United States Government Accountability Office

Report to Congressional Requesters

October 2019

TOBACCO USER FEES

Further Action Needed to Ensure Calculations Are Based on Complete and Accurate Data

Accessible Version

GAO-20-34

GAO Highlights

Highlights of GAO-20-34, a report to congressional requesters

View GAO-20-34. For more information, contact Mary Denigan-Macauley, 202-512-7114, or DeniganMacauleyM@gao.gov .

Why GAO Did This Study

Tobacco use causes more than 480,000 deaths each year, according to the Department of Health and Human Services (HHS). To protect the public, the Family Smoking Prevention and Tobacco Control Act granted FDA, an agency within HHS, authority to regulate tobacco products. To fund FDA's tobacco regulation activities—such as those aimed at preventing youth use of tobacco products—the act authorizes FDA to assess and collect a specified total amount of user fees from tobacco manufacturers and importers each fiscal year. The total amount of user fees are to be allocated based on the individual manufacturers' and importers' market share in six FDA-regulated tobacco product classes.

GAO was asked to review FDA's tobacco user fees. This report examines FDA's process for the calculation, billing, and collection of these fees. GAO reviewed the relevant law and regulations, as well as FDA policies and procedures, and interviewed FDA officials.

What GAO Recommends

GAO is recommending that FDA consult with TTB and CBP to determine and document procedures for FDA to obtain quality data so the agency can complete its annual reconciliation process in a timely manner. HHS agreed with GAO's recommendation.

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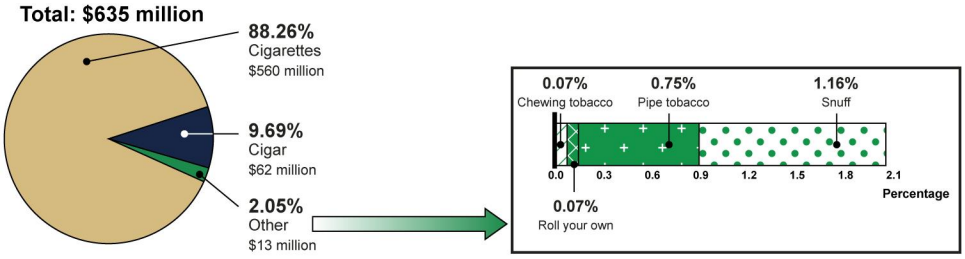
What GAO Found

In fiscal year 2017, the latest data available at the time of our analysis, the Food and Drug Administration (FDA) assessed about $635 million in user fees to tobacco manufacturers and importers of six classes of FDA-regulated tobacco products—cigarettes, snuff, chewing tobacco, roll-your-own tobacco, pipe tobacco, and cigars. (See figure.)

User Fees Assessed by Tobacco Product Class, Fiscal Year 2017



Source: GAO analysis of FDA data. | GAO-20-34

Data table for User Fees Assessed by Tobacco Product Class, Fiscal Year 2017

Cigarettes	88.26% ($560 million)	--	--
Cigar	9.69% ($62 million)	--	--
Other	2.05% ($13 million)	Chewing tobacco	0.08%
		Roll your own	0.07%
		Pipe tobacco	0.75%
		Snuff	1.16%
Total	Total : $635 million		

FDA has a process that is designed to ensure accurate calculation, billing, and collection of tobacco user fees. However, the agency has not completed a key step in this process—its year-end reconciliation—since doing so for fiscal year 2015. FDA procedures provide that the agency will conduct this year-end reconciliation annually after receiving necessary data from the Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB) and U.S. Customs and Border Protection (CBP). FDA relies on this year-end reconciliation to ensure that its user fee calculations are based on complete and accurate data—that is, that all manufacturers and importers subject to tobacco user fees were assessed fees correctly, based on accurate market share data. Incomplete or inaccurate data for one manufacturer or importer affects the market share—and the user fee amount—for all other manufacturers and importers in its product class.

FDA has not completed this year-end reconciliation in recent years because of delays in obtaining the quality data it needs from TTB and CBP. While FDA has reported receiving most of the data for fiscal years 2016 through 2018 and has plans for completing the reconciliation for those years, the agency faces a risk of repeating delays in its reconciliation efforts in the future because it does not have

reasonable assurance that it will receive quality data in a timely manner moving forward. Until FDA consults with TTB and CBP to determine and document the procedures and time frames that will allow FDA to obtain the quality data it needs to complete this key step in a timely manner, the agency risks repeating these delays.

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Abbreviations

CBP	U.S. Customs and Border Protection
CTP	Center for Tobacco Products
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
TTB	Alcohol and Tobacco Tax and Trade Bureau

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

October 17, 2019

The Honorable Greg Walden
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Honorable Brett Guthrie
Republican Leader
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Tobacco is the leading cause of preventable death, disease, and disability in the United States, and it is a significant contributor to health care costs.[1] Tobacco use causes more than 480,000 deaths per year, according to the Department of Health and Human Services (HHS). To protect the public and create a healthier future for all Americans, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) granted HHS's Food and Drug Administration (FDA) authority to regulate the manufacturing, marketing, and distribution of tobacco products.[2]

The Tobacco Control Act authorizes FDA to assess and collect user fees from tobacco manufacturers and importers for FDA's tobacco regulation activities, such as those aimed at preventing youth use of tobacco products.[3] The act specifies the total amount of user fees FDA can assess and collect each fiscal year (e.g., $712 million in fiscal year 2019), as well as how these user fees are to be allocated among individual tobacco manufacturers and importers of six different classes of tobacco products: cigarettes, snuff, chewing tobacco, roll-your-own tobacco, pipe

[1]Department of Health and Human Services, *The Health Consequences of Smoking—50 Years of Progress: A Report of the Surgeon General* (Atlanta, Ga.: January 2014).

[2]Pub L. No. 111-31, div. A, 123 Stat. 1776 (2009) (hereafter, "Tobacco Control Act").

[3]In this report, "tobacco manufacturers" refers to companies that manufacture tobacco products domestically.

tobacco, and cigars.[4] The act requires FDA to assess user fees for each manufacturer and importer based on its market share of each tobacco product class. Manufacturers and importers are required to provide FDA with information on the volume of tobacco products they have introduced into the U.S. market, as well as on the amount of federal excise taxes they have paid on these products; the agency uses these data to calculate manufacturers' and importers' market share and user fees.[5] FDA bills and collects tobacco user fees from manufacturers and importers on a quarterly basis.

You asked us to review FDA's calculation, billing, and collection of tobacco user fees from tobacco manufacturers and importers for fiscal years 2015 through 2017. This report examines FDA's process for the calculation, billing, and collection of tobacco user fees.

To address our objective, we examined (1) the Tobacco Control Act and related regulations, (2) FDA's documented policies and procedures used to manage the calculation, billing, and collection of tobacco user fees, and (3) relevant federal internal control standards.[6] We also interviewed FDA officials about the mechanisms FDA used to ensure it had the information it needed to calculate, bill, and collect accurate user fees for all eligible tobacco manufacturers and importers. We compared the process FDA designed to manage the calculation, billing, and collection of tobacco user fees to criteria from relevant federal internal control standards regarding quality information, communication with external parties, and control activities. For example, we reviewed FDA documentation to determine

[4]Under the Tobacco Control Act, tobacco products that FDA regulated beginning in 2009 include cigarettes, snuff, chewing tobacco, and roll-your-own tobacco. However, the act authorized FDA to undertake rulemaking to deem other tobacco products as subject to FDA regulation. In May 2016, FDA issued a final rule deeming other products meeting the statutory definition of "tobacco product," including cigars and pipe tobacco, to be subject to FDA regulation. 81 Fed. Reg. 28974 (May 10, 2016).

[5]Federal excise tax rates on different tobacco products are calculated in different ways. Cigarettes and small cigars are taxed on a per unit basis—the number of sticks. Roll-your-own and pipe tobacco are taxed by weight. For more information on federal excise taxes of tobacco products, see GAO, *Tobacco Taxes: Market Shifts toward Lower-Taxed Products Continue to Reduce Federal Revenue*, GAO-19-467 (Washington, D.C.: June 13, 2019).

[6]GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999) and GAO-14-704G (Washington, D.C.: September 2014). Internal control is a process effected by an entity's management, oversight body, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

whether key duties and responsibilities related to calculating, billing, and collecting tobacco user fees were adequately divided among different FDA offices and staff so that no one individual controlled all key aspects, which helps reduce the risk of error, waste, or fraud. We also reviewed FDA's procedures for calculating tobacco user fees for one fiscal quarter (1) for each tobacco product class, and (2) for each individual manufacturer and importer within five of the six tobacco product classes, based on its market share (measured by the federal tobacco excise taxes paid).[7] In addition, we reviewed the amounts FDA billed tobacco manufacturers and importers, as well as the agency's efforts to collect unpaid user fees.[8] We assessed the reliability of the data we received from FDA by reviewing related documentation, performing data reliability checks (such as examining data for missing values), and interviewing FDA officials, and determined these data were sufficiently reliable for our audit objective.

We conducted this performance audit from January 2018 to October 2019 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that

[7]For five of the six tobacco classes, we reviewed the calculations for the fourth quarter of fiscal year 2017 (the most recent complete data for all tobacco classes at the time of our review), and compared the calculated amounts to the amounts FDA billed for that quarter. As part of our review, we examined the data that tobacco manufacturers and importers submitted to FDA on the volume of tobacco products they introduced into the U.S. market and the amount of excise taxes paid on these products. For five of the six tobacco product classes—cigarettes, snuff, chewing tobacco, roll-your-own tobacco, and pipe tobacco—we reviewed data in the forms submitted by all manufacturers and importers for the fiscal year 2017 fourth quarter assessment. For the cigar product class (for which user fees are calculated using a different methodology), we reviewed data submitted by a random sample of 20 percent of the cigar manufacturers and importers for all of fiscal year 2017. Because of the large volume of data for the cigar class, we examined a random sample to provide a reasonable number of both small and large manufacturers and importers. While this sample is not generalizable to all cigar manufacturers and importers, it provides a reasonable check of the data FDA used to calculate quarterly user fees for cigar manufacturers and importers for fiscal year 2017. We could not independently verify that the volume and tax data reported to FDA by the tobacco manufacturers and importers was complete and accurate.

[8]We reviewed the amounts the agency billed (i.e., the invoices) and the agency's attempts to collect user fees assessed in fiscal years 2015 through 2017 for the manufacturers and importers with overdue user fees. We reviewed the notification letters that FDA sent informing tobacco manufacturers and importers that their invoices were 30, 60, and 90 days overdue for all 26 tobacco manufacturers and importers that were 90 days or more late as of the fourth quarter, fiscal year 2017.

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

Background

Authorized Tobacco User Fee Amounts

The Tobacco Control Act specifies the total amount of tobacco user fees that FDA is authorized to assess and collect each fiscal year (beginning with fiscal year 2009) and stipulates those fees must be used for FDA's tobacco regulation activities.[9] FDA collected about $4.5 billion in tobacco user fees from fiscal year 2010 through fiscal year 2018, according to FDA budget documents, and has ongoing authority to assess and collect $712 million from tobacco manufacturers and importers annually starting in fiscal year 2019.[10] See table 1 for the total user fees the Tobacco Control Act authorized FDA to collect, by fiscal year.[11]

Table 1: Total Tobacco User Fee Amounts Authorized by the Tobacco Control Act to Be Assessed and Collected, by Fiscal Year

(Dollars in Millions)

Fiscal Year	User Fee Amount
2009	85[a]
2010	235
2011	450
2012	477

[9]Fees are collected and available for obligation only to the extent and in the amount provided in advance in appropriation acts. The fees are to remain available until expended, which means there is no fiscal year limitation on their availability for obligation.

[10]The President's fiscal year 2020 budget includes a legislative proposal to increase the tobacco user fee by $100 million and to add manufacturers and importers of electronic nicotine delivery systems (such as electronic cigarettes) as entities subject to the user fees. Office of Management and Budget, *Budget of the U.S. Government, Fiscal Year 2020, Appendix,* 419. According to FDA officials, as of July 2019, the Administration had not taken a position on any specific legislation and had not proposed legislation.

[11]For fiscal years 2010 through 2019, Congress appropriated the total amounts of tobacco user fees authorized to be assessed and collected by FDA under the act. The fiscal year 2013 appropriation amount of $505 million, however, was reduced to $480 million available to FDA for obligation as a result of the sequestration order issued by the President on March 1, 2013.

Fiscal Year	User Fee Amount
2013[b]	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. | GAO-20-34

Note: The amounts shown are the total user fee amounts that the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) authorized to be assessed and collected by the Food and Drug Administration (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 appropriation acts, with the exception of user fees collected during the start-up period in fiscal year 2009. Pub. L. No. 111-31, § 101(b), 123 Stat. 1776, 1826-29 (2009) (codified at 21 U.S.C. § 387s(b) and (c)).

[a]Because the act was enacted in the third quarter of fiscal year 2009, the third quarter user fee amounts were assessed using a pro-rata amount.

[b]The fiscal year 2013 appropriation amount of $505 million was reduced to $480 million available to FDA for obligation as a result of the sequestration order issued by the President on March 1, 2013.

All of FDA's activities related to regulating tobacco products—including activities aimed at preventing youth use of tobacco products, educating the public about tobacco products and the risks associated with their use, and issuing regulations on the marketing and advertising of tobacco products—are funded through tobacco user fees, as required by the Tobacco Control Act.

- **FDA's Center for Tobacco Products (CTP),** which was established by the act, is responsible for executing FDA's tobacco regulation responsibilities.[12] Within CTP, the two main offices involved in carrying out FDA's tobacco user fee responsibilities are the Office of Management and the Office of Compliance and Enforcement.
  - CTP's Office of Management staff duties include—but are not limited to—calculating individual tobacco manufacturer's and importer's market share quarterly within each tobacco product class, as well as completing FDA's year-end reconciliation

[12]CTP and its offices conduct work in several areas, including developing and issuing regulations and guidance, reviewing submissions for new tobacco products to determine if such products can be legally marketed in the United States, enforcing prohibitions on the sale of certain tobacco products, engaging in public education about the risks associated with tobacco product use, and performing other activities. For more information about FDA regulation activities, see GAO, *Tobacco Product Regulation: Most FDA Spending Funded Public Education, Regulatory Science, and Compliance and Enforcement Activities*, GAO-14-561 (Washington, D.C.: June 20, 2014).

process to ensure its market share calculations for each fiscal year are based on complete and accurate data.

- CTP's Office of Compliance and Enforcement staff are involved in FDA's efforts to implement and enforce the Tobacco Control Act by (1) informing tobacco manufacturers and importers that they must pay the required quarterly tobacco user fee, if they have not done so, by the due date, and (2) working to obtain voluntary compliance, or taking advisory or enforcement actions, when manufacturers or importers continue to fail to comply with the user fee requirements.

- **FDA's Office of Financial Management** is responsible for calculating the quarterly assessments for each tobacco product class, and for activities related to the billing and collection of tobacco user fees. For example, FDA's Office of Financial Management generates quarterly invoices for individual manufacturers and importers based on CTP's market share calculations. Additionally, this office processes tobacco user fee payments received and works with CTP's Office of Compliance and Enforcement to help collect user fee payments from tobacco manufacturers and importers that do not pay a quarterly assessment by the due date.

Tobacco Control Act Requirements for Assessing and Collecting Tobacco User Fees

The Tobacco Control Act establishes requirements regarding the calculation, billing, and collection of tobacco user fees.

- **Calculation.** For each fiscal year, total user fees are to be allocated in two steps:

  1. **Class allocation.** The amount of total user fees for a fiscal year (e.g., $635 million for fiscal year 2017) is allocated among the different tobacco product classes subject to user fees; this allocation is based on each class's share of the gross domestic volume of tobacco products introduced into the U.S. market.[13]

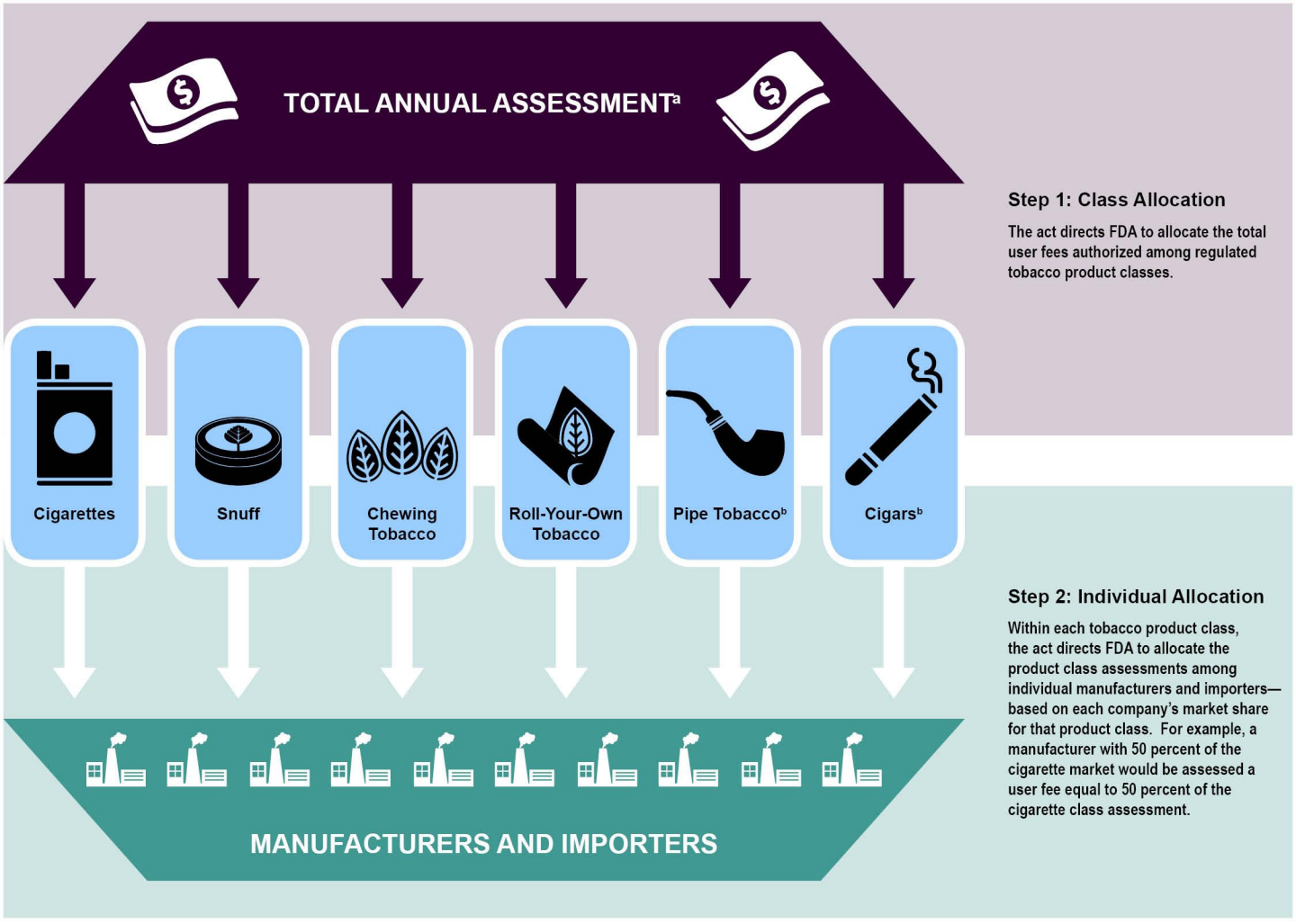
  2. **Individual allocation.** The amount of user fees allocated to each manufacturer or importer is proportional to its market share within a given class of tobacco products. For example, a manufacturer

[13]Pub. L. No. 111-31, § 101(b), 123 Stat. 1776, 1784, 1827 (2009), classified, as amended, at 21 U.S.C. § 387s(b)(2).

with 50 percent of the cigarette market would be required to pay 50 percent of user fees allocated for the cigarette product class. The act specifies that no manufacturer or importer of tobacco products shall be required to pay a user fee in excess of the percentage share of such manufacturer or importer.

See figure 1 for a summary of the tobacco user fee allocation process under the Tobacco Control Act.

Figure 1: User Fee Allocation Process Under the Tobacco Control Act



Source: GAO analysis of Tobacco Control Act; FDA and GAO (images). | GAO-20-34

[a]The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) specifies the total amount of tobacco user fees the Food and Drug Administration (FDA) is authorized to collect for each

fiscal year. Beginning with fiscal year 2019, the total amount FDA is authorized to collect is $712 million per year.

[b]Two tobacco product classes—pipe tobacco and cigar—were deemed to be subject to FDA regulation in 2016, and tobacco user fee assessments for these classes began in fiscal year 2017. For fiscal years 2015 and 2016, FDA reallocated the amount of user fees that would otherwise have been assessed to the pipe tobacco and cigar classes among the other four product classes: cigarettes, snuff, chewing tobacco, and roll-your-own tobacco.

- **Billing.** The act specifies that user fees are to be billed each quarter. Notifications to each manufacturer or importer of the amount of its quarterly tobacco user fee assessments are to be sent at least 30 days before the end of the quarter for which the assessment is made.
- **Collection.** Tobacco user fee payments are due the last day of each quarter. If a manufacturer or importer does not pay its user fee assessments by the last day of the relevant quarter, the act states that tobacco product shall be deemed adulterated.[14]

FDA Regulations and Processes to Calculate, Bill, and Collect Tobacco User Fees

Since the enactment of the Tobacco Control Act, FDA has issued several final rules (regulations) regarding its process to calculate, bill, and collect tobacco user fees, including the following:

- In 2014, FDA issued a final rule requiring tobacco manufacturers and importers to submit to FDA the information needed to calculate individual tobacco user fees, starting with fiscal year 2015. This rule applied to the four classes of tobacco products FDA initially regulated: cigarettes, snuff, chewing tobacco, and roll-your own tobacco. Fiscal year 2015 was the first year for which FDA obtained the data directly from manufacturers and importers to calculate individual tobacco user fee assessments.[15]

[14]When a tobacco product is deemed adulterated, it is illegal to distribute the product in interstate commerce or import the product into the United States. 21 U.S.C. §§ 387b(4) and 331(a).

[15]79 Fed. Reg. 39302 (July 10, 2014). From fiscal years 2009 through 2014, FDA obtained the information needed to calculate tobacco user fee assessments from the U.S. Department of Agriculture, which collected this information for a different program that ended in 2014. Beginning in fiscal year 2015, FDA required tobacco manufacturers and importers to submit to FDA on a monthly basis the data needed to calculate tobacco user fee assessments. 21 C.F.R. § 1150.5 (2019).

- In 2016, FDA issued a final rule extending FDA's regulatory authority to all tobacco products, including pipe tobacco and cigars (but excluding accessories of newly deemed products).[16] Using its deeming authority, FDA issued another final rule requiring that pipe tobacco and cigar manufacturers and importers submit to FDA the information required to calculate user fees for these tobacco product classes.[17] FDA began collecting tobacco user fees from the pipe tobacco and cigar classes in fiscal year 2017.

See appendix I for a timeline of events related to FDA tobacco product user fees.

FDA's process for calculating, billing, and collecting user fees involves five steps. First, FDA collects the data needed to calculate the quarterly user fee allocations for each tobacco product class and, within each class, for individual manufacturers and importers. For its quarterly class allocation calculations, FDA collects data on the total volume (units) of tobacco products introduced into the U.S. market for each tobacco product class from the Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB)—these data are published on the TTB website.[18] FDA also collects data from individual manufacturers and importers on the volume of and federal excise taxes paid for their tobacco products introduced into the U.S. market in each product class. Tobacco companies submit these data to FDA as part of required monthly report

[16]81 Fed. Reg. 28974 (May 10, 2016). This rule is commonly referred to as the "Deeming Rule." The Tobacco Control Act specifies that FDA's regulatory authority for tobacco products includes accessories for these products.

[17]81 Fed. Reg. 28707 (May 10, 2016).

[18]The volume of tobacco products introduced into (or removed into) the U.S. market is the number of units of tobacco products removed from the manufacturer's factory or from internal revenue bond, or released from customs custody, as measured in pounds for chewing tobacco, snuff, roll-your-own and pipe tobacco or in the number of sticks for cigarettes or cigars. See 26 U.S.C. § 5702(j). TTB publishes the total volume of tobacco products removed into the U.S. market for each product class in its Monthly Statistical Release; these data are derived directly from reports submitted to TTB by tobacco manufacturers on the units of tobacco products manufactured domestically or received from Puerto Rico, as well as units of tobacco products imported from foreign countries and entered/withdrawn for consumption. FDA uses the latest complete calendar year data for its quarterly class allocation calculations in a given fiscal year. For example, to calculate quarterly class allocations for fiscal year 2017, the latest full calendar year was 2015.

submissions.[19] Second, FDA uses the TTB data it collected to calculate the quarterly class allocations.[20] Third, FDA calculates the user fees owed by individual manufacturers or importers within a given product class, based on their market share in each tobacco product class and the quarterly class allocation it previously calculated.[21] Fourth, FDA bills—that is, generates and mails user fee invoices to—tobacco product manufacturers and importers each quarter.[22] Fifth, FDA collects user fee payments. User fees that are not received by FDA by the last day of the quarter are considered late, and are subject to financial charges beginning 30 days past the invoice due date and for each 30-day period that the assessment remains unpaid. Figure 2 shows the steps in FDA's process to calculate, bill, and collect user fees.

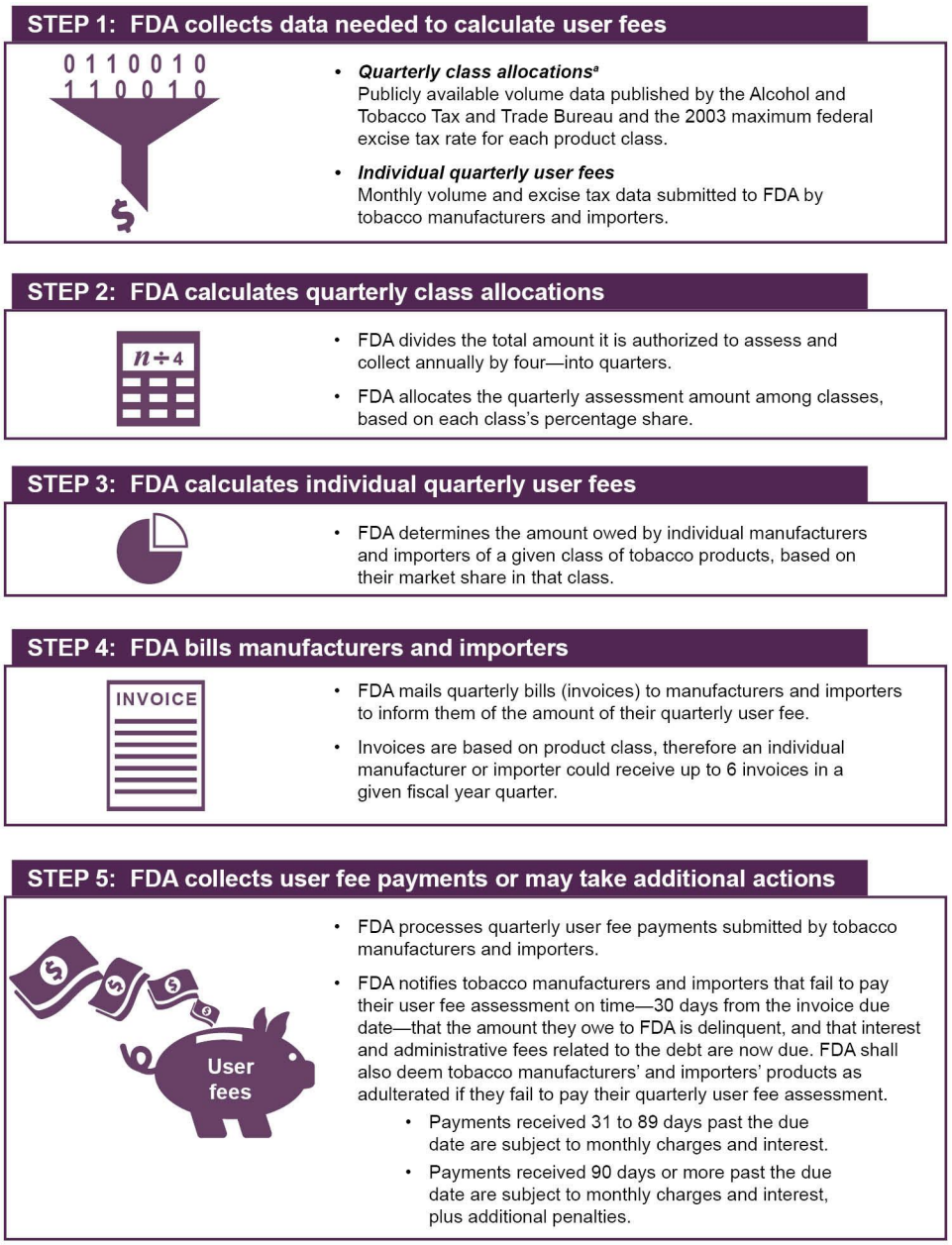
[19]FDA requires each tobacco manufacturer and importer subject to tobacco user fees to submit monthly reports to FDA. Specifically, manufacturers and importers are required to report their tobacco product removals (by class) and the amount of federal excise taxes paid for these removals on the FDA form 3852. FDA also requires manufacturers and importers to submit supporting documentation, which are certified copies of the forms submitted to TTB or U.S. Customs and Border Protection (CBP) related to their removal of tobacco products into domestic commerce and the payment of federal excise taxes imposed.

[20]According to FDA, the class allocation calculations are performed once per fiscal year. To calculate the amount allocated to each class for the quarter, FDA takes the total quarterly user fee allocation (total user fees authorized for a given year divided by four) and allocates it among the tobacco product classes based on their percentage share of the volume of tobacco products in the most recent full calendar year for which data are available. The 2003 maximum excise tax rate has been used since the start of FDA's tobacco user fee program (fiscal year 2009) to convert the volume of each tobacco product class to dollar amounts, from which the percentage share of each product class is determined. In 2014, FDA's final rule established FDA would continue to rely on the 2003 maximum excise tax rate, rather than current federal excise tax rates, as a conversion factor because it would limit changes in the tobacco user fee assessments to changes in the volume of product removed. 79 Fed. Reg. 39302, 39304 (July 10, 2014).

[21]For the cigarettes, roll-your-own tobacco, snuff, chewing tobacco, and pipe tobacco classes, FDA calculates individual market share for each manufacturer or importer by dividing the amount of federal excises taxes paid by each of them in the prior quarter by the total amount of federal excise taxes paid by all tobacco product manufacturers and importers in the same class in the prior quarter. For the cigar product class, FDA calculates individual market share for each manufacturer or importer by dividing the amount of federal excise taxes paid by each of them in the prior fiscal year by the total federal excise taxes paid by all domestic cigar manufacturers and importers in the prior fiscal year.

[22]Among other things, the invoice includes the amount of the quarterly assessment imposed and the date that user fee payments must be received by FDA.

Figure 2: Food and Drug Administration (FDA) Tobacco User Fee Calculation, Billing, and Collection Process



Source: GAO analysis of FDA documentation. | GAO-20-34

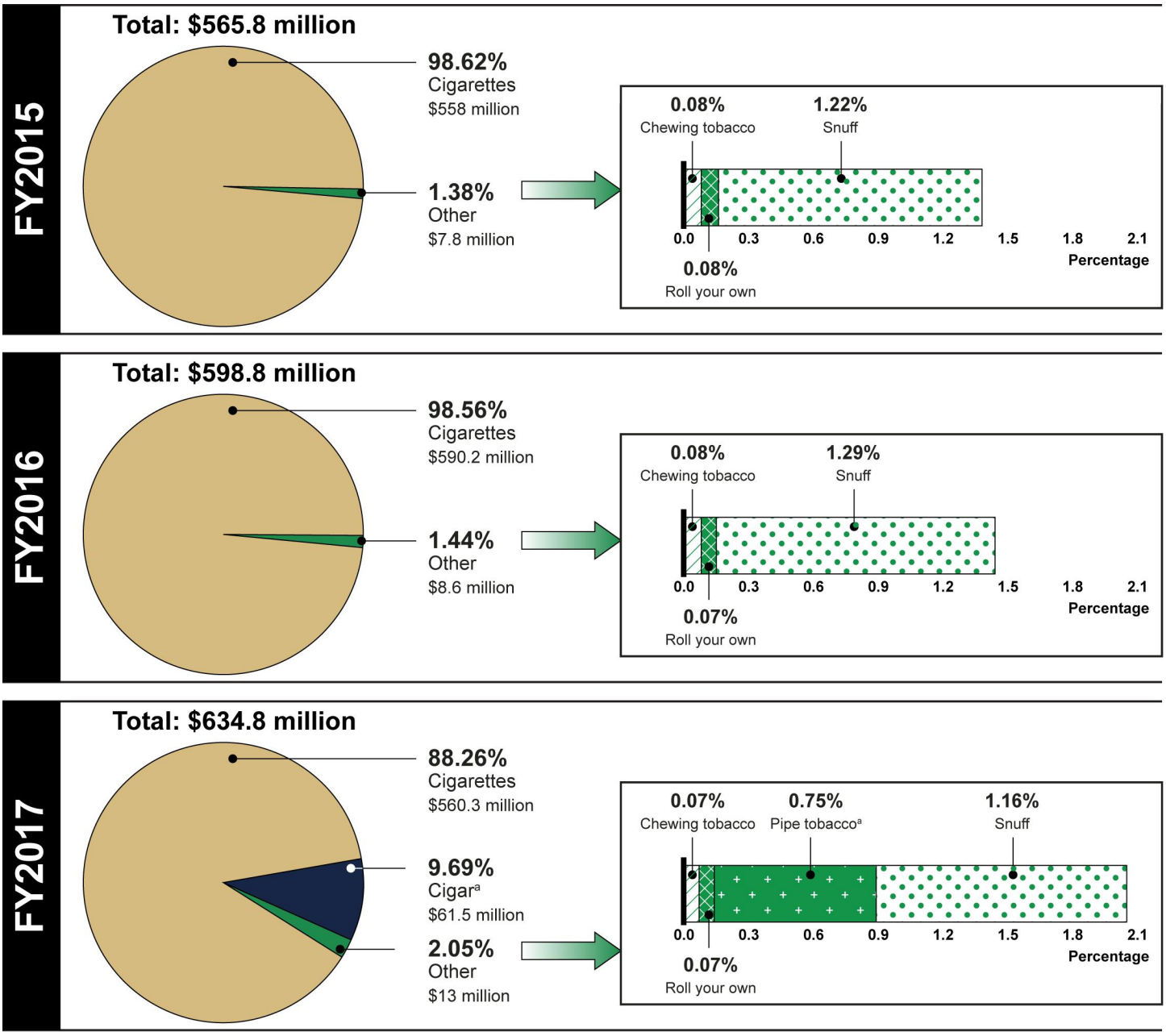
[a]According to FDA, the class allocation process is performed once per fiscal year, based on the Alcohol and Tobacco Tax and Trade Bureau data on volume (removals) for the most recent full calendar year. For example, to calculate user fees for fiscal year 2017, the most recent full calendar year was 2015. The 2003 maximum excise tax rate has been used since the start of FDA's tobacco

user fee program (fiscal year 2009) to convert the volume of each tobacco product class to dollar amounts, from which the percentage share of each product class is determined. In 2014, FDA's final rule established that FDA would continue to rely on the 2003 maximum excise tax rate, rather than the current federal excise tax rate, as a conversion factor because it would limit changes in the tobacco user fee assessments to changes in the volume of product removed. 79 Fed. Reg. 39302, 39304 (July 10, 2014).

Amount of Tobacco User Fees Assessed by Product Class

From fiscal year 2015—the first year that FDA obtained data directly from manufacturers and importers to calculate user fee assessments—through fiscal year 2017—the most recently available data at the time of our analysis—FDA assessed and collected about $1.8 billion in tobacco user fees. During this time, the vast majority of the total user fees assessed and collected each fiscal year were from manufacturers and importers of cigarettes. See figure 3 for user fees that FDA assessed, by product class, for fiscal years 2015 through 2017.

Figure 3: Amount and Percentage of Total Tobacco User Fees Assessed, by Product Class, Fiscal Years 2015 through 2017



Source: GAO analysis of FDA data. | GAO-20-34

Data table for Figure 3: Amount and Percentage of Total Tobacco User Fees Assessed, by Product Class, Fiscal Years 2015 through 2017

FY 2015

	Total	Cigarettes	Other
FY 2015	($565.8 million total)	98.62% ($558 million)	1.38% ($7.8 million)

FY 2015 Other Product Class Breakdown

	Chewing tobacco	Roll your own	Snuff
FY 2015	0.08%	0.08%	1.22%

FY 2016

	Cigarettes	Other
FY 2016 ($598.8 million total)	98.56% ($590.2 million)	1.44% ($8.6 million)

FY 2016 Other Product Class Breakdown

Chewing tobacco	Roll your own	Snuff
0.08%	0.07%	1.29%

FY 2017

	Cigarettes	Cigar[a]	Other
FY 2017 ($634.8 million total)	88.26% ($560.3 million)	9.69% ($61.5 million)	2.05% ($13 million)

FY 2017 Other Product Class Breakdown

Chewing tobacco	Roll your own	Pipe tobacco[a]	Snuff
0.07%	0.07%	0.75%	1.16%

[a]The Food and Drug Administration (FDA) did not assess tobacco user fees on the pipe tobacco and cigar classes for fiscal years (FY) 2015 or 2016 because these product classes were not subject to FDA regulation in those years. In May 2016, FDA extended its regulatory authority to all tobacco products, including pipe tobacco and cigars, and began assessing tobacco user fees on manufacturers and importers of pipe tobacco and cigars in the first quarter of fiscal year 2017.

FDA Has A Process for Administering Tobacco User Fees but Has Not Completed a Key Activity to Ensure Completeness and Accuracy

FDA's Process Is Designed to Ensure User Fee Calculations, Billings, and Collections Are Complete, Accurate, and Timely

FDA's process is designed to ensure the quarterly user fees it calculates, bills, and collects each fiscal year are complete and accurate. This process is also designed to ensure user fee invoices are billed to tobacco manufacturers and importers in a timely manner and to help the agency ensure user fee payments are collected in a similar manner. Additionally, FDA has designed procedures to retroactively adjust its quarterly individual user fee calculations to include relevant excise tax data not reported to FDA at the time these calculations were completed. The agency's year-end reconciliation process is designed to make these adjustments to ensure that the user fees assessed for a given fiscal year are complete and accurate.

Calculation. FDA's process related to its quarterly individual user fee calculations includes procedures to ensure its individual quarterly user fee assessments are complete and accurate. Tobacco manufacturers and importers provide monthly reports to FDA on the volume of and excise taxes paid on tobacco products introduced into the U.S. market, and those data are reviewed by CTP's Office of Management for accuracy. If CTP identifies incomplete data or inaccurate reporting, it will contact the appropriate manufacturer or importer in an attempt to resolve discrepancies (e.g., differences between what the company reported to FDA and the supporting document it provided) prior to calculating individual market share for the quarterly billing cycle. However, according to agency officials, if the team is unable to resolve any discrepancies by the time it must submit market share percentages to FDA's Office of Financial Management for the quarterly billing process, it uses the potentially incomplete or inaccurate data for its market share calculations. FDA officials stated that the agency may make adjustments to individual market shares and resulting user fees based on late or amended data it receives from manufacturers and importers after that data is received. While this is an option, FDA generally relies on its year-end reconciliation

process to make all adjustments resulting from late or amended data received at one time, according to FDA officials.

Billing: FDA's process related to quarterly tobacco user fee billing includes procedures to ensure the invoices it creates for individual tobacco manufacturers and importers are complete and accurate—based on CTP's market share percentages calculated using the monthly excise tax data submitted to FDA by manufacturers and importers—and mailed in a timely manner.[23] For example, FDA's billing procedures provide for quarterly user fee assessments to be calculated automatically in FDA's Tobacco Billing Portal.

Collection: FDA's process related to the collection of quarterly tobacco user fees includes procedures to help it ensure quarterly tobacco user fee payments received are complete, accurate, and timely recorded. FDA has also designed mechanisms to identify and collect payment from tobacco manufacturers and importers who do not pay their invoices by the quarterly user fee due date (i.e., the last day of the applicable fiscal year quarter). For example, FDA has an internal system that is designed to generate alerts to warn staff of unpaid invoices that are approaching 30, 60, and 90 days past due so FDA can issue notification letters to inform the tobacco manufacturers and importers that their invoices are overdue and provide instructions for making a payment.

(See appendix II for additional information on FDA's process for the calculation, billing, and collection of tobacco user fees.)

Outside of its tobacco user fee calculation, billing, and collection cycle, FDA's procedures state that FDA will review TTB data to develop a list of current tobacco permit holders that may be subject to user fees. According to FDA officials, reviewing this list helps the agency ensure it has included all manufacturers and importers within relevant tobacco product classes in its individual quarterly user fee calculations.[24] FDA procedures state that CTP's Office of Management contacts the permit holders that have not reported monthly data to FDA, if identified, to inform them that (1) they are required to report monthly data to FDA for

[23]FDA uses monthly excise tax data for the prior quarter for the five non-cigar product classes and monthly excise data for the prior fiscal year for the cigar product class.

[24]According to FDA's procedures, TTB would provide this list quarterly to FDA at the request of staff in the FDA CTP's Office of Management.

purposes of making user fee market share calculations, and (2) the permit holder may be required to pay quarterly tobacco user fees as a result of these data.[25]

User Fee Adjustments: FDA has also designed procedures to retroactively adjust its quarterly individual user fee calculations to include relevant excise tax data that were misreported or not reported to FDA at the time these calculations were completed. Individual quarterly user fee assessments are based on the market share of manufacturers and importers within each tobacco product class. As a result, FDA needs to recalculate all individual market share percentages within a given class of tobacco products if it receives new or amended data related to the excise taxes paid by manufacturers and importers in that class, to ensure compliance with the Tobacco Control Act.[26] According to FDA's procedures, FDA may recalculate its individual quarterly market share percentages to include changes identified by late or amended data submissions from individual tobacco manufacturers and importers, and FDA will recalculate market shares to include changes identified during its year-end reconciliation process.

- **Late or amended data submissions.** According to FDA's procedures, FDA can receive data from tobacco manufacturers and importers that did not previously submit monthly data to FDA and were therefore excluded from FDA's initial quarterly market share calculations. FDA can also receive late or amended data from tobacco manufacturers and importers that previously reported incomplete or inaccurate monthly data to FDA. According to FDA, in some instances, these late or amended data are data that FDA had requested during its monthly review process, but were received after FDA completed its quarterly market share calculations. According to FDA, companies may also voluntarily provide updated reports that the company itself determined were a correction to previously submitted data.

[25]FDA officials stated that this process is generally completed on a quarterly basis; however, the officials said that FDA may not request tobacco permit holder information from TTB in the fourth quarter because it expects to receive more detailed TTB data during its year-end reconciliation process.

[26]According to the Tobacco Control Act, no manufacturer or importer of tobacco products shall be required to pay a user fee in excess of their percentage share. See 21 U.S.C. § 387s(b)(3)(B).

- **Year-end reconciliation based on annual tax records from TTB and U.S. Customs and Border Protection (CBP).** FDA's procedures state that it will make annual adjustments to user fees for each fiscal year as part of its year-end reconciliation process. FDA's procedures state that, by FDA request, TTB and CBP will provide an annual report listing the tobacco excise taxes paid by each manufacturer and importer subject to the tobacco user fee requirement. FDA officials stated that FDA submits an annual request to TTB and CBP for their records of the excise taxes paid by each tobacco permit holder in the six relevant tobacco product classes for the prior fiscal year. As of July 2019, FDA officials stated that because TTB and CBP have up to 3 years to update and finalize their data files, CTP plans to update its procedures to include two reconciliation processes for each fiscal year. According to FDA officials, the first reconciliation, the year-end reconciliation process, would begin immediately following the end of a fiscal year, and the second reconciliation would occur 3 years after that fiscal year ends.

FDA's Year-End Reconciliation Process

Following the close of each fiscal year, the Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) initiates the year-end reconciliation process by requesting official records from the Alcohol and Tobacco Tax and Trade Bureau (TTB) and U.S. Customs and Border Protection (CBP). This process is designed to ensure that the tobacco user fees assessed that year are complete—that is, that all manufacturers and importers subject to user fees were assessed user fees—and accurate—that is, that the user fees assessed each quarter were based on accurate market share information.

As designed, the year-end reconciliation includes steps for FDA to compare the information the agency used to calculate quarterly user fees with independent information obtained from TTB and CBP on the individual tobacco manufacturers and importers who paid tobacco excise taxes (to ensure FDA has a complete list of those who should pay user fees) and the amounts paid (to ensure FDA used the right amounts to calculate market share and user fees).

Source: GAO analysis of FDA documents. | GAO-20-34

According to FDA officials, the year-end reconciliation is designed to identify and make any needed corrections to its individual market share calculations based on findings of new, amended, or missing excise tax payments using the annual tax data provided by TTB and CBP (see sidebar). For example, FDA officials stated that FDA will use the data obtained from TTB and CBP to help identify tobacco manufacturers or importers that should have been assessed user fees but were not, due to the companies not reporting monthly data to FDA as required (non-reporters). This process also enables FDA to identify and address fraudulent reporting by tobacco manufacturers and importers who knowingly failed to submit or submitted false information in monthly forms sent to FDA.

If FDA recalculates its quarterly market share percentages based on findings of new or amended excise tax data, FDA's procedures specify that FDA will then make necessary adjustments to individual tobacco user fee assessments. FDA officials stated that FDA can apply necessary market share adjustments to individual user fee assessments in a subsequent quarterly invoicing cycle, or after the agency completes its year-end reconciliation process based on annual tax data from TTB and CBP. According to FDA officials, in order to limit the need to re-invoice companies multiple times outside of the regular billing cycle, FDA prefers to send the adjusted invoices out once the year-end reconciliation process is complete. However, the officials stated that they can make changes outside of the year-end reconciliation. For example, the officials reported making adjustments to individual user fee assessments for the

cigar class once, for the first quarter of fiscal year 2017. In that instance, after receiving updated reports from two cigar companies that had initially reported incorrect excise tax data to FDA, FDA officials stated that the agency (1) recalculated the market share of cigar manufacturers and importers based on the amended data FDA received from both companies and (2) made necessary adjustments to the market share percentages and associated user fees for that class for that quarter.

FDA Has Not Completed Its Year-End Reconciliation Process to Ensure User Fees Are Based on Complete and Accurate Data since Fiscal Year 2015

According to FDA, the agency has not completed its year-end reconciliation process since completing the reconciliation for fiscal year 2015—the first year that FDA obtained data directly from manufacturers and importers to calculate user fee assessments. FDA designed the year-end reconciliation process to ensure the agency's individual user fee calculations are based on complete and accurate data and accurately reflect the market share of each tobacco manufacturer and importer. FDA procedures state that FDA will conduct an annual adjustment for each fiscal year using data received from TTB and CBP for individual manufacturers and importers.

According to FDA officials, the agency has been unable to complete the reconciliation process for fiscal years 2016 through 2018 because it identified problems with the quality of data it had initially received from TTB and CBP for those years.[27] FDA officials stated that the agency has worked with TTB and CBP, and officials believe they have determined the reasons for the data problems. Specifically, FDA officials said that changes in both the TTB and CBP internal data systems affected the data fields that FDA needs to complete the reconciliation process.

As of July 2019, FDA officials had received revised excise tax and volume data for fiscal years 2016 and 2017 from CBP and TTB. They also received revised 2018 data from CBP and had requested, but not yet

[27]According to FDA, the agency identified discrepancies in these data, including cases in which the excise tax data manufacturers and importers provided to FDA in their monthly reports were not included in the TTB data. Additionally, FDA stated that the fiscal year 2016 and 2017 data CBP initially provided showed some manufacturers and importers with tobacco products entering the U.S. market without corresponding excise tax payment amounts.

received, revised 2018 data from TTB. FDA officials said that once they have received the remaining 2018 data and determined that the data from both agencies are of sufficient quality, they will be able to perform the annual reconciliation process for those fiscal years.

According to FDA officials, before they can be certain the data are of sufficient quality, the agency needs to modify its internal data system to accommodate a new CBP data format, and then run the data through the updated system. As of July 2019, FDA projects these modifications to its data system will be completed by the end of calendar year 2019. Once the modifications are finished, FDA projects it will complete the reconciliation process for fiscal year 2016 within 3 to 6 months, and then complete the reconciliation for fiscal years 2017 and 2018 in 3- to 6-month intervals consecutively after that.

While FDA has identified the steps to perform the year-end reconciliation process for fiscal years 2016 through 2018, it could also face delays in the future, because it does not have reasonable assurance that it will receive quality data from TTB and CBP in a timely manner to complete the reconciliation process for future years. According to FDA officials, their efforts to obtain the data they need from TTB and CBP have focused on fiscal years 2016 through 2018, and they have not determined procedures or time frames for obtaining data from TTB and CBP for future years. However, according to FDA officials, the agency was considering possible actions for obtaining data in future years. One possible option the agency was exploring was the possibility of FDA gaining direct access to CBP's and TTB's data systems to obtain the data needed for the year-end reconciliation. According to officials, as of July 2019, CBP had offered this direct access to its data, and the officials expect to pursue this option with TTB officials for similar access. In addition, the agency reported efforts to schedule meetings with TTB and CBP to discuss establishing memorandums of understanding, or other written agreements, that would establish expectations—such as time frames and data format—with the agencies to obtain the quality data needed for the year-end reconciliation.

As of September 2019, FDA reported it had scheduled a meeting with CBP officials and was working to schedule a meeting with TTB officials, but the agency had not yet determined procedures or time frames for obtaining the needed data from these agencies for future years. Federal internal control standards call for agencies to use quality information to

achieve their objectives.[28] As part of this standard, agencies obtain relevant data from reliable sources in a timely manner and process these data into quality information that supports their internal control system. Federal internal control standards also call for agencies to externally communicate the quality information necessary to achieve its objectives. As part of this standard, agencies communicate quality information externally through reporting lines so that external parties can help the entity achieve its objectives and address related risks. For example, information communicated includes significant matters relating to risks, changes, or issues that impact the agency's internal controls. Consulting with TTB and CBP, determining procedures and time frames for FDA to receive the quality data it needs in future years, and documenting them in a written agreement would help to address this risk. Without completing the year-end reconciliation process in a timely manner, FDA cannot ensure that the data it uses to calculate individual user fees are complete and accurate. Until it works with TTB and CBP and resolves this issue, FDA is at increased risk that user fees may not be properly assessed on individual tobacco manufacturers and importers based on their market share of each tobacco product class.

Conclusions

FDA collects user fees from tobacco manufacturers and importers for its tobacco regulation activities—including important activities such as educating the public about the risks associated with the use of tobacco products and preventing youth use of these products. The agency has designed a process with several steps for assessing these fees, including a year-end reconciliation, to ensure that the calculations are complete and accurate—that is, that all companies subject to user fees pay them, and that no companies are assessed fees in excess of their market share. However, for several years, FDA has faced serious delays obtaining the quality data it needs from TTB and CBP to complete the year-end reconciliations, according to FDA. Until FDA consults with these agencies to determine and document the procedures and time frames that will allow FDA to obtain the quality data it needs to complete this key step in a timely manner, the agency risks repeating these delays. Without performing its year-end reconciliation, FDA is at increased risk of allowing some companies—such as those who did not report information to FDA

[28]GAO/AIMD-00-21.3.1 and GAO-14-704G.

or who did not report accurate information—to not pay their required share of user fees, while other companies pay too much.

Recommendation for Executive Action

The Commissioner of FDA should consult with TTB and CBP to determine and document—for example in Memorandums of Understanding or other written agreements—procedures and time frames for FDA to receive quality data from TTB and CBP that will allow FDA to complete its reconciliation process in a timely manner. (Recommendation 1)

Agency Comments

We provided a draft of this product to HHS for comment. In its comments, reproduced in appendix III, HHS generally agreed with our recommendation. The agency commented that it recognized GAO's thorough review of FDA's tobacco user fee program and stated that it is critically important for FDA to have a tobacco user fee collection program that is accurate, complete, and predictable. FDA also stated that it has prioritized making the necessary enhancements to its internal data system to accommodate the new format of TTB and CBP data files, and that these changes are on track to be completed by the end of 2019.

HHS also provided technical comments, which we 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 to the appropriate congressional committees, the Secretary of Health and Human Services, FDA Commissioner, and other interested parties. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

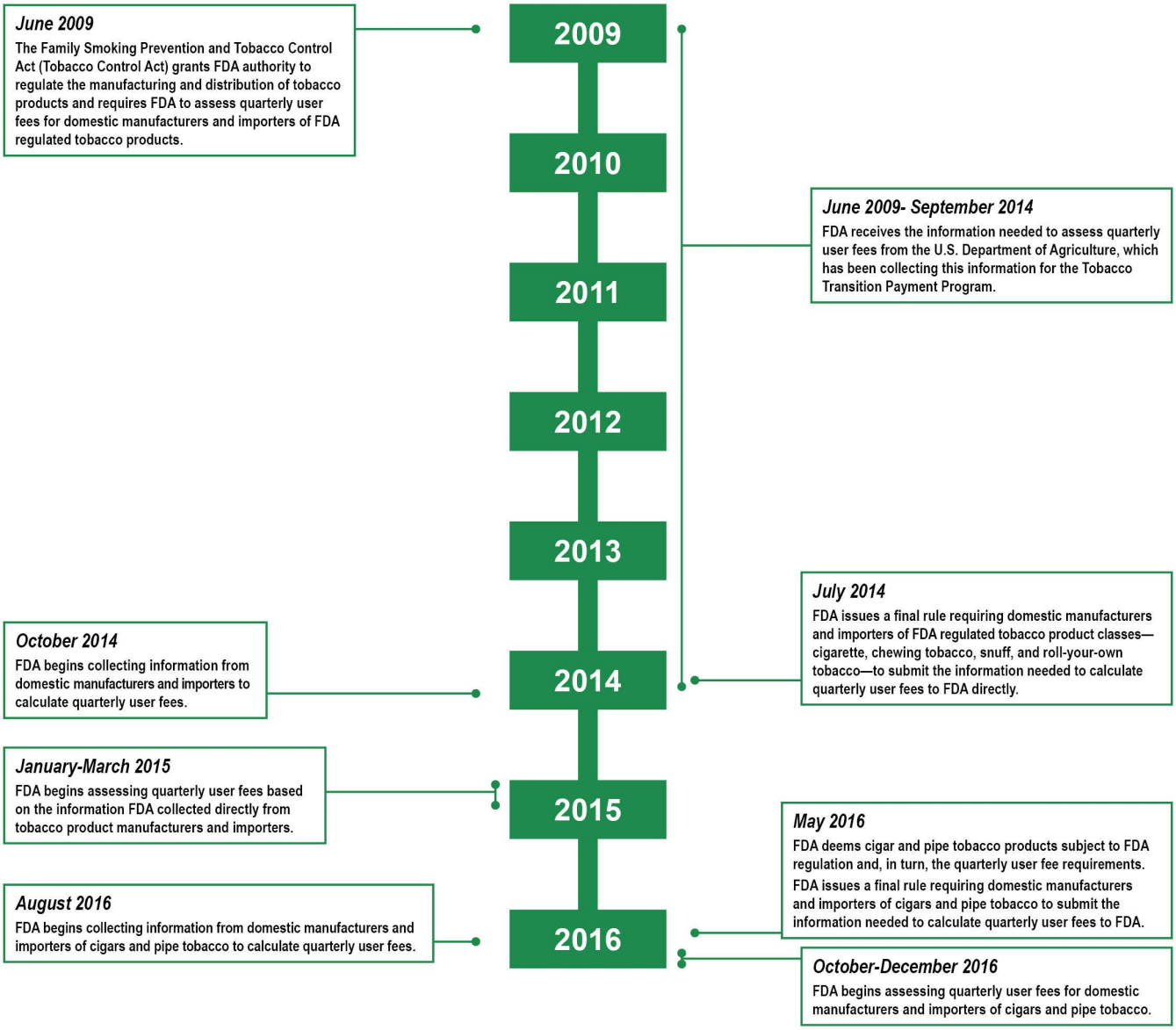
If you or your staff have any questions about this report, please contact me at (202) 512-7114 or DeniganMacauleyM@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are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

Sincerely yours,

Mary Denigan-Macauley
Director, Health Care

Appendix I: Timeline of Events Related to Food and Drug Administration Tobacco Product User Fees

Figure 4: Timeline of Events Related to Food and Drug Administration (FDA) Tobacco Product User Fees



Source: GAO analysis of FDA documentation, regulations, and statutes. | GAO-20-34

Appendix II: Additional Information on FDA's Process Related to Tobacco User Fee Calculation, Billing, and Collection

This appendix provides additional information on the Food and Drug Administration's (FDA) process, which is designed to ensure the quarterly user fees it calculates, bills, and collects each fiscal year are complete and accurate and that user fee invoices are billed to and collected from tobacco manufacturers and importers in a timely manner.

Calculation. FDA's process related to its quarterly user fee calculations include procedures to ensure the tobacco product class and individual manufacturer and importer allocations are accurate. According to FDA's procedures, at the start of each fiscal year, FDA Office of Financial Management, Division of User Fees staff (1) calculate the percentage share for each tobacco product class and (2) enter these percentage shares into FDA's User Fee System, which automatically calculates quarterly class allocations for each tobacco class.[1] According to FDA officials, FDA's Office of Financial Management, Division of User Fees staff, as well as Center for Tobacco Products's (CTP) Office of Management, User Fee Management Team staff, review the class allocation calculations to verify the percentage shares were accurately calculated for each tobacco product class before entering the class

[1]To calculate the percentage share, division staff use annual data published by the Alcohol and Tobacco Tax and Trade Bureau (TTB) on the total volume of tobacco products removed into the domestic market for each tobacco product class and applicable maximum 2003 federal excise tax rates.

percentages into FDA's User Fee System.[2] Prior to calculating individual market share percentages that are the basis for individual user fees, the User Fee Management Team within CTP's Office of Management reviews the monthly data reported to FDA by tobacco manufacturers and importers for accuracy. According to FDA's procedures, the CTP User Fee Management Team checks to ensure that the volume and excise tax data reported on each FDA form 3852 are accurate based on the accompanying supporting documents.[3] According to FDA procedures, if the CTP User Fee Team identifies incomplete or inaccurate monthly reports, it contacts the appropriate tobacco manufacturers or importers to request the missing documentation or an amended FDA form 3852 and tries to resolve any inaccuracies prior to calculating individual market share for the quarterly billing cycle.

Billing. According to FDA's procedures, the CTP User Fee Management Team submits market share percentages to the FDA Office of Financial Management, Division of User Fees in the month prior to the date that invoices are to be issued. For example, for the first quarterly invoicing cycle (October through December), the CTP User Fee Management Team would submit market share percentages on November 15 and invoices would be mailed by the Division of User Fees by December 1. Using the market share data, the Division of User Fees calculates the quarterly user fee amount assessed to individual manufacturers and importers within each tobacco product class as part of its quarterly invoicing process.[4] FDA officials stated that, prior to creating quarterly

[2]According to FDA officials, quarterly class allocation calculations are completed by an FDA Office of Financial Management budget analyst. To verify the quarterly class percentage shares were accurately calculated, FDA officials stated that a lead budget analyst will perform the same class allocation calculations—using the same published TTB removal data and 2003 federal excise tax rates—to ensure that the results match. We conducted our own quarterly class allocation calculations for fiscal year 2017, and our calculations matched FDA's calculations.

[3]We reviewed the data the agency used to calculate tobacco user fees for the fourth quarter, fiscal year 2017 and found the excise tax amounts reported by tobacco manufacturers and importers on their FDA form 3852s matched the amounts the agency used to calculate tobacco user fees for that quarter. We also tested FDA's calculation of the quarterly tobacco user fees for each unique tobacco manufacturer and importer for the fourth quarter, fiscal year 2017 and found the percentages and amounts we calculated matched the percentages and amounts FDA calculated for that quarter. These steps are completed for the quarterly user fee assessments before the year-end reconciliation process.

[4]According to FDA's billing procedures, quarterly user fee assessments are calculated automatically in FDA's Tobacco Billing Portal.

invoices, the Division of User Fees reviews CTP market share data to ensure it received all necessary data.[5] Prior to mailing quarterly invoices to individual tobacco manufacturers and importers, FDA officials stated that division staff verifies that the invoices created are complete and accurate by comparing the invoice information to the CTP market share data.[6]

Collection. FDA's Office of Financial Management, Division of User Fees utilizes different mechanisms to identify and notify tobacco manufactures and importers who do not pay their invoices by the quarterly user fee due date (i.e., the last day of the applicable fiscal year quarter).

- According to FDA's procedures, the Division of User Fees uses a program within FDA's User Fee System—referred to as the Dunning Tracker—to track relevant invoice data, including the date user fee payments are due and the amounts owed. The Dunning Tracker is designed to generate alerts to warn division staff of unpaid invoices that are approaching 30, 60, and 90 days past due so they can issue Dunning notification letters—which inform the tobacco manufacturers and importers that their invoices are overdue and provide instructions for making a payment. The Dunning notification letters also inform tobacco manufacturers and importers of the amount of additional charges assessed based on the number of days that the payment is late.[7] According to FDA officials, division staff verify that a Dunning notification letter is issued for each tobacco manufacturer or importer with an outstanding invoice and that the appropriate charges have been assessed.[8]

[5]We reviewed FDA's procedures to determine whether the key duties and responsibilities related to calculating, billing, and collecting tobacco user fees are adequately divided among different FDA offices. Nothing came to our attention that the agency's processes, as designed, are inadequate or ineffective in meeting the relevant provisions of the Tobacco Control Act for FDA to assess and collect tobacco user fees.

[6]We compared the amounts on FDA's tobacco user fee invoices to the amounts the agency calculated for the fourth quarter, fiscal year 2017, and found the amounts were consistent.

[7]Starting at 30 days past due, invoices are assessed administrative fees and interest and at 90 days past due additional financial penalties are added.

[8]We reviewed the 30, 60, and 90 day Dunning notification letters FDA sent to 26 unique tobacco manufacturers and importers with unpaid invoices that were at least 90 days past due—as of the fourth quarter, fiscal year 2017—and found that, for the invoices we reviewed, FDA followed its procedures related to notifying manufacturers and importers with outstanding invoices (starting at 30 days past due).

- According to FDA officials, the Division of User Fees also maintains an arrears list—a list of tobacco manufacturers and importers who have not paid their quarterly user fees on time. FDA's procedures provide that the Division of User Fees will share the arrears list with the CTP Office of Compliance and Enforcement to assist that office's efforts to obtain compliance with the user fee requirements. FDA officials stated that the office monitors the arrears list and takes enforcement action when appropriate. The officials said that the office will first issue information letters, separate from the Dunning notification letters, to each tobacco manufacturer and importer on the arrears list to try to obtain voluntary compliance on the user fee payments owed.[9] FDA officials stated that if the office is unable to obtain compliance after it issues the information letter, it may take further action, such as notifying the delinquent company that all tobacco products manufactured and imported by it are adulterated.[10] Agency officials told us that, in 2014, FDA notified three individual tobacco manufacturers that all the tobacco products they manufactured were adulterated due to these companies' failure to pay their tobacco user fees.

According to FDA's procedures, the Division of User Fees refers delinquent debt to the Department of Health and Human Services (HHS) Program Support Center when outstanding invoices reach 90 days past due.[11] The Program Support Center will pursue collection efforts per its standard procedures and issues two reports each month to the Division of User Fees to inform it of which debts have been collected and which are uncollectable.[12]

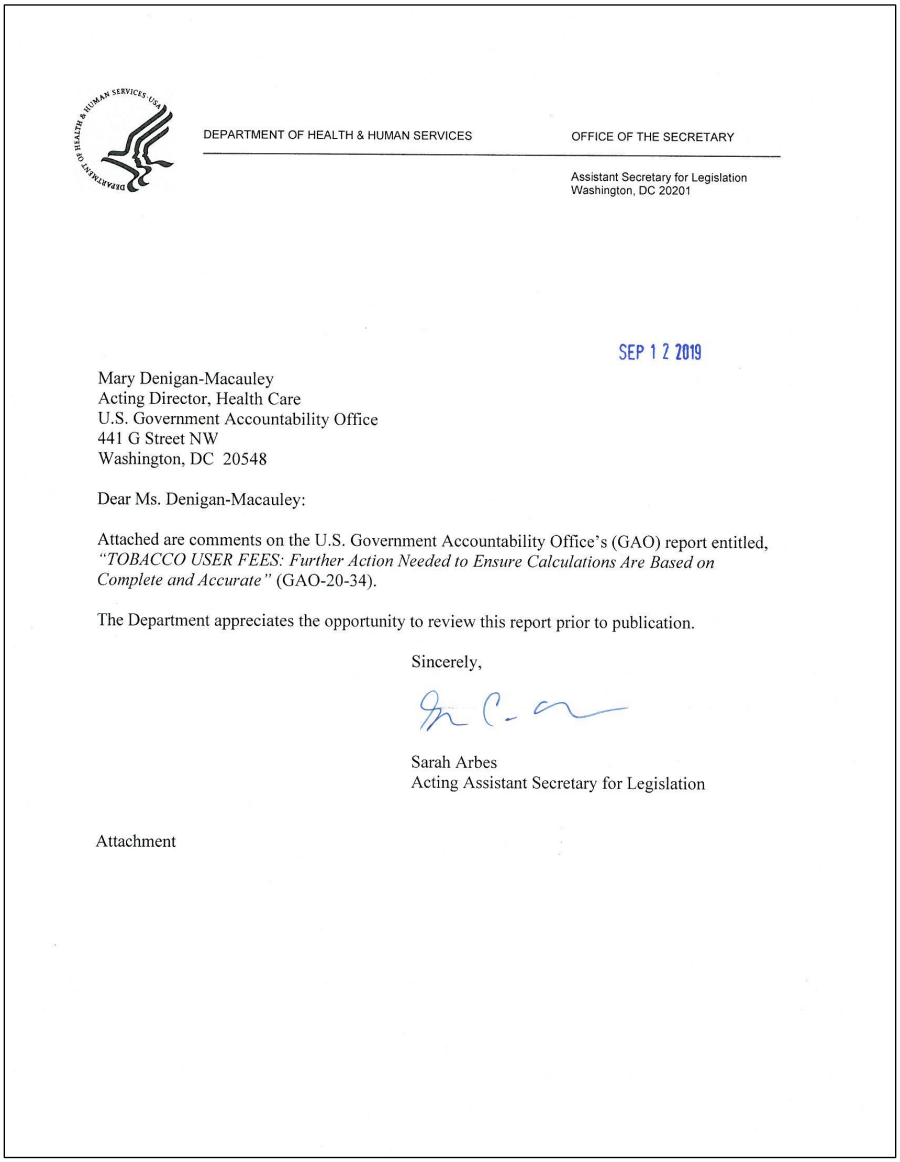
[9]According to FDA officials, the Dunning notification letter informs tobacco manufacturers and importers with outstanding invoices that they are required to pay their user fee.

[10]When a tobacco product is deemed adulterated, it is illegal to distribute the product in interstate commerce or import the product into the United States. 21 U.S.C. §§ 387b(4) and 331(a).

[11]FDA officials stated that the Program Support Center is a Treasury-designated debt collection center hosted by HHS that provides a full range of debt management and collection services.

[12]According to FDA officials, a debt is deemed uncollectable if it is returned from the Department of Treasury due to bankruptcy or other reasons.

Appendix III: 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

SEP 12 2019

Mary Denigan-Macauley
Acting Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Denigan-Macauley:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, *"TOBACCO USER FEES: Further Action Needed to Ensure Calculations Are Based on Complete and Accurate"* (GAO-20-34).

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

Sincerely,

Sarah Arbes
Acting Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED - TOBACCO USER FEES – FURTHER ACTION NEEDED TO ENSURE CALCULATIONS ARE BASED ON COMPLETE AND ACCURATE DATA (GAO-20-34)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

Recommendation 1

The Food and Drug Administration (FDA) consult with the Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB) and the U.S. Customs and Border Protection (CBP) to determine and document procedures for FDA to obtain quality data so the agency can complete its annual reconciliation process in a timely manner.

HHS Response

HHS concurs with GAO's recommendation and recognizes GAO's thorough review of FDA's tobacco user fee program. It is critically important for FDA to have a tobacco user fee collection program that is accurate, complete, and predictable. The program is designed specifically to assess fees based on the market share of each manufacturer and importer, and to ensure no manufacturer or importer are assessed fees in excess of their market share. As noted in the report, GAO reviewed all of FDA's procedures related to FDA's calculation, billing, and collection of tobacco user fees from tobacco manufacturers and importers, as well as internal controls of the process.

GAO's review included a thorough analysis of data reported by industry to the FDA against the data that was utilized to calculate the quarterly tobacco market share percentages for the fourth quarter of fiscal year 2017 to validate the calculations were correct; GAO found no discrepancies during this review and all calculations matched those completed by GAO. GAO also conducted a review of the calculations FDA made for the quarterly class allocations of a specific fiscal year and found no errors in the FDA's calculation. GAO also reviewed the amounts the agency billed as they related to the market share calculations and found that the agency properly billed the tobacco product manufacturers and importers.

FDA has many internal controls to ensure that each quarterly market share percentage calculated is accurate prior to assessing and invoicing industry. The following are examples of these controls.

- FDA carefully inspects each monthly report received from industry to ensure that all required documentation is provided. Should the submission be incomplete, the FDA contacts the manufacturer or importer to obtain the necessary information.
- FDA staff enter monthly report data into an electronic application which conducts an immediate analysis of all data fields required for calculation of quarterly market share percentages and alerts the FDA staff of errors that need to be reconciled.
- FDA utilizes the electronic application to generate reports to identify what tobacco industry permit holders are required to report to FDA and identifies those who have not

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED - TOBACCO USER FEES – FURTHER ACTION NEEDED TO ENSURE CALCULATIONS ARE BASED ON COMPLETE AND ACCURATE DATA (GAO-20-34)

met this requirement; FDA staff then contact these companies to request the missing information. In addition, FDA works with TTB staff throughout the year to obtain reports of tobacco permit status changes to update our internal records of whom is required to report to the FDA for purposes of calculating quarterly tobacco user fees.

- FDA makes the appropriate adjustments to previously calculated tobacco market share percentages if a monthly report is received late, after the quarterly tobacco market share percentage calculation, which would substantively impact the market share calculations and issues adjusted invoices as necessary.

FDA has processes in place to encourage industry to submit complete, accurate, and timely reports to the Agency so that our initial assessments are correct. The FDA Tobacco User Fee Reporting Form (FDA 3852) also includes language indicating that under section 1001 of title 18, anyone who makes a materially false, fictitious or fraudulent statement is subject to criminal penalties.

In its conclusion and recommendation, GAO emphasized the need for FDA to obtain quality data to complete the annual reconciliation process in a timely manner. FDA has been partnering with TTB and CBP to obtain the necessary data to complete the reconciliation process. FDA, TTB and CBP have experienced challenges over the past several years that were a result of information technology system upgrades at TTB and CBP as well as staff turnover in those agencies. TTB and CBP, however, have been engaged with FDA to identify alternative methods to provide FDA with the necessary data; the data that is being requested is complex and requires an intricate understanding of the data fields.

Since FDA's last engagement with GAO in July 2019, the FDA has scheduled a face-to-face meeting with CBP and is actively working with TTB to do the same. The purpose of these meetings is to clearly outline FDA's data requirements, including timeframe expectations, and document specific processes and procedures for FDA, CBP, and TTB. FDA's goal is to document the outcome of these meetings in written agreements with each agency. FDA plans to propose including very clear expectations for timelines, step-by-step procedures, precise data fields to meet FDA's needs, and a plan to minimize the impact of any future CBP and TTB system changes.

In line with GAO's recommendation, FDA has already updated the user fee program SOP and the Tobacco User Fee Application (TUFA) training guide to reflect the specific timeframes for requesting the one-year and three-year data for completing the true-up process. FDA is prioritizing the necessary enhancements to the Tobacco User Fee Application (TUFA) and are working with our contractors to implement the changes as soon as possible to accommodate the new format of exported TTB and CBP data files; these changes remain on track to be completed by the end of calendar year 2019.

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED - TOBACCO USER FEES – FURTHER ACTION NEEDED TO ENSURE CALCULATIONS ARE BASED ON COMPLETE AND ACCURATE DATA (GAO-20-34)

FDA is committed to maintaining the reliability and integrity of our tobacco user fee program. This includes the partnership efforts with TTB and CBP to ensure more predictable timeframes for executing the annual reconciliation process.

Text of Appendix III: Comments from the Department of Health and Human Services

Page 1

Mary Denigan-Macauley Acting Director, Health Care

U.S. Government Accountability Office

441 G Street NW Washington, DC 20548

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Sincerely,

Sarah Arbes

Acting Assistant Secretary for Legislation

Attachment

Page 2

GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED - TOBACCO USER FEES – FURTHER ACTION NEEDED TO ENSURE CALCULATIONS ARE BASED ON COMPLETE AND ACCURATE DATA (GAO-20-34)

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Recommendation 1

The Food and Drug Administration (FDA) consult with the Department of the Treasury's Alcohol and Tobacco Tax and Trade Bureau (TTB) and the U.S. Customs and Border Protection (CBP) to determine and document procedures for FDA to obtain quality data so the agency can complete its annual reconciliation process in a timely manner.

HHS Response

HHS concurs with GAO's recommendation and recognizes GAO's thorough review of FDA's tobacco user fee program. It is critically important for FDA to have a tobacco user fee collection program that is accurate, complete, and predictable. The program is designed specifically to assess fees based on the market share of each manufacturer and importer, and to ensure no manufacturer or importer are assessed fees in excess of their market share. As noted in the report, GAO reviewed all of FDA's procedures related to FDA's calculation, billing, and collection of tobacco user fees from tobacco manufacturers and importers, as well as internal controls of the process.

GAO's review included a thorough analysis of data reported by industry to the FDA against the data that was utilized to calculate the quarterly tobacco market share percentages for the fourth quarter of fiscal year 2017 to validate the calculations were correct; GAO found no discrepancies during this review and all calculations matched those completed by GAO. GAO also conducted a review of the calculations FDA made for the quarterly class allocations of a specific fiscal year and found no errors in the FDA's calculation. GAO also reviewed the amounts the agency billed as they related to the market share calculations and found that the agency properly billed the tobacco product manufacturers and importers.

FDA has many internal controls to ensure that each quarterly market share percentage calculated is accurate prior to assessing and invoicing industry. The following are examples of these controls.

- FDA carefully inspects each monthly report received from industry to ensure that all required documentation is provided. Should the submission be incomplete, the FDA contacts the manufacturer or importer to obtain the necessary information.

- FDA staff enter monthly report data into an electronic application which conducts an immediate analysis of all data fields required for calculation of quarterly market share percentages and alerts the FDA staff of errors that need to be reconciled.

- FDA utilizes the electronic application to generate reports to identify what tobacco industry permit holders are required to report to FDA and identifies those who have not

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met this requirement; FDA staff then contact these companies to request the missing information. In addition, FDA works with TTB staff throughout the year to obtain reports of tobacco permit status changes to update our internal records of whom is required to report to the FDA for purposes of calculating quarterly tobacco user fees.

- FDA makes the appropriate adjustments to previously calculated tobacco market share percentages if a monthly report is received late, after the quarterly tobacco market share percentage calculation, which would substantively impact the market share calculations and issues adjusted invoices as necessary.

FDA has processes in place to encourage industry to submit complete, accurate, and timely reports to the Agency so that our initial assessments are correct. The FDA Tobacco User Fee Reporting Form (FDA 3852) also includes language indicating that under section 1001 of title 18, anyone who makes a materially false, fictitious or fraudulent statement is subject to criminal penalties.

In its conclusion and recommendation, GAO emphasized the need for FDA to obtain quality data to complete the annual reconciliation process in a timely manner. FDA has been partnering with TTB and CBP to obtain the necessary data to complete the reconciliation process. FDA, TTB and CBP have experienced challenges over the past several years that were a result of information technology system upgrades at TTB and CBP as well as staff turnover in those agencies. TTB and CBP, however, have been engaged with FDA to identify alternative methods to provide FDA with the necessary data; the data that is being requested is complex and requires an intricate understanding of the data fields.

Since FDA's last engagement with GAO in July 2019, the FDA has scheduled a face-to-face meeting with CBP and is actively working with TTB to do the same. The purpose of these meetings is to clearly outline FDA's data requirements, including timeframe expectations, and document specific processes and procedures for FDA, CBP, and TTB. FDA's goal is to document the outcome of these meetings in written agreements with each agency. FDA plans to propose including very clear expectations for timelines, step-by-step procedures, precise data fields to meet FDA's needs, and a plan to minimize the impact of any future CBP and TTB system changes.

In line with GAO's recommendation, FDA has already updated the user fee program SOP and the Tobacco User Fee Application (TUFA) training guide to reflect the specific timeframes for requesting the one-year and three-year data for completing the true-up process. FDA is prioritizing the necessary enhancements to the Tobacco User Fee Application (TUFA) and are working with our contractors to implement the changes as soon as possible to accommodate the new format of exported TTB and CBP data files; these changes remain on track to be completed by the end of calendar year 2019.

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FDA is committed to maintaining the reliability and integrity of our tobacco user fee program. This includes the partnership efforts with TTB and CBP to ensure more predictable timeframes for executing the annual reconciliation process.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Mary Denigan-Macauley (202) 512-7114 or DeniganMacauleyM@gao.gov

Staff Acknowledgments

In addition to the contact named above, Kim Yamane (Assistant Director), Matthew Byer (Analyst in Charge), Sam Amrhein, Julie Flowers, Jackie Hamilton, Derry Henrick, Vikki Porter, and LaDonna Towler made key contributions to this report.

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