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FDA's Approach to Overseeing Online Tobacco Retailers Needs Improvement

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Why OIG Did This Review

Youth tobacco use in the United States remains of high concern. Because online tobacco sales happen without buyers interacting with sellers face to face, these sales present a potentially easy way for minors to buy tobacco products without having their ages verified. The Food and Drug Administration (FDA) regulates the manufacturing, distribution, and marketing of tobacco products. As part of multiple efforts to this end, FDA conducts investigations of online tobacco retailers to determine whether they are in violation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). If a retailer violates the Tobacco Control Act, FDA may impose an advisory action—such as a warning letter—or an enforcement action. This study assesses FDA’s efforts to oversee online tobacco retailers’ compliance with the Tobacco Control Act.

How OIG Did This Review

We analyzed annual summary data from FDA from 2010 through 2020 to determine the extent of FDA’s advisory and enforcement actions and to identify trends in FDA’s oversight of online retailers. We also interviewed FDA officials and collected written responses from FDA to understand the following: how the online investigations program operates, FDA’s challenges in implementing the program, and FDA’s actions to address these challenges. Finally, we reviewed FDA’s public website to gather information on FDA’s oversight of online tobacco retailers.

FDA’s Approach to Overseeing Online Tobacco Retailers Needs Improvement

Key Takeaway

This review raises questions about the effectiveness of FDA’s efforts to prevent youth access to tobacco products online. In the first 10 years of its oversight, FDA’s actions toward online tobacco retailers were limited to warning letters and its oversight has had poor transparency.

What OIG Found

From 2010 through 2020, for the 16,000 online tobacco websites that FDA’s contractor flagged for review, FDA issued warning letters to 899 websites but took no enforcement actions. Although FDA can verify compliance immediately following warning letters, it is unclear to what extent FDA conducted additional oversight of these online tobacco retailers at later dates and found subsequent

violations that could result in FDA taking enforcement actions.

FDA faces challenges—many unique to the online environment—to taking action against online tobacco retailers that violate the Tobacco Control Act. For example, websites may correct violations or “disappear” before FDA can issue an enforcement action. Adding to these challenges is the fact that FDA has not taken certain steps that could help it address gaps in its ability to oversee online tobacco retailers. For example, FDA has not completed rulemaking on non-face-to-face (e.g., online) tobacco sales, nor has it worked with the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF)—part of the Department of Justice—to potentially obtain information on online tobacco retailers, beyond that which is already obtained by FDA. Finally, FDA provides limited transparency into its oversight, limiting the public’s ability to hold it accountable for preventing youth access to tobacco online.

What OIG Recommends

We recommend that FDA (1) collaborate with ATF on oversight of online tobacco retailers; (2) complete its rulemaking on non-face-to-face sales of tobacco products, as required by the Tobacco Control Act; (3) collect data to support process and outcome measures for its oversight of online tobacco retailers; and (4) publish information and performance data on its oversight of online tobacco retailers. FDA concurred with our first and fourth recommendations and neither concurred nor nonconcurred with our second and third recommendations.

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OBJECTIVE

To assess the Food and Drug Administration's (FDA's) oversight of online tobacco retailers.

Youth tobacco use in the United States remains of high concern.¹ In particular, e-cigarettes, a type of electronic nicotine delivery system (ENDS), have eclipsed other forms of tobacco to become the most commonly used tobacco product among youth.² In 2020, close to 20 percent of high schoolers, or over 3 million students, reported that they currently use e-cigarettes.³ Since then, e-cigarette use among youth may have declined, although a substantial proportion of youth still use these products.^{4, 5}

Preventing youth access to tobacco is one of three focus areas of FDA's Youth Tobacco Prevention Plan, which is a component of FDA's Comprehensive Plan for Tobacco and Nicotine Regulation. Curbing marketing of tobacco products aimed at youth and educating youth on the dangers of tobacco use are the two other focus areas of FDA's Youth Tobacco Prevention Plan.⁶

Unlike in-person sales, online sales of tobacco products do not include a face-to-face interaction between the buyer and the retailer. Without this interaction, online sales represent a potentially easy way for minors to buy tobacco products without having their ages verified. In addition, research has shown that 95 percent of youth ages 13 to 17 report having smartphones or access to one, and close to half of youth report using the internet on a "near-constant basis," which risks exposing them to marketing and sales of tobacco products.⁷ This underscores the importance of FDA's oversight of online tobacco retailers within its efforts to limit youth access to tobacco products.

The Tobacco Control Act

In 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which authorized the FDA to regulate tobacco products in the United States.⁸ Specifically, the Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act and granted FDA authority to regulate the manufacturing, distribution, and marketing of cigarettes and smokeless and roll-your-own tobacco products.⁹ User fees from manufacturers and importers of certain classes of tobacco products are the sole source of funding for FDA's regulation of tobacco products.¹⁰

The Tobacco Control Act authorized FDA to inspect and investigate the activities of manufacturers, importers, and retailers to assess their compliance with age and marketing restrictions on tobacco sales.¹¹

Among other things, the Tobacco Control Act also required FDA to issue rules on the sale and marketing of tobacco products that do not occur through a face-to-face transaction at a retailer based at a physical location.¹² Specifically, the Tobacco Control Act required FDA to issue rules on the non-face-to-face sale and distribution of tobacco products and the advertising and promotion of tobacco products sold non-face-to-face by 18 months and 2 years after the enactment of the Tobacco Control Act, respectively.¹³ The Tobacco Control Act required these rules specifically to prevent non-face-to-face sales to minors and to protect them from the associated promotion and marketing.¹⁴ In 2011, FDA issued an advanced notice of proposed rulemaking to this end, but never completed its rulemaking.¹⁵

The Prevent All Cigarette Trafficking Act

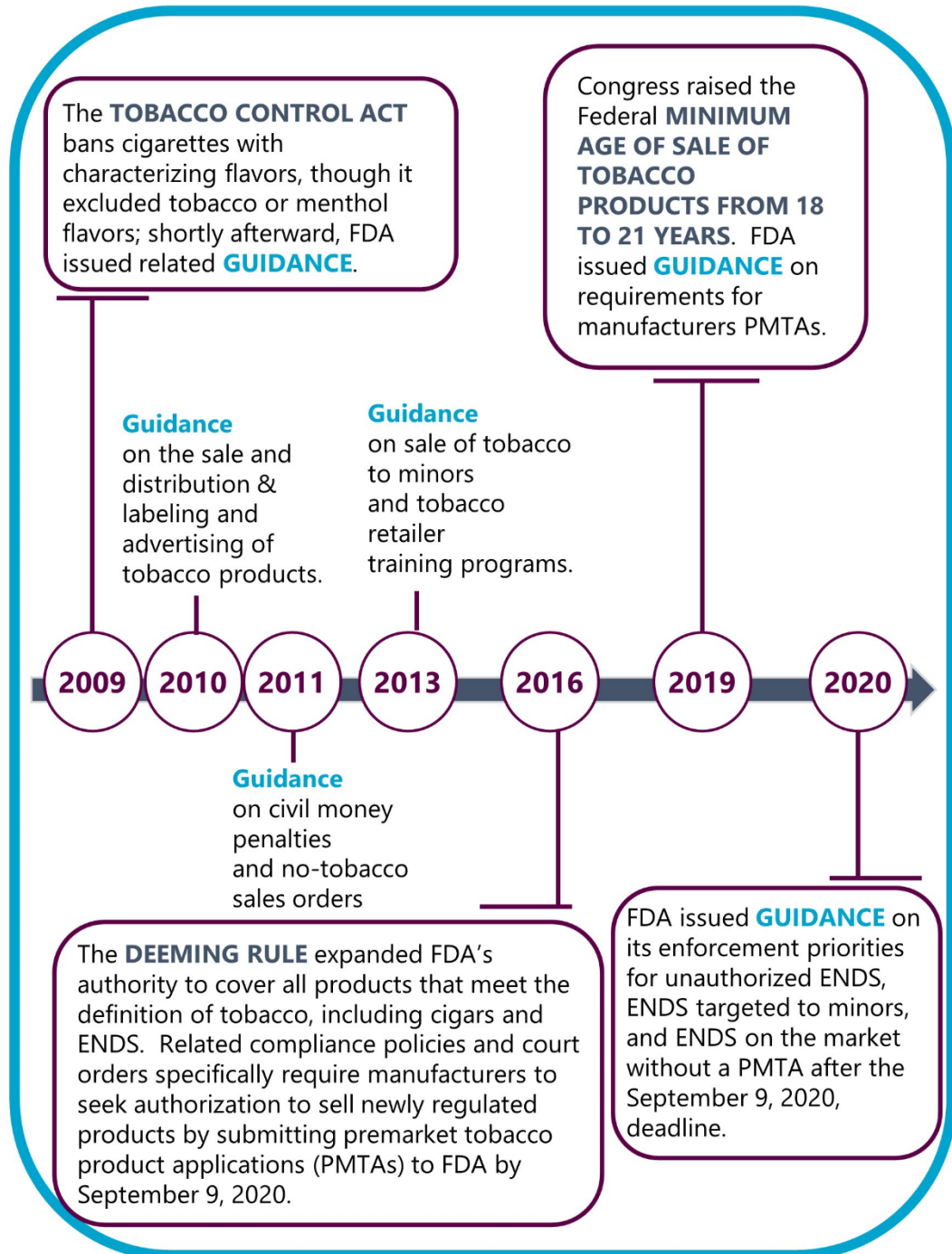
In addition to the Tobacco Control Act, the Prevent All Cigarette Trafficking Act (PACT) Act of 2009 limits the sale of tobacco products.¹⁶ The PACT Act, which came into effect in 2010, prohibits retailers from using the United States Postal Service to deliver cigarettes and smokeless tobacco products directly to consumers.¹⁷ The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) within the Department of Justice enforces the PACT Act. Among other requirements, the PACT Act requires all online retailers that enter tobacco products into interstate commerce for delivery using a common carrier or private delivery service, including online retailers, to register with ATF.¹⁸ In 2021, Congress amended the PACT Act to cover online retailers of ENDS products in addition to cigarettes and smokeless tobacco products.¹⁹ Although the PACT Act does not apply to private delivery companies, these companies may have policies restricting or prohibiting the shipment of tobacco products.²⁰

Additional Legislative and Administrative Action to Enhance FDA's Oversight of Tobacco

Since the passage of the Tobacco Control Act, additional legislative and administrative actions have enhanced and added clarity to FDA's oversight of tobacco products. See Exhibit 1 for a timeline of these and other selected actions that have enhanced FDA's oversight over tobacco products.²¹

Exhibit 1: Timeline of selected actions that have enhanced FDA’s oversight over tobacco products

Since the passage of the Tobacco Control Act, additional **law, regulation,** and **guidance** have enhanced FDA’s oversight of tobacco products.



Source: OIG analysis, 2022.

FDA Oversight of Online Tobacco Retailers

FDA's approach to overseeing tobacco includes an array of efforts—aimed at manufacturers, importers, and retailers—that work in concert. Its oversight of online retailers is one of those efforts.

To monitor compliance with the Tobacco Control Act, FDA conducts surveillance of the promoting, advertising, and labeling of tobacco products. Its surveillance includes online media and websites that advertise or sell tobacco products to consumers in the United States. To identify websites for surveillance, FDA uses information from multiple sources, mostly its contractor that uses technology to flag specified criteria. It also uses its public complaint portal, which may receive tips about potential violations.²³

FDA oversight of advertising and promotion of tobacco

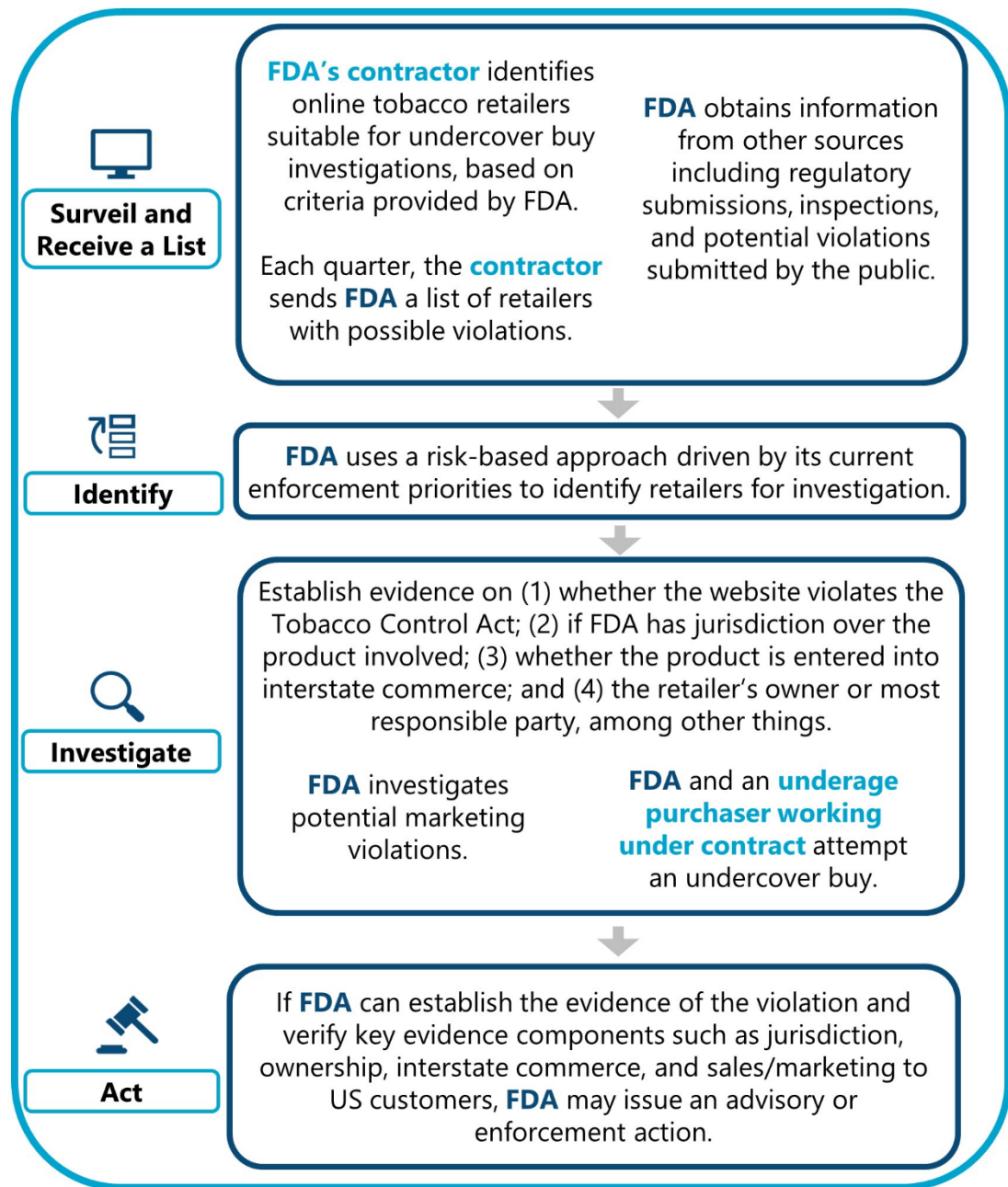
In addition to its surveillance of websites selling tobacco, FDA monitors tobacco advertising and labeling in social media, print media, and other venues. In June 2019, FDA and the Federal Trade Commission sent warning letters to four e-liquid manufacturers whose social media posts violated the Tobacco Control Act.²² In a September 2019 letter to ENDS manufacturer JUUL Labs, Inc., FDA expressed concerns about its social media marketing. Also, in September 2019, FDA issued a warning letter to JUUL Labs, Inc. after learning that it had improperly marketed ENDS as modified risk tobacco products in talks to students in high schools.

FDA may investigate an online retailer when its surveillance identifies a potential violation of the Tobacco Control Act. FDA generally conducts two types of online investigations. The first assesses an online retailer's compliance with advertising and labeling requirements such as displaying the proper warning labels; compliance with the ban on flavored cigarettes; and compliance with other Federal restrictions on tobacco sales, marketing, and advertising. The second is an undercover buy, in which an underage purchaser, supervised in person by a contractor and an FDA staff member, attempts to buy a tobacco product from an online retailer.

When FDA's investigation identifies a potential violation of the Tobacco Control Act, FDA must establish additional information to support an action against a retailer. FDA must confirm that there is a violation; confirm FDA's jurisdiction over the product in question; identify the online retailer's owner or most responsible party; and determine whether the product was entered into interstate commerce.

FDA uses contractors to assist in certain aspects of its online surveillance activities. See Exhibit 2 for detail on the surveillance and investigation process.

Exhibit 2: FDA’s investigations process for online retailers



Source: OIG interview with FDA officials, 2021.

FDA Actions When Retailers Violate the Tobacco Control Act

FDA has the authority to take advisory and enforcement actions when it determines that a retailer has violated the Tobacco Control Act. Advisory actions include warning letters. A warning letter represents FDA's attempt to bring a retailer into compliance and establish prior notice. Enforcement actions include civil money penalties (CMPs) and no-tobacco-sale orders (NTSOs). A CMP is a fine that FDA assesses for violating the Tobacco Control Act. An NTSO is an order that prohibits a retailer from selling tobacco products indefinitely or for a specified period of time. In certain cases, FDA may pursue other enforcement actions including criminal prosecution, seizing tobacco products, or an injunction.²⁴

The penalties for violating the Tobacco Control Act increase with subsequent violations. Generally, FDA issues a warning letter the first time it finds a retailer in violation. If FDA finds the retailer in violation during subsequent investigations, it may issue CMPs that increase with each subsequent violation. When FDA finds that a retailer has committed repeated violations of the same FDA requirements, it may pursue an NTSO. See Exhibit 3 below for a schedule of FDA's progressive actions.

Exhibit 3: FDA's schedule of penalties for violating restrictions on the sale and distribution of tobacco products as of March 17, 2022²⁵

Violation Count	Penalty
First violation	Warning letter
Second violation within a 12-month period	CMP of up to \$320
Third violation within a 24-month period	CMP of up to \$638
Fourth violation within a 24-month period	CMP of up to \$2,559
Fifth violation within a 36-month period	CMP of up to \$6,397
Sixth violation within a 48-month period	CMP of up to \$12,794
Five or more repeated violations within 36 months	NTSO of 30 calendar days or 6 months or permanent

Source: 87 Fed. Reg. 15100 (Mar. 17, 2022). FDA updates CMP amounts annually in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

Related Office of Inspector General (OIG) work

OIG previously issued a data brief evaluating FDA's oversight of tobacco manufacturing establishments. The data brief examined tobacco manufacturing establishment registration and product listing as well as FDA's inspection and enforcement actions from 2010 to 2015. We found that FDA largely met its requirement to inspect manufacturing facilities biennially, and that it concluded that no enforcement action was needed after the inspections.²⁶ The data brief did not include any recommendations for FDA. OIG also has work underway to examine FDA's tobacco compliance check inspection(s) program for retailers that operate from a physical location.²⁷ Finally, OIG is auditing FDA's premarket tobacco product application process for ENDS.²⁸

Methodology

The scope of this review is limited to FDA's investigations of online retailers, which are part of its overall efforts to limit youth tobacco use. We based this study on annual summaries of investigation activity from FDA; an interview with FDA officials responsible for oversight of online retailers; written questions and answers with FDA; and materials on FDA's website.

We requested annual summary data of investigation activity for calendar years 2010 through 2020 from FDA. We requested the counts of online retailers FDA identified, investigations it completed, violations it observed, and advisory or enforcement actions it issued. FDA provided these data with the exception of counts of online investigations it completed, which it did not have available. We analyzed these data to determine the extent of FDA advisory and enforcement actions and to identify the trends and patterns in FDA's oversight of online retailers.

In addition, we interviewed FDA officials to understand how the online investigations program operates, FDA's challenges in implementing the program, and FDA's actions to address those challenges. We followed up with FDA with sets of written questions and used FDA's responses to further our understanding of its oversight.

Lastly, we reviewed FDA's public website to gather information on relevant law, regulation, and guidance; FDA's oversight of online retailers; priorities in enforcing the Tobacco Control Act; and strategies to reduce youth access to tobacco.

We did not independently verify the data and information FDA provided.

Standards

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.

FINDINGS

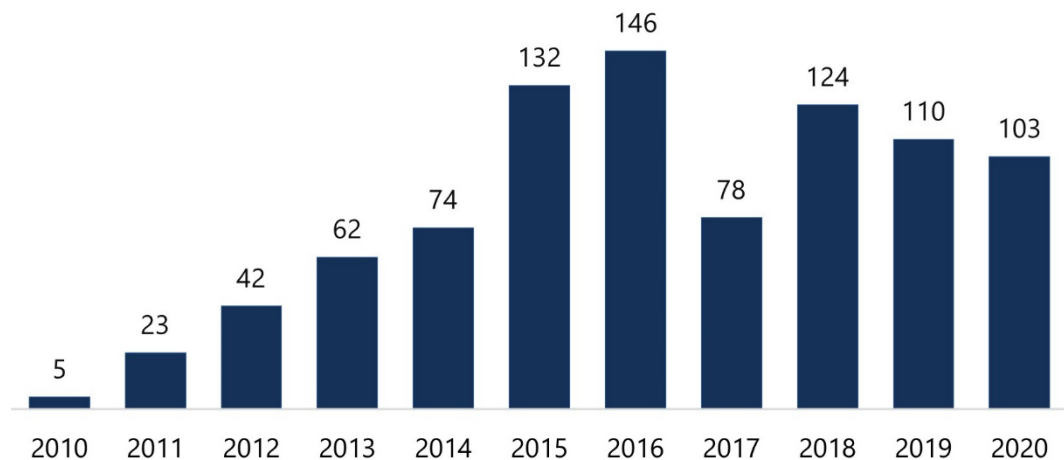
From 2010 through 2020, FDA issued warning letters to online tobacco retailers but did not take any enforcement actions

FDA told us that it views success as impeding violative activities and changing industry practices. A warning letter is an advisory action that FDA regards as a first step toward taking an enforcement action such as a CMP or an NTSO for violating the Tobacco Control Act. To take an enforcement action, FDA must prove that a violative retailer had a subsequent violation during a later investigation.

FDA issued 899 warning letters to online tobacco retailers that violated the Tobacco Control Act

Among the 16,511 websites flagged for meeting certain criteria, FDA issued warning letters to 899 of them. FDA's contractor flagged the websites as meeting criteria such as using the words "light," "mild," or "grape." For flagged websites, FDA conducts additional analysis to determine which websites have potential violations, support FDA's enforcement priorities, and are appropriate for an FDA online investigation. FDA told us that, after issuing warning letters to online retailers, it provides feedback on corrective actions proposed by firms. FDA also told us that it can instantly verify whether online retailers have taken corrective actions—a key difference from physical retailers that would require a revisit by an inspector. See Exhibit 4 below for the number of warning letters FDA issued to online tobacco retailers by year.

Exhibit 4: The number of warning letters issued by FDA to online tobacco retailers grew steadily through 2016 before tapering off.



Note: COVID-19 affected 2020 enforcement activities.
Source: OIG analysis of FDA online tobacco retailer enforcement data, 2022.

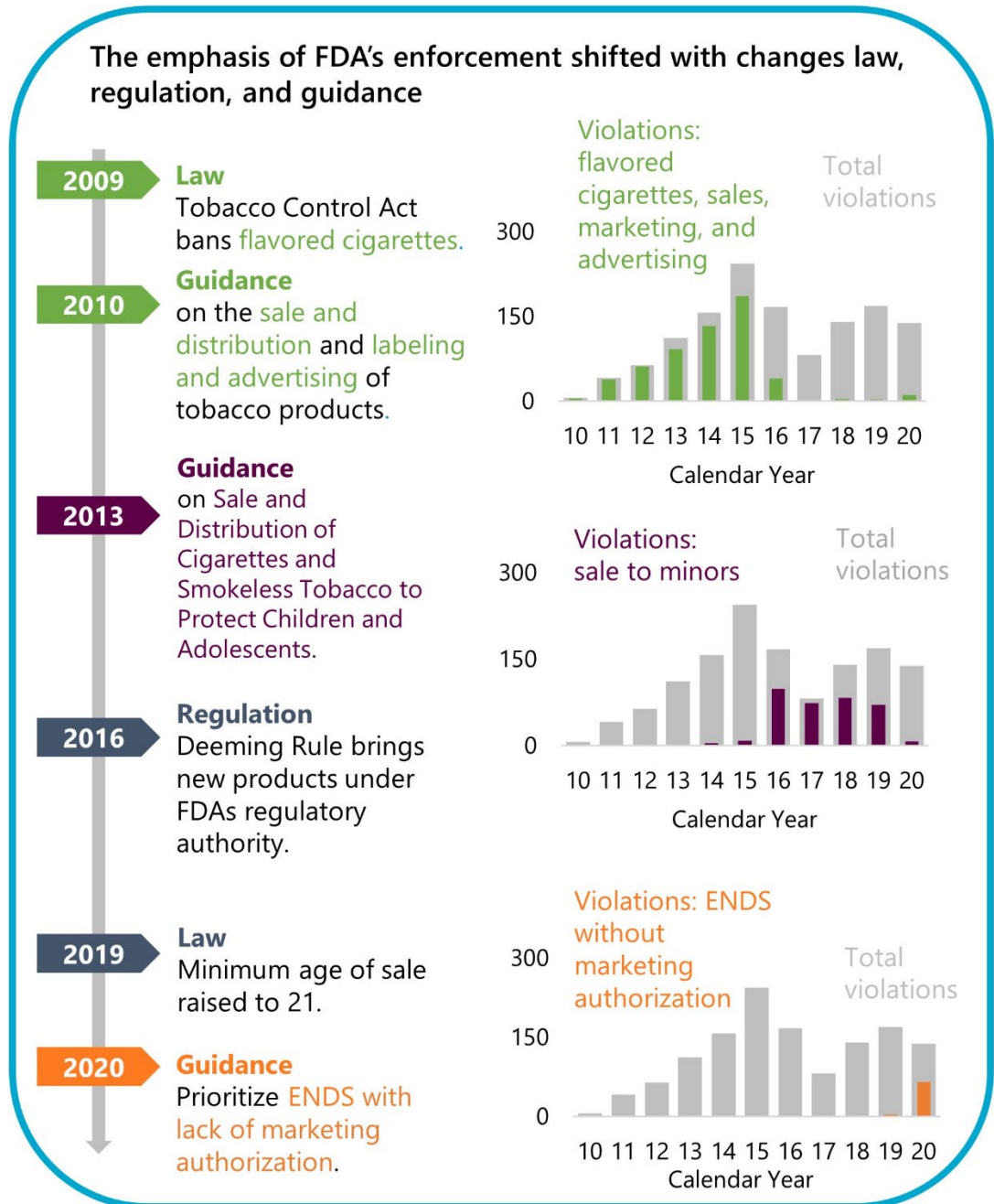
Although FDA has taken enforcement actions against retailers operating in physical locations, it told us that a CMP or NTSO is generally not the next step for violative online retailers after issuing a warning letter.²⁹ FDA's Center for Tobacco Products told us that it refers some cases that require additional followup to other parts of FDA, such as its Office of Criminal Investigations or Office of Regulatory Affairs. Yet, beyond verifying compliance immediately following warning letters, it is unclear to what extent FDA investigated these online retailers at later dates and found subsequent violations that could result in FDA issuing CMPs and NTSOs. This is important because, although FDA has the ability to instantly verify compliance following a warning letter, FDA can be certain of sustained compliance only by following up with the retailer later.

The violations that FDA cited in warning letters reflected its evolving oversight of tobacco products

As FDA's authorities over tobacco evolved, its enforcement followed suit. For example, after the Tobacco Control Act came into effect in 2009, FDA focused on violations of the ban on flavored cigarettes and sales, marketing, and advertising. By 2013, FDA had additional guidance on the sale of tobacco to minors, and its enforcement to prevent underage sales increased up to the onset of the COVID-19 pandemic, when it was not possible for minors to sit at a computer together with FDA staff to attempt undercover buys. In 2020, new FDA guidance prioritized ENDS that lacked marketing authorizations.

Within the 899 warning letters it issued, FDA cited 1,320 unique violations among online retailers since 2010. The warning letters most frequently cited online tobacco retailers for advertising and labeling violations. See Exhibit 5 for the numbers and types of violations FDA cited as a result of online retailer investigations.

Exhibit 5: The numbers and types of violations that FDA cited shifted with changes in law, regulation, and guidance.



Note: COVID-19 affected enforcement activities in 2020.
 Source: OIG analysis of FDA enforcement data for online tobacco retailers, 2022.

FDA faces challenges to taking action against online tobacco retailers that violate the Tobacco Control Act

Challenges around the volume, volatility, and transparency of online retailers make it difficult for FDA to initiate an advisory or enforcement action against retailers that violate the Tobacco Control Act. One FDA official described online tobacco sales as a “wild West” environment where retailers can evade FDA’s oversight.

The limitless capacity of the internet to host retailers means that the sheer volume of websites that FDA must surveil is likely in the tens of thousands. This surveillance is further complicated by the evolving ways in which youth access the internet, such as through social media and by technology-driven changes in retailing, such as home delivery apps. To address the large volume of retailers, FDA supplies its contractor with risk-based criteria to conduct keyword searches, algorithmic web searches, and searches of e-commerce websites such as eBay or Facebook Marketplace to identify websites for potential investigation. Although this approach helps FDA narrow the number of online retailers, it still leaves FDA with 7,000–8,000 potential targets for investigation every quarter. FDA then works with its contractor to further narrow the list of potential targets per criteria it provides.

Once FDA begins an investigation, it faces challenges with transparency and volatility that may prevent it from establishing the investigative facts it needs to take action against a violative retailer. For example, it can be difficult to determine the owner or most responsible party for an online retailer. Also, the retailer may go offline entirely, thereby undermining FDA’s investigation. Furthermore, retailers may alter or shift the content of their websites, which could undermine FDA’s efforts to address a violation. Finally, changes to content could mean that a retailer has become compliant with the law—negating the need to continue with the investigation.



To initiate an action

FDA must confirm:

- (1) that the website violated the Tobacco Control Act;
- (2) that FDA has jurisdiction over the product involved;
- (3) that the product was entered into interstate commerce; and
- (4) the identity of the retailer’s owner or most responsible party.

Even if FDA issues a warning letter to an online retailer, the nature of the online marketplace can make it challenging for FDA to work with the retailer to obtain compliance or take progressive enforcement actions for subsequent violations. To issue a CMP, subsequent CMPs, and eventually an NTSO, FDA must establish a pattern of violations with the same owner and same website over time.³⁰ However, it is not only unclear to what extent FDA conducted additional oversight of these online retailers and found subsequent violations, but also, websites can come and go much more easily than a store at a physical location, making it harder to establish a pattern of violations. For example, a retailer who receives a warning letter could easily hide its

identity or launch new websites where it commits the same violations, thereby skirting progressive enforcement action. Furthermore, the online retailer may choose not to work with FDA to become compliant or, as an FDA official told us, it may just “disappear.”

FDA officials offered an example of a special oversight effort that highlighted the challenges of compliance and enforcement in online tobacco sales. See Exhibit 6 below for details of this example.

Exhibit 6: FDA did not issue warning letters to 11 of 30 high-volume online domestic retailers selling prohibited ENDS products.

In part prompted by data from CDC’s 2019 National Youth Tobacco Survey showing a jump in ENDS use among teenagers, FDA issued an enforcement policy aimed at ENDS products likely to appeal to minors in early 2020. Using data provided by its contractor, FDA identified 400 online domestic retailers selling ENDS products. From those retailers, using Alexa rankings of website traffic, FDA created a list of 30 high-volume online retailers that sold flavored, cartridge-based ENDS products, which are prohibited.

FDA **issued warning letters to 19 of the 30 highest-volume** domestic online retailers selling ENDS products. They were able to do so because they could:



- identify **violations** of regulations,
- establish **ownership** of website, or
- establish **current activity** of website.

FDA **did not issue warning letters to 11 of the highest-volume** domestic online retailers selling ENDS products because:



- the website was **no longer active**,
- the online retailer **stopped selling** the flavored ENDS products, or
- the online retailer made **other changes** to the website that impacted the case.

Source: FDA written response to OIG request for information, 2022.

FDA has not taken certain steps that could help it address gaps in its ability to oversee online tobacco retailers

FDA has taken actions to mitigate the challenges associated with overseeing online tobacco retailers, but it could do more. For example, shortly after starting the program, FDA engaged contractors to help it sift through the volume of online retailers and to conduct undercover buys. It has worked with e-commerce websites that host online tobacco retailers, payment processors, and social media platforms to leverage their internal oversight and governance to help FDA enforce compliance with the Tobacco Control Act. FDA told us that it has also called upon internal resources,

such as its Office of Criminal Investigations, and other government resources, such as the U.S. Customs and Border Protection and the Federal Trade Commission, to identify and hold online retailers accountable. Still, FDA's approach to overseeing online tobacco retailers has gaps.

FDA does not obtain detailed information on online tobacco retailers from ATF

FDA lacks the kind of detailed information from online retailers that ATF collects under the PACT Act. That information includes ownership and contact information, among other things.³¹ The Food, Drug, and Cosmetic Act, as amended by the Tobacco Control Act, does not require tobacco retailers to register with FDA. FDA told us that it does not work with ATF to regulate the sale of tobacco products by online retailers but does share information on investigations.³² However, because FDA does not draw on ATF's information about online retailers, FDA is left without information that could be key to its investigations. For example, ATF's information could help FDA identify an online retailer's owner or most responsible party—a vital step in holding an online retailer that violates the Tobacco Control Act accountable.

FDA has yet to issue a final rule to strengthen its approach to overseeing online tobacco retailers

FDA has not fulfilled the Tobacco Control Act's requirement to issue rules on the sale and marketing of tobacco products in non-face-to-face settings. FDA's rulemaking process offers opportunities for the public to offer feedback and suggestions on proposed regulations, including those intended to enhance oversight of online tobacco retailers. Although FDA solicited public feedback on non-face-to-face tobacco sales in its 2011 advanced notice of proposed rulemaking, FDA withdrew the notice in 2017. Since then, changes in internet technology and in the tobacco marketplace make it important for FDA to complete its rulemaking. Doing so will provide additional, up-to-date public input and the opportunity for FDA to improve and strengthen its oversight of online tobacco sales.

FDA lacks data as well as process and outcome measures for its oversight of online tobacco retailers

FDA was unable to tell us how many investigations of online retailers it has conducted and does not set targets for the numbers of investigations it will conduct. For this review, FDA was able to provide us with data only about investigations that resulted in its taking action against online retailers that violated the Tobacco Control Act. Accordingly, it is also unclear how often FDA conducted additional oversight of retailers to determine sustained compliance. FDA told us that online investigations are difficult to quantify because they may cover multiple websites and various online media, and even include inspection of a physical establishment such as a manufacturer, vape shop, and/or retailer. Also, FDA considers its investigations to be one tool within an array of efforts to control youth access to tobacco. Nonetheless, a

lack of process measures reflecting the extent and results of investigations and outcomes measures tied to the program's goals hampers FDA's accountability to stakeholders and its ability to monitor and improve oversight.

Finally, FDA provides limited transparency into its oversight, limiting the public's ability to hold it accountable for preventing youth access to tobacco online

Information and data on FDA's oversight of online retailers are important for holding FDA accountable to parents and other stakeholders, but FDA makes little of either available. This makes it difficult to know what FDA's oversight of online retailers is accomplishing.

FDA does not publish information on the purpose or goals of its oversight of online retailers, which limits transparency into how it attempts to prevent youth access to tobacco on the internet. Some content on FDA's website mentions its surveillance of websites and publications, but FDA does not dedicate a page to describing the surveillance, its purpose, and its goals—in general or with respect to online retailers. This means that FDA is missing the opportunity to inform the public and stakeholders about its efforts to curb youth access to tobacco online and how it measures the success of those efforts.

Likewise, FDA publishes little data on its investigations of online retailers, which limits the public's ability to hold it accountable. Along with transparency about the purpose and goals of FDA's oversight of online retailers, data on the extent and results of its investigations are key to accountability. Publicly accessible data are limited to isolated statistics in a few reports or press releases on FDA's website. This contrasts with FDA's Tobacco Retailer Compliance Inspection Program for retailers that sell tobacco from a physical location. For that program, FDA makes all of its inspections data available in both searchable and downloadable formats. We understand that FDA aims to safeguard its enforcement strategy so as not to compromise the integrity of its investigations of online retailers. However, its experience with tobacco retailers



FDA's Electronic Reading Room

A page on FDA's website has warning letters it issued to tobacco and nontobacco entities including food and pharmaceutical companies. Users can filter the list for tobacco entities, but the filtering still leaves letters to retailers, manufacturers, and importers all grouped together, requiring the user to click through and open each letter to determine which type(s) of entity it relates to. Warning letters issued prior to 2017, which account for about half of the warning letters FDA issued, are only available on a third-party archive site that is not linked to the reading room.

at physical locations demonstrates room for increased transparency in its oversight of online retailers.

CONCLUSION AND RECOMMENDATIONS

Preventing youth access to tobacco on the internet remains a challenging public health goal. Youth tobacco use remains high. The way youth purchase tobacco and the way tobacco is marketed continue to evolve (e.g., through social media). Our findings raise questions about the effectiveness of FDA's oversight of online tobacco retailers, which is one prong in FDA's multipronged approach to preventing youth access to tobacco. Although the fluid nature of online retail may make it difficult, especially to impose financial penalties against violative retailers, our analysis highlights opportunities FDA missed to improve its oversight of online retailers. Leveraging those opportunities can advance FDA's efforts toward preventing youth access to tobacco. Furthermore, the lack of transparency into FDA's oversight, including data showing the extent and outcomes of its investigations, obscures FDA's track record beyond knowledge that in 10 years, it has issued 899 warning letters.

Therefore, we recommend that, at a minimum, FDA:

Collaborate with ATF on oversight of online tobacco retailers

Given their shared interests in overseeing tobacco products, FDA should work toward a more robust exchange of information with ATF. According to FDA, they already share some information informally. As the agency responsible for enforcing the PACT Act, ATF maintains a database that would be helpful to FDA. That database includes information on online retailers that have registered with ATF and their owners' identities. This information may be useful for FDA to establish investigative facts. To collaborate, FDA could work with ATF to establish a Memorandum of Understanding. The two agencies have done so before on their enforcement responsibilities with respect to adulterated alcoholic beverages.

Complete its rulemaking on non-face-to-face sales of tobacco products, as required by the Tobacco Control Act

This rulemaking could offer FDA insight for revising its oversight of online tobacco retailers that incorporates input from a wide range of public stakeholders. In its 2011 advance notice of proposed rulemaking on non-face-to-face sales of tobacco products, FDA asked for information on a number of topics including how the PACT Act (passed in 2009) would affect online sales; how retailers use communication technology to market tobacco products; and which forms of technology, advertising themes, and techniques are appealing to minors. Ten years later, these questions remain relevant given changes in technology and the tobacco marketplace, as well as expansion of the PACT Act in 2021.

Collect data to support process and outcome measures for its oversight of online tobacco retailers

Given that FDA's investigations of online retailers are an important tool—though not the sole tool—for reaching FDA's goals of impeding violative activities and changing industry practice, ensuring appropriate internal oversight of these activities is critical. Toward this end, collecting data on each investigation, its outcome, and any resulting FDA actions is foundational to understanding investigations' role, in light of FDA's array of oversight activities. In addition to collecting the oversight data, FDA should establish process measures that would use this data to describe the extent and results of investigations. Outcome measures should also be established that, at a minimum, include the extent to which violative retailers attain and sustain compliance. The oversight data and process and outcome measures should help FDA determine whether its oversight is achieving its goals.

Publish information and performance data on its oversight of online tobacco retailers

FDA should ensure that information and performance data are easy to find on its website and user-friendly. FDA should establish procedures to ensure that the performance data are updated on a routine basis.

By taking these steps, FDA significantly increases its public accountability for preventing youth access to tobacco on the internet. Publishing information about the purpose and goals of FDA's oversight of online retailers will raise public awareness of its efforts. Similarly, publishing performance data from process and outcomes measures for completed investigations will help parents, industry, and other stakeholders understand what FDA is doing to oversee online tobacco retailers and whether its oversight is making a difference.

Beyond promoting transparency and accountability, raising the profile of FDA's oversight of online tobacco retailers can have other benefits. For example, it may raise awareness about the public's ability to alert FDA to possible violations of the Tobacco Control Act among online tobacco retailers. Also, making more information available to parents and promoting parental engagement could help prevent youth access to tobacco on the internet. Not least, as FDA told us, its oversight activities can shine a public spotlight on violative behavior and motivate public health and trade groups to take action.

We believe that the benefits merit an effort to strike a balance between greater transparency and safeguarding details of FDA's enforcement strategy.

AGENCY COMMENTS AND OIG RESPONSE

FDA concurred with two of our recommendation and neither concurred nor nonconcurred with the remaining two, as detailed below.

First, FDA concurred with our recommendation that it collaborate with ATF on oversight of online tobacco retailers. FDA stated that it planned to explore developing a Memorandum of Understanding with ATF. FDA also described how it would work with ATF to determine what information ATF collects that may be useful to FDA's online tobacco retailer surveillance efforts. In its Final Management Decision, FDA should detail its efforts to collaborate with ATF and any progress toward a Memorandum of Understanding.

FDA neither concurred nor nonconcurred with our second recommendation that it complete its rulemaking on non-face-to-face sales of tobacco products, as required by the Tobacco Control Act. Instead, FDA affirmed its commitment to issuing rules to implement the Tobacco Control Act and stated that other laws and requirements—including those enforced by States or other jurisdictions—may achieve the same ends as a rule on non-face-to-face tobacco sales. We maintain that completing this rulemaking is an important step toward FDA's goal of preventing youth access to tobacco products. Through the rulemaking process, FDA has an opportunity to gather and make use of valuable insight from public stakeholders to strengthen FDA's oversight of online tobacco retailers. We ask that, in its Final Management Decision, FDA clarify how and when it intends to complete its rulemaking on non-face-to-face tobacco sales.

FDA also neither concurred nor nonconcurred with our third recommendation that it collect data to support process and outcome measures for its oversight of online tobacco retailers. In its response, FDA expressed concerns that sharing information about ongoing investigations of online tobacco retailers may jeopardize investigations, thus enabling bad actors to evade FDA oversight. Furthermore, FDA stated that some aspects of its oversight may not be easily quantified, such as the extent to which posting warning letters deters retailers from violating FDA requirements. We maintain that collecting data, as our recommendation calls for, will help FDA understand the extent to which online retailer investigations achieve intended goals. Online retailer investigations are just one aspect of FDA's array of online tobacco oversight, which makes it critical to understand the performance of this activity specifically. Additionally, we clarified that our expectations around public reporting are for completed investigations. In its Final Management Decision, FDA should explain its rationale for whether it intends to collect data to support process and outcome measures for its oversight of online retailers.

Finally, FDA concurred with our fourth recommendation that it publish information and performance data on its oversight of online tobacco retailers. FDA stated that it

would create a webpage dedicated to online tobacco retailer surveillance, including information about compliance and enforcement efforts. FDA also expressed concerns about publishing information that may disclose its enforcement strategy. OIG acknowledges the importance of preserving the integrity of FDA's enforcement strategy. We also maintain that more transparency around FDA's online surveillance efforts will increase public accountability for these efforts. FDA should provide an update on, and when available, a link to its new webpage in its Final Management Decision.

For the full text of FDA's comments, see Appendix A.

APPENDIX

Appendix A: Agency Comments

Following this page are the official comments from FDA.



DATE: October 3, 2022

TO: Suzanne Murrin
Deputy Inspector General
Office of Evaluation and Inspections

FROM: Beethika Khan, Ph.D.
Associate Commissioner for Economics and Analysis
Director, Office of Economics and Analysis
Office of Policy, Legislation, and International Affairs

Beethika Khan -S
Digitally signed
by Beethika Khan
-S
Date: 2022.10.03
14:19:32 -04'00'

SUBJECT: Draft Report, OEI-01-20-00241

Attached are the Food and Drug Administration's general and technical comments to the Office of Inspector General's September 1, 2022 draft report entitled *FDA's Approach to Overseeing Online Tobacco Retailers Needs Improvement*. Thank you for the opportunity to provide feedback.

Attachments

U.S. Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993

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FDA's General Comments

OIG Draft Report: *FDA's Approach to Overseeing Online Tobacco Retailers Needs Improvement*, OEI-01-20-00241

Thank you for the opportunity to review and comment on OIG's draft report.

FDA's online tobacco surveillance program uses a multi-pronged approach to comprehensively monitor all aspects of online activity related to tobacco products, including sales, distribution, marketing, and advertising. Routine surveillance helps identify potential violations of the law and regulations. FDA then conducts an investigation of potential violations, including determining whether a violation occurred, if FDA has jurisdiction over the product, whether the product entered into interstate commerce, and ownership information. If supported by the evidence, FDA will take action. Depending on the nature of the violation and the retailer's past compliance history, FDA may issue a warning letter. FDA may also pursue enforcement actions such as a civil money penalty or fine, injunction, seizure, or criminal prosecution.

FDA's online tobacco surveillance program is flexible, allowing the Agency to shift focus with relative ease, as informed by the Center for Tobacco Product's enforcement priorities, reports of violations received by the public, and if an emergent public health issue arises.

FDA's online tobacco surveillance program has played a major role in supporting FDA's highest tobacco enforcement priorities, which include electronic nicotine delivery systems (ENDS) products that lack the required FDA marketing authorization.

This year, FDA began enforcing the new federal law for Non-Tobacco Nicotine (NTN) products, which took effect on April 14, 2022. After July 13, 2022, any NTN product that has not received premarket authorization from FDA cannot be legally marketed. FDA's online tobacco surveillance program plays an important role in its work to enforce the new law. To date, FDA has sent warning letters to more than 25 manufacturers that had not submitted premarket applications to FDA and were continuing to sell or distribute unauthorized NTN e-liquid online. FDA has also issued 3 warning letters to online retailers for illegally selling NTN products to underage purchasers.

The Agency appreciates OIG's consideration of the information we provided from our review of the preliminary draft report. We are separately providing technical comments to the draft intended to provide clarity and accuracy. For example: 1) a more accurate description of the steps in FDA's investigations process for online tobacco retailers regarding the contractors' roles, steps of the process, and reporting inspection data in fiscal years for consistency with Congressional reporting and contracting, and; 2) reflection of the fact that most companies comply after receipt of a warning letter and therefore enforcement action is not necessary.

FDA's comments on OIG's specific recommendations are below.

Collaborate with ATF on oversight of online tobacco retailers.

FDA concurs with the recommendation that there may be additional opportunities to collaborate with ATF. FDA has previously collaborated with ATF on other issues and will explore

developing a Memorandum of Understanding (MOU), if appropriate. By the end of October 2022, FDA will communicate with ATF to determine the appropriate ATF contacts to obtain relevant PACT Act data. Subsequently, we will work with ATF to determine: 1) the type of information ATF has regarding websites selling and marketing tobacco products online; 2) whether the information can assist FDA's efforts related to online compliance and enforcement activities, and; 3) whether ATF is able to share the non-public information with FDA. We recognize that there may be information that ATF cannot share even under an MOU.

Complete its rulemaking on non-face-to-face sales of tobacco products, as required by the Tobacco Control Act.

FDA remains committed to issuing rules to implement the Tobacco Control Act. We note that many of the benefits of such a rule are also realized in other restrictions and requirements such as those under the PACT Act, imposed by states and other jurisdictions, and those placed on tobacco product manufacturers upon receiving a Marketing Granted Order from FDA for their premarket tobacco product application.

Collect data to support process and outcome measures for its oversight of online retailers.

FDA understands the potential benefit of this recommendation and will explore ways to maximize transparency without jeopardizing investigations. The Agency has investigative processes in place related to online investigations of websites selling or marketing tobacco products, but limits information publicized about ongoing online investigations to avoid disclosing enforcement strategy, which could help retailers evade compliance and enforcement. We post warning letters on the public Warning Letter webpage used by all FDA Centers. We also publicize cases that are important for the public to know about. For example, FDA recently issued a press statement about a warning letter on the day it issued, August 18, 2022, to alert the public of a firm marketing illegal flavored nicotine gummies. This was the first warning letter for this type of product, which is of particular public health concern because of its resemblance to kid-friendly food or candy products and the potential to cause severe nicotine toxicity or even death among young children. We have observed that since the issuance of the warning letter, the company's website shows the product subject to the warning letter as "discontinued." This is just the first step in continued monitoring and surveillance to verify continued compliance.

The Agency's goal remains industry compliance with the Federal Food, Drug and Cosmetic Act. Compliance may be achieved in a number of ways, including ways that can't be measured. For example, we know that the issuance of warning letters, and publicizing such letters, can serve as an important deterrent to prevent violations.

FDA understands the value of process measures for its oversight of online retailers. The Agency is evaluating our internal processes to determine if they need to be updated and better documented.

Publish information on the purpose and performance of its oversight of online tobacco retailers.

FDA concurs with OIG's recommendation. While FDA posts all warning letters and related press statements to the FDA website, we must balance not disclosing enforcement strategy that could help retailers evade compliance and enforcement. As a result of OIG's recommendation, by March 2023, FDA will create a dedicated webpage on our website to provide the public with

information specific to FDA’s tobacco online surveillance program. We will include information about the online surveillance program and additional related undercover compliance and enforcement efforts that may be helpful and informative to the public, including purpose and performance.

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

Matt Blackburn served as the team leader for this study. Others in the Office of Evaluation and Inspections who conducted the study include Jac Carreiro, Caitlin Foster, and Rachel Pavia. Office of Evaluation and Inspections headquarters staff who provided support include Althea Hosein, Michael Novello, Christine Moritz, and Sarah Swisher.

This report was prepared under the direction of Joyce Greenleaf, Regional Inspector General for Evaluation and Inspections in the Boston Regional Office, and Kenneth Price, Deputy Regional Inspector General.

Contact

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ENDNOTES

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