Enforcement Action Plan for Promotion and Advertising Restrictions

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This document represents the Food and Drug Administration's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

1 Background

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31; 123 Stat. 1776) was enacted on June 22, 2009, providing the Food and Drug Administration (FDA) with the authority to regulate tobacco products in order to protect the public health generally, and to prevent and reduce tobacco use by minors. In enacting the Tobacco Control Act, Congress found, among other things, that the use of tobacco products by children is a pediatric disease and virtually all new users of tobacco products are under the minimum legal age to purchase such products (sections 2(1) and (4) of the Tobacco Control Act). Advertising, marketing, and promotion of tobacco products have been "especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth" (section 2(15) of the Tobacco Control Act).

Additionally, the rates of tobacco use and tobacco-related mortality are higher among certain racial and ethnic groups, including American Indian and Alaska Natives, Asian men and African-American men. As the National Cancer Institute (NCI) noted in Monograph 19, "[t]argeting of various population groups – including . . . specific racial and ethnic populations . . . has been strategically important to the tobacco industry."[1] The first Surgeon General's Report to address the tobacco industry's history of targeting its marketing to minority communities was published in 1998.[2] Additionally, studies from the early 1990s document that tobacco advertising was disproportionately targeted to young people and to minority communities.[3, 4] A longitudinal study conducted from 1990 to 1994 in four types of Los Angeles ethnic neighborhoods found that, "[c]ompared with White neighborhood thoroughfares, African American and Hispanic neighborhoods contained a greater tobacco ad density, and all minority neighborhoods contained greater tobacco ad concentration along the roadsides. . . . These data are consistent with the assertion that tobacco companies target ethnic minorities with higher rates of advertising and ethnically tailored campaigns."[5] A meta-analysis published in 2007 confirmed that

"African Americans are exposed to a higher volume of pro-tobacco advertising in terms of both concentration and density."[6]

In addition to the volume of advertising, the methods used in targeting advertisements to some specific communities have also been studied. For example, studies have shown that *Ebony* magazine was 10 times more likely than *People* magazine to have an advertisement for menthol cigarettes and that the Spanish version of *People* was 2.6 times more likely than the English version to contain a menthol advertisement.[7] NCI's Monograph 19 discusses how advertising for mentholated brands to African-Americans was designed around specific lifestyle appeals and themes.[8] However, as NCI noted, "little attention has been paid to understanding tobacco marketing aimed at American Indians and Alaska Natives, despite their high prevalence of tobacco use."[9] Tobacco marketing to Asian Americans is also under-studied.

In 2006, tobacco manufacturers spent $12.5 billion or $34 million per day to market tobacco products.[10] The majority (74%) of tobacco marketing consisted of price discounts (e.g., price discounts to retailers and other price promotions).[11] Marlboro, Newport, and Camel have been the three most advertised cigarettes and have accounted for more than 80% of brands smoked by adolescents.[12]

Although the overall prevalence of cigarette smoking among children and adolescents has declined over the years, there was a large and rapid increase in smoking prevalence in the early 1990s, peaking around 1997.[13] There was a significant decline in the early years of this century, but recent data indicate that the rate of decline stalled from 2003-2009.[14] The rate of decline stalled for various racial and ethnic groups, except African-American female high school students, for whom no slowing or leveling off occurred in the rate of decline after 1999.[15]

Section 105(a) of the Tobacco Control Act (21 U.S.C. 387f-1(a)) requires the Secretary to develop and publish an action plan to enforce restrictions, including those provided in the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents* (21 C.F.R. Part 1140)[16] on promotion and advertising of menthol and other cigarettes to youth. Section 105(a) of the Tobacco Control Act also requires that the Secretary develop the enforcement action plan in consultation with public health organizations and other stakeholders with demonstrated experience and expertise in serving minority communities. This action plan must also include provisions designed to ensure enforcement of the restrictions, including those provided in the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents*, on the promotion and advertising of menthol and other cigarettes to youth in minority communities.

To meet the consultation requirement, FDA created two dockets to solicit information, research, and views from all interested persons about the advertising and promotion of menthol and other cigarettes to youth in general, and to youth in minority communities. In the first docket, *Tobacco Product Advertising and Promotion to Youth and Racial and Ethnic Minority Populations,*[17] FDA requested information on ways in which the

advertising and promotion of tobacco products may affect tobacco use among racial and ethnic minority populations; input on designing an action plan regarding enforcement of the regulations on advertising and promotion of menthol and other cigarettes to youth generally and to youth in minority communities; and information that will assist the Tobacco Products Scientific Advisory Committee (TPSAC) to better understand, report on, and make recommendations regarding the impact of the use of menthol in cigarettes among children, African-Americans, Hispanics, and other racial and ethnic minority communities.

FDA also established a docket and published an announcement for a *Web-Based Public Meeting to Discuss Issues Related to the Development of an Enforcement Action Plan; Request for Data, Information, and Views*.[18] FDA held the Web-based public meeting on June 30, 2010, to seek participation, information, and views from all interested parties, including but not limited to, public health organizations, minority community groups and leaders, other stakeholders with demonstrated expertise and experience in serving minority communities, groups serving youth, patient groups, advertising agencies, the regulated industry, and other interested parties.[19] In addition to general information, FDA sought information on the following topics as they relate to the restrictions on promotion and advertising of menthol and other cigarettes to youth: 1) how FDA can identify companies and others who promote and advertise menthol or other cigarettes to youth in violation of applicable restrictions; 2) how FDA can identify companies and others who promote and advertise menthol or other cigarettes to youth in minority communities in violation of applicable restrictions; 3) how FDA can better understand the types and placement of promotion and advertising of menthol and other cigarettes to youth; 4) how FDA can better understand the types and placement of promotion and advertising of menthol and other cigarettes to youth in minority communities; 5) how FDA can understand the themes and techniques used in promotion and advertising of menthol and other cigarettes to youth; and 6) how FDA can understand the themes and techniques used in promotion and advertising of menthol and other cigarettes to youth in minority communities.

Representatives from several organizations made presentations at the Web-based public meeting. FDA also encouraged stakeholders and other interested parties to submit data, information, and views on these topics as well as other pertinent information to the relevant docket.

FDA has also reviewed available scientific information, including but not limited to, Centers for Disease Control and Prevention's (CDC) *Best Practices for Comprehensive Tobacco Control Programs (2007),*[20] information from the Task Force on Community Preventive Services,[21] the World Health Organization's (WHO) *MPOWER (2009)* strategies,[22] the Institute of Medicine's (IOM) *Ending the Tobacco Problem (2007),*[23] and information from established State tobacco control and prevention programs.[24]

2 Overview of Promotion and Advertising Restrictions

Section 102 of the Tobacco Control Act (21 U.S.C. 387a-1) directed FDA to publish a final rule identical in its provisions, with certain exceptions, to the final rule issued by FDA in August 1996. On March 19, 2010, FDA published in the Federal Register its final regulations entitled, *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, and these regulations became effective on June 22, 2010.[25] These final regulations at 21 C.F.R. Part 1140 are designed to: 1) restrict access to cigarettes and smokeless tobacco by persons under the age of 18; and 2) reduce the appeal of such products to persons under the age of 18, through restrictions on marketing, labeling, and advertising.

Specifically, the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents* impose the following restrictions:

Prohibition of Sale and Distribution to Persons Younger than 18 Years of Age (Youth Access):

Retailers of tobacco products MUST:

- Not sell cigarettes or smokeless tobacco to persons younger than 18 years of age. 21 C.F.R. 1140.14(a).
- Verify the age of purchasers of cigarettes or smokeless tobacco who are under the age of 27 by means of photographic identification that contains the bearer's date of birth. 21 C.F.R. 1140.14(b).
- Sell cigarettes or smokeless tobacco in direct, face-to-face transactions, with certain exceptions. 21 C.F.R. 1140.14(c), 1140.16(c).
- Not have tobacco vending machines or self-service displays in their facilities unless they can ensure that persons younger than 18 years of age are never present or not permitted to enter at any time. 21 C.F.R. 1140.16(c).
- Not break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or a number of unpackaged cigarettes that is smaller than the quantity in a minimum cigarette package size of 20 cigarettes, or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use. 21 C.F.R. 1140.14(d), 21 C.F.R. 1140.16(b).
- Not distribute or cause to be distributed free samples of tobacco products, except for samples of smokeless tobacco products in a qualified adult-only facility, as defined by the regulations at 21 C.F.R. 1140.16(d)(2)(iii). 21 C.F.R. 1140.16(d). This provision also applies to manufacturers and distributors.
- Not sell or distribute, or cause to be sold or distributed, cigarettes or smokeless tobacco with labels, labeling, or advertising not in compliance with subpart D of 21 C.F.R. Part 1140 (specifically, 21 C.F.R. 1140.30, 1140.32, and 1140.34) and other applicable requirements. 21 C.F.R. 1140.16(e). This provision also applies to manufacturers and distributors.

Labeling and Advertising:

Manufacturers, Distributors, and Retailers of tobacco products MUST:

- Not market, distribute, license, or sell any item (other than cigarettes or smokeless tobacco or roll-your-own paper) or service that bears the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical to or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco. 21 C.F.R. 1140.34(a). This provision only applies to manufacturers and certain distributors.
- Not offer any gift or item (other than cigarettes or smokeless tobacco) to any person purchasing cigarettes or smokeless tobacco in consideration of the purchase of the cigarettes or smokeless tobacco product or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase. 21 C.F.R. 1140.34(b).
- Not sponsor any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name, logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification, identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco. 21 C.F.R. 1140.34(c).
- Notify FDA 30 days prior to the dissemination of advertising or labeling for cigarettes or smokeless tobacco in a medium not listed in 21 C.F.R. 1140.30(a)(1). 21 C.F.R. 1140.30(a)(2). The notice must describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age. *Id.*

The causing of any of the activities identified in 21 C.F.R. 1140.34 is also prohibited.

There are two additional provisions of the regulations, 21 C.F.R. 1140.16(a) and 1140.32(a), that restrict labeling and advertising of tobacco products. However, as discussed below, FDA intends to exercise enforcement discretion to not enforce these two provisions at this time.[26]

- 21 C.F.R. 1140.16(a) [restriction on the use of trade name or brand name of a non-tobacco product as the trade name or brand name for a cigarette or smokeless tobacco product]. FDA is aware of concerns regarding this provision and is considering what changes, if any, would be appropriate to address those concerns. While FDA has this issue under consideration, it intends to exercise its enforcement discretion concerning 21 C.F.R. 1140.16(a) not to commence enforcement actions under this provision for the duration of its consideration where:
    - (1) The trade or brand name of the cigarette or smokeless tobacco product was registered, or the product was marketed, in the United States on or before June 22, 2009; or
    - (2) The first marketing or registration in the United States of the tobacco product occurs before the first marketing or registration in the United States of the non-tobacco product bearing the same name; provided,

however, that the tobacco and non-tobacco product are not owned, manufactured, or distributed by the same, related, or affiliated entities (including as a licensee).

- 21 C.F.R. 1140.32(a) [use of black text on a white background]. The United States District Court for the Western District of Kentucky recently issued an order permanently enjoining FDA from enforcing section 21 C.F.R. 1140.32(a) (formerly 21 C.F.R. 897.32(a) of the 1996 final rule) (*Commonwealth Brands, Inc. v. United States*, No. 1:09-CV-117-M (W.D. Ky. Jan. 4, 2010)). The injunction prevents enforcement of this provision against the parties to the case in any jurisdiction in the United States. On March 8, 2010, the government filed an appeal from that order. In light of the court's order in *Commonwealth Brands*, FDA intends to exercise its enforcement discretion concerning 21 C.F.R. 1140.32(a) not to commence enforcement actions under this provision during the pendency of the litigation irrespective of whether the entity is a party to the pending lawsuit or located in the Western District of Kentucky.

The Tobacco Control Act amends the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 301 *et seq.*, and contains additional provisions relating to the promotion and advertising of tobacco products. Relevant sections of the Tobacco Control Act and the FD&C Act, as amended by the Tobacco Control Act, include, among others:

- Section 201(rr)(4) of the Tobacco Control Act (21 U.S.C. 321(rr)(4)) – a tobacco product shall not be marketed in combination with any other article or FDA-regulated product.
- Section 201 of the Tobacco Control Act, amending section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) -- requires that cigarette packages and advertisements bear new, larger, and more prominent health warnings. FDA must issue regulations requiring that graphic images accompany the new health warning statements on cigarette packs and advertisements. Companies must submit rotation plans for the new health warning statements to the FDA for review and approval. These requirements are effective 15 months after issuance of the regulations requiring graphic images.
- Section 204 of the Tobacco Control Act, amending section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402) -- requires that smokeless tobacco packages and advertisements bear new, larger, and more prominent health warnings. Companies must submit rotation plans for the new health warning statements to the FDA for review and approval. These provisions took effect on June 22, 2010.
- Section 903(a)(1) of FD&C Act (21 U.S.C. 387c(a)(1)) – a tobacco product shall be deemed misbranded if its labeling is false or misleading in any particular. In addition, FDA may issue regulations implementing other misbranding provisions of FD&C Act, including the requirement that a tobacco product bear its (if it has one) established name prominently, and the requirement that its labeling bear adequate directions for use, or adequate warnings against use by children, that are necessary for the protection of users.

- Section 905 of FD&C Act (21 U.S.C. 387e) – requires every person who registers under FD&C Act to provide to FDA a list of all tobacco products that are being manufactured, prepared, compounded, or processed by that person for commercial distribution, and include copies of the labeling and a representative sampling of advertisements for such tobacco products.
- Section 907(a)(1)(A) of FD&C Act (21 U.S.C. 387g(a)(1)(A)) – this special rule for cigarettes bans all cigarettes containing an artificial or natural flavor (other than tobacco or menthol) or an herb or spice that is a characterizing flavor, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee.
- Section 910(b)(1)(F) of FD&C Act (21 U.S.C. 387j(b)(1)(F)) -- requires any application for review of a new tobacco product to include specimens of the labeling proposed to be used for such tobacco product.
- Section 911(b)(2)(A)(ii) of FD&C Act (21 U.S.C. 387k(b)(2)(A)(ii)) – As of July 22, 2010, manufacturers, including importers of finished tobacco products, may not introduce into the domestic commerce of the U.S. any tobacco product for which the label, labeling, or advertising contains the descriptors "light," "mild," or "low," or any similar descriptor, irrespective of the date of manufacture, without an FDA order in effect under section 911(g) of FD&C Act (21 U.S.C. 387k(g)) (permitting the marketing of a modified risk tobacco product).
- Sections 911(a) & (b) of FD&C Act (21 U.S.C. 387k(a) & (b)) – prohibit any person from introducing or delivering for introduction into interstate commerce any modified risk tobacco product without an FDA order in effect under section 911(g) of FD&C Act (21 U.S.C. 387k(g)). Whether a product is a modified risk tobacco product is based on representations made in the label, labeling, or advertising of such product and/or other actions directed to consumers taken by the manufacturer with respect to such product.
- Section 911(d) of FD&C Act (21 U.S.C. 387k(d)) – any application for a modified risk tobacco product must include any proposed advertising and labeling for the product.
- Section 911(h)(5) of FD&C Act (21 U.S.C. 387k(h)(5)) – an order permitting a modified risk tobacco product to be commercially marketed may require that the product comply with requirements relating to advertising and promotion of the tobacco product.

It is also unlawful to advertise cigarettes or smokeless tobacco on any medium of electronic communications subject to the jurisdiction of the Federal Communications Commission.[27]

FDA has issued various guidance documents to provide the public and regulated industry information regarding FDA's current thinking with respect to certain requirements established by the Tobacco Control Act. These guidances are available on FDA's website at http://www.fda.gov/TobaccoProducts/default.htm.

3 Strategy for Implementation of the Enforcement Action Plan

FDA's goals for the enforcement of the requirements established by the Tobacco Control Act and applicable advertising and promotion regulations are to prevent the sale and distribution of cigarettes and smokeless tobacco to children and adolescents, and to reduce exposure to marketing efforts that entice children and adolescents to start smoking. To this end, FDA plans to utilize a multipronged approach that includes surveillance, inspections, enforcement actions, and education. The primary focus of the plan will be on enforcement of the laws and regulations pertaining to the promotion and advertising of menthol and other cigarettes to youth generally, and to youth in minority communities. Specifically, FDA's enforcement action plan includes the following components:

- Tobacco Marketing Surveillance
- State Tobacco Retailer Compliance Check Inspection Program, FDA Inspections, and Imports Program
- Enforcement Tools
- Education to Encourage Voluntary Compliance
- Future Strategy and Considerations

The tobacco marketing surveillance component of the plan is intended to promptly identify potentially violative tobacco products and promotion and advertising activities of manufacturers, distributors, and retailers.

FDA plans to work with contracted States to ensure that inspections of retailers are conducted to identify violations and that violations are promptly reported to FDA. In addition, FDA plans to conduct inspections of manufacturers and distributors to assess compliance and identify violations. FDA also plans to conduct inspections through agency personnel and through the State tobacco retailer compliance check inspection program for identified promotion and advertising violations by manufacturers, distributors, or retailers and for violative tobacco products.

If violations are identified, FDA plans to use appropriate enforcement tools in order to address these violations and to facilitate compliance with the promotion and advertising restrictions. These tools include but are not limited to: Warning Letters, civil money penalties, no-tobacco-sale orders, seizures, injunctions, and/or criminal prosecution.

In addition, the plan includes an education component to increase the regulated industry's awareness of the new laws and regulations and to encourage voluntary compliance with the restrictions on promotion and advertising of menthol and other cigarettes to youth, including youth in minority communities.

FDA plans to monitor the progress and effectiveness of the enforcement action plan to ensure that the components of the plan meet FDA's goals and to determine if other

restrictions or tools are needed to effectively limit access to cigarettes and smokeless tobacco by persons under the age of 18 and to reduce the appeal of such products to persons under the age of 18, including youth in minority communities.

3.1 Tobacco Marketing Surveillance

FDA plans to conduct routine surveillance of tobacco marketing activities of regulated industry to ensure compliance with the requirements established by the Tobacco Control Act and the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*. This surveillance would include monitoring and evaluating promotional and advertising materials, including materials that promote menthol and other cigarettes. Examples of where tobacco product promotion and advertising may be found include: newspapers, magazines, periodicals, posters, placards, nonpoint-of-sale promotional material (including direct mail), and point-of-sale promotional material (including point-of-sale materials in audio or video formats).

FDA also plans to monitor and evaluate various sources of information, including promotional and advertising materials, through a variety of mechanisms to identify potentially violative tobacco products and promotion and advertising activities of manufacturers, distributors, and retailers. These sources of information include, but are not limited to:

- Regulatory submissions made to FDA
- Point-of-sale advertising and other promotional materials for tobacco products
- Internet promotional materials
- Complaints

3.1.1 Regulatory Submissions Made to FDA

The Tobacco Control Act contains several provisions that require labeling and/or advertising information be included in various regulatory submissions made by manufacturers and distributors, and as applicable, retailers of tobacco products, including:

- Section 201 of the Tobacco Control Act, amending section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) – companies must submit rotation plans for the new health warning statements required under this section on cigarette packages and advertisements to FDA for review and approval. These requirements are effective 15 months after FDA issues regulations requiring that graphic images accompany the new health warning statements.

- Section 204 of the Tobacco Control Act, amending section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 (15 U.S.C. 4402) - companies must submit rotation plans for the new health warning statements required under this section on smokeless tobacco product packages and

advertisements to FDA for review and approval. These requirements took effect on June 22, 2010.

- Section 905(i)(1)(B) of FD&C Act (21 U.S.C. 387e(i)(1)(B)), as amended by the Tobacco Control Act – persons required to register under FD&C Act must file a list of their tobacco products accompanied by a copy of all consumer information and other labeling for the products, a representative sampling of advertisements for the products, and upon request by FDA for good cause, a copy of all advertisements for a particular tobacco product.

- Section 910(b)(1)(F) of FD&C Act (21 U.S.C. 387j(b)(1)(F)), as amended by the Tobacco Control Act - any application for a new tobacco product must include specimens of the labeling proposed to be used for such tobacco product.

- Section 911(d) of FD&C Act (21 U.S.C. 387k(d)), as amended by the Tobacco Control Act – any application for a modified risk tobacco product must include any proposed advertising and labeling for the product.

Information presented in these submissions may be monitored and evaluated to ensure compliance with applicable laws and regulations, including the restrictions on promotion and advertising of menthol and other cigarettes to youth, including youth in minority communities. There is no requirement under the Tobacco Control Act to obtain prior approval of advertisements before they may be used to promote a tobacco product (FDA, however, may issue regulations requiring prior approval of advertisements for modified risk tobacco products or statements made on any tobacco product labels, *see* section 903(b) of FD&C Act [21 U.S.C. 387c(b)], as amended by the Tobacco Control Act). However, all advertisements, as well as labeling and other promotional materials, must be in compliance with FD&C Act, as amended by the Tobacco Control Act, and implementing regulations if they are used to promote the sale of a tobacco product in the United States.[28]

FDA intends to watch for trends of violative promotion and advertising of menthol and other cigarettes, and determine whether the materials appear to target youth, including youth in minority communities. FDA intends to make adjustments to its surveillance activities when needed.

3.1.2 Point-of-Sale Advertising and Other Promotional Materials for Tobacco Products

Point-of-sale advertising materials are located at any place where a consumer can purchase cigarettes or smokeless tobacco for his or her own consumption. Point-of-sale advertisements are visible and accessible to the youth population, and are associated with encouraging youth, particularly younger teens, to try smoking.[29]

FDA plans to address point-of-sale advertising in the State Tobacco Retailer Compliance Check Inspection Program. Additionally, if FDA receives a complaint regarding alleged

violations involving point-of-sale materials, FDA plans to evaluate the information and determine whether an inspection is warranted.

FDA plans to conduct routine surveillance of nonpoint-of-sale advertising for tobacco products contained in materials such as newspapers, periodicals and other publications, and magazines with high youth readership, including those that target minority populations. A list of targeted surveillance materials may be generated using the results of available readership surveys, market analysis tools, and literature reviews.

FDA also plans to review selected promotional materials to assess whether marketing of menthol and other cigarettes is in compliance with applicable laws and regulations. If violations are identified, FDA plans to take prompt enforcement action. FDA plans to monitor and analyze trends of violations associated with tobacco product advertising and promotion and make adjustments to surveillance activities, as needed.

3.1.3 Internet Promotion

Surveillance of Internet promotion of tobacco products is important because the use of the Internet by the youth population is extensive. Tobacco product promotion and advertising on the Internet are more easily accessible by the youth population. Tobacco product Internet retailers use websites to sell tobacco products. Websites with "smoking lifestyle," "smoking is cool," and similar messages are increasing, which appeal to youth through the use of graphics and youth-oriented language.[30]

FDA plans to conduct routine surveillance of websites of regulated industry that promote and advertise tobacco products, particularly those with high youth viewership and those that target minority populations. A list of websites for targeted surveillance may be generated using the results of available surveys, market analysis tools, and literature review.

FDA is concerned that tobacco companies may use social media sites such as Facebook and MySpace to promote their products because these sites are popular among and easily accessible to the youth population.[31] Although some websites require age-verifiable personal information, others do not require age verification or inconsistently verify the age of their users.[32]

FDA plans to examine and monitor website pages and Internet promotion and advertising by tobacco manufacturers, distributors, and retailers to ensure compliance with applicable promotion and advertising restrictions. If violations are identified, FDA intends to take prompt enforcement action. FDA plans to monitor and analyze trends of violative Internet promotion and make adjustments to its surveillance activities as needed.

3.1.4 Complaints

FDA strongly encourages anyone, including members of the public, to report instances of noncompliance with the requirements established by the Tobacco Control Act and the regulations, including the restrictions on the promotion and advertising of menthol and other cigarettes to youth, including youth in minority communities.

FDA plans to establish various mechanisms that consumers can use to report tobacco product advertising and promotion violations, including a separate user-friendly, tobacco product advertising and promotion complaint website, a toll-free telephone line, a specific address where written correspondence may be sent, and an e-mail address. In addition, FDA will consider making these mechanisms available in various languages.[33]

FDA currently evaluates complaints that involve regulatory violations related to tobacco product promotion and advertising. These complaints include allegations of violations related to promotion and advertising targeted to youth, including youth in minority communities. These complaints may come from various sources, such as State Programs, competitors, consumers, other stakeholders, and anonymous whistleblowers. FDA may conduct inspections or investigations to follow up on a complaint and gather evidence needed to pursue further action, when appropriate.

Consumers may report complaints locally using FDA's Consumer Complaint Coordinators (CCCs) located in FDA offices throughout the United States and Puerto Rico. CCCs will document the complaint about an FDA-regulated product, and follow up as appropriate. State coordinator contacts are listed at the following website address: http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm. Complaints reported to the CCC may also trigger an inspection for alleged violations.

FDA plans to monitor and analyze trends of complaints received and the violations associated with tobacco product advertising and promotion. Information obtained from these analyses will assist FDA in evaluating its enforcement activities and strategies.

3.1.5. Other Surveillance

Tobacco companies have reportedly provided financial support and highly visible sponsorship to various Hispanic civic groups, and athletic, cultural and entertainment events such as rodeos, dance productions, parades, festivals and activities related to national heritage month observations.[34] FDA may attend these and other events to ensure that regulated entities are complying with the law, including the restrictions on promotion and advertising of menthol and other cigarettes to youth.

3.2 State Tobacco Retailer Compliance Check Inspection Program, FDA Inspections, and Imports Program

3.2.1 State Tobacco Retailer Compliance Check Inspection Program

The Tobacco Control Act authorizes FDA to contract with States and U.S. Territories, to the extent feasible, to carry out inspections of retailers in connection with the enforcement of the laws regarding tobacco products, including the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, at 21 C.F.R. Part 1140. On February 17, 2010, FDA announced its intent to award contracts to State agencies to assist FDA in inspecting retail

establishments that sell cigarettes and/or smokeless tobacco products. It is the intent of FDA to contract with every State,Territory, and Indian Tribe.

As part of each award, the contractor is required to provide a detailed plan for ensuring that inspections are conducted at a variety of different locations, such as rural, urban and suburban areas and minority communities, and outlet types throughout the State or Territory.

These retail inspections will cover the age and identification (youth access) requirements, as well as requirements relating to tobacco product promotion and advertising. Items relating to tobacco product promotion and advertising requirements covered by the surveillance inspections will include, among others: rebates or coupon redemptions, free samples of tobacco products, non-tobacco gifts or other items offered with the purchase of tobacco products, coupons, credits or proofs of purchase of tobacco products honored for non tobacco items, and evidence of any tobacco brand name sponsorship of an entertainment or sporting event or team.

FDA plans to work closely with the States and Territories to ensure that retailer inspections include inspections in racial and ethnic minority communities, and plans to determine whether additional inspections are needed in those areas. Specifically, FDA plans to work with the contracted State agencies to identify retail establishments located in minority communities and to ensure that those areas are covered during the contract period. FDA intends to evaluate noncompliance rates in these areas with respect to the items covered by the surveillance inspections and may re-direct inspectional resources to those areas with high noncompliance rates.

When identifying which retailers to inspect in each State, FDA plans to consider several factors. One factor may be focusing on areas within the States that are considered at higher risk for regulatory violations. For example, FDA may request that inspections be conducted in geographic areas of a State/Territory with high rates of youth cigarette smokers (e.g., higher than the national average of 19.5%),[35] areas where youth report easy access to cigarettes, areas located in close proximity to middle and high schools, or regions with socioeconomic populations historically associated with market targeting.

FDA may direct an inspection of a particular retailer if a complaint or report is received, including unlicensed establishments and non-traditional vendors.

FDA plans to collaborate with the Tobacco Control Network, tobacco control advocates, community leaders, State law enforcement and other Federal agencies to ensure efforts are appropriately coordinated and help prevent noncompliance. In addition, FDA intends to work with States and local communities, including minority communities, to assist with strategies to address youth smoking prevention, including youth smoking prevention in minority communities, for those communities seeking such assistance, to promote public awareness of the new requirements and provide information on how to report violative activities to the FDA.

3.2.2 FDA Inspections

FDA plans to conduct inspections of manufacturers and distributors. If appropriate, inspections of manufacturers and distributors may be conducted by FDA in response to a complaint. If FDA receives a complaint regarding a retailer, FDA plans to work with the States and may request that the inspection be conducted through the State Tobacco Retailer Compliance Check Inspection Program. FDA intends to ensure investigations and/or inspections are conducted at these facilities, where appropriate, to assess compliance with applicable laws and regulations.

3.2.3 Imports Program

FDA intends to work with the U.S. Customs and Border Protection (CBP) to ensure tobacco products that enter U.S. borders comply with the requirements established by the Tobacco Control Act and applicable regulations. CBP, an agency within the Department of Homeland Security, is responsible for administering the nation's laws relating to imports, exports and the collection of duties. However, FDA is responsible for determining whether an FDA-regulated article offered for importation into the United States is in compliance with the laws enforced by FDA.

3.3 Enforcement Tools

Initiating enforcement actions in response to identified and documented violations of the requirements established by the Tobacco Control Act is important to obtaining compliance and to preventing and reducing youth smoking, including smoking by youth in minority communities.

FDA has the authority to take enforcement action against violative tobacco products and against persons who violate the requirements established by the Tobacco Control Act and applicable regulations. FDA may utilize several enforcement tools, including but not limited to, the following which are discussed further below: Warning Letters, civil money penalties, no-tobacco-sale orders, seizures, injunctions, and/or criminal prosecutions. FDA may take into consideration whether violative promotion and advertising activities target youth, including youth in minority communities, when determining the most appropriate enforcement action to pursue. FDA is not required to prove that violations of FD&C Act, as amended by the Tobacco Control Act, and applicable regulations were committed knowingly or intentionally. Responsible persons who work in FDA-regulated businesses have a continuous duty to ensure that they are conforming to the law.

3.3.1 Warning Letters

A Warning Letter is an advisory action that communicates the FDA's position on a compliance matter. FDA issues Warning Letters to regulated entities to notify them that in FDA's view, they have violated certain requirements established by the Tobacco Control Act or regulations. A Warning Letter is FDA's principal means of achieving prompt voluntary compliance. Responsible officials in positions of authority in regulated firms have a legal duty to implement whatever measures are necessary to ensure that their products, practices, processes, or other activities at all times comply with the law. Accordingly, FDA is not required to send a Warning Letter before it takes regulatory or judicial action.

Warning Letters are intended to advise regulated industry that failure to comply with the requirements established by the Tobacco Control Act and applicable regulations relating to tobacco products may result in FDA enforcement action(s), including but not limited to, civil money penalties, no-tobacco-sale order, seizure, injunction, and/or criminal prosecution.

When FDA has issued a Warning Letter to regulated industry regarding a violation of its laws and regulations relating to tobacco products, FDA intends to determine, generally through a re-inspection of the facility, whether the company has taken appropriate corrective action. Warning Letters issued by the FDA are generally posted on FDA's website, which is accessible to the public.

3.3.2 Civil Money Penalties[36]

Civil money penalties are monetary penalties that are assessed by FDA for violations of FD&C Act, as amended by the Tobacco Control Act, and implementing regulations. The Tobacco Control Act authorizes FDA to impose civil money penalties as follows:

- In general, any person, including a manufacturer, distributor, or retailer, who violates a requirement of FD&C Act and implementing regulations for tobacco products is liable for a civil money penalty in an amount not to exceed $15,000 for each violation or $1,000,000 for all violations adjudicated in a single proceeding. Section 303(f)(9)(A) of FD&C Act (21 U.S.C. 333(f)(9)(A)), as amended by the Tobacco Control Act. Violations of certain provisions of FD&C Act are subject to enhanced penalties. *See* Section 303(f)(9)(B) of FD&C Act (21 U.S.C. 333(f)(9)(B)), as amended by the Tobacco Control Act.

- For violations of restrictions promulgated under section 906(d) of FD&C Act (21 U.S.C. 387f(d)), as amended by the Tobacco Control Act, including the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, at 21 C.F.R. Part 1140, the Tobacco Control Act provides two schedules of maximum penalties that can be assessed against retailers for violations of such regulations -- one for retailers with an approved training program and another for retailers that do not have an approved training program. Section 103(q)(2)(A) of the Tobacco Control Act.

Additional information about such programs may be found in FDA's Draft Guidance for Industry, "Tobacco Retailer Training Programs."[37]

In determining the amount of civil money penalty to be assessed against a manufacturer, distributor, or retailer, the following factors will be considered: the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require. Section 303(f)(5)(B) of FD&C Act (21 U.S.C. 333(f)(5)(B)). FDA may also take into consideration whether violative promotion and advertising activities target youth, including youth in minority communities, in determining the amount of the civil money penalty.

3.3.3 No-Tobacco-Sale Orders[38]

FDA also has authority to issue no-tobacco-sale orders. Section 303(f)(8) of FD&C Act (21 U.S.C. 333(f)(8)), as amended by the Tobacco Control Act. These orders, which are issued to retailers, prohibit the sale of tobacco products indefinitely or for a specified period of time at a particular retail outlet.

A no-tobacco-sale order may be imposed against a retailer who is found to have committed repeated violations of restrictions promulgated under section 906(d) of FD&C Act (21 U.S.C. 387f(d)), as amended by the Tobacco Control Act, including the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*, at 21 C.F.R. Part 1140. The term "repeated violation" is defined to mean "at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation." Section 103(q)(1)(A) of the Tobacco Control Act.

In determining whether a no-tobacco-sale order should be imposed, FDA will consider whether a retailer has taken effective steps to prevent violations of the minimum age requirements for the sale of tobacco products, including:

- adopting and enforcing a written policy against sales to minors;
- informing its employees of all applicable laws;
- establishing disciplinary sanctions for employee noncompliance; and
- requiring its employees to verify age by means of photographic identification or electronic scanning device.

3.3.4 Seizures, Injunctions, and Criminal Prosecutions

FDA's enforcement tools also include seizures (section 304 of FD&C Act, 21 U.S.C. 334), injunctions (section 302 of FD&C Act, 21 U.S.C. 332), and criminal prosecutions (section 303 of FD&C Act, 21 U.S.C. 333). A seizure is a proceeding initiated against products, including tobacco products, that are in violation of FD&C Act. Under this

proceeding, the U.S. government files a Complaint for Forfeiture, asking the court to condemn the violative product and declare forfeiture for violation of the law by the product itself, and also files a warrant for arrest, directing the U.S. Marshal to seize the violative product. Parties who have an interest in the product, such as owners or agents, may claim it and litigate on the product's behalf.

In addition, FDA may seek an injunction against any person, including a manufacturer, distributor, and/or responsible individual, who violates a requirement of the law and implementing regulations. An injunction is a civil process initiated to stop or prevent a violation of the law, such as, to halt the distribution of violative tobacco products in interstate commerce, and/or to correct the conditions that caused the violation to occur. An injunction may be sought, for example, if a firm has a history of violations, and has promised correction in the past, but has not made the corrections.

Under certain circumstances, FDA may refer violations of FD&C Act and the regulations issued under it for criminal prosecution, including misdemeanor or felony prosecutions.

3.4 Education to Encourage Voluntary Compliance

FDA recognizes that comprehensive education campaigns may encourage retailers to comply voluntarily with the requirements established by the Tobacco Control Act and applicable regulations that affect their businesses. By educating both retailers who sell tobacco products and consumers about the new federal requirements, FDA seeks to encourage retailers to comply with the law. Educational campaigns also raise awareness and encourage retailers and consumers to monitor the promotion and advertising of tobacco products within their communities.

In 2010, FDA launched national retailer and community education campaigns to raise the awareness of the federal tobacco regulations, compliance requirements, and their goal to protect children and adolescents from nicotine addiction and the deadly effects of tobacco use by limiting the sale, distribution, and marketing of cigarettes and smokeless tobacco. To complement these ongoing national efforts and to encourage voluntary compliance in minority communities, FDA plans to develop a retailer education campaign that focuses on retailers operating in racial and ethnic minority communities.

3.4.1 Live Retailer Training Sessions

On June 22, 2010, several important requirements established by the Tobacco Control Act went into effect. FDA recognizes that the retail community plays a vital role in protecting youth from becoming the next generation of Americans to die prematurely from tobacco-related disease. Therefore, FDA conducted live outreach sessions to educate the retail community on how to comply with the new regulations, *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect*

Children and Adolescents, and other requirements established by the Tobacco Control Act that affect retailers.

FDA held the training sessions at five venues across the country, starting in the Northeast. FDA selected the meeting sites to represent a selection of urban areas, including racial and ethnic minority communities, across the country with available public transportation. The sites included Boston, Atlanta, Chicago, Dallas, and Los Angeles. FDA encouraged retailers in neighboring areas and States to attend the session in person, via telephone, or by webcast. There was no charge to attend these training sessions. FDA provided retailers who were present at the meeting or who participated by webcast or by telephone the opportunity to ask questions. At each session, FDA provided training and took questions on the topics outlined below:

- Who is subject to the regulations
- What tobacco products are regulated
- Prohibition of sale and distribution of cigarettes and smokeless tobacco to persons younger than 18 years of age
- Self-service displays and vending machines
- Minimum cigarette and smokeless tobacco package sizes
- Prohibition of free samples of cigarettes and restrictions of free samples of smokeless tobacco
- Coupons
- Sponsorships
- Non-tobacco gifts or items
- Flavored cigarettes
- "Light, Low and Mild" cigarettes
- Tobacco Retailer Training Programs

3.4.2 Break the Chain of Tobacco Addiction

To educate retailers across the country, FDA launched the "Break the Chain of Tobacco Addiction" Retailer Education Campaign on June 22, 2010, the effective date of the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents*. The Campaign seeks to raise retailers' awareness of the federal tobacco regulations, their purpose, and the consequences of noncompliance. It also intends to engage retailers as important members of communities working with the FDA to protect kids by preventing the unlawful sale, distribution, advertising, and promotion of cigarettes and smokeless tobacco products. The campaign utilizes a broad array of interpersonal, organizational, community, mass media, and digital communication channels to equip retailers with the tools and information they need to carry out and comply with the new regulations.

3.4.3 Protecting Kids from Tobacco

To educate communities across the United States about the new requirements relating to tobacco products, FDA launched the "Protecting Kids from Tobacco" Campaign on

March 19, 2010, the publication date of the *Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents*. Among other objectives, the campaign intends to raise the awareness of community members about the new regulations and their purpose and to encourage them to monitor their communities for instances of noncompliance. FDA developed the Campaign using information gathered through listening sessions and environmental scans (community surveys), and launched it with a dedicated Web area and print and digital collateral materials, a Center-wide call center, and a press event with Secretary Sebelius, of the U.S. Department of Health and Human Services.

3.4.4 Retailer Education in Minority Communities

FDA plans to build on its national Retailer Education Campaign and develop a strategic campaign that focuses on retailer education in racial and ethnic minority communities. This effort would be developed using best practices in comprehensive communication planning, including (1) identifying goals and measurable objectives, (2) defining and researching targeted audiences, (3) exploring settings, channels, and activities to effectively reach targeted audiences, (4) identifying potential partners and developing partnership plans, and (5) developing communication strategies. Campaign materials and messages would be designed and tested for cultural appropriateness and would take into consideration geographic, racial and ethnic, and language diversity.

In addition, FDA has tasked the Tobacco Products Scientific Advisory Committee (TPSAC) to prepare a report on 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. FDA intends to consider TPSAC's report and recommendations in evaluating its educational activities and make adjustments as appropriate.

3.4.5 Community Assistance

As an extension of FDA's "Protecting Kids from Tobacco" Campaign, FDA plans to facilitate the provision of technical assistance to State and local community tobacco control advocates seeking assistance in preventing underage tobacco use, including assistance with strategies to address the prevention of underage tobacco use in communities with a disproportionate use of menthol cigarettes by minors. FDA plans to announce the availability of community assistance as appropriate on the FDA Center for Tobacco Products (CTP) Webpage and in print products and encourage communities to request assistance via the CTP Call Center (1-877-CTP-1373) and email (AskCTP@fda.hhs.gov).

3.5 Future Strategy and Considerations

FDA recognizes the importance of implementing enforcement strategies that are effective in achieving the public health goals of the Tobacco Control Act. Therefore, FDA will monitor the progress and re-assess the applicability of the components of the plan as new

regulations, policies, recommendations, and priorities take effect, and make necessary adjustments to the plan.

In various docket submissions, FDA has received recommendations that it monitor existing surveys, such as youth smoking rates and exposure to tobacco advertising, and monitor tobacco marketing expenditures. In addition, it was recommended that FDA monitor data by national, state, and geographical regions, as well as by minority status. FDA will consider appropriate evaluation measures to assess the outcomes and impact of the program.

Other recommendations made to FDA include the need to communicate important information to other agencies and organizations involved in tobacco control, and to make information available in multiple languages. FDA intends to continue to provide updates and useful information to the public, other agencies, and organizations through various communication channels.

FDA plans to continue to collaborate with Federal and State agencies, public health organizations, tobacco and minority advocacy groups, community leaders, professional organizations and other stakeholders. FDA intends to work with these organizations to ensure that information is adequately communicated and that enforcement efforts are effective in State and local communities.

FDA will monitor the progress and effectiveness of its enforcement action plan to ensure that it achieves FDA's goals and to determine whether other restrictions or tools are needed to effectively reduce the marketing of menthol and other cigarettes to youth, including minority youth.

4 REFERENCES

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

[2] U.S. Department of Health and Human Services. *Tobacco Use Among U.S. Racial/Ethnic Minority Groups-African Americans, American Indians and Alaska Natives, Asian Americans and Pacific Islanders and Hispanics: A Report of the Surgeon General*. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 1998. Available at http://profiles.nlm.nih.gov/NN/B/B/G/C/_/nnbbgc.pdf.

[3] O. Mitchell, and M. Greenberg, *Outdoor Advertising of Addictive Products*, N J Med. 1991 May;88(5):331-3. at 331. (finding that billboards in Black and Hispanic neighborhoods in four New Jersey cities disproportionately contained advertisements for tobacco and alcohol products).

[4] S.D. Ammerman, and M. Nolden, *Neighborhood-Based Tobacco Advertising Targeting Adolescents*, West J of Med; 1995; 162:514-518. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1022829/pdf/westjmed00058-0028.pdf.

[5] J.L. Stoddard, et al., *Tailoring Outdoor Tobacco Advertising to Minorities in Los Angeles County*, J. Health Commun; 1998 Apr-Jun;3(2):137-46.

[6] Brian A. Primack, et al., *Volume of Tobacco Advertising in African American Markets: Systematic Review and Meta-Analysis*, Public Health Rep.; 2007 Sep-Oct;122(5):607-15 at 607. Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1936959/pdf/phr122000607.pdf.

[7] E.D. Balbach, et al., *R.J. Reynold's Targeting of African Americans: 1988-2000*. Am J Public Health. 2003;93:822-827.

[8] National Cancer Institute. *The Role of the Media in Promoting and Reducing Tobacco Use*. Tobacco Control Monograph No. 19. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute. NIH Pub. No. 07-6242, June 2008; p. 57. Available at http://www.cancercontrol.cancer.gov/tcrb/monographs/19/index.html.

[9] *Id*. at 15.

[10] U.S. Federal Trade Commission (FTC), *Cigarette Report for 2006*, 2009. Available at http://www.ftc.gov/os/2009/08/090812cigarettereport.pdf .

[11] *Id*.

[12] N.J. Kaufman, *et al. Changes in Adolescent Cigarette-brand Preference, 1989 to 1996*. Am J Health Behav. 2004;28:54–62.

[13] Centers for Disease Control and Prevention, "Cigarette Use Among High School Students – United States, 1991-2009." MMWR July 9, 2010; 59(26);797-801. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5926a1.htm .

[14] *Id*.

[15] *Id*.

[16] 75 Fed. Reg. 13,225 (March 19, 2010). Available at http://www.regulations.gov/search/Regs/contentStreamer?objectId=0900006480ac184d&disposition=attachment&contentType=html.

[17] 75 Fed. Reg. 29,776 (May 27, 2010). Available at http://www.gpo.gov/fdsys/pkg/FR-2010-05-27/html/2010-12684.htm

[18] 75 Fed. Reg. 34,750 (June 18, 2010). Available at http://edocket.access.gpo.gov/2010/pdf/2010-14809.pdf.

[19] For more information, please visit http://www.fda.gov/TobaccoProducts/NewsEvents/ucm215780.htm.

[20] Centers for Disease Control and Prevention. *Best Practices for Comprehensive Tobacco Control Programs-- 2007.* Atlanta: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office of Smoking and Health; October 2007.
[21] http://www.thecommunityguide.org/tobacco/index.html
[22] World Health Organization, *WHO Report on the Global Tobacco Epidemic* (2009). Available at http://whqlibdoc.who.int/publications/2009/9789241563918_eng_full.pdf.
[23] Institute of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation* (2007).
[24] A sampling of resources consulted is as follows: California (http://www.cdph.ca.gov/programs/tobacco/Pages/default.aspx); Florida (http://www.doh.state.fl.us/Tobacco/tobacco_home.html); Hawaii (http://hawaii.gov/health/healthy-lifestyles/tobacco/index.html); Mississippi (http://msdh.ms.gov/msdhsite/_static/43,0,94.html); New York (http://www.health.state.ny.us/prevention/tobacco_control/); Texas (http://www.cprit.state.tx.us/pdfs/TobaccoPlan08FINAL.pdf); Washington (http://www.doh.wa.gov/tobacco/Strat-Plan/09stratplan.pdf).
[25] 75 Fed. Reg. 13,225 (March 19, 2010). Available at http://www.regulations.gov/search/Regs/contentStreamer?objectId=0900006480ac184d&disposition=attachment&contentType=html.
[26] 75 Fed. Reg. 25,271 (May 7, 2010). Available at http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM210766.pdf.
[27] Public Health Cigarette Smoking Act, 15 U.S.C. § 1335 (1971), and Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. § 4402 (1986).
[28] Advertisements must also be in conformance with the provisions on health warnings in the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1333, and the Comprehensive Smokeless Tobacco Health Education Act of 1986, 15 U.S.C. § 4402, as amended by the Tobacco Control Act.
[29] Centers for Disease Control and Prevention, *supra* note 19.
[30] Center for Media Education (CME), *Youth Access to Alcohol and Tobacco Web Marketing: The Filtering and Rating Debate*, October 1999. Available at http://web.archive.org/web/20000815095453/www.cme.org/publications/scrnfltr/report_1104.pdf. T. Hong & M.J. Cody, *Presence of Pro-Tobacco Messages on the Web*, Journal of Health Communication; 7(4):273-307, July-Sept., 2002.
[31] B. Freeman and S. Chapman, *British American Tobacco on Facebook: undermining article 13 of the global World Health Organization Framework Convention on Tobacco Control*. Tobacco Control 2010; 19(3): e1-e9.
[32] Letter from American Association for Respiratory Care, et al. to U.S. Food and Drug Administration (Jul. 26, 2010) (on file with FDA-Center for Tobacco Products).
[33] Letter from Asian Pacific Partners for Empowerment, Advocacy and Leadership, et. al to U.S. Food and Drug Administration (Jul. 26, 2010) (on file with FDA-Center for Tobacco Products).
[34] Letter from National Alliance for Hispanic Health to U.S. Food and Drug Administration (Jul. 26, 2010) (on file with FDA-Center for Tobacco Products).
[35] Centers for Disease Control and Prevention. *Youth Risk Behavior Surveillance – United States 2009.* Surveillance Summaries, June 4 MMWR 2010;59(No. SS-5) at 10. Available at http://www.cdc.gov/mmwr/pdf/ss/ss5905.pdf
[36] For more information about civil money penalties, please see *Draft Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers*. Available at: http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM224464.pdf.
[37] For more information about the retailer training program, please see *Draft Guidance for Industry: Tobacco Retailer Training Programs*. Available at: http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm218898.htm.
[38] For more information about no-tobacco-sale orders, please see *Draft Guidance for FDA and Tobacco Retailers: Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers*. Available at: http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM224464.pdf