**Report to Congress**

**Progress and Effectiveness of the Implementation of the Family Smoking Prevention and Tobacco Control Act**

U.S. Department of Health and Human Services

Food and Drug Administration

Date 5/23/13

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs

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## Executive Summary

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to authorize FDA to oversee the manufacture, marketing, distribution, and sale of regulated tobacco products and protect the public from the harmful effects of tobacco product use. This report, which satisfies the requirements of section 106(a) of the Tobacco Control Act, provides an assessment of FDA efforts to implement the Tobacco Control Act since it was signed into law on June 22, 2009.

Among the major accomplishments achieved in these early years is the creation of the FDA Center for Tobacco Products. This report describes the establishment of the new Center with dedicated tobacco program funding, as authorized by the Tobacco Control Act.

Other key accomplishments include:

- Establishing an initial framework for industry registration, product listing, and disclosure of ingredients and harmful and potentially harmful constituents in tobacco products and tobacco smoke.
- Pursuant to the FD&C Act, requiring cigarette, roll-your-own, and smokeless tobacco product manufacturers to seek FDA authorization before marketing a new product or making changes to existing products.
- Enforcing the statute's prohibition on the use of marketing terms for regulated tobacco products that imply reduced risk (such as "light," "mild," or "low") without FDA authorization.
- Developing a process for the review and evaluation of applications for new tobacco products and modified risk tobacco products.
- Implementing the statute's ban on cigarettes with certain characterizing flavors.
- Increasing regulatory science capabilities through research to better understand regulated tobacco products and patterns of tobacco use.
- Restricting access and marketing of cigarettes and smokeless tobacco products to youth.
- Implementing a compliance and enforcement program to ensure industry compliance with regulatory requirements.
- Establishing public education campaigns about the dangers of regulated tobacco products.

As required by the Tobacco Control Act, the report also describes impediments to progress during this time and provides data on certain tobacco product applications as well as on the number of full time equivalents (FTEs) engaged in implementing the FDA tobacco program.

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## I. *Overview*

Tobacco use is the single most preventable cause of disease, disability, and death in the United States. Each year, an estimated 443,000 Americans die prematurely from smoking or exposure to secondhand smoke; more than the number of deaths due to alcohol, illegal drug use, homicide, suicide, car accidents, and HIV/AIDS combined.[1] Approximately 8.6 million people in the United States live with a serious illness caused by smoking.[2]

In 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act), granting authority to the U.S. Food and Drug Administration (FDA) to regulate tobacco products. This new authority gave FDA comprehensive tools to protect the public from the harmful effects of tobacco use, including thorough science-based regulation of the manufacturing, marketing, and distribution of tobacco products.

FDA was given immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. For the American public this means, among other things:

- New tobacco products of these types cannot come on the market without FDA review, which includes consideration of the potential public health impact;
- Products can no longer be marketed as reduced risk or reduced harm without scientific evidence showing both that they reduce harm and the risk of disease to individual users and that marketing them would benefit the population as a whole; and
- Access to new information about the harmful and potentially harmful constituents of these tobacco products and tobacco smoke.

The Tobacco Control Act also authorizes FDA to deem other tobacco products to be subject to FDA's regulatory authority in Chapter IX of the Food, Drug, and Cosmetic Act (FD&C Act). FDA publicly announced in the Unified Agenda of January 8, 2013, that it will issue a proposed rule to deem products that meet the statutory definition of a "tobacco product," which includes "any product made or derived from tobacco that is intended for human consumption" that is not a drug, device, or combination product under the FD&C Act, to be subject to FDA's regulatory authority in Chapter IX.[3] All newly-deemed tobacco products would automatically be subject to certain provisions in the FD&C Act, such as registration, product listing, ingredient listing, user fees for certain products, and the adulteration and misbranding provisions of the statute.

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[1] *See Centers for Disease Control.* "Fact Sheets: Smoking & Tobacco Use." www.cdc.gov/tobacco.

[2] *Ibid.*

[3] *See* "Department of Health and Human Services Semiannual Regulatory Agenda." 78 Fed. Reg. 1579 (Jan. 8, 2013).

This report satisfies the requirements of Section 106(a) of the Tobacco Control Act, which states:

> *Not later than 3 years[4] after the date of enactment of this Act, and not less than every 2 years thereafter, the Secretary of Health and Human Services shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report concerning--*
>
> > *(1) the progress of the Food and Drug Administration in implementing this division, including major accomplishments, objective measurements of progress, and the identification of any areas that have not been fully implemented;*
> >
> > *(2) impediments identified by the Food and Drug Administration to progress in implementing this division and to meeting statutory timeframes;*
> >
> > *(3) data on the number of new product applications received under section 910 of the Federal Food, Drug, and Cosmetic Act and modified risk product applications received under section 911 of such Act, and the number of applications acted on under each category; and*
> >
> > *(4) data on the number of full time equivalents engaged in implementing this division.*

## II. *Progress of the FDA in implementing the Family Smoking Prevention and Tobacco Control Act*

FDA's first priority following the passage of the Tobacco Control Act was creating the Center for Tobacco Products (CTP), FDA's first new center in 21 years. CTP oversees the implementation of the FDA tobacco program, pursuant to the Tobacco Control Act. The Center has been tasked with developing the scientific, regulatory, and public education infrastructure necessary to implement and track FDA's goals for reducing the harms associated with tobacco products, preventing initiation of tobacco use, particularly among youth, and encouraging cessation so that more Americans stop using tobacco products. Key objectives involved in launching CTP included recruiting talented officials to lead the center, hiring skilled staff, setting up necessary infrastructure and technology resources, and putting in place processes to meet statutory deadlines and directives.

Establishing the Center for Tobacco Products

The Tobacco Control Act authorized FDA to use appropriated funds during fiscal year (FY) 2009 for the initial start-up costs of tobacco regulation activities. In the last quarter of FY 2009, CTP began collecting user fees authorized under the FD&C Act to fund the agency's tobacco regulation activities. The Tobacco Control Act stipulates that these user fees may only be spent

[4] 123 Stat. 1776, 1783 explains that the three-year time period shall commence on the first day of the first fiscal quarter following the initial 2 consecutive fiscal quarters 2010 for which the Secretary of Health and Human Services has collected fees under section 919 of the Federal Food, Drug, and Cosmetic Act. Thus, the due date for this report is April 1, 2013.

for FDA tobacco regulation activities. Conversely, the law provides that no funds, other than these user fees, may be spent on FDA tobacco regulation activities.

Section 919 of the Act identifies the total dollar amount of user fees authorized to be assessed and collected each year, on a quarterly basis, from tobacco manufacturers and importers. Tobacco user fees are "no year" funds and may be carried over from one fiscal year to the next. Fees are allocated among classes of regulated tobacco products, currently cigarettes, snuff, chewing tobacco, and roll-your-own tobacco[5], based on the volume of the different tobacco product classes reported to the U.S. Department of Treasury's Bureau of Alcohol, Tobacco Tax and Trade for excise tax purposes. Under a memorandum of understanding, the U.S. Department of Agriculture (USDA) has been providing FDA with the information on percentage market share by class of tobacco product and by individual company within each tobacco product class. Utilizing information received from USDA, FDA is able to assess user fees as directed by section 919 of the Tobacco Control Act for individual domestic manufacturers and importers based on their respective market share in each tobacco product class.[6] As of February 28, 2013, 99 percent of user fees assessed were being collected from manufacturers and importers.

During its start-up phase, FDA established the regulatory framework and staffing foundation to begin tobacco product regulation. All statutory obligations were met and recruitment and hiring proceeded as projected. It is important to note that full use of existing unexpended balances was planned for by the agency. The agency is required to continue to build the scientific base for tobacco product regulation and to fully implement the Tobacco Control Act. For example, now that much of the foundational work has been completed, FDA's tobacco program obligations in FY 2013 have been aggressive. As of February 28, 2013, the agency has obligated 63 percent of its spending plan ($540 million) and is on target to fully obligate its FY 2013 planned level of $847 million.

Hiring CTP's Director and Deputy Director

After a national search, Dr. Lawrence Deyton, M.D., M.S.P.H., was selected as CTP's founding Director in September 2009. Dr. Deyton is an expert on public health, tobacco use, and veterans' health issues, and is a clinical professor of medicine and health policy at George Washington University School of Medicine and Health Sciences. Prior to joining FDA, Dr. Deyton was Chief Public Health and Environmental Hazards Officer for the U.S. Department of Veterans Affairs. He also served in leadership positions in the National Institute of Allergy and Infectious Diseases at the National Institutes of Health (NIH).

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[5] Domestic manufacturers and importers of other tobacco products not currently regulated under Chapter IX of the FD&C Act, such as cigars and pipe tobacco, are not currently assessed user fees. *See* FD&C Act Sec. 919(b)(2)(B)(iii).

[6] In specifying how to determine these assessments for listed classes of tobacco products other than cigars, Section 919 of the FD&C Act references sections of the Fair and Equitable Tobacco Reform Act of 2004 (FETRA)(Pub. L. No. 108-357) (7 U.S.C. 518 et seq.) that are administered by the U.S. Department of Agriculture (USDA). Assessments for cigars would be determined separately pursuant to Section 919(b)(5).

In March 2013, Dr. Deyton was succeeded by Mitchell Zeller, J.D. Mr. Zeller has been working on FDA issues for more than 30 years, including seven years as the Associate Commissioner and Director of the FDA's Office of Tobacco Programs from 1993 to 2000. Mr. Zeller has also served as the Executive Vice President of the American Legacy Foundation, which was created out of the 1998 Master Settlement Agreement to address the health effects of tobacco use. He also has prior experience as a public interest attorney and a congressional counsel.

In June 2012, FDA Commissioner Margaret A. Hamburg, M.D. named Richard J. Turman as CTP's Deputy Director. Prior to joining CTP, Mr. Turman served as the Principal Deputy Assistant Secretary for Financial Resources at the U.S. Department of Health and Human Services (HHS) and as the Associate Director for Budget at NIH.

The priorities of the Center Director and Deputy Director include expanding effective communications across FDA and CTP, within HHS, and among stakeholders on matters related to tobacco product regulation and FDA's regulatory authorities, as well as advancing HHS's tobacco-related goals.

Staffing the Center

After filling the leadership positions in CTP, the center grew from a handful to hundreds of employees dedicated to protecting public health, including regulatory counsels, policy analysts, scientists, researchers, management officers, communications specialists, and other professionals needed to design and implement a comprehensive program of tobacco product regulation as required by the FD&C Act.

The following table displays full-time equivalent (FTE) program levels from FY 2009 through FY 2013.[7]

| Fiscal Year | Program Level FTE |
|---|---|
| 2009 Actual | 0[8] |
| 2010 Actual | 113 |
| 2011 Actual | 256 |
| 2012 Actual | 426 |
| 2013 Request | 546 |

Objective measures of progress

In the four years since the enactment of the Tobacco Control Act, FDA has made significant progress developing a framework for tobacco product regulation that is designed to reduce the impact of tobacco on public health, to keep people, especially our nation's youth, from starting to

[7] Tobacco Program Funding covers employees at CTP and other FDA employees assigned to tobacco product regulation, including in the Office of Commissioner (OC), the Office of General Counsel, HHS (OGC), and the Office of Regulatory Affairs (ORA).

[8] From the time CTP was established on June 22, 2009 until the end of that fiscal year, 22 FDA personnel were temporarily detailed to CTP.

use tobacco, and to make it easier for current consumers who wish to quit. For example, FDA has published 8 rules and regulatory documents and 24 guidance and draft guidance documents related to tobacco products, a complete listing can be found in Appendix A.

Other key accomplishments include:

- Establishing an initial framework for industry registration, product listing, and disclosure of ingredients and harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke.
- Pursuant to the FD&C Act, requiring cigarette, roll-your-own, and smokeless tobacco product manufacturers to seek FDA authorization before marketing a new product or making changes to existing products.
- Implementing and enforcing the statute's prohibition on the use of marketing terms for regulated tobacco products that imply reduced risk (such as "light," "mild," or "low") without FDA authorization.
- Developing a process for the review and evaluation of applications for new products, modified risk, and substantially equivalent tobacco products.
- Implementing and enforcing the statute's ban on cigarettes with certain characterizing flavors.
- Increasing regulatory science capabilities through research to better understand regulated products and patterns of tobacco use.
- Restricting access and marketing of cigarettes and smokeless tobacco products to youth.
- Implementing a compliance and enforcement program to ensure industry compliance with regulatory requirements.
- Establishing public education campaigns about the dangers of regulated tobacco products.

These accomplishments demonstrate the commitment of FDA to exercise its new regulatory authority under the FD&C Act to effectively regulate the manufacture, marketing, and distribution of tobacco products and to advance tobacco product regulations appropriate for the protection of public health.

## III. *The Regulatory Framework for Tobacco Products*

As the regulatory framework for tobacco products continues to evolve, FDA has set forth comprehensive objectives to:

1. Understand the regulated products.
2. Review new products and product changes to protect public health.
3. Prohibit false, misleading, and unsubstantiated product claims that state or imply reduced risk.
4. Decrease the harms of tobacco products.
5. Expand the science base for regulatory action.
6. Restrict marketing and distribution to protect public health.
7. Ensure industry compliance with FDA regulations.
8. Educate the public.

FDA's progress toward achieving these core framework objectives is discussed in detail below.

### *1. Understand the regulated products*

The FD&C Act, as amended by the Tobacco Control Act, empowers FDA to build knowledge of regulated tobacco products. In part, this is accomplished through three specific reporting requirements. First, companies must register manufacturing facilities and provide a list of all their regulated products.[9] To assist industry with compliance, FDA issued a final guidance document in November 2009.[10] Second, companies are required to provide a list of all ingredients for regulated products.[11] To assist companies with this requirement, FDA published a final guidance in December 2009 detailing procedures for submitting ingredient information, including what information to submit, how information should be submitted, and when it is appropriate to do so.[12]

Third, the FD&C Act directs FDA to establish and periodically revise a list of HPHCs in tobacco products and requires all tobacco product manufacturers to measure and report HPHC quantities to FDA by brand and subbrand.[13] HPHCs are those constituents in a tobacco product or tobacco smoke that are, or have the potential to be inhaled, ingested, or absorbed into the body and that cause or have the potential to cause direct or indirect harm to users or non-users of tobacco products.[14]

In developing the HPHC list, FDA solicited input and recommendations from the FDA's Tobacco Products Scientific Advisory Committee. FDA also released a list of HPHCs for public comment[15] before establishing a list of these constituents in April 2012.[16] The established list, is available in Appendix B, and identifies 93 HPHCs. The list also identifies each constituent with

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[9] FD&C Act Sec. 905

[10] "Guidance for Industry: Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments." 74 Fed. Reg. 58298 (Nov. 12, 2009).

[11] FD&C Act Sec. 904(a)(1)

[12] "Guidance for Industry on Listing of Ingredients in Tobacco Products." 77 Fed. Reg. 62795 (Dec. 1, 2009).

[13] FD&C Act Sec. 904(a)(3) and Sec. 915

[14] Examples of constituents that have the potential to cause direct harm to users or non-users of tobacco products include constituents that are toxicants, carcinogens, and addictive chemicals and chemical compounds. Examples of constituents that have the potential to cause indirect harm include constituents that may increase the exposure to the harmful effects of a tobacco product constituent by potentially facilitating initiation, impeding cessation, or increasing the intensity of use of tobacco products. *See* "Guidance for Industry and FDA Staff: "Harmful and Potentially Harmful Constituents" in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act." 76 Fed. Reg. 5387 (Jan. 31, 2011).

[15] "Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke; Request for Comments." 76 Fed. Reg. 50226 (Aug. 12, 2011).

[16] "Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke; Established List." 77 Fed. Reg. 20034 (April 3, 2012).

one of the following disease effects: cancer, cardiovascular disease, respiratory effects, developmental or reproductive effects, and addiction. In April 2012, FDA also released a draft guidance document for industry related to the reporting of HPHCs.[17]

A provision in the Tobacco Control Act requires FDA to publicly display information about HPHCs, including the amount of each chemical present in specific brands and sub-brands of tobacco products, in a way that is understandable and not misleading to the public by April 1, 2013.[18] FDA intends to make such detailed information about chemicals in tobacco products and tobacco smoke available, but only when the agency can assure the public that the information released is understandable and not misleading. Therefore, FDA is not releasing any information at this time. Currently, the agency is evaluating the data it has received from manufacturers and will be conducting rigorous scientific studies to ensure that the required information is presented in a way that is understandable and not misleading to the public. When FDA completes these important activities, the agency will be in a position to publish the required information consistent with the statutory requirements. By doing so, FDA will help consumers make more informed decisions about tobacco products.

Under Section 901 of the FD&C Act, products currently regulated by FDA under Chapter IX of the FD&C Act, include: cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. In addition, FDA is authorized to deem, by regulation, other tobacco products to be subject to this Chapter. FDA has publicly announced its intention to deem products that meet the statutory definition of "tobacco product," which is "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product" that is not a drug, device, or combination product under the FD&C Act.[19]

***2. Review new products and product changes to protect public health***

Historically, tobacco manufacturers regularly altered characteristics of their products to improve taste, appeal to new users, and retain current users as their preferences change. The FD&C Act authorizes FDA's regulation of tobacco products to protect public health by requiring manufacturers to seek FDA authorization before marketing a new product, including making changes to an existing product. Section 910 of the Act defines a "new" tobacco product as a product not commercially marketed in the United States as of February 15, 2007, or a product already on the market that is modified after that date.[20] This premarket review process gives FDA the ability to ensure that the marketing of any new product, including a modified product, is

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[17] "Draft Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under The Federal Food Drug and Cosmetic Act." 77 Fed. Reg. 20030 (published for comments on April 3, 2012).

[18] FD&C Act Sec. 904(d)

[19] FD&C Act Sec. 201(rr)

[20] *See* FD&C Act Sec. 910(a)(2)(A)(i)(I) and Sec. 905(j)(1)(A)(i). Products commercially marketed in the United States as of February 15, 2007, are not subject to premarket review requirements. *See* also "Draft Guidance for Industry and FDA Staff – Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007." 76 Fed. Reg. 22903 (published for comments on April 25, 2011).

appropriate for the protection of public health and allows for greater awareness and understanding of the changes being made to tobacco products.

Under the premarket review process, there are three ways a new tobacco product, including an existing product that is modified, can obtain FDA authorization for distribution or retail sale: a premarket tobacco product application; an application demonstrating substantial equivalence (SE) to certain commercially marketed products; or an application for exemption from demonstrating SE.

Premarket tobacco product applications

One pathway for a new tobacco product to receive market authorization is through the Premarket Tobacco Product Application (PMTA) process.[21] In September 2011, FDA issued a draft guidance document about PMTA submissions describing what the FD&C Act requires to be submitted in a new tobacco product application.[22] The draft guidance also sought comment on the information to be included in the application that the agency would use to determine whether the marketing of a new tobacco product is appropriate for the protection of the public health, as determined with respect to the risks and benefits to the population as a whole, including users and non-users of tobacco products, and taking into account the impact on cessation and initiation.

Demonstrating substantial equivalence to certain commercially marketed products

Demonstrating SE to a product already on the market is a second pathway to marketing authorization under specific circumstances. Under the SE pathway, whenever an existing tobacco product is modified, the manufacturer must submit a report with sufficient scientific data and information to FDA to demonstrate that the product characteristics,[23] as compared to the predicate product are the same,[24]or the tobacco product has different characteristics but does not raise different questions of public health.[25]

Pursuant to Section 910(a)(2)(B) of the Act, products that were first introduced or delivered for introduction into interstate commerce for commercial distribution between February 15, 2007, and March 22, 2011, and for which SE reports were submitted prior to March 23, 2011, can remain on the market unless FDA issues an order that they are "not substantially equivalent (NSE)." FDA refers to these SE reports as "provisional." An SE report for a tobacco product not covered by this provision is considered a "regular" report and the product covered by the application cannot be marketed unless FDA first issues an order finding the product substantially equivalent and in compliance with the FD&C Act. FDA issued a guidance document in January 2011 describing the content and data to be included in the report and the process for its review.[26]

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[21] FD&C Act Sec. 910

[22] "Draft Guidance for Industry Applications for Premarket Review of New Tobacco Products." 76 Fed. Reg. 60055 (published for comments on Sept. 28, 2011).

[23] Characteristics are defined in section 910(a)(3)(B) of the FD&C Act as "the materials, ingredients, design, composition, heating source, or other features of a tobacco product."

[24] FD&C Act Sec. 910(a)(3)(A)(i)

[25] FD&C Act Sec. 910(a)(3)(A)(ii)

[26] "Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products." 77 Fed. Reg. 789 (Jan. 6, 2011).

Exemption from demonstrating substantial equivalence

The third pathway for new tobacco products is a request for an exemption from the SE requirements. This pathway is available for products modified by the addition or deletion of an additive or a change in the quantity of an existing additive, if:

- FDA finds the modification to be minor;
- FDA determines an SE report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health; and
- an exemption is otherwise appropriate.[27]

In July 2011, FDA issued a final rule on "Exemptions from Substantial Equivalence Requirements"[28] that established the procedures for requesting an SE exemption.

Status of new product applications under Section 910

FDA review of a new product, including a modified product, requires scientific and technical expertise in order to assess how the product design, ingredients, and other characteristics impact the public health. As of February 28, 2013, FDA had not received any premarket applications for new tobacco products and has focused its review efforts on applications seeking to demonstrate SE.

Process for review of substantial equivalence reports

At this time, regular SE submissions are reviewed in the order they are received, and provisional SE submissions receive a Public Health Impact (PHI) Review, in which applications are given a tier assignment (1-4). Those with a tier 1 assignment, indicating the highest potential negative public health impact, are the first provisional applications to be reviewed. The PHI review process was necessary because over 3,000 provisional applications arrived within a short span of time prior to the March 23, 2011, filing deadline.

The review for an SE report involves a stepped process in order to ensure consistency, transparency, and predictability. FDA first performs a Jurisdictional Review to determine whether the product is currently subject to regulation as a tobacco product. FDA then carries out a Completeness Review to determine if the report is administratively complete. If additional information is needed, FDA sends an Administrative Advice and Information (AI) Request letter to the applicant requesting specific information.

After this review, FDA performs a Predicate Tobacco Product Eligibility Determination, which is the process for evaluating whether the proposed predicate tobacco product (the tobacco product to which the proposed new tobacco product is being compared in the SE Report) meets the FD&C Act criteria to be a predicate. FDA currently prioritizes predicate reviews for regular

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[27] FD&C Act Sec. 905(j)(3)

[28] "Tobacco Products, Exemptions From Substantial Equivalence Requirements." 76 Fed. Reg. 38961 (July 5, 2011). 21 CFR § 1107

SE submissions since the products covered in a regular SE submission are not authorized to be commercially marketed unless FDA issues an order of substantial equivalence.

FDA performs a Scientific Review of SE submissions to assess the chemistry, toxicology, engineering, and other appropriate scientific properties of the tobacco product and determines whether its characteristics are the same as the predicate product or if there are different characteristics, and whether the new product raises different questions of public health. If additional scientific information is needed, FDA sends a Scientific AI letter to the applicant requesting specific information and asking the applicant to respond within 60 days. FDA completes the scientific review upon receipt of that information or seeks further clarification as needed. Before making a determination that a product is SE or NSE, FDA must determine whether any other additional information is needed. FDA then makes its determination and communicates the determination to the applicant.

As of February 28, 2013, FDA had received a total of 4,321 submissions seeking to demonstrate SE to a predicate product, including, 3,544 "provisional" submissions that were received before March 23, 2011, and apply to products already marketed in the United States. The remaining 777 applications are "regular" submissions for products not currently on the market.

FDA has completed Jurisdictional Reviews for 3,782 of the 4,253 SE submissions. FDA has conducted Completeness Reviews for 2,638 SE submissions. FDA has performed a PHI review and provided a tier assignment (1 – 4) for 3,440 provisional SE reports. FDA has completed Predicate Tobacco Product Eligibility Determinations for 175 regular SE submissions. Of the 4,321 SE submissions received, 69 were withdrawn by the applicants. Manufacturers may withdraw an SE application at any time in the SE review process if they are not able to meet FDA's regulatory standards, or for other business reasons.

In addition, as of February 28, 2013, FDA had received and acknowledged 28 submissions seeking exemption from the SE reporting requirements; these are now under review. FDA had also received 530 requests by manufacturers for verification that a product was commercially marketed in the United States as of February 15, 2007, and not only in a test market. Of these, FDA has provided verification for 315 requests and three requests were withdrawn by the companies.

There are many factors that can affect the timing of a determination by FDA, including the completeness of an application or whether there is a need for manufacturers to submit more information or provide an additional explanation so that FDA can complete its assessment. It is important to note that there was a wide range of quality in SE reports submitted thus far by the tobacco industry, which is new to FDA regulation. In almost all cases, reports that have been submitted lack both information referenced in FDA guidance documents to facilitate FDA review and information required for FDA to make its determination.

Examples of some of the general issues that FDA is observing across multiple applicants include:

- Reports containing contradictory statements, particularly about whether the product characteristics were the same or different;

- Reports naming an unacceptable predicate product;
- Reports lacking information to completely understand product composition, including information about the tobacco blend used in the product;
- Reports missing specifications on components used in the manufacture of the finished product;
- Reports with HPHC measurements that were scientifically inadequate or did not include information needed to evaluate data quality; and
- Reports in which information on product design was incomplete, preventing a scientific assessment.

In response to industry feedback, where possible, FDA is streamlining the SE review process:

- FDA increased opportunities for communication with industry by encouraging teleconferences between the assigned FDA regulatory project manager and the submitter.
- FDA has taken steps to facilitate quicker responses to questions.
- FDA modified the initial review for completeness to focus only on administrative issues, so that applicants can be notified more quickly about submission deficiencies.
- FDA hosted webinars for tobacco manufacturers specifically to discuss the types of information that the agency needs to complete the review of SE reports.
- On September 22, 2011, FDA issued a draft guidance document with responses to frequently asked questions about demonstrating SE of a new tobacco product.
- FDA launched a new section on its website: *Tobacco Product Review and Evaluation* providing comprehensive information on the pathways available to legally market new tobacco products, including SE.

FDA is committed to carefully and thoroughly reviewing all submissions in order to protect the public health as required by the FD&C Act. FDA is also committed to a consistent, transparent, and predictable review process and to completing reviews of all new product applications in a timely manner. [29]

### *3. Prohibit false/misleading/unsubstantiated product claims that state or imply modified risk*

A regulated tobacco product may not be distributed or marketed with any statement or claim (expressed or implied) about reduced risk or harm associated with the product, unless the manufacturer demonstrates, and FDA finds that the product, as actually used, will significantly reduce harm and risk to users and will benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products.[30] In certain circumstances where scientific information is not available and cannot be made available without conducting long-term epidemiological studies and certain statutory criteria are

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[29] On June 25, 2013, FDA announced its first decisions on new tobacco products through the SE pathway and authorized the marketing of two new tobacco products and denied the marketing of four others. FDA also announced it had formally withdrawn 136 SE Reports at the request of the applicants, and it had refused to accept 20 SE Exemption Requests because the manufacturers did not meet the requirements for such an exemption.

[30] FD&C Act Sec. 911(g)

met, an "exposure modification order" may be issued. Such an order requires a finding that the product reduces or eliminates exposure to a substance for which the available scientific evidence suggests that a measurable and substantial reduction in morbidity and mortality is reasonably likely to be demonstrated in future studies. These requirements seek to prevent false, misleading and unsubstantiated product claims about the safety or relative harmfulness of tobacco products.

A draft guidance was released for public comment in March 2012 for those manufacturers that seek to market a modified risk tobacco product (MRTP), which is defined as "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."[31] The draft guidance for MRTP applications provides recommendations on how to organize, submit, and file an application, what scientific studies and analyses to submit, and what information to collect through post-market surveillance and studies if an FDA order permitting the marketing of the product is issued.[32] FDA has been meeting with manufacturers to discuss studies the manufacturers have proposed to provide the scientific evidence needed to demonstrate that marketing of a modified risk product will significantly reduce harm and risk of tobacco-related disease to individual tobacco users and benefits the health of the population as a whole. As of February 28, 2013, no MRTP applications had been filed with FDA.

Additionally, Section 911 of the FD&C Act specifically prohibits the use of the descriptors "light," "mild," or "low" or similar terms in regulated tobacco product labeling without an FDA order allowing the descriptors to be used. FDA issued a guidance document in June 2010 for industry about the use of "light," "mild," "low," or similar descriptors with respect to regulated products.[33] As of February 28, 2013, FDA has issued 65 Warning Letters that include charges related to the prohibition of "low," "light," or "mild" descriptors on regulated tobacco products under section 911 of the FD&C Act. In addition, FDA has sought Civil Money Penalties in two cases for tobacco product retailers violating the prohibition on the use of "low," "light," or "mild" descriptors on regulated tobacco products. FDA regularly updates its Health Fraud webpage to highlight these Warning Letters and promote public awareness of the illegal use of "light," "mild," and "low" claims for tobacco products that do not have an FDA order permitting such claims. In addition, FDA has conducted webinars, which included an overview of the requirements of the FD&C Act, Warning Letters issued, and violations cited under section 911 of the FD&C Act, to help educate the public and to encourage voluntary compliance by regulated industry.

### *4. Decrease the harms of tobacco products*

The FD&C Act directs FDA to prevent and reduce the harms caused by regulated tobacco products by, among other authorities, issuing tobacco product standards if the agency finds it

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[31] FD&C Act Sec. 911(b)(1)

[32] "Draft Guidance for Industry: Modified Risk Tobacco Product Applications." 77 Fed. Reg. 20026 (published for comments on April 3, 2012).

[33] "Guidance for Industry and FDA Staff: Use of "Light," "Mild," "Low," or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products." 75 Fed. Reg. 32953 (June 10, 2010).

appropriate for the protection of the public health. Section 907(a)(3) of the Act allows FDA to develop such product standards with consideration of scientific evidence concerning the risks and benefits to the population as a whole, including users and nonusers, and the likely impacts on cessation for existing users of tobacco products and initiation for nonusers. Examples given in the FD&C Act of the types of product standards that FDA might issue include provisions related to nicotine yields, levels of harmful constituents, and product construction and properties.[34]

In addition, FDA is enforcing the special rule in Section 907(a)(1)(a) of the FD&C Act that prohibits cigarettes with certain characterizing flavors, such as candy and fruit, in order to address their appeal to youth. In June 2010, Indonesia brought a challenge, under the World Trade Organization (WTO) dispute settlement procedures, regarding the Tobacco Control Act ban on certain characterizing flavors and the process by which it was implemented. One of Indonesia's central claims was that the provision breached the U.S. obligation to provide national treatment in that it provides less favorable treatment to an imported Indonesian product (clove cigarettes) than to a "like" domestic product (menthol cigarettes). In April 2012, the WTO Appellate Body affirmed a dispute settlement panel's findings that the provision breached the United States' national treatment obligation under the WTO Agreement. Under WTO rules, the United States and Indonesia agreed that the "reasonable period of time" for the United States to come into compliance with the WTO rulings would expire on July 24, 2013.[35] The statutory ban on characterizing flavors remains in effect.

***5. Expand the science base for regulatory action***

A strong science base is a key underpinning of the tobacco regulatory framework and FDA's ability to develop guidance and regulations, and to review product applications.

To further develop a comprehensive science base to inform effective tobacco product regulation, HHS has prioritized the establishment of a research program to cover a broad array of scientific questions that might impact tobacco regulatory decisions.[36] Within FDA, CTP is tasked with using the science that is currently available and carrying out new research that will drive tobacco regulatory action based on the best available science.

In order to carry out this task, CTP has initiated the development of a research program to inform future regulatory options and meet directives in the FD&C Act. CTP is reviewing relevant scientific literature to identify research gaps related to the regulation of tobacco products, and

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[34] FD&C Act Sec. 907(a)(4)

[35] On July 23, 2013, the United States announced that it had come into compliance with the WTO rulings. However, on August 23, 2013, Indonesia requested a special WTO Dispute Settlement Body meeting to request WTO authorization to impose countermeasures based on Indonesia's allegation that the United States has not come into compliance. The United States objected to Indonesia's request, referring the matter to arbitration.

[36] *See* U.S. Department of Health and Human Services. *Ending the Tobacco Epidemic: A Tobacco Control Strategic Action Plan.* (Nov. 10, 2010).

priority research questions were elicited from various stakeholders. The resulting research questions were categorized into seven broad areas: [37]

- Diversity of tobacco products;
- Reducing addiction;
- Reducing toxicity and carcinogenicity;
- Adverse health consequences;
- Communications;
- Marketing of tobacco products; and
- Economics and policies.

Underscored within these research areas is the need to address vulnerable populations since both the use of tobacco products and the resulting adverse health outcomes impact different populations in different ways. Populations of interest include people with mental health or medical co-morbidities, the military/veterans, the lesbian, gay, bi-sexual, transgendered, questioning (LGBTQ) community, and pregnant women/women of reproductive age. There are also a series of potential contributing factors including age, gender, race, ethnicity, income, occupation, and geographic location.

To advance these research priorities, FDA has embarked on collaborations and awarded contracts to fund research with other government agencies, non-government science research organizations and academic institutions.

Tobacco Products Scientific Advisory Committee

The FD&C Act mandated that FDA establish a 12-member Tobacco Products Scientific Advisory Committee (TPSAC) to provide appropriate advice, information and recommendations to the Secretary of HHS and the FDA Commissioner. The committee's members and the Chair were selected by the Secretary, as per the Act, from among individuals technically qualified by training and experience in the fields of medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products and who are of appropriate diversified professional backgrounds. The Committee shall be composed of 7 healthcare professionals; 1 officer/employee of a state, local or federal government; 1 representative of the general public; 1 representative of the tobacco manufacturing industry; 1 representative of small business tobacco manufacturing industry; and 1 representative of tobacco growers. Members serve for terms of up to four years.[38]

The TPSAC is directed to provide advice, information, and recommendations on tobacco-related topics, including: the effects of the alteration of nicotine yields from tobacco products, whether

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[37] For a more detailed list of priority research questions, see "Center for Tobacco Products, FDA: Research Priorities." *Center for Tobacco Products.* www.fda.gov/downloads/TobaccoProducts/NewsEvents/UCM293998.pdf.

[38] For a complete listing of TPSAC members see "Roster of the Tobacco Products Scientific Advisory Committee." *Food and Drug Administration.* http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/ucm180906.htm.

there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved, and other issues as requested by the Secretary. FDA is required to refer to TPSAC, and TPSAC is required to review, any application filed by a manufacturer for a modified risk tobacco product and may review, among other things, other premarket tobacco product applications and petitions filed by a manufacturer for exemption from requirements relating to good manufacturing practices.

Specific TPSAC reports and recommendations required by the FD&C Act include the impact of the use of menthol in cigarettes on the public health, including such use among children, African Americans, Hispanics and other racial and ethnic minorities and the nature and the impact of the use of dissolvable tobacco products on the public health, including such use on children.[39] TPSAC issued its findings and recommendations regarding the public health impact of menthol in July 2011.[40]

TPSAC concluded that, "Removal of menthol cigarettes from the marketplace would benefit public health in the United States." However, TPSAC did not recommend a specific mechanism, timeline, or regulatory action that FDA might pursue to address this conclusion.

Concurrently, a multi-step review process was undertaken by FDA to assess the science related to menthol. In developing its evaluation, FDA took the following steps:

- Weighed the collective body of evidence for the impact of menthol cigarette use on public health;
- Evaluated peer-reviewed literature, industry submissions and materials provided to TPSAC; and
- Performed or commissioned analyses to fill in and inform some gaps in the literature.

FDA then submitted its preliminary independent scientific report to a peer review panel. The agency reviewed the peer review comments and prepared responses to them. FDA has made this preliminary independent scientific review available for public comment in the *Federal Register*. The agency also posted the peer reviewed comments and its response to those comments. Based on the evidence and related findings, FDA will consider what actions, if any, are appropriate.[41]

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[39] *See* FD&C Act Sec. 907(e) and (f)

[40] *FDA Tobacco Products Scientific Advisory Committee.* "Menthol Cigarettes and Public Health: Review of the Scientific Evidence and Recommendations" (July 21, 2011). www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM269697.pdf.

[41] On July 23, 2013, FDA issued an Advance Notice of Proposed Rulemaking (ANPRM) seeking additional information to help the agency make informed decisions about potential regulatory options it might consider, such as establishing tobacco product standards, among others, related to menthol in cigarettes. The agency also made available for public comment relevant scientific information, including the FDA's independent Preliminary Scientific Evaluation of the Possible Public Health Effects of Menthol Versus Nonmenthol Cigarettes. FDA also posted the peer reviewer comments and its response to these comments on its website. In addition, the FDA announced plans to support new research on the differences between menthol and nonmenthol

Including its initial meeting in March 2010, the full TPSAC has met 12 times and there have been two meetings of the Tobacco Products Constituents Subcommittee of TPSAC and 2 meetings of the Menthol Report Subcommittee.[42] In March 2012, TPSAC submitted its recommendations to FDA on the nature and impact of the use of dissolvable tobacco products.[43]

NIH research collaborations

In February 2010, FDA launched its Advancing Regulatory Science Initiative to ensure that advances in science and technology are rapidly translated to inform regulatory efforts. As part of the FDA Initiative, NIH has established an organizational structure for managing and coordinating FDA-supported tobacco research at NIH through funding opportunities studies, and the establishment of research centers specialized in tobacco research.

*NIH grants and supplements*

In order to accelerate the pace of tobacco research relevant to tobacco regulation, FDA is funding several competitive NIH research opportunities with award budgets of $100,000 to $2,000,000 for one- or two-year research studies related to a variety of areas including the toxicity and addictiveness of tobacco products, consumer perceptions and behaviors related to tobacco products, and product claims and communications.[44] A grant for extended five-year research applications is also available. As of February 28, 2013, FDA had funded 44 research grants through NIH.[45]

*Population Assessment of Tobacco and Health Study*

A large scale and critically important research collaboration with NIH is the Population Assessment of Tobacco and Health (PATH) Study. PATH is a national longitudinal cohort study of 59,000 people ages 12 and older in the United States who are tobacco users or at risk for tobacco product use. The study will evaluate initiation and use patterns including use of new products, dual use (using more than one tobacco product), poly use (using more than two tobacco products), and switching between tobacco products; study patterns of tobacco product cessation and relapse; evaluate the effects of regulatory changes on risk perceptions and other tobacco-related attitudes; and assess differences in attitudes and behaviors, and key health outcomes among racial/ethnic, gender, and age subgroups. By measuring and accurately reporting on the

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cigarettes and to develop a youth education campaign focused on preventing and reducing tobacco use, including menthol cigarettes.

[42] A complete listing of TPSAC meetings is available at www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/default.htm.

[43] FDA Tobacco Products Scientific Advisory Committee. "Summary: TPSAC Report on Dissolvable Tobacco Products." (March 1, 2012). www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/TobaccoProductsScientificAdvisoryCommittee/UCM295842.pdf.

[44] *See* "Funding Opportunities." *Center for Tobacco Products*. www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/AbouttheCenterforTobaccoProducts/ucm292048.htm.

[45] See : FDA – NIH research portfolio at http://Prevention.NIH.gov/tobacco/portfolio.aspx

social, behavioral, and health effects associated with tobacco product use in the United States, the PATH study will build on an empirical evidence base to inform the development and assessment of tobacco product regulatory activities by FDA.

*Tobacco research center initiatives*
In August 2012, FDA and NIH announced funding to establish Tobacco Centers of Regulatory Science (TCORS). The TCORS program will lead to the creation of a broad coordinated national scientific base of tobacco regulatory research. FDA anticipates funding 14 meritorious TCORS applications in September 2013. Each center is expected to focus thematically on areas in which there are significant gaps in knowledge and other critical areas that will contribute to the science base FDA will use to develop meaningful product regulation. TCORS are expected to fill an urgent need for investigators who have the quality and breadth of training necessary to conduct cutting-edge research related to the regulation of tobacco products and play leadership roles in training new researchers in the field.

Another example of a collaborative research effort with NIH is the FDA-funded center to study nicotine addiction. The overarching goal of this center, established through the National Institute on Drug Abuse (NIDA), is to examine how marked reduction in the nicotine content of cigarettes may impact the use and adverse health effects of such products in current users.

*Other collaborative research activities*
FDA has developed a partnership with the Centers for Disease Control and Prevention (CDC) focused on tobacco research. There are currently projects which use laboratory-based approaches to expanding our knowledge of how best to regulate tobacco products. These include analyses of tobacco products and mainstream smoke, method development for biomarkers, exposure assessments under actual use conditions, and further method development for HPHCs.

In order to provide critical data on the impact of tobacco regulation on populations, FDA has provided funding to expand the scope and increase the frequency of data collection for the National Adult Tobacco Survey (NATS) and National Youth Tobacco Survey (NYTS), both conducted by CDC. NATS is a large, nationally representative cross-sectional, random-digit dialed telephone survey of adults 18 years of age and older. NATS data includes tobacco use prevalence, including novel tobacco products, susceptibility among young adults, as well as perceptions regarding tobacco use, exposure to marketing and promotions, and intentions to quit using tobacco. NYTS is a large, annual, nationally representative survey of middle and high school students that focuses exclusively on tobacco. Data from this survey will allow FDA to monitor awareness of, susceptibility to and experimentation with and use of a wide range of tobacco products. The survey will examine addiction, quitting behaviors, minors' access to tobacco, exposure to tobacco product marketing and promotions, and awareness of health warnings.

FDA is also working with other partners to build scientific knowledge to inform tobacco product regulation. With Sandia National Laboratories, FDA scientists are developing a modeling framework for FDA to use in understanding the impact of certain potential policy and marketing authorization decisions on population health.

FDA's National Center for Toxicological Research (NCTR) and CTP are collaborating on research projects related to tobacco product toxicology, biomarkers of harm, and measures of addictiveness. In addition, CTP is working with NCTR to develop a knowledge base and data mining approach for tobacco constituents that can be used to analyze industry documents on product ingredient and constituent data collected under sections 904(a)(4) and 904(b) of the FD&C Act.

*Scientific publications and communications*
FDA scientists have been actively disseminating the results of their research endeavors through manuscripts submitted for publication in scientific journals, as well as submitting abstracts and speaking at major national and international scientific conferences. As of February 28, 2013, CTP scientists had submitted over 70 manuscripts and abstracts and given over 40 presentations at scientific meetings. Topics included:

- Risk perception of dissolvable tobacco products in adults and youth;
- Assessing consumer understanding and risk perception of HPHCs;
- Developing and incorporating tobacco-related questions into the National Health Interview Survey;
- Exploring how little cigars are actually smoked;
- Evaluating tobacco use and cardiovascular diseases;
- Assessing tobacco product incidence in poison control data;
- Developing graphic health warnings;
- Perceptions and behaviors related to cigars, little cigars, cigarillos, water pipes and e-cigarettes;
- Consumer perceptions of risk of tobacco products and studies of modified risk claims; and
- Abuse potential of non-nicotine tobacco smoke components.

FDA has also been proactive in organizing workshops to exchange information with interested stakeholders on important scientific topics related to modified risk tobacco products, FDA's tobacco products research program, and tobacco product analysis.[46]

*FDA tobacco regulatory science fellowships*
FDA, in collaboration with the Institute of Medicine (IOM) of the National Academies, has launched a new tobacco regulatory science fellowship program designed for mid-career professionals to gain experience and expertise to further define and develop the field of regulatory science as it relates to the regulation of tobacco products and FDA's new authorities under the Tobacco Control Act. The fellowship program provides participants with opportunities to actively participate in the development of science-based public health strategies,

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[46] *See* "Scientific Evaluation of Modified Risk Tobacco Product (MRTP) Applications (August 25-26, 2011)" at www.fda.gov/TobaccoProducts/NewsEvents/ucm259201.htm; "FDA Center for Tobacco Products Research Program: Expanding the Research Base for Tobacco Product Regulation (Feb. 29, 2012)" at www.fda.gov/TobaccoProducts/NewsEvents/ucm259201.htm; and "Tobacco Product Analysis: A Scientific Workshop (April 11-12, 2012)" at www.fda.gov/TobaccoProducts/NewsEvents/ucm288107.htm.

serve as the lead for defined projects, meet with policy leaders and develop new competencies, including new knowledge, skills and experience related to tobacco products and their use. The fellowship is a 12-month multidisciplinary residential program based directly out of CTP's offices. The center currently has three fellows and plans to expand the program.

***6. Restrict marketing and distribution to protect public health***

Restrictions on marketing and distribution of regulated tobacco products are critical tools authorized by the Tobacco Control Act to protect the public health in a variety of ways, including by preventing youth from purchasing tobacco products.

Final rule on cigarettes and smokeless tobacco

The Tobacco Control Act required the FDA to publish, in the *Federal Register,* a final rule on cigarettes and smokeless tobacco identical in its provisions, with certain exceptions, to part 897 of the rule published in the *Federal Register* on August 28, 1996.[47] This rule, "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents," published in March 2010, prohibits the sale of cigarettes or smokeless tobacco to people younger than 18 years of age. Among other things, it also bans the sale of cigarette packages with fewer than 20 cigarettes; requires face-to-face sales of cigarettes and smokeless tobacco, with certain exemptions for vending machines and self-service displays in adult-only facilities; and prohibits free samples of cigarettes. Further, the rule limits the distribution of free samples of smokeless tobacco products to circumstances where specific conditions are met, bars tobacco brand name sponsorship of any athletic, musical, or other social or cultural event, or any team or entry in those events, and proscribes the sale or distribution of items such as hats and t-shirts with cigarette and smokeless tobacco brands or logos.[48]

Additionally, FDA has issued an advanced notice of proposed rulemaking to obtain information related to the outdoor advertising of cigarettes and smokeless tobacco.[49]

Remote sales

In order to prevent sales to minors, the FD&C Act also required FDA to issue regulations regarding the non-face-to-face sale and distribution of regulated tobacco products between retailers and consumers as well as the promotion, and marketing of such products.[50] Following passage of the Tobacco Control Act, the Prevent All Cigarette Trafficking (PACT) Act of 2009

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[47] FD&C Act Sec. 102(a)(2) of the Tobacco Control Act

[48] 75 Fed Reg. 13225 (March 19, 2010). 21 CFR Part 1140

[49] The Advanced Notice of Proposed Rulemaking was issued pursuant to Section 102(a)(2) of the Tobacco Control Act, which instructed FDA to reissue the original 1996 rule with modifications to 897.30(b), as appropriate, in light of governing First Amendment case law, including *Lorillard Tobacco Co. v. FDA*, 533. U.S. 525 (2001). Part 897.30(b) of the original 1996 rule included a prohibition on outdoor advertising for cigarettes or smokeless tobacco within 1,000 feet of a public playground, elementary or secondary school. *See* "Request for Comment on Implementation of the Family Smoking Prevention and Tobacco Control Act." 75 Fed. Reg. 13241 (March 19, 2010).

[50] FD&C Act Sec. 906(d)(4)(A)

was enacted and went into effect.[51] Among other things, this law requires Internet and other remote sellers of cigarettes, smokeless tobacco, and roll-your-own tobacco to verify the age of customers prior to sales through commercially-available databases and to use a delivery method that requires verification of the age and identification of the person accepting the tobacco products.[52]

Prior to issuing a regulation as required by Section 906(d)(4)(A)(i) of the FD&C Act, FDA determined that additional information was needed concerning non-face-to-face sales and distribution practices in light of the PACT Act. In September 2011, the FDA published an advanced notice of proposed rulemaking in the *Federal Register* to request comments, data, research, or other information related to non-face-to-face sale and distribution of tobacco products; the advertising, promotion, and marketing of such products; and the advertising of tobacco products via the Internet, email, direct mail, telephone, smart phones, and other communication technologies that can be directed to specific recipients.[53] Currently, FDA is evaluating responses and data to determine the next steps.

Enforcement action plan on advertising to youth and regulation of free tobacco samples

As required by section 105(a) of the Tobacco Control Act, FDA issued its "Enforcement Action Plan for Promotion and Advertising Restrictions," in October 2010.[54] This Enforcement Action Plan (EAP) describes how FDA plans to enforce restrictions on the promotion and advertising of menthol and other cigarettes, including efforts directed toward youth and particularly toward youth in minority communities. The various components of the EAP are intended to promptly identify and address tobacco products that potentially violate the FD&C Act and illegal sales and distribution of regulated tobacco products. Under the EAP, FDA will also monitor advertising activities by regulated industry. Additionally, as required by section 102(a)(2)(D)(4) of the Tobacco Control Act, FDA submitted a report to Congress in December 2010 that identified activities addressing the distribution of free samples of regulated tobacco products.

FDA continues to implement and develop its enforcement activities required under the Tobacco Control Act related to both the EAP and distribution of free samples of regulated tobacco products. FDA monitors the progress and effectiveness of these programs to ensure that overall goals and objectives are met and to determine if other restrictions or tools are needed. FDA also educates regulated industry to promote voluntary compliance and collaborates with governmental agencies, consumers, regulated industry, and other stakeholders.

### *7. Ensure industry compliance with FDA regulations*

Compliance training and assistance

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[51] Pub. L. No. 111-154; 124 Stat. 1087

[52] *Ibid.*

[53] "Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products." 76 Fed. Reg. 55835-55837 (Sept. 9, 2011).

[54] "Enforcement Action Plan for Promotion and Advertising Restrictions." 75 Fed. Reg. 60759 (Oct. 1, 2010).

Rigorous compliance training and education are key components of a successful enforcement program to ensure that the overall goals and objectives of the Tobacco Control Act are achieved. In order to work with regulated tobacco retailers, manufacturers, distributors, wholesalers, importers, as well as other federal, state, local, and tribal authorities to achieve enforcement goals, FDA has established a comprehensive program for training and assistance about the requirements of the Tobacco Control Act.

FDA initially focused its compliance training efforts on tobacco retailers in order to facilitate retailer compliance with the final rule on cigarettes and smokeless tobacco, which became effective in June 2010. Between July and September 2010 CTP staff traveled to five locations across the country to provide information to retailers and small tobacco product manufacturers about the requirements of the rule. These five sessions were panel discussions that provided a forum for questions and answers. Participants could attend in person, call into the sessions, or participate using the Internet.

FDA compliance training efforts later evolved into interactive webinars covering topics pertinent to the broader FDA-regulated tobacco industry. As of February 28, 2013, FDA had conducted 23 of these interactive webinars. Eleven of these webinars focused on topics pertinent to tobacco retailers, while ten were more relevant to tobacco manufacturers. Two covered topics of interest to both sectors of regulated industry. [55]

As required by Section 901(f) of the FD&C Act, FDA established the Office of Small Business Assistance (OSBA) within CTP to assist small tobacco product manufacturers and retailers in complying with the Tobacco Control Act. The office has a dedicated webpage, e-mail address, and staff to assist small businesses with their questions, comments, and concerns. OSBA had received approximately 1,900 inquiries through February 28, 2013. All inquiries received are tracked to ensure timely and appropriate responses. In addition, these questions can become topics for future compliance training webinars or other outreach efforts.

FDA has also contracted with an American Indian-owned company to further its efforts to collaborate with American Indian tribes and gain insight on the best approaches to disseminate information about the Tobacco Control Act to Indian tribes and to tobacco business located on tribal lands. This contractor will also help FDA notify these communities of the availability of formal collaborations for Tribal Nations and organizations to assist FDA in its compliance and enforcement activities as envisioned in the Tobacco Control Act.

For some compliance and enforcement matters, FDA works with other divisions within HHS, U.S. Customs and Border Protection (CBP), the Alcohol and Tobacco Tax and Trade Bureau (TTB), the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF), the Federal Trade Commission (FTC), the Department of Justice (DOJ), the National Association of Attorneys General, and other entities, as needed, to ensure compliance and enforcement efforts are coordinated.

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[55] *See* "FDA Compliance Webinars." *Center for Tobacco Products.* www.fda.gov/TobaccoProducts/ResourcesforYou/BreakTheChain/ucm220111.htm.

In addition, FDA conducts outreach to non-federal government stakeholders involved in tobacco control efforts through a variety of mechanisms including attending conferences and conducting meetings by telephone and videoconference. This outreach has provided opportunities to assist these entities with incorporating FDA's tobacco retail inspection program into their existing tobacco control framework.

Retailer compliance

Vigorous enforcement of tobacco laws and regulations is carried out through tobacco retail compliance check inspections. The resulting compliance and enforcement actions can help protect the health of America's youth and the public health generally by reducing youth access to regulated tobacco products. It also helps to prevent the marketing and advertising of regulated tobacco products to children and adolescents.

Section 702(B) of the FD&C Act instructs FDA to contract, where feasible, with the states, to carry out inspections of retailers in connection with the enforcement of the Tobacco Control Act. This framework required FDA to implement a tobacco retail compliance and enforcement program that is unique within FDA.

On March 23, 2010, FDA published its initial "Request for Proposals (RFP) to States and U.S. Territories" to launch a program to assist FDA with inspections of retail establishments and other enforcement activities applicable to FDA-regulated tobacco retailers. Since then, FDA has issued additional solicitations for similar inspection activities. FDA will seek alternatives, such as conducting inspections using FDA personnel, in the jurisdictions where contracts are not feasible.

FDA awarded contracts to 15 states in FY 2010 and 37 states and the District of Columbia in FY 2011. FDA awarded contracts to six additional states and territories in FY 2012 and has awarded one additional contract in FY 2013 for a total of 45 contracts. The agency expects to award contracts to additional jurisdictions in FY 2013. FDA will work to continue these contracts and further expand the program. A complete listing of these contracts is available in Appendix C.

These compliance check inspections determine a retailer's compliance with applicable provisions in the Tobacco Control Act and its implementing regulations that include, but are not limited to, the final Rule "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents."

The retail inspection program provides a framework for a nationwide FDA enforcement strategy through the credentialing of more than 900 state and territorial officials and a comprehensive training program for these FDA-commissioned inspectors and program coordinators. These inspectors conduct two types of compliance check inspections for FDA. The first type of compliance check inspection is generally an undercover purchase by 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.

FDA had to develop the inspection forms, determine the most appropriate means for collecting the inspection data (most inspectors use mobile devices and have a backup paper system), develop an IT system to support the inspection data from dozens of state and territorial agencies across the country, and develop means to incorporate this inspection data into FDA's existing IT systems.

FDA continues to update and enhance its mobile device inspection tool using customized software known as the Tobacco Inspection Management Systems Mobile Application. The tool helps reduce the amount of equipment inspectors need, reduce or eliminate the need to mail, fax, or scan paper forms to and from field inspectors, and reduces data entry, thereby decreasing the time for conducting and reviewing inspections and gathering evidence.

Each year FDA has expanded its retail inspection program and continues to enhance this program by streamlining processes; updating training; and upgrading IT systems, applications and hardware. As additional provisions applicable to retailers are implemented, they will be included in these contracts for compliance check inspections.

Advisory and enforcement authorities:
When potential violations are observed during a compliance check inspection of a tobacco retailer, FDA reviews the evidence and determines what action should be taken. FDA may utilize several administrative and enforcement tools provided for in the Tobacco Control Act and the FD&C Act, including: warning letters, civil money penalties (CMP), no-tobacco-sale orders, seizures, injunctions, and/or criminal prosecutions. Many of these tools are also used when violations by other FDA-regulated entities such as manufacturers, distributers, importers, and online retailers are found by FDA.

A warning letter is the agency's principal means of notifying regulated industry of a violation and is used to achieve prompt voluntary compliance with the law. FDA generally issues warning letters to tobacco retailers the first time violations are observed during a compliance check inspection.

A CMP complaint is used to initiate an administrative legal action against a retailer that can result in the imposition of a fine. FDA generally issues CMP complaints to tobacco retailers when violations are observed during compliance check inspections after inspections that resulted in a warning letter. FDA follows the penalty schedule outlined in Section 103(c) and (q) of the Tobacco Control Act and included in Appendix D of this report.

The results of all compliance check inspections, including those inspections with no observed violations, are available on the FDA website in a searchable database with links to all issued warning letters and CMP complaints.

Measurable accomplishments in the retail inspection program since the date of enactment through February 28 include:

- Awarding more than $62 million in contracts to 45 states and territories to assist CTP in enforcing tobacco marketing, sale, and distribution laws and regulations at retail locations;
- Conducting more than 147,000 compliance check inspections of regulated tobacco retailers utilizing state and territorial contractors;
- Issuing over 7,740 warning letters to retail establishments where violations were found during compliance check inspections;
- Issuing over 520 CMP administrative actions to retail establishments where subsequent violations were found during follow-up compliance check inspections; and
- Developing a searchable database of retail compliance check inspection results.

Promotion, advertising, and labeling compliance

Active and effective enforcement of tobacco laws and regulations governing the promotion, advertising, and labeling of tobacco products can help to protect the public health by preventing the sale and distribution of misbranded and adulterated tobacco products, including those with marketing and advertising materials that violate the requirements of the Tobacco Control Act.

FDA enforces the Tobacco Control Act and its regulations for the promotion, advertising and labeling of regulated tobacco products including: review and evaluation of regulatory submissions that include tobacco product labeling, representative advertising, and consumer information materials; routine monitoring and surveillance of websites and publications that sell, distribute, promote, or advertise regulated tobacco products; and surveillance of event promotion and sponsorship by tobacco manufacturers, distributors, or retailers.

In establishing its compliance and enforcement program for warning statements on smokeless tobacco product labeling and advertising, FDA consulted with DOJ as well as FTC, from which responsibilities under the Comprehensive Smokeless Tobacco Health Education Act of 1986 (Smokeless Tobacco Act),[56] as amended by section 204 of the Tobacco Control Act, were transitioned to FDA.

FDA has issued a number of letters to manufacturers requesting information regarding their marketing and advertising practices to ensure compliance with applicable provisions under laws enforced by FDA. For example, FDA has requested information on events that include the distribution of free samples of smokeless tobacco products, internet marketing activities, and other relevant information to determine compliance.

Since the date of enactment through February 28, 2013, FDA's promotion, advertising, and labeling compliance and enforcement program has accomplished the following:

- Identifying more than 2,000 websites where regulated tobacco products might be sold, distributed or advertised and determining that over 160 of these websites were in violation of the Tobacco Control Act.

[56] 15 U.S.C. 4402

- Conducting surveillance of approximately 6,600 unique publications, identifying and evaluating approximately 2,500 advertisements of regulated tobacco products in the U.S. market to determine compliance with advertising and promotion requirements;
- Issuing over 95 warning letters as a result of CTP's internet and publication surveillance and review and evaluation of consumer/public complaints (some warning letters covered multiple websites);
- Issuing two warning letters as a result of event promotion and sponsorship surveillance, resulting in compliance in both instances;
- Reviewing approximately 160 product listing submissions with labeling, advertising, and consumer information materials;
- Reviewing 35 smokeless tobacco warning plans and 10 smokeless tobacco warning plan supplements in accordance with the Smokeless Tobacco Act, as amended by Section 204 of the Tobacco Control Act;
- Reviewing 16 notices of the use of other media, which included 25 websites, for advertising and promotion of tobacco products; and
- Issuing nine information requests to tobacco product manufacturers seeking additional information on promotional activities and sponsorship, and nine requests to manufacturers seeking access to their direct-mailer materials and product websites, with all requests for direct-mailer materials and active websites granted.

Manufacturer compliance and enforcement activities

As directed in Section 905(g) of the FD&C Act, FDA conducts biennial inspections of registered tobacco product establishments that manufacture regulated tobacco products in the U.S. market. These inspections are designed to determine compliance with requirements of the FD&C Act. These include registration, product and ingredient listing, packaging, labeling, and advertising requirements, and marketing authorization for new or modified risk tobacco products.

To ensure this compliance and enforcement program is effectively implemented, FDA provides its tobacco investigators with comprehensive and continued training on the inspection requirements. These requirements differ in many ways from inspections requirements for products traditionally regulated by FDA.

Further, FDA collaborates with CBP on import operations for tobacco products. FDA conducts field exams and maintains import bulletins and alerts that identify tobacco products in violation of the FD&C Act, which may be detained. Imported tobacco products must conform to the same regulatory requirements as domestic tobacco products. Examples of products that may be detained include those that are labeled or advertised using the descriptors "light," "mild," or "low," without an FDA order, and cigarettes or their component parts that are labeled as having certain characterizing flavors.

FDA has expanded the capacity of agency laboratories to analyze tobacco products. These laboratories conduct analysis of tobacco samples to develop methods, validate methods, establish products standards and baselines, and identify ingredients to support future FDA enforcement actions. FDA plans to continue expanding the capabilities of these laboratories.

In the area of manufacturing compliance and enforcement FDA's measurable accomplishments through February 28, 2013, include:

- Conducting 73 inspections of registered tobacco product facilities;
- Conducting 11 investigations that included sponsorship events and distribution of free sample events; and
- Reviewing over 50,000 lines of imported tobacco products, completing over 1,100 field exams and more than 1,600 label exams, and refusing 59 entries, in collaboration with CBP. FDA issued two import bulletins and subsequent import alerts that directed many of these reviews and exams.

Complaint submissions

FDA established a complaint submission system with a website and hotline for the public and other stakeholders to report possible violations of the Tobacco Control Act. FDA recently started providing another option for reporting potential violations with its new Potential Tobacco Product Violations Reporting form.[57] The information provided is reviewed by FDA to determine what follow-up action, if any, is appropriate. FDA does not initiate enforcement actions solely on the basis of complaints from the public.

FDA is developing a database for these complaints. Since the system was launched in March 2010 through the end of 2012, FDA received and determined appropriate action for approximately 500 complaints.

***8. Educate the public***

Public education campaigns

The Tobacco Control Act amends the FD&C Act by giving FDA the authority to regulate tobacco products, including educating the public about the dangers of regulated tobacco product use. To advance efforts to protect the public from the harmful effects of tobacco use, FDA is developing integrated, far-reaching, and evidence-based public education campaigns related to FDA's regulatory activities. These campaigns are focused on preventing tobacco initiation, and promoting tobacco use cessation, particularly among the nation's youth and young adults.

As part of this comprehensive strategy for public education, FDA announced the award of nine contracts in calendar year 2012, dedicating up to $600 million over five years to conduct sustained, multi-media campaigns that will enable FDA to educate the public, and vulnerable youth populations in particular, about the harms and risks of regulated tobacco products in order to help prevent initiation and encourage cessation. Specifically, these campaigns will equip the public with important facts about:

- The health risks of regulated tobacco products;
- The addictiveness of regulated tobacco products;
- HPHCs in regulated tobacco products; and

[57] "Report Potential Tobacco Product Violations." *Center for Tobacco Products.* www.fda.gov/TobaccoProducts/ProtectingKidsfromTobacco/ucm330160.htm.

- The public health basis for marketing restrictions on regulated tobacco products, such as those on using the descriptors "light," "mild," or "low."

In awarding these contracts, FDA developed two expert campaign contractor pools: one open to competition from all potential contractors designed to focus on general market campaigns, and one limited to small business contractors designed to focus on vulnerable and underserved populations. A complete listing of contract awardees is included in Appendix E.

As early as December 2013, FDA plans to launch the first of its multiple, integrated public health campaigns focused on preventing tobacco initiation and promoting tobacco use cessation among the nation's youth and young adults by educating them on the dangers of regulated tobacco products. The campaigns will include a mix of traditional television and print ads, local events, and digital strategies. The campaigns will focus on the following distinct, targeted audiences: at-risk youth ages 12-15 that are African American; Hispanic; Asian/Pacific Islander; reside in rural communities; or identify as LGBTQ. Another set of campaigns will target general market youth ages 12-17 who have not yet initiated tobacco use and those who are intermittent users. FDA is also committed to reaching additional at-risk populations with high tobacco prevalence including Native American and Alaskan Native audiences.

In addition, FDA is overseeing a variety of research and analytic activities to strengthen and inform public education initiatives and efforts. This includes awarding a five-year, $60 million contract to conduct rigorous outcome evaluations on the effectiveness of individual FDA tobacco-related public education campaigns, overall messaging, and related communications activities.

This combination of establishing and evaluating evidence-based national campaigns will enable FDA to implement effective models for educating the public about the risks and dangers of regulated products. These efforts will also complement public education initiatives by partner agencies on tobacco related issues.

Regulatory actions for prescribed health warnings

FDA also seeks to inform the public about the negative health consequences of tobacco product use with the product warning labels required under Title II of the Tobacco Control Act.

*Graphic health warnings*

The Federal Cigarette Labeling and Advertising Act (FCLAA),[58] as amended by Section 201 of the Tobacco Control Act, contains requirements for health warnings and graphic label statements depicting the negative health consequences of smoking that must appear on cigarette product packages and advertisements. FCLAA, as amended by Section 201 of the Tobacco Control Act, also requires the submission of plans for the rotation and distribution of labeling statements on cigarette product packages and advertisements to FDA for review and approval, rather than to the FTC.

[58] 15 U.S.C. Sec. 1331

On June 11, 2011, FDA published the final rule entitled "Required Warnings for Cigarette Packages and Advertisements." The rule would require warnings, which consist of a textual warning statement, a corresponding color graphic image depicting the negative health consequences of smoking, and a toll-free smoking cessation assistance resource phone number (together known as a "required warning"), to appear on all cigarette packages and advertisements. The rule would require the warnings to be either indelibly printed or permanently affixed, in the same orientation as the other information on the packages, and clearly visible on the top 50 percent of the front and back panels of cigarette packages and the top 20 percent of the area of cigarette advertisement.

Prior to selecting the required warnings, FDA conducted an Internet-based consumer research study with over 18,000 participants that examined 36 proposed graphic health warnings. FDA evaluated the relative effectiveness of each graphic health warning for conveying information about various health risks of smoking, encouraging cessation, and discouraging smoking initiation. The results of the study, along with relevant scientific literature, indicated that the warnings selected by FDA would effectively communicate the negative health consequences of smoking to a wide range of populations including smokers and nonsmokers. Other research has shown that graphic health warnings are associated with smokers' increased motivation to quit smoking and indicates that, in general, graphic health warnings are more effective if they are combined with cessation-related information such as a toll-free smoking cessation assistance line.

In August 2012, the United States Court of Appeals for the D.C. Circuit upheld the D.C. district court's decision vacating the rule.[59] A two-judge majority held that the rule violated the First Amendment because the government did not provide sufficient evidence that the rule directly advances a government interest. As a consequence, FDA's 2011 graphic health warning rule for cigarettes will not be implemented, and FDA will undertake research to support a new rulemaking consistent with the Tobacco Control Act. Current FTC requirements for health warnings on cigarettes remain in effect.

*Smokeless tobacco health warnings*

The Smokeless Tobacco Act, as amended by Section 204 of the Tobacco Control Act, requires health warning statements that must appear on smokeless tobacco product packages and advertisements, and requires the submission of warning plans for smokeless tobacco product packages and advertisements to FDA for review and approval, rather than to the FTC. As amended, Section 3(b)(3) of the Smokeless Tobacco Act requires the equal distribution and display of warning statements on packaging, and the quarterly rotation of warning statements in advertising, for each brand of smokeless tobacco product, "in accordance with a plan submitted by the tobacco product manufacturer, importer, distributor, or retailer" and approved by FDA.

[59] R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205 (D.C. Cir. 2012)

In September 2011, FDA published a draft guidance discussing, among other things, the statutory requirement to submit warning plans, who submits a warning plan, the scope of a warning plan, and what information should be submitted to FDA.[60]

Public outreach

FDA is committed to building a deep knowledge of tobacco product manufacturing, marketing and distribution as well as establishing and maintaining meaningful and appropriate relationships with industry. This includes manufacturers, distributors and wholesalers, retailers and trade associations. These relationships increase FDA's understanding of the tobacco industry and its members while building the industry's understanding of the FDA and regulatory process.

FDA is also committed to establishing and maintaining meaningful and appropriate relationships with public health groups and other organizations involved in tobacco control and public health and to fostering collaboration with other government agencies with responsibilities relative to tobacco products or related public health issues. This facilitates the dissemination of information on tobacco-related priorities and activities to public health stakeholders including state, tribal, territorial, and local tobacco control programs. Other federal government partners include CDC, NIH, TTB, ATF, and the Substance Abuse and Mental Health Services Administration (SAMHSA).

CTP maintains regular contact with a broad array of organizations to ensure their full understanding of the goals and objectives of the Tobacco Control Act and awareness of opportunities to actively participate in the regulatory process. This consistent outreach conveys FDA's desire and commitment to stay engaged with communities interested in FDA's regulation of tobacco products. It creates opportunities to communicate about ways to amplify FDA's education campaigns and serves to strengthen and advance the development and implementation of FDA's regulatory actions, policies and initiatives.

Outreach efforts to the industry and public health communities include a listening session program. These sessions provide opportunities for interested parties to share their perspectives on topics including SE, Roll-Your-Own Tobacco Mislabeled as Pipe Tobacco, Electronic Cigarette Regulation, Cigar Regulation, Smoking Cessation via Nicotine Inhaler, Illicit Trade of Tobacco Products, Tobacco Related Health Disparities, and Tobacco Evaluation, Surveillance, and Research.

As of February 28, CTP had held over 30 listening sessions with a broad array of parties including:

- *21st Century Smoke*
- *Altria*
- *American Cancer Society*
- *American Lung Association*
- *American Wholesale Marketers Association (AWMA)*
- *Aradigm Corporation*

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[60] "Draft Guidance: Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products." 76 Fed. Reg. 55923 (published for comments Sept. 9, 2011).

- *Campaign for Tobacco Free Kids*
- *Cigar Association of America*
- *Cigars International*
- *Chronic Obstructive Pulmonary Disease (COPD) Foundation*
- *Council of Independent Tobacco Manufacturers of America*
- *National Heart Forum*
- *Drew Estate Cigars*
- *Electronic Cigarette Industry Group*
- *FIN E-Cigarettes*
- *General Cigar*
- *International Premium Cigar and Pipe Retailers*
- *Legacy*
- *Liggett Vector Brands*
- *Lorillard*
- *MayaTech*
- *National Association of Convenience Stores (NACS)*
- *National Networks for Tobacco-Related Health Disparities*
- *North American Quitline Consortium*
- *PARRS Brands*
- *Republic Tobacco*
- *Jet Cigs E-Cigarettes*
- *Pipe Tobacco Council*
- *Roswell Park Cancer Institute*
- *Small Manufacturers Association for the Reasonable Treatment of Tobacco*
- *Smoke Free Alternative Trade Association*
- *Snoke – E-Cigarette Company*
- *Survos*
- *Swedish Match*
- *The Institute for Global Tobacco Control*
- *Tobacco Control Legal Consortium*
- *University of Medicine and Dentistry of New Jersey Center for Tobacco Control Evaluation, Surveillance and Research*
- *University of North Carolina Gillings School of Public Health*

In addition to listening sessions, FDA participates in many tobacco industry and public health events. Some of the tobacco industry events have included: the Tobacco Merchants Association Annual Meeting and Conference, the National Association of Tobacco Outlets Annual Show and NACS Show. Some of the public health related events have included: the National Conference on Tobacco or Health, the Annual Conference of the Association of State and Territorial Health Officials, National Association of Local Boards of Health Annual Meeting, the National Association of County and City Health Officials Annual Conference, the Annual Conference of the American Public Health Association, and the Annual Conference of the Society for Research on Nicotine and Tobacco.

Often these exchanges serve as an opportunity to give notice of open dockets available for comment and reminders of the comment periods' closing dates. FDA has received questions as a result of this outreach and provided timely responses.

International Engagement

In order to advance its regulatory mission to reduce tobacco use and harms in the United States, FDA engages international stakeholders and industry organizations in an effort to educate others about FDA's authorities and obtain information from the global tobacco control community, including regulators in other countries. These opportunities enable FDA to explain its tobacco control authorities to interested parties and allow FDA to gather, analyze and develop international data, and research that can inform the development of effective policy, guidance, and regulations aimed at protecting Americans from tobacco-related death and disease.

For example, in September 2010 FDA hosted an "Embassy Briefing" to introduce FDA's new tobacco program to Washington D.C.'s diplomatic community. In November 2011, FDA also co-sponsored the first *International Tobacco Regulators Conference* with the World Health Organization (WHO), which brought together 65 foreign government officials from 25 countries to discuss tobacco control issues of common interest. In November 2012, FDA participated as an observer in the 5th Session of the Conference of the Parties for the Framework Convention on Tobacco Control. In addition, FDA is an active member of the WHO Tobacco Laboratory Network, an effort dedicated to advancing the development of laboratory methods, standards, expertise, and capacity for tobacco products testing and research; the International Standards Organization's Technical Advisory Group for Tobacco and Tobacco Products (TC 126); and the Cooperation Centre for Scientific Research Relative to Tobacco. FDA will continue to identify opportunities for international engagement on tobacco control issues to support its regulatory mission.

Ombudsman

An important part of FDA's public outreach is conducted by the CTP Ombudsman. The role of the Ombudsman is to: (1) advise the Center Director on ways to assure that CTP's procedures, policies, and decisions are of the highest quality and are fair and equitable; (2) to examine complaints from stakeholders; and (3) to facilitate the resolution of disputes with impartiality, neutrality, and fairness. The Ombudsman is an independent source for stakeholders to address complaints and inquiries, seek the resolution of disputes of a scientific, regulatory, or procedural nature, and discuss appeal and dispute resolution options. The Ombudsman engages in outreach to stakeholders by attending, and presenting and networking at external meetings and conferences, as well as stakeholder forums hosted by CTP.

## IV. *Challenges and opportunities*

With the Tobacco Control Act in place, the United States has reached a new frontier in combating tobacco use and FDA's CTP is at the forefront of this effort.

Some of the challenges FDA has faced in these early years are the growing pains inherent in building a regulatory body from the ground up. FDA has worked through the logistical challenges of creating infrastructure and an organizational structure, recruiting and hiring

qualified staff with applicable experience in a short time frame, and developing the processes, procedures and dedicated information technology resources to carry out regulatory functions.

There are challenges intrinsic to the regulation of tobacco products, which are markedly different from other products traditionally regulated by FDA. In this early stage, for example, FDA has had to create and validate entirely new scientific testing procedures for the measurement of HPHCs in tobacco products and tobacco smoke and develop metrics for the evaluation of product applications, including the 4,253 substantial equivalence applications now under review. With limited institutional experience to rely upon, FDA also had to establish and implement a tobacco retail compliance program that is unique even within FDA. Moreover, with tobacco product regulation, FDA has had the challenge of regulating an industry that is entirely new to federal product regulation and often unfamiliar with what is expected in the FDA regulatory process.

In addition, FDA had been unable to implement certain provisions in the Tobacco Control Act that were challenged in the courts, such as the requirement that all cigarette packages bear one of nine new textual warnings and include color graphics depicting the negative health consequences of smoking. The government decided not to seek further review of the D.C. Circuit decision in R.J. Reynolds Tobacco Co. v. FDA, Nos. 11-5332; 12-5063 (D.C. Cir.), formerly CA No. 11-1482 (D.D.C.), invalidating FDA's rule regarding graphic health warning labels for cigarettes. The court of appeals remanded the matter to the agency, and FDA will undertake research to support a new rulemaking consistent with the Tobacco Control Act.

Moving forward, FDA will be challenged to sustain the momentum needed to achieve its goals for reducing the harms and risks associated with tobacco product use, given the common misperception that decades of tobacco control research, program and policy efforts have solved this problem. The reality is that despite decades of scientific research and public health efforts, tobacco use continues to be the leading cause of preventable death and disease in the United States. Cigarette smoking results in 5.1 million years of potential life lost in the United States annually and the total economic burden of cigarette smoking is estimated to be $193 billion in annual health care and productivity costs.[61]

Perhaps the greatest opportunity FDA has to overcome this pressing public health problem is to dramatically decrease the access and appeal of tobacco products to youth. According to the Surgeon General's 2012 report, "Tobacco Use: A Preventable Epidemic," 90 percent of smokers start smoking by age 18 and 99 percent start by age 26. Although the report notes years of steady progress, declines in the use of tobacco by youth and young adults have slowed for cigarette smoking and stalled for smokeless tobacco use. FDA aims to use the tools at its disposal to continue the decline in tobacco use and to reinvigorate public determination to arrest the epidemic by making the next generation tobacco free.

## V. *Conclusion*

[61] *Centers for Disease Control.* "Economic Costs Associated with Smoking." www.cdc.gov/tobacco/data_statistics/fact_sheets/economics/econ_facts/index.htm#costs.

FDA regulation of tobacco products has opened a bold new chapter in America's fight to decrease the 443,000 preventable deaths caused by tobacco use each year. It is an essential cornerstone of the broader effort led by HHS in partnership with other federal agencies and public health practitioners working in state, territorial, tribal, and local governments. Within HHS, coordination between FDA, NIH, CDC, and SAMHSA has focused on maximizing the impact and efficiency of agency programs focused on tobacco control.

In the nearly four years since the enactment of the Tobacco Control Act, FDA has made substantial progress toward establishing a comprehensive, effective, and sustainable framework for tobacco product regulation aimed at protecting the public from the harms of tobacco products, encouraging cessation among tobacco users, and preventing new users from starting.

These major strides include, among other things:

- Creating the new Center for Tobacco Products;
- Undertaking critical scientific research to inform the evaluation of tobacco products and the development of product standards;
- Promulgating science-based regulations and guidance;
- Enforcing compliance with new tobacco product requirements; and
- Developing effective strategies to educate the public about the characteristics and dangers of regulated tobacco products.

FDA remains committed to advancing these achievements to make tobacco-related death and disease part of America's past, not its future.

## Appendix A

## Regulations, Guidance Documents, and Other Regulatory Documents Issued by FDA Related to the Family Smoking Prevention and Tobacco Control Act

| Type | Title | Date Issued |
|---|---|---|
| Final Rule | Exemptions From Substantial Equivalence Requirements | 7/5/2011 |
| Final Rule | Required Warnings for Cigarette Packages and Advertisements | 6/22/2011 |
| Final Rule | Amendments to General Regulations of the Food and Drug Administration | 11/30/2010 |
| Final Rule | Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco | 3/18/2010 |
| Notice of Proposed Rulemaking (NPRM) | Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents (Amends Brand Name Provision (1140.16(a)) | 11/10/2011 |
| Advanced Notice of Proposed Rulemaking (ANPRM) | Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products; Extension of Comment Period | 12/6/2011 |
| Advanced Notice of Proposed Rulemaking (ANPRM) | Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products | 9/9/2011 |
| Advanced Notice of Proposed Rulemaking (ANPRM) | Outdoor Advertising Provision | 3/19/2010 |
| Guidance | Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers | 11/21/2012 |
| Guidance | Meetings with Industry and Investigators on the Research and Development of Tobacco Products | 5/24/2012 |
| Guidance | Further Amendments to General Regulations of the Food and Drug Administration to Incorporate Tobacco Products | 3/30/2012 |
| Guidance | Required Warnings for Cigarette Packages and Advertisements | 10/24/2011 |

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|---|---|---|
| Guidance | Enforcement Policy Concerning Certain Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco | 5/7/2011 |
| Guidance | "Harmful and Potentially Harmful Constituents" in Tobacco Products as Used in Section 904(e) of the Federal Food, Drug, and Cosmetic Act | 1/31/2011 |
| Guidance | Reports: Demonstrating Substantial Equivalence for Tobacco Products | 1/5/2011 |
| Guidance | Use of "Light," "Mild," "Low," or Similar Descriptors in the Label, Labeling, or Advertising of Tobacco Products | 6/10/2010 |
| Guidance | Tobacco Health Document Submission | 4/20/2010 |
| Guidance | General Questions and Answers on the Ban of Cigarettes that Contain Certain Characterizing Flavors (Edition 2) | 12/23/2009 |
| Guidance | Timeframe for Submission of Tobacco Health Documents | 12/21/2009 |
| Guidance | Listing of Ingredients in Tobacco Products | 12/1/2009 |
| Guidance | Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments | 11/12/2009 |
| Draft Guidance | Civil Money Penalties for Tobacco Retailers - Responses to Frequently Asked Questions | 2/8/2013 |
| Draft Guidance | Modified Risk Tobacco Product Applications | 4/3/2012 |
| Draft Guidance | Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act | 4/3/2012 |
| Draft Guidance | Applications for Premarket Review of New Tobacco Products | 9/27/2011 |
| Draft Guidance | Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions | 9/22/2011 |
| Draft Guidance | Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products | 9/9/2011 |
| Draft Guidance | Establishing that a Tobacco Product was Commercially Marketed in the United States as of February 15, 2007 | 4/22/2011 |

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|---|---|---|
| Draft Guidance | Compliance with Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents [Revision to Draft Guidance]* | 3/23/2011 |
| Draft Guidance | Tobacco Retailer Training Programs | 7/16/2010 |
| Draft Guidance | Preliminary Timetable for the Review of Applications for Modified Risk Tobacco Products under the Federal Food, Drug, and Cosmetic Act | 11/27/2009 |
| Draft Guidance | The Scope of the Prohibition Against Marketing a Tobacco Product in Combination with Another Article or Product Regulated under the Federal Food, Drug, and Cosmetic Act | 9/30/2009 |
| Established List | Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke | 4/3/2012 |
| Enforcement Action Plan | Promotion and Advertising Restrictions | 10/31/2011 |

## Appendix B

**Established List of the Chemicals and Chemical Compounds Identified by FDA as Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke**

| Constituent | Carcinogen (CA), Respiratory Toxicant (RT), Cardiovascular Toxicant (CT), Reproductive or Developmental Toxicant (RDT), Addictive (AD) |
|---|---|
| Acetaldehyde | CA, RT, AD |
| Acetamide | CA |
| Acetone | RT |
| Acrolein | RT, CT |
| Acrylamide | CA |
| Acrylonitrile | CA, RT |
| Aflatoxin B1 | CA |
| 4-Aminobiphenyl | CA |
| 1-Aminonaphthalene | CA |
| 2-Aminonaphthalene | CA |
| Ammonia | RT |
| Anabasine | AD |
| o-Anisidine | CA |
| Arsenic | CA, CT, RDT |
| A-α-C (2-Amino-9H-pyrido[2,3-b]indole) | CA |
| Benz[a]anthracene | CA, CT |
| Benz[j]aceanthrylene | CA |
| Benzene | CA, CT, RDT |
| Benzo[b]fluoranthene | CA, CT |
| Benzo[k]fluoranthene | CA, CT |
| Benzo[b]furan | CA |
| Benzo[a]pyrene | CA |
| Benzo[c]phenanthrene | CA |
| Beryllium | CA |
| 1,3-Butadiene | CA, RT, RDT |
| Cadmium | CA, RT, RDT |
| Caffeic acid | CA |
| Carbon monoxide | RDT |
| Catechol | CA |
| Chlorinated dioxins/furans | CA, RDT |
| Chromium | CA, RT, RDT |
| Chrysene | CA, CT |

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|---|---|
| Cobalt | CA, CT |
| Coumarin | Banned in food |
| Cresols (o-, m-, and p-cresol) | CA, RT |
| Crotonaldehyde | CA |
| Cyclopenta[c,d]pyrene | CA |
| Dibenz[a,h]anthracene | CA |
| Dibenzo[a,e]pyrene | CA |
| Dibenzo[a,h]pyrene | CA |
| Dibenzo[a,i]pyrene | CA |
| Dibenzo[a,l]pyrene | CA |
| 2,6-Dimethylaniline | CA |
| Ethyl carbamate (urethane) | CA, RDT |
| Ethylbenzene | CA |
| Ethylene oxide | CA, RT, RDT |
| Formaldehyde | CA, RT |
| Furan | CA |
| Glu-P-1 (2-Amino-6-methyldipyrido[1,2-a:3',2'-d]imidazole) | CA |
| Glu-P-2 (2-Aminodipyrido[1,2-a:3',2'-d]imidazole) | CA |
| Hydrazine | CA, RT |
| Hydrogen cyanide | RT, CT |
| Indeno[1,2,3-cd]pyrene | CA |
| IQ (2-Amino-3-methylimidazo[4,5-f]quinoline) | CA |
| Isoprene | CA |
| Lead | CA, CT, RDT |
| MeA-α-C (2-Amino-3-methyl)-9H-pyrido[2,3-b]indole) | CA |
| Mercury | CA, RDT |
| Methyl ethyl ketone | RT |
| 5-Methylchrysene | CA |
| 4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanone (NNK) | CA |
| Naphthalene | CA, RT |
| Nickel | CA, RT |
| Nicotine | RDT, AD |
| Nitrobenzene | CA, RT, RDT |
| Nitromethane | CA |
| 2-Nitropropane | CA |
| N-Nitrosodiethanolamine (NDELA) | CA |
| N-Nitrosodiethylamine | CA |
| N-Nitrosodimethylamine (NDMA) | CA |

| | |
|---|---|
| N-Nitrosomethylethylamine | CA |
| N-Nitrosomorpholine (NMOR) | CA |
| N-Nitrosonornicotine (NNN) | CA |
| N-Nitrosopiperidine (NPIP) | CA |
| N-Nitrosopyrrolidine (NPYR) | CA |
| N-Nitrososarcosine (NSAR) | CA |
| Nornicotine | AD |
| Phenol | RT, CT |
| PhIP (2-Amino-1-methyl-6-phenylimidazo[4,5-b]pyridine) | CA |
| Polonium-210 | CA |
| Propionaldehyde | RT, CT |
| Propylene oxide | CA, RT |
| Quinoline | CA |
| Selenium | RT |
| Styrene | CA |
| o-Toluidine | CA |
| Toluene | RT, RDT |
| Trp-P-1 (3-Amino-1,4-dimethyl-5H-pyrido[4,3-b]indole) | CA |
| Trp-P-2 (1-Methyl-3-amino-5H-pyrido[4,3-b]indole ) | CA |
| Uranium-235 | CA, RT |
| Uranium-238 | CA, RT |
| Vinyl acetate | CA, RT |
| Vinyl chloride | CA |

## Appendix C

### State Contracts for Tobacco Retail Compliance Check Inspections as of February 28, 2013

| State | Agency | Total Awarded To Date* |
|---|---|---|
| Alabama | Alabama Department of Public Health | $3,546,488 |
| Arizona | Arizona Department of Health Services | $1,674,139 |
| Arkansas | Arkansas Tobacco Control Board | $2,126,997 |
| California | California Department of Public Health, Food and Drug Branch | $3,128,796 |
| Colorado | Colorado Department of Public Health and Environment | $2,846,347 |
| Connecticut | Connecticut Department of Mental Health and Addiction Services | $1,248,956 |
| Delaware | Delaware Department of Homeland Security, Division of Alcohol and Tobacco Enforcement | $321,982 |
| Georgia | Georgia Department of Revenue, Alcohol and Tobacco Division | $1,285,686 |
| Guam | Guam Department of Mental Health and Substance Abuse | $280,758 |
| Hawaii | Hawaii Department of Health, Alcohol and Drug Abuse Division | $504,629 |
| Idaho | Idaho Department of Health and Welfare | $891,596 |
| Illinois | Illinois Department of Revenue, Illinois Liquor Control Commission | $1,954,934 |
| Indiana | Indiana Alcohol and Tobacco Commission, Indiana State Excise Police | $1,614,781 |
| Iowa | Iowa Department of Commerce, Alcoholic Beverages Division | $963,040 |
| Kansas | Kansas Department of Revenue, Alcoholic Beverage Control | $1,462,716 |
| Kentucky | Kentucky Department of Alcoholic Beverage Control | $857,493 |
| Louisiana | Louisiana Office of Alcohol and Tobacco Control | $1,166,014 |
| Maine | Maine Center for Disease Control and Prevention, Division of Chronic Disease | $2,183,970 |
| Maryland | Maryland Department of Health and Mental Hygiene, Alcohol and Drug Abuse Administration | $1,886,301 |

| | | |
|---|---|---|
| Massachusetts | Massachusetts Department of Public Health, Tobacco Cessation and Prevention Program | $1,706,397 |
| Michigan | Michigan Department of Community Health, Bureau of Substance Abuse and Addiction Services | $1,859,484 |
| Minnesota | Minnesota Department of Health and Human Services, Alcohol and Drug Abuse Division | $1,141,958 |
| Mississippi | Mississippi Attorney General's Office, Alcohol and Tobacco Enforcement Unit | $2,937,165 |
| Missouri | Missouri Department of Mental Health, Division of Alcohol and Drug Abuse | $1,753,465 |
| Montana | Montana Department of Public Health and Human Services | $113,256 |
| New Hampshire | New Hampshire Liquor Commission, Division of Enforcement and Licensing | $399,168 |
| New Jersey | New Jersey Department of Health and Senior Services, Division of Family Health Services, Office of Tobacco Control | $1,642,052 |
| New Mexico | New Mexico Human Services Department, Behavioral Health Services Division | $1,342,642 |
| North Carolina | North Carolina Department of Health and Human Services, Division of Mental Health | $1,149,248 |
| Northern Mariana Islands | Northern Mariana Islands Department of Commerce, Alcoholic Beverage and Tobacco Control Division | $409,671 |
| Ohio | Ohio Department of Alcohol and Drug Addiction Services | $1,761,465 |
| Oklahoma | Oklahoma Alcoholic Beverage Laws Enforcement Commission | $619,158 |
| Pennsylvania | Pennsylvania Department of Health, Bureau of Health Promotion and Risk Reduction, Division of Tobacco Prevention and Control | $1,790,302 |
| Puerto Rico | Puerto Rico Department of Health | $701,563 |
| Rhode Island | Rhode Island Department of Behavioral Healthcare, Developmental Disabilities and Hospitals | $1,248,157 |
| South Carolina | South Carolina Department of Alcohol and Other Drug Services | $437,014 |
| Tennessee | Tennessee Department of Agriculture, Regulatory Services Division | $711,061 |
| Texas | Texas Department of State Health Services | $2,034,411 |
| Utah | Utah Department of Health, Division of Disease Control and Prevention | $552,611 |
| Vermont | Vermont Department of Liquor Control | $254,840 |

| | | |
|---|---|---|
| Virginia | Virginia Department of Alcoholic Beverage Control | $2,749,503 |
| Washington | Washington State Liquor Control Board | $1,944,427 |
| Washington, D.C. | DC Department of Health, Addiction Prevention and Recovery Administration | $596,020 |
| West Virginia | West Virginia Department of Health and Human Resources, Bureau for Behavioral Health and Health Facilities | $1,498,449 |
| Wisconsin | Wisconsin Department of Health Services, Division of Public Health, Bureau of Community Health Promotion, Tobacco Prevention and Control Program | $869,294 |
| Totals | | $62,290,316 |

* Awards begin in FY2010 and continued through FY2011 and FY2012. This includes the initial award, any modifications made during the course of the contract and any subsequent annual award.

## Appendix D

## Schedule of Civil Monetary Penalties Outlined in

## Section 103(c) and (q) of the Family Smoking Prevention and Tobacco Control Act

*Civil Monetary Penalties for Retailers with Approved Training Programs*

| Violation Number | Fine |
|---|---|
| 1 | Issuance of a warning letter to the retailer |
| 2 | $250 in the case of a second violation within a 12-month period |
| 3 | $500 in the case of a third violation within a 24-month period |
| 4 | $2,000 in the case of a fourth violation within a 24-month period |
| 5 | $5,000 in the case of a fifth violation within a 36-month period |
| 6 | $10,000 as determined by the Secretary on a case-by-case basis in the case of a sixth or subsequent violation within a 48-month period |

*Civil Monetary Penalties for Retailers without Approved Training Programs*

| Violation Number | Fine |
|---|---|
| 1 | $250 in the case of the first violation |
| 2 | $500 in the case of a second violation within a 12-month period |
| 3 | $1000 in the case of a third violation within a 24-month period |
| 4 | $2,000 in the case of a fourth violation within a 24-month period |
| 5 | $5,000 in the case of a fifth violation within a 36-month period |
| 6 | $10,000, as determined by the Secretary on a case-by-case basis, in the case of a sixth or subsequent violation within a 48-month period |

## Appendix E

## National Public Education Campaigns Contract Awards

National Public Education Campaigns Support Services Solicitation

Full and Open — Base Contract Awardees

- American Legacy Foundation
- Campbell-Ewald
- DraftFCB
- Grey
- Mullen
- RIESTER

Small Business — Base Contract Awardees

- Better World Advertising
- Rescue Social Change Group
- Sensis Agency

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

Martha Coakley
Massachusetts Attorney General
Mike DeWine
Ohio Attorney General
National Association of Attorneys General
2030 M Street, N.W., 8th Floor
Washington, D.C. 20036

NOV 14 2013

Dear Attorneys General Coakley and DeWine:

Thank you for your letters of September 24 and October 23, 2013, cosigned by 42 state and territorial Attorneys General, urging immediate action by the Food and Drug Administration (FDA) to issue regulations to address the sale, manufacturing and marketing of electronic cigarettes, also known as e-cigarettes. You address and provide information on the growth in sales, marketing, and use of electronic cigarettes in the United States and express your concerns regarding their appeal to and use by youth. Your correspondence also references recent data from the Centers for Disease Control and Prevention (CDC) that use of these products by youth has doubled in the last year and that more than one in ten high school students have tried e-cigarettes.

FDA shares your concerns about the public health impact and lack of existing clinical studies on the potential health risks posed by electronic cigarette use, as well as the manufacture and marketing of these products in ways which could be appealing to minors, such as employment of the use of cartoon characters and flavors such as bubblegum, cherry, and grape.

The data in the CDC report[1] show a dramatic rise in usage of e-cigarettes by youth. This is cause for great concern since the long-term effects of these novel tobacco products, including whether these products may lead to use of other tobacco products, are not yet understood. We share your concerns regarding the emergence of novel tobacco products over which FDA currently does not have regulatory authority, such as e-cigarettes, and the concerns they raise about safety and marketing to children. We acknowledge the growing popularity of e-cigarettes, which are available in candy and fruit flavors. The CDC findings reinforce why FDA intends to extend its authority over products that meet the statutory definition of "tobacco product," when it issues the proposed deeming rule as a first step toward establishing an appropriate regulatory framework to reduce the disease and death from tobacco use.

The proposed deeming rule, which would expand FDA's authority to include products that meet the statutory definition of "tobacco product," continues to be a top priority for FDA. The proposed rule is currently under review at the Office of Management and Budget.

[1] Morbidity and Mortality Weekly Report (MMWR); "Notes from the Field: Electronic Cigarette Use Among Middle and High School Students – United States, 2011-2012."

Once FDA finalizes this rulemaking, provisions in Chapter IX of the Federal Food, Drug, and Cosmetic Act that apply to tobacco products generally would automatically apply to all newly deemed products meeting the statutory definition of "tobacco product." For example, newly deemed tobacco products would be subject to FDA's premarket review requirements. However, FDA has the authority to undertake other rulemakings, for example, to expand the ban on characterizing flavors to other tobacco products, in addition to cigarettes, if FDA determines that it is appropriate to do so to protect the public health.

Thank you for contacting us to express support for this important issue and for your ongoing work to protect the citizens of your states and territories, particularly children, from the harmful health effects of tobacco use. FDA looks forward to our continued work with the National Association of Attorneys General and each of you individually in your jurisdictions. Please share this response with the cosigners of your letters.

Sincerely,

Sally Howard
Deputy Commissioner
Policy, Planning, and Legislation

# RIN 0910-AG38
# Tobacco Products Deeming Regulations

**November 26, 2013**
**Meeting with Office of Management and Budget**

**Michael Shannon, Vice President, External Affairs**
**Patricia Kovacevik, Director Regulatory Affairs and Associate General Counsel**

Lorillard

blu CIGS

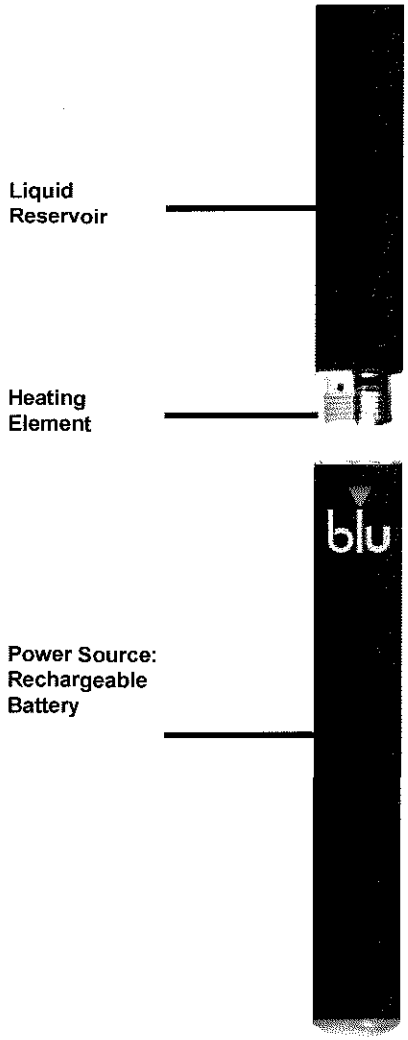
*Presentation at FDLI Conference, October 18. 2012*

# Introduction

- Lorillard acquired e-cigarette assets – the blu eCigs in April 2012
- blu is the top selling e-cigarette in the U.S.
- We believe that e-cigarettes will play an important role in harm reduction
  - with or without reduced exposure or reduced risk claims

# What are e-cigarettes?

- Typically vaporize a mixture of water, glycerin and/or propylene glycol, nicotine and flavorings (1)
  - Also nicotine-free versions
- Basic Components
  - Power source – disposable or rechargeable
  - Heating element – atomizer
  - Liquid reservoir – also serves as mouthpiece
    - Some models have integrated atomizer and liquid reservoir called cartomizers




(1) This description is not intended to characterize the actual ingredients of any particular brand of e-cigarettes

# Question before us today

- Given the requirements of the Tobacco Control Act (TCA) and the unique attributes of the e-cigarette industry…

What kind of regulatory system should FDA adopt?

# FDA regulation of e-cigarettes

***At a minimum, regulators should:***

- Acknowledge that the TCA was written for cigarettes and smokeless tobacco products and that regulations must account for differences between traditional tobacco products and e-cigarettes
- Encourage development of a robust body of research related to e-cigarette safety & consumer behavior
- Require rigorous standards for product quality
- Permit and encourage innovation and product improvements
- Ensure e-cigarettes are promoted appropriately
- Require e-cigarettes to be available to adults only
- Provide level playing field for the industry

# Key issues for FDA regulation

- Grandfather date
- Product safety
- Quality standards (GMPs)
- Product modifications
- Sales and marketing requirements
- Research standards
- METPs and MRTPs

# Date for Grandfather status

***TCA specifies February 15, 2007 grandfather date:***

- The TCA was written, and this date selected, with traditional tobacco products in mind
- Date is arbitrary as TCA was enacted into law on June 22, 2009 and a carryover from previous bills pending before prior Congresses
- The same grandfather date would make even less sense for e-cigarettes
  - Very few products on the market at that time
  - Industry is fragmented and plagued with uncertainty
  - Important product quality improvements continue which will benefit e-cigarette user

# Date for Grandfather status

- A February 15, 2007 grandfather date could result in a ban on the category
  - Given limited selection of products on the market prior to this date:
    - Products remaining would have inferior technology
    - Technology advancements for safety and function would be lost
    - Smoke liquid limited to 100% Chinese-based
- 905(j) (SE) reports may not be a realistic option
  - Predicates no longer exist
  - Intellectual property issues
- FDA Backlog: New Tobacco Product applications, as currently defined for tobacco products, require years of lead time

# Date for Grandfather status

- What options might FDA have?
  - Date of deeming regulation as grandfather date
  - Date of deeming regulation plus a reasonable grace period
- Modifying grandfather date is supported by numerous FDA precedents:
  - CTP amended grandfather date for use of non-tobacco brand name required by 1996 Rule
  - CTP exercised enforcement discretion: *e.g.*, deadline for submitting HPHC testing and warning rotation plans for smokeless tobacco products
  - Numerous examples for drugs and devices

# Quality standards

- Improvements to production processes and quality systems for e-cigarettes are an imperative
- FDA needs to develop GMPs:
  - Adverse event reporting
  - Recall procedures
  - HPHC testing
  - Component testing and supplier verification
  - Design controls
  - Complaint investigations
  - Corrective And Preventive Action (CAPA)

# Product modifications

- E-cigarette technology continues to improve
- FDA regulation needs to provide sufficient flexibility to allow product improvements
  - At this time, current implementation of 905(j) (SE) process for cigarettes and smokeless tobacco products is not a realistic or workable solution for e-cigarette regulation
- Many e-cigarette components are already subject to established quality standards
  - CE (Conformité Européenne) marking required to show conformity with EU safety, health, and environmental protection requirements
  - Batteries subject to international standards

# Product modifications

- FDA should focus on elements of e-cigarettes that could have an impact on public health and facilitate other product changes
- Possible options
  - Define categories for minor modifications to components that would not require a submission
  - Require conformity with design control process for modifications to e-cigarette components other than liquid (similar to Special 510(k) for medical devices)

# Sales and marketing requirements

- FDA should prevent youth exposure and access by imposing requirements on the sale and marketing of on-line e-cigarettes
  - Require age verification
- Some e-cig companies are still promoting their products as "safer" than traditional tobacco products or as cessation products
  - FDA should prohibit factually inaccurate or unsupported express or implied health claims, reduced exposure claims, or cessation claims
  - Unless such specific claims are approved by FDA

# E-cigarette research needs

- Before regulation is adopted, sound scientific research is needed to understand e-cigarettes
- FDA should publish guidance on its research priorities related to e-cigarettes
- METP and MRTP have tremendous harm reduction potential
- Current MRTP path, which includes a new product approval path, is onerous and does not support innovation

# E-cigarette research needs

- Establish validated testing methods for e-cigarette products
  - Validated analytical chemistry methods
  - Standardize machine yield measurement methods
  - Potential CORESTA study group on e-cigarettes
- Characterize safety of ingredients and vapor
- Identify biomarkers of exposure and other clinical effects
- Understand nicotine kinetics
- Determine potential for leaching
- Examine population effects related to initiation and cessation
- Evaluate vaping topography – and many more…

# Conclusions

- E-cigarette regulation is needed but it must be practical, fair, and based on sound science
- Regulation must not stifle innovation
- Harm reduction opportunity is beneficial to all stakeholders