U.S. FOOD & DRUG ADMINISTRATION

CENTER FOR TOBACCO PRODUCTS

COMPLIANCE AND ENFORCEMENT REPORT

Accomplishments and Activities of
FDA's Center for Tobacco Products
Office of Compliance and Enforcement

October 1, 2013–December 31, 2018

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Reporting on CTP's Compliance and Enforcement Activities Over the Last Five Years: An Introduction From a Director's Perspective

A Message from Ann Simoneau, J.D.
Director, Office of Compliance and Enforcement, FDA Center for Tobacco Products

I am proud to share this report covering the activities of the Office of Compliance and Enforcement (OCE) within FDA's Center for Tobacco Products (CTP) for the period Oct. 1, 2013–Dec. 31, 2018. The report highlights our past and ongoing efforts designed to ensure that regulated industry understands and complies with the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) and related regulations, to protect public health.

The activities summarized in this report were built on the foundation of the prior years' achievements, following enactment of the Tobacco Control Act and establishment of CTP. These previous accomplishments are summarized in the first Compliance and Enforcement Report, available on CTP's website. Major developments that occurred since the last report include the finalization in 2016 of a landmark regulation known as the "deeming rule," which significantly broadened the scope of tobacco products regulated by FDA, and the announcement in 2017 of FDA's "Comprehensive Plan for Tobacco and Nicotine Regulation," a tobacco regulatory framework that focuses on the issues of nicotine and addiction.

As permitted by the Tobacco Control Act, the deeming rule extended FDA's regulatory authority to all products that the law defines as "tobacco products," including e-cigarettes, cigars, and hookah and pipe tobacco. The deeming rule has proven especially important as the tobacco product landscape transforms and we observe a disturbing recent spike in the popularity of e-cigarettes among youth, even as youth use of traditional cigarettes has markedly declined.

Many activities covered in this report are related to new requirements under the deeming rule. All CTP offices worked together to develop resources to help affected tobacco product retailers and manufacturers—including some in the industry whose products were not previously regulated by FDA—understand relevant legal requirements and how to comply. And we worked to ensure industry compliance, taking appropriate enforcement action when violations were found.

Another turning point came in 2017, with FDA's announcement of the "Comprehensive Plan for Tobacco and Nicotine Regulation" roadmap for the agency's tobacco regulatory efforts. The segment of the plan known as the Youth Tobacco Prevention Plan (YTPP), in particular, has guided recent enforcement activities to stem youth access to, and use of, e-cigarettes and other tobacco products—especially flavored products, which appear to be a significant part of the youth tobacco use problem.

Enforcement-related actions taken by our office to protect youth have included a nationwide undercover inspection effort—the largest coordinated enforcement effort in the agency's history—in which OCE identified retailers selling e-cigarettes to kids and took action against those retailers as appropriate. Additional actions have been taken related to the role of manufacturers in youth appeal of, and access to, these products.

After statistics showed a spike in e-cigarette use among youth, the need for our continued compliance and enforcement efforts was more evident than ever.

This report presents an overview of our last five years' compliance and enforcement activities to protect youth, as well as adults, from tobacco-caused disease and death. These activities include:

- *Monitoring compliance through surveillance, inspections, and investigations.* Activities included inspecting physical tobacco retail establishments—2018 saw OCE's millionth such inspection; reviewing online sales and advertising; and inspecting tobacco manufacturers, including certain vape shops, and requesting certain information.
- *Taking appropriate action when industry does not comply.* Actions included issuing warning letters and seeking civil money penalties or no-tobacco-sale orders.
- *Providing compliance information to regulated industry.* OCE, in conjunction with CTP's Offices of Health Communication and Education, Regulations, and Science, provided numerous resources to regulated industry during the period of time covered by this report to help them comply with their statutory requirements and FDA's tobacco regulations.

This report is designed to convey a sense of OCE's critical contributions to CTP's mission of preventing people from starting to use tobacco products, encouraging tobacco users to quit, and ultimately reducing the harm caused by tobacco use. OCE remains committed to these goals and will continue its efforts to protect the public health by seeking compliance with the requirements under the law.

Thank you,

/Ann Simoneau/

Overview of FDA's Regulatory Authority Over Tobacco Products

The Tobacco Control Act

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was signed into law on June 22, 2009, and gave FDA the authority to regulate the manufacture, distribution, and marketing of tobacco products. The Tobacco Control Act gave FDA immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.

The Deeming Rule

The Tobacco Control Act also gave FDA authority to "deem" additional tobacco products to be subject to its tobacco authorities. On May 10, 2016, FDA finalized the deeming rule, which deems all products meeting the statutory definition of tobacco products, including components or parts (but excluding accessories), to be subject to FDA's tobacco product authorities under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Tobacco Control Act, including:

- Electronic nicotine delivery systems (ENDS), such as e-cigarettes, e-cigars, vape pens
- Cigars
- Pipe tobacco
- Nicotine gels
- Waterpipe (hookah) tobacco
- Dissolvables not already under FDA's authority
- Future tobacco products

The deeming rule includes restrictions that are intended to prevent the sale and distribution of "covered" tobacco products to minors. Covered tobacco products are deemed tobacco products but exclude components or parts that are not made or derived from tobacco. These requirements include:

- Not allowing covered tobacco products to be sold (in person or online) to persons under the age of 18
- Requiring age verification by photo identification for anyone under the age of 27 attempting to purchase a covered tobacco product
- Not allowing the sale of covered tobacco products in vending machines (unless in an adult-only facility)

Additionally, the deeming rule prohibits the distribution of free samples of all deemed tobacco products. The new rule also requires health warnings on cigars, roll-your-own tobacco, cigarette tobacco, and covered tobacco products.

In addition, manufacturers of deemed finished tobacco products—meaning deemed tobacco products that are sealed in final packaging and intended for consumer use—must submit certain information to FDA, including tobacco health documents and ingredient listings, and must report harmful and potentially harmful constituents in their tobacco products. Manufacturers of finished tobacco products are also required to register their establishments, provide product listings, and receive marketing authorization from FDA before a new tobacco product can be marketed in the U.S.

You can find information about other provisions of the deeming rule and applicable compliance dates in the chart titled "Effective and Compliance Dates Applicable to Retailers, Manufacturers, Importers, and Distributors of Newly Deemed Tobacco Products" on CTP's website.

Examples of OCE Programs Impacted by the Deeming Rule

Grandfathered (GF) Status Reviews of Predicate Tobacco Products

New tobacco products may not be legally marketed in the United States unless FDA has issued an order permitting their marketing.[1] Substantial equivalence (SE) and exemption from substantial equivalence (SE exemption) are two of the pathways under which FDA may issue an order or written notification that would allow a new tobacco product to be legally marketed in the United States. As part of the review of an SE exemption request or SE report, OCE works closely with CTP's Office of Science to conduct reviews for compliance with the FD&C Act and GF determinations for predicates used in the applications. OCE also makes GF determinations as part of its voluntary standalone GF determination program, as explained later in this report.

Registration and Listing

Every person who owns or operates any establishment in any state or territory engaged in the manufacture, preparation, compounding, or processing of a tobacco product is required to register annually with FDA and file a list of its regulated tobacco products. FDA uses the Tobacco Registration and Product Listing Module (TRLM) of FDA's Unified Registration and Listing System (FURLS) to electronically collect this information. This information assists OCE in its compliance and enforcement activities, including biennial inspections of manufacturers. Further, FDA has posted the submitted registration and listing information publicly as a means of providing public access to the information, which is required by Section 905(f) of the FD&C Act, and as a service to interested stakeholders.

Implementing the Deeming Rule:

REGISTERED ESTABLISHMENTS AND TOBACCO PRODUCT LISTINGS[2]

To accommodate the newly regulated products, OCE updated the TRLM to increase its capacity for these newly regulated establishments to register and submit product listings. OCE also produced a **webinar** to explain how to use the registration and listing system because many establishments previously not required to comply with these requirements now must register their manufacturing establishments and submit their product listings with OCE.

	Prior to August 8, 2016	As of December 31, 2018
REGISTERED ESTABLISHMENTS	**92**	**3500**
TOBACCO PRODUCT LISTINGS	**6668**	**>606,000,000**

1 New tobacco products first introduced or delivered for introduction into interstate commerce for commercial distribution after Feb. 15, 2007, and prior to March 22, 2011, and for which a 905(j) (or substantial equivalence) report was submitted no later than March 22, 2011, can be legally marketed unless FDA issues a not substantially equivalent order.

2 Registration and listing information is provided and periodically updated by regulated entities, which may impact the completeness and accuracy of the information.

New Required Warning Statements

Beginning Aug. 10, 2018, FDA began enforcement of the requirement that covered tobacco products (excluding cigars and pipe tobacco), as well as roll-your-own and cigarette tobacco products, manufactured on or after Aug. 10, 2016, include a health warning statement regarding the addictiveness of nicotine on packages and advertisements. The required statement reads: "WARNING: This product contains nicotine. Nicotine is an addictive chemical."

In addition to this statement, packages and advertisements must bear the following information on their labels, under section 903(a)(2) of the FD&C Act:

- The name and place of business of the tobacco product manufacturer, packer, or distributor;
- An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; and
- The statement: "Sale only allowed in the United States" on labels, packaging, and shipping containers of tobacco products (required under section 920(a)(1) of the FD&C Act).

Cigar Warning Plans

The deeming rule requires that all cigar packages that are manufactured, packaged, sold, offered for sale, distributed, or imported for sale or distribution within the United States must bear one of the following required warning statements on the package label:

- **WARNING:** Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
- **WARNING:** Cigar smoking can cause lung cancer and heart disease.
- **WARNING:** Cigars are not a safe alternative to cigarettes.
- **WARNING:** Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.

Implementing the Deeming Rule:

WARNING STATEMENT REQUIREMENTS FOR CERTAIN TOBACCO PRODUCTS

To assist affected industry in complying with the requirement for an addictiveness warning statement on certain tobacco products, FDA made available on its website several **visual examples** of how the warning statement may appear on packaging.

- **WARNING:** Cigar use while pregnant can harm you and your baby.
  or
  SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.*
- **WARNING:** This product contains nicotine. Nicotine is an addictive chemical.

** Regulated entities may choose to display either one of the warning statements regarding reproductive health. FDA expects that providing this optional alternative will benefit entities bound by the Federal Trade Commission (FTC) consent decrees, and this requirement is appropriate for the protection of public health.*

Except for cigars sold individually and not in a product package, the six required warning statements must be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of cigar sold in product packaging, in accordance with an FDA-approved warning plan. Advertisements for cigars must include one of the six required warning statements, and these warnings must be rotated quarterly for each brand of cigars in accordance with an FDA-approved warning plan.

Warning plans are submitted by the responsible cigar manufacturer, importer, distributor, or retailer. In most cases, the entity that is responsible for placing or directing the placement of the warnings on the packages submits a warning plan for its packaging to OCE for review and approval.

Likewise, the manufacturer, importer, distributor, or retailer who creates advertising, causes advertising to be created, or is otherwise responsible for inclusion of the warning on advertising for a brand generally submits a warning plan for its advertisements to OCE for review and approval.

Between Oct. 1, 2013, and Dec. 31, 2018, OCE reviewed and approved over 300 cigar warning plans.

Note About Warning Statement Requirements for Cigars and Pipe Tobacco

At this time, FDA does not intend to enforce the health warning requirements for cigar and pipe tobacco products. The U.S. District Court for the District of Columbia issued an order on July 5, 2018, enjoining FDA from enforcing the health warning requirements for cigars and pipe tobacco until 60 days after final disposition of the plaintiffs' appeal of the court's order on the health warning requirements.

Cigar and pipe tobacco firms may choose to voluntarily comply with the warning requirements and sections 903(a)(2) and 920(a)(1) while the injunction is in effect. The warning requirements remain in effect for other product categories, including ENDS products, hookah tobacco, and cigarette tobacco and roll-your-own tobacco products.

Compliance and Enforcement Activities

Compliance and Enforcement Actions

OCE's compliance activities include, among other things, inspecting brick-and-mortar tobacco retail establishments; monitoring and surveillance of websites, publications, and social media that sell, distribute, promote, or advertise regulated tobacco products; and inspecting registered domestic tobacco manufacturing establishments, including vape shops.

The FD&C Act provides OCE with several tools that it may use when violations are observed, including: advisory actions, such as warning letters; enforcement actions, such as civil money penalties (CMPs) and no-tobacco-sale orders (NTSOs); and judicial actions, such as seizures, injunctions, and criminal prosecutions.

Between Oct. 1, 2013, and Dec. 31, 2018, OCE issued more than 71,000 warning letters to regulated tobacco entities.

Actions taken against brick-and-mortar retailers, including warning letters, CMPs, and NTSOs, are displayed in a searchable database. This database also includes the results of compliance check inspections of tobacco retailers in which no violations were observed.

Warning letters issued to other regulated tobacco entities may be viewed in FDA's Electronic Reading Room.

ENFORCEMENT SPOTLIGHT: YOUTH TOBACCO PREVENTION PLAN TO STOP YOUTH USE OF, AND ACCESS TO, TOBACCO PRODUCTS, ESPECIALLY ENDS PRODUCTS

In April of 2018, FDA announced a new Youth Tobacco Prevention Plan, a key component of FDA's Comprehensive Plan for Tobacco and Nicotine Regulation, to stop youth use of, and access to, tobacco products, especially ENDS products. As part of this announcement, FDA announced that a nationwide inspection blitz was underway to determine if retailers were selling ENDS products, specifically JUUL products, to kids in brick-and-mortar stores and online. As a result of this blitz, a total of 56 warning letters and six civil money penalty complaints were issued to retailers for selling JUUL and other e-cigarette products to minors.

Subsequently, in the summer of 2018, OCE issued more than 1,300 warning letters and CMPs to retailers who illegally sold JUUL and other e-cigarette products to minors during a nationwide, undercover blitz of brick-and-mortar and online stores. It was the largest coordinated enforcement effort in FDA's history.

Retailer Compliance Check Inspection Program

OCE estimates that there are currently more than 360,000 retailers that sell tobacco products in the United States. The Tobacco Control Act specifically directed FDA to contract with states, U.S. territories, and Indian tribes, when feasible, to assist with tobacco compliance check inspections of retail establishments to determine compliance with applicable provisions of the Tobacco Control Act and its implementing regulations. FDA may contract with third-party entities when it is not feasible to contract with the states or territories, or may conduct investigations using FDA personnel.

The FDA Tobacco Retail Inspection Contracts webpage contains pertinent information about each jurisdiction where FDA has contracted, including the most recent contract start date in those jurisdictions.

OCE has facilitated the commissioning of more than 700 local government officers and employees who have collectively conducted more than 1 million compliance check inspections—***more than 800,000 of which were conducted between Oct. 1, 2013, and Dec. 31, 2018.***

These inspectors conduct two types of compliance check inspections for FDA. The first type of compliance check inspection is generally an undercover purchase by a team composed of an FDA-commissioned inspector and minor to determine whether retailers are checking identification and if they are selling regulated tobacco products to minors. The second type of compliance check inspection involves only FDA-commissioned inspectors and generally determines compliance with other retail provisions in effect, such as the restrictions on impersonal modes of sales (i.e., vending machines and self-service displays), the ban on cigarettes with certain characterizing flavors, and the ban on the sale of packages containing fewer than 20 cigarettes. During this type of inspection, inspectors present the retailer with a notice of inspection and announce their presence by showing their FDA credentials.

Though the agency tries to obtain voluntary compliance through education and outreach, when potential violations are observed during a compliance check inspection of a tobacco retailer, OCE reviews the evidence collected by the retail inspectors and determines what action should be taken. OCE may utilize several administrative and enforcement tools and/or judicial actions as mentioned previously.

If a regulated tobacco product is sold to a minor during an undercover purchase inspection, OCE sends the retailer a Compliance Check Inspection Notice shortly after the inspection. This notice, which is not an official action, promptly provides the retailer with information about the inspection, such as the time and date of the inspection, a photo of the facility inspected, and a statement that the minor was able to purchase a tobacco product, resulting in a potential violation.

Retailer Warning Letters

OCE generally issues a warning letter to a retailer the first time a violation of the federal tobacco laws and regulations that OCE enforces has been identified. Warning letters are advisory actions used to obtain compliance, stating that the retailer has a continuing obligation to comply with federal law, that FDA will periodically inspect the establishment, and that future violations may result in FDA taking enforcement action (such as CMPs and NTSOs) without further notice. Warning letters also include an explanation of FDA's jurisdiction, the retailer's violations, and a request for a written response detailing the retailer's plan for corrective actions.

A warning letter issued to a retailer may encompass one or more violations of the FD&C Act, and it may not represent an exhaustive list of all violations that have occurred at that establishment. The most commonly observed violations during tobacco retailer compliance check inspections are the sale of regulated tobacco products to minors and the failure to verify the date of birth by checking photo ID. ***Between Oct. 1, 2013, and Dec. 31, 2018, OCE issued more than 70,000 warning letters to retailers for violations observed during compliance check inspections.***

Civil Money Penalty Complaints

If OCE identifies a violation during a follow-up or subsequent inspection at the same retail establishment that previously received a warning letter, OCE may issue a CMP complaint, which initiates an administrative legal action against the retailer. OCE seeks CMPs in accordance with the schedule published in the Tobacco Control Act and further explained in FDA guidance documents. Two relevant guidance documents, both of which were revised as of December 2016, are: "Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers (*Revised)" and "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers: Responses to Frequently Asked Questions (*Revised)."

Between Oct. 1, 2013, and Dec. 31, 2018, OCE issued more than 18,000 civil money penalty complaints.

No-Tobacco-Sale Order Complaints

If OCE finds a retail establishment has committed repeated violations, OCE may, under the law, pursue an NTSO prohibiting the sale of tobacco products by a retail outlet. The term "repeated violations" is defined as "at least five violations of particular requirements over a 36-month period at a particular retail

Implementing the Deeming Rule:

FIRST WARNING LETTERS ISSUED TO RETAILERS FOR SALES OF DEEMED TOBACCO PRODUCTS TO KIDS

In September 2016, one month after the deeming rule extended FDA's authority to ENDS, cigars, hookah tobacco, and other deemed tobacco products, OCE **issued the first 55 warning letters** to retailers for selling these products to kids.

During nationwide compliance check inspections and online surveillance, minors were able to purchase some of these newly regulated tobacco products in a variety of youth-appealing flavors, including bubble gum, cotton candy, cherry crush, strawberry cake pop, banana split, and gummy bear.

Between August 2016 and Dec. 31, 2018, FDA issued over 33,000 warning letters to retailers. Many of these warning letters were for the sale of deemed tobacco products to kids.

outlet." Under the NTSO, a retailer is prohibited from selling regulated tobacco products at the specified location during the period of time specified in the NTSO. The first time OCE pursues an NTSO against a retail establishment, OCE intends to seek a 30-day NTSO period in the complaint. If subsequent violations are observed at a retail establishment that has already received an NTSO order, OCE may seek an additional NTSO for a longer period of time.

In general, OCE files NTSO complaints seeking the maximum time period, which is described in a guidance document entitled "Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order." However, based on information that may subsequently become available to OCE, including information provided by the retailer in an answer to the complaint or during a settlement conference or hearing, OCE may reduce the length of the NTSO. In October 2015, OCE initiated its first NTSO complaints against retail establishments seeking to prohibit the sale of regulated tobacco products in those establishments for 30 days. ***Between Oct. 1, 2013, and Dec. 31, 2018, OCE issued 145 no-tobacco-sale order complaints to retailers.*** OCE lists all NTSOs, including their effective dates, on its website.

Not Substantially Equivalent (NSE) Letters to Retailers

To legally market a new tobacco product in the United States, a manufacturer must receive a written order from FDA. FDA's traditional "safe and effective" standard for evaluating medical products does not apply to tobacco products. Instead, FDA regulates tobacco products based on a public health standard intended to reduce the toll of tobacco use. There are three pathways to market for new tobacco products: premarket tobacco product application (PMTA); substantial equivalence (SE); and exemption from substantial equivalence (SE exemption).

CTP reviews SE reports to determine if the new tobacco product is substantially equivalent to the predicate product in the report, and in compliance with the requirements of the FD&C Act. If it is determined that the applicant has met these criteria, CTP will issue an SE marketing order. If it is determined that the applicant has not met these criteria, CTP will issue a not substantially equivalent (NSE) order. When an NSE order is issued, a tobacco product is misbranded and adulterated, effective immediately, and, among other things, it is illegal to sell or distribute the product in interstate commerce and to import the product into the United States.

If FDA inspectors conducting routine compliance check inspections find tobacco products subject to an NSE order at a retail location, the owner of that retail location may receive a notification from OCE about the legal status of the product found in the store. This notification also encourages the retailer to work with its tobacco product supplier or the product's manufacturer to discuss possible options for its NSE product inventory. ***Between Oct. 1, 2013, and Dec. 31, 2018, OCE issued over 1,100 such letters to retailers.***

Promotion, Advertising, Labeling, and Distribution Surveillance and Investigations

OCE conducts routine surveillance of sales, distribution, marketing, labeling, and advertising activities related to regulated tobacco products—on the Internet, including in social media; in publications; at promotional events; and through other compliance and enforcement activities. ***Between Oct. 1, 2013, and Dec. 31, 2018, OCE monitored more than 20,000 websites.***

FDA may also send letters to companies requesting information about specific products or activities. When violations are observed through these surveillance and investigation activities, OCE generally issues a warning letter. Some commonly observed violations from OCE's surveillance of promotion, advertising, and labeling activities include sales to minors; marketing tobacco products as "low," "light," or "mild" or otherwise making modified risk claims without an FDA order in effect; prohibited distribution of free samples; and failure to display required warning statements on product packaging or advertising.

Between Oct. 1, 2013, and Dec. 31, 2018, OCE issued more than 160 warning letters to companies for making modified risk claims, including "low," "light," or "mild" claims, for tobacco products without an order from FDA. And, in that same timeframe, OCE issued an additional 400 warning letters for other violations of the law related to tobacco product sales, advertising, and labeling online, in print, and at promotional events.

Examples of these warning letters are:

- In August 2015, OCE issued three warning letters to tobacco manufacturers who described their cigarettes on product labeling as "additive-free" and/or "natural" without a modified risk order in place allowing the products to be marketed with such claims. A "modified risk tobacco product" is "any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." This includes products, the label, labeling, or advertising of which represents implicitly or explicitly that the product or its smoke does not contain or is free of a substance and/or that the product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products. A manufacturer who seeks to claim that a product poses fewer risks than other tobacco products may submit a modified risk tobacco product (MRTP) application to FDA with scientific evidence to support that claim. These products described as "natural" and "additive-free" on their labeling need an FDA modified risk tobacco product order before they can be legally introduced as such into interstate commerce.
- In December 2016, OCE issued warning letters to four tobacco manufacturers for illegal sales of flavored cigarettes labeled as little cigars or cigars. Although labeled as little cigars or cigars, the products met the definition of cigarettes in the Tobacco Control Act, because they were likely to be offered to, or purchased by, consumers as cigarettes based on their overall presentation, appearance, and packaging and labeling.
- In October 2018, OCE coordinated with FDA's Center for Drug Evaluation and Research to issue the first joint warning letter to a firm for various violations of the FD&C Act, including selling two e-liquids containing the prescription drugs tadalafil and/or sildenafil. These products were also marketed with images of FDA-approved prescription drugs that treat erectile dysfunction and/or anti-obesity medications. As a result, FDA determined that the company was selling or distributing its e-liquid products in ways that conveyed, or misled consumers into believing, that FDA had approved those tobacco products, when it had not.

Implementing the Deeming Rule:

WARNING LETTERS FOR SELLING E-LIQUIDS THAT RESEMBLE KID-FRIENDLY FOOD PRODUCTS

Through its surveillance activities, OCE identified several e-liquid products that were being sold and marketed with youth-appealing labeling. OCE also received complaints that some e-liquids were packaged in food-imitating or youth-appealing packaging, and that firms were targeting children.

In May of 2018, OCE and the Federal Trade Commission issued joint warning letters to 13 online manufacturers, distributors, and retailers for selling misbranded tobacco products. All illegally sold e-liquids had labeling and/or advertising that caused them to resemble kid-friendly food products, including juice boxes, candy, or cookies, and some of them included cartoon-like imagery. Six of the retailers also illegally sold the e-liquid products to minors and one of the retailers was in violation for marketing a tobacco product in combination with a food.

Also in May of 2018, OCE issued four additional warning letters to online manufacturers and retailers for selling misbranded tobacco products with labeling and/or advertising that caused them to resemble kid-friendly food products, including cereal, grape soda, or pancakes, and some of them included cartoon-like imagery. Kids are at risk from these products that look more like food than tobacco products. There is the possibility that children will ingest e-liquid products that contain nicotine, which has the potential to cause serious injury or death.

In August of 2018, OCE announced that all 17 manufacturers, distributors, and retailers that received warning letters in May had stopped selling the tobacco products with the offending labeling and advertising.

In September 2018, OCE issued 22 more warning letters to other companies for similar violations related to food-imitating products.

Manufacturer Inspections, Import Activities, and Other Investigations

OCE works closely with the Tobacco Operations Staff within FDA's Office of Regulatory Affairs (ORA) to conduct tobacco inspections of registered establishments that manufacture tobacco products, and to conduct investigations at certain events to ensure that tobacco product manufacturers or retailers do not distribute prohibited free samples and companies are not sponsoring events using the brand name of a cigarette or smokeless tobacco product. Inspections and investigations are conducted to determine compliance with the applicable requirements of the FD&C Act and its implementing regulations.

During a manufacturing inspection, an inspector may:

- Review processes and procedures;
- Observe and evaluate operations;
- Document and collect information;
- Identify violations;
- Communicate potential violations to firm management; and/or
- Document any proposed corrective action plans.

Between Oct. 1, 2013, and Dec. 31, 2018, 350 manufacturer inspections of registered establishments were completed.

When violations are observed during inspections, investigations, or other surveillance activities, OCE may take action including initiating warning letters and import alerts. Between Oct. 1, 2013, and Dec. 31, 2018, OCE issued warning letters to manufacturers, distributors, and importers for violations that included failure to register a domestic manufacturing establishment, failure to pay required user fees, and unauthorized distribution of a new tobacco product without a marketing authorization in place.

FDA also has five active tobacco import alerts. Import alerts inform the FDA field staff and the public that the agency has enough evidence to allow for the detention without physical examination of products that appear to be in violation of FDA's laws and regulations. Import alerts are currently in place for: flavored cigarettes or their components or parts; regulated tobacco products whose labeling or advertising uses the descriptors "light," "mild," or "low"; smokeless tobacco products without the required warning label; certain tobacco products found to be NSE; and regulated tobacco products for non-payment of user fees.

Implementing the Deeming Rule:

LETTERS TO INDUSTRY REQUESTING IMPORTANT PRODUCT MARKETING INFORMATION

In October 2018, OCE notified 21 manufacturers of deemed tobacco products, including some flavored ENDS products, that it had come to the attention of the agency that these firms may be manufacturing/importing tobacco products without the required premarket authorization. OCE requested that these firms provide:

- Evidence that the product was commercially marketed (other than for test marketing) as of Feb. 15, 2007, and that the product is therefore a GF tobacco product;
- Evidence that the product is a deemed product that was on the market on Aug. 8, 2016, and that the product has not been modified since that date;
- Evidence that the product was first introduced or delivered for introduction into interstate commerce for commercial distribution after Feb. 15, 2007, and prior to March 22, 2011, and that an SE report was submitted for the product no later than March 22, 2011;
- Evidence that FDA has issued an order permitting the marketing of the product; and/or
- Evidence, which may include a statement from the firm, that the firm is currently not marketing the product.

Vape Shop Inspections

A vape shop is an establishment that engages in activities related to ENDS products. For example, a vape shop retailer might sell ENDS devices, ENDS replacement pieces, ENDS hardware, ENDS e-liquids, and other ENDS-related products to individuals for personal consumption. A vape shop may mix or prepare e-liquids, create or modify aerosolizing apparatuses, repackage ENDS products, or relabel ENDS products. Depending on the activities that a vape shop engages in, it could be a retailer, manufacturer, or both. OCE finalized a guidance document in March 2019, entitled "Interpretation of and Compliance Policy for Certain Label Requirement; Applicability of Certain Federal Food, Drug, and Cosmetic Act Requirements to Vape Shops," that provided FDA's current thinking on vape shop activities and how it intends to enforce certain requirements of the FD&C Act that pertain to vape shops. OCE also developed and posted multiple compliance training webinars covering topics pertaining to vape shops. More information about webinars is provided later in this report.

OCE conducts inspections of vape shop establishments, many of which mix and/or sell flavored ENDS products. During these inspections, OCE seeks to determine the type of activities that are performed at the establishment and compliance with applicable requirements under the FD&C Act and its implementing regulations. ***From August 2016 (when the deeming rule became effective) through Dec. 31, 2018, OCE conducted more than 800 vape shop inspections.***

Recalls

A recall is an action to remove from the market a regulated product that is either defective or potentially harmful. Recalls may be voluntary or mandatory, and are almost always voluntary. Sometimes a company discovers a problem and recalls a product on its own. Other times a company recalls a product after FDA raises concerns. If FDA finds there is a reasonable probability that a tobacco product contains a manufacturing or other defect not ordinarily contained in tobacco products on the market that would cause serious, adverse health consequences or death, the agency will issue an order requiring the appropriate person to immediately cease distribution of such tobacco product. In all recall situations, FDA oversees a company's strategy and assesses the adequacy of the recall. Between Oct. 1, 2013, and Dec. 31, 2018, OCE was notified of two tobacco product recalls initiated by the manufacturers of the products. Both recalls involved smokeless tobacco product packages containing a foreign material.

Collaboration

OCE works closely with states, territories, tribes, other governmental organizations, and the public in fulfilling OCE's mission to ensure that regulated tobacco products and those that manufacture, distribute, sell, and market tobacco products are complying with applicable laws and regulations.

Collaboration with Other Federal and State Tobacco Programs and Organizations

Federal, state, and local governments are committed to working together to reduce youth access to, and use of, tobacco products. Beyond OCE's retail inspection contracts, OCE collaborates on a regular basis with other programs to inform policies that help ensure that regulated industry follow existing laws designed to reduce the health burden of tobacco use on the American public. These programs include those administered by the Office on Smoking and Health within the Centers for Disease Control and Prevention and the Synar Program administered by the Substance Abuse and Mental Health Services Administration.

OCE also collaborates with other federal partners such as the Federal Trade Commission (FTC) in joint compliance and enforcement efforts, including the joint warning letters described earlier in this report. Additionally, OCE collaborates with state-based organizations, such as the National Association of Attorneys General (NAAG), to share information to inform their tobacco control programs.

Tribal Engagement

CTP understands the importance of collaboration and consultation, as appropriate, with federally recognized tribal governments; respects tribal sovereignty; and honors the government-to-government relationship we have with federally recognized American Indian and Alaska Native tribes.

Retailers and manufacturers on tribal lands must also comply with all applicable federal laws and regulations. OCE has consulted with tribes via letters, calls, and webinars regarding various CTP compliance and enforcement activities, including retail inspections and requirements as a result of the deeming rule.

In addition to the many resources OCE provides on the CTP website, OCE has developed resources specifically for tribes and tribal retailers. These materials include a fact sheet and a video delivered directly to retailers on a video card. OCE updated its tribal retailer video Protect Our Future: Prevent Tobacco Sales to Minors to include references to the deeming rule. This compliance training video for retailers explains FDA's rules regarding the sale of regulated tobacco products. The video is intended to assist retailers and other stakeholders in Indian Country to understand the laws and how complying with them will help protect Native youth.

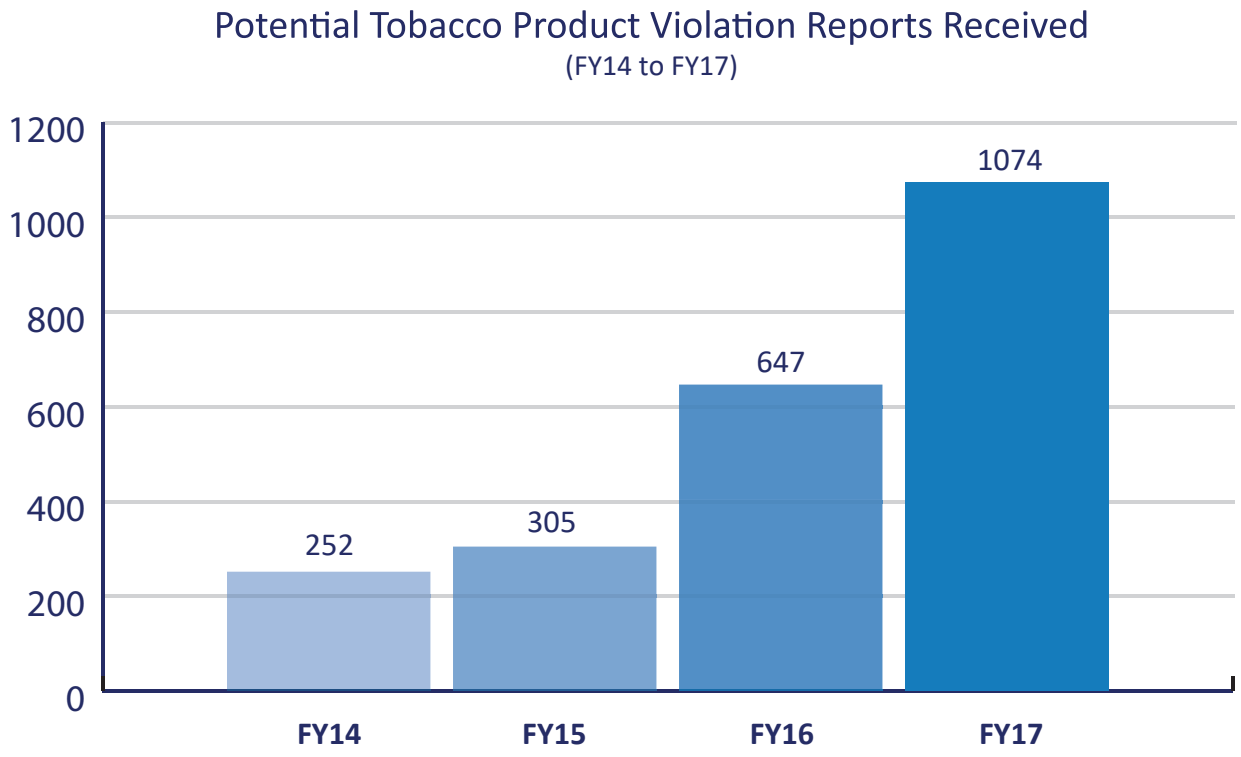
Potential Tobacco Product Violation Reports

OCE is committed to continuing to improve America's health with assistance from the public and ongoing outreach to stakeholders. Any stakeholder, including a consumer, may report to OCE a potential violation of the tobacco laws that we enforce via FDA's online reporting form. OCE reviews all reports of potential tobacco violations and conducts its own investigations of complaints. After reviewing a report, we may, among other things:

- Conduct a compliance check inspection of a tobacco retailer;
- Initiate monitoring and surveillance of the tobacco product website; or
- Inspect a tobacco product manufacturing establishment.

Between FY14 and FY17, OCE received over 2,270 potential tobacco violation reports, many of which were for potential violations related to deemed tobacco products such as flavored cigars and ENDS, for issues such as sales to minors, unlawful distribution of free samples of tobacco products, and products lacking required premarket authorization.

Although FDA does not base advisory and/or enforcement actions on a Potential Tobacco Product Violation Report or information provided by the public, independent OCE investigations of these reports have resulted in warning letters and various enforcement actions. OCE's enforcement tools are discussed in more detail in the "Compliance and Enforcement Actions" section of this report.



Enhanced Safety Reporting Portal to Address E-Cigarette Battery Safety

OCE reviews reports of tobacco product problems or adverse events that the agency receives through the Department of Health and Human Services' (HHS) Safety Reporting Portal (SRP) and from other sources, to better understand the events and to inform actions to protect the public health. OCE, and other offices in CTP, worked to enhance the SRP to be able to gather more information regarding complaints associated with overheating and exploding ENDS (e.g., e-cigarettes).

To help improve the quantity and quality of reports, OCE developed a brief video, available on CTP's website, to encourage reporting of adverse events associated with e-cigarettes and their components, such as batteries. In this video, submitters are encouraged to include the types of information that would help us better understand safety concerns associated with e-cigarettes and other ENDS products. This includes information such as: the name of the manufacturer, brand name, model and serial number of the product, brand name and model of the battery, and other information about the battery.

Informing and Assisting Industry

To help regulated industry understand and comply with the statutory requirements and FDA's tobacco regulations, OCE developed a set of stakeholder engagement tools and resources. OCE worked with CTP's Office of Regulations to develop new and updated "Guidance for Industry" documents that assist regulated industry in understanding and complying with the law.

Office of Small Business Assistance

CTP's Office of Small Business Assistance (OSBA), an office within OCE, provides technical and other non-financial assistance to small tobacco product manufacturers and other small businesses to help them to comply with the tobacco provisions of the FD&C Act. OSBA answers questions from regulated industry, including small tobacco product manufacturers and retailers, consumers of regulated tobacco products, and the public. The office responds to thousands of calls, emails, and correspondence every year to assist in answering specific questions about requirements of the law and how to comply.

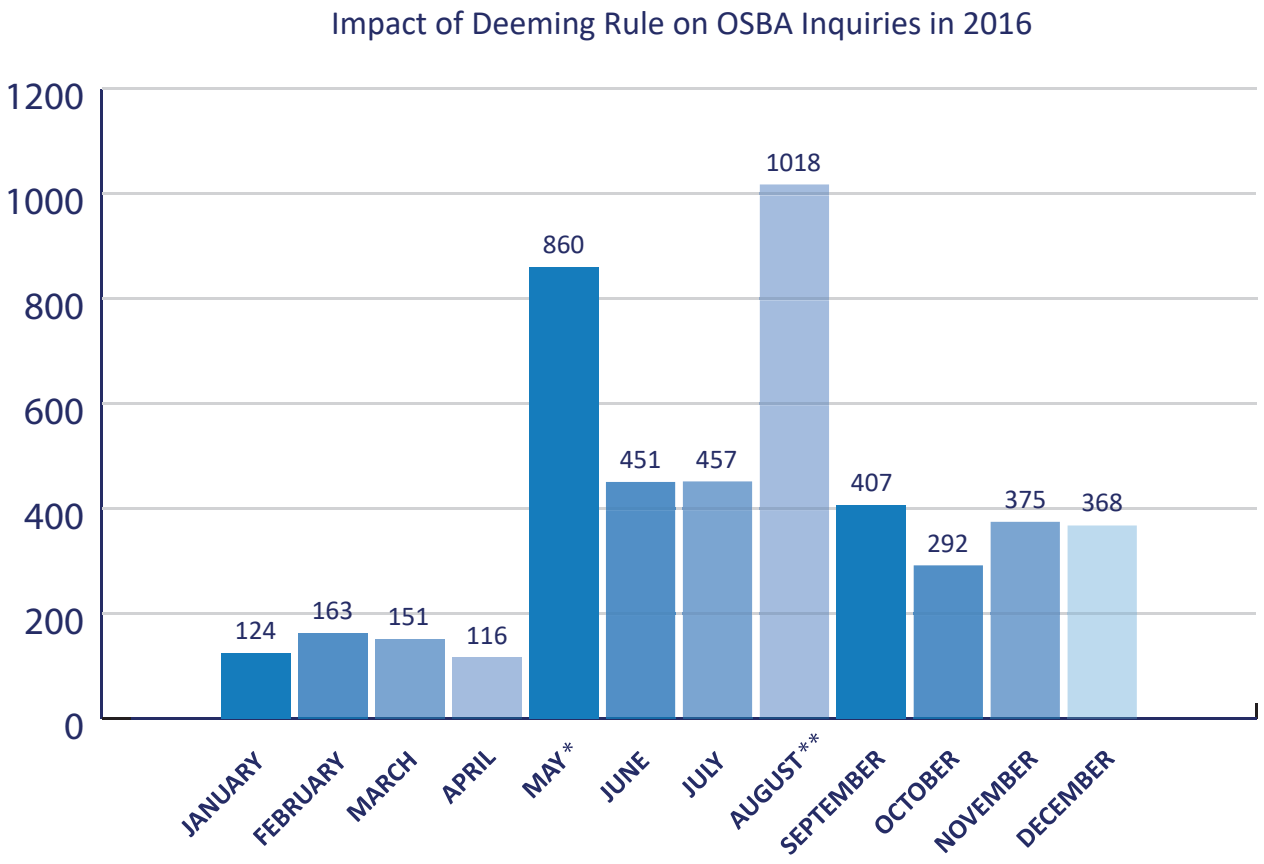
OSBA, working with CTP's Office of Health Communication and Education, updated its website presence to provide enhanced access to informational resources used by industry to navigate tobacco regulatory requirements and to assist small businesses with a one-stop shop on how to comply with the law.

The publication of the deeming rule significantly increased the number of inquiries to the OSBA. This increase was expected, due to the number of previously unregulated entities that are now regulated as a result of the deeming rule.

The number of inquiries that OSBA received peaked in May 2016, when the final deeming rule was published, and spiked again in August 2016, when the rule became effective.

Some of the most commonly asked categories of questions related to the deeming rule included:

- Establishment Registration and Product Listing
- Imported Tobacco Products
- Labeling
- Free Samples
- Vape Shops
- Cigars
- Retailer Provisions
- Premarket Tobacco Product Applications



*** May 10, 2016 - Deeming rule published**

**** August 8, 2016 - Effective date of deeming rule**

CTP Webpages

The CTP website provides information for regulated industry on FDA regulation of tobacco products including tobacco product review, science, and requirements for marketing and labeling. The website also provides several resources for the public including information about FDA's public education campaigns that illustrate the dangers of tobacco products.

OCE maintains several areas on the website that can assist industry with complying with FDA's regulations and statutory requirements. The website also provides information on how to report potential tobacco product violations and how to report unexpected health issues associated with the use of tobacco products.

Guidance Documents

FDA issues guidance documents to help industry comply with the law and related regulations. Guidance documents represent FDA's current thinking on a wide range of tobacco-related issues. The Center maintains a sortable list of tobacco-related guidance documents on its website.

Compliance Training Webinars

In 2011, OCE began hosting a series of webinars designed to provide FDA tobacco compliance education and information to retailers and to small business manufacturers to encourage compliance with FDA's tobacco laws and regulations. ***Between Oct. 1, 2013, and Dec. 31, 2018, more than 35 webinars have been developed and posted on OCE's website.*** FDA continues to update and provide new webinars (totaling more than 70) to assist regulated industry, such as its 2018 "Tips for Retailers" webinar and recent webinar series on CMP and NTSO complaints.

After the deeming rule was finalized, many of the webinars focused on this rule and its impact, to help tobacco retailers, importers, and manufacturers learn the steps they must take to comply with the deeming rule's requirements for the marketing and sale of all tobacco products.

In addition to webinars, OCE has employed other stakeholder engagement tools to provide needed compliance training and education to regulated industry and our public health partners. OCE has presented at conferences and meetings such as the Food and Drug Law Institute (FDLI), Convenience Distribution Association (CDA) Marketplace, Convenience Store Products (CSP) Total Nicotine Forum, and National Conference on Tobacco or Health (NCTOH).

Implementing the Deeming Rule:

COMPLIANCE TRAINING WEBINARS

- FDA's Import Operations: How FDA Regulates Imported Products
- Internet and Publication Surveillance
- Cigar Warnings and Warning Plan Requirements
- Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS) - Draft Guidance
- Meeting with Office of Science
- Registration and Product Listing Requirements for Domestic Establishments
- Environmental Considerations for Tobacco Product Applications Submitted to CTP
- Small Manufacturers, Importers, and Vape Shops That Manufacture or Import Newly Regulated Tobacco Products
- The Final "Deeming Rule" - All Tobacco Products Subject to the Federal Food, Drug, and Cosmetic Act
- New Regulatory Requirements for Vape Shops
- New Regulatory Requirements for Tobacco Manufacturers and Importers
- New Regulatory Requirements for Tobacco Retailers
- Retail Compliance Check Inspections: An Overview for Tobacco Retailers
- Q&A Webinar for Retailers Who Sell Newly Regulated Tobacco Products
- Timing and Tips - Newly Deemed Tobacco Product Applications
- Required Warning Statements for Cigars
- Using the Tobacco Registration and Listing Module (TRLM) of FURLS - Tips and Recent Enhancements
- A Retailer's Guide to "Covered" Tobacco Products
- Small Tobacco Product Manufacturers-Domestic Establishment Inspections
- Retailer Requirements: New Warning Statement Requirements for Certain Tobacco Products
- Introduction to Civil Money Penalty and No-Tobacco-Sale Order Complaints

Letters to Industry

OCE issues letters to industry to provide updates, help industry understand FDA regulations and policies, and request information, per Section 904(b) of the FD&C Act, among other reasons. These letters are available on the FDA website to assist regulated industry in understanding and complying with the Tobacco Control Act and its implementing regulations.

Examples of letters that OCE sent to industry are listed below:

- Certain Tobacco Products Found to be Not Substantially Equivalent
  (Feb. 21, 2014)
- Other Media Notifications
  (Sept. 16, 2014)
- Notice of Creation of Searchable Databases of Establishment Registration and Tobacco Product Listing Information
  (Jan. 22, 2015)
- Notice to Industry: Additional Tobacco Products Now Regulated by the Food and Drug Administration
  (May 6, 2016)
- Letter to Industry: Cigar Warning Plan Requirements
  (Sept. 1, 2016)

Voluntary Standalone Grandfathered (GF) Determinations and Public Database

As mentioned earlier in the report, a GF tobacco product is a product commercially marketed (other than for test marketing) in the United States as of Feb. 15, 2007. GF products are regulated under the FD&C Act, but do not require prior authorization to be legally marketed. Although not required by law, a manufacturer may voluntarily submit information for OCE to complete a GF status review of a tobacco product, which is referred to as a standalone GF determination. GF status may be established by submitting information to the agency such as dated copies of advertisements, catalog pages, promotional material, trade publications, bills of lading, invoices, purchase orders, etc. GF tobacco products may also serve as a predicate tobacco product in an SE Report.

On Jan. 24, 2017, FDA made available to the public the Standalone Grandfathered Determinations Public Database. This database, which is updated periodically, only contains GF determinations from voluntarily submitted requests for a GF status review of a tobacco product. The database does not list all GF tobacco products, because manufacturers are not required to receive a formal GF determination from OCE. Under certain circumstances, such as during a manufacturing inspection, companies may be requested to provide documentary evidence of the marketing status of those products for which a GF determination has not been made. The public database currently contains more than 3,700 products—of which over 2,200 are deemed products—for which OCE has received GF determination submissions and has determined are GF.

Compliance Check Inspection Database

As discussed earlier in this report, as part of OCE's Compliance Check Inspection Program, contracted inspectors conduct inspections of tobacco product retailers to determine retailer compliance with the Tobacco Control Act and its implementing regulations. After OCE analyzes the inspection information submitted by the inspectors and makes final compliance determinations, all retail inspection results are made available to the public in a searchable database on our website.

The searchable database can also be accessed using the "Inspection Database" link at the bottom of CTP's Compliance, Enforcement, and Training webpage.

Mobile Application—FDA Age Calculator

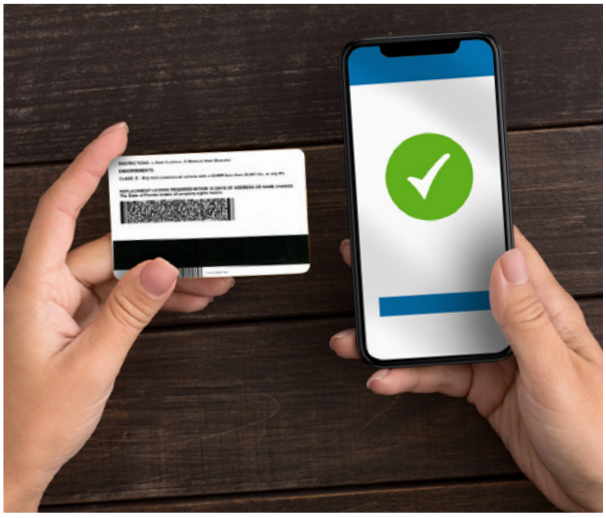
OCE noted during some inspections of tobacco retailers that retailers sold a regulated tobacco product to a minor even after asking for identification from the minor. In response, in July 2017, OCE released a free voluntary smartphone application, "FDA Age Calculator," on the Google Play and iTunes app stores to help retailers comply with age restriction laws. With the "FDA Age Calculator," retailers can use their personal smartphones to help determine if the purchaser is at least 18 years of age (the federal minimum age to buy a tobacco product).

OCE also updated the app to allow retailers to adjust the age that the app uses when calculating if the purchaser is old enough to purchase tobacco products. OCE recognizes that some jurisdictions have a more restrictive minimum age to purchase tobacco products, such as 19 or 21. Retailers in these areas can set a new cut-off age to reflect their jurisdiction's minimum age requirement. This update allows the app to continue to be a beneficial tool in preventing youth from accessing tobacco products from all retailers, regardless of varying state and local age restrictions. During compliance check inspections of tobacco retailers, OCE will continue to determine if retailers are complying with the federal minimum age of 18 years to purchase tobacco products.

This is Our Watch—Retailer Education Materials

To give retailers tools they need to comply with tobacco regulations, CTP's Office of Health Communication and Education (OHCE) has developed a free, voluntary educational program called "This is Our Watch." This program helps tobacco retailers better understand FDA tobacco regulations, the importance of compliance, and the importance of protecting the nation's youth from the harms of tobacco use.

The materials include a letter to retailers, a poster, register signage, regulation fact sheets, and an age verification calendar (recently made available in a digital version). Retailers who wish to order copies of the materials can order at no cost through the CTP Exchange Lab.



Looking Ahead: CTP's Continued Commitment to Compliance and Enforcement—A Critical Tool in Achieving Our Mission

A Message from Mitch Zeller, J.D.
Director, FDA Center for Tobacco Products

I am pleased to have shared this report providing an overview of the critical contributions of CTP's Office of Compliance and Enforcement (OCE). The experts in OCE, with director Ann Simoneau at the helm, help ensure retailers and manufacturers comply with the law. Their tireless efforts are vital to CTP's ability to meet our mission to reduce tobacco-related death and disease in the United States.

With all the progress made, we at CTP are always mindful that the compliance efforts in 2013–2018 highlighted in this report, like those of prior years, serve not only as protective public health achievements in their own right, but also as the foundation for a great deal of work that remains to be done. We acknowledge that big change doesn't happen overnight, and that tobacco use remains the leading cause of preventable death in the United States, as it is globally. As evidenced within this report, we are facing evolving challenges, including a disturbing number and upward trajectory of youth using e-cigarettes. Other tobacco products also remain very popular with youth. To address these challenges, we will continue to use all compliance and enforcement tools provided to us under the law—and revisit compliance policy and escalate enforcement as necessary—to address sales of e-cigarettes to minors and other violations.

These compliance and enforcement efforts complement other critical CTP activities, including developing the science base for product regulation, developing and issuing regulations and guidance for industry, reviewing submissions for marketing new tobacco products, and engaging in public education and outreach activities about the risks associated with tobacco product use.

As we move forward in these key program areas—including continuing to implement our comprehensive plan for the regulation of nicotine and tobacco—we will continue to rely immeasurably on the dedicated team in OCE.

Thank you,

/Mitch Zeller/

U.S. FOOD & DRUG ADMINISTRATION

CENTER FOR TOBACCO PRODUCTS