U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
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FDA Oversight of Tobacco Manufacturing Establishments

RESULTS AT A GLANCE

The Tobacco Control Act authorized FDA to regulate domestic tobacco manufacturers beginning in 2009. To monitor the Tobacco Control Act's implementation, OIG analyzed registration and inspection data for tobacco manufacturing facilities from 2010 to 2015. We found:

- **In the first 6 years that FDA was authorized to regulate tobacco, 171 tobacco establishments registered with it.**
- **Cigarettes account for two-thirds of the consumer-use tobacco products that registrants listed.**
- **FDA largely met its requirement to inspect tobacco establishments biennially.**
- **FDA concluded that no enforcement action was needed after its inspections of manufacturing establishments.**
- **FDA issued 14 warning letters to manufacturers—mostly for violations of advertising and labeling—as a result of its surveillance of tobacco marketing.**

Smoking is the leading cause of preventable disease and death in the United States, responsible for more than 480,000 deaths annually.[1] Until 2009, tobacco products were largely exempt from Federal oversight. That year, Congress passed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which authorized the Food and Drug Administration (FDA) to begin regulating tobacco products in the United States.[2] The Tobacco Control Act granted FDA comprehensive authority over domestic tobacco products and established the Center for Tobacco Products (CTP) at FDA to oversee the manufacturing, distribution, and marketing of these products.[3] User fees from tobacco manufacturers and importers are the sole source of funding for FDA's regulation of tobacco products.

CTP's goal is to reduce harm from all regulated tobacco products by preventing people from starting to use tobacco products, encouraging tobacco users to quit, and reducing the adverse health impacts for those who continue to use tobacco products.[4] Toward this goal, CTP and FDA's Office of Regulatory Affairs (ORA) collaborate in the oversight of tobacco manufacturers.

FDA has a wide range of tools to meet its goals, including the ability to set policy and issue guidance; to regulate the production and

distribution of tobacco products; to conduct research; and to educate the public on the effects of regulated tobacco products.[5]

On August 8, 2016, FDA's jurisdiction expanded to include additional tobacco products such as electronic nicotine delivery systems (e.g., e-cigarettes and vape pens), cigars, hookah tobacco, and nicotine gels.[6]

Our work focuses on FDA's efforts to regulate and oversee domestic tobacco manufacturing establishments in the early years of implementing the Tobacco Control Act (see Exhibit 1). This data brief presents descriptive information about how tobacco establishments register and provide product listings, as well as FDA's inspections and enforcement actions related to tobacco manufacturing establishments, spanning 2010 to 2015. During this timeframe, FDA required only manufacturers of cigarettes, smokeless tobacco, roll-your-own tobacco, and cigarette tobacco to register and list their products.

Exhibit 1: Focus Areas for FDA's CTP

Source: FDA, *About CTP: What CTP Does*. Accessed at http://www.fda.gov/TobaccoProducts/AboutCTP/ucm451269.htm on July 27, 2017.

The blue box indicates the CTP focus area that is the subject of this data brief.

Registration

Domestic establishments involved in the manufacturing, preparation, compounding, or processing of tobacco products in the United States must register annually with FDA.[7] Owners and operators of tobacco establishments (subsequently referred to as registrants; see the box with key terms below) may submit information to FDA using paper forms or FDA's online registration system, the FDA Unified Registration and Listing System.[8] Registrants must submit their initial registration immediately upon engaging in the manufacturing of tobacco products and reregister annually no later than December 31 of that same year.[9]

Registration must include the name and address of each establishment, as well as the name and places of business of the registrants.[10] A single registrant may register multiple establishments. Though registrants are not required to do so, they can identify the type of work that the establishment does, such as relabeling and packaging.

KEY TERMS

- **Establishment:** A place of business under one ownership at one general physical location, that is involved in the manufacturing, preparation, compounding, or processing of tobacco products.
- **Operator:** A person who has management authority over an establishment.
- **Owner:** A person who has an ownership interest in an establishment.
- **Registrant:** We use this term to refer to an **operator**, **owner**, or both.

Source: Food, Drug, and Cosmetic Act § 201(e) and FDA, *Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (Revised*)*, November 2016.

Product Listing

Registrants must provide FDA with a list of tobacco products manufactured, prepared, compounded, or processed by an establishment for commercial distribution.[11] The product listing must include all labeling and—for certain tobacco products—a representative sample of advertising for that product.[12] Registrants must also report certain changes to their product lists twice a year.[13] FDA uses product listing information to determine compliance with provisions of the law, such as requirements for packaging, labeling, and advertising. Finally, registrants must clearly identify each product listing by the product name (e.g., "Pall Mall Blue Box") and category (e.g., cigarettes, paper, filter, or smokeless tobacco).[14] For purposes of submitting product listing information, FDA distinguishes tobacco products as either "Consumer Use" (ready for consumer markets) or "For Further Manufacturing" (generally, components of unfinished tobacco products), depending on the intended use of the product. In November 2016, FDA announced its intent to enforce registration and listing requirements for finished tobacco products only.[15]

Inspections

FDA must inspect each registered establishment that manufactures, compounds, or processes tobacco products at least biennially from the date of registration.[16, 17] FDA began inspecting tobacco establishments on October 1, 2011. FDA investigators from ORA inspect tobacco establishments to ensure that they are in compliance with provisions of the Food, Drug, and Cosmetic Act and that products are not adulterated or misbranded. Provisions include but are not limited to the following: registration and product listing; ingredient listing; requirements for packaging, labeling, and advertising; and marketing authorization for certain tobacco products.[18] Although FDA has the authority to establish Good Manufacturing Practices for tobacco products, it has not yet done so.[19] Good Manufacturing Practices assure proper design, monitoring, and

control of manufacturing processes and facilities in order to protect public health. Once FDA establishes Good Manufacturing Practices for tobacco products, its investigators will also inspect for compliance with those requirements.

During these inspections, FDA reviews processes and procedures; observes and evaluates manufacturing operations; documents and collects information; identifies violations; communicates potential violations and objectionable conditions to the establishment's management; and documents any proposed corrective action plans.[20] Following an inspection, FDA issues one of three classifications based on its findings: "No Action Indicated," when the inspectors find no objectionable conditions or practices; "Voluntary Action Indicated," when findings are serious enough to record but do not require regulatory action; or "Official Action Indicated," when inspectors find significant, objectionable conditions or practices and regulatory action is warranted.

Inspection findings of significant, objectionable conditions warrant regulatory actions and receive a classification of "Official Action Indicated."

During the next routine inspection of an establishment, FDA follows up on the outcome of the actions it recommended. If FDA finds that the establishment did not address its recommendations, it may take an advisory action, such as issuing a warning letter, or it may take an enforcement action, such as imposing a civil monetary penalty, making a seizure, issuing an injunction, or launching criminal prosecution.

Surveillance

In addition to inspections, FDA conducts routine surveillance of tobacco marketing activities to ensure compliance with aspects of the Food, Drug, and Cosmetic Act. For example, a tobacco product's labeling and advertising cannot use modified risk descriptors such as "light," "mild," or "low" without an FDA order.[21] This surveillance of marketing activities includes monitoring and evaluating promotional and advertising materials. FDA may examine websites, social media, newspapers, magazines, posters, and other promotional materials. It identifies these materials through regulatory submissions made to FDA (e.g., the product labels and advertisements that manufacturers are required to submit upon registration); point-of-sale advertising and other promotional materials for tobacco products; the Internet; and complaints.[22] FDA's surveillance can result in advisory actions, such as warning letters, or enforcement actions.[23]

METHODOLOGY

We based this data brief on four data sources: (1) FDA Unified Registration and Listing System data from calendar years (CYs) 2010 through 2015; (2) data on inspections of tobacco establishments from fiscal years (FYs) 2011 through 2015; (3) enforcement action data from inspections and surveillance of tobacco marketing activity from FYs 2011 through 2015; and

(4) interviews with FDA officials. We determined the number of tobacco establishments that registered annually from 2010 through 2015 with FDA, as well as the number of products they listed.

Our analysis had some limitations. We were unable to determine the extent to which registrants listed all products, as well as whether all tobacco establishments registered as required. We did not assess the appropriateness of the enforcement actions that FDA took or did not take. We were unable to determine whether FDA precisely met the biennial inspection requirement because the data that we received from FDA did not include the month of registration. Therefore, we could determine only whether FDA inspected a tobacco establishment within the *year* that the inspection was due, rather than within the specific month.

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

RESULTS

In the first 6 years of the Tobacco Control Act's implementation, 171 tobacco establishments registered with FDA

Tobacco establishments started registering with FDA slowly, with 20 establishments registering in 2010.[24] This slow start may have resulted from initial uncertainty about registration requirements. For example, FDA acknowledged that the tobacco industry may have needed additional time to provide submissions.[25]

Tobacco establishments' annual registrations fluctuated between 2012 and 2015. Some registrants did not register their establishments annually as required, while others registered their establishments unnecessarily, according to FDA. For example, from CY 2011 through CY 2015, 29 registrants missed their annual registration at least once, and 8 missed registration for 2 years. Furthermore, the opening and closing of tobacco establishments in this time period might have contributed to the fluctuation.

Exhibit 2: Registration of Tobacco Establishments, CYs 2010–2015

Source: OIG analysis of FDA registration data, 2017.

FDA cannot determine the total number of establishments that should register each year, but FDA staff told us that they sometimes learn through other sources—such as FDA inspections and establishments' competitors—about establishments that fail to register. FDA told us that in such cases, it would take appropriate action.

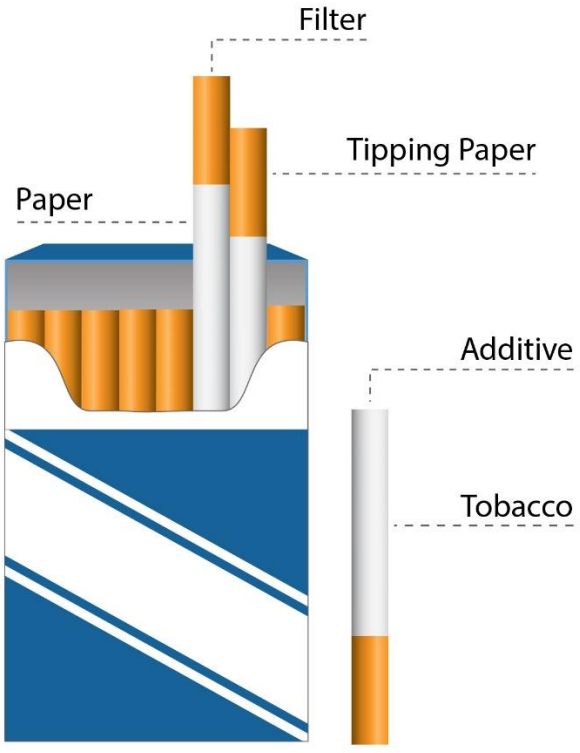
Although they are not required to do so, registrants may provide information about the type of manufacturing activities that occur at each establishment. Of the registrants that provided information since 2010, most identified their activities as manufacturing and/or storing: 39 percent listed "manufacturing" and 30 percent listed "storing." Registrants may list more than one type of production activity for a single establishment. For example, registrants may list different types of manufacturing such as blending, packaging, and labeling, indicating that the establishment is involved in many parts of the process.

Cigarettes account for two-thirds of the consumer-use tobacco products that registrants listed

As part of the registration process, registrants must submit product lists. From 2010 through 2015, registrants submitted product lists for 7,191 unique products. Product lists include components of tobacco products for further manufacturing use, such as paper and filters, as well as finished products that are for consumer use, such as cigarettes and chewing tobacco.[26] For example, a pack of cigarettes is a finished product, composed of multiple components (see Exhibit 3).

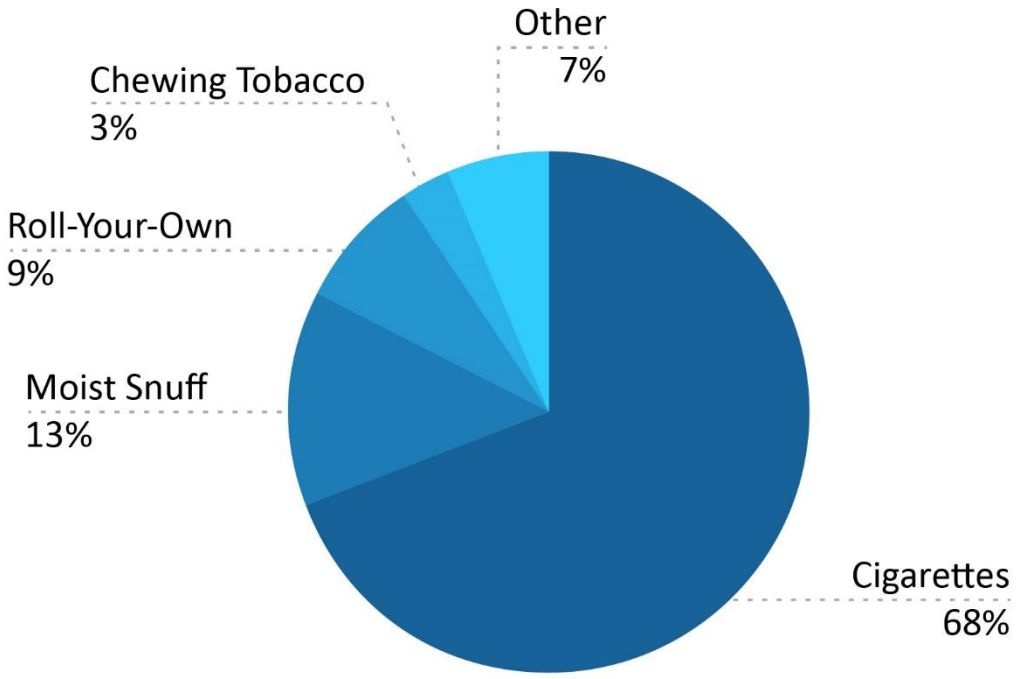
FDA can use the product lists when it inspects establishments to determine whether registrants submitted complete lists.

Exhibit 3. Example of Components of a Cigarette Pack



About three-quarters of the tobacco products listed with FDA are for consumer use. Cigarettes, moist snuff, and roll-your-own tobacco products make up 90 percent of the total number of consumer-use products. Cigarettes compose 68 percent of the total, while moist snuff and roll-your-own products compose 13 and 9 percent, respectively (see Exhibit 4).

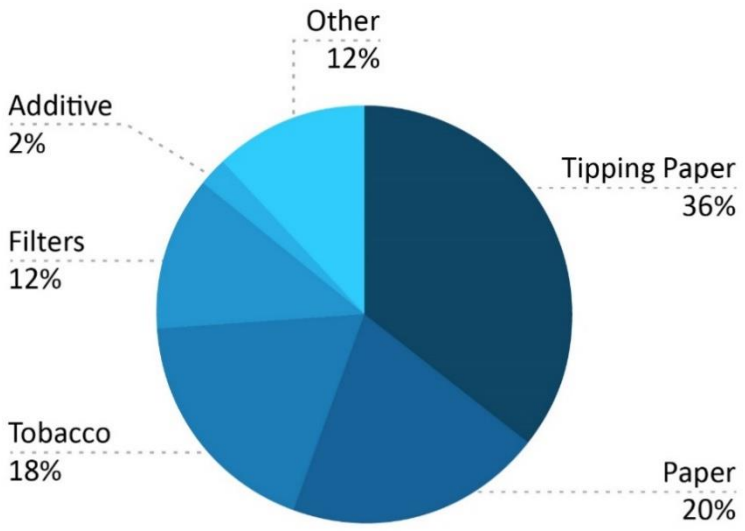
Exhibit 4. Tobacco Products for Consumer Use According to Product Lists Provided to FDA, CYs 2010–2015



Source: OIG analysis of FDA product listing data, 2016.

The remaining one-quarter of tobacco products listed with the FDA are for components of tobacco for further manufacturing. Tipping paper and paper account for over half of these products (see Exhibit 5).

Exhibit 5. Tobacco Products for Further Manufacturing According to Product Lists Provided to FDA, CYs 2010–2015



Source: OIG analysis of FDA product listing data, 2017.

FDA largely met its requirement to inspect tobacco manufacturing establishments biennially

FDA inspected 103 of the 171 registered establishments at least once between FY 2012 and 2015, meeting its inspection requirement. Three of the 171 establishments merged with other registered establishments during the time period we examined, and FDA inspected them under their new ownership, resulting in a total of 168 unique establishments. Of the 65 establishments that initially registered but were not inspected by FDA, 58 were not actively manufacturing FDA-regulated tobacco products, according to FDA, and did not require an inspection because they were not required to register. In addition, some establishments had due dates for inspections that were after the time period examined in this review. Finally, two establishments due for inspection were located on Tribal land. See Exhibit 1 in Appendix A for the reasons FDA did not inspect the 65 establishments.

The inspections included a review of registration and product listing; ingredient listing; packaging, labeling and advertising requirements; and marketing authorization for certain tobacco products.

FDA told us that it needed additional time before starting inspections of establishments that are affiliated with Tribes and located on Tribal land. These federally recognized Tribes are unique governments that required FDA to follow established government-to-government policies.[27, 28] After FDA understood its obligations with regard to Tribal governments and determined how best to meet them, it began routine biennial inspections of Tribal establishments in FY 2014. FDA split the initial Tribal inspections across

2 FYs. One of the establishments on Tribal land did not receive an inspection within those 2 FYs (FYs 2014 and 2015).

Between FY 2012 and 2015, FDA inspected 70 of the 103 establishments twice, meeting its inspection requirement. Of the remaining 33 establishments, FDA did not inspect them twice for the following reasons: the establishments were not actively manufacturing regulated tobacco products and therefore did not require an inspection; they were located on Tribal land; or they had inspection dates falling after the time period examined in this review. See Exhibit 2 in Appendix A for the reasons FDA did not inspect these 33 establishments twice. FDA conducted a total of 173 inspections.

FDA concluded that no enforcement action was needed after its inspections of manufacturing establishments

None of the 173 inspections of tobacco establishments resulted in any official action. FDA classified the results of almost all (161 of 173) of its inspections as No Action Indicated. FDA classified none as Official Action Indicated, which indicates that it did not find any instances of noncompliance severe enough to necessitate enforcement actions, such as civil monetary penalties.

No Action Indicated: No objectionable conditions or practices

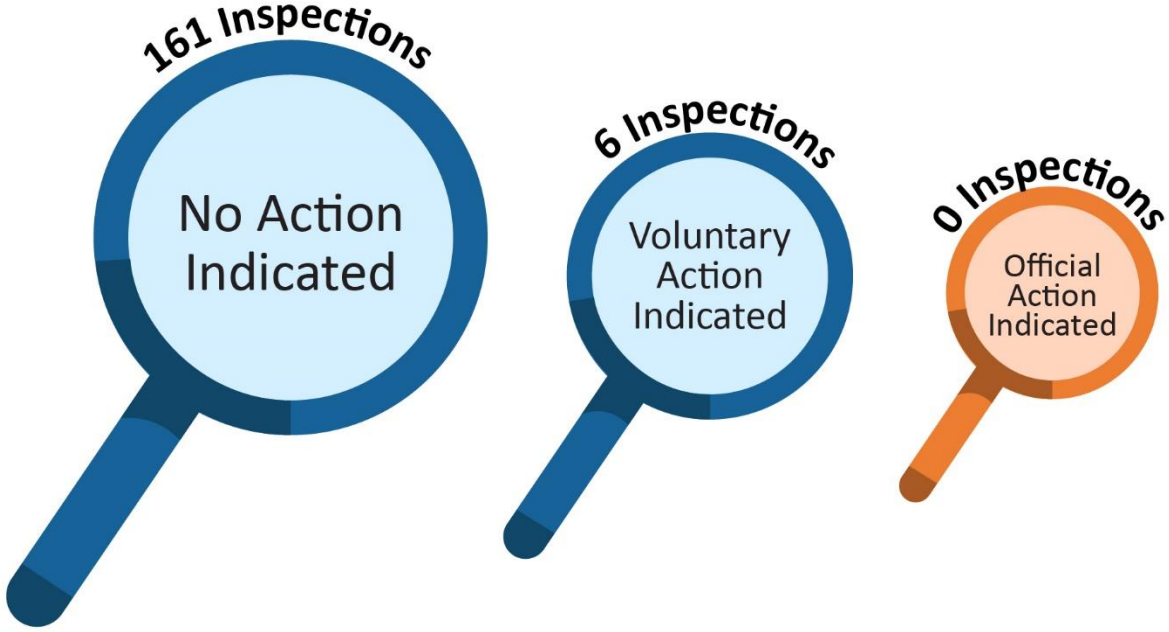
Voluntary Action Indicated: Findings are serious enough to record but do not require regulatory action

Official Action Indicated: Significant, objectionable conditions or practices that warrant regulatory action

FDA classified the results of 6 of the 173 inspections as Voluntary Action Indicated, meaning that it identified objectionable conditions that did not meet the threshold for regulatory (advisory, administrative, or judicial) action. FDA cited five of these six establishments for product labeling problems. FDA also cited one of the five establishments for failure to register and failure to submit a list of harmful or potentially harmful constituents. FDA cited the sixth establishment for failure to provide product and ingredient lists and for failure to pay user fees. See Exhibit 6 for the number and type of classifications that FDA assigned to inspections.

The remaining six inspections did not result in a classification. In three cases, when inspectors went to the establishments, they found that the establishments were either no longer in business or not actively manufacturing tobacco products. The other three inspections were still open at the time when FDA provided data to OIG.

Exhibit 6: Classifications for Tobacco Establishment Inspections, FYs 2012–2015



Source: OIG analysis of FDA inspection data, 2017.

FDA issued 14 warning letters to manufacturers—mostly for violations of advertising or labeling—as a result of its surveillance of tobacco marketing

In addition to conducting inspections, FDA conducts routine surveillance of marketing activities for tobacco products. For example, FDA reviews manufacturers' websites to determine whether tobacco product labeling and advertising are false or misleading. FDA also reviews marketing activities to ensure that manufacturers, distributors, and retailers are not sponsoring or causing to be sponsored certain types of public events (e.g., musical or artistic events). Through its surveillance activities from FYs 2011 through 2015, FDA identified 20 violations, related to advertising and labeling; sponsorships of public events; and the sale of flavored cigarettes, such as a "mint blend." In one case, it identified a failure to pay assessed user fees. It issued 14 warning letters in response to these violations.

According to FDA, these warning letters serve as an opportunity for regulated entities to come into compliance voluntarily. Although regulated entities have no legal obligation to respond to the letters, they must be in compliance with the Food, Drug, and Cosmetic Act. Failure to do so may result in additional FDA actions, such as a civil monetary penalty, seizure, or injunction. See Exhibit 7 for the numbers and type of violations covered by these warning letters.

Exhibit 7: Surveillance Warning Letters, by Year and Type of Violation

	FY11 **3 Letters***	FY12 **0 Letters**	FY13 **4 Letters***	FY14 **2 Letters***	FY15 **5 Letters**
Advertisement/ Labeling	3		4	2	4
Sponsoring an Event	2		1		
Selling a Flavored Product			2	1	
Failure To Pay User Fee					1

*Some letters included more than one type of violation

Source: OIG analysis of FDA surveillance warning letters, 2016.

CONCLUSION

Since the passage of the Tobacco Control Act, FDA has taken important steps in its oversight of tobacco products by implementing requirements for registration, listing, and inspection. In the first 6 years of the Tobacco Control Act's implementation, 171 establishments—covering more than 7,000 unique products—registered with FDA. FDA largely met its inspection requirement to inspect registered establishments biennially, although it initially delayed inspecting establishments on Tribal lands.

Given establishments' slow start in registration and missed annual renewals, it is important for FDA to ensure that all registrants update annually and provide full product list information. Complete and accurate information on registrants will aid FDA in fulfilling its oversight role, which has now broadened to include establishments with products such as vape pens, e-cigarettes, and cigars.

APPENDIX A

Exhibit 1: Reasons FDA Did Not Inspect Tobacco Manufacturing Establishments at Least Once

Reason FDA did not inspect establishment at least once	Number of establishments
Establishment was not actively manufacturing FDA-regulated tobacco products	58
Establishment was not due for inspection based on registration date	6
Establishment was located on Tribal land	1
Total	**65**

Source: OIG analysis of FDA registration and inspection data, 2017.

Exhibit 2: Reasons FDA Did Not Inspect Tobacco Manufacturing Establishments Twice

Reason FDA did not inspect establishment twice	Number of establishments
Establishment was not actively manufacturing tobacco products after first inspection	15
Establishment was located on Tribal land	7
FDA conducted second inspection outside of scope of this data brief	6
Establishment went out of business	2
Establishment was not due for inspection based on previous inspection date	3
Total	**33**

Source: OIG analysis of FDA registration and inspection data, 2017.

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To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

ENDNOTES

[1] Centers for Disease Control and Prevention, *Smoking and Tobacco Use*. Accessed at https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/ on June 21, 2017.
[2] Family Smoking Prevention and Tobacco Control Act, P.L. No. 111-31 (June 22, 2009), adding chapter IX to the Food, Drug, and Cosmetic Act.
[3] Food, Drug, and Cosmetic Act § 901(e).
[4] FDA, *Center for Tobacco Products Overview*. Accessed at http://www.fda.gov/TobaccoProducts/AboutCTP/ucm383225.htm on June 21, 2017.
[5] See, e.g., Food, Drug, and Cosmetic Act § 906(d), (e), and (f).
[6] 81 Fed. Reg. 28974 (May 10, 2016).
[7] Food, Drug, and Cosmetic Act § 905.
[8] FDA Form 3741.
[9] Food, Drug, and Cosmetic Act § 905(b), (c), and (d).
[10] Food, Drug, and Cosmetic Act § 905(b), (c), and (d).
[11] Food, Drug, and Cosmetic Act § 905(i)(1).
[12] Food, Drug, and Cosmetic Act § 905(i)(1)(B).
[13] Food, Drug, and Cosmetic Act § 905(i)(3).
[14] Food, Drug, and Cosmetic Act § 905(i) and FDA, *Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (Revised*)*, November 2016. Accessed at https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM191940.pdf on June 21, 2017.
[15] FDA, *Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments (Revised*)*, November 2016. Accessed at https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM191940.pdf on June 21, 2017.
[16] Food, Drug, and Cosmetic Act § 905(g).
[17] FDA also conducts preapproval inspections and for-cause inspections of tobacco establishments. For-cause inspections can be triggered, for example, by complaints from consumers or industry.
[18] FDA, *Letter to Tobacco Product Registered Establishments*, August 16, 2011.
[19] Food, Drug, and Cosmetic Act § 906(e).
[20] FDA, *Inspections and Operations Manual, Chapter 5: Establishment Inspections*. Accessed at http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM150576.pdf on June 21, 2017.
[21] Food, Drug, and Cosmetic Act § 911(a).
[22] FDA, *Enforcement Action Plan for Promotion and Advertising Restrictions*, October 2010. Accessed at http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM227882.pdf on June 21, 2017.
[23] Ibid.
[24] 74 Fed. Reg. 58298, 58299 (Nov. 12, 2009). FDA originally required establishments to register by December 31, 2009, but later stated that it would not enforce the registration requirement until February 28, 2010.
[25] 74 Fed. Reg. 58298, 58299 (Nov. 12, 2009).
[26] From the data provided by the registrants, we cannot determine the extent to which registrants complied with requirements to submit product information initially or to report biannually any changes to their product lists, including the introduction or discontinuation of any products. In fact, FDA can determine whether a registrant has submitted a complete list only when it inspects the tobacco establishment.
[27] U.S. Department Of Health And Human Services, *Tribal Consultation Policy*, 2010; Exec. Order No. 13,175, November 6, 2000.
[28] Before beginning inspections of Tribal establishments, FDA reached out to Tribal leaders and Tribal government officials to educate them about the Tobacco Control Act and discuss it with them.