DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1141

[Docket No. FDA–2010–N–0568]

RIN 0910–AG41

Required Warnings for Cigarette Packages and Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations to add a new requirement for the display of health warnings on cigarette packages and in cigarette advertisements. The proposed rule would implement a provision of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany the nine new textual warning statements that will be required under the Tobacco Control Act. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act (FCLAA) to require each cigarette package and advertisement to bear one of nine new textual warning statements. This proposed rule, once finalized, would specify the color graphics that must accompany each of the nine new textual warning statements.

DATES: Interested persons may submit either electronic or written comments on this proposed rule by January 11, 2011. See section IV.G of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2010–N–0568 and/or RIN number 0910–AG41, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper, disk, or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Gerie Voss or Kristin Davis, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850–3229, 877–287–1373, *gerie.voss@fda.hhs.gov* or *kristin.davis@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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I. Legal Authority and Background

The Tobacco Control Act was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FCLAA, and providing FDA with the authority to regulate tobacco products (Pub. L. 111–31; 123 Stat. 1776). Section 201 of the Tobacco Control Act modifies section 4 of FCLAA (15 U.S.C. 1333) to require that nine new health warning statements appear on cigarette packages and in cigarette advertisements:

- WARNING: Cigarettes are addictive
- WARNING: Tobacco smoke can harm your children

- WARNING: Cigarettes cause fatal lung disease
- WARNING: Cigarettes cause cancer
- WARNING: Cigarettes cause strokes and heart disease
- WARNING: Smoking during pregnancy can harm your baby
- WARNING: Smoking can kill you
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers
- WARNING: Quitting smoking now greatly reduces serious risks to your health.

Section 201 also states that "the Secretary [of Health and Human Services] shall issue regulations that require color graphics depicting the negative health consequences of smoking" to accompany the nine new health warning statements.

Section 202(b) of the Tobacco Control Act amends section 4 of FCLAA (15 U.S.C. 1333) to add a new subsection [1] that permits FDA to, after notice and an opportunity for the public to comment, adjust the format, type size, color graphics, and text of any health warning statement if such a change would promote greater public understanding of the risks associated with the use of tobacco products. Similarly, section 202(b) of the Tobacco Control Act permits FDA to adjust the format, type size, and text of any other disclosures required under the FD&C Act, using the same process and upon the same basis as for adjusting the health warning statements.[2] Among the provisions of the FD&C Act that provide authority to require disclosures is section 906(d) (21 U.S.C. 387f(d)). This provision authorizes FDA to issue regulations restricting the sale or distribution of cigarettes and other tobacco products, including restrictions on the advertising and promotion of such products, if FDA determines the restriction is appropriate for protecting the public health.

These requirements are supplemented by the FD&C Act's misbranding provisions, which require that product advertising and labeling include proper warnings. For example, a tobacco product is deemed misbranded under section 903(a)(1) or (a)(7)(A) of the FD&C Act (21 U.S.C. 387c(a)(1) or (a)(7)(A)) if its labeling or advertising is false or misleading in any particular. Under section 201(n) of the FD&C Act (21 U.S.C. 321(n)), in determining whether labeling or advertising is misleading, the agency considers, among other things, the failure to reveal material facts concerning the consequences that may result from the customary or usual use of the product. Similarly, under section 903(a)(8)(B) of the FD&C Act (21 U.S.C. 387c(a)(8)(B)), a tobacco product is deemed misbranded unless the manufacturer, packer, or distributor includes in all advertisements and other descriptive printed matter a brief statement of, among other things, the relevant warnings. Moreover, a tobacco product is deemed misbranded under section 903(a)(7)(B) of the FD&C Act (21 U.S.C. 387c(a)(7)(B)) if it is sold or distributed in violation of regulations prescribed under section 906(d) of the FD&C Act. Under section 701(a) of the FD&C Act (21 U.S.C. 371(a)), FDA has authority to issue regulations for the efficient enforcement of the FD&C Act.

Cigarette smoking kills an estimated 443,000 Americans each year, most of whom began smoking when they were under the age of 18 (Ref. 1). Tobacco use is the foremost preventable cause of premature death in America, and has been shown to cause cancer, heart disease, and other serious adverse health effects (Ref. 2). In enacting the Tobacco Control Act, Congress found that providing FDA with authority to regulate tobacco products, including the advertising and promotion of such products, would result in significant benefits to the American public in human and economic terms (section 2(12) of the Tobacco Control Act). The U.S. government has a substantial interest in reducing the number of Americans, particularly children and adolescents, who use cigarettes and other tobacco products in order to prevent the life-threatening health consequences associated with tobacco use (section 2(31) of the Tobacco Control Act). Virtually all new users of tobacco products are minor children and a reduction in tobacco use by this population alone could significantly reduce tobacco-related death and disease in the United States (Ref. 3 at pp. 5–6).

In 1964, the Surgeon General of the Public Health Service issued the landmark report titled "Smoking and Health," which comprehensively assessed the available scientific evidence relating to the health effects of cigarette smoking and concluded that cigarette smoking is a health hazard of sufficient importance in the United States to warrant appropriate remedial action. Subsequently, Congress passed the Federal Cigarette Labeling and Advertising Act (FCLAA) of 1965 (Pub. L. 89–92); this legislation required that a printed warning appear on cigarette packages to warn consumers of the potential hazards of cigarette smoking. This warning requirement was modified by later amendments to FCLAA, including the Comprehensive Smoking Education Act (CSEA) of 1984 (Pub. L. 98–474), which extended the warning requirement to cigarette advertising. The current requirements for cigarette package and advertising warning statements are set forth in FCLAA.

Although FCLAA has required the inclusion of textual health warnings on cigarette packages and in cigarette advertisements for many years, there is considerable evidence that the current warnings are given little attention or consideration by viewers (*Id.* at p. 168). These warnings, which have not changed in over twenty-five years, have been described as "invisible" and fail to convey relevant information in an effective way (Ref. 4; Ref. 5 at p. 291). The current warnings also fail to include any graphic component. In proposing this current regulation, FDA examined the scientific literature and found substantial evidence indicating that prominent warnings including a graphic component would offer significant public health benefits over the current warnings used in the United States (*see* Section III). FDA also found evidence of a strong worldwide consensus that effective tobacco health warnings should be large and should include a graphic image component. For example, the World Health Organization's (WHO) Framework Convention on Tobacco Control (FCTC),[3] an evidence-based treaty that provides a regulatory strategy for addressing the serious negative impacts of tobacco products, calls for warnings that are rotating, "large, clear, visible and legible." The treaty recommends that the warnings occupy 50 percent or more of the principal display areas, and states that they may be in the form of or include pictures or pictograms. WHO FCTC art. 11.1(b). Worldwide, over 30 countries/jurisdictions have implemented pictorial warnings on tobacco packages and requirements for pictorial warnings are pending in several other countries/jurisdictions.[4]

[1] Section 202(b) of the Tobacco Control Act amends section 4 of FCLAA (15 U.S.C. 1333) to add a new subsection (d), "Change in Required Statements." However, section 201 of the Tobacco Control Act also amends section 4 of FCLAA to add a new subsection (d), "Graphic Label Statements."

[2] Provisions regarding adjustments to the health warnings and other disclosures are also in sections 4(b)(4) and 4(d) of FCLAA, as amended by section 201 of the Tobacco Control Act.

[3] There are 168 signatories to the WHO's Framework Convention on Tobacco Control as of August 2010. At this time, the United States is a signatory but has not ratified this treaty.

[4] Countries/jurisdictions that have implemented pictorial warning requirements for tobacco packaging include: Australia; Belgium; Brazil; Brunei; Canada; Chile; Colombia; Cook Islands; Djibouti; Egypt; Hong Kong; India; Iran; Jordan;

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Therefore, as directed by section 201 of the Tobacco Control Act, and in the interest of the public health, we are proposing to modify the required warnings that appear on cigarette packages and in cigarette advertisements to include color graphics depicting the negative health consequences of smoking. Specifically, we are proposing to add a new part 1141 to Title 21 of the Code of Federal Regulations, which would require new warnings on cigarette packages and in cigarette advertisements. These new required warnings would consist of the nine textual warning statements set forth in section 201 of the Tobacco Control Act accompanied by color graphics depicting the negative health consequences of smoking. As required by section 201 of the Tobacco Control Act, the new warnings would appear prominently on packages and in advertisements, occupying at least 50 percent of the area of the front and rear panels of cigarette packages and 20 percent of the area of advertisements. Under sections 201 and 202 of the Tobacco Control Act, FDA may adjust the type size, text, and format of the textual warning statements. For example, under section 4(d) of FCLAA (as amended by section 201 of the Tobacco Control Act), FDA may adjust the type size, text, and format as FDA determines appropriate so that both the textual warning statements and the accompanying graphics are clear, conspicuous, legible and appear within the specified area. Such adjustments, including adjustments to the text of some of the textual warning statements, are included for some of the new warnings FDA is proposing.

These proposed modifications to the warnings currently required in the United States would promote greater public knowledge of the health risks of using cigarettes and would help reduce the initiation of smoking and the prevalence of cigarette use among Americans, and thus help prevent the life-threatening health risks posed by cigarettes. Specifically, the new required warnings are designed to clearly and effectively convey the negative health consequences of smoking on cigarette packages and in cigarette advertisements, which would help both to discourage nonsmokers, including minor children, from initiating cigarette use and to encourage current smokers to consider cessation to greatly reduce the serious risks that smoking poses to their health.

Latvia; Malaysia; Mauritius; Mexico; Mongolia; New Zealand; Pakistan; Panama; Paraguay; Peru; Romania; Singapore; Switzerland; Taiwan; Thailand; Turkey; United Kingdom; Uruguay; and Venezuela. Countries/jurisdictions with pending requirements include: France; Guernsey, Honduras; Malta; Norway; Philippines; and Spain.

II. Cigarette Use in the United States and the Resulting Health Consequences

In the United States, cigarette smoking is the leading cause of preventable death and disease (Ref. 6), resulting in more deaths each year than AIDS, alcohol, illegal drug use, homicide, suicide, and motor vehicle crashes combined (Ref. 7). Each day, an estimated 6,600 Americans (nearly 4,000 of them under the age of 18) become new smokers (Ref. 8 at p. 59), and due to the highly addictive nature of cigarettes, many will find it difficult to quit smoking, despite the severe health risks associated with cigarette use. Most smokers begin smoking before they are 18 years old (Ref. 3 at p. 6)—more than 80 percent of established adult smokers began smoking before age 18 (Ref. 9)—and about half of adolescents who continue to regularly smoke will eventually die from smoking-attributable disease (Ref. 10). Smoking causes at least 443,000 premature deaths annually in the United States, and each year cigarettes are responsible for approximately 5.1 million years of potential life lost, direct health care expenditures of approximately $96 billion, and at least $96.8 billion in annual productivity losses in the United States (Ref. 1). The public health benefits that would result from reducing the number of Americans who smoke, and thus preventing the life-threatening consequences associated with cigarette use, are substantial.

A. Smoking Prevalence Among Adults and Children

Adults. A significant percentage of U.S. adults are cigarette smokers. For example, results from the 2009 National Health Interview Survey (NHIS) indicate that approximately 46.6 million U.S. adults (or 20.6 percent of the adult population) are cigarette smokers (Ref. 6). Among these adult smokers, the vast majority—78.1 percent, or approximately 36.4 million people—smoke every day (*Id.*). There are also subsets of the adult population with smoking prevalence rates that are significantly higher than the overall average. For example, the highest prevalence rates have been observed in adults with low education levels. Data indicate that 49.1 percent of adults with a General Education Development certificate (GED) and 28.5 percent of adults with less than a high school diploma were current smokers in 2009, compared with 5.6 percent of adults with a graduate degree (*Id.*).

Children. Among children, data from the 2009 Youth Risk Behavior Survey (YRBS), a nationally representative survey of students in grades 9–12 in the United States, showed that almost half (46.3 percent) of U.S. high school students had tried cigarette smoking, and an estimated 19.5 percent of students were current cigarette smokers (Ref. 11 at p. 10). Of these current cigarette smokers, 7.8 percent reported that they had smoked more than 10 cigarettes per day on the days they smoked (*Id.* at p. 11). Overall, approximately 7.3 percent of high school students in 2009 were frequent cigarette users, and 11.2 percent of students under the age of 18 had been daily smokers at some point during their lifetime (*Id.* at pp. 10–11). Furthermore, follow-up studies of youth smokers have indicated that a significant number of students who are light smokers (*i.e.,* students who are not daily smokers or who smoke less than 10 cigarettes per day) in high school will become heavy smokers after leaving high school (Ref. 12).

Trends. During the period of 1998–2009, the proportion of U.S. adults who were current cigarette smokers declined from 24.1 percent to 20.6 percent. However, the proportion did not decline from 2008 to 2009 (20.6 percent in both years), and during the five-year period of 2005 to 2009, rates showed virtually no change (20.9 percent in 2005 and 20.6 percent in 2009) (Ref. 6).

For children, data from the YRBS show that smoking prevalence rates increased rapidly in the early 1990s, peaking around 1997. Prevalence then declined during the late 1990s, but the rate of decline slowed during 2003–2009 (Ref. 13). According to 2009 data from the University of Michigan's Monitoring the Future survey, cigarette smoking rates among 8th, 10th, and 12th grade U.S. students declined only slightly from 2007 to 2009, at a much slower pace than observed previously. Specifically, over the two-year time period from 2007 to 2009, smoking prevalence fell by just 0.6, 0.9 and 1.5 percentage points among 8th, 10th, and 12th graders, respectively (Ref. 12). Data from this survey also indicate that the proportion of students who perceive a great risk associated with being a smoker has leveled off in the past several years (*Id.*).

B. Initiation of Smoking Among Adults and Children

As discussed in section II.A, roughly one-fifth of Americans are current cigarette smokers. Although the cigarette industry regularly loses customers through user cessation and

through deaths caused by smoking, each year millions of U.S. adults and children become new smokers.

For example, results from the 2008 National Survey on Drug Use and Health (NSDUH) indicate that the number of persons aged 12 or older who smoked cigarettes for the first time within the past 12 months was 2.4 million (Ref. 8 at p. 59). This estimate was similar to the 2007 estimate (2.2 million) but statistically significantly higher than the estimates for 2002 (1.9 million), 2003 (2.0 million) and 2004 (2.1 million) (*Id.*). This 2008 estimate averages out to approximately 6,600 new cigarette smokers every day (*Id.*). Most of these new cigarette smokers (nearly 4,000) were under the age of 18 (*Id.*). However, it is also notable that the number of people who began smoking at age 18 or older showed a significant increase over the last several years, jumping from approximately 600,000 in 2002 to 1 million in 2008 (*Id.* at p. 60).

In addition, data from the 2008 NSDUH indicate that almost 1 million Americans aged 12 or older had started smoking cigarettes daily within the past 12 months. Of these new daily smokers, 37.2 percent (350,000 persons) were younger than age 18 when they started smoking daily. In other words, each day in 2008 approximately 1,000 U.S. children became new daily smokers (*Id.*). This is particularly concerning from a public health perspective, as studies suggest that the age individuals begin smoking can greatly influence how much they smoke per day and how long they smoke, which will ultimately influence their risk of tobacco-related disease and death (Refs. 14 through 16). Data from animal studies also suggest that nicotine can cause permanent brain changes in the adolescent brain that lead to addiction and that these changes are greater in adolescents than in adults (Ref. 17). Furthermore, data from human studies indicate that the younger smokers start, the more likely they are to become addicted (*Id.*).

C. Costs to Society and Health Effects of Cigarettes

Cigarettes are responsible for premature deaths from a variety of diseases, a substantial burden on the U.S. healthcare system, and significant economic losses to society (Ref. 1). Smoking is the primary causal factor for at least 30 percent of deaths from cancer, including 90 percent of deaths from lung cancer, almost 80 percent of deaths from chronic obstructive pulmonary disease (COPD), and nearly one-fifth of all deaths from cardiovascular disease (Ref. 1 and Ref. 2 at pp. 39 and 43).

1. Costs of Smoking to Society

Data from the Centers for Disease Control and Prevention's (CDC) Smoking-Attributable Mortality, Morbidity, and Economic Costs (SAMMEC) system for 2000–2004, the most recent years for which analyses are available, indicate that cigarette smoking and exposure to cigarette smoke are responsible for at least 443,000 premature deaths each year (Ref. 1). For every person who dies from smoking, approximately 20 more people (8.6 million persons) suffer from at least one serious smoking-related illness, primarily heart disease and COPD (Ref. 18). The three leading causes of smoking-attributable death for current and former smokers were lung cancer, ischemic heart disease, and COPD (Ref. 1). Cigarettes also have significant deleterious effects on nonsmokers. For example, maternal smoking during pregnancy resulted in an estimated 776 infant deaths annually during 2000–2004, and each year an estimated 49,400 lung cancer and heart disease deaths were attributable to exposure to secondhand smoke (*Id.*).

Overall, each year cigarettes are responsible for approximately 5.1 million years of potential life lost, direct health care expenditures of approximately $96 billion, and at least $96.8 billion in productivity losses due to premature deaths in the United States (*Id.*). The total costs of smoking to society are much higher, as this estimate of productivity losses does not include costs associated with smoking-related disability, employee absenteeism, or costs associated with secondhand-smoke attributable disease morbidity and mortality (*Id.*). These health care expenditures and productivity losses result in a combined economic burden from cigarette smoking of approximately $193 billion per year (*Id.*). There are also costs to the smoker and his or her family. One study estimated that the total cost of smoking over a lifetime, including private costs to the smoker and costs imposed on society (*e.g.,* second hand-smoke and costs of Medicare, Medicaid, and Social Security) come to nearly $40 per pack of cigarettes smoked (Ref. 19 at p. 11).

2. Negative Health Effects of Cigarettes

The healthcare burdens, productivity losses, and deaths attributed to smoking are related to an array of diseases and health conditions caused by cigarettes. Beginning with the landmark 1964 report "Smoking and Health," the U.S. Surgeon General has issued a series of reports addressing the health consequences of smoking and nicotine addiction. According to the most recent Surgeon General's Report, "The Health Consequences of Smoking," which summarizes thousands of peer-reviewed scientific studies and is itself peer-reviewed, smoking remains the leading preventable cause of death in the United States, and cigarettes have been shown to cause an ever-expanding number of diseases and health conditions (Ref. 2 at pp. 9 and 25). As stated in the 2004 Report, "[s]moking harms nearly every organ of the body, causing many diseases and reducing the health of smokers in general * * * [and] [q]uitting smoking has immediate as well as long-term benefits, reducing risks for diseases caused by smoking and improving health in general" (*Id.* at p. 25). The following discussion presents a summary of some of the diseases and conditions caused by cigarettes, and of the impact smoking cessation has on some of these conditions.

Cancer. Cigarette smoking has long been tied to a variety of cancers. For example, there is overwhelming evidence that smoking causes lung cancer, and that the worldwide epidemic of lung cancer is attributable largely to smoking (*Id.* at p. 43). Studies indicate that the risk for developing lung cancer can be 20 or more times higher for smokers compared to lifelong nonsmokers, and the risk of lung cancer increases in smokers with the duration of smoking and the number of cigarettes smoked (*Id.*). There are extensive data showing that quitting smoking decreases the risk of lung cancer, and that this risk continues to decline as the duration of not smoking increases in comparison to the risk among continuing smokers (*Id.* at p. 49). However, the risk does not decline to the level of risk for those who have never smoked, even after 15 to 20 years of not smoking *(Id.* at p. 43).

It also has been established for some time that cigarette smoking also causes a variety of other cancers, including laryngeal cancer, oral cavity and pharyngeal cancers, esophageal cancer, and bladder cancer (*Id.* at pp. 62, 67, 116, and 167). Furthermore, smoking has also been shown to cause pancreatic cancer, kidney cancer, stomach cancer, cervical cancer, and acute myeloid leukemia (*Id.* at p. 25).

For all of these cancers, increasing smoking prevention and cessation would cause a significant decrease in the risk (*Id.* at ch. 2). For example, smoking cessation halves the risk for cancers of the oral cavity and esophagus as soon as five years after cessation (*Id.* at p. 117).

Cardiovascular disease. Smoking is causally related to all of the major

clinical cardiovascular diseases, with higher levels of smoking and longer duration of smoking increasing the risk of disease (*Id.* at p. 397). Heart disease and stroke are the main types of cardiovascular disease caused by smoking and represent the first and third leading causes of death in the United States (*Id.* at p. 363). Studies have shown that smokers have a 70 percent greater death rate from coronary heart disease than nonsmokers, a twofold to fourfold greater incidence of coronary heart disease, and a twofold to fourfold greater risk of sudden death than nonsmokers (Ref. 20 at pp. 58–59). The beneficial impact of smoking cessation on these risks has also been well established. For example, one year after quitting smoking, a former smoker's additional risk of heart disease compared to a person who has never smoked is reduced by about half and, after 15 years of abstinence, this risk is similar to that of a person who never smoked (Ref. 2 at p. 363).

Current smoking is also associated with a twofold to fourfold increase in the risk of stroke; smoking cessation steadily decreases this risk and, after 5 to 15 years of not smoking, the risk of stroke is indistinguishable from that for lifetime nonsmokers (*Id.* at p. 394).

Smoking has also been shown to cause abdominal aortic aneurysm. Studies have shown that the risk of death from abdominal aortic aneurysm was increased more than fourfold in current smokers and twofold in former smokers; smoking is one of the few avoidable causes of this frequently fatal condition (*Id.* at pp. 396–97).

Respiratory diseases. Smoking has negative effects on the entire lung—it impairs lung defenses against infection and causes the sustained lung injury that leads to COPD (*Id.* at p. 423). Cigarettes have been shown to cause a range of acute respiratory illnesses, including increased risk of pneumonia, and chronic respiratory diseases, which are leading causes of illness and death in the United States and worldwide (*Id.* at pp. 423, 508–509).

For example, cigarette smoking is the leading cause of COPD in the United States, and this major public health problem could be almost completely prevented by smoking abstinence (*Id.* at p. 501). Although smoking cessation reduces the risk of COPD, the risk of COPD mortality among former smokers, even after 20 years or more of abstinence, remains elevated compared with the risk among people who have never smoked (*Id.*).

Maternal smoking during pregnancy causes a reduction in lung function in infants, and children who smoke experience impaired lung growth and an early onset of lung function decline (*Id.* at pp. 508–509). Smoking during adulthood also leads to a premature onset of accelerated age-related decline in lung function, while smoking cessation can return the rate of lung function decline to that of persons who have never smoked (*Id.* at pp. 480 and 509). Results from several investigations suggest that the benefits of smoking cessation for FEV1 decline (a measure of the air capacity of the lungs) are greatest for persons who stop smoking at younger ages (*Id.* at p. 480).

Smoking also results in poor asthma control and it causes a range of respiratory symptoms in children, adolescents, and adults, including coughing, phlegm, wheezing, and shortness of breath (*Id.* at p. 509). Smoking cessation reduces the rates of these respiratory symptoms and of respiratory infections (*Id.* at p. 467).

Reproductive effects. Smoking has well-documented negative effects on fertility, on pregnancies, and on infants and children born to women who smoke. For example, studies show that women who smoke have reduced fertility (*Id.* at p. 541). Women who smoke during pregnancy are more likely to experience premature rupture of the membranes, placenta previa, and placental abruption (*Id.* at p. 576). Smoking also increases rates of preterm delivery and shortened gestation, and studies have indicated that women who smoke are twice as likely to have low birth weight infants as women who do not smoke (*Id.* at pp. 576 and 569). Smoking also causes an increased risk of sudden infant death syndrome (SIDS) for infants whose mothers smoke during and after pregnancy (*Id.* at pp. 587 and 601).

Other effects. Smoking has been shown to have a variety of other negative health effects. For example, cigarette smokers have poorer overall health status compared to nonsmokers; this may manifest as increased absenteeism from work and increased use of medical care services (*Id.* at p. 818). Smokers have an increased risk of adverse surgical outcomes related to wound healing and respiratory complications compared to nonsmokers (*Id.*). In postmenopausal women who smoke, smoking is associated with low bone density (*Id.* at p. 716). Smokers are also at an increased risk for hip fractures, which account for a significant proportion of the morbidity and mortality associated with osteoporosis (*Id.* at pp. 717–719). Smoking also increases the risk for periodontitis, cataract, and for the occurrence of peptic ulcer disease in persons who are *Helicobacter pylori* positive (*Id.* at pp. 736, 777, 780 and 813). Furthermore, smokers are at a greater risk of dying from peptic ulcer disease than nonsmokers (*Id.* at p. 807).

Addiction. Nicotine addiction is another negative effect of cigarette smoking. Nicotine is the primary chemical compound in tobacco that causes addiction, and the magnitude of public health harm caused by cigarettes is inextricably linked to the addictive nature of these products (Ref. 21 at p. 14; Ref. 5 at p. xi). Nicotine is psychoactive (mood altering) and can provide pleasurable effects; it also causes physical dependence characterized by withdrawal symptoms that usually accompany nicotine abstinence (Ref. 21 at p. 14). The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine (*Id.* at p. 9). Smokers develop tolerance to the effects of nicotine over time as well as a physical dependence on these effects, and as a result need greater amounts of nicotine over time to produce the same effects; thus smokers tend to smoke more over time to avoid withdrawal symptoms (*Id.* at pp. 50, 197–98). Withdrawal symptoms are common among persons attempting to quit smoking—in one study, 78 percent of subjects reported significant withdrawal symptoms (*Id.* at pp. 201–202).

In addition to physical dependence, nicotine addiction also results in conditioned behavior in smokers in response to situations and environmental stimuli associated with cigarette use. Smokers typically use cigarettes in certain patterns—*e.g.,* upon waking in the morning, after a meal, with a cup of coffee or an alcoholic beverage—and this patterned behavior is strongly reinforced by the pleasurable effects of nicotine (*Id.* at pp. 306–308; Ref. 17). Other stimuli associated with smoking itself, such as the smell of cigarette smoke or the sight of cigarette-associated paraphernalia, also become part of the conditioning process by repeated association with the desired physiological effects of nicotine (Ref. 21 at p. 307; Ref. 17). As these processes repeat over time as a result of regular smoking, these situations and stimuli become a powerful cue to smoke due to their association with the rewarding effects of nicotine, and the desire to smoke triggered by these situations can persist long after withdrawal symptoms subside (Ref. 17).

As a result of nicotine addiction, only a minority of smokers can achieve permanent abstinence in an initial quit

attempt. There are data suggesting that more than 70 percent of smokers in the United States report that they want to quit, and approximately 44 percent report that they try to quit each year (Ref. 19 at p. 15). This estimate is likely a significant underestimate of the actual number of quit attempts because unsuccessful quit attempts, particularly if short-lived or in the past, are often not reported in surveys. One study reported that at three months, 90.1 percent of quit attempts lasting less than one day, 63.7 percent of those lasting between a day and one week, and 38.9 percent of those lasting between one week and one month failed to be reported to researchers conducting surveys (Ref. 22). Many of the quit attempts that are reported are unsuccessful. For example, among the 19 million adults who reported attempting to quit in 2005, epidemiologic data suggest that only 4 to 7 percent were successful (Ref. 19 at p. 15). Similarly, the Institute of Medicine (IOM), considering data for 2004, found that although approximately 40.5 percent of adult smokers reported attempting to quit in that year, only between 3 and 5 percent were successful (Ref. 5 at p. 82). Furthermore, adults with education levels at or below the equivalent of a high school diploma have the highest smoking prevalence levels but the lowest quit ratios (*i.e.*, the ratio of persons who have smoked at least 100 cigarettes during their lifetime but do not currently smoke to persons who report smoking at least 100 cigarettes during their lifetime) (Ref. 23).

Adolescents also experience low success rates when attempting to quit. Most Americans who use tobacco products begin using when they are under the age of 18 and become addicted before reaching the age of 18 (Refs. 3 and 7). Although many adolescents believe "they can quit [smoking] at any time and therefore avoid addiction," nicotine dependence can be rapidly established (Ref. 5 at p. 89; see also Ref. 19 at p. 158). Research has shown that some adolescents report symptoms of withdrawal and craving within days or weeks of beginning to smoke (Ref. 24). As a result, many adolescents are nicotine dependent despite their relatively short smoking histories (Ref. 25). An analysis of data from the 2007 YRBS found that 60.9 percent of high school students who ever smoked cigarettes daily tried to quit smoking, but only 12.2 percent were successful (*Id.*). Research among adolescents also highlights their poor understanding of the difficulty of quitting smoking—for example, one study found that only 3 percent of 12th grade daily smokers estimated that they would still be smoking in 5 years, while in reality 63 percent of this population is still smoking daily 7 to 9 years later (Ref. 5 at p. 91).

Benefits of reduced prevalence. Dramatic declines in the deaths caused by the conditions discussed above can be achieved by further reducing smoking prevalence rates. Smoking cessation has major and immediate health benefits for men and women of all ages, regardless of health status (Ref. 26 at p. i). Smoking cessation decreases the risk of the health consequences of smoking, and former smokers live longer than continuing smokers. For example, persons who quit smoking before age 50 have one-half the risk of dying in the next 15 years compared with continuing smokers (*Id.* at p. v).

More importantly, preventing nonsmokers, particularly children, from starting smoking in the first instance would allow them to avoid nicotine addiction and the severe adverse health consequences of smoking. Preventing initiation would result in enormous public health benefits. As Congress found when enacting the Tobacco Control Act, "reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco-induced disease. Such a reduction in youth smoking would also result in approximately $75,000,000,000 in savings attributable to reduced health care costs" (section 2(14) of the Tobacco Control Act).

III. Data Concerning Health Warnings

A. Current Warnings on Cigarette Packages and Advertisements Are Inadequate

Section 201 of the Tobacco Control Act requires FDA to issue regulations mandating the use of color graphics depicting the negative health consequences of smoking to accompany the nine warning statements that are specified in section 4(a)(1) of FCLAA (15 U.S.C. 1333(a)(1)). The warning statements must be randomly displayed (*i.e.,* in each 12-month period, all of the different warnings must appear in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed) on cigarette packages and rotated quarterly in alternating sequence in cigarette advertisements, as provided by sections 4(c)(1) and 4(c)(2) of FCLAA (15 U.S.C. 1333(c)(1), (2)), as amended by the Tobacco Control Act. Congress directed that stronger and larger warning statements, accompanied by graphics, would replace the current text-only requirements. Data from studies indicate the current warnings on cigarette packages and advertisements are ineffective at communicating health risk information to consumers.

Cigarette packages and advertisements can be effective channels for communication of important health information. The warning on a cigarette package can provide a clear, visible vehicle to communicate risk at the most crucial time for smokers and potential smokers. Pack-a-day smokers are potentially exposed to warnings more than 7,000 times per year (Refs. 27–29). When utilized effectively, cigarette packages and advertisements can serve as an important channel for communicating health information to broad national audiences that include both smokers and nonsmokers.

The inclusion of strong health warnings on packages and in advertisements can thus provide a critical opportunity to educate consumers about the health risks of cigarettes, support intentions among current smokers who want to quit or decrease cigarette consumption, and discourage nonsmokers, particularly youth, from initiating cigarette use. Prominent displays of warnings increase their effectiveness; larger warnings, with pictures, are more likely to be noticed by consumers, communicate information about health risks to consumers, and reinforce intentions among tobacco users who want to quit (Ref. 30).

However, cigarette warnings in the United States have not been changed or improved in more than 25 years. The unchanging nature of these warnings, as well as their relatively small size and lack of a graphic image component, severely impairs their ability to effectively communicate to consumers. Research has repeatedly illustrated that the current warnings used in the United States frequently go unnoticed or fail to convey relevant information regarding health risks.

1. Current Warnings Have Not Changed in More Than Twenty-Five Years

In response to the Surgeon General's first major report on smoking and health in 1964, Congress passed FCLAA to require warning labels on all cigarette packages. The warning, which was required to be conspicuous and legible, was written in small print and located on one of the side panels of each cigarette package. It stated "CAUTION: Cigarette Smoking May Be Hazardous to

Your Health." This language appeared on all cigarette packs sold from January 1, 1966, through October 31, 1970. In 1969, Congress passed the Public Health Cigarette Smoking Act (Public Law 91–222), which slightly modified the warning statement on cigarette packages, but did not yet require any warnings on cigarette advertisements. The new warning language, "Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Health," appeared on cigarette packages sold in the United States from November 1, 1970, through October 11, 1985. In 1972, the Federal Trade Commission (FTC) issued consent orders requiring six major cigarette manufacturers and distributors to include in all their cigarette advertisements a clear and conspicuous disclosure of the warning required to be on packages (Ref. 31 at 460–65).

In 1981, the FTC issued a report to Congress that concluded that the then-current health warning labels had little effect on public awareness and attitudes toward smoking. The FTC stated that the existing warning likely was ineffective because it "(1) is overexposed and worn out, (2) lacks novelty, (3) is too abstract, and (4) lacks personal relevance" (Ref. 32 at pp. 7–16).

Subsequently, Congress again modified cigarette warnings by passing the CSEA, which required the following four rotational health warnings on packages and advertisements [5]:

- "SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy."
- "SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health."
- "SURGEON GENERAL'S WARNING: Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth and Low Birth Weight."
- "SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide."

In addition, the law established the location and format for these warning statements and mandated that the warnings be rotated quarterly, which helped keep them from becoming stale. Despite a FTC recommendation to change the size and shape of warnings, Congress retained the size and rectangular format of previous warnings.

More than twenty-five years have passed since these last changes, and there is a substantial body of evidence that these warnings do not effectively communicate information about the adverse health effects of smoking to the American public, as discussed in more detail below. Given the extreme hazards cigarettes pose to the public health, the revised warnings required under section 4 of FCLAA (15 U.S.C. 1333) and provided in this proposed rule are critical to the effective communication of the health risks of smoking, and should encourage current smokers to consider cessation and discourage nonsmokers from initiating use of cigarettes.

2. Current Warnings Often Go Unnoticed

The CSEA requires the current warnings to be "conspicuous and legible" with the same package location and font size required on the date of enactment (*i.e.,* October 12, 1984). However, researchers have found that these health warnings go largely unnoticed and unconsidered by both smokers and nonsmokers. For example, a major study into tobacco policy in the United States by the IOM in 2007 concluded that U.S. package warnings are both "unnoticed and stale" (Ref. 5 at p. 291). The Chair of the IOM's Committee on Reducing Tobacco Use has described the warnings on cigarette packs as "invisible" (Ref. 4).

Research regarding warning statements in cigarette advertisements has shown similar results. For example, one study of the recall and eye-tracking of adolescents viewing tobacco advertisements found: 43.6 percent of adolescents did not even look at the warning statement included in the advertisement; just 36.7 percent looked at the warning long enough to read any of its words; and the average viewing of the warning only accounted for 8 percent of the total viewing time (Ref. 33). Researchers in this study also determined that adolescents are unable to recall the content of the current cigarette warnings or to correctly recognize the warnings from a list, indicating that the current warnings are likely to be ineffective among younger consumers (*Id.*).

Another study of adolescents also found that they are not seeing, reading, and remembering health warnings on cigarette packages and advertisements (Ref. 34). In this study of ninth-grade students, only 32 percent of regular smokers recalled seeing one of the current warnings which states: "Quitting Smoking Now Greatly Reduces Serious Risks To Your Health" (*Id.*). In addition, almost 20 percent incorrectly reported having seen a simulated health warning that is not among one of the four current required warnings (*Id.*).

Data from a 1989 study indicate that consumers also fail to notice or read health warnings on outdoor billboards and taxicab cigarette advertisements (though these advertising media are no longer in common use). According to this study, which was published in the Journal of the American Medical Association, drivers only read the entire warning message on 5 percent of highway billboard advertisements and were only able to fully read the health warning on 18 of the 39 street advertisements used in this study (Ref. 35). Participants were unable to read, even partially, the Surgeon General's warnings in any of the 47 taxicab advertisements used in this study (*Id.*). Yet, those same consumers were able to identify the brand name and imagery on 100 percent of the highway billboards (*Id.*). Likewise, these participants were able to identify the brand name in 100 percent and the imagery in 95 percent of the taxicab advertisements (*Id.*). These results indicate that the current warnings are not appropriately conspicuous in advertisements compared to the rest of the advertising message, as discussed in more detail below.

3. Current Warnings Fail To Convey Relevant Information in an Effective Manner

Even when consumers notice and contemplate the current health warnings on cigarette packages and in advertisements, there is clear evidence that these warnings fail to appropriately convey crucial information such as the nature and extent of the health risks associated with smoking cigarettes. The current small, wordy text-based messages are ambiguous, providing less health information than is provided regarding many other consumer goods that have significantly less harmful impact on people's health (Ref. 36).

In its 2007 Report, the IOM concluded that the current U.S. warnings fail to convey relevant health information in an effective way (Ref. 5 at p. 291). The IOM cited an International Tobacco Control Policy Evaluation Study, which found that 85 percent of Canadian respondents cited packages (which, in Canada, contain prominent text and graphic health warnings) as a source of health information, while only 47 percent of U.S. smokers cited packages as a health information source (*Id.* at 294, citing Ref. 37).

Studies also have shown that the current warnings do not motivate consumers to look at them long enough to consider the concept being communicated. For example, researchers have found that the warning

[5] Slightly different health warnings were required on outdoor billboard advertisements.

statements fail to attract attention or to make the consumer appropriately aware of the health risks of smoking (Ref. 38). In a study of U.S. and Canadian smokers and nonsmokers, researchers found that participants voluntarily examined warnings on Canadian packages, which include prominent text and graphics, for longer durations than U.S. package warnings, because the current text-only messages used in the United States are not memorable for consumers (*Id.*). The mere textual presentation of vague hazard information in the current U.S. warnings is not sufficient to motivate perceptions of risk (*Id.*).

The content and format of the current warnings have failed to successfully draw and hold consumers' attention, especially when placed in competition with the other text, images, and graphics that cigarette companies have used on packaging and in advertising, which have been thoroughly tested, regularly updated, and artfully crafted by tobacco companies. According to the most recent data from the FTC, tobacco companies spent approximately $12.49 billion on advertising and promotion in 2006 (Ref. 39 at p. 1). Tobacco companies frequently have employed marketing and advertising experts to craft campaigns with messages targeted to certain demographics (Ref. 40 at p. 7). The messages developed by companies in cigarette advertisements cover 96 percent of the space, are continuously updated to incorporate current trends, and are targeted based on market research. In contrast, the current health warnings cover only 4 percent of advertising space, are solely textual, are not targeted to any population group, and consist of only four rotating messages that have not been updated for more than two and a half decades. On cigarette packages, these warnings appear only on one side panel. As a result, the important health messages frequently are functionally invisible in comparison to the rest of the advertisement and package (Ref. 33 at p. 88).

Moreover, even if consumers notice the current warnings, those with less education may not be able to adequately comprehend the text-only messages. In its 2007 Report, the IOM expressed concern about the ability of consumers with less education to recall the information included in text-based messages (Ref. 5 at p. 295). The IOM cited a study of Canadian smokers' knowledge about the country's prior warning requirements, which, like the current U.S. health warnings, only contained four textual warning statements. In that study, researchers noted that comparatively few women with lower educational attainment were aware of messages warning of the impacts of smoking on life expectancy, heart disease, or pregnancy (Ref. 41). Because the current U.S. smoking population has various levels of education (including a high percentage of people with low educational attainment) and includes teenagers (who have yet to complete their education), the current text-only warnings are inadequate.

B. Larger, Graphic Warnings Communicate More Effectively: International Experience

In 2001, Canada introduced graphic health warnings depicting the adverse health consequences of smoking on the upper 50 percent of the two primary panels of cigarette packages. Those warnings, like the warnings proposed here, include a photograph or other image, a marker word "WARNING," and a warning statement. By mid-2009, 28 countries also required graphic warnings and more countries are planning to do so.

In its 2007 Report, the IOM concludes that the available scientific evidence indicates that larger, graphic health warnings would promote greater public knowledge of the health risks of using tobacco and would help reduce consumption (Ref. 5 at p. 295). Similarly, an article published by WHO concludes that, taken as a whole, the research on graphic health warnings show that they are (1) more likely to be noticed than text-only warnings, (2) more effective for educating smokers about the health risks of smoking and for increasing the time smokers spend thinking about the health risks, and (3) associated with increased motivation to quit smoking (Ref. 42).

1. Getting Consumers' Attention

Several design features are associated with greater salience (*i.e.,* noticeability and readability) of health warnings, including the size and position of warnings on the cigarette package. Smokers are more likely to recall larger warnings, as well as warnings that appear on the front of packages (Ref. 5 at p. C–3). Warnings that include pictures or graphics likewise are more noticeable and more likely to be recalled than text-only warnings (*Id.* at p. C–4).

In Canada, awareness of warnings on cigarette packages was almost universal among smokers and very high even among nonsmokers after that country required cigarette packages to display large, graphic warnings on the front and rear panels. In a 2001 cross-sectional survey sponsored by the Canadian Cancer Society, 90 percent of Canadian smokers and 49 percent of nonsmokers noticed changes to the Canadian health warnings after the introduction of pictorial warnings (Ref. 43). Similarly, a survey of youth sponsored by Health Canada showed that 73 percent of those who have never smoked, 86 percent of "puffers" (*i.e.,* those who had tried smoking but never smoked a whole cigarette), and 90 percent of those who have smoked beyond puffing reported seeing health warnings on cigarette packages in 2002, a year after the introduction of graphic warnings in Canada (Ref. 44). In a study of young adults, 98.5 percent of smokers, 88.9 percent of occasional smokers, and 67.5 percent of those who have never smoked reported that they were aware of the Canadian graphic health warnings (Ref. 45).

Survey evidence also shows that awareness of health warnings on cigarette packages increased significantly after Australia required large, graphic warnings in 2006. In one study, smokers were more likely to report that over the past month they noticed the enhanced warnings and read or looked closely at them compared to the old warnings (Ref. 46). Among students in year levels 8 to 12 in Melbourne, cognitive processing of cigarette warnings (*i.e.,* reading, attending to, thinking and talking about the warnings) increased in the year that Australia adopted graphic warnings (Ref. 47). Developmental focus group research conducted for Australia as it considered whether to require graphic warnings similarly reported that graphic warnings on cigarette packs were potentially more likely to help people remember the health effects and warnings (Ref. 48).

Experimental studies also indicate that requiring large, graphic warnings would significantly increase the salience of health warnings on cigarette packages. In one experimental study, U.S. college students were shown images of the Canadian cigarette warnings and the current warnings appearing on cigarette packs sold in the United States. Compared to the U.S. warnings, the Canadian graphic warnings significantly increased aided recall of the warnings, increased depth of message processing, and increased the perceived strength of the message (Ref. 49). Similarly, in focus group research conducted among young adults in the United States, participants reported that the Canadian warnings were more visible and more informative than the warnings appearing on cigarette packages in the United States (Ref. 50).

2. Influencing Consumers' Awareness of Cigarette-Related Health Risks

Large, pictorial warnings graphically convey the harm and danger that tobacco use causes, eliciting an immediate impact. Effective communication of the health risks associated with cigarette use is critical from a public health perspective, as smokers who perceive a greater health risk from smoking are more likely to want to quit and to be successful in their quit attempts (Ref. 37). National surveys conducted on behalf of Health Canada indicate that approximately 95 percent of youth smokers and 75 percent of adult smokers report that the Canadian pictorial warnings have been effective in providing them with important health information (Ref. 5 at p. 294). The 2001 survey conducted by the Canadian Cancer Society found that the country's pictorial warnings, which had recently been introduced, resulted in 58 percent of smokers reporting that they thought about the health effects of smoking more frequently than previously (Ref. 43). Among Canadian adult smokers in Ontario, 51 percent of study participants reported that the pictorial warnings made them think about the health effects of smoking (Ref. 51). Canadian smokers were more likely to report cigarette packages as a source of information about the health risks of smoking than smokers in the United States and other countries with text-only warnings (Ref. 37).

Similarly, a study conducted for officials in Australia found that graphic warnings increased participants' knowledge and awareness of the health risks of smoking, especially among current smokers and recent quitters (Ref. 52). A street intercept study in Australia suggests that graphic warnings may also increase smokers' perceptions of their personal risks of smoking. In that study, 51 percent of participants stated that the graphic warnings on cigarette packs increased their perceived risk of dying from smoking (Ref. 53).

Graphic warnings appear to influence risk perceptions among youth as well as adults. In a cross-sectional survey of middle and high school students in Greece, participants were shown several graphic warnings prepared by the European Union as well as text-only warnings. Study participants consistently selected the graphic warnings as more effective in making them think about the effects of smoking on health (Ref. 54). Similarly, in a youth survey conducted by Health Canada, approximately two-thirds of youth nonsmokers reported looking at the pictorial warnings at least once a week and, as indicated above, 95 percent agreed that the warnings had been effective in providing them with important information about the health effects of smoking (Ref. 5 at p. C–5).

In an Internet-based study of current and former young adult smokers in the United States, the Canadian graphic warnings were rated as significantly more effective than the current U.S. warnings on cigarette packs for conveying concerns about the health risks of smoking (Ref. 55).

3. Impacting Smoking Intentions and Behaviors

In addition to increasing consumer awareness of the health risks of smoking, the proposed graphic warnings also seek to impact changes in smoking behavior. There are some studies indicating that large, graphic warnings increase smokers' intentions to quit smoking or motivate them to quit smoking.

The 2001 survey sponsored by the Canadian Cancer Society shows that 44 percent of adult smokers stated that the Canadian graphic health warnings increased their motivation to quit smoking (Ref. 43). In another study of Canadian young adults (ages 20 to 24), 37 percent of male participants and 48 percent of female participants reported that the warnings on cigarette packs led them to think about quitting smoking (Ref. 45). In this same study, 36 percent of male participants and 34 percent of female participants also indicated that the cigarette warnings might make young people less likely to start smoking. Some studies indicate that exposure to graphic warnings increases quit intentions among youth smokers as well. A study of Australian adolescents shows that experimental and established youth smokers thought more about quitting after the introduction of graphic warnings in Australia (Ref. 47).

There is also evidence suggesting that graphic warnings may be more effective at preventing youth initiation than text-only warnings. For example, in a cross-sectional survey of middle and high school students in Greece where participants were shown several graphic warnings prepared by the European Union as well as text-only warnings, the adolescents rated the graphic warning labels as more effective in preventing them from smoking (Ref. 54).

A few studies also indicate that large graphic health warnings may increase quit attempts. In Canada, smokers who quit smoking after the introduction of graphic warnings were 2.78 times more likely to identify health warnings as a motivation for their quitting than former smokers who quit during the two years before graphic warnings appeared on Canadian cigarette packages (Ref. 29). In one Australian study, participants reported increased attempts to quit smoking after cigarette packs displayed graphic warnings, although there was no association with short-term quit success (Ref. 46).

Some studies also indicate that large, graphic warnings may induce individual smokers to reduce consumption. The Canadian Cancer Society survey indicated that 21 percent of smokers reported that on one or more occasions they chose not to smoke a cigarette due to the warnings on cigarette packages (Ref. 43). The survey also indicated that 27 percent of participants reported that the then-new graphic warnings motivated them to smoke less inside their homes (*Id.*). In another study involving young adults in Canada, 22.6 percent of current male smokers and 26.6 percent of current female smokers reported that in the past month, noticing the warning on cigarette packages led them to decide not to have a cigarette (Ref. 45). In a study of Australian youth smoking behavior, adolescents who were experimenting with smoking or were established smokers indicated that they thought more about forgoing cigarettes after graphic warnings appeared on cigarette packages in 2006 (Ref. 47).

One study suggests that graphic warnings may help persons who have quit smoking remain abstinent from smoking. In that study, 26 percent of former smokers in Canada reported that the then-new graphic warnings on cigarette packages helped them remain abstinent (Ref. 29).

Canadian national survey data also suggest that graphic warnings may reduce smoking rates. Smoking prevalence among Canadians aged 15 or older dropped from 24 percent in 2000 (before the graphic warnings were introduced) to 22 percent in 2001 and 21 percent in 2002 (Ref. 56). It is not possible to draw a direct causal connection between the graphic warnings and these data because other smoking control initiatives, including an increase in the cigarette tax and new restrictions on public smoking also occurred during the same period. At the same time, however, these data are suggestive that large graphic warnings may reduce smoking consumption.

After considering the available scientific evidence, the IOM concluded in its 2007 Report that "[o]n the basis of the evidence accumulated thus far, [larger,] graphic warnings of the kind required in Canada, Brazil and Thailand 'would promote greater public understanding of the risks' of using

tobacco and would help reduce consumption" in the United States (Ref. 5 at p. 295).

C. Benefits of FDA's Proposed Required Warnings

FDA has carefully assessed the scientific literature studying the impact of graphic images on the salience (*i.e.,* noticeability and readability) of warnings, on the effective communication of the health risks of smoking, and on changes to smoking behavior. Although much of the available research involved comparisons of warnings that differ in more than one aspect (*i.e.,* text size, use of graphics, and number of images), the overall body of available research has illustrated that the use of large text, color graphics, and multiple rotating health statements will significantly improve the communication of the health risks of smoking to the general public in the United States and delay wear-out of these important health messages.

Our assessment of the literature and our experience as a public health agency provide support for requiring that the nine textual warning statements listed in section 4(a)(1) of FCLAA (15 U.S.C. 1333(a)(1)) appear on cigarette packages and in cigarette advertisements, and that each textual warning statement be accompanied by a specified color graphic image. It also supports the proposal that the required warnings should comprise the top 50 percent of the area of each of the front and rear panels of cigarette packages and 20 percent of the area of cigarette advertisements in the United States in accordance with section 4 of FCLAA (15 U.S.C. 1333(b)). The statute and this proposal is consistent with the international consensus reflected in the WHO's Framework Convention on Tobacco Control, *i.e.,* the proposed warnings would be rotating, large, clear, visible, and legible, and would occupy "50 percent or more of the principal display areas" of packages. WHO FCTC art. 11.1(b). Further, we believe that the available evidence demonstrates that the addition of color graphics to the nine new textual warning statements would ensure that warnings on packages and in advertisements effectively provide critical information to consumers while continuing to afford tobacco manufacturers and retailers ample space (over 50 percent of packages and 80 percent of advertisements) to convey other information regarding the product.

1. The Addition of Graphic Images Will Have a Significant, Positive Impact on Public Health

As summarized in section III.B, research on cigarette warnings with a graphic component has found that they are more effective in educating consumers about smoking risks than text-only warnings (Ref. 42), and are more likely to be effective in impacting smoking behaviors (Ref. 27). Moreover, the available scientific literature suggests that cigarette packages with larger, text-only warnings are inferior to cigarette warnings with a graphic component in both communicating health information and encouraging smoking cessation.

For example, data comparing the Canadian graphic warnings and the United Kingdom (UK) text-only warnings, after the UK substantially increased the number and size of its warnings (from 6 warnings that covered 6 percent of the front and back of cigarette packages to 16 warnings that covered 30 percent of the front and 40 percent of the back of the packages), found that the Canadian pictorial warnings had a greater impact on smokers than the new UK warnings (Ref. 36). Specifically, data collected 2.5 years after the implementation of the Canadian pictorial warnings and 2.5 years after the implementation of the larger, text-only UK warnings found that, while the UK respondents reported greater levels of salience (*i.e.,* noticing and reading the warnings) than Canadian smokers, Canadian smokers were significantly more likely to stop smoking a cigarette as a result of the graphic warnings and to report that the graphic warnings had led them to think about quitting. Canadian smokers also were significantly more likely than those in the UK to report that the warnings made them think about the health risks of smoking.

Likewise, data comparing the impact of Australia's graphic warnings (introduced in 2005) and the UK's larger, text-only warnings showed similar support for the use of a graphic component (Ref. 46). Specifically, researchers found greater increases in the two strongest predictors of subsequent quitting—cognitive responses (*i.e.,* thinking about the health risks of smoking) and foregoing cigarettes—after Australia introduced its graphic warnings than after the UK introduced its enhanced text-only warnings. This is especially noteworthy, given that when the border is taken into account, the graphic warnings on the front of the packages in Australia were smaller than the UK's text-only warnings on the front of the packages.

It is worth noting that the UK amended its Tobacco Products (Manufacture, Presentation and Sale) (Safety) regulations in 2007 to require graphic warnings to appear on all cigarette packages as of October 2009.

Furthermore, although both text and graphic cigarette warnings are subject to wear-out over an extended period of time, research has shown that graphic warnings maintain their impact longer than text-only warnings. Approximately four years after the introduction of the 16 Canadian graphic warnings, youth and adult smokers reported little or no decrease in their effectiveness (Ref. 42; Ref. 36; Ref. 5 at C–4). Similarly, the use of color graphics in the proposed required warnings, coupled with the increase in the number of rotating health statements required under section 4 of FCLAA (15 U.S.C. 1333) and this proposed rule from four to nine, will help ensure that the new cigarette health warnings being proposed will retain beneficial effects over time (Ref. 5 at C–4).

2. The Revised Textual Statements Will Communicate More Effectively

The proposed required warnings would also modify the textual warning statements currently required on cigarette packages and in advertisements. Section 201(a) of the Tobacco Control Act sets forth nine text statements that will replace the four statements currently required under FCLAA once any final rule becomes effective. These nine statements objectively communicate some of the major health risks associated with smoking in a more effective manner compared to the warning statements currently required in the United States. As the IOM explained, specific, unambiguous warnings (*e.g.,* "cigarettes cause lung cancer") are more likely to be noticed and less likely to be discounted than vague warnings (*e.g.,* "cigarettes are hazardous to your health"), and warnings should target an appropriate literacy level (*Id.* at C–3). The new textual warning statements set forth in the Tobacco Control Act represent an improvement over the current warnings in that they are specific and unambiguous and they succinctly describe documented outcomes of cigarette use and exposure. For example, the vague warning that "Cigarette Smoke Contains Carbon Monoxide" will no longer be used, and two of the longer warnings currently in use, "Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy" and "Smoking

by Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight," will be replaced with shorter, more readable statements (*e.g.,* "Cigarettes cause fatal lung disease," "Cigarettes cause cancer," "Cigarettes cause strokes and heart disease," "Smoking during pregnancy can harm your baby," and "Smoking can kill you"). The proposed required warnings also will be easier to understand because of the addition of the graphic component (*Id.* at 295).

Thus, the nine specific textual warning statements set forth in section 201(a) of the Tobacco Control Act would effectively convey the major health risks of smoking, which will help discourage nonsmokers from initiating cigarette use, and encourage current smokers to consider cessation, particularly when combined with graphic images depicting the negative consequences of smoking. We intend to monitor the effects of these required warnings once they are put into use. In addition, there will continue to be social science research conducted regarding the relative efficacy of various required warnings. We will use the results of our monitoring and such research to determine whether any of the textual warning statements or accompanying graphic images should be revised in a future rulemaking.

D. FDA's Process for Development and Plan for Selection of the Required Warnings

Section 4(d) of FCLAA (15 U.S.C. 1333(d)), as amended by section 201 of the Tobacco Control Act, requires FDA to issue "regulations that require color graphics depicting the negative health consequences of smoking" to accompany the textual warning statements specified in section 4(a)(1) of FCLAA (15 U.S.C. 1333(a)(1)). In considering and developing appropriate color graphics to accompany the textual warning statements, FDA assessed the graphic warnings that other countries have required for tobacco products. In addition, FDA worked with various experts in the fields of health communications, marketing research, graphic design and advertising to develop the required warnings published with the proposed regulation.

The proposed required warnings, consisting of the color graphics FDA developed and the textual warning statements, are available as electronic files in portable document format (PDF) in this docket and on FDA's Web site at *http://www.fda.gov/cigarettewarnings.* For the final rule, the required warnings will be contained in documents titled "Cigarette Required Warnings—English and Spanish" and "Cigarette Warnings—Other Foreign Language Advertisements," as is further discussed in section IV.D. Drafts of these two documents are included in the docket as well.

The set of required warnings available with this proposed rule encompasses a variety of themes and graphic techniques. The required warnings are designed to communicate risk information to a diverse range of audiences, including youth, young adults, and adults, and of smokers as well as potential smokers. The images in some of the required warnings are photographic while others are graphic illustrations. Some images are more visually disturbing than others. The fonts, typography, and layouts vary.

FDA believes that the graphics in the proposed required warnings appropriately depict the negative health consequences of smoking. Further, FDA believes that these graphics are consistent with the types of pictorial warnings required or developed by other international governmental authorities, such as Canada, the European Union, and Australia, whose sets of warnings include a balance of images, some more visually disturbing than others. FDA also believes that including a varied set of warnings is consistent with the existing scientific literature concerning the effectiveness of graphic health warnings.

The existing research shows that the effectiveness of health warnings in communicating the health risks of smoking may vary according to the audience, reflecting factors such as socioeconomic background, gender, age, and smoking status and behavior (Ref. 57 at p. 22). A variety of health warnings facilitates better targeting of specific groups whose primary concerns about smoking tend to vary (*Id.* at p. 46). Specific issues that may make smoking desirable (or undesirable) for one group might be quite different for another group (*Id.* at p. 44). Similarly, using a variety of different warnings has been found to be significant in counteracting over-exposure and wear-out of health warnings (*Id.* at p. 46). In addition, in some cases, the strength of the content of the message is what determines its impact, while in other cases, peripheral factors, such as how and where the message is delivered and its visual impact are the most significant determinants (*Id.* at p. 28). In order to be effective with a broad audience, health warnings should be developed with these different factors in mind (*Id.*).

The existing research indicates that a balanced set of graphic warnings that includes a range and variety of images is effective. For example, the use of health warnings with "frightening" or "disturbing" tonal qualities appears effective (*Id.* at pp. 37–39). Consistent with this research, some of the images published with the proposed regulation are more "frightening" or visually disturbing than others.

Research also indicates that other types of graphic warnings, including those that do not include "frightening" or "disturbing" imagery, can be effective (Ref. 52 at pp. 24–25). For example, graphic health warnings that convey the risks of secondhand smoke for babies and children without being "frightening" or "disturbing" appear to have widespread impact (*Id.;* Ref. 57 at pp. 34–35). The set of proposed required warnings includes health warning statements and accompanying images that convey the risk of secondhand smoke on children and babies and the risk of smoking while pregnant.

Similarly, evidence also shows that warnings about specific health risks, such as cancer, heart disease, and stroke, are more effective than general warnings, and that the effectiveness of graphic warnings relating to specific health concerns tends to vary for different smoker groups, reflecting their perceived relevance (Ref. 52 at pp. 24–25; Ref. 57 at p. 34). The statements and images published with this proposed rule portray specific health risks using a variety of themes and techniques in order to reach different smoker groups.

According to the existing research, graphic warnings that focus on the benefits of quitting may also be effective (Ref. 57 at p. 35). The set of published images includes warnings addressing the benefits of quitting.

In addition to the types of messages and images, the salience or noticeability of health warnings is enhanced by the use of larger type size, contrasting colors, and different typography (*Id.* at p. 28). Research assessing responses to warnings on tobacco product packaging, as well as responses to safety warnings generally, indicate that the effectiveness of warnings is enhanced through techniques such as larger font sizes, upper case lettering, and bold type (*Id.* at p. 33). A number of the proposed required warnings utilize these techniques.

Although FDA expects that any final rule will include a total of nine different required warnings, it has developed a larger set of images for the proposed rule. FDA is seeking comments on what required warnings to include in the final rule, including comments on the color graphics that are included in this proposal.

In addition to seeking comment on what color graphics to require in the final rule, FDA is conducting research on the proposed required warnings. The larger set of required warnings developed for this proposed rule will allow for more productive research into the relative efficacy of the different proposed color graphics. The research will: (1) Measure consumer attitudes, beliefs, and intended behaviors related to cigarette smoking in response to the proposed color graphics and their accompanying textual warning statements; (2) determine whether consumer responses to the proposed color graphics and their accompanying textual warning statements differ across various groups based on smoking status, age, or other demographic variables; and (3) evaluate the relative effectiveness of the proposed color graphics and their accompanying textual warning statements at conveying information about various health risks of smoking, and additionally, at encouraging smoking cessation and discouraging smoking initiation (*See* 75 FR 7604 (February 22, 2010); 75 FR 52352 (August 25, 2010)). FDA is in the process of conducting this research. Once the research is complete and final analyses of the results are available, FDA will place a report of the results of the analyses in the docket and announce the report's availability by a notice in the **Federal Register** so the public has an opportunity to comment on the results.

After considering the public comments, research results, and scientific literature, FDA plans to select a set of nine required warnings for the final rule, each of which is comprised of one color graphic that is paired with one of the nine textual warning statements. Thus, FDA intends to select nine images from among the larger set of images in this proposed rule for actual use. The agency believes that nine required warnings will be sufficient to achieve its goal of effectively communicating the health risks of smoking and to prevent wear-out of the proposed required warnings for several years.

In addition, another set of color graphics is proposed for use solely in advertisements with a small surface area (*i.e.,* less than 12 square inches). The color graphics in this set differ in their composition from the other color graphics in that the details of the images should be clear, conspicuous, and legible even when the graphics are reduced in size to be placed on surfaces with a relatively small area. FDA proposes that the final version of "Cigarette Required Warnings—English and Spanish" also contain graphics from this set, which would only be used in advertisements with a small surface area. But even an advertisement with a relatively small surface area would need to be large enough so that the required graphic and accompanying textual warning statement are clear, conspicuous, and legible.

IV. Description of Proposed Regulations

The Tobacco Control Act mandates that FDA issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany the nine health warning statements that must appear on cigarette packages and in cigarette advertisements under FCLAA (15 U.S.C. 1333). FDA proposes to implement this requirement for cigarette packages and advertisements by adding a new part 1141 to title 21 of the Code of Federal Regulations governing cigarette package and advertising warnings.

The graphic warnings rule, when finalized, is intended to help educate consumers about the health risks of cigarettes, to support intentions among current smokers to quit or decrease cigarette consumption, and to discourage nonsmokers, particularly youth, from initiating cigarette use. We seek comment on the proposed part 1141 described below. If you have comments on specific provisions of the proposed regulation, we request that you identify these provisions in your comments. In addition, if you have concerns that would be addressed by alternative text, we request that you provide this alternative text in your comments.

A. Section 1141.1—Scope

Proposed § 1141.1 would set forth the scope of the proposed regulations. Proposed § 1141.1(a) explains that part 1141 would set forth the requirements for the display of the health warnings on cigarette packages and advertisements required by section 4 of FCLAA (15 U.S.C. 1333), as amended by the Tobacco Control Act. This paragraph would also indicate that FDA has the authority to require additional statements on cigarette packages and advertisements in accordance with the FD&C Act or other authorities (such as FCLAA). For example, section 4 of FCLAA, as amended by section 206 of the Tobacco Control Act, requires the agency to initiate a rulemaking to determine whether cigarette and other tobacco product manufacturers should be required to disclose the tar and nicotine yields in advertisements and/or on packages. In addition, section 906(d) of the FD&C Act authorizes FDA to issue regulations restricting the sale or distribution of cigarettes and other tobacco products, including restrictions on the advertising and promotion of such products, if FDA determines the restriction is appropriate for protecting public health.

Proposed § 1141.1(b) would limit the applicability of the proposed requirements by clarifying that these requirements would not apply to manufacturers or distributors of cigarettes that do not manufacture, package, or import cigarettes for sale or distribution in the United States.

In accordance with section 4(a)(4) of FCLAA (15 U.S.C. 1333(a)(4)), proposed § 1141.1(c) would provide that a cigarette retailer would not be in violation of the proposed rule if cigarette packages displayed or sold by the retailer do not comply with all the requirements set forth in the proposed rule, so long as the packages contain a health warning, are supplied by a license- or permit-holding tobacco product manufacturer, importer, or distributor, and are not altered by the retailer in a way that materially impacts the display of the required warnings on the packages. Thus, manufacturers, importers, and distributors would have primary responsibility for ensuring that the required warnings on cigarette packages comply with all the provisions of proposed part 1141, but retailers would have some responsibility as well. Specifically, retailers would be responsible for ensuring that all cigarette packages they display or sell contain a warning regarding the health risks associated with smoking cigarettes. In addition, retailers could not alter the warning in a way that is material to the requirements of FCLAA and this proposed rule, including by obscuring the warning (*e.g.,* by placing a sticker or other item on top of it), by shrinking or severing the warning (in whole or in part), or by otherwise changing it in a material way. However, retailers would not be responsible for verifying that the warnings on packages they display or sell contain the combination of textual statements and accompanying color graphics required by FCLAA, or that they comply with other specifications required in FCLAA or proposed part 1141.

Similarly, proposed § 1141.1(d) implements section 4(c)(4) of FCLAA (15 U.S.C. 1333(c)(4)) and would provide that a retailer would not be considered in violation of part 1141 if it posts an advertisement that does not comply with all of the proposed requirements, so long as the advertisement was not created by or on behalf of the cigarette retailer and the

retailer is not otherwise responsible for inclusion of the required warnings. Note that, in accordance with section 4(b) of FCLAA (15 U.S.C. 1333(b)), any manufacturer, distributor, importer, or retailer who is responsible for the creation of a cigarette advertisement is responsible for compliance with FCLAA and proposed part 1141. This paragraph also specifies that this provision would not relieve a retailer of liability if it publicly displays an advertisement that fails to contain a health warning or if it alters an advertisement in a way that materially impacts the display of the required warning. Therefore, except for when it is responsible for the creation of an advertisement or otherwise responsible for the inclusion of the warning, a retailer is not responsible for ensuring that its cigarette advertisements contain the combination of textual statements and accompanying color graphics required by FCLAA, or that they comply with other specifications required in FCLAA or proposed part 1141. However, retailers must ensure that their cigarette advertisements contain a warning of smoking's risks. They are also responsible for complying with the other requirements applicable to retailers, including those in part 1140 of Title 21 of the Code of Federal Regulations.

B. Section 1141.3—Definitions

Proposed § 1141.3 would establish definitions of terms used in the proposed rule.

Proposed § 1141.3 would define the terms "cigarette," "commerce," "package," "person," and "United States," respectively, for the purposes of part 1141, as those terms are defined in section 3 of FCLAA (15 U.S.C. 1332).

Proposed § 1141.3 would define "distributor," for the purposes of part 1141, as any person who furthers the distribution of cigarettes at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. In addition, this paragraph would specify that common carriers are not considered distributors for the purposes of part 1141.

Proposed § 1141.3 would define the terms "front panel" and "rear panel" as the two largest display surfaces of the cigarette package. FDA is proposing this definition to ensure that all entities properly identify the sides or surfaces of the cigarette package on which the required warnings must appear. On almost all cigarette packages, these two panels are oriented directly opposite from one another and are the same size.

Proposed § 1141.3 would define "importer," for purposes of this part, as any person who introduces into commerce any cigarette that (1) was not manufactured in the United States and (2) is intended for sale or distribution to consumers in the United States.

Proposed § 1141.3 would define "manufacturer" as any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette product.

Proposed § 1141.3 would provide a definition of "required warning." This term is used to refer to the combination of one of the textual warning statements and the accompanying color graphic depicting the negative health consequences of smoking required under section 4 of FCLAA and this part.

Proposed § 1141.3 would define "retailer" as any person who sells cigarettes to individuals for personal consumption, or who operates a facility where vending machines or self-service displays of cigarettes are permitted.

C. Section 1141.10—Required Warnings

The Tobacco Control Act directs FDA to require that color graphics depicting the negative health consequences of smoking accompany each of the textual warning statements that must be randomly displayed (*i.e.,* in each 12-month period, all of the different warnings must appear in as equal a number of times as is possible on each brand of the product and be randomly distributed in all areas of the United States in which the product is marketed) on cigarette packages and rotated quarterly in alternating sequence in cigarette advertisements under FCLAA. FDA is proposing that cigarette packages and advertisements contain such a combination graphic-textual warning in proposed § 1141.10.

Proposed paragraph (a) would set forth the requirements specific to cigarette packages. Proposed § 1141.10(a)(1) would require that each cigarette package sold, offered for sale, distributed, or imported for sale or distribution within the United States contain a required warning. This required warning would have to appear on both the front and rear panels of the cigarette package. As defined in proposed § 1141.3, this required warning would consist of one of the nine textual warning statements set forth in FCLAA (15 U.S.C. 1333) and the accompanying color graphic depicting the negative health consequences of smoking.

Proposed § 1141.10(a)(2) would provide that the warnings required under paragraph (a)(1) must be obtained from the document titled "Cigarette Required Warnings—English and Spanish." Due to the multi-color nature of the required warnings, they cannot be printed in the Code of Federal Regulations, and due to the visual complexity of the images, it will not be feasible to accurately describe the images and their colors in the Code of Federal Regulations. Thus, FDA proposes to provide the required warnings for regulated entities in "Cigarette Required Warnings—English and Spanish," which will contain downloadable electronic files used to generate each required warning. This approach would also help regulated entities ensure that their packages contain required warnings that are consistent with the requirements of FCLAA and proposed part 1141, when finalized.

Proposed § 1141.10(a)(2) would also mandate that the required warnings be accurately reproduced from the electronic images in "Cigarette Required Warnings—English and Spanish." Thus, regulated entities would have to ensure that the required warnings they place on packages are not distorted or otherwise inaccurately reproduced from the electronic images in "Cigarette Required Warnings—English and Spanish." For example, the colors used to display the required images would have to be reproduced accurately from the colors used in "Cigarette Required Warnings—English and Spanish." The use of the electronic files from "Cigarette Required Warnings—English and Spanish" to generate the required warnings should enable companies to reproduce the warnings with relative ease. FDA recognizes that there may be minor variations in the exact colors used to reprint the required warnings across all cigarette packages due to differences in inks and printing processes, but FDA expects that the colors in the graphics that appear on packages and in advertisements will look the same as the colors in the graphics set forth in "Cigarette Required Warnings—English and Spanish."

Finally, proposed § 1141.10(a)(2) would also specify that the electronic images obtained from "Cigarette Required Warnings—English and Spanish" must be adapted as necessary to meet the requirements of section 4 of FCLAA (15 U.S.C. 1333) and this part, and the electronic files provided in "Cigarette Required Warnings—English and Spanish" would be in a format that could be modified as necessary to comply with this proposed rule. Specifically, regulated entities would be able to modify the size of the required warnings to ensure they are the required

size and occupy the required area of the cigarette package. However, any modifications to such files would need to result in an accurate reproduction of the electronic images contained in "Cigarette Required Warnings—English and Spanish," as proposed by § 1141.10(a)(2). For example, the width-to-height ratio (*i.e.,* the aspect ratio) of the images should be preserved when the images are compressed or expanded, so that the resulting image is not distorted.

Proposed § 1141.10(a)(3) would mandate that the required warnings appear directly on the package and be clearly visible underneath the cellophane or other clear wrapping. In order for the required warnings to appear conspicuously and legibly as mandated by section 4 of FCLAA (15 U.S.C. 1333), they must not be obscured. Thus, any outer wrappings on the package must be clear so that the warnings can be seen and read by consumers. Similarly, any other material that is placed on the outside of packages, such as price information or promotional material (*e.g.,* coupons), must not be placed over or otherwise obscure the required warning.

As required under section 4 of FCLAA (15 U.S.C. 1333), proposed § 1141.10(a)(4) would mandate that the required warnings occupy at least 50 percent of the area of the front panel and rear panel of each cigarette package. These area requirements would help ensure that the required warnings are prominent and conspicuous enough to gain consumers' notice in the first instance, and are easily viewed and read by consumers once they are noticed. This will help ensure that consumers comprehend the critical information conveyed in the required warnings. As to location, proposed § 1141.10(a)(4) states that the required warnings must occupy at least the top 50 percent of the area of the front and rear panels of the packages. For cigarette cartons, where the front and rear panels have significantly longer horizontal than vertical axes, the textual warning statement and accompanying graphic might be distorted if they were placed on the top 50 percent of these panels because the top runs along the longer horizontal axis. Thus, under section 4(b)(4) and (d) of FCLAA, proposed § 1141.10(a)(4) would specify a format for these warnings so that they occupy at least the left 50 percent of the front and rear panels. With this format, the required warnings can be sized for placement on cigarette cartons without distortion.

Proposed § 1141.10(a)(5) would mandate that the required warnings and the other information on the panels be oriented in the same direction. Thus, for example, if the front panel of a cigarette package contains information, such as the brand name of the product, in a left to right orientation, the required warning must not be placed such that it appears at a right angle to this text. Rather, the required warning and its component textual statement should also appear in a left to right orientation. This requirement would help ensure the required warnings on cigarette packages are conspicuous and legible to consumers, as required by section 4 of FCLAA. In addition, FDA is proposing this restriction under section 906(d) of the FD&C Act (21 U.S.C. 387f(d)). Requiring all the text on the panel of a cigarette package that contains a required warning to be oriented in the same direction would help ensure that the warnings are noticed and read by consumers and, therefore, would be appropriate for the protection of the public health.

Proposed paragraph (b) of proposed § 1141.10 would set forth the requirements specific to cigarette advertisements. Proposed § 1141.10(b)(1) would mandate that manufacturers, importers, distributors, and retailers include required warnings in all their cigarette advertising within the United States. Thus, all advertisements, regardless of form—which could include materials such as magazine and newspaper ads, pamphlets, leaflets, brochures, coupons, catalogues, retail or point-of-sale displays (including functional items such as clocks or change mats), posters, billboards, direct mailers, and Internet advertising (*e.g.,* Web pages, banner ads, etc.)—would have to contain required warnings.

Consistent with section 4(b) of FCLAA (15 U.S.C. 1333(b)), proposed § 1141.10(b)(2) would mandate that the textual component of the required warning appear in the English language, with two exceptions. First, per proposed § 1141.10(b)(2)(i), if an advertisement appears in a non-English language publication, the textual portion of the required warning would need to appear in the predominant language of the publication. The predominant language is the primary language used in the non-sponsored content in the publication. For example, in the case of a newspaper where the non-sponsored content (*e.g.,* news stories, articles of opinion, and features) are in a foreign language but the sponsored content (*e.g.,* advertising) is wholly or partially in English, the predominant language would be the foreign language used in the non-sponsored content, and the required warning would have to appear in that foreign language. Because such non-English language publications in the United States are targeted towards consumers who speak the predominant language of the publication, this will help ensure that the required warning effectively communicates to the target audience that will view the advertisement. Second, per proposed § 1141.10(b)(2)(ii), if an advertisement is in an English language publication but is presented in a language other than English, the textual portion of the required warning would need to be presented in the same foreign language principally used in the advertisement. English language publications in the United States are generally targeted towards the consumer population as a whole or towards consumers with a particular interest in the subject matter of the publication rather than towards consumers who speak a particular language; however, foreign language advertisements in English-language publications are targeted towards consumers who speak the foreign language used in the advertisement. Therefore, requiring foreign language advertisements in English-language publications to present the required warning in the same language that is used elsewhere in the advertisement will help ensure that the target audience of the advertisement is able to read and understand both the promotional content and the important warning information.

Proposed § 1141.10(b)(3) would require that English and Spanish language required warnings be obtained and accurately reproduced from "Cigarette Required Warnings—English and Spanish." As discussed above, the required warnings cannot be accurately reprinted or described in the Code of Federal Regulations, and FDA is thus proposing to provide the required warnings for regulated entities in "Cigarette Required Warnings—English and Spanish," which will contain downloadable copies of the electronic files used to generate each required warning. In addition to offering the English-language versions of the required warnings that would be used on all packages and in most advertisements, the document would offer Spanish-language versions of the required warnings for use in advertisements that either appear in Spanish-language publications or that are presented primarily in Spanish (*see* 15 U.S.C. 1333(b)). These versions are offered in recognition of the fact that Spanish is the foreign language most commonly used for cigarette

advertisements in the United States. However, color graphics for other foreign language warnings would need to be obtained from the document titled "Cigarette Required Warnings—Other Foreign Language Advertisements," as is discussed in more detail below. As with cigarette packages, the required warnings placed in cigarette advertisements would have to be accurate reproductions of those set forth in "Cigarette Required Warnings—English and Spanish." In addition, the required warnings would need to be adapted as necessary to meet the requirements of section 4 of FCLAA (15 U.S.C. 1333) and part 1141. The electronic files provided in "Cigarette Required Warnings—English and Spanish" would be in a format that would allow regulated entities to resize the required warnings as necessary to comply with the other provisions of this part, though any modifications made would need to result in an accurate reproduction of the electronic images contained in the documents.

Proposed § 1141.10(b)(4) would require regulated entities to obtain color graphics for foreign language required warnings, other than Spanish language warnings, from the electronic files contained in "Cigarette Required Warnings—Other Foreign Language Advertisements," into which they must insert a true and accurate translation of the textual warning language required by FCLAA. "Cigarette Required Warnings—Other Foreign Language Advertisements" would offer downloadable electronic files of the color graphics and specify (in English) the text that is to accompany each color graphic. These files would allow for insertion of foreign language translations of the required textual statements, so that regulated entities can generate the appropriate required warnings for their foreign language advertisements, as well as for their advertisements that appear in foreign language publications. Advertisers would need to ensure that the required English textual statements are accurately and appropriately translated into the appropriate foreign language. If a warning statement is not accurately translated, the advertisement would be in violation of FCLAA. In addition to ensuring accurate translation, it would be the advertiser's responsibility to ensure that the foreign language text complies with the format specifications set forth in section 4 of FCLAA (15 U.S.C. 1333). Thus, for example, the text should not be placed in a manner that interferes with the accompanying color graphic. Proposed § 1141.10(b)(4) would also mandate that the required warnings be adapted as necessary to meet any other requirements of section 4 of FCLAA (15 U.S.C. 1333) and proposed part 1141. The electronic files provided in "Cigarette Required Warnings—Other Foreign Language Advertisements" would allow regulated entities to resize the required warnings as necessary to comply with the other provisions of part 1141, though any modifications would need to result in accurate reproductions of the electronic images contained in the documents.

As required by section 4 of FCLAA (15 U.S.C. 1333), proposed § 1141.10(b)(5) would mandate that the required warnings comprise at least 20 percent of the area of each advertisement. This will help ensure that the required warnings are appropriately clear, conspicuous, and legible by consumers, so that the important health information in the required warnings can be adequately seen and comprehended. Proposed § 1141.10(b)(5) would also specify that the required warnings are to be placed in accordance with the other requirements set forth in FCLAA for the display of such warnings. For example, section 4 of FCLAA (15 U.S.C. 1333) contains requirements related to the placement of the required warnings, as well as requirements related to the border that must enclose each warning in cigarette advertising. FDA intends to separately address some of these other FCLAA requirements, as well as the provisions in section 4(c) of FCLAA (15 U.S.C. 1333(c)) related to the submission of plans regarding the random display of warnings on packages and rotation of warnings in advertisements.

Proposed § 1141.10(c) would mandate that the required warnings be indelibly printed on or permanently affixed to packages and advertisements. Removable or impermanent warning displays on packages and in advertisements would not comply with the requirements of FCLAA, in that the required warnings could become separated from the package or advertisement and thus would not meet the requirement that they be conspicuous on the package or advertisement. The purpose of the amendments made to FCLAA by the Tobacco Control Act is to strengthen the warnings for greater impact on consumers. Removable warnings would run counter to this purpose. For example, if the required package warning was printed or stickered on a clear outer wrapper, and this wrapper was meant to be removed in order for the package (or cigarettes within the package) to be accessed, the consumer could access the package of cigarettes numerous times without viewing the warning and receiving the impact of the critical health message.

D. Section 1141.12—Incorporation by Reference of Required Warnings

Section 1141.12 proposes that two documents, "Cigarette Required Warnings—English and Spanish" and "Cigarette Required Warnings—Other Foreign Language Advertisements," be incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Any final regulation will provide information on how to obtain the two documents. Draft versions of both documents are available in the docket. These draft versions of the documents contain placeholders for the color graphics; once FDA selects the required warnings for the final rule, it intends to include the electronic files for these required warnings in the final versions of both documents. The material incorporated by reference must meet the Office of the Federal Register's requirements for incorporating material by reference, and thus the way these two documents are displayed may be changed for the final rule to meet such requirements.

Section 1141.12(a) proposes the incorporation by reference of "Cigarette Required Warnings—English and Spanish." This document would contain the required warnings that must be included on all cigarette packages, and in cigarette advertisements in which the text of the required warning must be set forth in the English language or the Spanish language. Regulated entities would utilize "Cigarette Required Warnings—English and Spanish" to obtain the required warnings and reproduce them on cigarette packages and in advertisements in accordance with proposed part 1141. This document would offer downloadable electronic files for each of the required warnings.

FDA expects that the final version of "Cigarette Required Warnings—English and Spanish" will provide a total of nine different images, each of which is comprised of one color graphic that is paired with one of the nine textual warning statements set forth in FCLAA. In addition, for each of these nine sets, FDA expects that the final version would include six formatting options in accordance with sections 4(a)(2) and 4(b)(2) of FCLAA (15 U.S.C. 1333(a)(2) and (b)(2)). Specifically, each of the nine sets would have one formatting option where the textual portion of the required warning is presented in black text on a white background and one

formatting option where the textual portion of the required warning is presented in white text on a black background for use on packages. In addition, each of these sets would include a version of the two previous formatting options enclosed in a rectangular border for use in advertisements in accordance with section 4(b)(2) of FCLAA (15 U.S.C. 1333(b)(2)). Furthermore, each of the nine sets would contain an English version of these advertisement formatting options and a Spanish version of these advertising formatting options. FDA is requesting comments on the different proposed required warnings (*i.e.,* the combinations of the textual warning statements and accompanying color graphics). For more information regarding FDA's research analyses, see section III.D.

In addition, FDA is proposing a subset of color graphics for use in advertisements with a small surface area (*i.e.,* less than 12 square inches). These color graphics differ in their composition from the other color graphics in this document. FDA is proposing this subset of color graphics to ensure that the details of the images are clear, conspicuous, and legible even when the image is reduced in size to occupy 20 percent of a surface with an area of less than 12 square inches. FDA proposes that a final version of "Cigarette Required Warnings—English and Spanish" contain such options, which would be used (in combination with one of the nine textual statements) only in advertisements with a small surface area. However, even an advertisement with a relatively small surface area would need to be large enough so that the required graphic and accompanying textual warning statement are clear, conspicuous, and legible.

Section 1141.12(b) proposes the incorporation by reference of "Cigarette Required Warnings—Other Foreign Language Advertisements." This document would contain the electronic files that are to be used to generate the required warnings for advertisements in which the text of the required warning must be set forth in a foreign language (other than Spanish) under proposed § 1141.12(b). Regulated entities would utilize "Cigarette Required Warnings—Other Foreign Language Advertisements" to generate the required warnings for such advertisements. This document will offer downloadable files of the color graphic for each of the required warnings and specify (in English) the text that is to accompany each color graphic. The downloadable files would allow for insertion of foreign language translations of the required textual statements, so that regulated entities can generate the appropriate required warnings for their foreign language advertisements, as well as for their advertisements that appear in foreign language publications.

E. Section 1141.14—Misbranding of Cigarettes

Section 1141.14(a) proposes that a cigarette shall be deemed to be misbranded unless its labeling and advertising bear one of the required warnings. Under section 903(a)(1) and (a)(7)(A) of the FD&C Act (21 U.S.C. 387c(a)(1) and (a)(7)(A)), a tobacco product, including a cigarette, is deemed misbranded if its labeling or advertising is false or misleading in any particular. Under 201(n) of the FD&C Act (21 U.S.C. 321(n)), in determining whether something is misleading, it: "shall be taken into account * * * not only representations made or suggested * * * but also the extent to which the labeling or advertising fails to reveal facts * * * material with respect to consequences which may result from the use of the article to which the labeling or advertising relates * * * under such conditions of use as are customary or usual." The required warnings, which concern risks associated with the use of cigarettes, are clearly material with respect to consequences that may result from the use of cigarettes. These required warnings convey information about the addictive nature of cigarettes (which is inextricably linked to all the health harms caused by cigarettes) as well as the major, potentially deadly health consequences of smoking, including the causal relationship between smoking and cancer (cigarettes have been shown to cause more than 10 different cancers), fatal lung disease (*e.g.,* COPD, which is a major public health problem in the United States), heart disease and stroke (the first and third leading causes of death in the United States), and negative pregnancy outcomes. In addition, the warnings provide information on the negative, potentially fatal health effects cigarettes can have for non-users, including the harm tobacco smoke can cause to children and non-smoking adults (*e.g.,* fatal lung disease). The warnings also provide critical information on the significant health benefits of quitting. Overall, the required warnings provide highly material information that every consumer should know about the consequences of cigarettes under customary conditions of use.

In order to ensure that the required warnings are conspicuous, prominent, and legible, each individual cigarette package or advertisement is required to contain only one of the nine required warnings under this proposed rule, although all nine statements are material for cigarettes in general. It generally would not be feasible to fit all nine statements and their accompanying color graphics and have them be conspicuous, prominent, and legible. Moreover, while any individual package or advertisement will not convey the information from all nine required warnings, all nine warnings will be on public display at any given time as the Tobacco Control Act requires the warnings to be randomly displayed in as equal a number of times as possible on cigarette packages for all cigarette brands and in quarterly rotation in advertisements under section 4(c) of FCLAA (15 U.S.C. 1333(c)). Thus, consumers will be exposed to conspicuous, prominent, and legible displays of all nine warning statements (which apply to all cigarettes) in the marketplace at any given time, and as a result will receive a summary of the major risks of smoking.

It is worth noting that the warning disclosure requirements for tobacco products are different than the disclosure requirements that apply to other products that FDA regulates, as (1) the warning information for cigarettes is different in its applicability than the warning information for other products, (2) the disclosure requirements for other products have a different purpose than the cigarette warnings, and (3) the mechanisms for exposure to warning information are different for tobacco products than for other products FDA regulates. For example, medical products such as drugs and devices have risks that are specified for each particular product; these risks are set forth in the FDA-required product labeling for each product. The statutory and regulatory requirements for prescription and restricted medical products require that each product's labeling and advertising disclose all material risk information about the particular product (*See* 21 U.S.C. 352(a), (c), (f), (n), (q) and (r); 321(n); see also 21 CFR 201.100(d)(1) and (d)(3); 201.105(c)(1); 801.109(d); and 21 CFR part 202). This information also has a different purpose than cigarette warning information. For example, disclosure of all the material risk information associated with a particular prescription or restricted medical product helps healthcare professionals by giving them some of the information they need to

know about the medical product that will enable them to safely use or prescribe it. Similarly, this risk information helps consumers know whether medical products may be appropriate for them as well as what they should tell their healthcare professionals about before taking or using or while taking or using a product. It also lets consumers know what risks they might experience and what steps they need to take for safety reasons (*e.g.,* no driving) because of taking or using a product. It would not be appropriate to provide partial information of this type because the full summary of information is needed to ensure safe use.

In contrast, the warnings for cigarette products set forth in FCLAA apply to every cigarette product. Cigarettes have health risks that are associated with their use generally. Furthermore, there is no safe method of using cigarette products, so this warning information has a different purpose than medical product warning information, in that it is intended to influence awareness of cigarette-related health risks and, as a result, encourage cessation and discourage initiation, rather than to help ensure that a particular cigarette product is safely used.

The exposure to product information is also different for medical products versus cigarette products. For cigarette products, the warnings will be printed prominently and conspicuously on all packages. These required warnings will thus be seen by smokers, such as each time that smokers buy cigarettes or take a cigarette out of its package (as discussed in Section III.A, pack-a-day smokers can be exposed to warnings more than 7,000 times per year). All nine of the required warnings also will be seen by potential smokers each time they are at a point-of-sale considering purchasing a package of cigarettes. The same is not true of prescription or restricted medical products, as the risk information is specific to each product, is not commonly displayed prominently and conspicuously for all products at the point of purchase, and is not likely to be seen by consumers each time they take or use a product.

In addition, section 1141.14(b) proposes that a cigarette advertisement or package will be deemed to include a brief statement of relevant warnings for the purposes of section 903(a)(8) of the FD&C Act (21 U.S.C. 387c(a)(8)) if it bears one of the required warnings. Under section 903(a)(8)(B) of the FD&C Act (21 U.S.C. 387c(a)(8)(B)), a tobacco product is deemed misbranded unless the manufacturer, packer, or distributor includes in all advertisements and other descriptive printed matter a brief statement of, among other things, the relevant warnings. The warnings required by section 4 of FCLAA for cigarette advertising and packages are "relevant warnings" with respect to cigarettes as that phrase is used in section 903. For the purpose of this provision, "descriptive printed matter" includes the product package label, which, under this proposed rule, would be required to bear certain warnings. FDA is thus proposing that packages and advertisements that bear one of the required warnings in accordance with the proposed rule would satisfy the requirement to include a brief statement of the relevant warnings for the purposes of section 903(a)(8). Similarly, FDA is proposing that a cigarette distributed or offered for sale in any State shall be deemed to be misbranded under section 903(a)(8) unless the manufacturer, packer, or distributor includes in all advertisements and packages issued or caused to be issued by the manufacturer, packer, or distributor with respect to the cigarette one of the required warnings.

F. Section 1141.16—Disclosures Regarding Cessation

Section 1141.16 proposes that one or more of the required warnings include specified information about an appropriate smoking cessation resource. The goal would be to provide a place where smokers and other members of the public can obtain smoking cessation information from staff trained specifically to help smokers quit by delivering unbiased and evidence-based information, advice, and support. There are a number of possible alternatives here, including use of an existing or new quitline or Web site, where smokers and other members of the public can obtain current unbiased, factual smoking cessation information. We are proposing that the final rule require that a specified reference to a smoking cessation resource be included in the required warnings. We propose that the resource that is required to be referenced must meet specific criteria designed to ensure that the cessation information, advice, and support provided are unbiased and evidence-based. Specifically, we are proposing that the referenced resource must meet the following criteria:

- It must provide factual information about the harms to health from smoking and the health benefits of quitting.
- It must provide factual information about what to expect when trying to quit smoking (*e.g.,* common withdrawal symptoms and their duration, circumstances that can trigger cravings).
- It must provide practical advice (problem-solving/skills training) about how to deal with common issues faced by users trying to quit (*e.g.,* how to deal with cravings and withdrawal).
- It must provide evidence-based advice about how to formulate a plan to quit smoking.
- It must provide evidence-based information about effective relapse prevention strategies.
- It must provide factual information on smoking cessation treatments, including FDA-approved cessation medications.
- The information, advice, and support provided must be evidence-based; must be unbiased, including with respect to products, services, persons, and other entities; and must be relevant to tobacco cessation. For example, it can include factual information about the health risks of smoking but it cannot include derogatory statements regarding cigarette manufacturers, importers, distributors, or retailers or advocate public policy changes.
- Other than as described in the criteria for what information may or must be provided, the resource must not advertise or promote any particular product or service. The resource may provide one or more FDA-approved over-the-counter cessation products, provided it does so in a manner that does not advertise or promote a particular product.
- It must not selectively present information about a subset of FDA-approved cessation products or product categories while failing to mention other FDA-approved cessation products or product categories or reference any drug or other medical product that FDA has not approved for tobacco cessation.
- It must not encourage the use of any non-evidence based smoking cessation practices.

If the resource chosen is a Web site, we propose that it meet the following additional criteria:

- The Web site must not contain a link to any Web site unless it meets all of the listed criteria.
- The Web site may refer to one or more toll-free telephone numbers, provided they meet the applicable criteria.

If the resource chosen is a toll-free telephone number, we propose that it meet the following additional criteria:

- The staff that provide smoking cessation information and advice are trained specifically to help smokers quit by delivering unbiased and evidence-based information, advice, and support.
- The service has appropriate controls to ensure the applicable criteria are met.

The smoking cessation information would be included as part of one or more of the required warnings and therefore would not appear outside of the areas specified for the required warning (*i.e.,* 50 percent of the area of each of the front and rear panels of cigarette packages and 20 percent of the area of advertisements). Thus, no additional space on cigarette packages or in advertising would be needed to display this information. Some or all of the images in the two documents that will be incorporated by reference in the final rule would contain this smoking cessation referral information where this information, along with the textual warning statement and accompanying graphic, are clear, legible, and fit within the specified area. FDA requests comments regarding the selection of an appropriate smoking cessation resource and the applicable criteria identified in the bullets above.

Reducing the number of Americans who smoke by increasing the likelihood that smokers will quit smoking would provide substantial public health benefits by reducing the life-threatening consequences associated with continued cigarette use. Moreover, studies have found that health warnings are more effective if they are combined with cessation-related information (Ref. 5 at p. C–7). Thus, FDA is proposing to require information about an appropriate smoking cessation resource under section 906(d) of the FD&C Act as appropriate for the protection of the public health.

G. Proposed Effective Date

Section 201(b) of the Tobacco Control Act specifies that the requirements for health warnings on cigarette packages and advertisements for cigarettes are effective fifteen months after the issuance of the regulations that FDA is proposing in this proposed rule, and that a final rule must be issued not later than 24 months after the date of enactment of the Tobacco Control Act. Therefore, FDA proposes that any final rule will become effective fifteen months after the date the final rule publishes in the **Federal Register**. During this time, parties should take whatever steps they need to plan and implement business operations that will comply with the final rule. As of the effective date, no tobacco product manufacturer, importer, distributor, or retailer of cigarettes may advertise or cause to be advertised within the United States any cigarette product unless the advertising complies with the final regulation. Also, cigarette packages that do not comply with the requirements of the final rule must not be manufactured for sale or distribution in the United States as of the effective date.

As specified in section 201(b) of the Tobacco Control Act, however, if a packaged cigarette product was manufactured prior to the effective date of the final rule but does not contain the warning statements and graphics required under the final rule, the product may be introduced into commerce in the United States within thirty days from such effective date. Therefore, manufacturers, distributors, importers, and retailers may continue to introduce into domestic commerce existing inventory that may not contain the warning statements and graphics required under the final rule for an additional thirty days after the effective date of any final rule. After the 30-day period, manufacturers must not introduce into domestic commerce any cigarette packages that do not contain the warning statements and graphics required under the final rule, irrespective of the date of manufacture. While this limitation only applies to manufacturers, we note that keeping products without the new, updated warnings on the market for an extended period of time is not in the interest of public health. We request comments regarding mechanisms for enforcing this rule and its effective date, such as ways to differentiate cigarette packages sold from existing inventory from those that were manufactured after the effective date.

V. Paperwork Reduction Act of 1995

The required warning disclosures are the "public disclosure of information originally supplied by the Federal government to the recipient for th[at] purpose," and are, therefore, not within the scope of the Paperwork Reduction Act. *See* 5 CFR 1320.3(c)(2).

VI. Executive Order 13132: Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Environmental Impact

FDA has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Analysis of Impacts

A. Introduction and Summary

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). This proposed rule would be an economically significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This proposed rule would have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in a 1-year expenditure that would meet or exceed this amount.

FDA's estimate of the benefits of the proposed rule is determined by the predicted reduction in the number of U.S. smokers and the consequent reduction in the number of people who will ultimately become ill or die from causes related to smoking. FDA estimates that this proposed rule will reduce the number of smokers by 537,000 in 2013, with small additional reductions over the following 20 years. We estimate the present value of the rule-induced benefits at a 3 percent discount rate to be $10.1 to $28.4

billion, including $8.96 to $26.89 billion in gained life-years, $202.1 to $606.2 million in reduced non-fatal emphysema, $393.1 million in reduced fire losses, and $498.9 million in medical cost reductions. At a 7 percent discount rate, our estimates of total benefits become $2.29 to $6.03 billion, including $1.80 to $5.41 billion due to the increase in life-years, $64.9 to $194.7 million in reduced emphysema, $180.6 million in reduced fire losses and $244.0 million in medical cost reductions. The annualized benefits range from $676.0 million to $1.91 billion with a 3 percent discount rate and from $216.6 to $569.6 million with a 7 percent discount rate. Most of the public health benefits from the proposed rule would be realized in the future; perhaps several decades after the rule took effect. In other words, the benefits estimated here for the typical dissuaded smoker consist of health gains to be realized decades in the future.

The estimated totals may understate the full public health benefits of the proposed rule because they fail to quantify reductions in smokers' non-fatal illnesses other than emphysema, the reduction in external effects attributable to passive smoking, and the reduction in infant and child fatalities caused by mothers' smoking during pregnancy.

TABLE E1—BENEFITS OF REGULATION

Impacts of the rule	Annualized benefits ($ mil)					
	3 percent			7 percent		
	Low	Medium	High	Low	Medium	High
Smokers' Life-Years Saved	602.5	1,205.0	1,807.5	170.4	340.7	511.1
Emphysema Reductions	13.6	27.2	40.7	6.1	12.2	18.4
Fire Loss Averted	26.4	26.4	26.4	17.1	17.1	17.1
Medical Expenditure Reduction	33.5	33.5	33.5	23.0	23.0	23.0
Total	676.0	1,292.1	1,908.2	216.6	393.1	569.6

Note: Table entries are annualized over twenty years, but many of the benefits represented will not be realized until well beyond the twentieth year of the proposed rule's implementation.

The total estimated costs of the final rule include $219.2 million to $529.5 million in one-time costs and $6.2 million in annual costs. Annualized over 20 years, the total costs range from $20.3 million to $40.6 million with a 3 percent discount rate and from $25.1 million to $52.5 million with a 7 percent discount rate, as shown in Table E2. These costs will arise primarily due to the need to change cigarette package labels and remove point-of-sale promotions that do not comply with the new restrictions. FDA could not quantify every regulatory cost. Some commercial sectors will experience costs for short-term dislocations of current business activities, but the costs would be mitigated for those businesses that anticipate the industry's adjustments.

In addition to the costs described above, the rule will lead to private costs in the form of reduced revenues for many firms in the affected sectors. These sector-specific revenue reductions are for the most part distributional effects and cannot be counted as social costs.

TABLE E2—COSTS OF REGULATION

Requirements of the rule	Annualized costs ($ mil)					
	3 percent			7 percent		
	Low	Medium	High	Low	Medium	High
Private Sector						
Labeling Change	11.0	20.0	29.2	14.9	27.0	39.4
Market Testing	0.3	0.7	2.4	0.4	1.0	3.3
Point-of-Sale Advertising	3.0	3.0	3.0	4.0	4.0	4.0
Subtotal	14.3	23.7	34.6	19.3	32.0	46.7
Government						
FDA	6.0	6.0	6.0	5.8	5.8	5.8
Subtotal	6.0	6.0	6.0	5.8	5.8	5.8
Total	20.3	29.7	40.6	25.1	37.8	52.5

As tobacco industry revenues decline, state and Federal tobacco tax revenues will also fall. If excise tax rates on tobacco products remain at current levels, annual state tax revenues would fall by approximately $106.1 million and annual Federal tax revenues by $80.5 million.

B. Need for Rule

According to the nation's health experts, tobacco use remains the most important preventable cause of morbidity and premature mortality in the United States, accounting each year for over 400,000 deaths (Ref. 58; Ref. 1). Written with the goal of ameliorating the enormous toll on the public health that is directly attributable to the consumption of cigarettes, the Tobacco

Control Act mandates the publication of this proposed rule. Section 201 of the Tobacco Control Act modifies section 4 of FCLAA (15 U.S.C. 1333) to require that nine new health warning statements, along with color graphics depicting the negative health consequences of smoking, appear on cigarette packages and in cigarette advertisements. In the following analysis, we estimate the costs and benefits of this statutory requirement.

C. Benefits

We estimate the benefits of the proposed rule by comparing expected life-cycle events of smokers with those of nonsmokers. Nonsmokers tend to live longer and contract fewer lung and other diseases, so the benefits in our analysis include the discounted value of life-years gained, cases of emphysema avoided and medical services freed for other uses. We also include an estimate of the monetary value of the property and lives saved as a result of the rule-induced reduction in the number of accidental fires caused by smoking.

1. Reduced Smoking Rates

The changes outlined in this proposed rule are projected to decrease smoking initiation and increase smoking cessation. For each of the first twenty years of the proposed rule's implementation (2012–2031),[6] FDA calculates the predicted decrease in the number of U.S. smokers by multiplying together the following:

(a) The estimated effect (a percentage point change) of cigarette warning labels on the national smoking rate, and

(b) The population in a particular year in the absence of the proposed regulation (as projected by the U.S. Census Bureau).

To obtain estimates of the effect of cigarette warning labels on smoking rates (item (a) in the list above), we look to the experience of Canada, which has required the use of graphic warning labels since December, 2000 (Ref. 59). The advantage of this approach lies in our ability to observe actual consumer behavior—in the form of changes in smoking rates—before and after a graphic warning label requirement went into effect. The warning labels to be required in the proposed rule are generally similar to those developed by Health Canada and other international authorities. As in Canada, the labels required by the proposed rule would occupy at least half the front and rear display panels of a cigarette package. Moreover, under the proposed rule, there would be a mix of warning statements and images that depict the negative consequences of smoking. Although the proposed rule would follow much the same approach as the Canadian warning label requirements, it would differ in some ways: Canada has 16 labels in rotation, rather than 9; warning statements appear in English on one side of a package and in French on the other; and health and cessation information is included on leaflets within Canadian cigarette packages (Ref. 60). These details, combined with general differences in legal and social trends, indicate that Canada's experience with warning labels can give only a general idea of the changes in smoking rates to be expected as a result of the proposed rule. In addition, other smoking control initiatives, including an increase in the cigarette tax and new restrictions on public smoking also occurred in both the United States and Canada during the period of our analysis. These and other confounding factors make our estimate of the effect of proposed warning labels highly uncertain.

Health Canada (Ref. 61) reports Canadian smoking rates for ages 15 and above for each year from 1999 through 2008. FDA obtained smoking rates for adults, aged 18 and above, in the United States from the National Health Interview Survey (Ref. 62). We used the results from these two reports to calculate the U.S.-Canada smoking rate difference for each year.

Using data from Health Canada (Ref. 63), the National Institutes of Health (Ref. 64) and the National Health Interview Survey (Ref. 62), FDA finds that Canadian smoking rates followed a roughly linear downward trend from 1985–2000, while U.S. smoking rates declined logarithmically over the same time period; the predicted smoking rate decrease was 0.67 percentage points per year in Canada and, as of the year 2000, 0.24 percentage points per year in the United States. Using the estimated trends, we predict smoking rates for the United States and Canada, and the difference between them, for each year up to 2008. We then subtract the predicted U.S.-Canada smoking rate differences from the actual differences observed in the data. Implicit in this method is the assumption that these otherwise unexplained differences may be attributed solely to the presence in Canada of graphic warning labels. We do not account for potential confounding variables; our method is therefore a rudimentary approach to estimating the smoking reduction that would be effected by the proposed warning labels and may be producing results that are off by one or more orders of magnitude. FDA requests comments on this issue.

Using this rudimentary approach, FDA estimates that the average unexplained difference between the United States and Canada in national smoking rates is 0.212 percentage points higher for the 2001–2008 period than for 1999–2000. Applying this estimate to population projections (Ref. 65) and summing over all age groups yields an estimate that the rule would reduce (either through cessation or avoided initiation) the United States' smoking population by approximately 537,000 in 2013, with the total decrease rising to approximately 619,000 in 2031 due to population growth.

2. Expected Life-Years Saved

The largest health consequence of smoking is the increased rate of mortality from cardiovascular disease, cancer, and certain other illnesses. As a result, the largest benefits of this proposed rule stem from the increased life expectancies for those individuals who, in the absence of this proposed rule, would be smokers and thus susceptible to premature mortality from one of these often-fatal diseases. We calculate the number of life-years saved using differences in the probabilities of survival for smokers and nonsmokers. Sloan *et al.* (Ref. 66) construct life tables for various categories of individuals, including "non-smoking smokers" and typical 24-year-old smokers. A non-smoking smoker is someone who does not use cigarettes but otherwise exhibits the lifestyle and personal characteristics[7] of the average smoker. A typical 24-year-old smoker does not necessarily smoke for his or her entire life, but instead faces cessation probabilities that are in line with values observed for all ages in the National Health Interview Survey; the life expectancy effects of cessation at older ages are netted out of life expectancy effects of avoiding smoking at age 24 (results reported below). Sloan *et al.*'s life tables allow us to calculate how many additional deaths, per 100,000 population, may be expected among typical smokers than among non-smoking smokers between the 24th and 25th birthdays, the 25th and 26th, and so on until the 100th birthday. (To simplify the calculation, FDA assumes

[6] The effects of anti-smoking policies occur over a long period of time, so we want to include at least one full generation in our analysis. Using a twenty-year time horizon allows us to do this while still avoiding the extreme uncertainty regarding effects occurring in the more distant future.

[7] In their multivariate regression analysis, Sloan *et al.* control for alcohol intake, body mass index, financial planning horizon, race, education and marital status.

that differences in survival probabilities for smokers and nonsmokers are negligible below age 24 and above age 100.) Overall, Sloan *et al.* find that a typical 24-year-old female smoker can expect to live another 55.5 years, while a comparable nonsmoker can expect another 57.8 years of life, producing an overall regulation-induced gain of 2.4 life-years per individual who is prevented from starting to smoke. Comparing male 24-year-old typical and non-smoking smokers, life expectancy increases from 49.8 to 54.2 years, producing a gain of 4.4 years. The gap between male and female life expectancy results may be due to different physiological responses to equal amounts of smoking, different lifetime cessation patterns or different smoking intensities. Taylor *et al.* (Ref. 67), for instance, find that male smokers are more likely than female smokers to consume more than a pack a day. Sloan *et al.* do not report how much of the male-female difference in their estimated life expectancy effects may be attributed to each possible mechanism.

While FDA considers Sloan *et al.*'s methodology to be the most suitable in the literature for purposes of the present analysis, several other studies of survival probabilities among smokers who quit early in life compared with smokers who persist in smoking into later decades suggest that the average life expectancy gains of not smoking may be much higher for both males and females. Since these other studies have found larger increases in life expectancy attributable to smoking avoidance, the Sloan *et al.* results may be considered conservative.

We assume that each person who reaches age 24 during the twenty years (2012–2031) of our analysis and is dissuaded from smoking extends his or her life by the gender-specific amount Sloan and co-authors report. For older individuals, whose post-smoking cessation survival probabilities cannot be plausibly assumed to equal those of individuals who were nonsmokers at age 24, we predict life extensions using former smoker life tables that we construct using Sloan *et al.*'s results and cessation probabilities from the 1998 National Health Interview Survey (Ref. 62).

3. Benefits of Reduced Premature Mortality

OMB Circular A–4 (Ref. 68) advises that the best means of valuing benefits of reduced fatalities is to measure the affected group's willingness-to-pay to avoid fatal risks. Three life-year values (also known as values of a statistical life-year, or VSLY) used frequently in the literature and in previous analyses are $100,000, $200,000 and $300,000 (Ref. 69; Ref. 70; 74 FR 33030, July 9, 2009), which we update to $105,000, $210,000 and $315,000 in 2009 prices. These values constitute our estimates of willingness-to-pay for a year of life preserved in the present. The economic assessment of a future life-year requires discounting its value to make it commensurate with the value of present events. For this analysis, we use 3 percent and 7 percent discount rates to calculate the present value of the life-years we predict will be saved.

For each dissuaded smoker, we multiply a VSLY by the relevant age- and gender-specific life extension and then discount appropriately to arrive at a per-person value of reduced mortality. For 24-year-olds, this value ranges from $9,166 (for a female applying a VSLY of $105,000 and a 7 percent discount rate to her 2.4 life-years gained due to smoking avoidance) to $358,864 (for a male applying a VSLY of $315,000 and a 3 percent discount rate to his 4.4 life-years gained due to smoking avoidance). Multiplying the per-person values by the predicted number of dissuaded smokers yields estimates of rule-induced mortality benefits that range from $3.61 to $53.78 billion.

This range tends to overstate the net benefits of reduced smoking because it does not account for lost consumer surplus associated with the activity of smoking. Cutler (Ref. 69) suggests that lost consumer surplus might equal around fifty percent of the dollar value of life-year gains, which necessitates dividing the estimated gross benefits in half. This adjustment is based on a very simple linear model of cigarette demand that is not definitive; a more data-intensive model may produce an adjustment factor very different from fifty percent. FDA requests comments, additional data and research on this adjustment. Net benefits estimates, for all VSLY ($105,000, $210,000 and $315,000) and both discount rates (3 percent and 7 percent) and produced using the Cutler adjustment factor, appear in Table E3.

These totals may understate the full value of rule-induced reductions in mortality because they fail to quantify any reduction in either the external effects attributable to passive smoking or the infant and child fatalities caused by mothers' smoking during pregnancy. Sloan *et al.* (Ref. 66) indicate that, historically, the inclusion of spouse and infant deaths increased estimates of smoking's mortality effects by approximately 26.3 percent. We do not incorporate this adjustment into our analysis, however, since recent public smoking restrictions and educational campaigns have reduced external smoking exposure to well below historical levels, though not to zero.

TABLE E3—PRESENT VALUE OF LIFETIME REDUCED SMOKER MORTALITY

Value of a Statistical Life-Year = $105,000		Value of a Statistical Life-Year = $210,000		Value of a Statistical Life-Year = $315,000	
3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate
$8,963,863,457	$1,804,953,192	$17,927,726,915	$3,609,906,384	$26,891,590,372	$5,414,859,576

4. Reduced Emphysema

In the previous section, we estimated the benefits that will accrue as a result of the rule-induced reduction in premature deaths from lung cancer, cardiovascular disease and other smoking-related illnesses. Cigarette smoking is also a major risk factor for diseases that are less immediately fatal. As with premature death, individuals are assumed to be willing to give up valuable resources in the present in order to avoid the pain and distress associated with these non-fatal illnesses.

Emphysema, a form of COPD,[8] is perhaps the most notable such illness. Sloan *et al.* (*Id.*) estimate young smokers' lifetime illness profiles and report that smoking has a larger effect on expected years with emphysema than on expected years with cancer, coronary heart disease or any of the

[8] Chronic obstructive bronchitis is a smoking-related illness that is closely related to emphysema so that the two conditions are now generally categorized together as chronic obstructive pulmonary disease (COPD). Because the sources we use in this section only report the health and welfare effects of emphysema, our resulting benefits estimates include only a portion of the total social gains associated with rule-induced COPD reductions.

other conditions they study.[9] In order to quantify the value of rule-induced reductions in years spent experiencing emphysema, we scale our estimates of the value of a statistical life-year ($105,000, $210,000 and $315,000, as discussed in section VIII.C.3) by a ratio representing the tradeoff individuals are willing to make between perfect health and the state of having emphysema. Sullivan and Ghushchyan (Ref. 71) estimate this tradeoff with a regression of EQ–5D health index scores on disease indicators. EQ–5D survey responses—to questions about five areas of health, including mobility, pain, and ability to perform usual activities—are mapped so that a score of one represents best-measurable health, a score of zero represents death, and fractional values represent intermediate levels of health. Sullivan and Ghushchyan's regression analysis indicates that a year with emphysema decreases, on average, a patient's welfare as much as the loss of 0.0667 years of perfect health. Multiplying this average welfare loss by life-year values of $105,000, $210,000 and $315,000 yields estimates of $7,000, $14,000 and $21,000 for the amounts individuals are willing to pay to avoid a year of emphysema.

Sloan *et al.* (Ref. 66) estimate that a 24-year-old smoker can expect, on average, an extra 0.46 discounted years (using a discount rate of 3 percent) or 0.22 discounted years (using a discount rate of 7 percent) of emphysema over his or her lifetime, as compared with an otherwise equivalent nonsmoker. Sloan and co-authors do not report the effect of smoking on emphysema years for members of other age cohorts, so FDA takes the conservative approach of estimating benefits only for those individuals who reach age 24 sometime during the first twenty years of the proposed rule's implementation. (Smoking cessation brought about by this rule will almost certainly reduce emphysema for some individuals who are over age 24 at the time of the rule's implementation. However, due to data constraints, we omit the benefits to these older individuals; this is why we describe our estimate as conservative.)

Multiplying our predictions of per-smoker decreased discounted disease-years by Sullivan and Ghushchyan's welfare loss per year of emphysema and FDA's estimates of the rule-induced reduction in the number of smokers (*see* section VIII.C.1 for a discussion of methodology), discounting appropriately, and dividing in half (per Ref. 69) yields a rule-induced welfare gain of $64.9 to $606.2 million. Results appear in Table E4. Smokers also suffer from other non-fatal illnesses but we do not include those losses in this analysis. Since we do not quantify reductions in smokers' non-fatal illnesses other than emphysema, these estimates represent lower bounds on the value of rule-induced morbidity reductions.

TABLE E4—PRESENT VALUE OF 24-YEAR-OLDS' LIFETIME REDUCED EMPHYSEMA

Value of a Statistical Life-Year = $105,000		Value of a Statistical Life-Year = $210,000		Value of a Statistical Life-Year = $315,000	
3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate
$202,075,479	$64,886,926	$404,150,958	$129,773,852	$606,226,437	$194,660,778

5. Reduced Fire Costs

Each year, fires started by lighted tobacco products kill and injure people and destroy structures and other property. In the United States in 2007, civilian deaths caused by smoking-related fires totaled 720, with direct property damage of $530 million (Ref. 72). A reduction in the number of smokers, and the coinciding number of cigarettes smoked, will reduce the number of future fires.

The percentage reduction in fires may not equal the percentage reduction in cigarette consumption, however, because since 2003 forty-nine states have passed legislation that requires cigarettes to be self-extinguishing or fire-safe (with the effectiveness dates of some of these state laws extending into 2011). FDA acknowledges some uncertainty in the effectiveness rate of fire-safe cigarettes;[10] for this analysis, we estimate that 50 percent of apparently rule-induced future fire reductions would have been avoided even without the proposed rule due to fire-safe cigarette design.

Using a $7.9 million value of a statistical life (Ref. 75, which is the 2006 value updated to 2009 dollars using Ref. 76), FDA projects fire-cost savings of $393.1 million (at a three percent discount rate) or $180.6 million (at a seven percent discount rate); of these totals, 9.7% consists of averted property damage and the rest of lives saved. These estimated savings may significantly underestimate the potential benefits because they exclude the value of reduction in fire-caused non-fatal injuries.

6. Medical Services

Sloan *et al.* (Ref. 66) estimate that smokers use more medical services over their life cycles than do comparable nonsmokers, with a specific net cost of $3,757 per female 24-year-old smoker and $2,617 per male 24-year-old smoker (in 2000 dollars and with a 3 percent discount rate). If these payments are distributed equally from ages 24 to 100, given FDA's projected 20-year reductions in smoking prevalence, smoking-related medical expenditures would fall by $1.87 billion, of which $997.7 million would be realized as savings by smokers themselves and $870.6 million by nonsmokers (in the form of decreases in private insurance premiums or taxes used to fund government health programs such as Medicare). With a 7 percent discount rate, the total decrease in expenditure becomes $915.5 million, with $488.0 million of those savings accruing to smokers and $427.5 million to nonsmokers.

In the absence of the rule, some portion of smoking-related medical expenditures accrues to health service providers as economic rent (also known as producer surplus). Any reduction of this portion would not contribute to the social benefit of the rule but would instead be a transfer of value from producers to consumers and other payers. If, however, the supply of smoking-related medical services is highly elastic, especially in the long run, producer surplus would be small. For this reason, FDA does not adjust for potential rent transfer. We do, however, include only the decrease in medical expenditure by smokers as a contribution to the rule's benefits.

[9] Due to the slow progressive nature of emphysema, patients with emphysema experience a diminished quality of life for longer periods than do patients with other smoking-related illnesses, which more rapidly progress to death.

[10] One of the first states to enact these laws, New York, requires cigarettes to self-extinguish 75% of the time (Ref. 73). First-year (2004) data in New York show a reduction in smoking-caused fires by about 33% from the average of the three previous years of complete data (Ref. 74).

Because nonsmokers' payments take the form of a subsidy for smoking-related medical services, some portion of their expenditure in the absence of the rule is greater than smokers' own willingness-to-pay for medical services. Hence, the avoidance of this portion of the spending would transfer value from smokers to nonsmokers but not contribute to an overall social benefit of the rule. We do not know the size of this portion relative to nonsmokers' overall rule-induced expenditure change, so we take the conservative approach of excluding nonsmokers' expenditures from our benefits calculation.

As a final adjustment, we divide the remaining expenditure change in half to account for smokers' lost consumer surplus associated with the activity of smoking. This yields a rule-induced benefit of $498.9 million (at a 3 percent discount rate) or $244.0 million (at a 7 percent discount rate).

7. Summary of Benefits

The discussion above demonstrates the considerable magnitude of the economic benefits available from smoking reduction efforts. Estimates are summarized in Table E5. FDA requests comments on the sources and methods used to produce these results.

TABLE E5—PRESENT VALUE OF BENEFITS ($ MIL)

	VSLY = $105,000		VSLY = $210,000		VSLY = $315,000	
	3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate
Life-Years	8,963.9	1,805.0	17,927.7	3,609.9	26,891.6	5,414.9
Non-Fatal Emphysema	202.1	64.9	404.2	129.8	606.2	194.7
Fire Loss	393.1	180.6	393.1	180.6	393.1	180.6
Medical Expenditure Reduction	498.9	244.0	498.9	244.0	498.9	244.0
Total	10,057.9	2,294.5	19,223.8	4,164.3	28,389.8	6,034.1

8. Uncertainty Analysis

Estimation of the effectiveness of the proposed rule (on reducing the future U.S. smoking rate) is subject to a large uncertainty that is not fully reflected in the benefits estimates appearing in the preceding sections, which only reflect different estimates of the value of a statistical life year. In this section, we show the uncertainty associated with our estimate of the effectiveness of the proposed rule.

Our primary estimate, that the U.S. smoking rate will decrease by 0.212 percentage points, was calculated in the following steps. First, we found the decrease in Canadian smoking rates since 1999 over and above what would have been expected using the pre-2001 trend. We then subtracted the analogous unexplained decrease in the U.S. smoking rate over the same period. This middle step was driven by the idea that the U.S. experience could proxy for recent social or policy changes (such as public smoking restrictions) that may have had effects on Canada's smoking rate and thus needed to be subtracted in order to isolate the effect of graphic warning labels. The last step was to calculate the difference between U.S. and Canadian unexplained decreases in smoking before and after graphic warning labels were introduced in Canada. We attributed the remaining unexplained difference to graphic warning labels.

However, the U.S. social and policy climate may have been so different from Canada's during the years 1999–2008 that this proxy is inappropriate. To account for this possibility, we calculate the unexplained difference in Canadian smoking rates before and after graphic warning labels were introduced, this time omitting any U.S. adjustments. (Anti-smoking policies and programs other than the graphic warning labels are assumed to be incorporated in the pre-2001 trend, with no additional effects of these variables occurring post-introduction of graphic warning labels.) This approach indicates that graphic warning labels may have been responsible for a 1.648 percentage point decrease in the Canadian smoking rate. If the proposed rule were to achieve this effectiveness level in the United States, benefits would be approximately eight times larger than those reported earlier in this analysis.

On the other hand, because FDA has had access to very small data sets, our effectiveness estimates are in general not statistically distinguishable from zero; we therefore cannot reject the possibility that the proposed rule would not change the U.S. smoking rate. In this case, the proposed rule would not generate any quantifiable benefits, so the appropriate lower bound on benefits is zero. Ranges of benefits, representing the zero-effect case and the Canada-only modeling approach, appear in Table E6. The wide ranges shown in the table highlight the uncertainty inherent in our approach.

TABLE E6—PRESENT VALUE OF BENEFITS, RANGES ($ BILLION)

	VSLY = $105,000		VSLY = $210,000		VSLY = $315,000	
	3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate
Life-Years	[0, 69.7]	[0, 14.0]	[0, 139.3]	[0, 28.1]	[0, 209.0]	[0, 42.1]
Non-Fatal Emphysema	[0, 1.6]	[0, 0.5]	[0, 3.1]	[0, 1.0]	[0, 4.7]	[0, 1.5]
Fire Loss	[0, 3.1]	[0, 1.4]	[0, 3.1]	[0, 1.4]	[0, 3.1]	[0, 1.4]
Medical Expenditure Reduction	[0, 3.9]	[0, 1.9]	[0, 3.9]	[0, 1.9]	[0, 3.9]	[0, 1.9]
Total	[0, 78.2]	[0, 17.8]	[0, 149.4]	[0, 32.4]	[0, 220.1]	[0, 46.9]

D. Costs

The proposed rule would create new burdens for cigarette manufacturers. In particular, manufacturers would incur the large up-front costs associated with a major labeling change.[11] Cigarette manufacturers and retailers would be responsible for the removal of noncompliant point-of-sale advertising. Consumers are likely to ultimately bear a share of these costs in the form of increased prices. In addition, the tobacco industry and possibly other sectors will experience lost sales and employment, but these revenue transfers will be offset by gains to other sectors, as discussed in the "Distributional Effects" section of this document.

1. Number of Affected Entities

Labeling and advertising requirements would affect domestic cigarette manufacturers and importers of foreign-made cigarettes. Statistics of U.S. Businesses' data show that there were 24 cigarette manufacturing firms in the United States in 2007 (Ref. 77). An undetermined number of importers would also be affected.

Noncompliant point-of-sale advertising would be removed by manufacturers (or importers) and retailers. We use detailed data from the 2002 Economic Census report on product line sales for establishments with payroll to estimate the percentage of various types of retail establishments that sell tobacco products. Searching by the Economic Census product line 20150 (cigars, cigarettes, tobacco, and smokers' accessories), we find accommodation and food service establishments (NAICS 72) and retail trade establishments (NAICS 44–45) that report tobacco sales (Ref. 78, Ref. 79). Although some establishments in other industries may have unreported sales of tobacco products, the product line sales data provide a reasonable basis to determine which types of establishments would be affected by the proposed rule.

TABLE E7—ESTABLISHMENTS WITH PAYROLL THAT SELL TOBACCO PRODUCTS, 2002 ECONOMIC CENSUS

Kind of business	NAICS	Number in NAICS	Number selling tobacco products	Percentage selling tobacco products
General merchandise	452	40,723	6,991	17
Food & beverage	445 excluding 44512.	119,592	65,255	55
Convenience [a]	44512	29,212	24,871	85
Gasoline stations with convenience [a]	44711	93,691	86,152	92
Gasoline stations	44719	27,755	8,745	32
Health & personal care	446	81,797	17,761	22
Other retail establishments	(a)	595,558	3,470	1
Accommodation and food services	72 excluding 7224.	516,734	12,347	2
Drinking places	7224	48,856	11,490	24
Tobacco stores	453991	6,184	6,184	100
Nonstore retailers	454	49,000	848	2
Vending machine operators	4542	5,921	892	15
Total		1,615,023	245,006	15

[a] Includes NAICS 441, 443, 444, 448, 451, 453 excluding 453991.
Sources: Ref. 79; Ref. 78.

Because the 2007 Census data on product line sales for retail establishments with employees are not yet available, we update the number of various types of retail establishments using 2007 Statistics of U.S. Businesses data but assume the share of establishments selling tobacco products is unchanged (since 2002) within each category. Likewise, we lack 2007 Census data on product line sales for nonemployer establishments. Without additional information, we assume that, within a NAICS category, the share of establishments selling tobacco products will be the same for nonemployer establishments in 2007 as for establishments with payroll in the 2002 Census. As shown in Table E8, we estimate that about 249,000 retail establishments with payroll and 126,000 nonemployer establishments sell tobacco products.

TABLE E8—ESTABLISHMENTS THAT SELL TOBACCO PRODUCTS

Kind of business	NAICS	Percentage selling tobacco products [a]	Establishments with payroll		Nonemployer establishments	
			Number [b]	Estimated number selling tobacco products	Number [c]	Estimated number selling tobacco products
General merchandise stores	452	17	47,456	8,147	32,978	5,661
Food & beverage stores	445 excluding 44512.	55	122,858	67,037	104,026	56,761
Convenience stores	44512	85	28,173	23,986	(e)	
Gasoline stations with convenience stores.	44711	92	95,389	87,713	(e)	

[11] All of the up-front costs of this rule are assumed to occur at the beginning of the first period of the time horizon of this rule (2011). The cost tables present raw undiscounted calculations of these up-front costs. For summary tables requiring a present value, these costs are discounted 1 year to the present (2010).

TABLE E8—ESTABLISHMENTS THAT SELL TOBACCO PRODUCTS—Continued

Kind of business	NAICS	Percentage selling tobacco products [a]	Establishments with payroll		Nonemployer establishments	
			Number [b]	Estimated number selling tobacco products	Number [c]	Estimated number selling tobacco products
Gasoline stations	44719	32	20,144	6,347	9,454	2,979
Health and personal care stores	446	22	89,406	19,413	138,800	30,138
Other retail stores	([d])	1	600,537	3,499	735,266	4,284
Accommodation and food services	72 excluding 7224.	2	585,541	13,991	281,104	6,717
Drinking places	7224	24	46,948	11,041	27,170	6,390
Tobacco stores	453991	100	6,458	6,458	([e])	
Nonstore retailers	454 excluding 4542.	2	42,565	737	782,759	13,547
Vending machine operators	4542	15	5,158	777	27,595	4,157
Total		15	1,690,633	249,147	2,139,152	126,477

[a] Percentage of establishments with payroll from Table E7.
[b] Ref. 77.
[c] Ref. 80.
[d] Includes NAICS 441, 443, 444, 448, 451, 453 excluding 453991.
[e] Data on nonemployer establishments unavailable for this NAICS category.

2. Costs of Changing Cigarette Labels

In order to estimate the cost of changing cigarette labels to comply with the proposed rule, FDA used three sources. The "Methodology Report" for the forthcoming "Model to Estimate Costs of Using Labeling as a Risk-Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration" provided the basic framework (Ref. 81). The Methodology Report contains few numerical values, but we obtained preliminary estimates of several cost components and updated product counts through personal communication with our contractor, RTI International (Ref. 82). Because the forthcoming model is not yet complete, we filled in missing pieces using the RTI Final Report entitled "FDA Labeling Cost Model," which describes an earlier model developed by RTI for FDA to estimate the cost of food label changes (Ref. 83). We were able to combine the models because the older food labeling model serves as the basis for the forthcoming general labeling model.

The front and back of every cigarette package must be redesigned to incorporate graphic warnings occupying the entire top half. This type of change requires what is known as a complete redesign in the 2003 model or as a major change in the forthcoming model. In addition, the requirement to incorporate 9 different warnings will increase costs beyond what the labeling models estimate. FDA accounted for the additional warnings by first calculating the cost of a complete redesign for cigarettes and then inflating the specific cost components expected to increase due to the requirement for 9 warnings.

The RTI labeling models incorporate three potential cost components of a labeling change: label design costs (incurred on a per-UPC basis), testing costs (incurred on a per-formulation basis), and inventory costs (incurred on a per-unit basis). For this analysis, we restrict the calculation of market testing costs to the largest firms and perform certain other modifications to make the estimated cost match the likely effects of the proposed rule. The large cigarette manufacturers can plausibly be expected to conduct quantitative studies and focus group testing for each of their brands to gauge the effect of the new graphic warnings and to study how they might best be able to mitigate their effects. By contrast, small manufacturers with lower sales revenues are highly unlikely to conduct expensive market testing in response to the new requirements.

We estimate that 3,234 cigarette UPCs (Ref. 82), would be affected by this proposed rule. FDA conservatively assumes that because the required change is so radical, none of the labeling changes can be coordinated with a previously-scheduled labeling change.

Based on communication with RTI about the forthcoming model (*Id.*), FDA estimates that, per UPC, administrative labor costs are $375 to $1,014, graphic design labor costs are $1,120 to $3,206, prepress labor costs are $1,482 to $3,816, recordkeeping labor costs are $33 to $434, prepress materials costs are $100 to $2,439, and printing plate costs are $4,840 to $10,580.[12] Summing these costs yields a per-UPC design cost of $7,950 to $21,489. Multiplying by the number of affected UPCs and inflating by 10 percent to account for rush charges associated with a compliance period shorter than 24 months results in total label design costs of $28 million to $76 million (Ref. 83).

Manufacturers incur inventory costs if they discard unused inventory at the end of the compliance period. Because cigarette manufacturers do not keep large inventories of labels, FDA assumes that all inventory will be exhausted during the 15-month compliance period, leaving no inventory cost. Table E9 summarizes the total costs of a standard label redesign for cigarettes.

[12] Rotogravure, the most expensive printing method, is used for cigarette labeling.

TABLE E9—COST OF A LABEL REDESIGN FOR CIGARETTES

	Low	Medium	High
Label Design Cost[a]			
Number of UPCs	3,234	3,234	3,234
Administrative labor cost ($)	375	695	1,014
Graphic design labor cost ($)	1,120	2,163	3,206
Prepress labor cost ($)	1,482	2,649	3,816
Recordkeeping labor cost ($)	33	234	434
Prepress materials ($)	100	1,225	2,439
Printing plate cost ($)	4,840	7,710	10,580
Cost per product UPC ($)	7,950	14,676	21,489
Total label design cost, 24-month compliance ($)	25,710,300	47,462,184	69,495,426
Total label design cost, < 24-month compliance ($)	28,281,330	52,208,402	76,444,969
Total Cost ($)	28,281,330	52,208,402	76,444,969

[a] Undiscounted costs assumed to be incurred at the start of the first period of the time horizon of this rule.

Administrative costs, recordkeeping costs, and labor costs associated with graphic design and prepress activities would probably be unaffected by the requirement to use 9 different picture-warning pairs. By contrast, we expect printing plate costs and prepress materials costs to be 9 times as large as previously calculated because of the requirement for 9 warnings. Table E10 shows the total costs of the cigarette labeling change, adjusted for the 9 warnings. The labeling cost increases to $169 million to $447 million.

TABLE E10—COST OF A LABEL REDESIGN WITH NINE WARNING LABELS

	Low	Medium	High
Label Design Cost[a]			
Number of UPCs	3,234	3,234	3,234
Administrative labor cost ($)	375	695	1,014
Graphic design labor cost ($)	1,120	2,163	3,206
Prepress labor cost ($)	1,482	2,649	3,816
Recordkeeping labor cost ($)	33	234	434
Prepress materials ($)	900	11,025	21,951
Printing plate cost ($)	43,560	69,390	95,220
Cost per UPC ($)	47,470	86,156	125,641
Total label design cost, 24-month compliance ($)	153,517,980	278,628,504	406,322,994
Total label design cost, < 24-month compliance ($)	168,869,778	306,491,354	446,955,293
Total Cost ($)	168,869,778	306,491,354	446,955,293

[a] Undiscounted costs assumed to be incurred at the start of the first period of the time horizon of this rule.

3. Market Testing Costs Associated With Changing Cigarette Package Labels

As stated above, FDA expects that only the large manufacturers will conduct market tests for their brands. Using several state directories of certified tobacco products, FDA estimates that 75 brands are marketed by the 4 largest domestic manufacturers (Refs. 84–89). The cost of focus group tests is estimated to range from $18 to $42 thousand; the cost of a quantitative study is estimated to range from $47 to $453 thousand (Ref. 82). The total cost of both types of market testing is estimated to be $65 to $495 thousand per brand. Multiplying by 75 brands yields a total cost estimate ranging from $5 to $37 million with a medium estimate of $11 million, as shown in Table E11. We assume that the requirement to use 9 different warning-text pairs does not affect these costs.

TABLE E11—COST OF MARKET TESTING

	Low	Medium	High
Market Testing Cost[a]			
Number of brands to be tested	75	75	75
Cost of focus group testing ($)	18,000	30,000	42,000
Cost of quantitative studies ($)	47,000	114,000	453,000
Market testing cost per brand ($)	65,000	144,000	495,000
Total Market Testing Cost ($)	4,875,000	10,800,000	37,125,000

[a] Undiscounted costs assumed to be incurred at the start of the first period of the time horizon of this rule.

4. Advertising Restrictions: Removal of Noncompliant Point-of-Sale Advertising

The principal effect of the restrictions on advertising in the proposed rule stem from the requirement that retailers and manufacturers of cigarettes remove any point-of-sale advertising for cigarettes that fails to conform to the requirements. In this analysis, we estimate the social resource costs for the removal. In the analysis of FDA's 1996 final tobacco rule, we based much of our estimate of the cost of removing noncompliant point-of-sale advertising on a report from the Barents Group that

used average removal costs for seven types of retail establishments, calculated using in-store surveys conducted by A.T. Kearney, Inc (61 FR 44580). We use the same baseline and retain our assumptions from 1996 about the level of effort required. We acknowledge, however, that this approach may overstate or understate the costs for a particular action or type of business.

Table E12 regroups the information from Table E8 according to the categories studied by AT Kearney. Because our analysis considers only the removal of point-of-sale advertising from physical retail locations, we do not include non-store establishments. Table E13 shows that in current dollars one-time per-establishment costs range from about $12 for "other establishments" to about $198 for convenience stores. To estimate the total costs to comply with the restriction on point-of-sale advertising, we apply the updated per-establishment costs from Table E13 to affected establishments. As shown in Table E14, the one-time costs to remove point-of-sale materials would total $45.4 million.

TABLE E12—ESTIMATED NUMBER OF ESTABLISHMENTS SELLING CIGARETTE PRODUCTS AFFECTED BY THE PROPOSED RULE

Kind of business	Establishments with payroll [a]	Nonemployer establishments [a]	Total
AT Kearney Category			
General Merchandise	8,147	5,661	13,808
Supermarket & Grocery	67,037	56,761	123,799
Convenience Stores	23,986	.....	23,986
Convenience Stores with Gas	87,713	.....	87,713
Service Stations	6,347	2,979	9,326
Drug Stores	19,413	30,138	49,552
Specialty Tobacco Stores	6,458	.....	6,458
Other establishments [b]	28,531	17,391	45,922
Total	247,633	112,931	360,564

[a] Source: Table E8.
[b] Includes miscellaneous retail establishments and accommodations and food services establishments (including drinking places), but excludes nonstore retailers.

TABLE E13—ESTIMATED AVERAGE PER-ESTABLISHMENT COSTS TO REMOVE PROHIBITED MATERIALS [a]

AT Kearney business category	Remove promotional materials ($)	
	1996 dollars	Current dollars
General Merchandise	23.42	30.94
Supermarket & Grocery	125.14	165.30
Convenience Stores	150.02	198.16
Convenience Stores with Gas	146.43	193.42
Service Stations	36.09	47.67
Drug Stores	11.72	15.48
Specialty Tobacco Stores	123.21	162.75
Other establishments [b]	9.37	12.38

[a] Sources: 61 FR 44585, Table 8; 1996 to 2009 (most recent) GDP deflator rose 32.1% (Ref. 76).
[b] Excludes adult-only establishments, nonstore retailers and vending machine operators.

TABLE E14—ESTIMATED ONE-TIME COSTS TO REMOVE POINT-OF-SALE MATERIALS FROM AFFECTED ESTABLISHMENTS

A.T. Kearney category	Number of establishments	Average cost ($)	Total one-time costs [b] ($ million)
General Merchandise	13,808	30.94	0.4
Supermarket & Grocery	123,799	165.30	20.5
Convenience Stores	23,986	198.16	4.8
Convenience Stores with Gas	87,713	193.42	17.0
Service Stations	9,326	47.67	0.4
Drug Stores	49,552	15.48	0.8
Specialty Tobacco Stores	6,458	162.75	1.1
Other establishments [a]	45,922	12.38	0.6
Total	360,564	.....	45.4

[a] Excludes adult-only establishments and non-store retailers.
[b] Undiscounted costs assumed to be incurred at the start of the first period of the time horizon of this rule.

Sources: Tables E12 and E13.

5. Government Administration and Enforcement Costs

FDA's estimated internal costs for administering and enforcing this regulation are uncertain. As a best estimate, however, FDA projects that 25 full-time equivalent employees (FTEs) would be needed to implement the proposed rule. Fully loaded employee costs vary with the type of employee (*e.g.* field inspectors versus administrative), but an average of $247,049 per FTE places the dollar cost at approximately $6.2 million per year.

6. Summary of Costs

Table E15 summarizes the cost estimates from the preceding sections and Table E16 displays the present value and annualized value of costs.

TABLE E15—SUMMARY OF COSTS

Requirements of the rule	Annual ($m) [a]	One-Time ($m) [b]		
		Low	Medium	High
Private Sector				
Labeling Change	.....	168.9	306.5	447.0
Market Testing	.....	4.9	10.8	37.1
Point-of-Sale Advertising	.....	45.4	45.4	45.4
Subtotal	.....	219.2	362.7	529.5
Government				
FDA	6.2	.....	.....	.....
Subtotal	6.2	.....	.....	.....
Total	6.2	219.2	362.7	529.5

[a] Undiscounted annual costs assumed to be incurred at the end of each period for a total of 20 years.
[b] Undiscounted one-time costs assumed to be incurred at the start of the first period of the time horizon of this rule.

TABLE E16—PRESENT VALUE AND ANNUALIZED VALUE OF COSTS [a]

Requirements of the rule	Present value ($ mil)						Annualized costs ($ mil)					
	3 percent			7 percent			3 percent			7 percent		
	Low	Med.	High	Low	Med.	High	Low	Med.	High	Low	Med.	High
Private Sector												
Labeling Change	164.0	297.6	433.9	157.8	286.4	417.7	11.0	20.0	29.2	14.9	27.0	39.4
Market Testing	4.7	10.5	36.0	4.6	10.1	34.7	0.3	0.7	2.4	0.4	1.0	3.3
Point-of-Sale Advertising	44.1	44.1	44.1	42.5	42.5	42.5	3.0	3.0	3.0	4.0	4.0	4.0
Subtotal	212.8	352.2	514.1	204.8	339.0	494.9	14.3	23.7	34.6	19.3	32.0	46.7
Government												
FDA	89.2	89.2	89.2	61.2	61.2	61.2	6.0	6.0	6.0	5.8	5.8	5.8
Subtotal	89.2	89.2	89.2	61.2	61.2	61.2	6.0	6.0	6.0	5.8	5.8	5.8
Total	302.0	441.4	603.3	266.0	400.2	556.0	20.3	29.7	40.6	25.1	37.8	52.5

[a] The present value of upfront costs differs from previous tables because here these costs have been discounted 1 year back to 2010. Similarly, annual costs have been discounted back to 2010 before being annualized, resulting in a slight difference between annual and annualized costs.

E. Cost-Effectiveness Analysis

We measure the effectiveness of the proposed rule as the sum of saved life-years and quality-adjusted life years. In order to assess the cost-effectiveness of the proposed rule, we must adjust the costs to account for effects that are not captured by life-years or quality-adjusted life years. As shown in detail in the previous section, we calculated the first twenty years' costs attributable to the proposed rule and found present values of $266.0 to $556.0 million (using a 7 percent discount rate) or $302.0 to $603.3 million (using a 3 percent discount rate). We add to each total the estimated monetary value of lost consumer surplus (previously netted out of life-years and emphysema benefits estimates); this yields overall costs of $2.14 to $6.17 billion (using a 7 percent discount rate) or $9.47 to $28.10 billion (using a 3 percent discount rate). In order to focus on the costs associated with extensions of quality-adjusted life (see Ref. 68 at pp. 11–12), we then subtract both medical cost reductions and the value of property savings due to reductions in accidental fires and arrive at a net cost of $1.88 to $5.91 billion (using a 7 percent discount rate) or $8.93 to $27.57 billion (using a 3 percent discount rate).

Discounting over the same twenty-year time period, we calculate that this proposed rule would lead to 476,000 to 549,000 discounted smoking preventions or cessations. Similarly, we find that 34,627 to 171,660 discounted quality-adjusted life-years would be saved (this includes both fractional life-years associated with reduced emphysema and full life-years associated with reduced premature

mortality).[13] This yields a cost per smoking prevention of $3,940 to $50,204, and a cost per life-year saved of $52,047 to $170,552.

TABLE E17—COST-EFFECTIVENESS

Cost ($)	3 Percent			7 Percent		
	Low	Medium	High	Low	Medium	High
Per Smoking Prevention	16,271	33,217	50,204	3,940	8,149	12,403
Per Life-Year Saved	52,047	106,255	160,594	54,176	112,050	170,552

F. Distributional Effects

This proposed rule would bring about a variety of distributional effects not yet discussed in detail. Sectors affiliated with tobacco and tobacco products would lose sales revenues. Simultaneously, non-tobacco-related industries would gain sales, because dollars not spent for tobacco products would be spent on other commodities.

1. Tobacco Manufacturers, Distributors, and Growers

FDA estimates that implementation of the proposed regulation may reduce the annual cigarette consumption of U.S. smokers by 80 million packs. Meanwhile, the FTC (Ref. 39) reports that, in 2006, 1.75 billion cigarette packs were manufactured and distributed to consumers. These numbers imply that tobacco manufacturer revenues would be 0.68 percent lower in the rule's first year, and 0.79 percent lower in 2031, than they were in 2006. The U.S. Census Bureau (Ref. 92) reports that tobacco manufacturers' revenues totaled $41.6 billion in 2006; hence, the rule-induced decrease in annual tobacco sales would range from approximately $284 to $328 million. These estimates would rise somewhat higher if we were accounting for the decrease in price that accompanies the decrease in demand for a good (in this case, cigarettes). Experimental evidence from Mexico (Ref. 93) indicates that graphic warning labels may decrease smokers' willingness-to-pay for cigarettes by 17 percent; however, without supply elasticity data, we cannot determine how much this decline in willingness-to-pay would change cigarettes' market price.

We estimate that the tobacco manufacturing, warehousing and wholesale trade sectors employ about 74,000 full-time workers (Ref. 77). Under the assumption of constant production-to-employment ratio, we project that a 0.68–0.79 percent reduction in sales would result in the displacement of 500–600 jobs among manufacturers, warehouses, and wholesalers.

Effects of the rule would also be observed in the agricultural sector. According to USDA's 2007 Census of Agriculture (Ref. 94), there are 16,234 tobacco farms. Upon implementation of the proposed rule, these farms may shift some of their acreage from growing tobacco to producing other agricultural products.

2. National and Regional Employment Patterns

Several studies estimate the contribution of tobacco to the U.S. economy or, alternatively, the losses to the U.S. economy that would follow a decline in tobacco-related consumption. Economists have shown both theoretically and empirically that, for the nation as a whole, employment gains from spending on other products would offset any employment losses from reduced spending on tobacco products (Ref. 95). The major tobacco-growing states, however, would experience some adverse economic effects. An economic simulation of the regional impacts of spending on tobacco products carried out in 1994 found that after 8 years, a 2 percent per year fall in tobacco consumption (which substantially exceeds the FDA forecast for this regulation) would cause the loss of 36,600 jobs for the Southeast Tobacco region of the United States (0.2 percent of regional employment), whereas the nontobacco regions of the United States would gain 56,300 jobs (Ref. 96). That study, if carried out today, would find a much smaller net effect because total employment in tobacco-related industries has fallen. Overall, FDA finds that the income and employment impacts associated with reduced tobacco consumption would be quite small.

3. Retail Sector

As would tobacco growers, distributors and manufacturers, tobacco retailers would be affected by any decrease in cigarette sales. Retailers would, however, be in a position to shift shelf space and promotional activities to non-tobacco products, in order to take advantage of the increase in demand for other products that would be expected to accompany the decrease in spending on cigarettes.

4. Advertising Industry

The overall impact of the proposed rule on the advertising industry is uncertain. Advertiser revenue may decrease because advertisements with graphic warning labels are less desirable from a cigarette seller's standpoint and thus tobacco manufacturers would choose to conduct less advertising. On the other hand, advertising industry revenue may increase due to cigarette sellers' need to re-design ads to accommodate new warning labels and to devise new promotional strategies. In either case, few net social costs or benefits would be generated. Moreover, the effect on advertising would likely be relatively small since spending on cigarette advertising has been declining substantially in recent decades. By 2006, expenditures on magazine advertising had fallen to about $50 million and outdoor advertising to under $1 million. Most of the remaining affected advertising expenditures were point-of sale promotions, which totaled $240 million (Ref. 39).

5. Excise Tax Revenues

In 2009, Federal tobacco tax revenues totaled $16.3 billion, while state and local tax revenues totaled $16.5 billion (Ref. 97). The proposed rule would decrease government tobacco tax revenues as fewer Americans consume cigarettes.

FDA estimates this change in excise tax revenues by multiplying together the percentage change in smoking, whose calculation was described in section C1, the projected population in a given year (Ref. 65), age-appropriate discounted lifetime cigarette consumption (in

[13] This total reflects reduced premature mortality for smokers themselves and for others caught in the path of cigarette-related fires. The National Fire Protection Association (Ref. 90) reports the percentages of fire fatalities by age category; along with the CDC's estimate of average American life expectancy (Ref. 91), these data allow FDA to calculate that the expected number of life-years lost by fire victims is 37.3.

packs) per smoker, and current Federal and average state tax rates (Ref. 98; Ref. 99). FDA calculates average consumption for 15-year-olds, 16- to 17-year-olds, and 18- to 23-year-olds using the May 2006, August 2006, and January 2007 Tobacco Use Supplements to the Current Population Survey (Ref. 100). Sloan *et al.* (Ref. 66) report lifetime discounted consumption for typical 24-year-old smokers.

FDA estimates that annual rule-induced decreases in excise tax collections would be approximately $106 million for state governments and $80.5 million for the Federal government. Assuming that excise taxes rise, on average, at the rate of inflation allows us to sum these values over the time horizon of our analysis, yielding an overall revenue loss to state governments of $1.35 to $2.93 billion and to the Federal government of $1.03 to $2.23 billion. Given inelastic cigarette demand (Ref. 95), some state governments could raise tobacco product excise rates to offset these revenue losses.

G. International Effects

Of the $87.9 billion worth of tobacco products consumed in the United States in 2009 (Ref. 101), only $156 million consisted of imported cigarettes, with another $897 million imported as tobacco in a less-processed state (Ref. 102; Ref. 103). As in the United States, foreign manufacturers, distributors, and growers of tobacco and tobacco products would lose revenue as a result of the proposed rule, though their loss would be a small fraction of the overall revenue loss. As consumers who would have been smokers purchase other products, there would be a shift in patterns of international trade. If the preferred substitute products are American-made, there would be a (very small) decrease in overall imports into the United States; otherwise, there would be a small increase in imports from the source countries of the newly-demanded goods and services and a corresponding decrease in imports from tobacco-producing countries.

The proposed rule does not apply to cigarettes manufactured for export, whose value totaled $417 million in 2009 (Ref. 102).

H. Regulatory Alternatives

We compare the proposed rule to two hypothetical alternatives: An otherwise identical rule with a 24-month compliance period and an otherwise identical rule with a 6-month compliance period. Even though we estimate costs and benefits for these alternatives, they do not provide viable regulatory options, as they are inconsistent with FDA's statutory mandate.

1. 24-Month Compliance Period

The cost of the labeling changes for this proposed rule depends far less than most labeling rules on the compliance period. The main effect of a longer compliance period would be to eliminate the 10 percent premium for overtime and rush charges added to the per-UPC label design activities for compliance periods shorter than 24 months (Ref. 83). All other costs are the same as in the 15-month analysis.

Table E18 shows that extending the compliance period to 24 months would reduce the up-front labeling change cost by $15 to $41 million, to a total of $154 to $406 million.

TABLE E18—COST OF A CIGARETTE LABEL REDESIGN WITH NINE WARNINGS WITH A 24–MONTH COMPLIANCE PERIOD [a]

	Low	Medium	High
Label Design Cost			
Number of UPCs	3,234	3,234	3,234
Administrative labor cost ($)	375	695	1,014
Graphic design labor cost ($)	1,120	2,163	3,206
Prepress labor cost ($)	1,482	2,649	3,816
Recordkeeping labor cost ($)	33	234	434
Prepress materials ($)	900	11,025	21,951
Printing plate cost ($)	43,560	69,390	95,220
Cost per product UPC ($)	47,470	86,156	125,641
Total label design cost, 24-month compliance ($)	153,517,980	278,628,504	406,322,994
Total Cost ($)	153,517,980	278,628,504	406,322,994
Change from 15-month Compliance Period	−15,351,798	−27,862,850	−40,632,299

[a] Undiscounted costs assumed to be incurred at the start of the first period of the time horizon of this rule.

Extending the compliance period to 24 months would delay the accrual of health and fire reduction benefits by nine months. An approximation of the effect of this delay may be found by discounting, at three and seven percent discount rates, the previously-calculated total benefits. As shown in Table E19, FDA finds that a 24-month compliance period would decrease benefits by between $113.5 and $622.5 million.

TABLE E19—PRESENT VALUE OF BENEFITS WITH 24-MONTH COMPLIANCE PERIOD ($ MIL)

	VSLY = $105,000		VSLY = $210,000		VSLY = $315,000	
	3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate
Life-Years	8,767.3	1,715.6	17,534.7	3,431.3	26,302.0	5,146.9
Non-Fatal Emphysema	197.6	61.7	395.3	123.4	592.9	185.0
Fire Loss	384.5	171.7	384.5	171.7	384.5	171.7
Medical Expenditure Reduction	487.9	231.9	487.9	231.9	487.9	231.9
Total	9,837.4	2,180.9	18,802.4	3,958.3	27,767.3	5,735.6

TABLE E19—PRESENT VALUE OF BENEFITS WITH 24-MONTH COMPLIANCE PERIOD ($ MIL)—Continued

	VSLY = $105,000		VSLY = $210,000		VSLY = $315,000	
	3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate
Change from 15-Month Compliance Period	−220.5	−113.5	−421.5	−206.0	−622.5	−298.6

2. Six-Month Compliance Period

In the 2003 labeling-cost model, overtime and rush charges equal 10 percent of the per-UPC label design costs with a 6-month compliance period. The model further assumes that 12 months is the shortest compliance period that can be met without resorting to covering up the old labels with stickers as a temporary solution. Therefore, the cost of discarded inventory is the same as under a 12-month compliance period, but there is an additional cost for applying appropriate stickers to cover the old package label design for a period of 6 months.

FDA assumes that no additional inventory will remain unused after 6 months of applying stickers. The number of units sold annually is about 10.7 billion.[14] Therefore, 5.3 billion units would be relabeled with stickers. We estimate the per-unit cost for the sticker and application cost to be between $0.017 and $0.045 (Ref. 83). Reducing the compliance period to 6 months would then increase compliance costs by $91 to $239 million to a total of $259 to $686 million. The use of 9 graphic-text combinations is not expected to materially affect this cost.

TABLE E20—COST OF A CIGARETTE LABEL REDESIGN WITH NINE WARNINGS WITH A SIX-MONTH COMPLIANCE PERIOD [a]

	Low	Medium	High
Label Design Cost			
Number of UPCs	3,234	3,234	3,234
Administrative labor cost ($)	375	695	1,014
Graphic design labor cost ($)	1,120	2,163	3,206
Prepress labor cost ($)	1,482	2,649	3,816
Recordkeeping labor cost ($)	33	234	434
Prepress materials ($)	900	11,025	21,951
Printing plate cost ($)	43,560	69,390	95,220
Cost per product UPC ($)	47,470	86,156	125,641
Total label design cost, 24-month compliance ($)	153,517,980	278,628,504	406,322,994
Total label design cost, < 24-month compliance ($)	168,869,778	306,491,354	446,955,293
Sticker Costs			
Stick and application costs per unit ($)	0.017	0.031	0.045
Number of units sold in 6 months	5,338,051,475	5,338,051,475	5,338,051,475
Total sticker cost ($)	90,501,325	168,073,889	239,182,072
Total Cost ($)	259,371,103	474,565,243	686,137,366
Change from 15-month Compliance Period	90,501,325	168,073,889	239,182,072

[a] Undiscounted costs assumed to be incurred at the start of the first period of the time horizon of this rule.

Reducing the compliance period to six months would hasten the accrual of health and fire reduction benefits by nine months. An approximation of the effect of this change in timing may be found by compounding, at three and seven percent discount rates, the previously-calculated total benefits. As shown in Table E21, FDA finds that a six-month compliance period would increase benefits by between $119.4 and $636.4 million.

TABLE E21—PRESENT VALUE OF BENEFITS WITH SIX-MONTH COMPLIANCE PERIOD ($ MIL)

	VSLY = $105,000		VSLY = $210,000		VSLY = $315,000	
	3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate	3% Discount rate	7% Discount rate
Life-Years	9,164.8	1,898.9	18,329.6	3,797.8	27,494.4	5,696.7
Non-Fatal Emphysema	206.6	68.3	413.2	136.5	619.8	204.8
Fire Loss	401.9	190.0	401.9	190.0	401.9	190.0
Medical Expenditure Reduction	510.0	256.7	510.0	256.7	510.0	256.7
Total	10,283.4	2,413.9	19,654.8	4,381.1	29,026.2	6,348.2
Change from 15-Month Compliance Period	225.5	119.4	430.9	216.8	636.4	314.1

[14] The AC Nielsen data for total equivalent units show sales totaling 38,632 million sticks in 2008 (Ref. 104), whereas The Maxwell Report states that industry volume was 345,300 million sticks in 2008 (Ref. 105). Thus the Nielsen data capture 38,632/345,300 = 11.2 percent of cigarettes sold. Nielsen data show total sales units of 1.195 billion in 2008. Dividing by 0.112 yields an estimate of 10.7 billion sales units per year.

3. Summary of Regulatory Alternatives

Table E22 summarizes the regulatory alternatives by displaying ranges for the present values of the total benefits and total costs. Estimated ranges for the cost ratios (per smoking prevention and per life-year saved) of the proposed rule and its regulatory alternatives appear in Table E23.

TABLE E22—SUMMARY OF REGULATORY ALTERNATIVES

Compliance period	Present value of total benefits ($ mil) [a]		Present value of total costs ($ mil) [b]	
	3%	7%	3%	7%
24-Month Total	9,837.4 to 27,767.3	2,180.9 to 5,735.6	285.2 to 561.9	248.6 to 515.0.
(Proposed Rule) 15-Month Total	10,057.9 to 28,389.8	2,294.5 to 6,034.1	302.0 to 603.3	266.0 to 556.0.
6-Month Total	10,283.4 to 29,026.2	2,413.9 to 6,348.2	391.9 to 837.5	353.8 to 782.7.

[a] Range in benefits is based on a VSLY of $105,000 to $315,000.
[b] Range in costs is based on low cost and high cost values.

TABLE E23—INCREMENTAL COST-EFFECTIVENESS OF REGULATORY ALTERNATIVES

	Discount rate = 3 percent				Discount rate = 7 percent			
	Low	Incremental CE *	High	Incremental CE *	Low	Incremental CE *	High	Incremental CE *
24-Month Compliance:								
Per Smoking Prevention	$16,252	N/A	$50,152	N/A	$3,819	N/A	$12,024	N/A
Per Life-Year Saved	51,986	N/A	160,426	N/A	52,512	N/A	165,336	N/A
15-Month Compliance:								
Per Smoking Prevention	16,271	$17,121	50,204	$52,545	3,940	$9,337	12,403	$29,324
Per Life-Year Saved	52,047	54,768	160,594	168,081	54,176	128,383	170,552	403,225
6-Month Compliance:								
Per Smoking Prevention	16,419	23,021	50,597	68,133	4,207	16,118	13,170	47,376
Per Life-Year Saved	52,521	73,641	161,852	217,946	57,847	221,637	181,095	651,438

* As the compliance period decreases, the number of rule-induced smoking preventions and life-years saved increases. Hence, the incremental costs of 15-Month Compliance are calculated relative to 24-Month Compliance, and the incremental costs of 6-Month Compliance are calculated relative to 15-Month Compliance.

I. Impact on Small Entities

The Regulatory Flexibility Act requires agencies to prepare an initial regulatory flexibility analysis if a proposed rule would have a significant effect on a substantial number of small entities. We expect this proposed rule to have a significant effect on a substantial number of small entities. Consequently, this analysis, together with other relevant sections of this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

1. Description and Number of Affected Small Entities

The proposed rule would affect small entities in several industries, from tobacco farming to the retail industry. Most of the nation's 16,234 tobacco farms are small; between 90.7 and 95.8 percent (between 14,732 and 15,555) of the farms growing tobacco in 2007 had total farm sales under the U.S. Small Business Administration (SBA) small business size standard of $750,000 (Ref. 94; Ref. 106).

Table E24 shows the breakdown of domestic cigarette manufacturers by employment size. Census data indicate that most cigarette manufacturing firms are small businesses, with only 4 of 24 firms employing more than 500 employees, while the small business size standard established by the SBA for this industry is 1,000, so a minimum of 20 small cigarette manufacturers would be affected (Ref. 77; Ref. 106).

TABLE E24—CIGARETTE MANUFACTURERS BY NUMBER OF EMPLOYEES

Size by number of employees	Number of firms
Less than 20	9
20 to 99	7
100 to 499	4

Source: Ref. 106.
SBA size standard: 1,000 employees.

Statistics of U.S. Businesses data show that 1,067 of 1,159 tobacco wholesale trade firms (92 percent) employ fewer than the 100-employee threshold that constitutes a small business according to the SBA (Ref. 77; Ref. 106). If the size distribution of cigarette importers is similar to that of all tobacco wholesale trade firms, then 92 percent of them would be affected small businesses.

Also likely to be affected by the regulation are small retail and service entities that sell cigarettes. Retail establishments bear shared responsibility with manufacturers for the cost of removing noncompliant advertising. SBA size standards for the retail trade and the accommodations and food services industries differ from size categories used by the U.S. Census. Table E25 shows the 2002 Census size categories that most closely match the SBA size standards. In all cases, the closest Census size category is smaller than the SBA size standard. As a consequence, any estimate based on the Census size categories may underestimate the number of small entities.

TABLE E25—SBA SIZE STANDARDS AND CENSUS SIZE CATEGORIES FOR RETAIL AND SERVICE FIRMS IN NAICS CATEGORIES WITH TOBACCO PRODUCT LINE SALES [a]

NAICS with tobacco product line sales	Description of NAICS category	SBA size standard (employees or $ million)	Census size category (employees or $ million)
General Merchandise			
452990	Other General Merchandise	11	10.
452 excluding 452990	Department, Discount Department, Warehouse Clubs, and Superstores	27	25.
Supermarket and Grocery			
4452 and 4453	Other Food and Beverage Stores	7	5.
445110	Supermarkets and Grocery	27	25.
445120	Convenience Stores	27	25.
447110	Convenience Stores with Gas	27	25.
447190	Service Stations	9	5.
446	Health and Personal Care Stores	7	5.
453991	Specialty Tobacco Stores	7	5.
B	Other Kinds of Business	Varies	Varies.

Source: Refs. 106–108.
[a] Includes only firms with payroll.
[b] Includes NAICS 4413, 443112, 444, 448, 451, 4532, 453998, 72 (excluding 72231), 722310.

The Census reports establishment numbers for business by product line, and establishment and firm size by type of business, but provides no size data by type of business and product line. To estimate the number of affected entities that SBA classifies as small, we begin by counting the number of firms that fall below the Census size standard shown in Table E25, including only firms in NAICS categories with tobacco product line sales. Next, we calculate the percentage of small firms in each NAICS category. Depending on the type of business, the percentage of small firms ranges from 41 percent for Discount Department, Warehouse Clubs, and Superstores to almost 100 percent for Convenience Stores.

TABLE E26—ESTIMATED PERCENTAGE OF SMALL RETAIL AND SERVICE FIRMS IN NAICS CATEGORIES WITH TOBACCO PRODUCT LINE SALES [a]

NAICS	Description of NAICS category	Number of firms	Number of firms below census size standard [b]	Percentage of small firms
General Merchandise				
452110, 452910	Discount Department, Warehouse Clubs, and Superstores	88	36	40.9
452990	Other General Merchandise	7,451	7,320	98.2
General Merchandise Subtotal		7,539	7,356	97.6
Supermarket & Grocery				
445110	Supermarkets & Grocery	34,017	33,328	98.0
4452 and 4453	Other Food and Beverage Stores	34,807	34,082	97.9
Supermarket & Grocery Subtotal		68,824	67,410	97.9
445120	Convenience Stores	18,705	18,676	99.8
447110	Convenience Stores with Gas	37,437	36,848	98.4
447190	Service Stations	19,822	18,103	91.3
4461	Drug Stores	36,198	33,894	93.6
453991	Tobacco Stores	3,238	3,017	93.2
	Other Kinds of Business	589,400	572,619	97.2

Source: Refs. 107, 108, 78, 79.
[a] Includes only firms with payroll.
[b] Based on the Census size standards shown in Table E25.

Finally, we apply the percentages in Table E26 to our current estimate of the number of affected establishments with payroll (Table E7). This approach implicitly assumes that small establishments are similar whether or not they sell tobacco products. In addition, we classify all nonemployer establishments as small. In total, we estimate that about 355,000 small retail and service establishments would be affected by the proposed rule. This number represents about 98 percent of the estimated 361,000 establishments selling tobacco products.

TABLE E27—ESTIMATED NUMBER OF SMALL ESTABLISHMENTS WITH TOBACCO PRODUCT LINE SALES BY KIND OF BUSINESS

Kind of business	Percentage of small [a]	Number with payroll [b]	Small with payroll	Non-employers [b]	Estimated total number of small establishments
General Merchandise	97.6	8,147	7,949	5,661	13,611
Supermarket & Grocery	98.0	67,037	65,679	56,761	122,441
Convenience Stores	99.8	23,986	23,949	0	23,949
Convenience Stores with Gas	98.4	87,713	86,333	0	86,333
Service Stations	91.3	6,347	5,797	2,979	8,775
Drug Stores	93.6	19,413	18,178	30,138	48,316
Specialty Tobacco Stores	93.2	6,458	6,017	0	6,017
Other Establishments	97.2	28,531	27,719	17,391	45,110
Total	.....	247,633	241,621	112,931	354,552

[a] From Table E26.
[b] From Table E12.

2. Description of the Potential Impacts of the Final Rule on Small Entities

a. *Effect on manufacturers.* In order to estimate how much of the label design and inventory costs would be incurred by small domestic cigarette manufacturers, FDA subtracts the proportion of those costs estimated to be incurred by large domestic manufacturers and foreign manufacturers. Scanner data indicate that, approximately 55 percent of UPCs can be readily identified as belonging to a brand marketed by one of the 4 largest cigarette firms by volume (Ref. 105; Refs. 84–89). Because the costs of labeling changes are roughly proportional to the number of UPCs, FDA then attributes 55 percent of the total label design and inventory costs to the 4 firms employing at least 500 people. FDA attributes an additional 3 percent of the labeling change costs to foreign manufacturers.[15] These adjustments leave 42 percent of labeling change costs, or $71 to $188 million, to be incurred by the 20 small manufacturers. Assuming costs are equal among these firms implies a per-firm cost of $3.5 to $9.4 million. Table E28 compares this estimated compliance cost to average annual receipts in order to gauge the potential impact of labeling change requirements on small cigarette manufacturing firms. Because the number of UPCs is probably larger for larger firms, costs are likely greater for larger firms than for smaller firms; if so this method overstates the impact on the smallest firms and understates the impact on the largest firms (within the category of firms employing fewer than 500 people).

TABLE E28—POTENTIAL IMPACT OF LABELING CHANGE COMPLIANCE COSTS ON THE 20 SMALL CIGARETTE MANUFACTURERS

Size by number of employees	Number of firms	Average annual receipts ($1,000)	Average labeling compliance costs ($1,000)		Average labeling compliance costs as a percent of average annual receipts	
			Low	High	Low	High
Less than 20	9	11,195	3,546	9,386	32	84
20 to 99	7	21,265	3,546	9,386	17	44
100 to 499	4	147,896	3,546	9,386	2	6

Source: Ref. 77.
SBA size standard: 1,000 employees.

b. *Effect on retailers.* As shown in Table E29, retail trade businesses account for almost all sales of tobacco products (Ref. 78; Ref. 79). About 90 percent of tobacco product line sales occur at gasoline stations, food and beverage stores, general merchandise stores, or tobacco stores. Convenience stores (with gasoline stations and stand-alone convenience stores) account for about half of all tobacco product line sales.

TABLE E29—SALES OF TOBACCO PRODUCT LINE BY KIND OF BUSINESS AND INDUSTRY SECTOR [a]

Kind of business and industry sector	Sales of tobacco product line by kind of business		Sales of tobacco product line by industry sector	
	($ bil)	(%)	($ bil)	(%)
Retail Trade				
NAICS 447—Gasoline Stations	.....	.....	22.2	43.3
Convenience Stores with Gas	21.2	41.3	.....	.....

[15] In 2008, 9.9 billion out of 345.3 billion individual cigarettes sold were imported. FDA assumes the same proportion holds for UPCs. These UPCs should not overlap with those produced by the 4 largest domestic producers.

TABLE E29—SALES OF TOBACCO PRODUCT LINE BY KIND OF BUSINESS AND INDUSTRY SECTOR [a]—Continued

Kind of business and industry sector	Sales of tobacco product line by kind of business		Sales of tobacco product line by industry sector	
	($ bil)	(%)	($ bil)	(%)
Gasoline Stations	1.0	2.0		
NAICS 445—Food and Beverage Stores			13.4	26.2
Supermarket & Grocery	7.7	15.0		
Convenience Stores	4.5	8.8		
Liquor Stores	1.2	2.4		
NAICS 452—General Merchandise			7.1	13.9
General Merchandise	7.1	13.9		
NAICS 453—Miscellaneous Store Retailers			5.8	11.3
Tobacco Stores	5.7	11.1		
Miscellaneous store retailers	0.1	0.3		
NAICS 446—Health and Personal Care Stores			1.5	3.0
Drug Stores	1.5	3.0		
NAICS 454—Nonstore Retailers			0.7	1.3
Nonstore Retailers	0.5	1.0		
Vending machine operators	0.2	0.4		
Other Subsectors [b]			0.1	0.2
Other Kinds of Business	0.1	0.2		
Accommodation & Food Services				
NAICS 72			0.4	0.8
Other establishments	0.3	0.5		
Drinking places	0.1	0.3		
Total			51.2	100

[a] Includes establishments with payroll with tobacco product line sales.
[b] Includes establishments in NAICS 441320, 443112, 444130, 444220, 448110, 448320, 451110, 451211, 451212, and 451220.

To illustrate the effects of the proposed rule on a typical small retail store, we look at one-time costs for a convenience store and a convenience store with gasoline. We select these businesses because, as illustrated in Table E29, sales of tobacco products in these stores account for about 50 percent of all tobacco sales. In addition, tobacco products are an important part of overall revenue for these stores, composing over 12 percent of total sales (as shown in Table E30).

TABLE E30—THE IMPORTANCE OF TOBACCO SALES BY KIND OF BUSINESS: RANKED BY THE PERCENTAGE OF TOTAL SALES FROM TOBACCO PRODUCT LINE

Kind of business	Sales from tobacco product line [a] ($ bil)	Total sales from all product lines ($ bil) [b]	Percentage of total sales from tobacco product line
Tobacco Stores	5.7	6.5	86.9
Convenience Stores	4.5	18.1	25.0
Nonstore Retailers	0.5	2.4	20.3
Convenience Stores with Gas	21.2	173.4	12.2
Vending Machine Operators	0.2	1.7	11.2
Miscellaneous store retailers	0.1	1.2	11.2
Liquor Stores	1.2	12.8	9.7
Other Kinds of Business	0.1	1.4	6.5
Drinking places	0.1	3.9	3.5
Gasoline Stations	1.0	29.4	3.5
General Merchandise	7.1	246.1	2.9
Supermarket & Grocery	7.7	383.5	2.0
Drug Stores	1.5	80.0	1.9
Other Accommodation & Foodservice	0.3	33.3	0.8
Total	51.2	993.9	5.2

[a] Tobacco sales from Table E29.
[b] Includes total sales for firms with tobacco product line sales. Refs. 78, 79.

For both types of convenience stores, Table E31 shows that for the smallest firms with less than $250,000 in annual sales, the one-time costs of the proposed rule would equal less than 2 percent of annual average sales of tobacco products. Furthermore, one-time costs total less than 0.1 percent of annual average sales of tobacco products for stores with $1 million or more in average annual sales. Although the impact on other small retail and service entities is uncertain, this example suggests that the proposed rule would be unlikely to create a significant direct

burden on small retail stores or service establishments.

TABLE E31—ONE-TIME COSTS AS A PERCENTAGE OF AVERAGE SALES OF TOBACCO PRODUCTS FOR CONVENIENCE STORES AND CONVENIENCE STORES WITH GASOLINE

Sales size of firm	Number of establishments	Sales ($ mil)	Sales of tobacco products	
			Average ($ mil)	One-time costs as percentage of average
Convenience Store—NAICS 445120 [a]:				
Less than $250,000	4,231	653	0.0	0.5
$250,000 to $499,999	5,296	1,920	0.1	0.2
$500,000 to $999,999	5,150	3,646	0.2	0.1
$1,000,000 to $2,499,999	3,586	4,915	0.3	0.1
$2,500,000 to $4,999,999	659	1,601	0.6	0.0
$5,000,000 to $9,999,999	324	712	0.5	0.0
$10,000,000 to $24,999,999	215	440	0.5	0.0
Convenience Stores with Gasoline—NAICS 447110 [b]:				
Less than $250,000	2,246	343	0.0	1.0
$250,000 to $499,999	3,801	1,425	0.0	0.4
$500,000 to $999,999	7,667	5,624	0.1	0.2
$1,000,000 to $2,499,999	14,309	22,303	0.2	0.1
$2,500,000 to $4,999,999	7,977	22,786	0.3	0.1

Source: Ref. 108.

[a] Tobacco product line sales account for 25.0 percent of sales for all firms in NAICS 445120 (see Table E30); One-time costs equal $198.16 (see Table E13).

[b] Tobacco product line sales account for 12.2 percent of sales for all firms in NAICS 447110 (see Table E30); One-time costs equal $193.42 (see Table E13).

3. Alternatives To Minimize the Burden on Small Entities

a. *Increase the compliance period to 24 months for small manufacturers or all manufacturers.* Allowing all manufacturers, or only small manufacturers, 24 months to comply with the labeling changes would reduce overtime and rush charges. Under a 24-month compliance period, labeling change costs would fall on average by $0.32 to $0.85 million per small firm. Table E32 compares the reduced estimated compliance cost to average annual receipts in order to gauge the potential impact of this regulatory alternative on cigarette manufacturing firms employing fewer than 500 people. As a comparison with Table E28 shows, this option would provide only modest relief. It would also delay the public health benefits of the proposed rule and be inconsistent with the statutory requirement.

TABLE E32—POTENTIAL IMPACT OF LABELING CHANGE COMPLIANCE COSTS ON THE 20 SMALL CIGARETTE MANUFACTURERS WITH A 24-MONTH COMPLIANCE PERIOD

Size by number of employees	Number of firms	Average annual receipts ($1,000)	Average labeling compliance costs ($,1000)		Average labeling compliance costs as a % of average annual receipts	
			Low	High	Low	High
Less than 20	9	11,195	3,224	8,533	29	76
20 to 99	7	21,265	3,224	8,533	15	40
100 to 499	4	147,896	3,224	8,533	2	6

Source: Ref. 77

SBA size standard: 1,000 employees

b. *Exempt small manufacturers from the labeling change requirements.* Exempting small manufacturers from the labeling change requirements would eliminate their incremental labeling costs (an average reduction of $3.5 to $9.4 million), thus providing maximum relief. The combined market share of the 4 largest manufacturers was 89.7 percent in 2008 (Ref. 105). The immediate impact would therefore be to allow 10.3 percent of cigarettes to be marketed without graphic warning labels when the rule went into effect. This proportion would grow over time, however, as some consumers would be expected to switch to brands marketed without graphic warnings. This approach would be inconsistent with both the statutory mandate and the public health objectives of this rule.

c. *Exempt small cigarette retailers from the point-of-sale advertising requirements.* Exempting small cigarette retailers from the point-of-sale advertising requirements would eliminate their need to remove noncompliant advertising, reducing their direct costs to zero. However, Table E27 shows that the overwhelming majority of retail establishments selling cigarettes are small. Although the few establishments operated by large firms might be expected to have higher volume, a significant proportion of consumers would continue to be exposed to advertising lacking the new graphic warnings. This situation would be inconsistent with the public health

objective of the proposed rule as well as FDA's statutory mandate.

IX. Comments

Interested persons may submit to the Division of Dockets Management (*see* **ADDRESSES**) either electronic or written comments regarding this document. As noted above, if you have comments on specific provisions of the proposed regulation, we request that you identify these provisions in your comments. In addition, if you have concerns that would be addressed by alternative text for the regulation, we request that you provide this alternative text in your comments. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

X. References

The following references have been placed on display in the Division of Dockets Management (*see* **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday. (FDA has verified Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register.**)

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List of Subjects in 21 CFR Part 1141

Advertising, Incorporation by reference, Labeling, Packaging and containers, Tobacco, and Smoking.

Therefore, under the Federal Cigarette Labeling and Advertising Act, the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that chapter I of title 21 of the Code of Federal Regulations be amended by adding part 1141 to subchapter K to read as follows:

PART 1141—CIGARETTE PACKAGE AND ADVERTISING WARNINGS

Subpart A—General Provisions

Sec.

Subpart B—Cigarette Package and Advertising Warnings

Subpart C—Additional Disclosure Requirements for Cigarette Packages and Advertising

Authority: Secs. 201 and 202, Pub. L. 111–31, 123 Stat. 1776; 15 U.S.C. 1333; 21 U.S.C. 371, 387c, 387f.

Subpart A—General Provisions

§ 1141.1 Scope.

(a) This part sets forth the requirements for the display of health warnings on cigarette packages and in advertisements for cigarettes. FDA may require additional statements to be displayed on packages and in advertisements under the Federal Food, Drug, and Cosmetic Act or other authorities.

(b) The requirements of this part do not apply to manufacturers or distributors of cigarettes that do not manufacture, package, or import cigarettes for sale or distribution within the United States.

(c) A cigarette retailer shall not be considered in violation of this part as it applies to the display of health warnings on a cigarette package if the package:

(1) Contains a health warning;

(2) Is supplied to the retailer by a license- or permit-holding tobacco product manufacturer, importer, or distributor; and

(3) Is not altered by the retailer in a way that is material to the requirements of section 4(a) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(a)) or this part, including by obscuring the warning, by reducing its size, by severing it in whole or in part, or by otherwise changing it in a material way.

(d) A cigarette retailer shall not be considered in violation of this part, as it applies to the display of health warnings in an advertisement for cigarettes if the advertisement is not created by or on behalf of the retailer and the retailer is not otherwise responsible for the inclusion of the required warnings. This paragraph shall not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a health warning or that contains a warning that has been altered by the retailer in a way that is material to the requirements of section 4(b) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(b)), this part, or section 4(c) of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333(c)), including by obscuring the warning, by reducing its size, by severing it in whole or in part, or by otherwise changing it in a material way.

§ 1141.3 Definitions.

For the purposes of this part,

Cigarette means:

(1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; and

(2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filler, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette described in paragraph (1) of this definition.

Commerce means:

(1) Commerce between any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island and any place outside thereof;

(2) Commerce between points in any State, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, or Johnston Island, but through any place outside thereof; or

(3) Commerce wholly within the District of Columbia, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Island, Kingman Reef, or Johnston Island.

Distributor means any person who furthers the distribution of cigarettes at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

Front panel and *rear panel* mean the two largest sides or surfaces of the package.

Importer means any person who introduces into commerce any cigarette that:

(1) Was not manufactured inside the United States; and

(2) Is intended for sale or distribution to consumers in the United States.

Manufacturer means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette product.

Package means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers.

Person means an individual, partnership, corporation, or any other business or legal entity.

Required warning means the combination of one of the textual warning statements and its accompanying color graphic, which are set forth in "Cigarette Required Warnings—English and Spanish" and "Cigarette Required Warnings—Other Foreign Languages," which are incorporated by reference at § 1141.12.

Retailer means any person who sells cigarettes to individuals for personal consumption, or who operates a facility where vending machines or self-service displays of cigarettes are permitted.

United States, when used in a geographical sense, includes the several States, the District of Columbia, the Commonwealth of Puerto Rico, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Islands, Kingman Reef, and Johnston Island. The term "State" includes any political division of any State.

Subpart B—Cigarette Package and Advertising Warnings

§ 1141.10 Required warnings.

(a) *Packages*—(1) It shall be unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes the package of which fails to bear, in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part, one of the required warnings on both the front and the rear panel.

(2) The required warning shall be obtained and accurately reproduced from the electronic images contained in "Cigarette Required Warnings—English and Spanish," which is incorporated by reference at § 1141.12, except that it must be adapted as necessary to meet the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part.

(3) The required warning shall appear directly on the package and shall be clearly visible underneath the cellophane or other clear wrapping.

(4) The required warning shall be located in the upper portion of the front and rear panels of the package and shall comprise at least the top 50 percent of these panels; *Provided, however,* that on cigarette cartons, the required warning shall be located on the left side of the front and rear panels of the carton and shall comprise at least the left 50 percent of these panels.

(5) The required warning shall be positioned such that the text of the required warning and the other information on that panel of the package have the same orientation.

(b) *Advertisements*—(1) It shall be unlawful for any manufacturer, importer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless its advertising bears, in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part, one of the required warnings.

(2) The text in each required warning shall be in the English language, except that:

(i) In the case of an advertisement that appears in a non-English publication, the text in the required warning shall appear in the predominant language of the publication whether or not the advertisement is in English; and

(ii) In the case of an advertisement that appears in an English language publication but that is not in English, the text in the required warning shall appear in the same language as that principally used in the advertisement.

(3) For English-language and Spanish-language warnings, each required warning shall be obtained and accurately reproduced from the electronic images contained in "Cigarette Required Warnings—English and Spanish," which is incorporated by reference at § 1141.12, except that it must be adapted as necessary to meet the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), including area and other formatting requirements, and this part.

(4) For foreign-language warnings, except for Spanish-language warnings, each required warning shall be the color graphic obtained and accurately reproduced from the electronic images contained in "Cigarette Required Warnings—Other Foreign Language Advertisements," which is incorporated by reference at § 1141.12, and into which a true and accurate translation of the textual warning is inserted in accordance with "Cigarette Required Warnings—Other Foreign Language Advertisements," except that the required warning must be adapted as necessary to meet the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333), including area and other formatting requirements, and this part.

(5) The required warning shall occupy at least 20 percent of the area of each advertisement, and shall be placed in accordance with the requirements in the Federal Cigarette Labeling and Advertising Act.

(c) *Irremovable or permanent warnings.* The required warnings shall be indelibly printed on or permanently affixed to the package or advertisement. Such warnings, for example, must not be printed or placed on a label affixed to a clear outer wrapper that is likely to be removed to access the product within the package.

§ 1141.12 Incorporation by reference of required warnings.

Certain material entitled: "Cigarette Required Warnings—English and Spanish," (edition 1.0, June 2011, Food and Drug Administration), appearing in §§ 1141.10(a)(2), (b)(3), and 1141.16(a); and "Cigarette Required Warnings—Other Foreign Language Advertisements," (edition 1.0, June 2011, Food and Drug Administration), appearing in §§ 1141.10(b)(4) and 1141.16(a) are incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from the Food and Drug Administration, Center for Tobacco Products, Office of Compliance, 9200 Corporate Blvd., Rockville, MD 20850, 1–877–CTP–1373, and from the Web sites listed in paragraphs (a) and (b) of this section. Also, this material is available for inspection at the National Archives and Records Administration (NARA). For more information on the availability of the following material, call NARA at 202–741–6030 or go to *http://www.archives.gov/Federal_register/codeof_Federal_regulations/ibr_locations.html*:

(a) "Cigarette Required Warnings—English and Spanish," available from FDA at *http://www.fda.gov/Tobacco*, referred to at §§ 1141.10(a)(2) and (b)(3) and § 1141.16.

(b) "Cigarette Required Warnings—Other Foreign Language Advertisements," available from FDA at *http://www.fda.gov/Tobacco*, referred to at §§ 1141.10(b)(4) and § 1141.16.

§ 1141.14 Misbranding of cigarettes.

(a) A cigarette shall be deemed to be misbranded under section 903(a)(1) of the Federal Food, Drug, and Cosmetic Act unless its labeling bears one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part. A cigarette shall be deemed to be misbranded under section 903(a)(7)(A) of the Federal Food, Drug, and Cosmetic Act unless its advertising bears one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part.

(b) A cigarette advertisement or package will be deemed to include a brief statement of relevant warnings for the purposes of section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act if it bears one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part. A cigarette distributed or offered for sale in any State shall be deemed to be misbranded under section 903(a)(8) of the Federal Food, Drug, and Cosmetic Act unless the manufacturer, packer, or distributor includes in all advertisements and packages issued or caused to be issued by the manufacturer, packer, or distributor with respect to the cigarette one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) and this part.

Subpart C—Additional Disclosure Requirements for Cigarette Packages and Advertising

§ 1141.16 Disclosures regarding cessation.

(a) The required warning shall include a reference to a smoking cessation assistance resource in accordance with, and as specified in, "Cigarette Required Warnings—English and Spanish" (incorporated by reference at § 1141.12) or "Cigarette Required Warnings—Other Foreign Language Advertisements" (incorporated by reference at § 1141.12), whichever is applicable.

(b) The smoking cessation assistance resource required to be referenced by paragraph (a) of this section must:

(1) Provide factual information about the harms to health associated with cigarette smoking and the health benefits of quitting smoking;

(2) Provide factual information about what smokers can expect when trying to quit;

(3) Provide practical advice (problem solving/skills training) about how to deal with common issues faced by users trying to quit;

(4) Provide evidence-based advice about how to formulate a plan to quit smoking;

(5) Provide evidence-based information about effective relapse prevention strategies;

(6) Provide factual information on smoking cessation treatments, including FDA-approved cessation medications;

(7) Provide information, advice, and support that is evidence-based, unbiased (including with respect to products, services, persons, and other entities), and relevant to tobacco cessation;

(8) Other than as described in this section, not advertise or promote any particular product or service;

(9) Not selectively present information about a subset of FDA-approved cessation products or product categories while failing to mention other FDA-approved cessation products or product categories or reference any drug or other medical product that FDA has not approved for tobacco cessation; and

(10) Not encourage the use of any non-evidence-based smoking cessation practices.

(c) If the smoking cessation assistance resource required to be referenced by paragraph (a) of this section is a Web site, it:

(1) Must not contain a link to any Web site unless it meets all of the criteria described in paragraph (b) of this section; and

(2) May include references to one or more toll-free telephone numbers only if they meet the criteria described in paragraphs (b) and (d) of this section.

(d) If the smoking cessation assistance resource required to be referenced by paragraph (a) of this section is a toll-free telephone number, it must:

(1) Ensure that staff providing smoking cessation information, advice, and support are trained specifically to help smokers quit by delivering unbiased and evidence-based information, advice, and support; and

(2) Maintain appropriate controls to ensure the criteria described in paragraph (b) of this section are met.

Dated: November 8, 2010.

Margaret A. Hamburg,

Commissioner of Food and Drugs.

Dated: November 8, 2010.

Kathleen Sebelius,

Secretary of Health and Human Services.

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