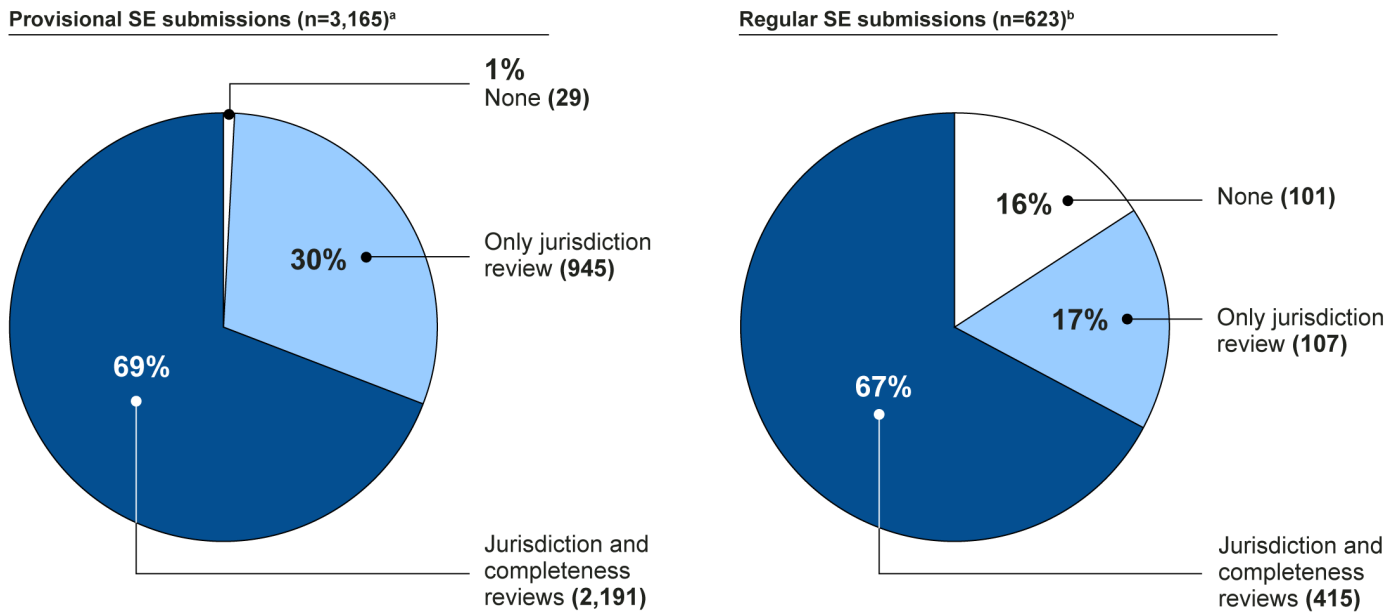
---

<sup>24</sup>FDA received the first SE submission on June 11, 2010.

<sup>25</sup>As of January 7, 2013, provisional SE submissions not yet through jurisdiction review were pending in that step for as long as about 2 years, and regular SE submissions not yet through jurisdiction review were pending in that step for about 1 year.



**Figure 4: Finished Review Steps for Provisional and Regular Substantial Equivalence (SE) Submissions Received by FDA, as of January 7, 2013**



Source: GAO analysis of FDA data.

Note: This figure represents 3,788 SE submissions (3,165 provisional and 623 regular) received by FDA as of January 7, 2013, including 64 submissions withdrawn by manufacturers as of that date. Submissions withdrawn in jurisdiction review are represented in the category labeled none, and submissions withdrawn in completeness review are represented in the category labeled only jurisdiction review. Submissions withdrawn in scientific review are represented in the category labeled jurisdiction and completeness reviews.

<sup>a</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>b</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.

CTP officials reported that as of late June 2013, CTP had started scientific reviews for all of the 415 regular SE submissions and 42 of the 2,191 provisional SE submissions that had finished the completeness

---

review step as of January 7, 2013.<sup>26</sup> CTP officials reported that CTP began scientific reviews for provisional SE submissions in May 2013, more than a year after they began scientific reviews for regular SE submissions in March 2012 because they prioritized completeness reviews for regular SE submissions over completeness reviews for provisional SE submissions. CTP officials reported that regular SE submissions went into scientific review based on the order that FDA received submissions (which generally aligned with the order that CTP finished each submission's completeness review). CTP officials also reported that CTP prioritized scientific reviews for provisional SE submissions based on the public health impact of the new tobacco product.<sup>27</sup> According to CTP officials, prioritization of provisional SE submissions based on public health impact was necessary because new tobacco products in provisional SE submissions may remain on the market unless CTP finds that the product is not substantially equivalent to a predicate tobacco product.

On June 25, 2013—about 3 years after FDA's receipt of the first SE submission—CTP made a final decision on 6 of the 3,788 SE submissions. CTP concluded that the new tobacco products in two of the submissions were substantially equivalent and that the products in the four other submissions were not. These six submissions were regular SE submissions received by FDA in fall 2011 (about 1 year and 8 months prior to CTP's final decisions). For each of the two substantially

---

<sup>26</sup>From January 2013 through late June 2013, FDA received an additional 165 regular SE submissions. In addition, as CTP was conducting completeness reviews of provisional SE submissions during the time period, it determined that in some cases the provisional SE submission incorrectly identified multiple new tobacco products (instead of a single tobacco product). CTP separated such submissions and, as a result, identified an additional 382 provisional SE submissions.

<sup>27</sup>In June 2012, CTP established four Public Health Impact Tiers for provisional SE submissions, and in August 2012, CTP—specifically, chemists in OS—began assigning provisional SE submissions to these tiers in order to prioritize scientific reviews for products with the greatest potential to raise different questions of public health. Tier 1 includes submissions with products that have high potential for raising different questions of public health, Tier 2 is for products with moderate potential, Tier 3 is for products with low potential, and Tier 4 is for products with the lowest potential. According to CTP officials, in assigning submissions to a tier, OS chemists apply a variety of criteria, such as whether the new tobacco products that are the subject of, and the predicate tobacco products referenced in, the submissions are different product types (which would result in a Tier 1 assignment) or differ only in the way in which they are labeled (which would result in a Tier 4 assignment). CTP randomizes submissions within each tier to determine the order for beginning scientific review for submissions in the same tier.

---

equivalent products, CTP found that the new product had different characteristics than the predicate tobacco product but did not raise different questions of public health. CTP found that four new tobacco products were not substantially equivalent to predicate tobacco products due to factors such as inadequate evidence that the products to which the new products were being compared were valid predicate products and lack of complete information on tobacco product characteristics.<sup>28</sup>

---

### CTP Took Over a Year and Half for Initial Review Steps for the Majority of Provisional SE Submissions

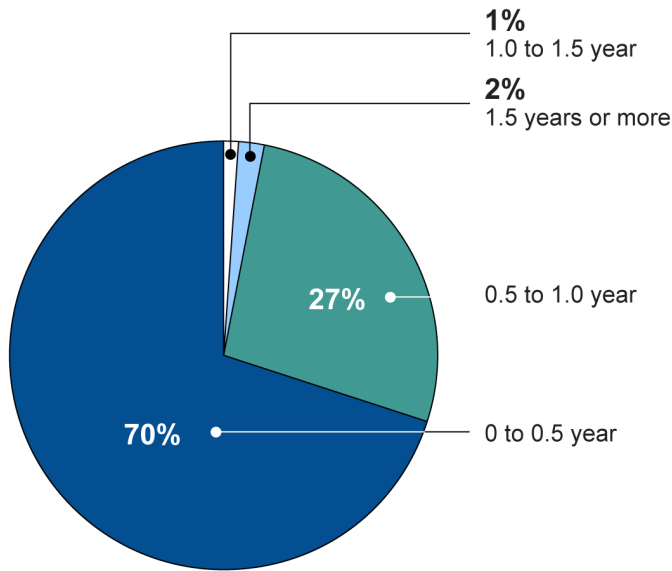
CTP took over a year and a half from FDA's receipt of a submission through the end of initial review steps for more than half of provisional SE submissions, and 6 months for more than half of the regular SE submissions. As of January 7, 2013, the median length of time to finish initial review steps—from FDA's receipt of a submission through the end of completeness review—for provisional SE submissions was about 1 year and 9 months, and the length of time ranged from about 9 months to about 2.5 years (see fig.5). The median length of time to finish initial review steps for regular SE submissions was about 6 months, ranging from about 1 month to about 2 years (see fig. 6).

---

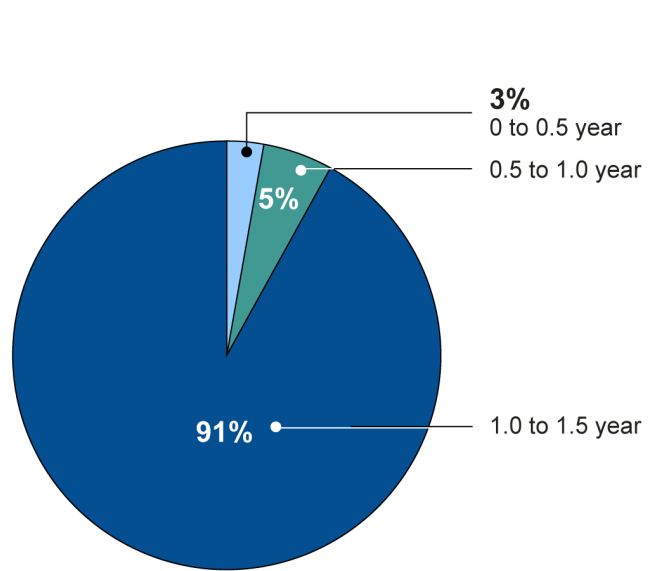
<sup>28</sup>Information about these final decisions, including SE orders issued by CTP and a summary of not substantially equivalent decisions, is available at <http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm339928.htm> (accessed July 3, 2013).

**Figure 5: Time Taken for Initial Review Steps for Provisional Substantial Equivalence (SE) Submissions**

**Jurisdiction review for provisional SE submissions<sup>a</sup>**  
(median = 0.5 year)



**Completeness review for provisional SE submissions<sup>b</sup>**  
(median = 1.3 years)



Source: GAO analysis of FDA data.

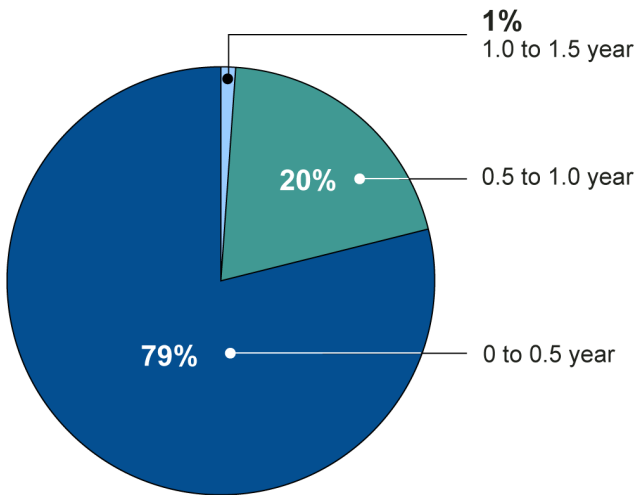
Note: Manufacturers use the SE pathway if a new tobacco product has the same characteristics as a predicate tobacco product (a product commercially marketed in the United States on February 15, 2007, or previously found by FDA to be substantially equivalent); or has different characteristics, but does not raise different questions of public health. 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 FDA's Center for Tobacco Products (CTP) issues an order that they are not substantially equivalent. Percentages for completeness review do not add up to 100 percent due to rounding.

<sup>a</sup>Jurisdiction review involves the CTP Office of Science's (OS) determination of whether the submitted product is an FDA-regulated tobacco product. This pie chart represents the length of time from FDA's receipt of a provisional SE submission to the end of jurisdiction review for 3,136 (out of 3,165) provisional SE submissions. As of January 7, 2013, CTP had not finished jurisdiction review for 29 provisional SE submissions.

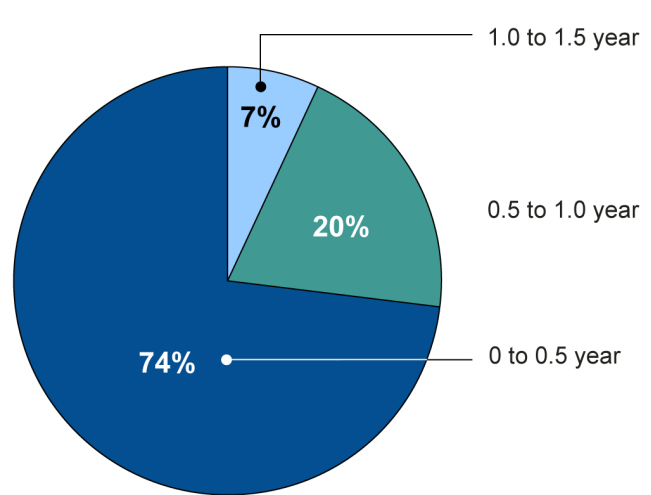
<sup>b</sup>Completeness review involves OS's determination of whether the center requires additional information to finish the review process. Completeness review does not begin until jurisdiction review is finished. This pie chart represents the length of time from the end of jurisdiction review to the end of completeness review for 2,191 of the 3,136 provisional SE submissions through jurisdiction review. As of January 7, 2013, CTP had started but not finished completeness review for 945 provisional SE submissions.

**Figure 6: Time Taken for Initial Review Steps for Regular Substantial Equivalence (SE) Submissions**

**Jurisdiction review for regular SE submissions<sup>a</sup>**  
(median = 0.2 years)



**Completeness review for regular SE submissions<sup>b</sup>**  
(median = 0.3 years)



Source: GAO analysis of FDA data.

Note: 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. 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 FDA's Center for Tobacco Products (CTP) issues an order that they are substantially equivalent. Percentages for completeness review do not add up to 100 percent due to rounding.

<sup>a</sup>Jurisdiction review involves CTP Office of Science's (OS) determination of whether the submitted product is an FDA-regulated tobacco product. This pie chart represents the length of time from FDA's receipt of a regular SE submission to the end of jurisdiction review for 522 (out of 623) regular SE submissions. As of January 7, 2013, CTP had not finished jurisdiction review for 101 regular SE submissions.

<sup>b</sup>Completeness review involves OS's determination of whether the center requires additional information to finish the review process. Completeness review does not begin until jurisdiction review is finished. This pie chart represents the length of time from the end of jurisdiction review to the end of completeness review for 415 of the 522 regular SE submissions through jurisdiction review. As of January 7, 2013, CTP had started but not finished completeness review for 107 regular SE submissions.

---

## CTP Officials and Manufacturers Identified Several Factors That Contributed to Review Times for New Tobacco Product Submissions

Several factors have contributed to the significant amount of time it took for review of SE submissions, according to CTP officials and industry representatives. These officials identified factors such as insufficient information provided by manufacturers in submissions; the prioritization of regular SE submission reviews over provisional SE submissions; and other factors.

CTP officials told us that insufficient information from manufacturers in SE submissions has had the most significant impact on review times for those submissions. According to CTP officials, the majority of SE submissions were incomplete and required follow-up with manufacturers to obtain additional information, such as a full description of both the new tobacco product and the predicate tobacco product. CTP officials reported that they spent significant time sending out AI letters requesting missing information from manufacturers and awaiting the manufacturers' responses. Our analysis found that administrative AI letters were associated with 2,559 SE submissions, and CTP officials told us that some submissions had more than one administrative AI letter. In these letters, CTP officials requested that manufacturers respond to requests within 60 days or 30 days. In addition, our analysis found that scientific AI letters were associated with 81 SE submissions. In these letters, CTP requested that manufacturers respond to requests within 60 days, but CTP officials reported that it had granted extensions of up to 4 months.

Industry representatives agreed that the lack of completeness of submissions had an impact on reviews, but they told us that guidance provided by CTP was neither timely nor adequate for manufacturers to provide what CTP would consider SE submissions with sufficient information. Manufacturers we interviewed said they were not able to include all information indicated in CTP guidance that was issued on January 5, 2011, for provisional SE submissions, which needed to be submitted by March 22, 2011, in order for those products to remain on the market provisionally.<sup>29</sup> Some industry representatives indicated that the time it took to prepare a submission was more than CTP estimated, and that the deadline for provisional SE submissions was not enough time to

---

<sup>29</sup>U.S. Department of Health and Human Services, Food and Drug Administration, *Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products* (Rockville, Md.: Jan. 5, 2011).

---

incorporate all of the requirements in the guidance in their submissions.<sup>30</sup> Additionally, industry representatives we interviewed reported that the January 2011 guidance did not direct manufacturers to include some information by the March 22, 2011, submission deadline that CTP later requested in its September 2011 draft guidance or AI letters, such as an environmental assessment.<sup>31</sup>

CTP placed 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 completeness reviews for regular SE submissions over provisional SE submissions, so resources were shifted away from provisional SE submissions. As a result of this decision—coupled with the fact that provisional SE submissions were received earlier than regular SE submissions—completeness review times for provisional SE submissions were longer than for regular 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

---

<sup>30</sup>CTP estimated the average time taken to provide required information for SE submissions at 360 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. See U.S. Department of Health and Human Services, Food and Drug Administration, *Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products*, (Rockville, Md.: Jan. 5, 2011).

<sup>31</sup>In September 2011, CTP issued a frequently asked questions document stating that manufacturers should include an environmental assessment in their submissions. According to CTP, an environmental assessment is information provided to CTP so it can determine the environmental impact of granting an SE submission. See U.S. Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, *Draft Guidance for Industry and FDA Staff Demonstrating The Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions* (Rockville, Md: Sept. 5, 2011).

---

would be the most effective at addressing the public health burden of tobacco use.<sup>32</sup>

Two more factors that had a significant impact on review times were a shortage of experienced tobacco product review staff and slow IT systems, according to CTP officials. These officials reported that when they started reviews of SE submissions the center had a shortage of experienced staff and that finding qualified staff was challenging. Additionally, CTP officials said that initial training of review staff contributed to review times as new staff were unable to review submissions until receiving the necessary training. CTP officials also told us that a slow IT system impacted the rate at which project managers could enter data during jurisdiction and completeness reviews of SE submissions, which slowed down those review times.

---

**CTP Has Worked to Address Factors That Contributed to Review Times, but Has Not Established Time Frames by Which to Assess Progress**

CTP has taken action to address the factors CTP officials identified as contributing to the significant amount of time the center has taken to review submissions. CTP has provided additional direction to manufacturers in an attempt to decrease delays due to agency requests for more information through AI letters. Specifically, it has held webinars and published frequently asked questions to provide more guidance to manufacturers that prepare submissions. Additionally, CTP officials told us that in November 2012 CTP began alerting manufacturers of upcoming scientific review of their submissions by issuing a notification to manufacturers 45 days prior to starting scientific review. According to CTP officials, this notification reminds manufacturers of the option to amend their submissions as needed prior to the start of scientific review, to facilitate higher quality submissions, and potentially avoid delays in scientific review due to the issuance of scientific AI letters. CTP also noted that it is working on a standardized form for manufacturers to use when submitting new tobacco product information for review.<sup>33</sup> According

---

<sup>32</sup>CTP officials told us that while provisional SE products could remain on the market prior to CTP issuing an order, CTP would have other authorities under which it could address any immediate concerns about the adverse health impact of a specific product.

<sup>33</sup>In June 2013, FDA opened a docket for public comment on electronic submissions of tobacco products. Docket No. FDA-2013-N-0602-0001. Electronic Submission of Tobacco Product Applications and Other Information; Public Workshop; Request for Comments. As a result of this request for public comment and a public workshop held by CTP, CTP intends to develop a standardized form for tobacco manufacturers to make new tobacco product submissions.



---

to CTP officials, this form may take time to develop as it will require FDA to issue regulations, but CTP officials anticipate that, when implemented, a standardized form should improve review times. To address the shortage of staff available for reviews, CTP officials told us they have increased OS staff from 12 staff in June 2010 to more than 100 staff in January 2013, including scientists and project managers involved in submission reviews. Also in 2012, CTP drafted a reviewers' guide to help train staff on aspects of the SE review process. According to CTP officials, the center plans to continue to revise its draft reviewer's guide as it further refines its new tobacco product review process. CTP officials also reported that CTP had upgraded its IT system as of early 2013, which has improved the time taken for data entry on SE submissions. They also reported that CTP plans to transition to a new IT system in late 2013.

Our analysis of data provided by CTP found that for regular SE submissions the length of time from the end of jurisdiction review through the end of completeness review improved over time. Among regular SE submissions received by FDA in fiscal year 2011 and for which CTP had finished completeness review as of January 7, 2013, the length of time from the end of jurisdiction review to the end of completeness review ranged from about 3 months to 1.5 years, with a median length of time of about 8 months. In contrast, the length of time for these steps for regular SE submissions received in fiscal year 2012 ranged from less than 1 day to 11 months, with a median of about 2 months. CTP officials reported that actions such as hiring review staff and providing training for review staff have resulted in improved review times.

While CTP is moving forward with its reviews of SE submissions and efforts to improve review times, CTP does not have time frames for reaching a final decision on submissions. 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 monitoring of actual performance against measures are an integral part of operating efficiently, achieving effective results, and planning appropriately.<sup>34</sup> There are no time frames set by statute for the SE

---

<sup>34</sup>While we focused on the timeliness of the reviews in this report, 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.

---

pathway, and CTP has not established performance measures that include time frames for making final decisions on the review of SE submissions. Although CTP officials agreed that establishing time frames would be useful for performance evaluation, CTP has not identified specific plans to establish such time frames. According to CTP officials, they have not yet established time frames because they first need to collect and analyze information about how long each review step should take. Yet without time frames, CTP is limited in its ability to evaluate policies, procedures, and staffing resources in relation to its review process and this, in turn, limits CTP's ability to reasonably assure efficiency and effectiveness. As a result, CTP is limited in its ability to determine the adjustments needed to make improvements. For example, CTP is limited in its ability to evaluate whether OS staff are performing efficiently and effectively in relation to specific review steps, and as a result, CTP may not appropriately make adjustments such as changing an individual staff member's responsibilities or increasing the number of available staff.

---

### CTP Granted Most Meeting Requests, but the Time from Request to Date Held Varied Widely

As of January 7, 2013, CTP granted more meetings than it denied. The number of calendar days from the date a meeting request was received to the date a meeting was held varied widely, and CTP officials reported that logistics and subject matter contributed to these variations.

---

### CTP Granted More Meetings Than It Denied

As of January 7, 2013, CTP's offices had responded—granted, denied, or transferred—to over 93 percent of the meeting requests they received through January 7, 2013.<sup>35</sup> Based on the data provided by CTP officials from the four offices that received meeting requests from outside entities, CTP's offices responded to 108 of the 116 meeting requests received as of January 7, 2013 (see table 4). Of these 108 responses, 72 of the meeting requests were granted, 22 were denied, and 14 were transferred to another office within CTP.<sup>36</sup> According to CTP officials, in some cases,

---

<sup>35</sup>The first meeting request was received by OCD on December 16, 2009.

<sup>36</sup>The data compiled by the CTP offices did not include data on whether the transferred meeting requests were either granted or denied by the office receiving the transferred request. As a result, a transferred meeting request may also be counted as granted or denied in the office that received the transferred request.

the CTP office denied a meeting request because the office was able to address the entity's questions by telephone and a formal meeting was no longer necessary. The remaining eight meeting requests were pending or withdrawn as of January 7, 2013. CTP officials told us that since January 7, 2013, they responded to three of the five pending meetings by granting two meetings and denying one. According to CTP officials, as of July 2013, the other two meetings were still pending because the meeting requester had not responded to CTP.

**Table 4: Meeting Requests Received by FDA Center for Tobacco Products (CTP) through January 7, 2013**

	Number granted	Number denied <sup>a</sup>	Number transferred <sup>b</sup>	Number pending	Number withdrawn	Total requests
Office of Center Director	22	6	4	0	0	32
Office of Compliance and Enforcement	3	6	2	1	0	12
Office of Policy	32	0	1	2	1	36
Office of Science	15	10	7	2	2	36
<b>Total requests</b>	<b>72</b>	<b>22</b>	<b>14</b>	<b>5</b>	<b>3</b>	<b>116</b>

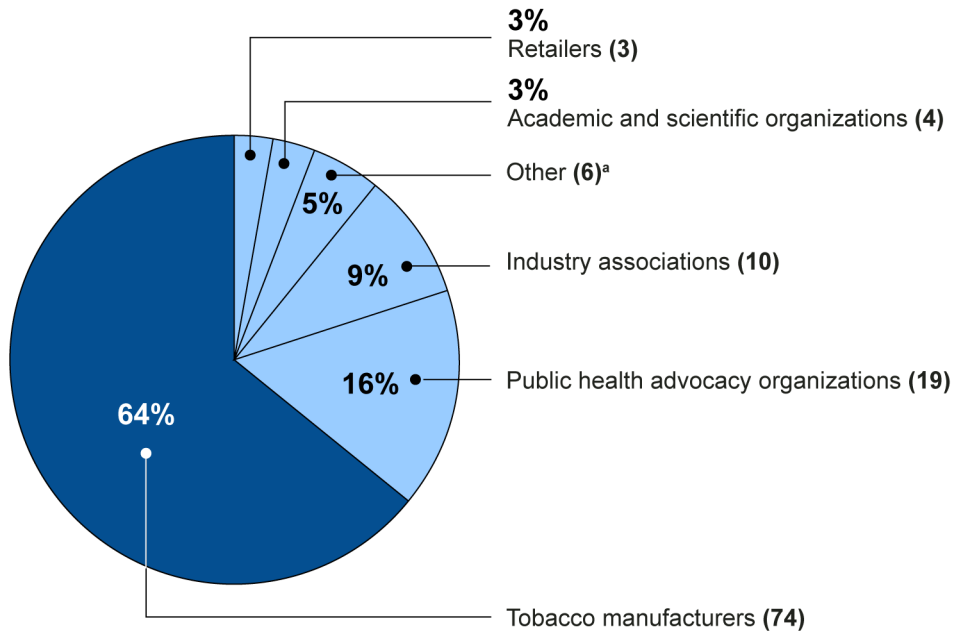
Source: GAO analysis of FDA data.

<sup>a</sup>According to CTP officials, in some cases, the CTP office denied a meeting request because the office was able to address the entity's questions by telephone and a formal meeting was no longer necessary.

<sup>b</sup>The data compiled by the CTP offices did not include data on whether the transferred meeting requests were either granted or denied by the office receiving the transferred request. As a result, a transferred meeting request may also be counted as granted or denied in the office that received the transferred request.

Of the 116 meeting requests from outside entities, most (74) were requested by tobacco manufacturers. Public health advocacy organizations had the second highest number with 19 meeting requests (see fig. 7).

**Figure 7: Meeting Requests Received by FDA Center for Tobacco Products (CTP) Offices, by Type of Entity**



Source: GAO analysis of FDA data.

Note: This figure presents the type of entity requesting meetings with CTP offices for the 116 meeting requests received through January 7, 2013.

<sup>a</sup>Other entities include an animal rights organization, two federal agencies, two local, state, or tribal governments, and one entity for which CTP data did not indicate the type of entity that requested the meeting.

Of the 74 meeting requests by tobacco manufacturers, 35 of the meeting requests were granted, 20 were denied, and 12 were transferred.<sup>37</sup> The remaining 7 meeting requests were pending or withdrawn as of January 7, 2013. For the other types of entities, most of the requested meetings were granted. For example, all 19 meetings requested by public health advocacy organizations were granted. The topics of meeting requests differed among entities. For example, CTP data indicate that tobacco manufacturers typically requested meetings about tobacco product regulation and public health advocacy organizations generally

<sup>37</sup>The data compiled by the CTP offices did not include data on whether the transferred meeting requests were either granted or denied by the office receiving the transferred request. As a result, a transferred meeting request may also be counted as granted or denied in the office that received the transferred request.

requested meetings in order to provide information to CTP that may be useful for CTP's work.

**The Time Taken from Meeting Request to Date Held Varied Widely; CTP Reported That Logistics and Subject Matter Contributed to Variations**

The number of calendar days taken from the date a CTP office received a meeting request to the date the meeting was held varied widely.<sup>38</sup> For example, in OP, the number of days from the date a meeting request was received to the date a meeting was held ranged from 3 days to almost five months, with half of the responses to meeting requests taking more than about 1.5 months. Further, for OCD, the number of days from the date a meeting request was received to the date a meeting was held ranged from 9 days to more than 8 months with at least half of the responses to meeting requests taking over 2.5 months. (See table 5.)

**Table 5: Calendar Days from Date Meeting Request Received to Date Meeting Held, by Center for Tobacco Products (CTP) Office**

CTP Office (number of requests granted) <sup>a</sup>	Calendar Days			
	Minimum	Median	Maximum	Average
Office of Center Director (n=22)	9	82	262	97
Office of Compliance and Enforcement (n=3)	1	39	112	51
Office of Policy (n=30)	3	45	150	52
Office of Science <sup>b</sup> (n=12)	22	86	149	79

Source: GAO analysis of FDA data.

<sup>a</sup>In general, the amounts in this table represent the number of calendar days from the date a meeting request was received by the CTP office to the date on which the meeting was held for 67 of the 72 meeting requests for which the request was granted. Data were insufficient for calculating the calendar days for the remaining meetings that were granted. All of the requests were received through January 7, 2013.

<sup>b</sup>For the Office of Science, the amounts represent the number of calendar days from the date a meeting request was received by any FDA office (instead of the date it was received by the Office of Science). Data maintained by the Office of Science did not include the dates that meeting requests were received by the office.

For tobacco manufacturers, the type of entity with the most meeting requests, the amount of time taken from the date the meeting request was received to the date the meeting was held also varied by office. For

<sup>38</sup>We analyzed the CTP offices separately because the data maintained by each office varied. For example, OS officials maintain data only on the date the meeting request was received by FDA while OCD officials maintain data only on the date the meeting request was received by OCD.

---

example, the minimum number of days from a meeting request to the date the meeting was held for OS was about a month, and the maximum was about 5 months, with half of the responses to meeting requests taking more than about 3 months. The minimum number of days from a meeting request to the date the meeting was held for OP was 3 days, and the maximum was almost 4 months, with half of the responses to meeting requests taking more than about 1.5 months.

According to CTP officials, logistics for scheduling meetings and the subject of the request contributed to the wide variation in time taken from the date of the request to the date the meeting was held. For example, OP officials said that the entity requesting the meeting may have to coordinate travel for several people across many locations in order to schedule a meeting and this coordination may contribute to a longer period of time before the meeting will take place. In addition, the subject matter of the request was another factor that CTP officials reported as contributing to the time taken by CTP offices to hold a meeting. For example, officials from OS said that CTP is a new regulatory agency and, as a result, it sometimes receives meeting requests on subject matters with which the center is unfamiliar and officials must involve many entities within both CTP and FDA to determine several things, including which office within CTP should host the meeting and what information the requested entity should prepare.

---

## FDA Spent Less than Half of the \$1.1 Billion in User Fees Collected

As of the end of fiscal year 2012, FDA had spent less than half of the tobacco user fees collected and CTP had spent less than planned. CTP officials reported that issues related to contracting contributed to lower than expected spending.<sup>39</sup>

---

<sup>39</sup>For the purposes of this report, 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.

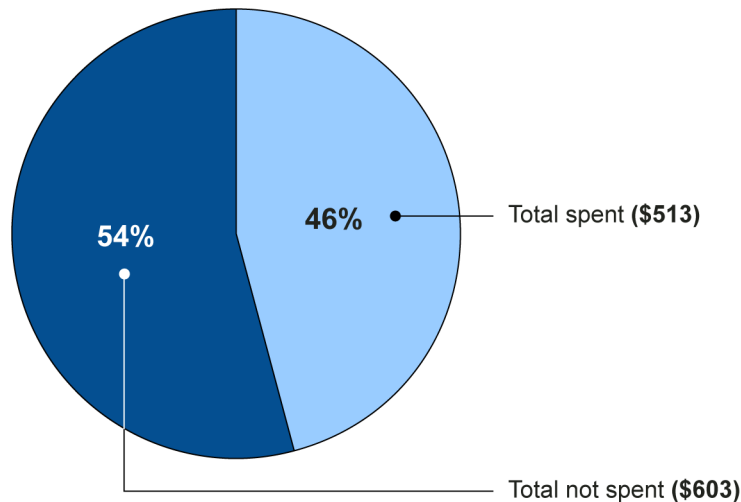
---

## FDA Spent Less than Half of the User Fees Collected and CTP Spent Less than Planned

As of the end of fiscal year 2012, FDA had spent less than half of the \$1.1 billion in tobacco user fee funds collected (46 percent) from fiscal year 2009 through fiscal year 2012, leaving more than \$603 million (54 percent) unspent.<sup>40</sup> (See fig. 8.) Of the almost \$513 million spent during this time, CTP spent almost \$468 million. The remaining funds were spent by other FDA entities, such as the Office of Regulatory Affairs.

**Figure 8: Total Tobacco User Fees Spent and Not Spent by FDA through Fiscal Year 2012**

Dollars (in millions)



Source: GAO analysis of FDA data.

Note: FDA currently relies on the U.S. Department of Agriculture to determine a manufacturer's market share for the purpose of assessing tobacco user fees. Based on this assessment, FDA bills and collects tobacco user fees from manufacturers on a quarterly basis and fees are generally received the quarter after they are billed. 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.

---

<sup>40</sup>The total amount collected is the amount received through fiscal year 2012, and does not include the tobacco user fee funds billed at the end of fiscal year 2012 and collected in the first quarter of fiscal year 2013 (which as of February 28, 2013, totaled about \$62 million).

---

In fiscal years 2011 and 2012, CTP spent less than the amounts it identified in its spend plan—that is, spent less than planned. According to CTP officials, the center’s spend plan identifies plans for spending CTP’s user fee funds on staffing, acquisitions, and operational needs.<sup>41</sup> The spend plan is based on user fee funds anticipated to be collected by FDA and user fee funds that CTP did not spend in the previous fiscal year.<sup>42</sup> Based on the spend plan for fiscal year 2011, all seven CTP offices had planned on spending a total of \$225.4 million for fiscal year 2011, and these offices spent \$106.4 million for that year.<sup>43</sup> CTP continued to spend less than planned for fiscal year 2012. (See table 6.) CTP officials reported that based on spending through the third quarter of fiscal year 2013, the difference between the amount of planned spending and the amount of actual spending in fiscal year 2013 will be less than the differences between planned and actual spending in previous years. CTP planned to spend more than \$810 million in fiscal year 2013, and as of June 30, 2013, CTP has spent or is committed to spend over \$712 million.<sup>44</sup>

---

<sup>41</sup>CTP also develops spend plans for other FDA entities that carry out tobacco-related activities (which include the Office of Regulatory Affairs, Headquarters, and Office of the Commissioner) based on discussions about the tobacco related activities that these other FDA entities will perform.

<sup>42</sup>User fees that have not been spent can be carried over to subsequent fiscal years.

<sup>43</sup>CTP did not develop a spend plan at the office or overhead level for fiscal year 2010, the first year of its operation. However, CTP planned to spend almost \$212 million in fiscal year 2010, which includes overhead, and spent about \$67 million.

<sup>44</sup>In addition, CTP officials project that they will have \$256 million in unspent tobacco user fee funds to carry over to fiscal year 2014, which is less than half of the amount they carried over to fiscal year 2013. CTP officials also project that unspent funds or funds carried over to subsequent fiscal years will continue to decrease.



**Table 6: Center for Tobacco Products (CTP) Planned and Actual Spending, Fiscal Years 2011 and 2012**

Dollars in millions

Fiscal year	CTP Non-Overhead		CTP Overhead <sup>a</sup>		Total <sup>b</sup>	
	Planned	Spent	Planned	Spent	Planned	Spent
2011	\$225.4	106.4	79.2	27.8	304.6	134.1
2012	\$585.0	245.7	25.6	26.0	610.5	271.7

Source: GAO summary of FDA data.

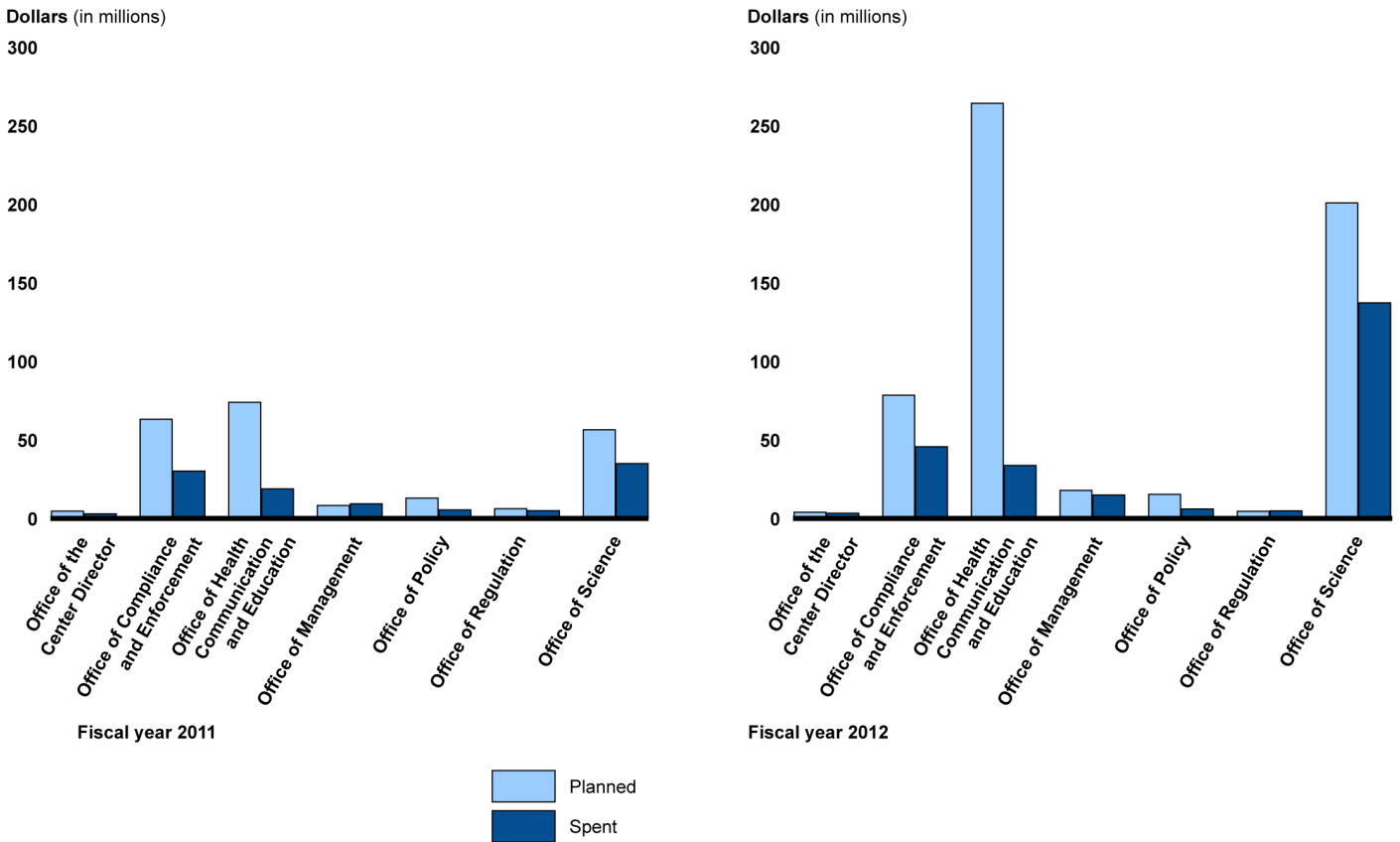
Note: Spending means obligations, including those for which expenditures have been made. The term obligation refers to a definite commitment by a federal agency that creates a legal liability to make payments immediately or in the future. In addition, amounts from CTP and overhead may not equal total due to rounding.

<sup>a</sup>Overhead includes information technology infrastructure and centralized funding for (among other things) furniture, office equipment, and center-wide training.

<sup>b</sup>This total does not include amounts planned or spent for other FDA entities and on U.S. General Services Administration rent. Other FDA entities include the Office of Regulatory Affairs, Headquarters and the Office of the Commissioner. In fiscal years 2011 and 2012, these entities spent \$11.1 million and \$24 million, respectively.

Specifically, six of the seven CTP offices spent less user fee funding than CTP planned for fiscal years 2011 and 2012. For example, for fiscal year 2011, CTP’s Office of Health Communication and Education, OCE, and OS planned to spend about \$30 million more than they actually spent; and the Office of Management was the only CTP office that planned to spend less than it actually spent—it planned to spend about \$1 million less than it spent. (See fig. 9.)

**Figure 9: Center for Tobacco Products (CTP) Planned and Actual Spending, by Office, Fiscal Years 2011 and 2012**



Source: GAO analysis of FDA data.

Note: Planned refers to the amount indicated in CTP’s annual spend plan. 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.

### CTP Officials Reported That Issues Related to Contracting Contributed to Lower than Expected Spending

CTP officials told us that issues related to contracting accounted for most of the difference between the amounts spent and planned spending. Specifically, they reported that the time it took to award contracts resulted in CTP not spending the funds that the center planned to spend for a given fiscal year. For example, according to CTP officials, CTP’s Office of Health Communication and Education had planned to award a \$55 million contract for communications support services for part of its public education campaign for fiscal year 2011. This office also planned to award a related \$145 million contract in fiscal year 2012 for a public health education campaign. However, most of the planned \$200 million

---

total was not awarded until the first quarter of fiscal year 2013.<sup>45</sup> CTP officials told us that both contracts were not awarded at these amounts in fiscal year 2011 or 2012 as planned because CTP and FDA spent significant amounts of time to determine the structure of the contract as FDA had never conducted a public education campaign of this magnitude.

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 than expected contracts were awarded, the scope of a contract changed, or CTP was short of staff to support the work of the contract.

- For fiscal year 2011, CTP's OCE had planned to award \$55 million in contracts with states to ensure compliance with tobacco regulations, but CTP awarded a total of \$24 million for that fiscal year because fewer states participated than expected.
- For fiscal year 2012, CTP's OS entered into an interagency agreement with the Centers for Disease Control and Prevention to develop analytical methods and establish baseline levels of harmful or potentially harmful constituents in tobacco products for \$20 million less than planned because of a change in scope of the activities for this contract.
- For fiscal year 2011, CTP's Office of Health Communication and Education entered into an interagency agreement with the National Institutes of Health to support regulatory communications activities. The agreement was \$3.5 million less than initially planned because the Office of Health Communication and Education was just being established at the time and it did not have enough staff to support this joint effort. As a result, the office reduced the scope of the contract.

In addition to issues related to contracting, CTP officials said that plans to hire more staff than it did and planned management related activities that were not undertaken were other reasons why the amounts spent were lower than planned. According to CTP officials, for fiscal years 2011 and 2012, CTP had planned to hire more staff than it did and this accounted for \$6 million and \$10 million of the differences between amounts planned

---

<sup>45</sup>In order to meet the guarantee of these contracts, the minimum amount was awarded in fiscal year 2012 and that amount was about \$300,000.

---

to be spent and spent, respectively. Further, according to CTP officials, lower than planned spending for other management activities (such as computer updates and planning potential reorganization) is another reason why the amounts spent by CTP were lower than planned. For example, for fiscal year 2011, the CTP spend plan included \$35 million for planning associated with establishing two new offices within CTP. According to CTP officials, this amount was expected to cover contingencies, such as computer updates or management development, if they were needed. However, the officials reported that this reserve was not used because funds were available in the Office of Management to handle any issues related to the addition of these new offices.

---

## Conclusions

Four years after the Tobacco Control Act established CTP and about 3 years after the first new tobacco product submission, FDA has received about 4,000 submissions and collected over \$1.1 billion in tobacco user fee funds. Although CTP has finished initial review steps for most of these submissions, as of June 2013, the center made a final decision on only 6 submissions and the time taken on reviews has been significant. Certainly, insufficient information provided by manufacturers in submissions, the prioritization of regular SE submission reviews over provisional SE submissions, and other factors have contributed to the time CTP has taken in its reviews. Yet, as CTP moves forward with its work, 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. An entity that is limited in its ability to evaluate its performance will be hard-pressed to determine what adjustments it should make to its operations or how to plan for the future.

---

## Recommendations for Executive Action

To improve CTP's ability to operate efficiently, achieve effective results, and plan appropriately, we recommend that the Secretary of Health and Human Services direct the Commissioner of FDA to

- establish performance measures that include time frames for making final decisions on SE submissions and Exemption from SE submissions, and
- monitor FDA's performance relative to those time frames, such as evaluating whether staff are performing reviews of these submissions efficiently and effectively.

---

## Agency Comments

We provided a draft of this report to HHS for comment. In its written comments, reproduced in appendix II, HHS agreed with our recommendations. Specifically, HHS stated that FDA will identify performance measures and time frames for regular SE and Exemption from SE review processes within 6 months of our report's publication and that FDA will monitor its progress to determine if subsequent SE reviews meet the identified time frames. In addition, HHS commented that FDA will identify performance measures and time frames for the provisional SE review process as FDA gains more experience reviewing these SE submissions. HHS further stated that based on the actual performance of meeting the identified time frames, FDA will make modifications to the review process, if appropriate, in order to meet agency objectives.

HHS also provided additional information on CTP activities in its comments. For example, HHS stated that CTP is working to reach determinations on SE and Exemption from SE submissions as expeditiously as possible, and that CTP has continued to make progress on conducting product reviews and in its process and timeliness for responding to requests for meetings with CTP offices. Regarding tobacco user fee funds, HHS commented that CTP is projecting that it will decrease the amount of unspent tobacco user fee funds to carry over at the end of fiscal year 2013 to the mid-\$200 millions, which is less than half of the amount carried over at the end of fiscal year 2012. HHS also suggested that our report should include information on all user fee spending, including spending by FDA entities other than CTP. We do report total user fees spent and not spent by FDA, including spending by both CTP and other FDA entities, through fiscal year 2012. In comparing spend plans with actual spending, we reported on spending by CTP, which comprised more than 90 percent of the \$513 million spent by FDA through fiscal year 2012. In reporting on CTP spending, we clearly note that other FDA entities, including the Office of Regulatory Affairs, Headquarters, and the Office of the Commissioner, spend tobacco user fee funds, and that these entities spent \$11 million in fiscal year 2011 and \$24 million in fiscal year 2012.

HHS also provided technical comments that were incorporated, as appropriate.

---

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Secretary of Health and Human Services, the Commissioner of FDA, and other interested parties. In addition, the report will be available at no charge on GAO's Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or at [crossem@gao.gov](mailto:crossem@gao.gov). Contact points for our Office of Congressional Relations and Office of Public Affairs can be found on the last page of this report. Other major contributors to this report are listed in appendix III.

Sincerely yours,

A handwritten signature in black ink that reads "Marcia Crosse". The signature is written in a cursive style with a long horizontal line extending to the right.

Marcia Crosse  
Director, Health Care

---

# Appendix I: Staffing Resources for Conducting Reviews of New Tobacco Product Submissions

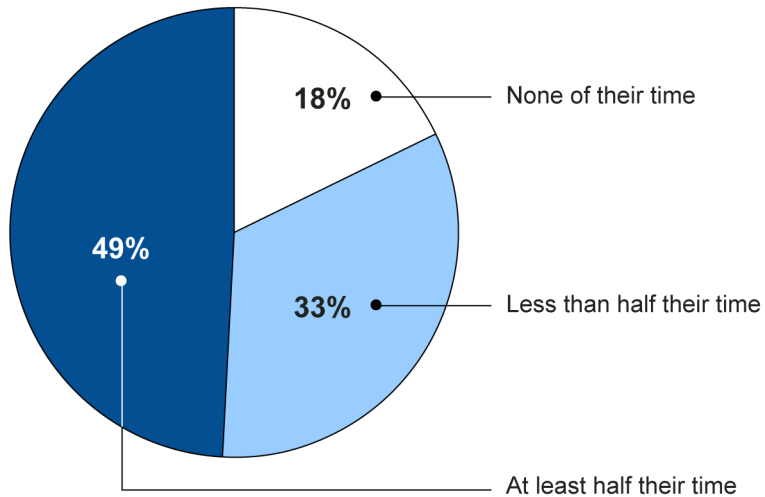
---

As of January 7, 2013, the Office of Science (OS)—the only Center for Tobacco Products (CTP) office involved in all steps of reviewing new tobacco product submissions—had 124 staff members on board, and the majority of the staff (102 or 82 percent) reported spending some portion of their time reviewing new tobacco product submissions. OS has other responsibilities in addition to reviewing new tobacco product submissions, including research to meet regulatory science needs and to evaluate the population and public health impact of tobacco products. According to OS officials, of the 102 staff who reported spending time on reviewing submissions, 60 percent or 61 staff reported that in general they spent at least half of their time working on reviews of new tobacco product submissions. The remaining 41 staff reported generally spending less half of their time on reviews of new tobacco product submissions.<sup>1</sup> (See fig. 10.)

---

<sup>1</sup>According to OS officials, specific details on how many full-time equivalent staff spent time on reviews of new tobacco product submissions were not available. In the absence of specific data, we obtained data from OS on the proportion of time (none of the time, less than 50 percent of the time, or 50 percent or more of the time) each OS position spent on new tobacco submissions, for staff on board as of January 7, 2013.

Figure 10: Center for Tobacco Products (CTP) Office of Science (OS) Staff Time Spent Conducting Reviews of New Tobacco Products



Source: GAO analysis of FDA data.

Note: This figure represents the percentage of staff that spent less than or at least half of their time working on reviews of new tobacco product submissions, as reported by 124 OS staff that were on board as of January 7, 2013. According to OS officials, specific details on how many full-time equivalent staff spent time on reviews of new tobacco product submissions were not available. In the absence of specific data, we obtained data from OS on the proportion of time (none of the time, less than 50 percent of the time, or 50 percent or more of the time) staff members in each OS position spent on new tobacco submissions, for staff on board as of January 7, 2013.

The amount of time an OS staff person reported spending on new tobacco product submissions varied by job title. Specifically, the 23 project managers, the OS officials responsible for coordinating the reviews of new tobacco product submissions, and 17 scientists (such as chemists and toxicologists) reported spending at least half of their time working on reviews of new tobacco product submissions. Meanwhile, the Deputy Director for Research and the Special Assistant to the Director reported spending less than half of their time on the review of new tobacco product submissions. (See table 7.)



**Appendix I: Staffing Resources for Conducting  
Reviews of New Tobacco Product  
Submissions**

**Table 7: Time Spent on Review of New Tobacco Product Submissions for the Center for Tobacco Products (CTP) Office of Science by Job Title**

Time on reviews of submissions	Office of Science Job titles			
<b>50 percent or more</b>	<ul style="list-style-type: none"> <li>• Director, Office of Science</li> <li>• Associate Director Regulatory Science Management</li> <li>• Associate Director for Science Policy</li> <li>• Medical Officer</li> </ul>	<ul style="list-style-type: none"> <li>• Regulatory Health Project Manager</li> <li>• Director, Regulatory Science Informatics</li> <li>• Regulatory Health Information Specialist</li> <li>• Director, Deputy Director, Product Science</li> </ul>	<ul style="list-style-type: none"> <li>• Chemist</li> <li>• Engineer</li> <li>• Toxicologist</li> <li>• Pharmacologist</li> </ul>	<ul style="list-style-type: none"> <li>• Interdisciplinary Scientist</li> <li>• Fellow</li> <li>• Statistician</li> </ul>
<b>Less than 50 percent</b>	<ul style="list-style-type: none"> <li>• Deputy Director for Research</li> <li>• Special Assistant to the Director</li> </ul>	<ul style="list-style-type: none"> <li>• Conflict of Interest Specialist</li> <li>• Health Scientist Administrator</li> </ul>	<ul style="list-style-type: none"> <li>• Psychologist/Behavioral Scientist/Neuroscientist</li> <li>• Epidemiologist</li> <li>• Social Scientist</li> </ul>	<ul style="list-style-type: none"> <li>• Interdisciplinary Scientist</li> <li>• Fellow</li> <li>• Statistician</li> </ul>

Source: GAO summary of FDA information.

Note: This table shows the job titles for which CTP staff reported generally spending 50 percent or more of their time on new tobacco product submission reviews or less than 50 percent of their time (but more than 0 percent) on new tobacco product submission reviews, as reported by Office of Science staff that were on board as of January 7, 2013. The number of staff for each job titled varied from 1 to 23 staff. The job title with 23 staff was regulatory health project manager.

# Appendix II: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation  
Washington, DC 20201

**AUG 13 2013**

Marcia Crosse  
Director, Health Care  
U.S. Government Accountability Office  
441 G Street NW  
Washington, DC 20548

Dear Ms. Crosse:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "New Tobacco Products: FDA Needs to Set Timeframes for Its Review Process" (GAO 13-723).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

A handwritten signature in black ink that reads "Jim R. Esquea".

Jim R. Esquea  
Assistant Secretary for Legislation

Attachment

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "NEW TOBACCO PRODUCTS: FDA NEEDS TO SET TIMEFRAMES FOR ITS REVIEW PROCESS" (GAO 13-723)**

The Department appreciates the opportunity to review and comment on this draft report.

On June 22, 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). This new law charged the Food and Drug Administration (FDA) with the regulation of new tobacco products, creating FDA's Center for Tobacco Products (CTP), and giving it unprecedented responsibility for the pre-market public health review of tobacco product applications and reports under a public health/population standard, which is a new regulatory standard substantially different from standards used by other FDA Centers.<sup>1</sup> Establishing and carrying out a consistent, transparent, and predictable public-health-based scientific regulatory review, over complex and highly engineered tobacco products that have never been regulated before, require careful consideration of many complex and critical scientific issues. FDA is currently evaluating the information obtained in the GAO draft report, and consistent with GAO's recommendations, FDA will establish performance measures that include timeframes for the review phases within the substantial equivalence (SE) and Exemption from SE review processes.

FDA takes the responsibility to make sound public-health-based scientific decisions on the marketing of new tobacco products seriously. To accomplish this, CTP has developed a rigorous, science-based process for the work related to the review of new tobacco products and substantial equivalence (SE) reports. As CTP develops the knowledge, procedures, and policies required to carry out an effective regulatory program, it will become more efficient and timely in exercising the authority provided by Congress.

**New Tobacco Product Submissions and CTP's Review Process**

CTP recognizes that the three pathways to market a tobacco product (pre-market tobacco application, substantial equivalence, and exemption from substantial equivalence) are new to the tobacco industry. During the first three years since its creation, CTP undertook a major effort to develop guidance and regulations to better inform the tobacco industry about specific regulatory review issues, including the scientific and public health elements needed for the evaluation of product applications.

CTP is working to reach determinations on SE reports and exemption from SE requests as expeditiously as possible. As noted by GAO in the draft report, the length of time from the end of jurisdiction review to the end of completeness review decreased from 8 months in FY2011 to 2 months in FY2012. This constitutes considerable progress and is a reflection of CTP's ongoing commitment to shortening review times.

CTP has continued to make progress on conducting product reviews since GAO provided FDA with its draft report. CTP has begun making SE and not substantially equivalent (NSE) determinations, and now has substantially reduced its backlog of regular SE reports awaiting initial scientific review. As of late June 2013, CTP had received 788 regular reports, completed

<sup>1</sup> For example, the Center for Drug Evaluation and Research addresses a drug's safety and effectiveness.

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "NEW TOBACCO PRODUCTS: FDA NEEDS TO SET TIMEFRAMES FOR ITS REVIEW PROCESS" (GAO 13-723)**

jurisdictional review of 748 of these reports, completed administrative review of 729 of these reports, and started scientific reviews for 479 of the regular SE submissions. FDA has initiated scientific review on all regular SE reports received as of November 9, 2012.

Provisional SE reports raise separate issues. During the course of 2011, CTP received in excess of 3,000 provisional SE reports to review. CTP received provisional reports on or before March 22, 2011, for products that were on the market on that date. These products can remain on the market unless FDA finds that they are NSE. Because the provisional reports can remain on the market pending a decision, CTP triages them so that those having the highest potential public health impact receive priority for scientific review.

Many factors can affect the timing of an SE determination, including the completeness of the submission and whether manufacturers need to submit more scientific information in order for CTP to make a determination. So far nearly all of the SE reports submitted to CTP by tobacco companies have had significant deficiencies. In almost all cases, the submissions lack the information that CTP needs to make a finding that a new product is substantially equivalent to a predicate product, omitting basic statutory elements required in a complete submission. CTP has sought to clarify, through guidance documents and webinars as well as interactions with individual companies on their previously submitted SE reports, the information that submissions should contain in order for CTP to evaluate them. Some of the general issues that FDA is observing across multiple submissions include:

- Reports contained contradictory statements, particularly about whether the new product characteristics were the same or different from those of the predicate product.
- Reports named an inappropriate predicate product.
- Reports lacked information regarding product composition, including information about the tobacco blend used in the product.
- Reports were missing specifications on components used in the manufacture of the finished product.
- The Harmful and Potentially Harmful Constituents (HPHC) measurements in many reports were scientifically inadequate or did not include information needed to evaluate data quality.
- For some reports, information on product design was incomplete, preventing a scientific assessment, and the information on product packaging (which can impact product stability) was lacking.

As noted in GAO's draft report, as manufacturers submit the full information that CTP needs to make SE determinations, CTP expects that the number of days required for scientific review of SE reports (exclusive of the time industry takes to respond to FDA letters) will substantially decrease. Also, as CTP improves its own processes and IT systems and hires additional staff, it will be able to conduct scientific reviews more quickly and efficiently.

CTP has made significant progress in its SE review process since January 2013. In order to speed up the process for an SE determination, CTP is now providing applicants with a

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "NEW TOBACCO PRODUCTS: FDA NEEDS TO SET TIMEFRAMES FOR ITS REVIEW PROCESS" (GAO 13-723)**

notification letter before CTP begins review. This letter notifies manufacturers that scientific review will begin in 45 days and they have the option to provide CTP with additional information before the start of scientific review. In addition, CTP has increased communication with applicants, provided feedback on questions posed by industry, and published FDA guidance to industry. CTP originally requested a 60-day response to administrative advice and information (AI) letters, but since April 2012, CTP has been requesting a 30-day response to administrative AI letters. CTP has also allowed 30 days for response to preliminary finding letters (which seek further correction of deficiencies following review of the SE report) in order to expedite the process for reaching an SE determination.

CTP has hired additional Regulatory Health Project Managers and worked to hire and retain experienced scientists in order to provide human capital resources to shorten the time required to conduct SE reviews. CTP also set up a cross-office work group, convened by the Center Director's Office, specifically to examine and improve hiring practices associated with SE reviews. As a result of HR and work group recommendations, FDA has been sharing certificates and utilizing hiring flexibilities to increase the number of qualified scientific staff. To improve processes, CTP is creating reviewers' guides to train review staff and facilitate consistency of reviews by different scientists and across SE Reports, as well as improve the efficiency of reviews.

CTP determined that the current eSubmissions IT system is not sufficient to address the document management and analytical review needs of CTP for SE and other regulatory submissions. CTP is developing a new system (OSiRIS – Office of Science Review Information System) that will support the tracking, management, and analytical review of SE submissions and exemptions, Pre-Market Tobacco Applications (PMTAs), Modified Risk Tobacco Products (MRTPs), and Investigational Tobacco Products (ITPs). The system will also facilitate general correspondence with industry as well as the scheduling and recording of industry meetings. OSiRIS is currently in the coding phase, with expected deployment at the end of 2013.

**Requests for Meetings with CTP Offices**

CTP has made progress in its process and timeliness for responding to requests for meetings with CTP offices since January 2013. CTP has developed a standard operating procedure (SOP) on the CTP policies and procedures for scheduling and documenting meetings with tobacco manufacturers, importers (industry) and researchers/investigators (investigators) who seek guidance relating to the research, development, and/or review of tobacco products. The SOP is consistent with the *CTP Guidance for Industry and Investigators; Meetings with Industry and Investigators on the Research and Development of Tobacco Products*, May 24, 2012 (Guidance). The purpose of the meeting is one factor that significantly impacts the length of time between the date of the meeting request and the date of its occurrence. Consistent with the Guidance, if a meeting is a listening session, the rate limiting step in scheduling is primarily logistics (e.g. staff availability). However, if CTP is to substantively address regulatory issues, it must prepare in advance of the meeting. To facilitate this, CTP's Office of Science (OS) requests that manufacturers submit background information for OS's review at least 45 days prior to the

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "NEW TOBACCO PRODUCTS: FDA NEEDS TO SET TIMEFRAMES FOR ITS REVIEW PROCESS" (GAO 13-723)**

meeting, and CTP meeting participants prepare for industry/investigator meetings by thoroughly reviewing the background materials submitted by the meeting requestor.

**Tobacco User Fee Funds**

FDA continues to make substantial progress in making careful use of the funding the Tobacco Control Act makes available for regulating tobacco products. As of July 31, 2013, CTP has obligated \$594 million and committed or delegated an additional \$235 million, which totals \$829 million, or 98 percent, of the FY2013 spend plan of \$847 million. CTP plans to spend additional funds on salaries and benefits, scientific research, and reimbursements to FDA offices in FY2013. Given these figures, CTP is projecting to decrease its carryover funds from \$603 million in FY2012 to the mid-\$200 millions for FY2013.

The Tobacco Control Act established the user fee amounts that FDA is authorized to collect for the regulation of tobacco products; GAO presents the amounts in Table 3 of the draft report. Although GAO presents the total amounts to be *collected*, it only reports on the *portion* of the Tobacco Program that CTP spends, excluding spending by the other FDA entities (e.g. Office of Regulatory Affairs, IT services, GSA rent, legal services, etc.) whose tobacco regulation-related activities are supported by FDA tobacco user fees. This is not a comparable presentation since CTP's expenditures alone can never approach the total fees collected. This leaves out significant expenditures of the Tobacco Program.

For example, in Table 6: Center for Tobacco Products (CTP) Planned and Actual Spending, Fiscal Years 2011 and 2012, actual CTP spending represented in the table for FY2011 and FY2012 was \$134.1 and \$271.7 million respectively, where actual spending for the whole Tobacco Program, was actually \$145.2 million for FY2011 and \$295.7 million for FY2012. When comparing total resources to total expenditures, GAO should use comparable figures or GAO should clarify that it is only reporting on the subset of spending that is done by CTP and indicate that other Tobacco Program spending is being excluded. The same analysis and caveats apply to FTE figures since CTP's FTE figures are only a subset of the Tobacco Program's total FTE figures, which are all supported by tobacco user fees.

**Response to GAO Recommendations**

To improve CTP's ability to operate efficiently, achieve effective results, and plan appropriately, GAO recommends that FDA establish performance measures that include timeframes for making final decisions on SE submissions and that FDA monitor its performance relative to these timeframes. Within 6 months of the publication of this report, FDA will identify performance measures and timeframes for regular SE and Exemption from SE review processes. FDA will implement these performance measures for regular SE reports received by the agency within 6 months after identification. In addition, FDA will monitor its progress to determine if subsequent SE reviews meet the identified timeframes. Based on the actual performance of meeting the identified timeframes, FDA will make modifications to the review process, if appropriate, in order to meet agency objectives.

**GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S (GAO) DRAFT REPORT ENTITLED, "NEW TOBACCO PRODUCTS: FDA NEEDS TO SET TIMEFRAMES FOR ITS REVIEW PROCESS" (GAO 13-723)**

FDA will take a phased approach to implementing these performance measures and timeframes. Because FDA is currently prioritizing the review of the regular SE reports and Exemption from SE requests, the performance measures and timeframes for these submissions will be implemented first. As FDA gains more experience with reviewing the provisional SE reports, it will begin to implement performance measures and timeframes with respect to those submissions.

---

# Appendix III: GAO Contact and Staff Acknowledgments

---

## GAO Contact

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

---

## Staff Acknowledgments

In addition to the contact named above, Kim Yamane, Assistant Director; Danielle Bernstein; Hernán Bozzolo; Britt Carlson; Cathleen Hamann; Richard Lipinski; and Lisa Motley made key contributions to this report.



---

---

## GAO's Mission

The Government Accountability Office, the audit, evaluation, and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

---

## Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's website (<http://www.gao.gov>). Each weekday afternoon, GAO posts on its website newly released reports, testimony, and correspondence. To have GAO e-mail you a list of newly posted products, go to <http://www.gao.gov> and select "E-mail Updates."

---

## Order by Phone

The price of each GAO publication reflects GAO's actual cost of production and distribution and depends on the number of pages in the publication and whether the publication is printed in color or black and white. Pricing and ordering information is posted on GAO's website, <http://www.gao.gov/ordering.htm>.

Place orders by calling (202) 512-6000, toll free (866) 801-7077, or TDD (202) 512-2537.

Orders may be paid for using American Express, Discover Card, MasterCard, Visa, check, or money order. Call for additional information.

---

## Connect with GAO

Connect with GAO on [Facebook](#), [Flickr](#), [Twitter](#), and [YouTube](#). Subscribe to our [RSS Feeds](#) or [E-mail Updates](#). Listen to our [Podcasts](#). Visit GAO on the web at [www.gao.gov](http://www.gao.gov).

---

## To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Website: <http://www.gao.gov/fraudnet/fraudnet.htm>

E-mail: [fraudnet@gao.gov](mailto:fraudnet@gao.gov)

Automated answering system: (800) 424-5454 or (202) 512-7470

---

## Congressional Relations

Katherine Siggerud, Managing Director, [siggerudk@gao.gov](mailto:siggerudk@gao.gov), (202) 512-4400, U.S. Government Accountability Office, 441 G Street NW, Room 7125, Washington, DC 20548

---

## Public Affairs

Chuck Young, Managing Director, [youngc1@gao.gov](mailto:youngc1@gao.gov), (202) 512-4800 U.S. Government Accountability Office, 441 G Street NW, Room 7149 Washington, DC 20548

