FDA

CENTER FOR TOBACCO PRODUCTS

COMPLIANCE AND ENFORCEMENT REPORT

This report covers the accomplishments and activities of FDA's Center for Tobacco Products, Office of Compliance and Enforcement, from June 22, 2009 through September 30, 2013.

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EXECUTIVE SUMMARY

CENTER FOR TOBACCO PRODUCTS

This report covers the accomplishments and activities of FDA's Center for Tobacco Products, Office of Compliance and Enforcement, from June 22, 2009 through September 30, 2013.

Despite major progress over the past half-century, tobacco use continues to be the leading cause of preventable death and disease in the United States. "Every day, more than 1,300 people in this country die due to smoking."[1] In an effort to stem the toll of suffering caused by tobacco product use, FDA is building a national tobacco product regulation program.

FDA obtained authority to regulate the manufacture, marketing, and distribution of tobacco products with the enactment of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) in 2009.[2] The Tobacco Control Act addresses fundamental "issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco."[3] The new law recognizes that "virtually all new users of tobacco products are under the minimum legal age to purchase such products,"[4] as each day more than 3,200 youth under age 18 smoke their first cigarette and more than 1,200 youth first use smokeless tobacco.[5] This comprehensive federal initiative is designed to help protect public health, and aims to prevent and reduce tobacco use across the entire population, particularly among young people.[6]

The Tobacco Control Act authorized the creation of the FDA's Center for Tobacco Products (CTP) to oversee the implementation and enforcement of the law. CTP's mandate includes the authority to set product standards, review premarket applications for new and modified risk tobacco products, require new warning labels, and enforce distribution, advertising, and promotion restrictions.

1. U.S. Department of Health and Human Services (USDHHS). The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014.
2. FDA was given immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The Tobacco Control Act also provides FDA with authority to regulate any other tobacco product that the agency by regulation deems to be subject to the law. See Federal Food, Drug, and Cosmetic Act §901(b), 21 U.S.C. § 387a(b) (2011).
3. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31 Div. A, § 3(2), 123 Stat. 1781 (2009) (codified at 21 U.S.C. § 387 note (2011)).
4. The Family Smoking Prevention and Tobacco Control Act §2(4).
5. Substance Abuse and Mental Health Services Administration (SAMHSA). Results from the 2012 National Survey on Drug Use and Health, NSDUH: Table 4.10A Past Year Initiation of Substance Use among Persons Aged 12 or Older Who Initiated Use Prior to the Age of 18, by Gender: Numbers in Thousands, 2011 and 2012. Rockville, MD: U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, 2013. Retrieved on October 16, 2013 from http://www.samhsa.gov/data/NSDUH/2012SummNatFindDetTables/DetTabs/NSDUH-DetTabsSect4peTabs10to11-2012.pdf.
6. See, e.g., The Family Smoking Prevention and Tobacco Control Act §2(31).

To help fulfill CTP's mission, CTP has established the Office of Compliance and Enforcement (OCE) to oversee the compliance and enforcement of the Tobacco Control Act's provisions and its implementing regulations.

OCE's activities are intended to ensure that regulated industry complies with the law. To achieve this end, OCE uses a three pronged approach **(see Figure 1):**

1. developing and providing compliance training and education;
2. monitoring regulated industry's compliance with the law through surveillance, inspections, and investigations; and
3. initiating advisory and enforcement actions such as issuing Warning Letters and seeking Civil Money Penalties against noncompliant industry, as appropriate.

OCE is committed to continue working with industry to educate it about the applicable legal requirements while also ensuring that industry is in compliance with these requirements. The compliance and enforcement program at CTP is just one part of FDA's action plan to reduce disease and death from tobacco use.

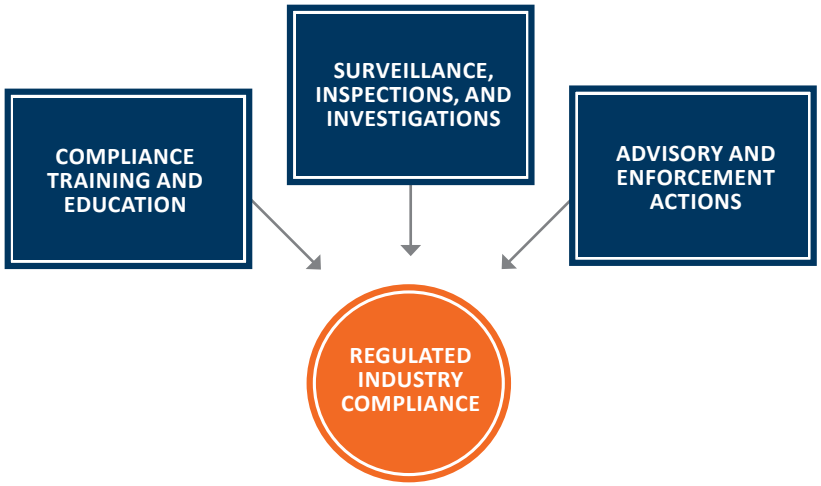


Figure 1

I. OVERVIEW

CENTER FOR TOBACCO PRODUCTS

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) was signed into law by President Barack Obama on June 22, 2009. The Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to provide the U.S. Food and Drug Administration (FDA) with the authority to regulate the manufacture, distribution, and marketing of tobacco products to address public health issues, including use of tobacco by young people and dependence on tobacco.[7] To oversee the implementation of the law, the Tobacco Control Act required the creation of FDA's Center for Tobacco Products (CTP), the sixth product-specific center at FDA. Currently, CTP regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.

CTP has a bold mission: to make tobacco-related death and disease part of America's past, not America's future, and, by doing so, ensure a healthier life for every family. Every day, more than 1,300 people in this country die from smoking[1] and each day more than 3,200 kids under the age of 18 smoke their first cigarette.[5] That's why tobacco product regulation and CTP's compliance program have never been more important than they are right now.

The Tobacco Control Act, among other things:

- Authorizes FDA to set standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products.[8]

Nearly **9** out of **10** daily smokers started smoking by age 18

- Gives FDA enforcement authority, provides enforcement tools, and requires FDA to contract with states and U.S. territories,[9] to the extent feasible, to carry out inspections of retailers within that state or territory.[10]

THE OFFICE OF COMPLIANCE AND ENFORCEMENT

The Office of Compliance and Enforcement (OCE) is one of six offices within CTP. Some of the major functions that OCE is responsible for are:

- Implementing and enforcing the provisions of the Tobacco Control Act and FDA regulations that restrict the sale, manufacturing, and marketing of tobacco products;
- Issuing enforcement actions for documented violations of the law;
- Coordinating compliance and enforcement activities;
- Compliance review of tobacco product document submissions;
- Contracting with states and territories to conduct compliance check inspections of tobacco product retailers;
- Surveillance of promotional activities of tobacco product manufacturers, importers, distributors, and retailers; and
- Providing small businesses with the technical assistance they need to comply with requirements of the law.

7 Family Smoking Prevention and Tobacco Control Act §3(1)-(2).
8 Family Smoking Prevention and Tobacco Control Act, § 3(3).
9 The term "State" means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico. See Federal Food, Drug, and Cosmetic Act §201(a)(1).
10 Federal Food, Drug, and Cosmetic Act §702(a)(1)(B)(i), 21 U.S.C. § 372(a)(1)(B)(i) (2011).

OCE is comprised of three divisions **(see Figure 2):** (1) the Division of State Programs; (2) the Division of Promotion, Advertising, and Labeling; and (3) the Division of Enforcement and Manufacturing.

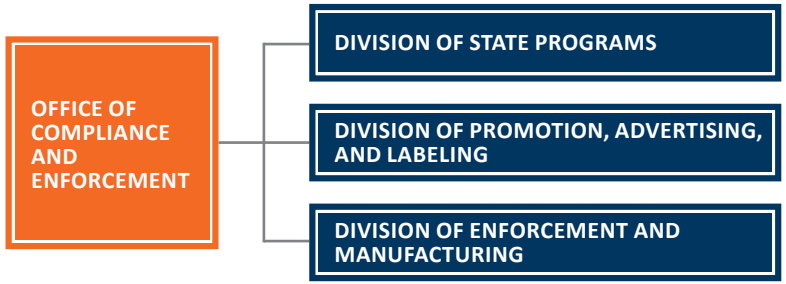


Figure 2

Division of State Programs

The Division of State Programs implements and manages FDA's State Tobacco Retail Compliance Check Inspection Program.

Among other things, the division:

- Coordinates the Tobacco Retail Compliance Check Inspection Program with U.S. states and territories and provides technical review and assistance for the negotiation and award process;
- Provides training for, and oversight of, inspectors and other contractors under FDA's State Tobacco Retail Compliance Check Inspection Program; and
- Reviews inspection results from the Tobacco Retail Compliance Check Inspection Program and initiates advisory and enforcement actions, including issuing Warning Letters and imposing Civil Money Penalties.

In July 2013, CTP hit a milestone by issuing its 10,000th Warning Letter to tobacco retail establishments for observed violations of federal laws. This achievement signifies the impact of the Compliance Check Inspection Program and its contribution towards assisting CTP in meeting its goal of protecting youth from tobacco addiction and disease.

Division of Promotion, Advertising, and Labeling

The Division of Promotion, Advertising, and Labeling monitors and reviews tobacco product promotion, advertising, and labeling. The division:

- Conducts routine surveillance and review of the tobacco industry's marketing, labeling, promotion, and advertising activities via the Internet, publications, regulatory submissions, inquiries, and complaints;
- Issues Warning Letters;
- Reviews labeling, advertising, and consumer information submissions;
- Reviews notifications for advertising and labeling in media not listed in 21 C.F.R. 1140.30(a)(1);
- Reviews warning rotation and random display plan submissions for smokeless tobacco packaging and advertising;
- Reviews tobacco manufacturer inspection reports for promotion, advertising, and labeling related matters; and
- Reviews investigation reports of facilities that distribute free samples of smokeless tobacco products.

Division of Enforcement and Manufacturing

The Division of Enforcement and Manufacturing monitors compliance with the law by tobacco product manufacturers, distributors, and importers. The division, among other things:

- Administers the Office of Small Business Assistance (OSBA), the primary point of contact to provide technical and other nonfinancial assistance to small tobacco product businesses to assist them in complying with the requirements of the Tobacco Control Act;
- Coordinates with FDA's Office of Regulatory Affairs (ORA) to perform inspections and review inspection reports of tobacco product manufacturers, and performs investigations of facilities that distribute free samples;
- Coordinates with ORA regarding consumer complaints, assessment of tobacco product recalls, and tobacco product imports;
- Issues advisory and enforcement actions against manufacturers and distributors;
- Reviews tobacco product manufacturers' registration of facilities and product listings;
- Issues import alerts; and
- Makes determinations about the "grandfathered" status of tobacco products.

LAWS AND REGULATIONS ENFORCED BY THE OFFICE OF COMPLIANCE AND ENFORCEMENT

Through the activities of CTP's Office of Compliance and Enforcement, FDA enforces the FD&C Act and fulfills certain responsibilities under the Comprehensive Smokeless Tobacco Health Education Act (Smokeless Tobacco Act), and as amended by the Tobacco Control Act.[11] FDA is enforcing tobacco product standards and other provisions regulating the manufacture, import, packaging, labeling, advertising, promotion, sale, and distribution of cigarettes, smokeless tobacco, roll-your-own tobacco, and cigarette tobacco.

In this regard, FDA enforces the provisions of the FD&C Act that are currently in effect. For example, section 907(a) of the FD&C Act prohibits a cigarette or any of its component parts (including the tobacco, filter, or paper) from containing as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including, but not limited to: strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke. Cigarettes marketed and sold in the United States in violation of this provision are adulterated under section 902(5) of the FD&C Act (21 U.S.C. § 387b(5)). Furthermore, cigarettes that purport to have a characterizing flavor but do not actually contain a characterizing flavor are misbranded under section 903(a)(1) of the FD&C Act (21 U.S.C. § 387c(a)(1)) and/or 903(a)(7)(A) of the FD&C Act (21 U.S.C. § 387c(a)(7)(A)) as their labeling and/or advertising is false or misleading because it makes the representation that the products contain a characterizing flavor.

11 The Tobacco Control Act also amended the Federal Cigarette Labeling and Advertising Act (FCLAA) to provide FDA authority to promulgate new graphic health warnings for cigarettes. On June 22, 2011, the Food and Drug Administration (FDA) published a final rule titled "Required Warnings for Cigarette Packages and Advertisements." The final rule required the display of certain health warnings on cigarette packages and in advertisements. On August 24, 2012, the United States Court of Appeals for the District of Columbia Circuit issued an order that vacated the rule and remanded the matter to FDA. *R.J. Reynolds Tobacco Co., et al. v. Food & Drug Administration, et al.*, 696 F.3d 1205 (D.C. Cir. 2012).

A tobacco product with a label, labeling, or advertising that uses the descriptors "low," "light," or "mild," or similar descriptors, is a "modified risk tobacco product" under section 911(b)(2)(A)(ii) of the FD&C Act. The introduction into interstate commerce of a modified risk tobacco product is prohibited unless an FDA order under section 911(g) is in effect with respect to such product. Distributors, wholesalers, and retailers are permitted, however, to distribute and sell products with a label, labeling, or advertising that uses the descriptors "light," "mild," or "low," or simlar descriptors, if they were manufactured before June 22, 2010 and introduced into domestic commerce by the manufacturer before July 22, 2010.

A tobacco product is also considered a modified risk tobacco product under section 911(b) of the FD&C Act if its label, labeling, or advertising explicitly or implicitly represents that: the product presents a lower risk of tobacco-related disease or is less harmful than one or more other commercially marketed tobacco products; the product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance; or the product or its smoke does not contain or is free of a substance. When modified risk tobacco products are introduced into interstate commerce without an appropriate FDA order in effect under section 911(g) of the FD&C Act, these products are adulterated under section 902(8) of the FD&C Act.

A smokeless tobacco product is misbranded under section 903(a) of the FD&C Act if its packaging or advertising fails to include any health warning label statements. A tobacco product is misbranded under section 903(a)(1) if its labeling is false or misleading in any particular. A tobacco product is misbranded under section 903(a)(7)(A) if, in the case of any tobacco product distributed or offered for sale in any state, its advertising is false or misleading in any particular. Under section 201(n) of the FD&C Act, in determining whether labeling or advertising is misleading, the agency considers, among other things, the failure to reveal material facts concerning the consequences that may result from the customary or usual use of the product.

FDA is also responsible for certain provisions of the Smokeless Tobacco Act, as amended by the Tobacco Control Act. For example, the Smokeless Tobacco Act requires the random display and distribution of required warnings on packaging, and quarterly rotation of all warnings in advertising for smokeless tobacco products, in accordance with a plan approved by the FDA. The warning plans are submitted by the manufacturer, distributor, importer, or retailer to FDA for review and approval.

FDA also enforces regulations promulgated under the Tobacco Control Act, including, but not limited to the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents* (21 C.F.R. Part 1140) that set out restrictions on the sale, distribution, labeling, and advertising of these products. Examples of these restrictions include, but are not limited to: a prohibition on selling cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco to anyone younger than 18 years of age; a requirement to verify—by means of photographic identification—that anyone younger than 27 purchasing these tobacco products is at least 18 years of age; a requirement to sell these tobacco products only in a direct, face-to-face exchange between the retailer and the consumer with limited exceptions; mandatory minimum size packages for cigarettes; a prohibition on the sponsoring of any athletic, musical, artistic, or other social or cultural event in the brand name used for any brand of cigarettes or smokeless tobacco; a prohibition on branded non-tobacco items; a prohibition on the distribution of free samples of cigarettes and a prohibition on the distribution of free samples of smokeless tobacco products, except in qualified adult-only facilities; and a requirement to submit notification to FDA prior to disseminating tobacco product labeling or advertising in a medium that is not one of the listed media in 21 C.F.R. 1140.30(a).

Under the Tobacco Control Act, FDA also has new authority over the manufacture of regulated tobacco products. For example, under the law, owners or operators of establishments in any U.S. state or territory engaged in the manufacture, preparation, compounding, or processing of a tobacco product are required, for the first time ever, to register annually with the FDA and submit a product listing. FDA then inspects these locations to verify compliance with the Act. This includes establishments that only export their product from the United States.

II. COMPLIANCE ACTIVITIES – EDUCATION, TRAINING, AND OUTREACH

CENTER FOR TOBACCO PRODUCTS

TRAINING SESSIONS AND WEBINARS

FDA understands that compliance with the Tobacco Control Act was a new experience for regulated industry starting in 2009. With implementation of the Tobacco Control Act, CTP has provided the public with needed resources to ensure that those who must understand the law and regulations have the resources to do so. CTP's preference is for voluntary compliance by regulated industry rather than having to take advisory and enforcement actions against it. Compliance outreach is one way CTP tries to reach these businesses and the public alike. OCE's compliance outreach has included training sessions throughout the country, public webinars, presentations, and assisting other offices within CTP in publishing guidance documents representing FDA's current thinking on specific topics. In addition to these compliance resources, there are additional educational services that CTP provides.

Between July and September 2010, OCE hosted a series of training sessions to provide retailers across the country with information on how to comply with federal tobacco laws and regulations. OCE hosted these sessions in Boston, MA; Atlanta, GA; Chicago, IL; Dallas, TX; and Los Angeles, CA.

In an effort to reach a wider audience, in 2011 FDA started hosting live, public webinars to help educate regulated industry and encourage compliance with federal tobacco laws and regulations. Public webinars allow people to watch and ask live questions. This greatly expands FDA's capacity to reach a larger and more diverse audience, including retailers and small businesses. Each webinar addresses a specific subject and many of the webinars are archived on CTP's website for future viewing. Industry can suggest topics for future webinars. Topics covered by these webinars include:

- What to Expect During a Tobacco Retailer Inspection
- The Civil Money Penalty Process
- Smokeless Tobacco Warning Plan Requirements
- Warning Letters for Tobacco Retailers
- Smokeless Tobacco Product Packaging and Advertising Requirements
- An Overview of the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*
- Impersonal Modes of Sale
- Common Issues Identified During FDA's Scientific Evaluation of Substantial Equivalence Reports
- The Import Process for Small Businesses
- Regulations Regarding Distribution of Free Samples of Smokeless Tobacco at "Qualified Adult-only Facilities"
- Substantial Equivalence Reports
- Establishment Registration and Product Listing Requirements
- Overview of Warning Letters and Common Violations on the Internet
- CTP's Domestic Manufacturing Inspection Program

Appendix A provides a complete list of OCE's public webinars through September 30, 2013, with the identification of the targeted audience for each webinar. OCE plans to continue to host additional public webinars. Additionally, a complete list and videos of the archived webinars can be found at: **http://go.usa.gov/rJPW**.

CONFERENCES, PRESENTATIONS, AND OTHER FORUMS

In addition to webinars, OCE, in conjunction with other offices within CTP, has also employed a variety of stakeholder engagement tools to provide needed compliance training and education to regulated industry and to CTP's public health partners at the federal, state, territorial, and local levels. These tools include presentations done in a variety of venues such as in-person meetings, teleconferences, as guests of other webinar productions, or providing "one-on-one" compliance education at CTP's exhibit booths at various conferences. **Figure 3** provides some previous examples of OCE's outreach initiatives.

Figure 3

GUIDANCE DOCUMENTS

In addition to the training sessions and webinars, CTP has issued guidance documents presenting FDA's current thinking on particular subjects to assist regulated industry in understanding and complying with relevant regulations and laws. Examples of the guidance documents issued include:

- Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments
- Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers
- Guidance for Industry: Compliance with *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*
- Guidance for Industry and FDA Staff: Use of "Light," "Mild," "Low," or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products

A complete list of guidance documents can be found at: **http://go.usa.gov/rJyx**.

III. ADVISORY AND ENFORCEMENT ACTIVITIES

CENTER FOR TOBACCO PRODUCTS

FDA's **compliance and enforcement program** is designed to ensure that industry and retailers fully comply with the law in order to reduce the profound health burden of tobacco use on the public and to protect America's youth. OCE works to prevent youth access to tobacco products by inspecting retail establishments. OCE also reviews print and online advertising and monitors promotional activities. To ensure future compliance, OCE takes advisory or enforcement actions, as appropriate, against retailers, manufacturers, distributors, or importers when there are violations. Additionally, OCE reviews required document submissions, facility registration, trade complaints, and product listings to help inform CTP of manufacturing, importing, distributing, and retailing practices.

The FD&C Act provides FDA with several tools that it may use against non-compliant parties including advisory actions, such as Warning Letters, and enforcement actions, such as Civil Money Penalties. A Warning Letter is an advisory action in which FDA notifies a regulated entity that FDA found that the party violated the law, and it is used to achieve prompt voluntary compliance and to establish prior notice. In a Warning Letter, FDA informs the regulated entity that failure to comply with the requirements of the FD&C Act and its implementing regulations may result in FDA enforcement action. FDA's enforcement options include initiating administrative actions or referring cases to the Department of Justice for initiation of judicial action. In administrative enforcement actions, FDA can seek to impose a Civil Money Penalty or a No-Tobacco-Sale Order. A Civil Money Penalty (CMP) Complaint is used to initiate an administrative legal action against a regulated entity that can result in the imposition of a fine, the Civil Money Penalty. A No-Tobacco-Sale Order is an order in which FDA prohibits the sale of tobacco products in a specific retail outlet when a retailer has committed "repeated violations"[12] of restrictions promulgated under section 906(d) of the FD&C Act. Possible judicial actions include seizures, injunctions, and criminal prosecutions.

Although the FD&C Act does not require that FDA always issue a Warning Letter before taking further action, the first time FDA identifies one or more violations it generally issues a Warning Letter that describes the violation or violations.[13]

OCE's activities, including inspecting physical retail establishments, monitoring and reviewing tobacco sales and advertising in publications and online, including other sales and promotional activities, inspecting manufacturing plants, investigating qualified adult-only facilities that distribute free samples of smokeless tobacco, and reviewing complaints, as well as other OCE observations, may lead to some of these stated advisory and enforcement actions.

12 See Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers at http://go.usa.gov/DxbG.
13 The Tobacco Control Act provides two schedules for assessing Civil Money Penalties for violations of restrictions promulgated under Section 906(d) of the FD&C Act, depending on whether the retailer has an approved training program. See Family Smoking Prevention and Tobacco Control Act §103(q)(2), 21 U.S.C. 333 note (2009). The penalty for a first violation is not to exceed $0 together with the issuance of a Warning Letter with respect to a retailer that has an approved training program and $250 with respect to a retailer that does not have an approved training program. FDA intends to promulgate regulations establishing standards for approved retailer training programs. Until it does, the Agency is seeking penalties in accordance with the schedule set out for retailers with an approved training program, whether or not the retailer has implemented a training program.

ACTIVITIES OF THE DIVISION OF STATE PROGRAMS

The Division of State Programs coordinates FDA's State Tobacco Retail Compliance Check Inspection Program. In this program, FDA contracts with states and territories to inspect tobacco retailers for compliance with the Tobacco Control Act and its implementing regulations, including the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents.*

State/Territory Contracts

In fiscal year (FY) 2010, FDA awarded competitive one-year contracts to 15 states to implement the Tobacco Retail Compliance Check Inspection Program.

In FY 2011, FDA contracted with a total of 37 states and the District of Columbia to conduct compliance check inspections. These contracts contained a base period of one year with two one (1) year option periods.

In FY 2012, CTP exercised all first year option contracts for the FY 2011 states. CTP also awarded an additional six contracts with a base year and two option periods. By the end of FY 2012, FDA had contracts with 44 states and territories.

In FY 2013, FDA awarded a new contract to the Vermont Department of Liquor Control, bringing the total amount of states and territories with FDA contracts, through September 30, 2013, to 45. FDA will continue to seek opportunities to ensure that tobacco compliance check inspections are performed in the remaining states and jurisdictions.

Appendix B offers the list of states and territories, their contracting agencies, and the award dates and amounts. The list of Tobacco Compliance Check Inspection Program contracts awarded with more information can also be found at: http://go.usa.gov/YaY9.

As part of an effort to communicate and inform the Native American tribes and tribal entities of CTP's mission, CTP has met with tribal organizations, attended conferences hosted by tribal organizations, and presented at a webinar hosted by a tribal organization. OCE is working to lay the groundwork for tobacco compliance, inspection, and enforcement activities and to ensure tribes and tribal organizations have the relevant tobacco compliance information and educational materials.

Collaboration Between Federal Prevention Programs

The federal, state, and local governments are committed to working together to reduce youth access to, and use of, tobacco products. Separate public health programs complement each other in the pursuit of this goal. Two of these programs that are administered by the federal government are FDA's State Tobacco Retail Compliance Inspection Program and the Substance Abuse and Mental Health Services Administration's (SAMHSA) Synar Program.

In 1992, the Synar amendment was passed into law by passage of the Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act (P.L. 102-321). The Synar legislation (section 1926), and its implementing regulation (45 C.F.R. 96.130), require states to enact and enforce laws prohibiting the sale or distribution of tobacco products to individuals under the age of 18 in order to receive their full Substance Abuse Prevention and Treatment Block Grant awards.

While FDA's program focuses on tobacco laws related to *federal* age and identification requirements for regulated tobacco product sales, along with *federal* advertising and marketing restrictions on regulated tobacco products, the Synar program requires states to enforce their own *state* laws restricting youth access to tobacco products, which may differ among states. The Synar program also requires states to conduct annual, random, unannounced inspections at a statistically valid random sample of tobacco outlets to assess compliance with state youth access laws. By contrast, FDA's inspections are not designed to be a statistically valid random sample, but instead are based on a plan developed by the states in conjunction with the FDA, which may consider several factors, including areas that are considered at higher risk for regulatory violations.

Another difference between the two programs is the difference in enforcement. All violations under the FDA program may lead to Warning Letters, Civil Money Penalties, or other enforcement options by the FDA, while Synar inspections may include an enforcement component, or they may not. States that choose not to enforce their state laws during Synar inspections must enforce them during other inspections.

While the FDA's State Tobacco Retail Compliance Inspection Program and the Synar program are committed to further collaboration to the extent possible, FDA funds cannot be used to support any contractor work beyond FDA's inspectional requirements.

Compliance Check Inspections

FDA's State Tobacco Compliance Check Inspection Program monitors tobacco product retailer compliance with applicable laws and the related regulations.

Typically, FDA issues a Warning Letter to a retailer for the first observation of violations. After FDA has issued a Warning Letter, it conducts a follow-up compliance check of that outlet without further notice to the retailer. If FDA identifies a violation during a follow-up compliance check or at a subsequent inspection at that retail establishment, it generally seeks CMPs to the extent they are appropriate.

All Warning Letters and CMP Complaints issued to retailers who operate retail establishments are displayed in a searchable online database located at: http://go.usa.gov/YagB. In addition, the database also includes the results of all compliance check inspections of tobacco retailers where no violations were observed.

OCE also mails tobacco retailers a Compliance Check Inspection Notification after an inspection occurred in which a minor was able to enter a retail establishment and purchase a regulated tobacco product. OCE sends these documents, which include a photograph of the storefront, to provide the retailer notification that an inspection involving a minor has occurred at their establishment, a potential violation was observed, and the date and approximate time of that inspection.

Table 1 shows an overview of retail establishment inspection activities of CTP. Each FDA action consists of a Warning Letter or a Civil Money Penalty. Each Warning Letter or Civil Money Penalty may cite one or more violations.

FDA INSPECTIONS AND ACTIONS (WARNING LETTERS AND CMPs) FOR FY 2010 - FY 2013*	TOTAL
Total Inspections	221,774
Total FDA Actions (Warning Letters and CMPs)	12,039
TOTAL VIOLATIONS**	18,960

*States began inspections at various times during each fiscal year based on when the contract was actually awarded and hiring, commissioning, and training was completed.
** There may be more than one observed violation in each FDA Action (a Warning Letter or a Civil Money Penalty) that the agency sent or imposed.

Table 1

FDA's State Tobacco Retail Compliance Check Inspection Program monitors whether a retailer is in compliance with specific requirements concerning the sale, distribution, and promotion of tobacco products.

The program requires states and territories under contract to conduct tobacco compliance check inspections at a variety of different locations (urban, suburban, rural, and racial and ethnic minority communities) and outlet types throughout the state or territory. FDA tobacco retailer compliance checks must include inspections conducted in areas that are considered at higher risk for regulatory violations, such as regions with lower socioeconomic populations and retail outlets in racial and ethnic minority communities, which are historically associated with targeted marketing by the tobacco industry.[14]

During some inspections, FDA uses minors (ages 16-17) to monitor whether a retailer is in compliance with the age and photo identification verification requirements and whether the retailer would sell to the minor. Retailers are prohibited from selling regulated tobacco products to any person under the age of 18 and must verify the age of any customer under 27 who wishes to purchase these products by photo identification. Appendix C depicts the percentage of inspections by state and territory where minors were able to purchase tobacco products during an FDA compliance check inspection. Appendix C also shows the percentage of establishments with a Sale to a Minor Violation that also had a Repeat Sale to Minor Violation.

Inspections also monitor retailer compliance with regulations that restrict methods of sale, distribution, and promotional activities of regulated tobacco products. For example, some regulations restrict the way a tobacco product may be accessed. Retailers are required to only sell regulated tobacco products in a direct, face-to-face exchange without the assistance of any electronic or mechanical device, with limited exceptions. One exception to this requirement is that a retailer may sell or distribute tobacco products through vending machines and self-service displays in facilities where the retailer ensures no person younger than 18 years of age is present or permitted to enter at any time. These methods are referred to as impersonal modes of sale.

There are also regulations addressing the quantity and package size of specific tobacco products that may be distributed or sold. Retailers may not sell unpackaged, individual cigarettes, or unpackaged cigarettes in a quantity less than 20. Single unpackaged cigarettes are commonly known as “loosies” and provide minors an option to buy cigarettes cheaply. In addition, packaged cigarettes must be sold or distributed by manufacturers, distributors, and retailers in packages that contain at least 20 cigarettes. This regulation is aimed to prevent the commonly known “kiddie packs,” which contain fewer cigarettes and are more attractive to minors.

Also prohibited is the distribution of free samples of cigarettes. Retailers are further prohibited from distributing free samples of smokeless tobacco unless distributed in a “qualified adult-only facility.” A “qualified adult-only facility” must meet a number of specific requirements listed in the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents* in order to legally distribute these free samples.

The above mentioned requirements give rise to the most commonly observed violations of the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*. These regulations do contain other requirements for retailers, distributors, importers, and manufacturers, including a restriction on sponsorship of events or teams in the brand name of cigarettes or smokeless tobacco, and they make the manufacturer responsible for removing all manufacturer-owned items that are non-compliant with the regulations from point-of-sale locations.

14 National Cancer Institute. *The Role of the Media in Promoting and Reducing Tobacco Use.* Tobacco Control Monograph No. 19. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute. NIH Pub. No. 07-6242, June 2008; p. 11. Available at http://www.cancercontrol.cancer.gov/tcrb/monographs/19/index.html.

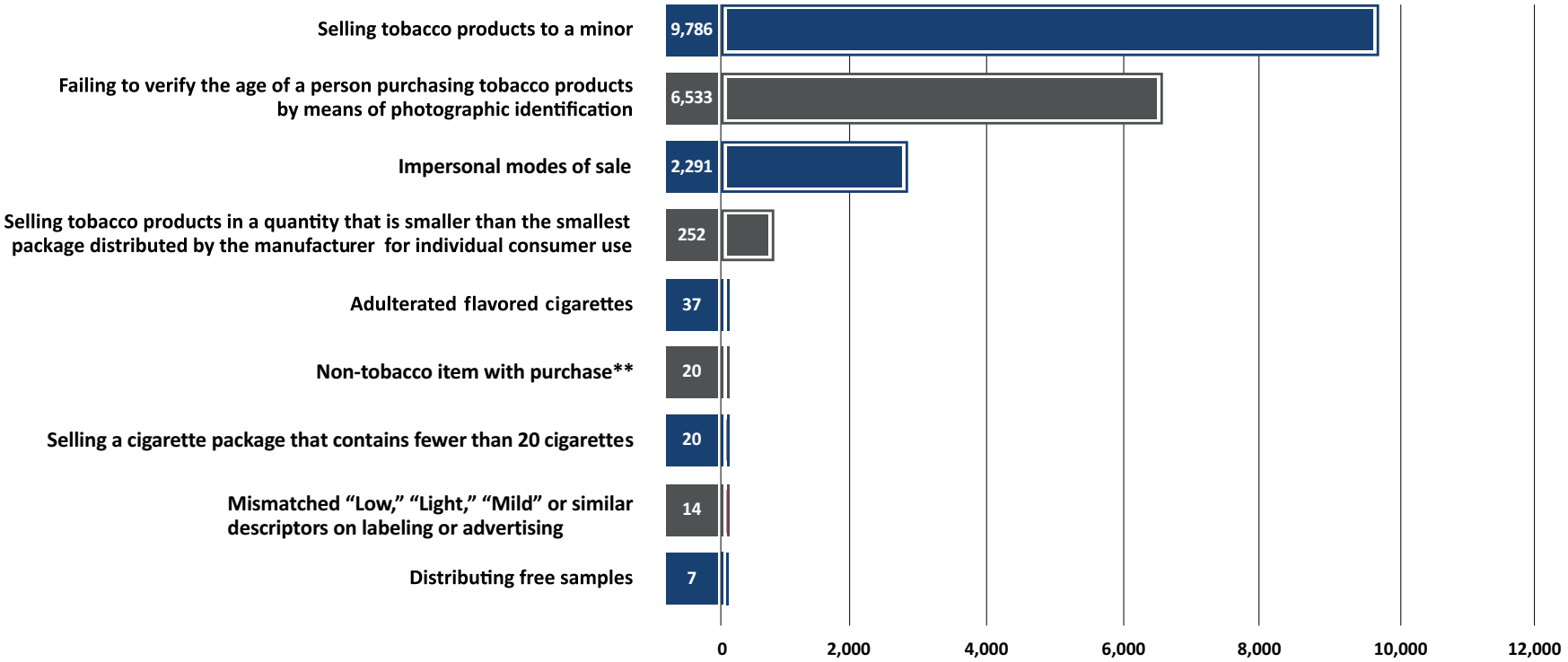
Other requirements that apply to tobacco retailers are detailed in the FD&C Act directly. For example, it is illegal to introduce or deliver for introduction into interstate commerce cigarettes that contain a characterizing flavor other than menthol or tobacco. If a cigarette does not contain a characterizing flavor, but its labeling or advertising purports to contain a characterizing flavor, the labeling or advertising is considered false or misleading, and it is still illegal to introduce or deliver for introduction into interstate commerce those products.

Tobacco products with a label, labeling, or advertising that uses the descriptors "low," "light," "mild," or similar descriptors, are "modified risk tobacco products" that cannot be introduced into interstate commerce unless an FDA order is in effect. FDA may take advisory or enforcement action against persons who introduce modified risk tobacco products into interstate commerce without an FDA order in effect. Retailers may only sell products whose label, labeling, or advertising uses the descriptors "low," "light," or "mild" if the product was manufactured before June 22, 2010 and introduced into domestic commerce by the manufacturer or importer before July 22, 2010, or if an FDA order is in effect. In certain situations, cigarettes, cigarette tobacco, and/or smokeless tobacco with labels, labeling, or advertising that do not correspond to the actual product may be misbranded under section 903 of the FD&C Act (21 U.S.C. § 387c), because the label, labeling, or advertising is false and/or misleading. For example: a vending machine in a retail establishment contains cigarettes not labeled by the manufacturer as "low," "light," or "mild," but the vending machine selection button which corresponds with those cigarettes states the product is "low," "light," or "mild." This would be a violation of the FD&C Act because the label, labeling, or advertising of the product – the vending machine selection button – is false or misleading. In **Graph 1**, these types of violations are referred to as "Mismatched 'Low,' 'Light,' 'Mild' or Similar Descriptors on Labeling or Advertising."

These examples are not an exhaustive list of violations at retail establishments which FDA may act upon, but are meant to serve as an illustration.

From the inception of FDA's State Tobacco Retail Compliance Check Inspection Program through September 30, 2013, OCE uncovered more than 18,000 violations through retail establishment inspections. **Graph 1** depicts the number of observances for the listed violations that FDA took action on up to September 30, 2013. Appendix D lists the statutory or regulatory reference for these violations. A significant number of the violations observed were retailers who sold tobacco products to minors, including some retailers who sold to a minor despite checking the photo ID.

Violations By Type*



Graph 1

* The graph represents the cumulative number of occurrences for the listed violations observed through FDA's retail establishment inspections from the beginning of the program through 9/30/13. There may be more than one observed violation in each FDA Action (a Warning Letter or a Civil Money Penalty) that the agency sent or imposed.

** On March 19, 2012, the United States Court of Appeals for the Sixth Circuit issued an Opinion and Judgment that, among other things, found §1140.34(b) to be unconstitutional under the First Amendment. See *Discount Tobacco v. United States*. Therefore, FDA will not seek to enforce this provision. §1140.34(b) states: "No manufacturer, distributor, or retailer may offer or cause to be offered any gift or item (other than cigarettes or smokeless tobacco) to any person purchasing cigarettes or smokeless tobacco in consideration of the purchase thereof, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase."

ACTIVITIES OF THE DIVISION OF PROMOTION, ADVERTISING, AND LABELING AND THE DIVISION OF ENFORCEMENT AND MANUFACTURING

OCE is responsible for compliance and enforcement efforts related to regulated entities' sales, marketing, labeling, advertising, and promotional activities. OCE's efforts include, among other things: initiating advisory and enforcement actions; review and evaluation of regulatory submissions that include tobacco product labeling, representative advertising, and consumer information materials; review and evaluation of notifications of the use of media in tobacco product labeling and advertising other than the media listed in 21 C.F.R. 1140.30(a)(1); routine monitoring and surveillance of websites and publications that sell, distribute, promote, or advertise regulated tobacco products; review and evaluation of smokeless tobacco product warnings and warning plans; surveillance of event promotion and sponsorship by tobacco manufacturers, distributors[15], or retailers; review of certain regulatory submissions, including exemption requests from substantial equivalence; inspecting manufacturing facilities; conducting directed inspections; reviewing complaints; and investigating facilities that distribute free samples of smokeless tobacco products.

Promotion, Advertising, and Labeling Requirements

OCE monitors, conducts surveillance, and evaluates the sale, distribution, marketing, advertising, and labeling of regulated tobacco products for compliance with the FD&C Act and its implementing regulations. Based on evidence gathered through this review, OCE may take advisory or enforcement actions against regulated entities.

Tobacco Marketing Surveillance

OCE conducts routine monitoring and surveillance of websites and publications that sell, distribute, promote, or advertise regulated tobacco products. In doing so, OCE reviews and evaluates, among other things, tobacco product labeling and advertising. Throughout this surveillance and review, OCE identifies websites and publications where regulated tobacco products might be sold, distributed, or advertised and monitors compliance of the promotional activities with the FD&C Act and its implementing regulations.

Through September 30, 2013, FDA has issued 136 Warning Letters for violations of requirements related to tobacco product promotion, advertising, and labeling online or in print publications. A single Warning Letter may cite one or more violations of the law. The following highlights some of the violations that were cited in OCE's Warning Letters:

Flavored Cigarette Violations

As of September 22, 2009, the FD&C Act prohibited cigarettes from containing a characterizing flavor other than tobacco or menthol. In November 2009, OCE issued 14 Warning Letters for illegal sales of flavored cigarettes on the Internet. As of September 30, 2013, OCE has issued a total number of 106 Warning Letters to online retailers and manufacturers selling flavored cigarettes.

15 See 21 C.F.R. Section 1140.3(c), which defines distributor as "any person who furthers the distribution of cigarettes or smokeless tobacco, whether domestic or ***imported,*** at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part." (Emphasis added).

Modified Risk Tobacco Product Violations

In May 2011, OCE issued 10 Warning Letters for illegal sales of modified risk tobacco products without an FDA order in effect. As of September 30, 2013, OCE has issued a total number of 102 Warning Letters that include charges related to the use of "low," "light," or "mild" descriptors or other modified risk tobacco product claims, described under section 911 of the FD&C Act. OCE regularly updates CTP's Health Fraud webpage to highlight these Warning Letters and promote public awareness of the inappropriate use of "light," "mild," and "low" claims for tobacco products that do not have an FDA order permitting the marketing of products with such claims.

Tobacco Brand Sponsorship

As of September 30, 2013, OCE issued three Warning Letters that cited brand name sponsorship violations. 21 CFR 1140.34(c) requires that no manufacturer, distributor, or retailer sponsors any athletic, musical, artistic, or other social or cultural event in the brand name or brand indicia of any brand of cigarettes or smokeless tobacco products.

Cigarette Tobacco/RYO Tobacco Labeled as "Pipe Tobacco"

FDA currently regulates cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco, all of which must comply with all applicable provisions of the law. On July 30, 2013, OCE issued four Warning Letters to three manufacturers and one retailer involving violative tobacco products labeled as "pipe tobacco" that were promoted or sold as cigarette tobacco or RYO tobacco. The Warning Letters include violations for selling modified risk tobacco products without an order in effect and/or selling prohibited flavored cigarette tobacco products.

Labeling and Advertising Submissions

OCE also reviews labeling and advertising submitted under section 905(i) of the FD&C Act for compliance with the provisions of the FD&C Act and its implementing regulations. Section 905(i) requires a product list of all tobacco products manufactured, prepared, compounded, or processed and specific product related documentation to be submitted for every person that registers a tobacco product establishment, as required by law. This documentation must include copies of the products' labeling and a representative sampling of the products' advertising, which are reviewed for compliance as well. In addition, OCE reviews notifications of the use of media (e.g., websites, social networks) for tobacco product labeling and advertising other than the media listed in 21 CFR 1140.30(a)(1).

The above examples are not an exhaustive list of OCE's promotion, advertising, and labeling compliance and enforcement activities, or of violations which FDA may act upon, but rather only serve as a description of such activities and some of the violations that FDA identified through surveillance and acted upon.

Smokeless Tobacco Product Warnings and Warning Plans

The Smokeless Tobacco Act, as amended by the Tobacco Control Act, requires smokeless tobacco products to have larger, more prominent, health warnings on their packaging and advertising. These warning statements are:

- WARNING: This product can cause mouth cancer.
- WARNING: This product can cause gum disease and tooth loss.
- WARNING: This product is not a safe alternative to cigarettes.
- WARNING: Smokeless tobacco is addictive.

Under the FD&C Act, a tobacco product is misbranded if its labeling or advertising is false and misleading in any particular. In determining whether advertising or labeling is false and misleading, FDA considers, among other things, the failure to reveal material facts concerning the consequences that may result from the customary or usual use of the product. Thus, the lack of any warning statement on a smokeless tobacco product's packaging or advertising renders the product misbranded. Through its surveillance and review, OCE has issued nine Warning Letters for smokeless tobacco products, whose packaging or advertising lacked warning statements.

The law also requires the submission of warning plans establishing the random display and distribution and quarterly rotation of all warnings on smokeless

tobacco product packaging and advertising to FDA for review and approval. In particular, warning plans for smokeless tobacco product packaging must provide that all of the required warning statements are:

- Randomly displayed in each 12-month period on each brand of the product;
- Randomly displayed in as equal a number of times as is possible on each brand of the product; and
- Randomly distributed in all areas of the United States in which the product is marketed.

Warning plans must also provide that the warning label statements are rotated quarterly in alternating sequence in advertisements for each brand of smokeless tobacco product. These requirements are currently in effect. As of September 30, 2013, FDA has approved 33 initial smokeless tobacco product warning plans and 11 supplemental plans to previously approved smokeless tobacco product warning plans.

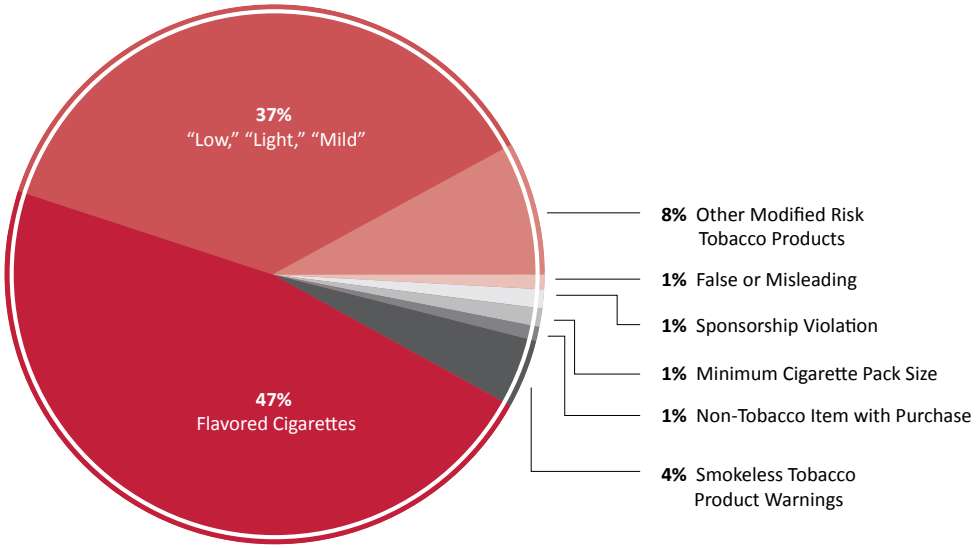
Table 2 depicts the number of labeling, promotional, and advertising violations identified through internet and publication surveillance and included in Warning Letters. **Graph 2** is the same data in pie chart format.

Violations Identified Through Internet and Publication Surveillance and Included in a Warning Letter

DESCRIPTION OF VIOLATION	VIOLATIONS OBSERVED
Flavored Cigarettes	106
"Low," "Light," "Mild"	83
Other Modified Risk Tobacco Products	19
False or Misleading	2
Sponsorship Violation	3
Minimum Cigarette Pack Size	2
Non-tobacco Item with Purchase*	2
Smokeless Tobacco Product Warnings	9

* On March 19, 2012, the United States Court of Appeals for the Sixth Circuit issued an Opinion and Judgment that, among other things, found §1140.34(b) to be unconstitutional under the First Amendment. See *Discount Tobacco v. United States.* Therefore, FDA will not seek to enforce this provision. §1140.34(b) states: No manufacturer, distributor, or retailer may offer or cause to be offered any gift or item (other than cigarettes or smokeless tobacco) to any person purchasing cigarettes or smokeless tobacco in consideration of the purchase thereof, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase.

Table 2



Graph 2

REGISTRATION AND LISTING

Every person who owns or operates any establishments in any state or territory engaged in the manufacture, preparation, compounding, or processing of a tobacco product is required to register annually with FDA. Additionally, as part of the registration, the person must file a list of its regulated tobacco products. This registration and product listing helps FDA ensure efficient oversight over the tobacco industry. FDA is currently enforcing registration and product listing requirements for domestic establishments engaged in the manufacturing of regulated tobacco products for consumer use and domestic establishments engaged in the manufacturing of tobacco, papers, filters, or pouches whether they are for further manufacturing use, or for consumer use. **Figure 4** shows the distribution of the 107 tobacco product establishments registered as of September 30, 2013.

Figure 4

TOBACCO PRODUCT MANUFACTURING INSPECTIONS AND FREE SAMPLE DISTRIBUTION AND SPONSORSHIP INVESTIGATIONS

Every registered establishment engaged in the manufacture, compounding, or processing of a tobacco product or tobacco products is to be inspected by FDA on a biennial basis. FDA inspects establishments to determine compliance with the provisions of the law that are currently in effect. Inspections are performed by FDA's Office of Regulatory Affairs (ORA) investigators who may be accompanied by subject matter experts from OCE. As of September 30, 2013, FDA completed 102 inspections of registered tobacco product manufacturers.

OCE also works with ORA to perform investigations at free sample distribution facilities to monitor compliance with the regulations for cigarettes and smokeless tobacco found at 21 C.F.R. Part 1140. The rule allows for distribution of free samples of smokeless tobacco products only if distributed in a "qualified adult-only facility." The rule establishes strict criteria for what constitutes a "qualified adult-only facility." These criteria include, among other things, requiring a law enforcement officer or government-licensed security guard to check photo identification of each person present; prohibiting the sale, service, or distribution of alcohol in the location; and it must be a temporary structure.[16] FDA also performs investigations to monitor compliance with tobacco brand sponsorship restrictions.

As of September 30, 2013, FDA has performed 18 investigations and issued one Warning Letter.

"GRANDFATHERED" PRODUCT DETERMINATION

A tobacco product that was commercially marketed in the United States as of February 15, 2007, (a "grandfathered" product) is not subject to the premarket requirements of the FD&C Act and may serve as the predicate tobacco product in a 905(j) report (demonstrating substantial equivalence) for a new tobacco product. The Division of Enforcement and Manufacturing reviews information that has been submitted to the FDA in order to determine a tobacco product's "grandfathered" status.

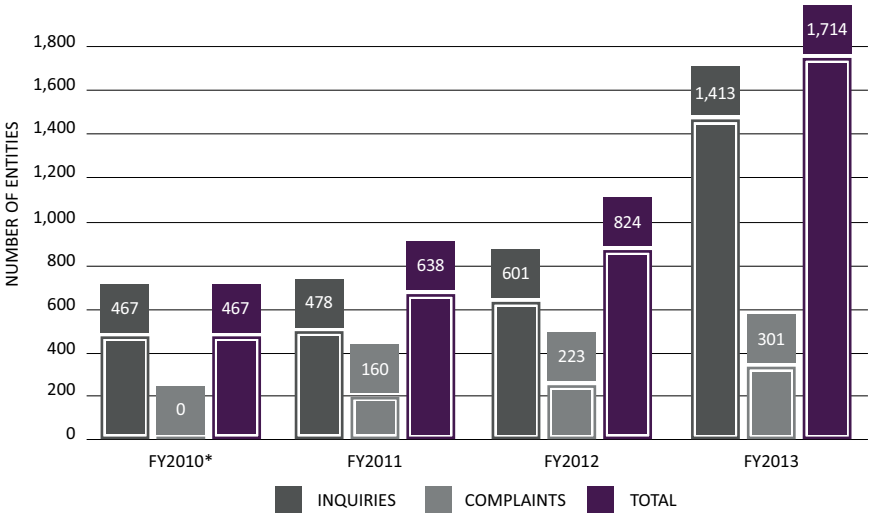
As of September 30, 2013, OCE completed reviews of 591 submissions for "grandfathered" product determinations and has issued letters to companies notifying them of the determination.

16 See 21 C.F.R. section 1140.16(d)(2)(iii) for a full list of the criteria that a "qualified adult-only" facility must meet.

IV. OFFICE OF COMPLIANCE AND ENFORCEMENT'S CONTINUING EFFORTS

CENTER FOR TOBACCO PRODUCTS

Compliance Related Inquiries & Complaints of Potential Violations FY2010 - FY2013



*Note in FY 2010, Inquiries and Complaints of Potential Violations were totaled in one general category.

Graph 3

OCE is committed to continuing to improve America's health with assistance from the public and ongoing outreach with stakeholders. OCE receives numerous complaints of potential violations. Each complaint OCE receives is evaluated and a determination is made as to what follow-up action, if any, is necessary. All reports to FDA remain private to the extent allowed by law, as explained in FDA's privacy policy.[17] In addition to complaints of potential violations, OCE routinely receives inquiries from stakeholders, including requests for information from the Office of Small Business Assistance on how to comply with the law. **Graph 3** shows the inquiries and complaints of potential violation totals for fiscal years 2010-2013.

In FY 2013, OCE received 301 complaints concerning potential violations by regulated industry for further evaluation and investigation along with receiving, processing, and responding to 1413 additional inquiries.

There are many mechanisms for the public to report potential violations of the law. Stakeholders can help FDA in its compliance and enforcement actions by contacting CTP to report a variety of potential violations. Anyone can contact CTP using the Potential Tobacco Product Violations Reporting Form at http://www.fda.gov/tobaccoproducts/protectingkidsfromtobacco/ucm330160.htm, call the Tobacco Call Center using CTP's toll-free number (1-877-CTP-1373), email CTP at CTPCompliance@fda.hhs.gov, or contact CTP by mail at FDA Center for Tobacco Products c/o Document Control Center, 9200 Corporate Boulevard, Rockville, MD 20850-3229. Reports can be submitted anonymously; however, reports accompanied by names and contact information are helpful in cases when FDA needs to follow up for more information. Reports submitted by the public and stakeholders do not constitute proof of a violation, but they may be helpful in identifying possible violations of the Tobacco Control Act and related regulations that FDA enforces. By

17 Materials regarding FDA's privacy program can be found at http://www.fda.gov/RegulatoryInformation/FOI/PrivacyAct/default.htm.

providing stakeholders with mechanisms to report potential violations, FDA is able to better monitor compliance with the laws. Actual violations of the law must be independently verified by FDA.

Additionally, in FY 2014, OCE's Tobacco Product Retail Compliance Check Inspection Program will continue to grow as additional jurisdictions start inspections. OCE's Division of Promotion, Advertising, and Labeling's routine surveillance and review of the tobacco industry's marketing, labeling, promotion, and advertising activities via the Internet, publications, regulatory submissions, "other media" notifications, warning plans submissions, inquiries, and complaints will also continue to grow. OCE will also continue to work with retailers and small business to educate them on the requirements under the law; review and monitor promotional, manufacturing, and distribution activities of tobacco product businesses; and initiate additional advisory and enforcement actions as appropriate. The Office of Small Business Assistance will also continue to be available to provide tobacco product businesses technical and other nonfinancial assistance. It is through activities such as the above, that the Office of Compliance and Enforcement contributes towards CTP's goal of making tobacco related death and disease part of America's past, not its future.

APPENDIX A • OCE'S PUBLIC WEBINARS AND TRAINING SESSIONS

DATE	TITLE	RETAILER	SMALL BUSINESSES
7|19|2010	Compliance Training – Boston, MA	●	
9|1|2010	Compliance Training – Atlanta, GA	●	
9|8|2010	Compliance Training – Chicago, IL	●	
9|22|2010	Compliance Training – Dallas, TX	●	
9|29|2010	Compliance Training – Los Angeles, CA	●	
3|29|2011	Overview of the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents*	●	
4|26|2011	Warning Letters & Civil Money Penalties	●	
5|18|2011	Impersonal Modes of Sale; Prohibition Against Breakage of Packages of Cigarettes and Smokeless Tobacco Products; Minimum Cigarette Packages Size; Discussion of Free Samples	●	
6|28|2011	Smokeless Tobacco Product Packaging and Advertising Requirements	●	
7|26|2011	Compliance Training for Retailers - Required Warnings for Cigarette Packages and Advertisements	●	
7|26|2011	Compliance Training for Small Tobacco Manufacturers – Required Warnings for Cigarette Packages and Advertisements		●
9|27|2011	Tobacco Retailer Compliance Quiz – A Review of Some of the Topics Presented in Previous Webinars	●	
10|4|2011	Warning Letters for Tobacco Retailers	●	
10|18|2011	Cigarettes and Smokeless Tobacco Warning Plan Requirements		●
11|1|2011	Draft Guidance for Industry Applications for Premarket Review of New Tobacco Products		●
11|15|2011	The Civil Money Penalty Process	●	
12|8|2011	Establishment Registration and Product Listing Requirements		●
1|17|2012	CTP's Domestic Manufacturing Inspection Program		●
2|7|2012	Compliance Training for Tobacco Retailers - What to Expect During a Tobacco Retailer Inspection	●	
2|21|2012	Warning Letter and Civil Money Penalty Update	●	
3|6|2012	Compliance Training for Small Businesses - Frequently Asked Questions		●
4|10|2012	Compliance Training for Tobacco Retailers and Small Businesses – Compliance Information on the CTP Website	●	●
4|24|2012	Substantial Equivalence Reports		●
5|22|2012	The Import Process for Small Businesses		●
6|19|2012	Regulations Regarding Distribution of Free Samples of Smokeless Tobacco at "Qualified Adult-only Facilities"		●
8|21|2012	Common Issues Identified During FDA's Scientific Evaluation of Substantial Equivalence Reports		●
9|5|2012	Compliance Check Inspection Notifications	●	
11|7|2012	Overview of Warning Letters and Common Violations on the Internet		●
4|10|2013	Substantial Equivalence – An Update		●
5|15|2013	Update on the Potential Tobacco Product Violations Reporting Form	●	
9|5|2013	Guidance for Industry: Tobacco Retailer Training Programs	●	
9|12|2013	Frequently Asked Questions	●	
9|25|2013	Announcement of Availability of a Compliance Training Video for Tobacco Retailers	●	

APPENDIX B • STATE AND TERRITORY CONTRACTS FOR TOBACCO RETAIL COMPLIANCE CHECK INSPECTIONS

STATE	AGENCY	TOTAL AWARDED THROUGH 9/30/13
Alabama	Alabama Department of Public Health	$4,908,950.75
Arizona	Arizona Department of Health Services	$2,268,366.00
Arkansas	Arkansas Tobacco Control Board	$2,984,288.01
California	California Department of Public Health, Food and Drug Branch	$5,254,908.00
Colorado	Colorado Department of Public Health and Environment	$3,800,209.00
Connecticut	Connecticut Department of Mental Health and Addiction Services	$1,900,824.00
Delaware	Delaware Department of Homeland Security, Division of Alcohol and Tobacco Enforcement	$487,588.54
Georgia	Georgia Department of Revenue, Alcohol and Tobacco Division	$1,506,513.49
Guam	Guam Department of Mental Health and Substance Abuse	$280,758.00
Hawaii	Hawaii Department of Health, Alcohol and Drug Abuse Division	$759,798.61
Idaho	Idaho Department of Health and Welfare	$1,617,091.20
Illinois	Illinois Department of Revenue, Illinois Liquor Control Commission	$2,699,320.39
Indiana	Indiana Alcohol and Tobacco Commission, Indiana State Excise Police	$2,458,485.00
Iowa	Iowa Department of Commerce, Alcoholic Beverages Division	$1,449,955.90
Kansas	Kansas Department of Revenue, Alcoholic Beverage Control	$1,935,442.00
Kentucky	Kentucky Department of Alcoholic Beverage Control	$1,292,705.37
Louisiana	Louisiana Office of Alcohol and Tobacco Control	$1,479,186.50
Maine	Maine Center for Disease Control and Prevention, Division of Chronic Disease	$2,909,729.98
Maryland	Maryland Department of Health and Mental Hygiene, Alcohol and Drug Abuse Administration	$2,676,243.00
Massachusetts	Massachusetts Department of Public Health, Tobacco Cessation and Prevention Program	$2,375,498.35
Michigan	Michigan Department of Community Health, Bureau of Substance Abuse and Addiction Services	$2,847,721.00
Minnesota	Minnesota Department of Health and Human Services, Alcohol and Drug Abuse Division	$1,710,162.00
Mississippi	Mississippi Attorney General's Office, Alcohol and Tobacco Enforcement Unit	$3,838,115.00
Missouri	Missouri Department of Mental Health, Division of Alcohol and Drug Abuse	$2,368,292.00
Montana	Montana Department of Public Health and Human Services	$229,921.00
New Hampshire	New Hampshire Liquor Commission, Division of Enforcement and Licensing	$606,689.00
New Jersey	New Jersey Department of Health and Senior Services, Division of Family Health Services, Office of Tobacco Control	$2,461,864.00
New Mexico	New Mexico Human Services Department, Behavioral Health Services Division	$1,998,094.58
North Carolina	North Carolina Department of Health and Human Services, Division of Mental Health	$1,714,886.00
Northern Mariana Islands	Northern Mariana Islands Department of Commerce, Alcoholic Beverage and Tobacco Control Division	$409,671.22
Ohio	Ohio Department of Alcohol and Drug Addiction Services	$2,704,278.87
Oklahoma	Oklahoma Alcoholic Beverage Laws Enforcement Commission	$969,687.00
Pennsylvania	Pennsylvania Department of Health, Bureau of Health Promotion and Risk Reduction, Division of Tobacco Prevention and Control	$2,487,344.42
Puerto Rico	Puerto Rico Department of Health	$1,340,007.00
Rhode Island	Rhode Island Department of Behavioral Healthcare, Developmental Disabilities and Hospitals	$1,889,434.00
South Carolina	South Carolina Department of Alcohol and Other Drug Services	$1,039,112.00
Tennessee	Tennessee Department of Agriculture, Regulatory Services Division	$972,888.00
Texas	Texas Department of State Health Services	$3,248,426.00
Utah	Utah Department of Health, Division of Disease Control and Prevention	$841,174.44
Vermont	Vermont Department of Liquor Control	$596,916.74
Virginia	Virginia Department of Alcoholic Beverage Control	$4,148,222.00
Washington	Washington State Liquor Control Board	$3,115,104.00
Washington D.C.	DC Department of Health, Addiction Prevention and Recovery Administration	$884,144.00
West Virginia	West Virginia Department of Health and Human Resources, Bureau for Behavioral Health and Health Facilities	$2,254,067.00
Wisconsin	Wisconsin Department of Health Services, Division of Public Health, Bureau of Community Health Promotion, Tobacco Prevention and Control Program	$1,330,591.00
Total		$91,052,674.36

Awards begin in FY 2010 and continued through FY 2011, FY 2012, and FY 2013. This includes the initial award, any modifications made during the course of the contract, and any subsequent annual award. Additional information about the awards can be found at: http://www.fda.gov/TobaccoProducts/ResourcesforYou/ucm228914.htm

APPENDIX C • INSPECTIONS OF TOBACCO RETAILERS INVOLVING SALES TO MINORS WHICH RESULTED IN FDA ACTION (WARNING LETTERS AND/OR CMPs) (10/1/10 THROUGH 9/30/13)

STATE	VIOLATION RATE*	EARLIEST DECISION DATE OF INSPECTION INVOLVING A MINOR	PERCENTAGE OF RETAILERS WITH REPEAT VIOLATIONS INVOLVING A MINOR
AL	6.5%	8|1|2011	6%
AR	13.4%	3|3|2011	13.8%
AZ	15.8%	3|17|2011	22.3%
CA	2.9%	2|16|2011	1.4%
CO	9%	2|3|2011	13.2%
CT	13.7%	12|1|2011	12.4%
DC	15.4%	4|3|2012	10.3%
DE	3.3%	3|21|2012	**
GA	5.5%	2|24|2012	**
HI	**	6|20|2013	**
IA	3.4%	6|19|2012	3.2%
ID	4.8%	8|3|2011	**
IL	14.2%	3|7|2011	21.4%
IN	8.8%	4|4|2012	8.4%
KS	3.6%	3|23|2011	2.4%
KY	2.8%	11|3|2011	4.4%
LA	8.5%	4|25|2012	0%
MA	8.2%	3|7|2011	11.8%
MD	16.8%	1|18|2011	25.3%
ME	1.7%	1|13|2011	1.7%
MI	14.8%	6|20|2012	8.8%
MN	6.3%	6|14|2012	3.3%
MO	25.7%	6|2|2011	31.8%
MS	7.3%	10|12|2010	14.3%
MT	2.3%	2|22|2013	**
NC	6.6%	6|5|2012	**
NH	10%	7|12|2012	17.2%
NJ	15.5%	3|14|2012	10.5%
OH	11%	8|2|2012	**
OK	7.7%	3|21|2012	8.3%
PA	8%	6|20|2011	21.1%
RI	8.9%	5|9|2012	4.2%
SC	**	8|7|2013	**
TN	4.8%	4|6|2011	5.1%
TX	7.9%	3|6|2012	4.6%
UT	4%	4|24|2012	7.6%
VA	7.5%	8|24|2012	4.3%
WA	12.8%	1|27|2011	12.4%
WI	**	7|18|2013	**
WV	9%	2|20|2013	**

* Violation Rate = Total number of inspections where a violation involving a sale to a minor occurred divided by the number of inspections involving a minor.
* Data represents the percentage of inspections in which a minor was able to purchase a tobacco product and in some cases covers multiple years. The number of inspections involving a minor that a state or territory completed varies based on a variety of factors such as: the state or territory's specific contract terms; the date FDA awarded the state or territory agency's contract; and the timing for hiring, commissioning, and training of personnel. Due to these variations, these violation rates cannot be readily compared across states, nor compared with violation rates collected under other initiatives, for example Synar.
** Minimal data available through 9/30/13.

APPENDIX D • DESCRIPTION OF SALE AND DISTRIBUTION VIOLATIONS DEPICTED IN THIS REPORT WITH STATUTORY OR REGULATORY REFERENCES

DESCRIPTION OF VIOLATION	STATUTORY OR REGULATORY REFERENCE
Sale to Minor	21 C.F.R. § 1140.14(a)
Failure to ID	21 C.F.R. § 1140.14(b)(1)
Impersonal Modes of Sale	21 C.F.R. § 1140.14(c) 21 C.F.R. § 1140.16(c)
Sale or Distribution of Individual Cigarettes or Unpackaged Cigarettes in Smaller than the Minimum Quantity of 20	21 C.F.R. § 1140.14(d)
Package Contains Fewer than 20 Cigarettes	21 C.F.R. § 1140.16(b)
Free Samples	21 C.F.R. § 1140.16(d)(1)
Non-Tobacco Item with Purchase*	21 C.F.R. § 1140.34(b)
"Low," "Light," "Mild" or Similar Descriptors on Labeling or Advertising	FD&C Act § 902(8) (21 U.S.C. § 387b(8))
Flavored Cigarettes	FD&C Act § 907(a)(1)(A) (21 U.S.C. § 387g(a)(1)(A)) FD&C Act § 902(5) (21 U.S.C. § 387b(5)); FD&C Act § 903(a)(1) (21 U.S.C. § 387c(a)(1))
Sponsorship Violation	21 CFR § 1140.34(c)
Other Modified Risk Tobacco Products Violation	FD&C Act § 911(a) (21 U.S.C. § 387k(a)) FD&C Act § 911(b) (21 U.S.C. § 387k(b)) FD&C Act § 902(8) (21 U.S.C. § 387b(8))
False or Misleading Labeling or Advertising	FD&C Act §903 (21 U.S.C. § 387c) FD&C Act § 903(a)(1) (21 U.S.C. § 387c(a)(1)) FD&C Act § 903(a)(7)(A) (21 U.S.C. § 387c(a)(7)(A))
Failure to Provide Brief Statement of Relevant Warnings	FD&C Act § 903(a)(8)(B)(i) (21 U.S.C. § 387c(a)(8)(B)(i))

* On March 19, 2012, the United States Court of Appeals for the Sixth Circuit issued an Opinion and Judgment that, among other things, found §1140.34(b) to be unconstitutional under the First Amendment. *(*See *Discount Tobacco v. United States.)* Therefore, FDA will not seek to enforce this provision. §1140.34(b) states: "No manufacturer, distributor, or retailer may offer or cause to be offered any gift or item (other than cigarettes or smokeless tobacco) to any person purchasing cigarettes or smokeless tobacco in consideration of the purchase thereof, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase."