



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1141

[Docket No. FDA-2019-N-3065]

RIN 0910-AI39

Tobacco Products; Required Warnings for Cigarette Packages and Advertisements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a proposed rule to establish new required cigarette health warnings for cigarette packages and 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 new textual warning statements. The Tobacco Control Act amends the Federal Cigarette Labeling and Advertising Act (FCLAA) of 1965 to require each cigarette package and advertisement to bear one of the new required warnings. This proposed rule, once finalized, would specify the color graphics that must accompany the new textual warning statements. FDA is proposing to take this action to promote greater public understanding of the negative health consequences of cigarette smoking.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by

[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions.")

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-N-3065 for "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements."

Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its

consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or email to oir_submission@omb.eop.gov. All comments should be identified with the title, "Tobacco Products; Required Warnings for Cigarette Packages and Advertisements."

FOR FURTHER INFORMATION CONTACT: Courtney Smith or Daniel Gittleson, Office of Regulations, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 877-287-1373, email: AskCTPRegulations@fda.hhs.gov.

With regard to the information collection: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, PRASStaff@fda.hhs.gov.

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I. Executive Summary

A. *Purpose of the Proposed Rule*

This proposed rule would establish new required cigarette health warnings for cigarette packages and advertisements. These new cigarette health warnings would consist of textual warning statements accompanied by color graphics depicting the negative health consequences of cigarette smoking. The new cigarette health warnings, once finalized, would appear prominently on cigarette packages and in cigarette advertisements, occupying the top 50 percent of the area of the front and rear panels of cigarette packages and at least 20 percent of the area at the top of cigarette advertisements.

Cigarette smoking remains the leading cause of preventable disease and death in the United States and is responsible for more than 480,000 deaths per year. Smoking causes more deaths each year than human immunodeficiency virus, illegal drug use, alcohol use, motor vehicle injuries, and firearm-related incidents combined. In developing this proposed rule, FDA determined that the public holds misperceptions about the health risks caused by smoking and that warning statements focused on less-known health consequences of smoking paired with concordant color graphics would promote greater public understanding of the risks associated with cigarette smoking, especially given that the existing Surgeon General's warnings currently used in the United States have been shown to go unnoticed and be "invisible." For the reasons discussed in the preamble to this proposed rule, FDA has determined that the proposed new

cigarette health warnings will advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking.

B. Summary of the Major Provisions of the Proposed Rule

This proposed rule would establish new required warnings to appear on cigarette packages and in cigarette advertisements. The proposed rule would implement a provision of the Tobacco Control Act that requires FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany new textual warning statements. The Tobacco Control Act amends the FCLAA to require each cigarette package and advertisement to bear one of the new required warnings. These new cigarette health warnings would consist of textual warning statements accompanied by color graphics, in the form of concordant photorealistic images, depicting the negative health consequences of cigarette smoking. As required under the FCLAA, the new cigarette health warnings, once finalized, would appear prominently on cigarette packages and in cigarette advertisements, occupying the top 50 percent of the area of the front and rear panels of cigarette packages and at least 20 percent of the area at the top of cigarette advertisements.

In addition, as required under the FCLAA, the proposed rule would establish marketing requirements that would include the random display and distribution of the required warnings for cigarette packages and quarterly rotations of the required warnings for cigarette advertisements. A tobacco product manufacturer, distributor, or retailer would be required to submit a plan for the random and equal display and distribution of the required warnings on packages and the quarterly rotation in advertisements for approval by FDA. In addition, the proposed rule would require each tobacco product manufacturer required to randomly and equally display and distribute warnings on packaging or quarterly rotate warnings on advertisements in accordance

with an FDA-approved plan, to maintain a copy of the FDA-approved plan, and to make the plan available for inspection and copying by officers and employees of FDA.

FDA developed the new cigarette health warnings included in this proposed rule through a science-based, iterative research process. The proposed warnings are intended to promote greater public understanding of the negative health consequences of cigarette smoking.

C. Legal Authority

This proposed rule is being issued in accordance with sections 201 and 202 of the Tobacco Control Act (Pub. L. 111-31), which amend section 4 of the FCLAA (15 U.S.C. 1333). This proposed rule is also being issued based upon FDA's authorities related to misbranded tobacco products under sections 903 (21 U.S.C. 387c); FDA's authorities related to records and reports under section 909 (21 U.S.C. 387i); and FDA's rulemaking and inspection authorities under sections 701 (21 U.S.C. 371), 704 (21 U.S.C. 374), and 905(g) (21 U.S.C. 387e(g)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

D. Costs, Benefits, and Informational Effects

The proposed new cigarette health warnings would promote greater public understanding of the negative health consequences of cigarette smoking by presenting information about the health risks of smoking to smokers and nonsmokers in a format that helps people better understand these consequences. Despite the informational effects of this proposed rule, there is a high level of uncertainty around quantitative economic benefits at this time, so we describe them qualitatively. The cost of this proposed rule consists of initial and recurring labeling costs associated with changing cigarette labels to accommodate the new cigarette health warnings, design and operation costs associated with the random and equal display and distribution of required cigarette health warnings for cigarette packages and quarterly rotations of the required

warnings for cigarette advertisements, advertising-related costs, and costs associated with government administration and enforcement of the rule. We estimate that, at the mean, the present value of the costs of this proposed rule is about \$1.6 billion using a three percent discount rate and roughly \$1.2 billion using a seven percent discount rate (2018\$). If the information provided by the cigarette health warning on each cigarette package was valued at about \$0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the proposed rule would equal or exceed the estimated annual costs.

Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation/Acronym	What It Means
CDC	Centers for Disease Control and Prevention
COPD	Chronic Obstructive Pulmonary Disease
D.C. Cir.	United States Court of Appeals for the District of Columbia Circuit
EO	Executive Order
EPA	Environmental Protection Agency
FCLAA	Federal Cigarette Labeling and Advertising Act
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDA	Food and Drug Administration
FTC	Federal Trade Commission
IOM	Institute of Medicine
ITC-4	International Tobacco Control Four Country Survey
NARA	National Archives and Records Administration
OFR	Office of the Federal Register
OMB	Office of Management and Budget
PAD	Peripheral arterial disease
PDF	Portable document format
PVD	Peripheral vascular disease
SES	Socioeconomic status
SIDS	Sudden infant death syndrome
TCA statements	Textual warning statements specified in section 4(1) of the FCLAA
TTB	Alcohol and Tobacco Tax and Trade Bureau
WHO	World Health Organization

II. Background

A. Need for the Regulation

To help inform consumers of the potential hazards of cigarette smoking, Congress passed the FCLAA that required that a printed text-only warning appear on cigarette packages (Pub. L. 89-92). The 1965 warning requirement was modified by later amendments to the FCLAA, including the Comprehensive Smoking Education Act of 1984 (Pub. L. No. 98-474), which extended the warning requirement to cigarette advertising and updated the one warning to four warnings, frequently referred to as the Surgeon General's warnings.

The FCLAA has required the inclusion of text-only warnings on cigarette packages and in cigarette advertisements for many years. As discussed in detail in section V.A, there is considerable evidence that the Surgeon General's warnings go largely unnoticed and unconsidered by both smokers and nonsmokers. These warnings, which have not changed in nearly 35 years, have been described as "invisible" (Ref. 1) and fail to convey relevant information in an effective way (Ref. 2 at p. 291). The Surgeon General's warnings also do not include any color graphics.

In 2009, in enacting the Tobacco Control Act, Congress further amended the FCLAA and directed FDA to issue new cigarette health warnings that would include a graphic component depicting the negative health consequences of smoking to accompany the new textual warnings (section 201 of the Tobacco Control Act). In enacting this legislation, Congress also provided that FDA may adjust the warnings if FDA found that such a change would promote greater public understanding of the risks associated with the use of tobacco products (section 202 of the Tobacco Control Act).

Approximately 34.3 million U.S. adults smoke cigarettes (defined as smoking at least 100 cigarettes during their lifetime and now smoking cigarettes every day or some days) and nearly 1.4 million U.S. youth (aged 12-17 years) smoke cigarettes (defined as past 30-day use) (Refs. 5 and 6). Results from the 2017 National Survey on Drug Use and Health demonstrate that, on average, each day in the United States, about 2,000 youth under age 18 smoke their first cigarette, and 320 youth become daily cigarette smokers (Ref. 7).

The health risks associated with cigarette smoking are significant. Cigarette smoking is the leading cause of preventable disease and death in the United States and is responsible for more than 480,000 deaths per year (Ref. 8). Smoking causes more deaths each year than human immunodeficiency virus, illegal drug use, alcohol use, motor vehicle injuries, and firearm-related incidents combined (Refs. 9 and 10). Over 16 million Americans alive today live with disease caused by smoking cigarettes (Ref. 8). In addition to lung cancer, heart disease, and chronic obstructive pulmonary disease (COPD), smoking also causes numerous other serious health conditions that are less-known effects of smoking and exposure to secondhand smoke, including many types of cancer, premature birth, low birth weight, sudden infant death syndrome (SIDS), respiratory illnesses, clogged arteries, reduced blood flow, diabetes, rheumatoid arthritis, and vision conditions such as age-related macular degeneration and cataracts (Ref. 8).

In developing this proposed rule, FDA carefully examined the scientific literature, including the 2014 Surgeon General's Report (Ref. 8), which identified 11 more health conditions that have been established to have sufficient evidence to infer a causal link to cigarette smoking--the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports. Those health conditions examined in the 2014 Surgeon General's Report are in addition to the more than forty unique health consequences already classified in

previous Surgeon General's Reports as being caused by smoking and exposure to secondhand smoke. Additional findings in the scientific literature demonstrate that the U.S. public-- including youth and adults, smokers and nonsmokers--holds misperceptions about the health risks caused by smoking (Refs. 3 and 11–16). Through its review of the scientific literature, as well as the Agency's science-based, iterative research and development process (described in sections V and VI), FDA determined that having warning statements focused on less-known health consequences of smoking accompanied by photorealistic images can promote greater public understanding of the risks associated with cigarette smoking, especially given the unnoticed and "invisible" 1984 Surgeon General's warnings currently used in the United States (see section V.A).

Therefore, consistent with section 4 of the FCLAA (as amended by sections 201 and 202 of the Tobacco Control Act), we are proposing a set of textual warning label statements, to be accompanied by concordant color graphics depicting the negative health consequences of smoking, to appear on cigarette packages and in cigarette advertisements. Specifically, we are proposing to replace part 1141 to Title 21 of the Code of Federal Regulations (21 CFR Part 1141), and the new part 1141 would require new cigarette health warnings¹ on cigarette packages and in cigarette advertisements. These new cigarette health warnings would consist of up to 13 textual warning label statements accompanied by color graphics depicting the negative health consequences of smoking. As required by section 4 of the FCLAA, the new cigarette health warnings would appear prominently on packages and in advertisements, occupying the top 50 percent of the area of the front and rear panels of cigarette packages and at least 20 percent of the area at the top of cigarette advertisements.

¹ For the purposes of discussion throughout this document, FDA uses the term "cigarette health warnings" to refer to the required warnings we are proposing.

As described in section VII, FDA has determined that the proposed new cigarette health warnings will advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking.

B. History of the Rulemaking

In the *Federal Register* of June 22, 2011 (76 FR 36628), FDA issued a final rule entitled "Required Warnings for Cigarette Packages and Advertisements," which specified nine images to accompany the nine textual warning statements for cigarettes set out in the Tobacco Control Act. The final rule was challenged in court, and on August 24, 2012, the United States Court of Appeals of the District of Columbia vacated the rule and remanded the matter to the Agency. *R.J. Reynolds Tobacco Co. v. Food & Drug Administration*, 696 F.3d 1205 (D.C. Cir. 2012), *overruled on other grounds by Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 22-23 (D.C. Cir. 2014) (en banc). On December 5, 2012, the Court denied the Government's petition for panel rehearing and rehearing en banc, and the Government decided not to seek further review of the Court's ruling. In a letter to Congress on March 15, 2013, the U.S. Attorney General reported FDA's intention to undertake research to support a new rulemaking consistent with the Tobacco Control Act (Ref. 17).

Central to FDA's work since that time has been evaluating how to address the D.C. Circuit's critiques of the prior rule and carefully considering how to develop a research plan and rulemaking process that will provide a robust record for a new cigarette health warnings rule. Through extensive legal, scientific, and regulatory analyses, FDA developed a science-based, iterative research process for developing new cigarette health warnings to put forth in this proposed rule that would advance the Government's substantial interest in promoting greater public understanding of the negative health consequences of smoking. Because these cigarette

health warnings, as shown through the robust scientific evidence described in detail in sections VI-VII, are factual and accurate, advance the substantial Government interest in promoting greater public understanding of the negative health consequences of smoking, and are not unduly burdensome, FDA believes the warnings would pass a First Amendment analysis under *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985) (or, if applied, *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980)). After reviewing public comments and weighing additional scientific, legal, and policy considerations, FDA intends to finalize some or all of the 13 cigarette health warnings proposed in this rule.

C. Incorporation by Reference

FDA is proposing to incorporate by reference certain material entitled "Required Cigarette Health Warnings." We have included an electronic portable document format (PDF) file, containing the proposed required warnings, as a reference in the docket (Ref. 18). Any final rule would provide information on how to obtain the final electronic, layered design files for each required warning, as well as technical specifications to help regulated entities appropriately select, crop, and scale the warnings to ensure the required warnings are accurately reproduced across various sizes and shapes of cigarette packages and cigarette advertisements. FDA would also provide instructions for how to access this material (e.g., via download through FDA's website or a file transfer protocol website). Any material incorporated by reference must meet the Office of the Federal Register's (OFR) requirements for incorporating material by reference (5 U.S.C 552(a) and 1 CFR part 51).

III. Legal Authority

The Tobacco Control Act was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate the manufacture, marketing, and distribution of

tobacco products to protect the public health and to reduce tobacco use by minors. Section 201 of the Tobacco Control Act amends section 4 of the FCLAA to require that nine new health warning statements appear on cigarette packages and in cigarette advertisements and directs FDA to "issue regulations that require color graphics depicting the negative health consequences of smoking" to accompany the nine new health warning statements. Under section 201 of the Tobacco Control Act, FDA may adjust the type size, text, and format of the cigarette health warnings as FDA determines appropriate so that both the color graphics and the accompanying textual warning label statements are clear, conspicuous, and legible and appear within the specified area (15 U.S.C. 1333(d)).

Section 202(b) of the Tobacco Control Act also amends section 4 of the FCLAA to add a new subsection² that permits FDA to, after providing notice and an opportunity for the public to comment, adjust the format, type size, color graphics, and text of any of the label requirements, or establish the format, type size, and text of any other disclosures required under the FD&C Act, if such a change would promote greater public understanding of the risks associated with the use of tobacco products. Such adjustments, including adjustments to the text of some of the warning statements and to the number of proposed required warnings, are included as part of this proposed rule.

These requirements are supplemented by the FD&C Act's misbranding provisions, which require that product labeling and advertising include required warnings. For example, a tobacco product is deemed misbranded under section 903(a)(1) or (a)(7)(A) of the FD&C Act if its labeling or advertising is false or misleading in any particular. Under section 201(n) of the

² Section 201(a) of the Tobacco Control Act amends section 4 of the FCLAA to add a new subsection (d), "Graphic Label Statements," which is codified at 15 U.S.C. 1333(d). Section 202(b) of the Tobacco Control Act amends section 4 of the FCLAA to also add a new subsection (d), "Change in Required Statements," which is also codified at 15 U.S.C. 1333(d). Both provisions of the Tobacco Control Act are correctly codified as "15 U.S.C. 1333(d)."

FD&C Act (21 U.S.C. 321(n)), in determining whether labeling or advertising is misleading, FDA considers, among other things, the failure to reveal material facts concerning the consequences that may result from the customary or usual use of the product. Similarly, under section 903(a)(8)(B) of the FD&C Act, a tobacco product is deemed misbranded unless the manufacturer, packer, or distributor includes in all advertisements and other descriptive printed matter, which FDA interprets as including packages, a brief statement of, among other things, the relevant warnings. Under section 701(a) of the FD&C Act, FDA has authority to issue regulations for the efficient enforcement of the FD&C Act, and sections 704 and 905(g) provide FDA with general inspection authority.

Section 909 of the FD&C Act authorizes FDA to require tobacco product manufacturers to establish and maintain records, make reports, and provide such information as the Agency may by regulation reasonably require to ensure that a tobacco product is not adulterated or misbranded and to otherwise protect public health.

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

Cigarette smoking is the leading cause of preventable disease and death in the United States and is responsible for more than 480,000 deaths per year (Ref. 8). Smoking causes more deaths each year than human immunodeficiency virus (HIV), illegal drug use, alcohol use, motor vehicle injuries, and firearm-related incidents combined (Refs. 9 and 10). In addition to lung cancer, heart disease, and COPD, smoking also causes numerous other serious health conditions, including many types of cancer, premature birth, low birth weight, SIDS, respiratory illnesses, clogged arteries, reduced blood flow, diabetes, rheumatoid arthritis, and vision conditions such as age-related macular degeneration and cataracts (Ref. 8).

A. Smoking Prevalence and Initiation in the United States

Approximately 34.3 million U.S. adults and nearly 1.4 million U.S. youth (aged 12-17 years) smoke cigarettes (Refs. 5 and 6). Over 16 million Americans alive today live with disease caused by smoking cigarettes (Ref. 8). Results from the 2017 National Survey on Drug Use and Health demonstrate that, on average, each day in the United States, about 2,000 youth under age 18 smoke their first cigarette, and 320 youth become daily cigarette smokers (Ref. 7).

Cigarettes remain the most commonly used tobacco product in the United States among adults, and a substantial percentage of U.S. adults are cigarette smokers (Ref. 5). Although cigarette smoking prevalence has generally declined over the past several decades, results from the 2017 National Health Interview Survey indicate that approximately 34.3 million U.S. adults (or 14.0 percent of the U.S. adult population) are current cigarette smokers (Ref. 5). Among these adult smokers, the vast majority--75 percent, or approximately 25.7 million people--smoke every day. Smoking prevalence remains higher than the national average among certain demographic subgroups of the adult population. For example, among adults with differing levels of education, the highest prevalence rates have been observed in adults with lower education levels. Data indicate that 36.8 percent of adults with a General Education Development (GED) certificate and 23.1 percent of adults with less than a high school diploma were current smokers in 2017, compared with 7.1 percent of adults with a college degree and 4.1 percent of adults with a graduate degree (Ref. 5).

The National Youth Tobacco Survey is a nationally representative survey of U.S. students attending public and private schools in grades 6 through 12. The 2018 National Youth Tobacco Survey data showed that past 30-day smoking prevalence among high school students was 8.1 percent, representing 1.2 million young people, of which 23.1 percent were frequent

smokers (defined as cigarette use on 20 or more of the past 30 days) (Ref. 6). The data also showed that past 30-day prevalence among middle school students was 1.8 percent, representing 200,000 youth, of which 19.7 percent were frequent smokers (Ref. 6). These youth who have smoked in the past 30 days are at particular risk of becoming nicotine dependent through smoking. In one study, 22 percent of 7th grade students who had initiated occasional smoking reported a symptom of nicotine dependence within 4 weeks after starting to smoke at least once per month (Ref. 19). Among 60 students with symptoms of nicotine dependence, 62 percent reported experiencing their first symptom before smoking daily or began smoking daily only upon experiencing their first symptom (Ref. 19). An analysis of the 2012 National Youth Tobacco Survey found that a substantial proportion of adolescents that use tobacco report symptoms of nicotine dependence, even with low levels of use (Ref. 20). Among adolescents who reported only smoking cigarettes, 42.6 percent reported having strong cravings to smoke, a symptom of nicotine dependence, in the past 30 days (Ref. 20).

B. Negative Health Consequences of Smoking

Cigarette smoking remains the leading cause of preventable disease and death in the United States. The 2014 Surgeon General's Report found that cigarette smoking was responsible for an average of over 480,000 premature deaths in the United States each year from 2005 to 2009, of which almost 440,000 occurred because of active smoking (Ref. 8). The report also found that cigarette smoking was directly responsible for 163,700 deaths from cancer, 160,600 deaths from circulatory conditions, and 113,100 deaths from pulmonary diseases each year. As a consequence of secondhand smoke exposure, there were an additional 7,330 deaths from lung cancer and 33,950 deaths from coronary heart disease annually. Cigarette smoking therefore

accounted for 87 percent of deaths from lung cancer, 79 percent of deaths from COPD, and 32 percent of deaths from coronary heart disease in the United States from 2005 to 2009.

It has also been estimated that approximately 14 million U.S. adults had serious medical conditions attributable to cigarette smoking in 2009 (Ref. 21). COPD accounted for the largest number of these conditions with an estimated 7.5 million Americans living with this condition because of smoking. Other serious conditions for which smoking-attributable morbidity was estimated included heart attack (2.3 million cases), cancer (1.3 million cases), and stroke (1.2 million cases) (Ref. 21). Because individuals can live for many years with some of these health conditions and, in some cases, smoking-attributable health conditions can develop after a smoker has stopped smoking (e.g., lung cancer) (e.g., Ref. 22), the morbidity burden from cigarette smoking is expected to remain high.

Cigarette smoking also causes many other health conditions; however, the link between smoking and these conditions is less known to the public. For example, a meta-analysis found that current smokers are twice as likely as never smokers to have age-related macular degeneration (Ref. 23), a degenerative condition of the tissues of the retina. Current smokers have also been found to have approximately 50 percent higher risk of age-related cataracts than never smokers according to meta-analysis (Ref. 24). Cigarette smokers have an increased risk of numerous circulatory and metabolic conditions. Another meta-analysis found that smokers have approximately 45 percent higher risk of diabetes than nonsmokers (Ref. 25). It is estimated that 1.8 million Americans have diabetes due to smoking (Ref. 21) and that 9,000 Americans die of diabetes due to smoking each year (Ref. 8). Current smokers are nearly three times as likely as never smokers to have peripheral arterial disease, a condition that can lead to amputation of limbs (Ref. 26). Male smokers have been found to be 40 to 50 percent more likely to have

erectile dysfunction due to diminished blood flow than nonsmokers (Refs. 27 and 28). Smokers also have increased risk of many types of cancer, beyond lung cancer. For example, current smokers have been found to have almost four times the risk of bladder cancer as never smokers (Ref. 29), and it has been estimated that smoking is responsible for 5,000 bladder cancer deaths in the United States each year (Ref. 30). Smoking has also been established to cause cancers of the head and neck, such as oral cancer. The American Cancer Society's Cancer Prevention Study II found elevated relative risks (i.e., the risk of the conditions among smokers compared to nonsmokers) for current smoking of 10.9 for males and 5.1 for females for lip, oral cavity, and pharyngeal cancers (i.e., male smokers have 10.9 times higher risk of developing these cancers than male nonsmokers, and female smokers have 5.1 times higher risk of developing these cancers than female nonsmokers) and 14.6 for males and 13.0 for females for laryngeal cancer (Ref. 31). These increased risks result in approximately 4,900 deaths from lip, oral, and pharyngeal cancers and 3,000 deaths from laryngeal cancer from smoking in the United States each year (Ref. 30).

Secondhand smoke exposure also increases disease risks, especially among infants and children. For example, secondhand smoke exposure has been found to be causally linked to stroke, lung cancer, and other disease in adults and lower respiratory illness in children (Ref. 8). Additionally, maternal smoking (i.e., smoking while pregnant) has been found to be associated with low birth weight (Ref. 32) and fetal growth restriction (Ref. 33). The California Environmental Protection Agency (EPA) has estimated that there are 24,500 cases of low birth weight due to maternal exposure to secondhand smoke (referred to as "environmental tobacco smoke") in the United States per year (Ref. 34). Other health consequences in children exposed to secondhand smoke include middle ear disease, respiratory symptoms, impaired lung function,

lower respiratory illness, and SIDS, and it is estimated that 400 infants die from SIDS due to exposure to secondhand smoke each year (Ref. 8).

V. Data Concerning Cigarette Health Warnings

A. *The Current 1984 Surgeon General's Warnings Are Inadequate*

As described in this section, cigarette warnings in the United States have not changed in nearly 35 years, and the size and location of the warnings have not changed in more than 50 years. The unchanged content of these health warnings, as well as their small size and lack of an image, severely impairs their ability to convey relevant information about the negative health consequences of cigarette smoking in an effective way (Ref. 2). Research has repeatedly illustrated that the current 1984 warnings used in the United States frequently go unnoticed or fail to convey relevant information regarding health risks (Ref. 4). Moreover, although many members of the U.S. public possess some general knowledge of the harms of smoking, substantial gaps in knowledge remain, and smokers have misinformation regarding cigarettes and the negative health effects of smoking (Refs. 36 and 37).

Cigarette packages and advertisements can serve as an important channel for communicating health information to broad audiences that include both smokers and nonsmokers. Daily smokers, who in 2016 averaged 14.1 cigarettes per day, are potentially exposed to the warnings on packages over 5,100 times per year, and, because these packages are not always concealed and are often visible to those other than the person carrying the package, warnings on those packages are potentially viewed by many others, including nonsmokers (Refs. 38 and 40). Smokers and nonsmokers, including adolescents, also are frequently exposed to cigarette advertising appearing in a range of marketing channels, including print and digital media, outdoor locations, and in and around retail establishments where tobacco products are

sold (Refs. 42 and 43). The importance of cigarette advertising is reflected in cigarette companies' substantial annual expenditures for cigarette advertising and promotion in the United States, which totaled \$1.3 billion in 2017 (not including the price discounts paid to cigarette retailers and wholesalers to help lower the price of cigarettes to consumers) (Ref. 41). Retail displays of cigarette packages and other in-store cigarette advertisements are typically located in areas of a store that are seen by a majority of consumers, such as near the checkout counter, and provide significant opportunities for communicating with smokers and nonsmokers (Refs. 44–47). The inclusion of health warnings on cigarette packages and in advertisements therefore can provide a critical opportunity to help smokers and nonsmokers of all ages better understand the negative health consequences of smoking. Prominent displays of such warnings are more likely to be noticed and to impact learning and knowledge than non-prominent displays (Refs. 3, 4, 39, 48-50). The World Health Organization's (WHO) Framework Convention on Tobacco Control has also recommended large pictorial cigarette warnings on tobacco products as a way to increase public awareness about the negative health effects of tobacco use (Ref. 51). Given the extreme risks cigarette smoking poses to the public health, new warnings, as described in detail below and as included in this proposed rule, are critical to promote greater public understanding of the negative health consequences of cigarette smoking.

1. The Current 1984 Surgeon General's Warnings Have Not Changed in Nearly 35 Years

In response to the Surgeon General's first major report on smoking and health in 1964, Congress passed the FCLAA to require warning labels on all cigarette packages. The text-only warning 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 packages sold from January 1, 1966, through October 31,

1970. In 1969, Congress passed the Public Health Cigarette Smoking Act (Pub. L. 91-222), which slightly modified the warning statement on cigarette packages, but did not require any warnings in 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 of their cigarette advertisements a clear and conspicuous disclosure of the same warning required to be on packages (Ref. 35).

In 1981, the FTC issued a report to Congress that concluded that the cigarette health warnings had little effect on public awareness and attitudes toward smoking. The FTC report stated that the existing warning likely was ineffective because it: (1) was overexposed and worn out; (2) lacked novelty; (3) was too abstract; and (4) lacked personal relevance (Ref. 52).

Subsequently, Congress again modified cigarette warnings by enacting the Comprehensive Smoking Education Act of 1984 (Pub. L. No. 98-474), which required the following four rotational health warnings on packages and advertisements³:

- 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.

³ Slightly different health warnings were required on outdoor billboard advertisements.

In addition, the law established the location and format for these warnings and mandated that they be rotated quarterly. Despite an FTC recommendation to change the size and shape of warnings, Congress retained the size and rectangular format of previous warnings (Ref. 218 at pp. 11, 12, 24, and 25; see also Ref. 52). As implemented, for example, this means the Surgeon General's warnings have continued to be printed in small type on one side panel of cigarette packages from October 12, 1985, to the present.

Nearly 35 years have passed since these changes and a substantial body of research shows that the current 1984 Surgeon General's warnings do not effectively promote greater public understanding of the negative health consequences of smoking and that there are better approaches to cigarette health warnings.

2. The Current 1984 Surgeon General's Warnings Do Not Effectively Inform the Public Because They Do Not Attract Attention, Are Not Remembered, and Do Not Prompt Thoughts About the Risks of Smoking

Pictorial cigarette warnings that increase message processing will aid consumer understanding of the negative health consequences of smoking. Cognitive theories and information processing models describe how information is gathered from the senses and is stored and processed in the brain (Ref. 111). Message processing is important to learning and understanding. Once an individual notices a warning, he or she mentally stores the information found in the warning and gives meaning to that information (Ref. 112). The individual mentally processes the information and builds on it, which helps them better recall and remember the information (Refs. 43 and 113). How much the information is mentally processed, reflected on, and thought about impacts how well the information is learned and understood (Ref. 114).

Attracting and maintaining attention is an important step in how communications, such as warning labels, can inform the public (Refs. 53 and 54). Findings from the International Tobacco Control Four Country Survey (ITC-4) found that self-reports of noticing the health warnings on cigarette packages were positively associated with health knowledge among adults across the four countries studied, including the United States (Ref. 3). However, eye-tracking studies, which assess attention to visual stimuli, have documented low levels of attention to the current Surgeon General's warnings in both adults and adolescents, meaning that they do not attract attention (Refs. 55 and 56). One study of adolescents viewing tobacco advertisements found that the average viewing time of the Surgeon General's warnings amounted to only 8 percent of the total advertisement viewing time; nearly half (43.6 percent) of adolescents did not look at the warnings at all; and about one-third (36.7 percent) did not look at the warning long enough to read any of its words (Ref. 55). In that study, adolescents were unable to recall the content of the current Surgeon General's warnings or to correctly recognize the warnings from a list, indicating that the current warnings are likely ineffective among adolescents (Ref. 55). Similarly, a study of middle school students who viewed tobacco advertisements with the Surgeon General's warnings found the total amount of time spent focusing on the warning statement averaged slightly less than one second (Ref. 56). Similar evidence that the Surgeon General's warnings do not attract attention was found with a sample of adult smokers in 2011 who were instructed to look at a tobacco advertisement with a warning for 30 seconds, and of that time participants spent an average of only 2.8 seconds looking at the Surgeon General's warning specifically (Ref. 57).

As discussed in the following paragraphs, researchers have also found that the current 1984 Surgeon General's warnings are largely unnoticed and unconsidered by both smokers and

nonsmokers. This is in accord with the findings of a major report on tobacco policy in the United States by the Institute of Medicine (IOM) in 2007, which stated that the 1984 warnings on U.S. cigarette packages are both "unnoticed and stale" (Ref. 2 at p. 291). Similar conclusions were drawn in a study with a nationally representative sample of middle and high school students in the United States in 2012. Less than half (46.9 percent) of students who saw a cigarette package with the Surgeon General's warning reported seeing the warning "most of the time" or "always" (Ref. 58).

Noticeability of the Surgeon General's warnings is also low for adults. Findings from the ITC-4 published in 2007 found that only 30 percent of U.S. adult smokers noticed the warning "often" or "very often" (Ref. 4). Even if people notice the warnings, less than 20 percent of smokers in the United States report reading the warning text "often" or "very often" (Ref. 4). Moreover, additional findings from the ITC-4 found that less than half (46.7 percent) of U.S. respondents considered cigarette packages as a source of information on the negative health effects of smoking compared to 84.3 percent of respondents in Canada, where pictorial health warnings are required (Ref. 3). A study in 2009 found that 60 percent of U.S. adult smokers said they "never" or "rarely" noticed warnings labels on cigarette packages in the past month (Ref. 59). More recently, an analysis of the Population Assessment of Tobacco and Health Study, an ongoing, nationally representative, longitudinal cohort study of adults and youth in the United States, found that the current health warnings on cigarette packages often go unnoticed (Refs. 60 and 61). In the most recent publicly available data (data collected from late 2016 through the end of 2017), nearly three-quarters (73.5 percent) of the U.S. population, including both youth and adults, indicated they "never" or "rarely" noticed the health warnings on cigarette packages in the past 30 days (Ref. 61) (data available at

<https://www.icpsr.umich.edu/icpsrweb/NAHDAP/studies/36231>). Among U.S. youth and adults who have noticed cigarette health warnings in the past 30 days, 52.0 percent of youth and 53.5 percent of adults responded that they "never" or "rarely" read or looked closely at the warnings in the past 30 days (i.e., do not attract attention) (Ref. 61).

Other data support that adolescents also do not see or read, and do not remember, the current 1984 Surgeon General's warnings on cigarette packages and advertisements. A study of ninth-grade students found that nearly one-third (27.8 percent) reported never seeing warning labels on cigarettes and nearly half (46.1 percent) could not correctly identify the location of the warnings on the package (Ref. 62).

Similar data suggest that people also failed to notice or read the current 1984 Surgeon General's warnings prior to the 1999 Master Settlement Agreement, when cigarette advertising was common on outdoor billboards. One study of adults found that drivers could read the entire warning message on only 5 percent of highway billboard advertisements and were only able to fully read the health warning on 18 of the 39 street billboards examined in the study (Ref. 63). All 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.

Not only do the current Surgeon General's warnings not attract attention, but they also are not remembered--and remembering is a key component to long-term understanding of the information beyond surface-level noticing of the information presented. Viewing time of U.S. cigarette warnings is positively associated with recall (Refs. 55 and 56). Studies have documented low recall of warning statements for both adults and adolescents. In a study conducted with 13- to 17-year-olds who viewed five tobacco advertisements containing Surgeon

General's warnings, only 19 percent were able to recall the general theme of the warning statement (Ref. 55). In another study, only between 20 and 53 percent of high school students could correctly recall each of the four Surgeon General's warnings even when they were provided with the actual wording, and some incorrectly recalled having seen a warning that was not being used at the time (Ref. 62). Similarly, low levels of recall were found in a study with high school students who viewed tobacco advertisements containing Surgeon General's warnings. Although most students (79 percent) reported seeing a warning, very few (15 percent) reported the warning statement's concept and even fewer (6 percent) correctly reported its exact message (Ref. 64).

Beyond being noticed and being remembered, additional measures of how well a message helps people understand its contents are to ask whether the message makes them think about the message's substantive information--showing an even deeper understanding of the information being communicated. These measures, often termed "cognitive elaboration," are well-validated and often used in studies of cigarette health warnings (See, e.g., Refs. 80 and 84). Research demonstrates that the current 1984 Surgeon General's warnings do not prompt thoughts about the risks of smoking, and they are also perceived to be ineffective at making people think about those risks. Less than 40 percent of U.S. adult smokers in the ITC-4 reported that the Surgeon General's warnings make them think about the health risk of smoking, a level that was consistent between 2002 and 2005 (Ref. 4). In a study in Buffalo, NY, 62 percent of adult smokers reported that the Surgeon General's warning labels made them think "a little" or "not at all" about the health risks of smoking (Ref. 59). Participants in a randomized clinical trial with smokers in California and North Carolina reported that the Surgeon General's warnings made them think about the warning message only a little (an average of 2.3 on a scale of 1 to 5) and

made them think about the harms of smoking only somewhat (an average of 2.9 on a scale of 1 to 5) (Ref. 65). That study also found that the Surgeon General's warnings were perceived as not impactful (Ref. 65).

Health communication research has found that adolescents also report that the current 1984 U.S. cigarette warnings do not prompt thoughts about the health risks of smoking. Among a nationally representative sample of U.S. middle and high school students who reported seeing a cigarette package, less than one-third (30.4 percent) reported that cigarette warning labels made them think about health risks "a lot" (Ref. 58). This proportion is even lower for adolescent current smokers, as only 13.8 percent reported that warnings made them think "a lot" about health risks (Ref. 58).

3. There Remain Significant Gaps in Public Understanding About the Negative Health Consequences of Cigarette Smoking

Consumers suffer from a pervasive lack of knowledge about and understanding of the negative health consequences of smoking. A nationally representative survey of 1,046 adult smokers found widespread misperceptions regarding cigarettes and the negative health effects of smoking (Refs. 36 and 37). Thirty-three percent of adult smokers in the sample did not know that cigarettes were a proven cause of cancer (Refs. 36 and 37). Additionally, a quarter of the sample did not know that smoking was still dangerous to health even without inhaling (Refs. 36 and 37). Another study of 776 adult and adolescent smokers and nonsmokers asked participants what illnesses are caused by smoking (Ref. 15). Whereas the majority of respondents identified lung cancer as a smoking-related lung disease, only half mentioned emphysema (Ref. 15). A much smaller proportion identified cardiovascular disease (Ref. 15). Very few (3 to 7 percent) named any other smoking-related cancer (besides lung, mouth, throat, or gum cancer), such as

pancreatic, cervical, bladder, or kidney cancer (Ref. 15). Very few mentioned negative cardiovascular effects, such as hypertension, atherosclerosis, aneurisms, or stroke, as smoking-related illnesses. In addition, people underestimated the percent of people diagnosed with lung cancer who would die from the condition (Ref. 15). Findings from another study indicate that approximately one-third of U.S. adult smokers believe that cigarettes have not been proven to cause cancer (Ref. 211).

Many studies show that the public has limited understanding of other smoking-related health consequences such as impotence (Refs. 3, 12, 13, and 67; U.S. studies); stroke (Refs. 15 and 67; U.S. studies); gangrene (Ref. 12; U.S. study); vision impairment/blindness (Refs. 11, 119, and 201; non-U.S. studies); emphysema and chronic bronchitis (Ref. 11; non-U.S. study); other cancers outside of lung cancer, such as bladder cancer (Refs. 11, 13, 15, and 67; both U.S. and non-U.S. studies); the effects of secondhand smoke on nonsmoker adults and children (Ref. 16; non-U.S. study); and impacts on reproductive health and pregnancy (Refs. 13 and 67; U.S. studies). Studies in the United States have also documented that people are largely unaware of the health risks of smoking specific to women, including infertility (Refs. 13, 14, and 67), osteoporosis, early menopause, spontaneous abortion, ectopic pregnancy, and cervical cancer (Ref. 14 and 67). Research findings also show gaps in public understanding of the negative health effects of smoking during pregnancy. For example, one focus group study conducted in four U.S. cities with current smoking women ages 18 to 30 years found that participants had low to moderate awareness of smoking outcomes related to pregnancy (Ref. 68). These findings suggest that the public does not understand the complete range of illnesses caused by smoking, indicating gaps in public understanding of the negative health consequences of smoking.

B. Cigarette Health Warnings That Are Noticeable, Lead to Learning, and Increase Knowledge Will Promote Public Understanding About the Negative Health Consequences of Smoking

To understand a message, individuals must first attend to the message (i.e., notice and be made aware of the message), and then they must process the information in the message (i.e., acquire knowledge of and learn that information) (Ref. 70). When introduced in other countries, pictorial cigarette warnings have been shown to increase understanding of the negative health consequences of smoking (Refs. 3, 4, 39, and 48). The following section describes studies that demonstrate how pictorial cigarette warnings promote greater public understanding about the health consequences of smoking as they: (1) increase the noticeability of the warning's messages; (2) increase knowledge and learning of the negative health consequences of smoking; and (3) benefit subpopulations that have disparities in knowledge about the negative health consequences of smoking. These studies incorporate measures that evaluate the impact of tobacco health warnings on understanding, many of which were drawn from the WHO's International Agency for Research on Cancer handbook on the methods for evaluating tobacco control policies (Ref. 71).

1. Cigarette Health Warnings that Are Noticeable Will Lead to Increased Attention to the Warning Message

To promote understanding of the content of a warning message, individuals must first notice the warning and must be made aware of the information contained in that warning (Refs. 53 and 54). In the scientific literature on consumer warnings, features that increase the noticeability of the warning label (also known as vivid features, such as images) increase the likelihood that people will see and pay attention to the warning message (Refs. 73 and 74). Physical features (e.g., use of pictures or color) that make a message more noticeable increase

attraction and attention to the message (Ref. 75). A meta-analysis found that warnings, not specific to cigarette warnings, that include such features were more likely to attract attention than warnings without these features (Ref. 76). One experiment among a sample of U.S. adult smokers and middle school students found that participants who viewed pictorial cigarette warnings with full color spent more time looking at the warning compared to participants who either viewed black and white pictorial warnings or text-only warnings (Ref. 77).

Communication theory and research explain the message characteristics that impact how an individual is exposed to, attends to, comprehends, and understands the content of the message (Refs. 43, 78, and 79). Messaging that includes vivid features (e.g., images) increases attention to as well as cognitive elaboration (or thinking about) and processing of the message, which leads to increased message comprehension (Ref. 80). Messages that include vivid features, such as images, are easier to imagine and are more engaging compared to messages that do not include vivid features. An online experiment with 2,156 adults that examined varying levels and combinations of vivid features (i.e., testimonial images, identifying information, nontestimonial explanatory statements, testimonial explanatory statements, and contextual information) found that increasing the number of vivid features of cigarette warnings increased engagement with the message (Ref. 81).

a. Pictorial cigarette warnings increase attention to warning messages, which leads to increased understanding of the negative health consequences of smoking.

Research supports the role of pictorial cigarette warnings in increasing attention to and noticeability of warnings about the harms of smoking. More noticeable pictorial cigarette warnings are more effective in communicating the harms of smoking compared to text-only cigarette warnings in other countries as well as in experimental studies conducted in the United

States (Refs. 3, 49, 50, 82, and 83). Pictorial cigarette warnings result in higher noticeability of and attention to the warning message compared to text-only cigarette warnings (Refs. 4, 48, 72, 77, 82–94). One study using data from ITC-Canada and ITC-Mexico assessed smokers' reactions to cigarette health warnings (Ref. 48). During the study period, Mexico had text-only cigarette warnings while Canada had pictorial cigarette warnings. Compared to adult smokers in Mexico, Canadian adult smokers reported greater levels of noticing the warning label and thinking about the harms of smoking. Another ITC study assessed noticing warnings in a sample of Chinese and Malaysian adult smokers (Ref. 83). After introduction of the new Malaysian pictorial cigarette warnings in 2009, there was a significant increase in the percentage of smokers who reported noticing the health warnings often or very often (54.4 percent pre-implementation compared to 67 percent post-implementation) (Ref. 83). Another study in the United States surveyed a sample of adolescents who had a parent, guardian, or other household member who participated in a randomized controlled trial in which a single pictorial or text-only warning was displayed on the parent's cigarette package for 4 weeks (Ref. 94). The pictorial cigarette warnings drew greater attention among adolescents in the study, and adolescents more accurately recalled the pictorial cigarette warning. In addition, the pictorial cigarette warning was recognized from a list of warnings more than the text-only cigarette warning.

Studies demonstrate that increasing notice of and attention to the information in a cigarette health warning promotes understanding of the message. Data from the ITC-4 showed that noticing health warnings on cigarette packages was associated with increased knowledge about the health consequences of smoking (Ref. 3). Smokers who reported noticing the cigarette health warnings were more likely to report believing that smoking causes the specific health consequences contained in the warnings, compared to those who did not notice the warnings.

Once individuals notice and attend to the warning, they are able to store and process the information in the warning that can be recalled later; these processes contribute to engagement with the message and lead to understanding. The important role of attention in message storing and processing is well supported by research (see, e.g., Ref. 54). For example, a study with smokers found that the frequency of noticing a cigarette health warning was associated with frequency of thinking about the dangers of smoking (Ref. 95). In addition, studies conducted in the United States with youth and adults have shown that longer time spent looking at a cigarette health warning was associated with greater recall of the information found on the warning (Refs. 56, 57, and 217), indicating that attention to a cigarette health warning leads to storing of the warning content and later recall of that information.

b. Pictorial cigarette warnings increase the likelihood that consumers will read, recall, and understand the warnings.

Research supports the role of pictorial cigarette warnings in increasing reading of and closely looking at the message warning as well as aiding comprehension and understanding of the information contained in the message warning. In a United States-based experimental study, repeated viewing of warning labels is associated with increased recognition and memory of the content of the label (Ref. 96). Research on recorded eye movement during reading of a warning label provides support for the link between reading and comprehension of the warning (Ref. 97). Measures of viewing duration (e.g., how long the eyes are fixed on specific words in the warning) are associated with how much participants are processing and can later recall that information (Refs. 56, 97, and 98).

Many studies support the finding that cigarette health warnings with vivid features (e.g., images) are read and looked at more closely compared to those without these features (Refs. 83,

86, 92; non-U.S. studies). One study of U.S. adult smokers showed that viewing a pictorial cigarette warning led to higher reported reading or looking closely at the warning, label memory and recall, and perceived label credibility compared to text-only cigarette warnings (Ref. 85). Another study of U.S. adult smokers showed that participants who had a pictorial cigarette warning put on their packs reported looking at the label more often and correctly recalled the label's contents more often than those with packs that had a text-only warning on them (Ref. 99). A study in Australia found that students reported more frequent reading and attending to the pictorial cigarette warnings after they were introduced, as compared to when text-only warnings were displayed (Ref. 100).

2. Pictorial Cigarette Warnings Can Address Gaps in Public Understanding About the Negative Health Consequences of Smoking

a. Pictorial cigarette warnings increase knowledge and accurate health beliefs by addressing gaps in public understanding about the negative health consequences of smoking.

Pictorial cigarette warnings increase consumer knowledge of the harmful effects of smoking, which promotes greater public understanding of the negative health consequences of smoking. Numerous non-U.S. studies support the role of pictorial cigarette warnings in promoting knowledge gains in cigarette-related health risks after implementation of those warnings (Refs. 3, 39, 48, 49, 100, 102–107, 202, and 203). One review examined health warning messages on tobacco products and concluded that health warnings increased correct knowledge about the negative health effects caused by smoking (Ref. 39). That review concluded that pictorial cigarette warnings are significantly more likely to draw attention, result in greater processing, and improve memory of the health warning (Ref. 39). Summarizing these effects among smokers, the National Cancer Institute concluded in its Tobacco Control

Monograph 21 that large pictorial health warnings on tobacco packages are effective in increasing smokers' knowledge (Ref. 66).

Visual depictions of smoking-related disease in pictorial cigarette warnings help address gaps in public understanding of the negative health consequences of smoking by providing new information beyond what is in the text of the warnings through reinforcing and helping to depict and explain the health effect described in the text (Ref. 101; see also Ref. 39 at p. 330). Many studies have shown that exposure to pictorial cigarette warnings promotes knowledge of the negative health effects of smoking (Refs. 3, 48, and 102–107). For example, a study using data from ITC-Canada and ITC-Mexico assessed smokers' reactions to cigarette health warnings (Ref. 48). During the study period, Mexico had text-only cigarette warnings while Canada had pictorial cigarette warnings. Compared to smokers in Mexico, Canadian smokers had higher levels of knowledge about smoking-related health outcomes, such as stroke, impotence, and mouth cancer. Another study using ITC-4 data showed that Canadian smokers were almost three times more likely than non-Canadian smokers to accurately believe that smoking causes impotence; during the time of the study, Canada was the only country to require pictorial cigarette warnings and the only country that had a warning about impotence (Ref. 3). Another study surveyed adult male smokers to assess changes in awareness of health risks from smoking after Malaysia implemented new pictorial cigarette warnings (Ref. 102). Findings showed that knowledge of health risks across 13 different health conditions was greater after pictorial cigarette warnings were introduced in Malaysia (Ref. 102). In March 2007, Australia became the first country to implement pictorial cigarette warning on cigarette packages with the message that smoking causes blindness. ITC data from adult smokers were analyzed assessing knowledge that smoking causes blindness (Ref. 103). Findings indicated that Australian smokers were

significantly more likely to report that smoking causes blindness compared to smokers in countries where there were no cigarette health warnings about blindness (Canada, the United Kingdom, and the United States) (Ref. 103). After the introduction of the blindness warning, Australian smokers were dramatically more likely than before to report knowing that smoking causes blindness (62 compared to 49 percent) (Ref. 103). Another study assessing smokers' beliefs about the health effects of smoking in South Australian smokers found that, post-implementation of pictorial cigarette warnings, participants reported more health beliefs about smoking-related negative health effects, such as blindness/eye damage, stroke, harm to unborn babies, mouth cancer, throat cancer, blocked arteries, as compared to their health beliefs when previous text-only warnings were required (Ref. 105).

Research supports that exposure to pictorial cigarette warnings leads to knowledge gains about the harms of smoking among adolescents, whereas, as discussed earlier, the current 1984 Surgeon General's warnings do not. A report of Canadian warnings indicated that pictorial cigarette warnings improved knowledge of specific negative health effects of smoking among adolescents (e.g., increased knowledge of bladder cancer, impotence in men, mouth cancer, gum or mouth disease, reduced growth in babies during pregnancy, and strokes) (Ref. 108). One study that surveyed Australian students in grades 8 through 12 found increases in the proportion of students who recognized the smoking-related effects of mouth cancer and peripheral vascular disease after the introduction of new pictorial cigarette warnings on those topics (Ref. 100). Another study examined the effects of viewing health warnings on beliefs about the specific negative health effects of smoking among adult smokers and adolescents (aged 16 to 18 years). For both adults and adolescents, exposure to pictorial cigarette warnings that highlighted specific health topics led to increases in correct beliefs about smoking causing the specific health topic in

the warning. For some topics (e.g., smoking causes strokes, smoking causes impotence), increases in correct health beliefs were only found in adolescents and not adults (Ref. 106).

There are a small number of recent studies conducted in the United States that failed to find an effect of pictorial cigarette warnings on increasing health beliefs about the negative effects of smoking (Refs. 77, 84, 109, and 110). The failure in those studies to find an association between exposure to pictorial cigarette warnings and increased health beliefs may be partly or fully attributable to the fact that, as previously described, the public already has a high pre-existing level of knowledge of the specific health consequences described in the warnings tested in those studies, some of which included warning statements set forth by Congress in the Tobacco Control Act. For example, a few studies have found increases in knowledge only of less-known conditions (e.g., blindness) but not of more well-known negative health effects (e.g., lung cancer) (Refs. 12 and 105). Notably, the increases in health beliefs from pictorial warnings were greatest for negative health effects that started with lower levels of prior beliefs about that health condition, such as gangrene and stroke (Ref. 12). This suggests that the impact of cigarette warnings on knowledge is greatest for topics that are not well known to the public.

In summary, pictorial cigarette warnings that convey the risk of specific negative health effects from smoking can increase beliefs and knowledge about the health consequences of smoking, particularly for negative health effects that are less known.

b. Pictorial cigarette warnings increase information processing and learning of new information about the negative health consequences of smoking.

Pictorial cigarette warnings that increase message processing will aid consumer understanding of the negative health consequences of smoking. Cognitive theories and information processing models describe how information is gathered from the senses and is

stored and processed in the brain (Ref. 111). Message processing is important to learning and understanding. Once an individual notices a warning, he or she mentally stores the information found in the warning and gives meaning to that information (Ref. 112). The individual mentally processes the information and builds on it, which helps them better recall and remember the information (Refs. 43 and 113). How much the information is mentally processed, reflected on, and thought about impacts how well the information is learned and understood (Ref. 114). Health warnings are therefore frequently assessed by looking to how noticeable they are; how well remembered their content is; and how much they prompt individuals to think about their content.

i. Pictorial cigarette warnings lead to increased thinking about the harms of smoking.

One way to process information found in a health message includes thinking about the message's content. Research (from both U.S. and international studies) has demonstrated that pictorial cigarette warnings lead to increased thinking (i.e., "cognitive elaboration") about the content of the warning (Refs. 49, 83, 84, 86, 87, 100, 102, 104, and 115). For example, one study of U.S. adult smokers found that participants who were exposed to pictorial cigarette warnings processed the information in deeper ways, such as thinking about their own health problems (e.g., diabetes) in the context of smoking (Ref. 99). Participants assigned to view pictorial cigarette warnings had more accurate recall and were better able to describe the content of the warning compared to those assigned to view the text-only warnings (Ref. 99). A meta-analysis of experimental studies conducted in twenty countries compared pictorial cigarette warnings to text-only cigarette warnings (Ref. 50). Compared to text-only warnings, pictorial cigarette warnings elicited more thinking about the message content (Ref. 50). Another study had U.S. adolescent and adult participants view one of nine pictorial cigarette warnings (Ref.

116). Exposure to pictorial cigarette warnings caused individuals to think about family members who smoke or how smoking could hurt the health of family members (Ref. 116).

- ii.* Pictorial cigarette warnings lead to exposure to and learning of new information about the negative consequences of smoking to smokers and nonsmokers.

Health warnings on cigarette packages can serve as prominent sources of health information for both smokers and nonsmokers (Ref. 2). Daily smokers in the United States, who in 2016 averaged 14.1 cigarettes per day, are potentially exposed to the pictorial cigarette warnings on packages over 5,100 times per year, and, because these packages are not always concealed and are often visible to those other than the person carrying the package, information found on those packages are potentially viewed by many others, including nonsmokers (Refs. 38–40). Indeed, a review of tobacco health warning studies in more than 13 countries, including the United States, concluded that pictorial warnings are an important source of health information for smokers as well as nonsmokers (Ref. 39).

Pictorial cigarette warnings have also been shown to be effective in communicating the health consequences of smoking to youth (Refs. 94 and 100). A report prepared for Health Canada showed that approximately 6 years after the introduction of pictorial cigarette warnings in Canada, more than 90 percent of Canadian youth agreed that the pictorial cigarette warnings had provided them with important and accurate information about the negative health effects of smoking cigarettes (Ref. 108). Pictorial cigarette warnings can also serve as effective sources of information for youth with smoking parents. One study interviewed adolescents whose parents received pictorial warnings on their cigarette packages as part of a randomized clinical trial (Ref. 117). When asked about the pictorial cigarette warnings, adolescents described how the warnings caught their attention. While many already reported believing that smoking was

dangerous before seeing the warnings, viewing the warnings strengthened and reinforced beliefs about the negative health consequences of smoking.

In the health communication scientific literature, messages that are accompanied by images closely linked to the message content (i.e., concordant) are shown to increase the likelihood that consumers will comprehend the message (Ref. 118). Because of this, pictorial cigarette warnings increase understandability and learning of the message. After implementation of Australia's pictorial cigarette warnings, focus group research findings concluded that images depicting the health consequences of smoking provided new information beyond what was contained in the text through providing a visual explanation of the negative health effects noted in the text (Ref. 101). For example, very few participants were aware that smoking caused peripheral vascular disease, and having an image of peripheral vascular disease provided a visual explanation of the effects of the disease, which led to learning of the consequences of smoking (Ref. 101). Studies in other countries have shown that participants tend to rate pictorial cigarette warnings as being more informative than text-only warnings (Refs. 119 and 120). A study with U.S. young adult smokers and nonsmokers evaluated the effect of pictorial cigarette warnings on learning (Ref. 121). Findings showed that participants rated pictorial cigarette warnings higher in increasing personal understanding of the health consequences of smoking and leading to learning new information compared to text-only warnings.

c. Pictorial cigarette warnings can increase understanding of the negative health consequences of smoking across diverse populations.

Research has shown that being a member of a group with lower socioeconomic status (SES), as measured by income and education levels, is associated with having lower knowledge of the negative health consequences of smoking; most smokers in the United States are in this

group (Refs. 5, 123, and 124). One study found that knowledge about the negative health effects of smoking was lower among older respondents, those with lower educational attainment, and those from racial or ethnic minority groups (Ref. 123). Some subpopulations, such as specific racial or ethnic minority groups (e.g., American Indian/Alaskan Natives), those with a lower level of education, and those experiencing serious psychological distress (Ref. 5), are disproportionately represented in lower SES subgroups, which have lower access to health information and are more likely to smoke cigarettes (Refs. 5, 204, and 205). Having a lower SES is also associated with lower health literacy compared to those with higher SES (Ref. 125).

One study compared data from higher and lower income adult smokers who participated in the ITC-4 and found that higher income smokers had 71 percent, 34 percent, and 83 percent higher odds of reporting knowledge that smoking causes heart disease, stroke, and lung cancer, respectively (Ref. 124). However, another study found that, among nonsmoking Canadian adolescents, having less spending money was associated with lower knowledge of the negative health effects of smoking but that disparities in knowledge were not as strong in adolescent smokers as they were in other studies with adults (Ref. 11).

In addition, smokers with less education may be less likely to notice and recall health information in cigarette warnings (Refs. 69 and 72). 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. 2). The IOM (Ref. 2) cited a study of Canadian smokers' knowledge about the country's prior warning requirements, which, like the current 1984 Surgeon General's warnings, only contained four textual warning statements. In that study, compared to women with higher educational attainment, comparatively fewer women with lower educational attainment were aware of messages that warn of the harmful effects of smoking on life

expectancy, heart disease, or pregnancy (Ref. 69). A study of pregnant women found that those with lower reading levels had less knowledge about the negative health effects of smoking (Ref. 136).

Pictorial cigarette warnings are likely to help reduce disparities among disadvantaged groups in consumer understanding about the harms of smoking. One study examined perceptions of pictorial cigarette warnings among low-income adult smokers using in-depth interviews (Ref. 126). Some participants reported that the image in the pictorial cigarette warning influenced their perceptions of smoking-related conditions because they contained new information and portrayed long-term health outcomes (e.g., diminished quality of life, irreparable physical damage, death) (Ref. 126).

Research has shown that pictorial cigarette warnings increase understanding of the health consequences of smoking across diverse settings and countries (Refs. 4, 87, 102, 119, and 206–210). These findings demonstrate that pictorial cigarette warnings are effective for diverse populations that differ in cultural, racial, ethnic, and socioeconomic backgrounds. One large study that randomized 3,371 adult smokers to view either pictorial cigarette warnings or text-only warnings found that participants who viewed the pictorial warnings had rated the warnings as being significantly more noticeable and more credible compared to participants who viewed the text-only warnings (Ref. 127). No statistically significant interactions were found between these results and race/ethnicity, education, or income, which suggests that the pictorial warnings had consistently greater noticeability and credibility across all the study subpopulations than the text-only warnings (Ref. 127). Other research suggests that among lower SES groups, pictorial cigarette warnings may lead to stronger effects in noticing the warning and thinking about smoking risks compared to those in higher SES groups because of the added benefits of the

information contained in the pictorial warning (Refs. 72 and 206). Collectively, the evidence demonstrates that pictorial cigarette warnings are effective across diverse populations and settings and likely will help reduce disparities found in consumer understanding about the harms of smoking.

VI. FDA's Process for Developing and Testing the Proposed Cigarette Health Warnings

Findings from the scientific literature indicate that an important first step in promoting public understanding of health risks is to raise public awareness of those risks, particularly if the risks are not commonly known (Refs. 130 and 131) (see section V.B). Measuring whether information is new helps identify opportunities to improve understanding through increased awareness. Additionally, communication science research has found that people are more likely to pay attention to information that is new, and attention plays a vital role in message comprehension and learning (Ref. 128).

As described in detail in this section, FDA undertook a science-based, iterative research and development process to consider whether revisions to the textual warning statements specified in section 4(1) of the FCLAA ("TCA statements") would promote greater public understanding of the risks associated with smoking and then to develop and test paired concordant color graphics to accompany the textual warning statements. As part of this process, FDA examined the nine TCA statements to consider whether to revise those statements to promote greater public understanding of the risks associated with cigarette smoking (see sections VI.A-C), which included a review of the risks associated with cigarette smoking and a focus on negative health effects that are less known, less understood, or about which the public holds misperceptions. After considering this information, FDA developed initial versions of revised textual warning statements ("revised statements"). Based on FDA's careful review of the

scientific literature on the health risks associated with cigarette smoking, evaluation of the public's general awareness and knowledge of those health risks, and assessment of the Agency's own consumer research on potential revised warning statements, FDA determined there is sufficient support to propose adjusting some of the text of the TCA statements, as authorized by section 4(d) of the FCLAA (as amended by section 202(b) of the Tobacco Control Act). While developing the revised statements, FDA worked in parallel to develop color graphics, in the form of photorealistic images, depicting the negative health consequences of cigarette smoking to accompany the statements (section 4(d) of the FCLAA; see section VI.D). Once FDA determined there was sufficient support to propose adjusting the text of the required warnings, identified textual warning statements for further testing, and developed photorealistic images to accompany those statements, we paired textual warning statements with concordant images to assess which statement-and-image pairings should be considered for this proposed rule. FDA selected 16 statement-and-image pairings to test in a final quantitative consumer research study. Results of this study (described in section VI.E), along with FDA's formative research, review of the scientific literature, and internal scientific and public health communications expertise, informed FDA's selection of the 13 cigarette health warnings in this proposed rule. The following subsections describe each of these steps in more detail.

The Agency invites comment on the warnings proposed in this rule, including its proposed revisions to the textual warning statements and its proposed photorealistic images. Given the degree of public and stakeholder interest in this area, and the legal complexities involved, FDA also seeks proposals for alternative text and images you believe would advance the Government's interest in promoting greater public understanding of the negative health consequences of smoking. If proposing alternative text and images to those in this proposed

rule, please provide scientific information supporting that the alternative text and images would, in fact, promote greater public understanding of the negative health consequences of smoking. Proposals for alternative images should accompany either one of FDA's proposed textual warning statements or an alternative textual warning statement you are proposing.

A. Review of the Negative Health Consequences of Cigarette Smoking

In determining whether FDA should, as authorized by section 4(d) of the FCLAA, adjust the format, type size, color graphics, and text of any of the label requirements to promote greater public understanding of the risks associated with the use of tobacco products, FDA reviewed the scientific literature as well as available nationally representative data on current consumer knowledge and misperceptions about the health risks of smoking. Despite the current 1984 Surgeon General's warnings on cigarette packages and in cigarette advertisements, the literature demonstrates that substantial proportions of U.S. smokers hold misperceptions about the health risks associated with cigarette smoking, particularly regarding cancer, heart disease, and other health conditions. For more discussion, see section V.A.3 ("There Remain Significant Gaps in Public Understanding About the Negative Health Consequences of Cigarette Smoking").

FDA considered the evidence presented in Surgeon General's Reports to identify all negative health consequences that are causally linked to cigarette smoking and exposure to secondhand smoke, including negative health consequences causally linked to cigarette smoking since the passing of the Tobacco Control Act in 2009. Surgeon General's Reports provide definitive syntheses of the available evidence on smoking and health and use such evidence to reach conclusions on causality that have public health implications (Ref. 8, p. 3). Surgeon General's Reports classify the strength of causal inferences in a four-level hierarchy based upon

work of the IOM (now the National Academy of Medicine) and the International Agency for Research on Cancer (IARC) (Refs. 200 and 212):

- Evidence is **sufficient** to infer a causal relationship.
- Evidence is **suggestive but not sufficient** to infer a causal relationship.
- Evidence is **inadequate** to infer the presence or absence of a causal relationship (which encompasses evidence that is sparse, of poor quality, or conflicting).
- Evidence is **suggestive of no causal relationship** (Refs. 154 at p. 18, 8 at pp. 3, 52, and 53).

These standardized determinations consider factors such as the consistency of results; the strength of the association between smoking and specific health effects; specificity; temporality; coherence, plausibility, and analogy; biologic gradient (dose-response evidence); and natural experiments (Ref. 154 at pp. 21–23). The rigor and consistent application of these causal standards has rendered Surgeon General's Reports the preeminent source regarding whether cigarette smoking and exposure to secondhand smoke are causally related to specific negative health consequences. Throughout this proposed rule, and in the context of the word "cause" or "causes" used in the textual warning statements included therein, FDA relied on the four-level classification provided in the Surgeon General's Reports. Further, the negative health consequences addressed in this proposed rule's warnings are all rated at the highest level, meaning that the proposed warnings' use of "cause" and "causes" is uniformly based upon the strongest possible level of scientific inference: "Evidence is sufficient to infer a causal relationship" (Ref. 8 at p. 3). A causal relationship supported at this level expresses "[t]he judgment that smoking causes a particular disease" and "has immediate implications for prevention of the disease" (Ref. 154, p. 18).

Since the first Surgeon General's Report published in 1964, evidence of the negative health consequences of cigarette smoking and secondhand smoke has expanded dramatically. For example, the 2014 Surgeon General's Report, entitled "The Health Consequences of Smoking: 50 Years of Progress" (Ref. 8), presented a robust body of scientific evidence documenting the health consequences from both smoking and exposure to secondhand smoke across a range of diseases and organ systems. In particular, the 2014 Surgeon General's Report added eleven diseases to the long list of diseases causally linked to cigarette smoking: liver cancer, colorectal cancer, age-related macular degeneration, orofacial clefts from maternal smoking during pregnancy, tuberculosis, stroke (for adults), diabetes, erectile dysfunction, ectopic pregnancy, rheumatoid arthritis, and impaired immune function (Ref. 8, pp. 4–5). The health conditions established to be causally linked to cigarette smoking in the 2014 Surgeon General's Report are in addition to the more than 40 unique health consequences of cigarette smoking and exposure to secondhand smoke determined by earlier studies (Ref. 8).

FDA determined that some of the health conditions newly identified in the 2014 Surgeon General's Report represented an opportunity to educate the public about negative health consequences of cigarette smoking that are subject to particularly low awareness and understanding. Historically, the large majority of public health messaging about the health risks associated with cigarette smoking has focused on a small subset of health conditions, notably lung cancer and addiction. The current Surgeon General's warnings for cigarette packages and advertisements, which have not been updated for nearly 35 years despite increasing evidence of additional, serious negative health effects of cigarette smoking, only include warnings on a limited number of health conditions (i.e., lung cancer, heart disease, emphysema, pregnancy complications, and general risks to health) (see section V for additional discussion of the current

Surgeon General's warnings). Both U.S. and non-U.S. studies have found that consumers are largely unaware of the negative health consequences of cigarette smoking not mentioned in current warnings as well as more specific information about the negative health effects and their mechanisms (Refs. 3, 11, 13-16, 67, 145, and 213–215). Additionally, and as discussed in section V, the current Surgeon General's warnings often go unnoticed and are not effective at informing the public of the health risks associated with cigarette smoking.

B. Developing Revised Textual Warning Statements

After FDA's initial review of the scientific literature on cigarette smoking-related consumer knowledge and misperceptions, as well as its epidemiological reviews of the causally linked health conditions identified in the recent Surgeon General's Reports and scientific literature, we evaluated whether revising some or all of the TCA statements to focus on negative health effects that are less-known or less understood by consumers would promote greater public understanding of the risks associated with cigarette smoking. FDA developed initial versions of revised statements for further review, testing, and refinement. These initial revised statements were reviewed by FDA internal epidemiological experts to ensure that the health conditions under consideration were causally linked to cigarette smoking or exposure to secondhand smoke, and that these smoking-attributed conditions were not rare.

Through a series of 16 qualitative focus groups with adolescent smokers, adolescents at risk for starting smoking, and adult smokers (OMB control number 0910-0674, "Qualitative Study on Cigarettes and Smoking: Knowledge, Beliefs, and Misperceptions"), FDA gathered additional input on consumers' awareness of the negative health consequences of cigarette smoking and assessed initial consumer responses to 17 revised statements⁴ and the nine TCA

⁴ FDA developed multiple revised versions of some TCA statements, developed no revised version for others, and

statements. These focus groups provided FDA with qualitative feedback on consumers' comprehension of each statement, the believability of the content of each statement (e.g., that smoking causes the health condition noted), if that health condition was new information to participants, and other feedback about the statement and how to make it more understandable or convey the intended message more clearly. Generally, participants reported the initial revised statements presented new information more than the TCA statements. FDA considered this information in identifying 15 revised statements⁵ for further quantitative (see section VI.C) and qualitative (see section VI.D) testing.

C. FDA's Consumer Research Study on Revised Textual Warning Statements

FDA next conducted a large quantitative consumer research study to assess which, if any, of the revised warning statements would promote greater public understanding of the risks associated with cigarette smoking as compared to the TCA statements (OMB control number 0910-0848, "Experimental Study on Warning Statements for Cigarette Graphic Health Warnings"). A secondary goal of this study was to inform the selection of health conditions and specific statements that, when paired with color graphics depicting the health conditions described in the warning statements, would form new cigarette health warnings for further testing.

also developed statements for which there is no TCA statement focused on that health condition.

⁵ The 15 revised statements FDA refined for further testing did not include revised versions of the following 4 TCA statements: *WARNING: Cigarettes are addictive*; *WARNING : Smoking can kill you*; *WARNING: Tobacco smoke causes fatal lung disease in nonsmokers*; and *WARNING: Quitting smoking now greatly reduces serious risks to your health*. FDA made this determination based on focus group feedback and findings from the scientific literature suggesting the health conditions described in these 4 statements are better-known health consequences of smoking and that revised statements on these conditions likely would not promote greater public understanding of the negative health consequences of smoking more than either the relevant TCA statements themselves or new statements on different health conditions.

1. Study Design

FDA's study on revised textual warning statements had two phases, both of which were completed during a single online session. The study sample comprised 2,505 participants. This included adolescents (aged 13 to 17 years), half of whom were current smokers and the rest of whom had never smoked but were at risk for starting smoking; younger adult (aged 18 to 24 years) current smokers; and older adult (aged 25 years and older) current smokers. Study participants in all age groups were randomly assigned to a condition that determined which warning statements they viewed during the study. Participants in the control condition viewed the nine TCA statements. Participants in each of the treatment conditions viewed one of 15 revised warnings statements plus 8 TCA warning statements. Table 1 provides a list of the 9 TCA statements and 15 revised warning statements that FDA evaluated in this study.

Table 1.--TCA and Revised Statements Studied in FDA's Consumer Research Study

TCA Statements (short name)	Revised Statements (short name)
WARNING: Cigarettes are addictive. (addictive)	WARNING: Smoking causes mouth and throat cancer. (mouth and throat cancer)
WARNING: Tobacco smoke can harm your children. (harm children)	WARNING: Smoking causes head and neck cancer. (head and neck cancer)
WARNING: Cigarettes cause fatal lung disease. (fatal lung disease in smokers)	WARNING: Smoking causes bladder cancer, which can lead to bloody urine. (bladder cancer)
WARNING: Cigarettes cause cancer. (unspecified cancer)	WARNING: Smoking during pregnancy causes premature birth. (premature birth)
WARNING: Cigarettes cause strokes and heart disease. (strokes and heart disease)	WARNING: Smoking during pregnancy stunts fetal growth. (stunts fetal growth)
WARNING: Smoking during pregnancy can harm your baby. (harm your baby)	WARNING: Smoking during pregnancy causes premature birth and low birth weight. (low birth weight)
WARNING: Smoking can kill you. (kill you)	WARNING: Secondhand smoke causes respiratory illnesses in children, like pneumonia. (pneumonia)
WARNING: Tobacco smoke causes fatal lung disease in nonsmokers. (fatal lung disease in nonsmokers)	WARNING: Smoking can cause heart disease and strokes by clogging arteries. (clogged arteries)
WARNING: Quitting smoking now greatly reduces serious risks to your health. (quit now)	WARNING: Smoking causes COPD, a lung disease that can be fatal. (COPD)

	<p>WARNING: Smoking causes serious lung diseases like emphysema and chronic bronchitis. (emphysema and chronic bronchitis)</p> <p>WARNING: Smoking reduces blood flow, which can cause erectile dysfunction. (erectile dysfunction)</p> <p>WARNING: Smoking reduces blood flow to the limbs, which can require amputation. (amputation)</p> <p>WARNING: Smoking causes type 2 diabetes, which raises blood sugar. (diabetes)</p> <p>WARNING: Smoking causes age-related macular degeneration, which can lead to blindness. (macular degeneration)</p> <p>WARNING: Smoking causes cataracts, which can lead to blindness. (cataracts)</p>
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In Phase 1 of the study, all participants viewed nine warning statements, one at a time, presented in random order. Participants in the control condition viewed the nine TCA statements. Participants in the treatment condition viewed 8 TCA statements plus 1 of 15 revised statements, for a total of 9 statements. Revised statements that did not have a TCA counterpart (e.g., the diabetes statement) are called "new content" statements for short. Each revised statement either was presented in place of a more general TCA statement on the same or similar health condition (e.g., a revised statement on head and neck cancer replaced the TCA unspecified cancer statement) or, for "new content" statements, was presented in place of a randomly selected TCA statement (e.g., a revised statement on diabetes was presented in place of the TCA statement on fatal lung disease in smokers). After viewing each individual warning statement, participants answered questions about that statement before viewing and answering questions about the next assigned statement. The study evaluated the following outcomes:

- Whether the warning statement was new information to participants ("new information") (i.e., participants reported that they had not previously heard of that specific health effect from cigarette smoking);

- Whether participants learned something from the warning statement ("self-reported learning");
- Whether the warning statement made participants think about the health risks of smoking ("thinking about risks");
- Whether the warning statement was believable ("believable");
- Whether the warning statement was informative ("informativeness") (i.e., participants reported that the warning was informative to them);
- Whether the warning statement was perceived to be a fact or an opinion ("factuality");
and
- Whether participants reported beliefs linking smoking and the health consequences in the warning statement ("health beliefs").

In Phase 2 of the study, all participants viewed nine warning statements presented at the same time. Participants assigned to the control condition viewed the nine TCA warning statements again. Participants assigned to the treatment conditions viewed one of several different combinations of nine revised warning statements. After viewing the nine warning statements, all participants answered questions about their beliefs about the link between smoking and each of the health consequences presented in the warning statements they viewed ("Health beliefs").

More details about the study methodology can be found in the study report, which we have included in this docket (Ref. 129).⁶

⁶ FDA will conduct a peer review of this consumer research study. FDA's peer review plans are available online at <https://www.fda.gov/science-research/science-and-research-special-topics/peer-review-scientific-information-and-assessments>.

2. Study Findings

The outcomes "new information" and "self-reported learning" provide useful data for determining whether a revised warning statement would promote greater understanding than a TCA statement of the risks associated with cigarette smoking, as described below. In general, relatively few participants reported that the content of the TCA statements was new information; more participants reported that the revised statements were new information than did participants who viewed the TCA statements on the same health conditions; and most participants reported that the "new content" statements were new information. For example, fewer than 24 percent of participants reported that the TCA statements were new information to them,⁷ whereas more than 66 percent of participants who viewed the "new content" statements (e.g., blindness, diabetes) reported that the "new content" statements were new information to them. When a specific health condition was covered by both a revised and TCA statement (e.g., cancer), the revised statement was new information to more participants than the TCA statement.

At the level of the individual warning statement, 10 of the 15 revised statements tested demonstrated statistically significant higher levels of both "new information" and "self-reported learning" when compared to a TCA statement (see Ref. 129, Table 4-1, "Summary of Significant Results"). Those 10 revised statements focused on the following negative health effects of cigarette smoking: age-related macular degeneration, cataracts, type 2 diabetes, peripheral vascular disease (amputation), bladder cancer, erectile dysfunction, head and neck cancer, heart disease and stroke (clogged arteries), stunted fetal growth, and COPD.

There were two revised statements that had statistically significant higher levels of "new information" but not "self-reported learning," both of which focused on pregnancy-related health

⁷ There was one exception: the TCA statement "Fatal lung disease in nonsmokers" was new information to 41.9 percent of participants.

consequences (premature birth; low birth weight). For two revised statements (emphysema and chronic bronchitis; pneumonia), participants had statistically significant higher levels of "self-reported learning" but not "new information." For one revised statement (mouth and throat cancer), participants did not have statistically significant higher levels of either of these two outcomes. Of the five revised warning statements that lacked statistically significant higher outcomes for both "new information" and "self-reported learning", four focused on a health condition for which another revised statement had statistically significant higher levels of both "new information" and "self-reported learning" (e.g., premature birth versus stunts fetal growth); only the revised warning statement on pneumonia did not.

More details about the full study results can be found in the study report, which we have included in this docket (Ref. 129).

3. How Study Findings Were Used

FDA determined that the scientific literature demonstrates that the outcomes "new information" and "self-reported learning" are predictive for the task of identifying which, if any, of the revised warning statements would promote greater public understanding of the risks associated with cigarette smoking as compared to a TCA statement. Communication science research shows that an important first step in promoting public understanding of health risks is to raise public awareness of those risks, particularly if the risks are not commonly known (Refs. 130 and 131) (see section V.B). Measuring whether information is new helps identify opportunities to improve understanding through increased awareness. Additionally, communication science research has found that people are more likely to pay attention to information that is new, and attention plays a vital role in message comprehension and learning (Ref. 128). Therefore, "new information" and "self-reported learning" are often linked and are

both predictive of improved understanding. Other study outcomes, such as "thinking about the risks" and "health beliefs," were unlikely to change with a single brief exposure to the text-only statements--as was provided in this first quantitative consumer research study--and therefore were not considered predictive of improved understanding in the way the "new information" and "self-reported learning" measures were.

Because the purpose of this first quantitative consumer research study was to determine which, if any, revised warning statements promote greater public understanding of the risks associated with cigarette smoking (as per section 4(d) of the FCLAA) when compared to a TCA warning statement, the study was not designed to put the revised statements in a rank order or compare individual results of one revised statement to another. Rather, FDA interpreted the presence of a statistically significant finding in a positive direction as support for a revised warning statement over its comparator TCA statement.⁸

FDA evaluated the research results for each individual warning statement to determine which statements would move on for further testing. Based on this analysis, a total of 10 revised statements and 5 TCA statements were selected for such further testing. As discussed above, at the level of the individual warning statement, 10 of the 15 revised warning statements tested demonstrated statistically significant higher levels of both "new information" and "self-reported learning" when compared to a TCA warning statement. FDA selected those 10 revised statements for further testing in the final consumer research study discussed below. Of the five revised warning statements that did not have statistically significant higher outcomes for both "new information" and "self-reported learning," four focused on a health condition for which

⁸ Five of the 15 revised statements were "new content" statements, without a comparator TCA statement on the same health condition. Those five revised statements were compared to a randomly selected TCA statement on a different health condition, which may have resulted in larger effects for these "new content" statements as compared to the effects for the remaining 10 revised statements.

another revised statement did have statistically significant higher levels for both "new information" and "self-reported learning"; only the revised statement on harms of secondhand smoke exposure in children (pneumonia) did not. Because there was not another revised statement on harms of secondhand smoke exposure in children, FDA selected the TCA statement on the same health condition (harm children) for further testing in the final quantitative consumer research study.

Additionally, as described above, FDA did not test a revised warning statement for four TCA statements (addictive, kill you, fatal lung disease in nonsmokers, quit now; see table 1 for full statements). Although these TCA statements were new information to relatively few participants and self-reported learning was low, FDA determined that it would provide a better basis for decision-making to pursue additional data on these four TCA statements, and thus included them for further testing.

Based on the Agency's analysis of the research results and evaluation of other considerations as just described, FDA selected a total of 15 textual warning statements for further testing. FDA selected the following five TCA statements for the final quantitative consumer research study:

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

Additionally, FDA selected the following 10 revised or "new content" statements for the final quantitative consumer research study (see section VI.E for a discussion of that study):

- WARNING: Smoking causes head and neck cancer.
- WARNING: Smoking causes bladder cancer, which can lead to bloody urine.
- WARNING: Smoking during pregnancy stunts fetal growth.
- WARNING: Smoking can cause heart disease and strokes by clogging arteries.
- WARNING: Smoking causes COPD, a lung disease that can be fatal.
- WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.
- WARNING: Smoking reduces blood flow to the limbs, which can require amputation.
- WARNING: Smoking causes type 2 diabetes, which raises blood sugar.
- WARNING: Smoking causes age-related macular degeneration, which can lead to blindness.
- WARNING: Smoking causes cataracts, which can lead to blindness.

D. Developing and Testing Images Depicting the Negative Health Consequences of Smoking to Accompany the Textual Warning Statements

Section 4(d) of the FCLAA, as amended by section 201(a) of the Tobacco Control Act, directs FDA to issue regulations that require color graphics depicting the negative health consequences of smoking to accompany textual warning statements on cigarette packages and in cigarette advertisements. In parallel with FDA's efforts to develop and test revised warning statements, the Agency also undertook an iterative, research-based approach to develop color graphics depicting the negative health consequences of cigarette smoking to accompany those statements. This process required considering how to help promote greater public understanding of the negative health consequences of cigarette smoking given that the general public comprises individuals with many varied backgrounds, knowledge, beliefs, and abilities to read and understand health information. According to National Assessment of Adult Literacy estimates,

about 12 percent of U.S. adults have proficient health literacy (i.e., the ability to access, understand, and use health information and services (Refs. 125 and 132). Among the remaining adults, 53 percent have intermediate health literacy, 22 percent have basic health literacy, and 14 percent have below basic health literacy (Ref. 125). Individuals with basic or below basic health literacy are more likely to be cigarette smokers (Refs. 133–135) and are more likely to have limited knowledge about the negative health consequences of smoking (Refs. 136 and 137). National surveys also indicate that about half of the U.S. adult population has only very basic or below basic quantitative skills, and only 9 percent of U.S. adults scored in the highest numeracy levels (i.e., the ability to understand and use numbers, including the ability to read and interpret data presented in tables, graphs, and bar charts) (Refs. 138 and 139).

To determine the best way to visually depict the negative health consequences of cigarette smoking to promote greater understanding among such a diverse population, FDA considered findings from health communication science research regarding best practices for helping the public better understand health risk information. As described in section V.B, it is well established in the scientific literature that vivid features (e.g., images) increase noticeability of and attention to textual health risk information (e.g., cigarette health warnings) and increase comprehension, understanding, and recall of health messages (Refs. 43, 50, 75, 78–81, 118, and 140–145). Research also indicates that visual depictions of textual health risk information are especially beneficial in aiding comprehension and understanding among subpopulations that have lower health literacy and numeracy skills (Refs. 118, 144, and 146–148), including greater disparities in knowledge about the negative health consequences of smoking (Ref. 69). However, multiple factors influence whether a specific type of visual depiction (such as an image compared to a bar chart or graph) ultimately aids or impedes message comprehension,

including the level of concordance between the text and accompanying visual depiction (e.g., using an image of an eye to depict the word "eye"); the level of cognitive effort required to understand the information (e.g., using a stacked bar chart to depict multiple data comparisons requires greater cognitive effort); and the type of communication channel used to deliver the message (e.g., information presented by a doctor as part of a conversation with a patient, versus information presented in a mass media campaign) (Refs. 118, 140–143, 146, 147, and 149–152). For example, some types of visual depiction, such as bar charts and graphs, are better suited to certain communication purposes such as depicting comparisons (bar charts) or conveying numerical information (graphs) (Refs. 142 and 152). When used to communicate health risk information to the public, bar charts and graphs are often misperceived, especially when not accompanied by further instruction on how to read and interpret the information (Refs. 140, 141, 149, and 151). Bar charts and graphs also require a higher degree of numerical proficiency and cognitive effort to promote consumer understanding than do other types of visual depiction, such as illustrations and photographs. In comparison, illustrations, photographs, and other pictorial visual depictions are more likely to aid comprehension when used for mass-communication purposes as these types of visual depictions are more easily made congruent (i.e., the type of visual is appropriate for the message) and concordant, and they require less numerical proficiency and cognitive effort to understand the information (Refs. 141, 142, 149, and 150). Therefore, based on this review of the literature, the proposed cigarette health warning message content, and the communication channel, FDA determined that textual warning statements paired with factually accurate, concordant photographs or photorealistic images of specific health conditions, presented in a realistic and objective format, would be most likely to advance the

Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking.

FDA then undertook a rigorous multistep process to develop, test, and refine images that: (1) are factually accurate; (2) depict common visual presentations of the health conditions (intended to aid understanding by building on existing consumer health knowledge and experiences) and/or show disease states and symptoms as they are typically experienced; (3) present the health conditions in a realistic and objective format that is devoid of non-essential elements; and (4) are concordant with the statements on the same health conditions.

After developing initial image concepts, FDA used information gathered through a series of 53 in-depth individual interviews with adolescents and adults (OMB control number 0910-0796, "Qualitative Study of Perceptions and Knowledge of Visually Depicted Health Conditions") to further refine the concepts. FDA evaluated the extent to which participants found the initial image concepts clear (in terms of recognizing what was being depicted in the image), attention-grabbing, worth remembering, credible, and relevant, and whether the concepts provided any new information. The interviews found that some image concepts were very clear, while others were less understood. When there were multiple image concepts on the same or similar health conditions, participants reacted similarly to those concepts. Overall, the majority of participants found the image concepts to be credible and rated most of the concepts as medium to high in terms of image clarity. FDA used the feedback from these qualitative interviews to further refine the initial image concepts, eliminate some image concepts from further consideration, and inform a future quantitative consumer research study (see section VI.E).

FDA used a photorealistic illustration format for the images rather than photographs, because this format best allowed depicting specific features of the health conditions as described

by the textual warning statements. The photorealistic illustration format also facilitated providing factually accurate images that depict common presentations of the health conditions in a realistic and objective format devoid of non-essential elements. Using photorealistic images allowed further editing and refinements for clarity and ease of understanding throughout the research and development process for new cigarette health warnings. A certified medical illustrator developed high quality, medically accurate, photorealistic images in close collaboration with FDA staff. After the photorealistic images were created, FDA paired each textual warning statement (the 9 TCA statements and the 15 revised statements tested in the first quantitative consumer research study) with a concordant image for further testing.

To do this further testing, FDA evaluated the photorealistic images through a series of 20 qualitative focus groups with adolescent smokers, adolescents at risk for starting smoking, and adult smokers (OMB control number 0910-0796, "Qualitative Study on Consumer Perceptions of Cigarettes Health Warning Images"). The focus groups examined what factual information the images conveyed to participants about the negative health consequences of cigarette smoking in the absence of a paired textual warning statement, as well as how concordant participants considered the images to be when paired with potential textual warning statements (both TCA statements and the revised statements). Based on feedback received in these focus groups, FDA further refined some images for additional clarity and eliminated other images that were not well understood or where potential confusion could not be resolved through additional revisions. FDA then completed final pairings of textual warning statements and concordant photorealistic images for testing in the final quantitative consumer research study.

As noted earlier (see section VI.C), FDA selected a total of 15 textual warning statements for further testing. However, two of the textual warning statements (fatal lung disease in

nonsmokers, COPD) shared similar concordant images (diseased lungs). To preserve the option of potentially requiring both warning statements but without using two similar images, FDA paired an additional concordant image that tested well in the qualitative focus groups (man with oxygen tank) with the COPD warning statement for further testing. Therefore, FDA prepared a total of 16 statement-and-image pairings to test in the final quantitative consumer research study.

E. FDA's Consumer Research Study on New Cigarette Health Warnings

Once FDA examined opportunities to promote greater public understanding of the risks associated with cigarette smoking, developed potential revised statements to address gaps in public understanding, tested the revised statements in a consumer research study, and developed concordant photorealistic images that depict the negative health consequences of smoking, the Agency prepared a set of 16 cigarette health warnings (statements paired with their concordant photorealistic images) to be tested in a final consumer research study. The purpose of the final research study was to assess the extent to which any of the cigarette health warnings, developed through FDA's science-based, iterative research process, increase understanding of the negative health consequences of cigarette smoking. For warnings to be considered for this proposed rule, FDA decided that a warning tested in this final consumer research study must demonstrate statistically significant improvements, as compared to the control condition, on both the two outcomes of "new information" and "self-reported learning" (more discussion about the study design, including the control and outcomes follows).

1. Study Design

FDA's final research study on new cigarette health warnings was a three-session internet-based consumer research study using an online research panel (OMB control number 0910-0866, "Experimental Study of Cigarette Warnings"). The study included 9,760 participants, including:

(1) adolescents (aged 13-17 years) who were current smokers and those at risk for starting smoking; (2) younger adults (aged 18-24 years) who were current smokers and nonsmokers; and (3) older-adults (aged 25 years and older) who were current smokers and nonsmokers. Study participants in all age groups were assigned to a condition that determined which warnings they viewed during the study. Participants in the control condition viewed one of the four current Surgeon General's cigarette warnings. Participants in each of the treatment conditions viewed one of 16 of the new cigarette health warnings (i.e., text-image pairings) FDA developed through the process described in sections VI.B-D. Table 2 provides a list of the 16 textual warning statements (paired with images) that FDA evaluated in this study.

Table 2.--Text of Cigarette Health Warnings Tested in FDA's Consumer Research Study

Statements
WARNING: Cigarettes are addictive.
WARNING: Tobacco smoke can harm your children.
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.
WARNING: Smoking causes head and neck cancer.
WARNING: Smoking causes bladder cancer, which can lead to bloody urine.
WARNING: Smoking during pregnancy stunts fetal growth.
WARNING: Smoking can cause heart disease and strokes by clogging arteries.
WARNING: Smoking causes COPD, a lung disease that can be fatal. [paired with an image of diseased lungs]
WARNING: Smoking causes COPD, a lung disease that can be fatal. [paired with an image of man with oxygen tank]
WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.
WARNING: Smoking reduces blood flow to the limbs, which can require amputation.
WARNING: Smoking causes type 2 diabetes, which raises blood sugar.
WARNING: Smoking causes age-related macular degeneration, which can lead to blindness.
WARNING: Smoking causes cataracts, which can lead to blindness.

All participants viewed their assigned warnings on both a mock three-dimensional cigarette package that could be rotated on screen and as part of a mock full-page magazine cigarette advertisement in either their current (e.g., on the side of the package for the Surgeon General's warnings) or proposed (e.g., on the top 50 percent of the front and rear panel of the package for the new cigarette health warnings) size and location.

The study took place over three sessions over more than two weeks for each respondent. During the first session, participants answered baseline questions about their beliefs about the negative health consequences of cigarette smoking. Next, they viewed their assigned warning on both the mock cigarette package and in the mock cigarette advertisement and answered questions assessing the following outcomes:

- Whether the warning was new information to participants ("new information");
- Whether participants learned something from the warning ("self-reported learning");
- Whether the warning made participants think about the health risks of smoking ("thinking about risks");
- Whether the warning was perceived to be informative ("perceived informativeness");
- Whether the warning was perceived to be understandable ("perceived understandability");
- Whether the warning was perceived to be a fact or opinion ("perceived factualness");
- Whether participants reported beliefs linking smoking and each of the health consequences presented in the warning ("health beliefs");
- Whether the warning was perceived to help participants understand the negative health effects of smoking ("perceived helpfulness understanding health effects");
- Whether the warning grabbed their attention ("attention"); and

- Whether the warning was recalled ("recall").

Approximately 1 day later, during the second session, participants viewed their assigned warning again and answered questions assessing their beliefs about the negative health consequences of cigarette smoking. Approximately 14 days after the second session, during the third session (i.e., a delayed post-test), participants answered questions about their beliefs about the negative health consequences of cigarette smoking as well as questions assessing recall of the warning they viewed.

More details about the study methodology, including the sample size calculation and analysis plan, can be found in the study report, which we have included in this docket (Ref. 153).⁹

2. Study Findings

The results of the final consumer research study allowed FDA to draw important conclusions that provide a basis for the cigarette health warnings included in this proposed rule. Overall, relative to the average of the Surgeon General's warnings, most of the new cigarette health warnings were reported to be new information; resulted in greater self-reported learning; led to thinking about risks; were higher on perceived informativeness, perceived understandability, and perceived helpfulness understanding health effects; increased agreement with accurate health beliefs over time; attracted attention; and were recalled.

As discussed above (see section VI.C.3), FDA determined that the outcomes "new information" and "self-reported learning" are predictive for the task of identifying which of the cigarette health warnings increase understanding of the negative health consequences of cigarette

⁹ As with the first consumer research study, FDA will conduct a peer review of this consumer research study. FDA's peer review plans are available online at <https://www.fda.gov/science-research/science-and-research-special-topics/peer-review-scientific-information-and-assessments>.

smoking. Participants were significantly more likely, relative to the control condition (i.e., the Surgeon General's warnings), to report that, for 13 of the 16 cigarette health warnings tested (except for the warnings related to addiction, smoking can kill, and quitting smoking), the new cigarette health warnings provided new information and resulted in greater self-reported learning (see Ref. 153, Table 4-1, "Summary of Results").

More details about the full study results can be found in the study report, which we have included in this docket (Ref. 153).

3. How Study Findings Were Used

Because the purpose of this final quantitative consumer research study was to identify which of the cigarette health warnings increase understanding of the negative health consequences of cigarette smoking, the study was not designed to put the cigarette health warnings in a rank order or compare individual results of one cigarette health warning to another. FDA evaluated the research results for each individual cigarette health warning to determine which warnings to include in this proposed rule.

FDA is including in this proposed rule only the warnings that demonstrate statistically significant improvements, as compared to the control condition (i.e., the Surgeon General's warnings), on both the outcomes of "new information" and "self-reported learning" (i.e., knowledge gain). Following review of the findings of the final quantitative consumer research study, FDA is proposing 13 cigarette health warnings that use the following 12 statements:

- WARNING: Tobacco smoke can harm your children.
- WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.
- WARNING: Smoking causes head and neck cancer.
- WARNING: Smoking causes bladder cancer, which can lead to bloody urine.

- WARNING: Smoking during pregnancy stunts fetal growth.
- WARNING: Smoking can cause heart disease and strokes by clogging arteries.
- WARNING: Smoking causes COPD, a lung disease that can be fatal. [paired with two images]¹⁰
- WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.
- WARNING: Smoking reduces blood flow to the limbs, which can require amputation.
- WARNING: Smoking causes type 2 diabetes, which raises blood sugar.
- WARNING: Smoking causes age-related macular degeneration, which can lead to blindness.
- WARNING: Smoking causes cataracts, which can lead to blindness.

The cigarette health warnings using the following three statements did not demonstrate statistically significant improvements, as compared to the control condition, on the outcomes of "new information" and "self-reported learning" and therefore are not included as part of this proposed rule:

- WARNING: Cigarettes are addictive.
- WARNING: Smoking can kill you.
- WARNING: Quitting smoking now greatly reduces serious risks to your health.

VII. FDA's Proposed Required Warnings

The initial section 4(d) of the FCLAA, as amended by section 201 of the Tobacco Control Act, directs FDA to issue "regulations that require color graphics depicting the negative

¹⁰ As discussed in section VI.D, FDA paired two concordant images (i.e., diseased lungs, man with oxygen tank) with the COPD warning statement for final testing. Both text and image pairings demonstrated statistically significant improvements, as compared to the control condition (i.e., the Surgeon General's warnings), on both the outcomes of "new information" and "self-reported learning" (i.e., knowledge gain).

health consequences of smoking" to accompany the textual warning statements specified in section 4(a)(1) of the FCLAA. A second section 4(d) of the FCLAA, as created by section 202(b) of the Tobacco Control Act, permits FDA, through notice and comment rulemaking, to adjust the format, type size, color graphics, and text of any of the label requirements if such a change would promote greater public understanding of the risks associated with the use of tobacco products. FDA interprets these provisions of the FCLAA to permit a rulemaking that establishes new cigarette health warnings and at the same time adjusts the text and color graphic requirements, including the number of required warnings, so long as the adjustments promote greater public understanding of the risks of the use of tobacco products.

As described in section VI.B, FDA undertook a science-based, iterative research and development process to consider whether revisions to the textual warning statements specified in section 4(1) of the FCLAA would promote greater public understanding of the risks associated with cigarette smoking. The empirical results demonstrate sufficient scientific support to adjust the textual warning statements. Also, as described in section VI.D, FDA carefully developed and tested concordant color graphics, in the form of photorealistic images, depicting the negative health consequences of smoking to accompany each of the textual warning statements included in this proposed rule. Based on the results of FDA's research, we intend to finalize some or all of the 13 new cigarette health warnings proposed in this rule. We invite comment on how many warnings should be selected for the final rule and whether fewer than, more than, or exactly nine warnings would advance the Government's interest in promoting greater public understanding of the negative health consequences of smoking.

The 13 proposed warnings, each of which consists of a textual warning statement paired with a concordant photorealistic image depicting the negative health consequences of smoking,

are available in an electronic PDF in this docket (Ref. 18). For the final rule, the required warnings will be contained in a document entitled "Required Cigarette Health Warnings," as is further discussed in section II.C.

These proposed required warnings, as shown through the robust scientific evidence described in detail in sections V and VI and in the remainder of this section, are factual and accurate, advance the Government's interest, and are not unduly burdensome (see section VIII for a more detailed discussion). In determining which proposed cigarette health warnings will be required in the final rule, FDA will consider public comments submitted to this docket, full research results from our final quantitative consumer research study (including peer reviewer comments), scientific literature, and other considerations as discussed in this proposal.

A. FDA's Proposed Required Warnings

As discussed above, we assessed whether the new cigarette health warnings, developed through FDA's science-based, iterative research process, will advance the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking. Based on available data and information available to us at this time, including results from FDA's final consumer research study (see section VI for a full description of the final consumer research study) (Ref. 153), we identified 13 cigarette health warnings for this proposed rule.

Each of the proposed warnings described in this section demonstrated statistically significant higher levels of providing new information and self-reported learning when compared to the control condition (i.e., the Surgeon General's warnings) (Ref. 153). While the final consumer research study was designed to measure a range of outcomes related to consumer understanding, as an initial matter, FDA is including in this proposed rule only the warnings that

demonstrate statistically significant improvements, as compared to the control condition (i.e., the Surgeon General's warnings), on both the outcomes of "new information" and "self-reported learning" (i.e., knowledge gain). As described above, the scientific literature demonstrates that these two outcomes are predictive for the task of assessing which of the new cigarette health warnings increase understanding of the risks associated with cigarette smoking. Other study outcomes provide additional, useful information and are reflected in the study report (Ref. 153).

FDA solicits comment on the individual cigarette health warnings included in this proposal, and we ask that comments provide data and factual information that would help us to further consider which proposed warnings to include in the final rule or whether such warnings should be altered, consistent with the Government's interest, and how. For additional consideration, the following subsections provide relevant scientific support for each of the proposed required warnings.

1. **WARNING: Tobacco smoke can harm your children.**

This proposed warning consists of the TCA statement "WARNING: Tobacco smoke can harm your children" paired with a concordant, factually accurate, photorealistic image depicting a negative health consequence of secondhand smoke exposure in children. The image shows the head and shoulders of a young boy (aged 8-10 years) wearing a hospital gown and receiving a nebulizer treatment for chronic asthma resulting from secondhand smoke exposure.

Since 2004, several Surgeon General's Reports have confirmed the causal link between exposure to secondhand smoke and several negative health consequences in children, including middle ear disease, respiratory symptoms, impaired lung function, lower respiratory illness, and SIDS (Refs. 8, 154, and 155). The 2006 Surgeon General's Report stated that the evidence is sufficient to conclude--the highest level of evidence of causal inferences from the criteria applied

in the Surgeon General's Reports--that secondhand smoke exposure from parental smoking causes the following negative health effects: lower respiratory illness in infants and children; middle ear disease in children, including acute and recurrent otitis media and chronic middle ear effusion; cough, phlegm, wheeze, and breathlessness among children of school age, and ever having asthma among children of school age; the onset of wheeze illnesses in early childhood; persistent adverse effects on lung function across childhood; and a lower level of lung function during childhood (Ref. 155). More recently published studies on the topic support the Surgeon General's Reports' conclusion that parental secondhand smoke influences child health, particularly respiratory health (Refs. 156–158).

2. **WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.**

This proposed warning consists of the TCA statement "WARNING: Tobacco smoke causes fatal lung disease in nonsmokers" paired with a concordant, factually accurate, photorealistic image depicting fatal lung disease. The image shows gloved hands holding a pair of diseased lungs containing cancerous lesions from chronic secondhand smoke exposure.

The 1986 and subsequent Surgeon General's Reports have confirmed the causal link between secondhand smoke exposure and lung cancer, a fatal lung disease, among nonsmokers (Refs. 155 and 159). The conclusion in the 2006 Surgeon General's Report extends to all secondhand smoke exposure, regardless of location of exposure (e.g., at home, at work, in other settings); the combined evidence from multiple studies indicates a 20 to 30 percent increase in the risk of lung cancer from secondhand smoke exposure associated with living with a smoker (Ref. 155). For example, a meta-analysis of 43 studies, including studies conducted in both the United States and outside of the United States, found that the relative risk of lung cancer among nonsmoking women who live with partners who smoke (i.e., the risk of the lung cancer among

nonsmokers living with smokers compared to nonsmokers not living with smokers) was 1.29 (Ref. 160). This means that nonsmoking women who live with partners who smoke have 1.29 times higher risk of lung cancer compared to nonsmoking women who live with partners who do not smoke. Recent studies support and extend these conclusions (Refs. 161–164). In addition to the many lung cancer deaths caused directly by smoking, researchers estimate that another 5 percent of all lung cancer deaths, or 7,300 deaths annually (as measured in 2006), can be attributed to secondhand smoke exposure (Ref. 165).

3. WARNING: Smoking causes head and neck cancer.

This proposed warning consists of the revised textual warning statement "WARNING: Smoking causes head and neck cancer" paired with a concordant, factually accurate, photorealistic image depicting neck cancer. The image shows the head and neck of a woman (aged 50-60 years) who has neck cancer caused by cigarette smoking. The woman has a visible tumor protruding from the right side her neck just below her jawline.

Common head and neck cancers include mouth, nose, pharynx, and larynx. Since 1979, Surgeon General's Report have recognized that smoking causes head and neck cancers, and the 2004 Surgeon General's Report stated that the evidence is sufficient to infer a causal relationship--the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports--between smoking and cancers of the oral cavity, pharynx, and larynx (Ref. 154), building on the strong conclusions of causality from previous reports. The magnitude of this relationship is substantial--male and female smokers who currently smoke and have smoked only cigarettes experience 10- and 5-fold higher risk of head and neck cancers than lifetime nonsmokers, respectively. The 2004 Surgeon General's Report summarized clinical studies showing that premalignant lesions in the mouth and throat are most commonly found in

areas that have direct contact with tobacco or smoke and that quitting smoking causes most premalignant lesions to regress and reduces oral and pharyngeal cancer incidence and mortality (Ref. 154). In 2015, there were 44,430 new cases of cancer of the oral cavity and pharynx and 12,292 new cases of cancer of the larynx (Ref. 166). There were approximately 14,000 deaths from head and neck cancer in 2016 (approximately 10,000 from cancer of the lip, oral cavity, and pharynx, and approximately 3,900 from cancer of the larynx) (Ref. 166). Most head and neck cancers are attributable to smoking, with almost 70 percent of lip, oral cavity, pharynx, and larynx cancer deaths from 2000 to 2004 attributable to smoking, representing 7,900 deaths a year (Ref. 30).

4. **WARNING:** Smoking causes bladder cancer, which can lead to bloody urine.

This proposed warning consists of the revised textual warning statement "WARNING: Smoking causes bladder cancer, which can lead to bloody urine" paired with a concordant, factually accurate, photorealistic image depicting bloody urine. The image shows a gloved hand holding a urine specimen cup containing bloody urine resulting from bladder cancer caused by cigarette smoking.

The association between smoking and bladder cancer has been noted since the first Surgeon General's Report in 1964, and a causal conclusion was reported in the 1990 report (Refs. 183 and 219). The 2014 Surgeon General's Report again confirmed that the evidence is sufficient to infer a causal relationship--the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports--between cigarette smoking and bladder cancer (Ref. 8). Recent research illustrates that even smoking a few cigarettes per day is associated with an increased risk of bladder cancer (Ref. 167) and that low intensity/long duration smoking is particularly associated with increased bladder cancer risk (Ref. 168). In

most cases, blood in the urine (called hematuria) is the first visible sign of bladder cancer (Ref. 169), although there are other causes of hematuria. The number of cases of bladder cancer related to smoking is considerable. There were 73,000 bladder cancer cases in the United States in 2015 and 16,650 deaths from bladder cancer in 2017 (Ref. 166). According to the American Cancer Society, 1 in 27 men and 1 in 89 women will develop bladder cancer during their lifetime (Ref. 170). The Centers for Disease Control and Prevention (CDC) has estimated that 40 percent of bladder cancer deaths in 2000 through 2004 were attributable to smoking, representing almost 5,000 deaths a year (Ref. 30).

5. **WARNING: Smoking during pregnancy stunts fetal growth.**

This proposed warning consists of the revised textual warning statement "WARNING: Smoking during pregnancy stunts fetal growth" paired with a concordant, factually accurate, photorealistic image depicting a negative health consequence of smoking during pregnancy: an infant with low birth weight resulting from stunted fetal growth. The image shows a newborn infant on a medical scale, and the digital display on the scale reads four pounds.

The 2004 Surgeon General's Report concluded for the first time that the evidence was sufficient to infer a causal relationship--the highest level of evidence of causal inferences based on the criteria applied in the Surgeon General's Reports--between maternal smoking and fetal growth restriction and preterm delivery (Ref. 154). The 2004 Surgeon General's Report summarized many studies that found a consistent and strong relationship between smoking and reduced birth weight as well as a strong dose-response relationship between smoking intensity and birth weight, and the 2010 Surgeon General's Report cited additional studies further supporting that conclusion (Ref. 171). New studies published since 2014 further support the causal relation between smoking and restricted fetal growth (Refs. 172–175).

In the United States, around eight percent of newborns have low birth weight each year (Ref. 176). The CDC reported that low birth weight was twice as common among smoking mothers compared to nonsmoking mothers in Ohio in a 6-month period in 1989, with 20 percent of cases of low birth weight among infants during the same period due to maternal smoking (Ref. 177). Low birth weight was almost 60 percent more common among mothers who smoked during pregnancy than mothers who did not in a study in Massachusetts in 1998 (Ref. 32). The California EPA estimated 24,500 cases of low birth weight due to maternal exposure to environmental tobacco smoke (i.e., secondhand smoking) in the United States per year (Ref. 34).

6. **WARNING: Smoking can cause heart disease and strokes by clogging arteries.**

This proposed warning consists of the revised textual warning statement "WARNING: Smoking can cause heart disease and strokes by clogging arteries" paired with a concordant, factually accurate, photorealistic image depicting a patient who recently underwent heart surgery to treat heart disease caused by smoking. The image shows the chest of a man (aged 60-70 years) wearing an open hospital gown. The man has a large, recently-sutured incision running down the middle of his chest and is undergoing post-operative monitoring.

Surgeon General's Reports since the 1970s have concluded that smoking is causally related to heart disease and stroke (Refs. 154 and 178). The 2014 Surgeon General's Report summarized the evidence and focused on new insights into causal mechanisms gained since the earlier report (Ref. 8). Coronary heart disease--often simply called heart disease--is a disorder of the blood vessels of the heart that can lead to a heart attack. A heart attack happens when an artery becomes blocked, preventing oxygen and nutrients from getting to the heart. Stroke occurs when blood supply to part of the brain is interrupted or reduced, depriving brain tissue of oxygen and nutrients (Ref. 179). Atherosclerosis, or clogged arteries, is a disease in which

plaque builds up inside the arteries that carry oxygen-rich blood to the heart and other parts of the body and can lead to heart attack and stroke through thrombosis, or blockage of the arteries (Refs. 8 and 179). Most coronary heart disease involves atherosclerosis, or clogged arteries. The 2004 Surgeon General's Report concluded that evidence from several different populations, multiple age groups, and both genders is sufficient to conclude that there is a causal relationship--the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports--between smoking and atherosclerosis and related health conditions such as heart disease and stroke (Ref. 154). Across many studies over time, a clear dose-response relationship has been established with smoking more cigarettes and smoking for a longer time linked to greater risk of heart disease and stroke. More recent evidence demonstrates that even a very low frequency of smoking (i.e., even as few as one cigarette per day) has a measurable increase in the risk for cardiovascular disease (Ref. 180). The 2004 Surgeon General's Report further concluded that the evidence is sufficient to infer a causal relationship--the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports--between smoking and subclinical (or very early signs of) atherosclerosis (Ref. 154).

The public health burden of heart disease and stroke is considerable. It has been estimated that, in the United States, over 2 million people have had a heart attack during their lifetime and over 1 million have had a stroke during their lifetime due to smoking (Ref. 21). The mortality burden is also substantial. There are approximately 635,000 deaths from heart disease and 140,000 deaths from stroke in the United States each year (Ref. 181). Recent data showed that the mortality risk (i.e., the risk of dying) for current smokers compared to never smokers from heart disease was 2.50 times greater for men and 2.86 times greater for women. The risk of having a stroke was 1.92 times greater for men and 2.10 times greater for women who were

current smokers compared to never smokers (Ref. 182). The proportion of all deaths from heart attack and stroke due to active smoking is notable--24.1 percent for heart disease deaths and 11.3 percent for stroke deaths. This represents approximately 100,000 deaths from heart attack due to smoking, and 15,000 stroke deaths due to smoking (Ref.8).

7. WARNING: Smoking causes COPD, a lung disease that can be fatal. [image of diseased lungs]

This proposed warning consists of the revised textual warning statement "WARNING: Smoking causes COPD, a lung disease that can be fatal" paired with a concordant, factually accurate, photorealistic image depicting COPD. The image shows gloved hands holding a pair of diseased, darkened lungs removed from a smoker with COPD. Because a similar image of diseased lungs was paired with the TCA statement regarding fatal lung disease in nonsmokers, FDA paired this revised statement with two different images for final testing (see next subsection).

Chronic obstructive pulmonary disease (COPD) includes the diseases emphysema and chronic bronchitis. The 1964 Surgeon General's Report concluded that smoking is a primary cause of chronic bronchitis, and subsequent reports summarized additional evidence to conclude, in the 2004 Surgeon General's Report, at the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports, that the evidence is sufficient to infer a causal relationship between active smoking and COPD morbidity and mortality (Refs. 154, 183, and 184). The 2014 Surgeon General's Report reinforced and extended this evidence to discuss the relationship between smoking and COPD mortality (Ref. 8). The 2014 Surgeon General's Report concluded that the evidence is sufficient to infer--once again, the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports--that

smoking is in fact the dominant cause of COPD in the United States (Ref. 8). The report also concluded that smoking causes all elements of COPD, including emphysema and damage to the airways of the lung (Ref. 8).

The public health burden of COPD is substantial. The National Heart, Lung, Blood Institute estimates that there are 12 million U.S. adults currently living who have been diagnosed with COPD and another 12 million who have COPD but have not yet been diagnosed (Ref. 185). It has also been estimated that approximately 7.5 million people currently living with COPD (whether diagnosed or undiagnosed) have the disease because of smoking (Ref. 21). The mortality risk from COPD for current smokers compared to never smokers was 25.61 times higher for men and 22.35 times higher for women, according to 50-year trends published in the *New England Journal of Medicine* (Ref. 182). There are about 128,000 COPD deaths in the United States each year, of which 101,000 (79 percent) are attributable to smoking (Ref. 8).

8. WARNING: Smoking causes COPD, a lung disease that can be fatal. [image of man with oxygen tank]

This proposed warning consists of the revised textual warning statement "WARNING: Smoking causes COPD, a lung disease that can be fatal" paired with a concordant, factually accurate, photorealistic image depicting a man receiving oxygen support because he has COPD caused by cigarette smoking. The image shows the head and neck of a man (aged 50-60 years) who has a nasal canula under his nose supplying oxygen; the oxygen tank can be seen behind his left shoulder. Because, based on the findings from previous qualitative testing (see section VI.D), both this warning statement and the TCA statement regarding fatal lung disease in nonsmokers were paired with similar images of diseased lungs (see previous subsection), FDA

decided to pair this revised statement with an additional concordant image for testing in the final quantitative consumer research study.

As explained in the previous subsection ("7. WARNING: Smoking causes COPD, a lung disease that can be fatal. [image of diseased lungs]"), COPD includes the diseases emphysema and chronic bronchitis. The 1964 Surgeon General's Report concluded that smoking is a primary cause of chronic bronchitis, and subsequent reports summarized additional evidence to conclude, in the 2004 Surgeon General's Report, at the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports, that the evidence is sufficient to infer a causal relationship between active smoking and COPD morbidity and mortality (Refs. 154, 183, and 184). The 2014 Surgeon General's Report reinforced and extended this evidence to discuss the relationship between smoking and COPD mortality (Ref. 8). The 2014 Surgeon General's Report concluded that the evidence is sufficient to infer--once again, the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports--that smoking is in fact the dominant cause of COPD in the United States (Ref. 8). The report also concluded that smoking causes all elements of COPD, including emphysema and damage to the airways of the lung (Ref. 8).

The public health burden of COPD is substantial. The National Heart, Lung, Blood Institute estimates that there are 12 million U.S. adults currently living who have been diagnosed with COPD and another 12 million who have COPD but have not yet been diagnosed (Ref. 185). It has also been estimated that approximately 7.5 million people currently living with COPD (whether diagnosed or undiagnosed) have the disease because of smoking (Ref. 21). The mortality risk from COPD for current smokers compared to never smokers was 25.61 times higher for men and 22.35 times higher for women, according to 50-year trends published in the

New England Journal of Medicine (Ref. 182). There are about 128,000 COPD deaths in the United States each year, of which 101,000 (79 percent) are attributable to smoking (Ref. 8).

9. **WARNING:** Smoking reduces blood flow, which can cause erectile dysfunction.

This proposed warning consists of the revised textual warning statement "WARNING: Smoking reduces blood flow, which can cause erectile dysfunction" paired with a concordant, factually accurate, photorealistic image depicting a man who is experiencing erectile dysfunction caused by smoking. The image shows a man (aged 50-60 years) sitting on the edge of a bed and leaning forward, with one elbow resting on each knee. The man's head is tilted down, with his forehead pressed into the knuckles of his right hand. Behind him on the bed, his female partner looks off in another direction.

The 2014 Surgeon General's Report concluded, for the first time, that the evidence is sufficient to infer a causal relationship--the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports--between smoking and erectile dysfunction (Ref. 8). This conclusion is supported by the consistency of the strength of the association across numerous studies that evaluated rates of erectile dysfunction among smokers. For example, a recent meta-analysis of studies that included 50,360 participants found that smoking more cigarettes and smoking for a longer time were associated with increased erectile dysfunction risk (Ref. 186).

Erectile dysfunction is likely under-reported in epidemiological studies; therefore, the effect estimates observed in studies are likely an underestimate. However, given that limitation of being under-reported in studies, at least 20 percent of all men have some degree of erectile dysfunction (Ref. 187). Among men between the ages of 40 and 70 years, approximately 50 percent have some degree of erectile dysfunction (Ref. 187). Smokers have been found to have a

40 percent increased risk of erectile dysfunction in studies such as the Health Professionals Follow-up Study and the Olmsted County Study of Urinary Symptoms and Health Status (Refs. 27 and 28).

10. **WARNING:** Smoking reduces blood flow to the limbs, which can require amputation.

This proposed warning consists of the revised textual warning statement "WARNING: Smoking reduces blood flow to the limbs, which can require amputation" paired with a concordant, factually accurate, photorealistic image depicting the feet of a person who had several toes amputated due to tissue damage resulting from peripheral vascular disease caused by cigarette smoking.

Peripheral arterial disease (PAD), also known as peripheral vascular disease (PVD), is a condition in which narrowed arteries reduce blood flow to the limbs, especially the legs. Plaque is made up of fat, cholesterol, calcium, fibrous tissue, and other substances in the blood. Over time, plaque can harden and narrow the arteries. This limits the flow of oxygen-rich blood to organs and other parts of the body. PAD/PVD usually affects the arteries in the legs (Ref. 188). Complications of PAD/PVD occur because of decreased or absent blood flow and may include amputation or loss of limb due to tissue not getting enough oxygen from blood and dying. The 1983 Surgeon General's Report entitled "The Health Consequences of Smoking: Cardiovascular Disease" summarized evidence regarding smoking and PAD/PVD and concluded that cigarette smoking is the most powerful risk factor predisposing to this condition and that smoking cessation plays an important role in its medical and surgical management (Ref. 189). Since that time, other Surgeon General's Reports have extended this evidence base, through the 2014 report (Ref. 8).

The population health burden of PAD/PVD is substantial. Overall prevalence of PAD/PVD was found to be 13.5 percent in 2012 in the Atherosclerosis Risk in Communities study, a multi-site, biracial, prospective cohort study investigating the causes and clinical effects of atherosclerosis in four U.S. communities (Ref. 190). A meta-analysis of studies of PAD/PVD and smoking found that the risk of the condition was 2.71 times greater for current smokers and 1.67 times greater for former smokers compared to never smokers (Ref. 26). In its summary of a recent prospective analysis using the Women's Health Study, which evaluated the relationships of smoking and smoking cessation with PAD/PVD, the 2014 Surgeon General's Report showed that risk estimates have increased over time (Ref. 8). Results from that study found higher risks than those in the meta-analysis; compared to never smokers, the risk of PAD/PVD in the Women's Health Study was 3.16 times greater for former smokers, 11.94 times greater for current smokers reporting less than 15 cigarettes per day, and 21.08 times greater for current smokers reporting 15 or more cigarettes per day (Ref. 191).

One estimate from a review of the scientific literature suggests that there are between 160,000 and 180,000 amputations due to PAD/PVD annually in the United States, and, among people with critical limb ischemia (i.e., a severe blockage of the arteries that greatly reduces blood flow due to PAD/PVD), 25 percent have amputations each year (Ref. 192). Another article estimates that "over 90% of all limb amputations in the Western world occur as a direct or indirect consequence" of PAD/PVD (Ref. 193).

11. **WARNING: Smoking causes type 2 diabetes, which raises blood sugar.**

This proposed warning consists of the revised textual warning statement "WARNING: Smoking causes type 2 diabetes, which raises blood sugar" paired with a concordant, factually accurate, photorealistic image depicting a personal glucometer device being used to measure the

blood glucose level of a person with type 2 diabetes caused by cigarette smoking. The digital display reading of 175 mg/dL and a notation on the glucometer indicate a high blood sugar level.

The 2014 Surgeon General's Report concluded, for the first time, that: (1) the evidence is sufficient to infer--the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports--that cigarette smoking is a cause of type 2 diabetes; (2) the risk of developing diabetes is 30 to 40 percent higher for active smokers than nonsmokers; and (3) there is a relationship between increased number of cigarettes smoked and increased risk of developing diabetes (Ref. 8). Across the 25 studies included in the 2014 Surgeon General's Report updated summary, the associations were strong and consistent and were found in many subgroups, and these results have been replicated in many different study populations and study locations.

The public health burden of smoking and diabetes is substantial. The prevalence of diabetes among U.S. adults was estimated to be 12.1 percent in 2005 through 2010 National Health and Nutrition Examination Survey data (Ref. 194). A meta-analysis of studies found the risk of type 2 diabetes to be 44 percent greater among current smokers and 23 percent greater among former smokers compared to never smokers (Ref. 25). Smoking has been estimated to cause 9,000 of the 70,810 deaths (12.7 percent) due to diabetes in the United States each year (Ref. 8).

12. **WARNING:** Smoking causes age-related macular degeneration, which can lead to blindness.

This proposed warning consists of the revised textual warning statement "WARNING: Smoking causes age-related macular degeneration, which can lead to blindness" paired with a concordant, factually accurate, photorealistic image depicting a closeup of an older man (aged 65

years or older) who has age-related macular degeneration caused by cigarette smoking. The man is receiving an injection in his right eye to prevent additional vessel growth.

Macular degeneration is an incurable eye disease that causes blindness. The 2014 Surgeon General's Report on cigarette smoking concluded, for the first time, that the evidence is sufficient to infer a causal relationship--the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports--between cigarette smoking and the two major types of advanced age-related macular degeneration (Ref. 8). The association is found across a range of populations and through various study designs. The prevalence of any macular degeneration among U.S. adults aged 40 years and older was estimated to be 6.5 percent (Ref. 216). A meta-analysis found that current smokers were approximately twice as likely (relative risks for cohort studies of 2.06 and for case-control studies of 2.38), as never smokers to have macular degeneration (Ref. 23).

13. **WARNING:** Smoking causes cataracts, which can lead to blindness.

This proposed warning consists of the revised textual warning statement "WARNING: Smoking causes cataracts, which can lead to blindness" paired with a concordant, factually accurate, photorealistic image depicting a closeup of the face of a man (aged 65 years or older) who has a cataract caused by cigarette smoking. The man's right pupil is covered by a large cataract.

A cataract is a clouding of the lens in the eye that affects vision. Without treatment, the area of clouding of the lens can increase and eventually leads to blindness. The 2004 Surgeon General's Report on cigarette smoking concluded that the evidence is sufficient to infer a causal relationship--the highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports--between smoking and nuclear cataracts (Ref. 154). A nuclear

cataract is one of the three types of cataracts and refers to the location of the clouding in the lens of the eye. The epidemiologic studies examined in the 2004 Surgeon General's Report found generally consistent associations between smoking and nuclear cataracts, with most studies reporting that smoking doubled or tripled the relative risk of nuclear cataracts; in addition, a dose-response relationship was observed as risk increased with the number of cigarettes smoked (Ref. 154). Data for other types of cataracts were less strong, and these subtypes are also less common in the population (Ref. 154). Authors have continued to identify smoking as a major causal risk factor in the development and progression of cataracts (Refs. 195–197). Studies of smoking cessation and risk of cataracts has affirmed that risk decreases, but is not equivalent to never smokers, upon elimination of the exposures of tobacco smoke (Ref. 198).

Prevalence of cataracts among U.S. adults aged 40 years and older in 2010 was estimated to be 17.1 percent by the National Eye Institute (Ref. 199). By age 75, more than half of non-Hispanic whites have cataracts (Ref. 199). A meta-analysis found that the risk of cataracts was about 50 percent higher for current smokers and 20 percent to 60 percent higher for former smokers compared to never smokers (Ref. 24).

VIII. First Amendment Considerations

The Government may, consistent with the First Amendment, require the disclosure of factual information in commercial marketing where the disclosure is justified by a Government interest and does not unduly burden protected speech. *Zauderer v. Office of Disciplinary Counsel*; *Nat'l Inst. of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361, 2372 (2018). The proposed new cigarette health warnings, including their images, fully satisfy those requirements.

The proposed warnings are factual and accurate. As described in greater detail in section VI.A above, "Review of the Negative Health Consequences of Cigarette Smoking," in

developing the new warnings, FDA relied on the 2014 Surgeon General's Report, entitled "The Health Consequences of Smoking: 50 Years of Progress" (Ref. 8), in addition to previous reports of the Surgeon General and other scientific literature, which together present a robust body of evidence documenting the health consequences from both active smoking and exposure to secondhand smoke across a range of diseases and organ systems. In particular, Surgeon General's Reports provide definitive syntheses of the available evidence on smoking and health (Ref. 8, p. 3). Surgeon General's Reports classify the strength of causal inferences in a four-level hierarchy based upon work of the IOM (now the National Academy of Medicine) and the IARC (Refs. 200 and 212). Because of the rigor and consistent application of these causal standards, the Surgeon General's Reports are the preeminent authority for determinations of conditions caused by cigarette smoking and by exposure to secondhand smoke. Every smoking-related condition in every warning statement that FDA tested is supported at the very highest level of evidence of causal inferences from the criteria applied in the Surgeon General's Reports.

Based upon this research and upon the substantial scientific literature on the significant gaps and misperceptions in public understanding of the negative health consequences of smoking (see section V.A.3 above, "There Remain Significant Gaps in Public Understanding About the Negative Health Consequences of Cigarette Smoking"), FDA developed initial versions of revised statements for further review, testing, and refinement. These initial revised statements were further reviewed by FDA internal epidemiological experts to confirm that the health conditions under consideration were causally linked to cigarette smoking or exposure to secondhand smoke.

In parallel with FDA's work to develop and test revised warning statements, the Agency also undertook an iterative, research-based approach to develop and test color graphics depicting

the negative health consequences of cigarette smoking to accompany the statements. As discussed in section VI.D above ("Developing and Testing Images Depicting the Negative Health Consequences of Smoking to Accompany the Textual Warning Statements"), FDA used a photorealistic illustration format for the images because this format best allowed FDA to ensure that the final images would be fully concordant with the ultimate textual statements addressing the same health conditions. The photorealistic illustration format also facilitated providing factually accurate images that depict common presentations of the health conditions in a realistic and objective format devoid of non-essential elements.

FDA also carefully considered the D.C. Circuit Court findings regarding the Agency's 2010-2011 cigarette warning rule, including the court's statements criticizing the images as having been designed "to evoke an emotional response" with "inflammatory images and the provocatively-named hotline." *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d at 1216 (D.C. Cir. 2012). The court further found that some of the images "could be misinterpreted by consumers" and some did "not convey any warning information at all." *Id.* (emphasis omitted) ("For example, the images of a woman crying, a small child, and the man wearing a T-shirt emblazoned with the words 'I QUIT' do not offer any information about the health effects of smoking."). As discussed below, FDA's science-based, iterative research process to develop and select the current proposed cigarette health warnings thoroughly addresses any such criticisms.

To ensure that all proposed warnings are unambiguous, are unlikely to be misinterpreted or misunderstood by consumers, and do convey warning information, FDA repeatedly tested potential text statements, potential images, and potential pairings of statements with images. To assess the 9 statements set out in the TCA and the 17 potential revised statements that were under consideration at the start of its consumer research, FDA conducted 16 qualitative focus

groups with adolescent smokers, adolescents at risk for starting smoking, and adult smokers. As discussed in section VI.B above ("Developing Revised Textual Warning Statements"), these focus groups provided qualitative feedback on consumers' comprehension of each potential statement; the believability of each statement's content (e.g., that smoking causes the health condition noted); whether the relationship between smoking and the relevant health conditions was new information for them; and other feedback to make the statement more understandable or convey the intended message more clearly.

This qualitative consumer focus group feedback informed FDA's selection and refinement of the warning statements for the next phase of research, a large (2,505 participant) quantitative consumer research study that tested potential statements on their own, without images. See details in section VI.C above ("FDA's Consumer Research Study on Revised Textual Warning Statements") and in the study results included in this docket (Ref. 129). Obviating any potential concern that the proposed new warnings would "not convey any warning information at all," *Reynolds*, 696 F.3d at 1216, FDA used the results of this quantitative research, especially "self-reported learning" and "new information" outcomes, to identify the warning statements, to be paired with accompanying concordant photorealistic images, for testing in the final quantitative consumer research study.

FDA's rigorous process for developing the proposed images likewise obviates any potential concerns of the kind raised in *Reynolds* that they might "not offer any information about the health effects of smoking" or be discordant from the text statements with which they are paired. *Id.* FDA used different development and research processes to select and study the images in this rule than it did for the 2010-2011 rulemaking. As discussed above, two of FDA's criteria for images require them to be factually accurate and to be concordant with the textual

warning statements on the same health condition. FDA sought repeated consumer feedback to ensure that its proposed images meet these criteria, including 53 indepth individual interviews with adolescents and adults, and later on, 20 qualitative focus groups with adolescent smokers, adolescents at risk for starting smoking, and adult smokers. Based on feedback received in these focus groups, FDA further refined some images for additional clarity and identified and eliminated images that were not well understood or where potential confusion could not be resolved through additional revisions. See details in section VI.D above ("Developing and Testing Images Depicting the Negative Health Consequences of Smoking to Accompany the Textual Warning Statements"). The Agency took careful and deliberate steps to develop and test images that are unambiguous and unlikely to be misinterpreted or misunderstood by consumers. Presenting the health condition in an objective format devoid of non-essential elements ensures that the focus of the image remains on the smoking-related health condition. The process FDA engaged in to develop and study the warnings was far more extensive than could be completed in the short timeframe for the prior rule.

The proposed warnings are clearly justified by the Government's interest in promoting greater public understanding of the negative health consequences of cigarette smoking. As the Supreme Court has recognized, "tobacco products are dangerous to health when used in the manner prescribed." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 135 (2000). Indeed, as discussed above, cigarette smoking remains the leading cause of preventable disease and death in the United States. Given the magnitude of this public health problem from cigarette smoking, in the Tobacco Control Act Congress required nine new health warning statements appear on cigarette packages and in cigarette advertisements; directed FDA to develop color graphics "depicting the negative health consequences of smoking" to accompany the warning

statements; and provided that FDA may adjust the warnings to "promote greater public understanding of the risks associated with the use of tobacco products" (sections 201 and 202 of the Tobacco Control Act). In reviewing and upholding the Tobacco Control Act's new warning requirements, the Sixth Circuit concluded that "[t]here can be no doubt that the government has a significant interest in...warning the general public about the harms associated with the use of tobacco products." *Disc. Tobacco City & Lottery, Inc. v. U.S.*, 674 F.3d 509, 519 (6th Cir. 2012).

FDA's research and review of the scientific literature has confirmed that many smokers and nonsmokers hold misperceptions about the health risks associated with cigarette smoking, even among the health conditions most commonly focused on in health warnings and public health education campaigns. And studies have shown that consumers are largely unaware of many of the negative health consequences of cigarette smoking not mentioned in the current 1984 warnings (see section V.A.3 above, "There Remain Significant Gaps in Public Understanding About the Negative Health Consequences of Cigarette Smoking"). Accordingly, the proposed rule is justified by the Government's substantial interest in informing consumers regarding the negative health consequences of smoking.

Furthermore, the proposed warnings do not unduly burden protected speech. As the Sixth Circuit held, the Tobacco Control Act's warning requirement for cigarettes is not unduly burdensome because a manufacturer has the ability to convey other information of its choosing in the remaining space available. *Disc. Tobacco City & Lottery, Inc. v. U.S.*, at 530-31. By statute, the required warnings for cigarette packages must comprise the top 50 percent of the front and rear panels, and for advertisements at least 20 percent of the area at the top of the advertisement. The Sixth Circuit found that "ample evidence support[s] the size requirements

for the new warnings" and "that the remaining portions of their packaging" are sufficient for the companies "to place their brand names, logos or other information." *Id.* at 531, 567. See also *Spirit Airlines, Inc. v. United States Dep't of Transp.*, 687 F.3d 403, 414 (D.C. Cir. 2012) (requirement for airlines to make total price the most prominent cost figure does not significantly burden airlines' ability to advertise). The scientific literature strongly supports that larger warnings, such as those of the size proposed in this rule, are necessary to ensure that consumers notice, attend to, and read the messages conveyed by the warnings, which leads to improved understanding of the specific health consequences that are the subject of those warnings (Refs. 3 and 4). See discussions above in, e.g., section V.A ("The Current 1984 Surgeon General's Warnings Are Inadequate"); section V.B.2.a ("Pictorial cigarette warnings increase knowledge and accurate health beliefs by addressing gaps in public understanding about the negative health consequences of smoking"). Accordingly, the proposed warnings are constitutional under *Zauderer*.

Although *Zauderer* provides the appropriate framework for review, the rule also satisfies the elements of the test for commercial speech articulated in *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n.* Under that test, agencies can regulate speech where the regulation advances a substantial Government interest and the regulation is no more extensive than necessary. This standard does not require the Government to employ "the least restrictive means" of regulation or to achieve a perfect fit between means and ends. *Board of Trustees v. Fox*, 492 U.S. 469, 480 (1989). Instead, it is sufficient that the Government achieve a "reasonable" fit by adopting regulations "in proportion to the interest served." *Id.*

As discussed above, the Government's interest in informing the public and correcting misperceptions about the risks of cigarette smoking is undeniably substantial. See *Disc. Tobacco*

City & Lottery, Inc., 674 F.3d at 519. The proposed warnings directly and materially advance the Government's interest by helping consumers understand the negative health consequences associated with cigarette smoking. As discussed above, the current 1984 warnings on cigarettes are virtually invisible and ineffective (see section V.A above, "The Current 1984 Surgeon General's Warnings Are Inadequate"). FDA has developed new warnings with new information, in the form of text paired with concordant images, to promote greater public understanding of the negative health consequences of smoking. FDA's extensive qualitative and quantitative consumer research--on potential statements, potential images, and potential pairings of statements and images--amply demonstrate that the proposed cigarette health warnings do in fact promote better understanding by the public of the negative health effects of smoking. All 13 of the proposed cigarette health warnings statistically significantly outperformed the control condition (i.e., the current 1984 Surgeon General's warnings) on the dimensions of "new information" and "self-reported learning." See discussion above in sections V.I.B ("Developing Revised Textual Warning Statements") through V.I.E ("FDA's Consumer Research Study on New Cigarette Health Warnings"), and the consumer research study reports, which we have included in the docket (Refs. 129 and 153). The warnings selected for this proposal will advance the Government's interest.

Finally, the regulation is appropriately tailored to achieve that result. The warnings relate to the dangers of smoking cigarettes and will be required on all cigarette packages and advertisements, so there is nothing over- or underinclusive in the rule's scope. As the Sixth Circuit held, the size of the warnings is justified by the ample data demonstrating that larger warnings "materially affect consumers' awareness of the health consequences of smoking," *Disc.*

Tobacco City & Lottery, Inc., 674 F.3d at 530, and there is sufficient remaining room for the manufacturers' speech.

Accordingly, the proposed rule is constitutionally permissible under the First Amendment.

IX. Description of the Proposed Rule

Section 4 of the FCLAA, as amended by sections 201 and 202 of the Tobacco Control Act, directs FDA to issue regulations requiring color graphics depicting the negative health consequences of smoking to accompany textual warning label statements, and permits FDA to adjust the format, type size, color graphics, and text of any of the label requirements, or establish the format, type size, and text of any other disclosures required under the FD&C Act, if such a change would promote greater public understanding of the risks associated with the use of tobacco products. This proposed rule would replace part 1141 in Title 21 of the Code of Federal Regulations to implement these FCLAA requirements. As described in detail in sections VI-VII, the proposed required warnings are intended to promote greater public understanding of the negative health consequences of cigarette smoking. We are seeking comments on these proposed provisions; if you have comments on specific provisions, we request that you identify the specific provisions in your comments.

A. General Provisions (Proposed Subpart A)

1. Scope (Proposed § 1141.1)

As directed by section 4 of the FCLAA, proposed § 1141.1(a) would explain that proposed part 1141 sets forth the requirements for the display of required warnings on packages and in advertisements cigarettes (proposed § 1141.3 includes a definition of cigarette). These requirements would be applicable to manufacturers, distributors, and retailers except as

described in this proposed section. Retailers who are also manufacturers would be subject to both the requirements for retailers and manufacturers, as applicable.

Proposed § 1141.1(b) provides that the requirements of this proposed part would not apply to manufacturers or distributors of cigarettes that do not manufacture, package, or import cigarettes for sale or distribution within the United States. This proposed subsection is consistent with section 4(a)(3) of the FCLAA. Manufacturers and distributors are defined in proposed § 1141.3.

In addition, retailers would not be in violation of the requirements of section 4 of the FCLAA and this proposed part for cigarette packaging that: (1) contains a warning; (2) is supplied to the retailer by a license- or permit-holding tobacco product manufacturer or distributor; and (3) is not altered by the retailer in a way that is material to 15 U.S.C. 1333 or proposed part 1141 (see proposed § 1141.1(c)). We believe most, if not all, retailers would fall under this scenario.¹¹ This proposed subsection is consistent with section 4(a)(4) of the FCLAA. However, this proposed subsection would require that a retailer ensure that all cigarette packages they display or sell contain a warning that is unobscured by stickers, sleeves, or other materials on the packages, for example.

Under proposed § 1141.1(d), the advertisement requirements in proposed § 1141.10 would apply to a retailer only if the retailer is responsible for or directs the warnings for advertising. Importantly, this provision would not relieve a retailer of liability if the retailer displays in a location open to the public an advertisement that does not contain a warning or that contains a warning that has been altered by the retailer in a way that is material to section 4 of the FCLAA or the requirements of this proposed part.

¹¹ We note that manufacturers who are also retailers would be subject to the proposed requirements as manufacturers.

Retailers would be in violation of the FCLAA and this proposed part if they alter cigarette packaging or advertising in a way that is material to the requirements of section 4 of the FCLAA or proposed part 1141, for example, by obscuring or covering up the warning (e.g., blocking with a sticker or marker), shrinking the warning, or using a sleeve to cover the warning. Retailers also would be liable if they display, in a location open to the public, an advertisement that does not contain a warning (proposed § 1141.1(d)).

2. Definitions (Proposed § 1141.3)

Proposed § 1141.3 provides the definitions for the terms used in the proposed rule. Proposed § 1141.3 sets forth the meaning of terms as they apply to proposed subparts A and B of part 1141. Proposed § 1141.3 includes the following definitions from the FCLAA (15 U.S.C. 1332):

- *Cigarette.* As defined in section 3(1) of the FCLAA, the term "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.* As defined in section 3(2) of the FCLAA, "commerce" means--
 - 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;

- 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
- Commerce wholly within the District of Columbia, Guam, the Virgin Islands, American Samoa, Wake Island, Midway Island, Kingman Reef, or Johnston Island.
- *Package or packaging.* As defined in section 3(4) of the FCLAA, "package" means a pack, box, carton, or container of any kind in which cigarettes are offered for sale, sold, or otherwise distributed to consumers. The proposed rule would use "packaging" interchangeably with package.
- *Person.* As defined in section 3(5) of the FCLAA, "person" means an individual, partnership, corporation, or any other business or legal entity.
- *United States.* As defined in section 3(3) of the FCLAA, "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.

In addition, FDA proposes the following definitions:

- *Distributor.* FDA proposes to define "distributor" as any person who furthers the distribution of cigarettes, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this proposed part.

This proposed definition of distributor would be consistent with the definition of distributor in section 900(7) (21 U.S.C. 387(7)) of the FD&C Act. FDA believes using this definition would help ensure consistent understanding of the scope of distributor across tobacco product regulations issued by FDA. For example, § 1140.3 (21 CFR § 1140.3) uses a definition of distributor that is the same as this proposed definition except that § 1140.3 uses "tobacco product" instead of "cigarette."

- *Front panel and rear panel.* FDA proposes to define "front panel" and "rear panel" to mean the two largest sides or surfaces of the package.

FDA is proposing to include a definition of front and rear panels because section 4 of the FCLAA, in setting out the placement requirements for the label statements, provides that each label statement shall comprise the top 50 percent of the front and rear panels of the package. This proposed definition would help ensure that all persons responsible for complying with the FCLAA and this proposed part 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.

- *Manufacturer.* FDA proposes to define "manufacturer" as any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette product; or imports any cigarette that is intended for sale or distribution to consumers in the United States.
- *Retailer.* FDA proposes to 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. This definition would include any person who sells cigarettes online (e.g., through a website or mobile phone application).

The proposed definitions of manufacturer and retailer are similar to those used in part 1140 (which establishes sale and distribution restrictions for cigarettes, as well as other tobacco products), but with some edits to reflect that the scope of this proposed part is cigarette packaging and advertisements.

3. Incorporation by Reference (Proposed § 1141.5)

Proposed § 1141.5 would identify the material that FDA proposes to incorporate by reference in this proposed part, entitled "Required Cigarette Health Warnings." This section states that FDA is proposing to incorporate by reference each required warning, consisting of a textual warning label statement and its accompanying color graphic. Any final rule would provide information on how to obtain the electronic, layered design files for each required warning, as well as technical specifications to help manufacturers appropriately select, crop, and scale the warnings to ensure the required warnings are accurately reproduced during implementation across various sizes of cigarette packaging and cigarette advertisements. This material would be available for download either through FDA's website or a file transfer protocol website. For ease of review for this proposed rule, we have included an electronic PDF file, containing the proposed required warnings, as a reference in the docket for this proposed rule (Ref. 18).

As described in section II.C, FDA intends to provide the required warnings selected for the final rule as electronic, layered design files and incorporate those by reference. The material incorporated by reference must meet the OFR's requirements for incorporating material by reference, and thus the way this material is displayed may be changed for the final rule to meet such requirements.

Proposed § 1141.5(a) would identify the material that FDA proposes to incorporate by reference, "Required Cigarette Health Warnings," and how to obtain the material from FDA. This material would include the electronic, layered design files for each required warning in a range of sizes and aspect ratios, including the textual statements in English and Spanish, font files, color spaces, the accompanying color graphics, and the white and black warning backgrounds and borders. These layered design files would be accompanied by technical specifications describing how to use the layered design files to help manufacturers appropriately select, crop, and scale the warnings to ensure the required warnings are accurately reproduced during implementation of the required warnings on cigarette packages and in cigarette advertisements. Manufacturers, distributors, and, when applicable, retailers would obtain the required warnings by downloading the files directly from FDA's website or via a file transfer protocol website and accurately reproduce them on cigarette packages and in advertisements as required by section 4 of the FCLAA and proposed part 1141.

This proposed section would also explain that the material is incorporated by reference with the approval of the Director of the Federal Register and where interested parties may obtain a copy of the material (1 CFR part 51). Specifically, if the proposed incorporation by reference is approved by the OFR and incorporated in the final rule, interested parties would be able to examine the incorporated material at that National Archives and Records Administration and at FDA's Dockets Management Staff.

Proposed § 1141.5(b) would list the source where interested parties may obtain a copy of the incorporated material, i.e., by contacting FDA's Center for Tobacco Products at the address listed.

B. Required Warnings for Cigarette Packages and Advertisements (Proposed § 1141.10)

To promote greater public understanding of the negative health consequences of cigarette smoking, proposed § 1141.10 would establish required warnings for cigarette packages and advertising. The proposed requirements comply with section 4 of the FCLAA and include a textual warning label statement (proposed § 1141.10(a)(1)) with an accompanying color graphic (proposed § 1141.10(a)(2)).

Proposed § 1141.10(a) would establish that a required warning must contain both one of the textual warning label statements and a color graphic to accompany the textual warning label statement. The textual warning label statements that would be required will be set out in any final rule. As FDA has described in section VI.D, we have identified concordant color graphics proposed to accompany each textual warning label statement. FDA invites comment on the proposed textual warning statements and accompanying color graphics. Given the degree of public and stakeholder interest in this area, and the legal complexities involved, FDA also seeks proposals for alternative text and images you believe would advance the Government's interest in promoting greater public understanding of the negative health consequences of smoking. If proposing alternative text and images to those in this proposed rule, please provide scientific information that supports that the alternative text and images would, in fact, promote greater public understanding of the negative health consequences of smoking. Proposals for alternative images should accompany either one of FDA's proposed textual warning statements or an alternative textual warning statement you are proposing. These comments and information will help inform the required warnings to be included in a final rule.

Section 4(d) of the FCLAA directs that the required warnings be clear, conspicuous, and legible. Accordingly, proposed § 1141.10(b) and (c) are intended to address those FCLAA

requirements. Proposed § 1141.10(b) would require that manufacturers and distributors (and retailers in the specific circumstances described in proposed § 1141.1(c)) obtain and accurately reproduce the required warning (which would comprise the combination of the textual warning label statement and its accompanying color graphic), from the electronic files contained in the material to be incorporated by reference at proposed § 1141.5. These entities would be responsible for ensuring that the required warnings are not distorted, obscured, or otherwise inaccurately reproduced from the incorporated material when reproduced for use in differing types of media (e.g., print, digital). For example, the required warnings would need to be accurately reproduced, including maintaining text specifications such as font face and size; using capital letters for the word "WARNING" in each statement; and maintaining the relationship of text to image for each warning. As per the requirements laid out in section 4 of the FCLAA, the text of the cigarette health warnings on packages must be black on a white background, or white on a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package.

Proposed § 1141.10(c) would establish generally that it is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarette unless the package of which bears a required warning (as described in proposed § 1141.10(a)) in accordance with section 4 of the FCLAA and this proposed part. This provision would apply to any package, including a pack, box, carton, or container, all of which are included in the definition of package in section 3(4) of the FCLAA. Thus, in the instance of a carton that contains packs of cigarettes, the carton and each pack would be required to bear a required warning. This proposed requirement helps to promote public understanding of the

negative health consequences of cigarette smoking by ensuring that all cigarette packages bear the required warning.

In addition, proposed § 1141.10(c)(1) would require that the warning appear directly on the package and be clearly visible underneath any cellophane or other clear wrapping. This proposed requirement is intended to ensure that the warning is not obscured in any way, e.g., any outer wrapping and tear tape would be required to be clear and otherwise not interfere with the required warning's visibility. For packages that are soft-sided (i.e., "soft pack" style packaging), the overwrap closure must not obscure the warning, and, for hinged lid packages, this would mean that no word of the textual warning statement may be severed when the package is opened.

Proposed § 1141.10(c)(2) would implement the requirements in section 4 of the FCLAA that the required warning comprise at least the top 50 percent of the front and rear panels of the package. For cartons (which are included in the definition of package), proposed § 1141.10(c)(2) would specify that the required warning be located on the left side of the front and rear panels of the carton and comprise at least the left 50 percent of these panels. This proposed requirement is intended to ensure that when cigarettes are sold in cartons and not as individual packs, the required warnings are clearly visible, conspicuous, and legible to consumers as required by the FCLAA. As described earlier in this section, the required warning would need to be on the carton and on each pack to ensure compliance with the FCLAA and this proposed part.

Proposed § 1141.10(c)(3) would specify that the required warning be positioned such that the text of the required warning and other information on that panel of the package have the same orientation. For example, if the front panel of a cigarette package contains information, such as the brand name of the cigarette, in a left to right orientation, the required warning could

not be placed such that it appears at a right angle to this text. Rather, the required warning, including the textual warning label statement, must also appear in a left to right orientation. This would help ensure that the required warnings on cigarette packages would be conspicuous and legible to consumers, as required by section 4 of the FCLAA and this proposed part.

Cigarette advertisements are addressed in proposed § 1141.10(d). This section would establish requirements related to cigarette advertising, including that it is unlawful for any manufacturer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless each advertisement bears a required warning in accordance with section 4 of the FCLAA and this proposed part. As per the requirements laid out in section 4 of the FCLAA, the text of the cigarette health warnings in advertisements must be black if the background is white and white if the background is black.

More specifically, for print advertisements and other advertisements with a visual component, the required warning must appear directly on the advertisement (proposed § 1141.10(d)(1)). Advertisements that would be subject to this proposed rule may appear in or on, for example, promotional materials (point-of-sale or non-point-of-sale), billboards, posters, placards, published journals, newspapers, magazines, other periodicals, catalogues, leaflets, brochures, direct mail, shelf-talkers, display racks, internet web pages, electronic mail correspondence, and also may include those communicated via mobile telephone, smartphone, microblog, social media website, or other communication tool;¹² websites, applications, or other programs that allow for the sharing of audio, video, or photography files; video and audio promotions; and items not subject to the sale or distribution ban in § 1140.34. Proposed

¹² FCLAA prohibits any advertising of cigarettes on radio, television, or other media regulated by the Federal Communications Commission.

§ 1141.10(d)(1) includes some of these examples for reference but neither the examples in § 1141.10 (d) nor this discussion are intended to be exhaustive.

Proposed § 1141.10(d)(2) would require that the warning comprise at least 20 percent of the area of the advertisement in a conspicuous and prominent format and location at the top of each advertisement, and that no part of the required warning would fall in the "trim area" (i.e., the area of an advertisement that is cut off as part of the print publishing process). To meet the proposed requirement, the required warning would need to be in the advertisement's "safe area" (i.e., not in the trim area) and not be placed in any area of an advertisement that may be cropped or folded during final publishing. For advertisements in digital media, proposed § 1141.10(d)(2) would mean that a required warning must be appropriately scaled in its coding for both standard desktop and mobile sizes to ensure that the full required warning is visible on the screen in its entirety (i.e., a user does not need to scroll in any direction to see any areas of the warning), is located at the top of the screen, and is displayed at each point of access to such advertisements. These proposed requirements are consistent with the language of section 4(b) of the FCLAA, which mandates that the required warning comprise at least 20 percent of the area of the advertisement and specifies that the advertisement appear in a conspicuous and prominent format and location at the top of the advertisement. We recognize that there is a wide variation in advertisement size and media, and we are requesting comments and information on how advertisements in different types of media might comply with these proposed requirements, including comments on issues related to small-size advertisements, advertisements in digital media, and non-visual advertisements.

Proposed § 1141.10(d)(3) would require that the text of the required warning be in English, with the two exceptions established in section 3(b) of the FCLAA. First, the text of the

required warning should not be in English when the advertisement appears in a non-English medium. In that case, the text of the required warning would be required to appear in the predominant language of the medium regardless of whether the advertisement is in English (the predominant language is the primary language used in the non-sponsored content in the publication). For example, if the predominant language of the medium is French, but the advertisement is in English, the text of the required warning would be required to be in French. Second, the text of the required warning would not need to appear in English when the advertisement appears in an English language medium but the advertisement is not in English; in this case, the text of the required warning would need to appear in the same language as that principally used in the advertisement. The purpose of the proposed requirement and the two proposed exceptions in § 1141.10(d)(3) is to help promote public understanding of the negative health consequences of cigarette smoking by ensuring that the textual warning label statement component of the required warning is in the language that is most likely to be understood by the majority of the public who would view the advertisement.

Proposed § 1141.10(d)(4) would state that for English-language or Spanish-language warnings, each required warning must be obtained from the electronic files contained in "Required Cigarette Health Warnings," which would be incorporated by reference (see proposed § 1141.5). The required warnings would need to be accurately reproduced as specified in "Required Cigarette Health Warnings," to help ensure that the required warnings are not distorted or obscured, and are prominent and legible, consistent with the requirements of the FCLAA and this proposed part.

Proposed § 1141.10(d)(5) would require that non-English-language warnings, other than Spanish-language warnings, be adapted using the English-language required warnings obtained

from the electronic files contained in "Required Cigarette Health Warnings," which would be incorporated by reference at proposed § 1141.5. As with the proposed requirement in § 1141.10(d)(4), the required warnings would be required to be accurately reproduced as specified in "Required Cigarette Health Warnings," but for these warnings this would also include the substitution and insertion of a true and accurate translation of the textual warning label statement in place of the English-language version. The proposed rule would require that the inserted textual warning label statement comply with all requirements of section 4 of the FCLAA and this proposed part. The manufacturer, distributor, or retailer would be required to accurately and appropriately translate the textual warning label statement into the appropriate non-English language or the advertisement would be in violation of the FCLAA and this proposed part. The translated required warning would also need to meet the area, format, and other requirements of the FCLAA and this proposed part.

Proposed § 1141.10(e) would require that the required warnings be indelibly printed on or permanently affixed to the package or advertisement. These required 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. This provision is intended to ensure that the required warnings cannot be easily ripped off, obscured, or otherwise tampered with, which would undermine the proposed requirement. For an advertisement in digital media to meet this proposed requirement, the required warning must remain on the advertisement at all times and be clear, conspicuous, and legible as required in section 4 of the FCLAA and this proposed part. Thus, for example, it would not be enough to display the required warning only for a period of time in an advertisement in digital media. We invite comments and information on how advertisements in digital media might appropriately satisfy this proposed requirement.

Proposed § 1141.10(f) would provide that no person may manufacture, package, sell, offer for sale, distribute, or import for sale or distribution within the United States cigarettes whose packages or advertisements are not in compliance with section 4 of the FCLAA and this proposed part, except as provided by proposed §§ 1141.1(c) and 1141.1(d).

Proposed § 1141.10(g) would establish marketing requirements applicable to cigarettes. The marketing requirements would include the random and equal display and distribution of the required warnings for cigarette packages and quarterly rotation of the required warnings in advertisements. The marketing requirements would also require submission of a plan that provides for the random and equal display and distribution of the required warnings on cigarette packaging and the quarterly rotation of the required warnings in cigarette advertising, as described under section 4 of FCLAA and part 1141 (referred to as "plan"). These proposed requirements would ensure that all of the required warnings would be displayed by the tobacco product manufacturer, distributor, or retailer at the same time.

As described in more detail in the following paragraphs, under proposed § 1141.10(g)(1), each required warning would be required to be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and the packages randomly and equally distributed in all areas of the United States in which the cigarette is marketed. A manufacturer, distributor, or retailer would be required to submit a plan for random and equal display and distribution of the required warnings for packaging to FDA for approval. In addition, proposed § 1141.10(g)(2) would establish quarterly rotation requirements for the required warnings in advertisements. Under this proposed requirement, the required warnings for advertisements must be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan approved by FDA. The manufacturer, distributor,

or retailer would be required to submit the plan for quarterly rotation of the required warnings in advertisements to FDA for approval.

For efficiency of review, each plan submitted under proposed § 1141.10(g)(1) and (2) should cover both packaging and advertising, rather than submitting each plan separately, to the extent applicable. The tobacco product manufacturer, distributor, or retailer should describe how their plan would achieve the random and equal display and distribution of the required warnings on packages and the quarterly rotation of the required warnings in advertisements.

Under proposed § 1141.10(g)(1), for each brand of cigarettes, the plan for packaging would explain how each of the required warnings would be randomly displayed during each 12-month period on each brand; how each of the warnings would be displayed in as equal a number of times as possible on each brand of the product; and how product packages would be randomly and equally distributed in all areas of the United States in which the product is marketed. FDA expects that a plan for the random and equal display and distribution of required warnings on packages would ordinarily be based on the date of manufacture or shipment of the product.

For each cigarette brand, the plan for advertising would be required to explain how the required warnings would be rotated quarterly in advertisements and how the quarterly rotations would occur in alternating sequence (proposed § 1141.10(g)(2)). Among other things, the plan should specify the initial rotation timeframe on which quarterly rotation is based and, if the rotation timeframe varies for different types/forms of advertising, specify the different quarterly timeframes associated with the different types/forms of advertising, and describe the quarterly schedule for rotating each of the required warnings for each cigarette brand. FDA would not consider a plan that merely restated the regulatory requirements to be sufficiently detailed to enable FDA to approve the plan.

After FDA approval of an initial plan, a supplement to the approved plan should be submitted to FDA and approved before making changes to the random and equal display or distribution of required warning statements on packages or the quarterly rotation of required warning statements in advertisements. For a new brand, a new plan or a supplement to an approved plan would be required to be submitted and approved before displaying or distributing packages and advertisements for that new brand.

However, in lieu of a supplement to an approved plan for a new brand, manufacturers may reference in their initial plan all brands in their product listing(s) under section 905(i) of the FD&C Act and incorporate any new brands into their approved plan, so long as no other changes are made to the plan. For retailer-generated advertising, retailers may list "all brands" in their plan, which would cover future brands, so long as the plan provides for the same schedule for quarterly rotation of the required warning statements for all brands.

Proposed § 1141.10(g)(3) would explain that FDA would review each plan submitted. FDA's review of a plan would only be for the purpose of determining compliance with the regulatory criteria for approval of a plan, as set forth in proposed § 1141.10(g)(1) and (2). FDA requests that each plan include representative samples of packages and advertisements with each of the required warnings. Such samples would place the plan in context and, therefore, facilitate FDA's review of the plan, not a review of the content of the package labels and advertisements. During the course of a review of a plan, FDA may request an amendment to a plan under review if FDA needs clarification of information in the plan or other additional information to determine whether FDA could approve the plan.

As described in proposed § 1141.10(g)(3), FDA intends to approve the plan if it would:

- (1) provide for the random and equal distribution and display of the required warnings on

packaging and the quarterly rotation of the required warnings in advertising, as set out in proposed § 1141.10(g)(1) and (2) and (2) assure that all required warnings would be displayed by the manufacturer, distributor, or retailer at the same time. Approval of a plan would not represent a determination by FDA that any specific package or advertisement complies with any of the other requirements of the FCLAA and proposed part 1141, including those regarding the placement, font type, size, and color of the warnings, or any other requirements under the FD&C Act and its implementing regulations. FDA intends to communicate the approval of a plan by issuing a letter to the submitter. After FDA approval of a plan, if a manufacturer, distributor, or retailer intends to make changes to the approved plan, they should first submit a supplement to FDA for review and approval. To provide FDA sufficient time to review a supplement to an approved plan, FDA strongly recommends allowing up to 6 months for FDA to review and approve a supplement. The amount of time it would take FDA to review a supplement, however, would depend upon the volume and quality of the submissions.

Plans, and any amendments or supplements, should be submitted to FDA's Center for Tobacco Products, Office of Compliance and Enforcement. FDA intends to allow electronic submissions, via FDA's Electronic Submissions Gateway (<https://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm>), and written submissions, directed to: Food and Drug Administration, Center for Tobacco Products, Office of Compliance and Enforcement, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. FDA strongly encourages electronic submission to facilitate efficiency and timeliness of submission and processing.

Proposed § 1141.10(g)(4) would establish that each manufacturer required to randomly and equally display and distribute warnings on packaging or quarterly rotate the required

warnings in advertisements in accordance with an FDA-approved plan under section 4 of the FCLAA and this proposed part must maintain a copy of the FDA-approved plan and make it available for inspection and copying by officers or employees of FDA. The FDA-approved plan must be retained while in effect and for a period of not less than 4 years from the date it was last in effect. FDA has selected 4 years as a means to help ensure that the FDA-approved plan would be available for at least one biennial FDA inspection under sections 704 and 905(g) of the FD&C Act. Retaining the FDA-approved plan for 4 years from the date it was last in effect would allow FDA to evaluate, for example, whether the warnings are randomly and equally displayed on product packaging during the time period in which such products are offered for sale to consumers. In addition, based on FDA's experience with smokeless plans, FDA has observed at times in conducting inspections that firms, including contract manufacturers, have not been aware of the FDA-approved plan that they should be following. Requiring that the FDA-approved plan is retained for 4 years from the date it was last in effect would help ensure that FDA has the opportunity to confirm during the course of an inspection that firms are aware of and following an approved plan.

As discussed in section X, FDA intends to establish an effective date for the submission of plans to FDA, by each person subject to proposed § 1141.10(g). This would require submission of plans no later than 5 months from the date of publication of any final rule. Although FDA believes this timeframe would provide sufficient time for the plan to be submitted to FDA and reviewed by FDA in advance of the effective date for the required warnings on packages and advertisements (which, consistent with section 4 of the FCLAA, would be 15 months from the publication date of any final rule), we encourage the submission of these plans as soon as possible once the final rule is published.

We invite comment on these proposed requirements, including whether and how the number of final required warnings selected would affect the random and equal display and distribution of the required warnings on packages and the quarterly rotation of the required warnings in advertisements.

C. Misbranding of Cigarettes (Proposed § 1141.12)

Proposed § 1141.12(a) sets out that a cigarette package would be deemed misbranded under section 903(a)(1) of the FD&C Act if its package and labeling do not bear one of the required warnings in accordance with section 4 of the FCLAA and this proposed part. In addition, proposed § 1141.12(a) would provide that a cigarette would be deemed misbranded under section 903(a)(7)(A) of the FD&C Act if its advertising does not bear one of the required warnings in accordance with section 4 of the FCLAA and this proposed part.

Proposed § 1141.12(b) would explain that a cigarette advertisement and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor, would be deemed to include a brief statement of relevant warnings for the purposes of section 903(a)(8) of the FD&C Act, if it bears one of the required warnings in accordance with section 4 of the FCLAA and this proposed part. However, FDA is proposing that a cigarette distributed or offered for sale in any State would be deemed misbranded under section 903(a)(8) of the FD&C Act unless the manufacturer, packer, or distributor includes in all advertisements and other descriptive printed matter 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 FCLAA and this proposed part. Section 201(a)(1) of the FD&C Act (21 U.S.C. 321(a)(1)) defines "State" as "any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico." The warnings required by section 4 of the FCLAA for cigarette

advertising and packages are "relevant warnings" with respect to cigarettes as that phrase is used in section 903 of the FD&C Act. For the purpose of this proposed provision, "other descriptive printed matter" would include the packages of cigarettes and would be required to bear one of the required warnings.

X. Proposed Effective Dates

FDA is proposing that the required warnings for packages and advertisements (proposed § 1141.10) would become effective 15 months after the date the final rule publishes in the *Federal Register*. This proposed effective date is consistent with the language of section 201(b) of the Tobacco Control Act, which contemplates that the amendments to the FCLAA established by the Tobacco Control Act would take effect 15 months after the issuance of the regulations set out in 201(a) of the Tobacco Control Act. FDA is also proposing an effective date for submission of plans under the FCLAA and this proposed part (§ 1141.10(g)) of no later than 5 months after the final rule publishes in the *Federal Register*. This would help ensure that FDA has time to review the plan in advance of the effective date requiring that packaging and advertising of cigarettes bear the required warnings.

Thus, cigarette packages that do not comply with the requirements of any final rule must not be manufactured for sale or distribution in the United States as of the effective date (i.e., 15 months after the date the final rule publishes in the *Federal Register*). Section 201(b) of the Tobacco Control Act provides that, beginning 30 days after the effective date, a manufacturer must not introduce into the domestic commerce of the United States any product, irrespective of the date of manufacture, that is not in conformance with section 4 of the FCLAA, as amended by the Tobacco Control Act. As provided by section 201(b), after the 30-day period, manufacturers would not be permitted to introduce into domestic commerce any cigarette packages that do not

contain the required warnings, irrespective of the date of manufacture. While this statutory limitation applies to only manufacturers, FDA believes that keeping products without the required warnings under any final rule on the market for an extended period would not be in the interest of public health. We request comments regarding ways to differentiate cigarette packages sold from existing inventory from those that were manufactured after the effective date.

In addition, as of 15 months from the publication of any final rule mandating that cigarette packages and advertisements bear the required warnings, no tobacco product manufacturer, 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 rule.

XI. Severability and Other Considerations

In accordance with section 5 of the Tobacco Control Act, the various requirements established by this proposed rule, when finalized, would be considered severable and the individual provisions of this rule would be considered workable on their own. Section 5 of the Tobacco Control Act states that, if any provision of a regulation issued under the Act is held to be invalid, the remainder of the regulation "shall not be affected and shall continue to be enforced to the fullest extent possible." (Section 5 of the Tobacco Control Act is codified at 21 U.S.C. 387 note.) Consistent with that directive, it is FDA's intent that the invalidity of any provision of the final rule shall not affect the validity of any other part of the rule. In the event any court or other lawful authority were to temporarily or permanently invalidate, restrain, enjoin, or suspend any provision of the final rule, FDA intends for the remaining parts to continue to be valid.

Each provision of the proposed rule is independently supported by data and analysis as described or referenced in this preamble and, if issued separately, would remain a proper exercise

of FDA authority under sections 201 and 202 of the Tobacco Control Act and sections 701, 704, 903, 905(g), and 909 of the FD&C Act, as amended by the Tobacco Control Act. If a court were to invalidate some but not all of the images within the cigarette health warnings, the corresponding textual warning statements would go into effect without the invalidated images, along with the remaining cigarette health warnings that pair a textual warning statement with an image. The remaining pairings and the textual warning statements without images would still be required to be randomly and equally displayed and distributed on packages and quarterly rotated in advertisements. This approach would advance the Government's interest in promoting greater public understanding of the negative health consequences of smoking.

In the event that a court were to invalidate all of the images within the cigarette health warnings, FDA intends for all the warnings to go into effect with only their textual warning statements, without the invalidated images. These too would be randomly and equally displayed and distributed on packages and quarterly rotated in advertisements as required. FDA believes this approach could serve as an interim measure to address Congress's intent to replace the stale Surgeon General's warnings and to promote greater public understanding of the negative health consequences of smoking while FDA worked to develop new pictorial warnings.

If a court were to invalidate some of FDA's revised textual warnings with their paired images but some remained valid, FDA intends that the remaining revised textual warning statements and their paired images would go into effect. Alternatively, FDA might also choose to require that the textual warning statements specified in section 4(1) of the FCLAA go into effect without an accompanying image. In determining the appropriate approach, relevant circumstances could include whether there were a sufficient number of warnings to be randomly and equally displayed and distributed on packages and quarterly rotated in advertisements as

required by statute. As described above, FDA proposes implementing text-only cigarette health warnings as an interim measure as a means to address Congress's intent to replace the stale Surgeon General's warnings and to promote greater understanding of the negative health consequences of smoking while FDA worked to develop new pictorial warnings.

FDA invites public comment on the application of the severability provision in section 5 of the Tobacco Control Act to this rulemaking and how any severed portions of a final rule would operate, advance the Government's interest, and address Congress's intent to replace the stale 1984 Surgeon General's warnings. FDA also seeks comment on whether additional codified language should be added for any of the scenarios described in this section.

FDA further requests public comment, in the event a court were to invalidate all of the images within the cigarette health warnings or were to vacate this rule once finalized, as to whether and how FDA should implement textual warning statements without images as an interim measure. Additionally, FDA requests comment on whether, in the event that a court were also to invalidate the size or location of revised cigarette warnings as directed by Congress (i.e., for packages, at least the top 50 percent of the front and rear panels of the packages), it should require that such interim textual warning statements comprise, for example, at least the top 30 percent of the front and rear panels of the packages, consistent with warnings for other categories of tobacco products that are comprised of textual statements only, while FDA sought to develop new pictorial warnings.

XII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order (EO) 12866, EO 13563, EO 13771, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). Executive Orders 12866 and 13563 direct us 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). EO 13771 requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." We believe that this proposed rule is an economically significant regulatory action as defined by EO 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We estimate that for a small manufacturer or importer who would be affected by this proposed rule, one-time costs could represent between 2.5 and 35.6 percent of their annual receipts and recurring costs could represent from 0.4 to 4.4 percent of their annual receipts. Hence, we find that the proposed rule will have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to 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 \$154 million, using the most current (2018) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would result in an expenditure in any year that meets or exceeds this amount.

This proposed rule would require that one of up to 13 new cigarette health warnings, each comprising a textual warning statement paired with an accompanying color graphic image,

appear on cigarette packages and in cigarette advertisements. The proposed rule would further require that, for cigarette packages, the required cigarette health warnings be randomly displayed in each 12-month period, in as equal a number of times as is possible on each brand of the product and be randomly distributed throughout the United States in accordance with a plan approved by FDA. The proposed rule would also require that, for cigarette advertisements, the required cigarette health warnings must be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan approved by FDA.

Pictorial cigarette health warnings promote greater public understanding about the negative health consequences of smoking as they increase the noticeability of the warning's message, increase knowledge and learning of the negative health consequences of smoking, and benefit diverse populations that have disparities in knowledge about the negative health consequences of smoking.

The direct economic benefits of providing information on cigarette health warnings are difficult to quantify, and we do not predict the size of these benefits at this time. We discuss the informational effects qualitatively.

The cost of this proposed rule consists of initial and recurring labeling costs associated with changing cigarette labels to accommodate the new cigarette health warnings, design and operation costs associated with the random and equal display and distribution of required cigarette health warnings for cigarette packages and quarterly rotations of the required warnings for cigarette advertisements, advertising-related costs, and costs associated with government administration and enforcement of the rule. Using a 20-year time horizon, we estimate that the present value of the costs of this proposed rule ranges from \$1.3 billion to \$1.9 billion, with a mean estimate of \$1.6 billion, using a three percent discount rate, and ranges from \$1.0 billion to

\$1.5 billion, with a mean estimate of \$1.2 billion, using a seven percent discount rate (2018\$). Annualized costs, which are presented below in table 3, range from \$88.6 million per year to \$129.7 million per year, with a mean estimate of \$107.5 million per year, using a three percent discount rate, and range from \$94.6 million per year to \$139.8 million per year, with a mean estimate of \$115.3 million per year, using a seven percent discount rate (2018\$).

Because it is not possible to compare benefits and costs directly when the benefits are not quantified, we employ a break-even approach. If the information provided by the cigarette health warning on each cigarette package was valued at about \$0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the proposed rule would equal or exceed the estimated annual costs.

Table 3.--Summary of the Informational Effects and Costs of the Proposed Rule (in millions of 2018\$)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Informational Effects		Pictorial cigarette health warnings promote greater public understanding about the negative health consequences of smoking as they increase the noticeability of the warning's message, increase knowledge and learning of the negative health consequences of smoking and help reduce disparities in knowledge about the negative health consequences of smoking across diverse populations. If the information provided by the cigarette health warning on each cigarette package was valued at about \$0.01 (for every pack sold annually nationwide), then the benefits that would be generated by the proposed rule would equal or exceed the estimated annual costs.						
Costs	Annualized Monetized \$millions/year	\$115.3	\$94.6	\$139.8	2018	7%	20 Years	Effective date of 15 months from date of publication of final rule.
		\$107.5	\$88.6	\$129.7	2018	3%	20 Years	

In line with EO 13771, in table 4 we estimate present and annualized values of costs and cost savings over an infinite time horizon. Based on these costs, when finalized this proposed rule would be considered a regulatory action under EO 13771.

Table 4.--EO 13771 Summary Table (in Millions of 2016\$, Over an Infinite Time Horizon)

Item	Primary Estimate (7%)
Present Value of Costs	\$985.8
Present Value of Cost Savings	\$0
Present Value of Net Costs	\$985.8
Annualized Costs	\$69.0
Annualized Cost Savings	\$0
Annualized Net Costs	\$69.0

Notes: All amounts have been discounted relative to year 2016 from year 2021, the latter of which is the estimated year in which the proposed rule would become effective once finalized. Because of this additional discounting step, the present value estimates presented here are in all instances lower than the comparable present value estimates associated with a 20-year time horizon. Effective date is 15 months from date of publication of the final rule.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 220) and at <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

XIII. Analysis of Environmental Impact

The labeling regulation is a class of actions that are ordinarily categorically excluded under 21 CFR 25.30(k). Additionally, the proposed action is not anticipated to pose serious harm to the environment and to adversely affect a species or the critical habitat of a species as stipulated under 21 CFR 25.21(b). The proposed action is of a type that does not individually or cumulatively have a significant effect on the human environment. No extraordinary circumstances exist that would require a preparation of an environmental assessment or an environmental impact statement.

XIV. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). A description of these provisions is given in the *Description* section immediately below, with an estimate of the

annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Required Warnings for Cigarette Packages and Advertisements

Description: The requirement for submission of plans for cigarette packages and advertisements, and the specific marketing requirements relating to the random and equal display and distribution of required warning statements on cigarette packaging and quarterly rotation of required warning statements in alternating sequence in cigarette product advertising, appear in proposed § 1141.10(d)(5). A record of the FDA-approved plan must also be established and maintained.

Description of Respondents: The respondents to this collection of information are manufacturers, distributors, and certain retailers of cigarettes who will be required to submit plans for cigarette packages and advertisements to FDA.

FDA intends to ask that each plan cover both packaging and advertising to the extent applicable. The tobacco product manufacturer, distributor, or retailer should demonstrate how

they plan to achieve the random and equal display and distribution of the required warning statements on packages and the quarterly rotation in advertisements. Required warnings for cigarettes must be randomly and equally displayed and distributed on packages, and rotated quarterly in advertisements, in accordance with an FDA-approved plan.

Plans should be submitted to FDA no later than 5 months after the date of publication of the final rule and before advertising or commercially marketing a product that is subject to the rule. Packages and advertisements of cigarettes would be required to bear the required warnings beginning 15 months after the date of publication of the final rule. FDA intends to request an amendment to a plan under review if FDA needs clarification of information in the plan or other additional information to determine whether it could approve the plan. Any such amendments would likely increase the overall review time.

After FDA approval of an initial plan, a supplement to the approved plan should be submitted to FDA and approved before making changes to the random and equal display or distribution of required warning statements on packages or the quarterly rotation of required warning statements in advertisements. For a new brand, a new plan or a supplement to an FDA-approved plan would be required to be submitted and approved before displaying or distributing packages and advertisements for that new brand.

However, in lieu of a supplement to an FDA-approved plan for a new brand, manufacturers may reference in their initial plan all brands in their product listing(s) under section 905(i) of the FD&C Act and incorporate any new brands into their approved plan, so long as no other changes are made to the plan. For retailer-generated advertising, retailers may list "all brands" in their plan, which would cover future brands, so long as the plan provides for the same schedule for quarterly rotation of the required warning statements for all brands.

FDA intends to allow electronic submissions, via FDA's Electronic Submissions Gateway, and written submissions. FDA strongly encourages electronic submission to facilitate efficiency and timeliness of submission and processing.

For each brand of cigarettes, the plan for packaging should explain how: each of the warnings will be randomly displayed during each 12-month period on each brand; each of the warnings will be displayed in as equal a number of times as possible on each brand of the product; and product packages will be randomly and equally distributed in all areas of the United States in which the product is marketed. FDA expects that a plan for random and equal display and distribution of warnings on packages will ordinarily be based on the date of manufacture or shipment of the product. For each cigarette brand, the plan for advertising should explain how the required warning statements will be rotated quarterly in advertisements and how the quarterly rotations will occur in alternating sequence. Among other things, the plan should specify the initial rotation timeframe on which quarterly rotation is based and, if the rotation timeframe varies for different types/forms of advertising, specify the different quarterly timeframes associated with the different types/forms of advertising, and describe the quarterly schedule for rotating each of the required warnings for each cigarette brand. FDA would not consider a plan that merely restated the regulatory requirements to be sufficiently detailed to enable FDA to approve the plan.

FDA's review of a plan would only be for determining compliance with the regulatory criteria for approval of a plan, as set forth in proposed §1140.10(g)(1) and (2). FDA requests that plans submitted for review include representative samples of packages and advertisements with each of the required warning statements. Such samples would place the plan in context and, therefore, facilitate FDA's review of the plan, not a review of the content of the package labels

and advertisements. Approval of a plan does not represent a determination by FDA that any package or advertisement complies with any of the other requirements regarding the placement, font type, size, and color of the warnings found in section 4 of the FCLAA and proposed part 1141, or any other requirements under the FD&C Act and its implementing regulations. FDA intends to communicate the approval of a plan with a letter to the submitter. After FDA approval of an initial plan, a supplement to the approved plan would need to be submitted to FDA for review and approved before making changes to the display or distribution of required warnings on packages or the rotation of required warning statements in advertisements. For a new brand, a new plan or a supplement to an approved plan would need to be submitted and approved before displaying or distributing packages and advertisements for that new brand. However, in lieu of a supplement to an approved plan for a new brand, manufacturers may reference in their initial plan all brands in their product listing(s) under section 905(i) of the FD&C Act and incorporate any new brands into their approved plan, so long as no other changes are made to the plan. For retailer-generated advertising, retailers may list "all brands" in their plan, which would cover future brands, so long as the plan provides for the same schedule for quarterly rotation of the required warning statements for all brands.

Table 5.-- Estimated One-Time Reporting Burden ¹

Type of Plan	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Initial Plans	59	1	59	150	8,850
Supplements	30	1	30	75	2,250
Total					11,100

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates are based on FDA's experience with information collections for other tobacco product plans (i.e., smokeless OMB control number 0910-0671 and cigars OMB

control number 0910-0768) and 2017 Treasury Alcohol and Tobacco Tax and Trade Bureau (TTB) data.

As discussed in the preliminary regulatory impact analysis (see section XII; Ref. 220), based on 2017 TTB data FDA estimates 59 entities will be affected by the rule. We estimate these 59 entities will submit a one-time initial plan, and it will take an average of 150 hours per respondent to prepare and submit a plan for packaging and advertising for a total of 8,850 hours. We estimate that about half of respondents will submit a supplement. If a supplement to an approved plan is submitted, FDA estimates it will take half the time per response. We estimate receiving 30 supplements at 75 hours per response for a total of 2,250 hours. FDA estimates that the total hours for submitting initial plans and supplements will be 11,100.

Proposed § 1141.10(g)(4) would establish that each tobacco product manufacturer required to randomly and equally display and distribute warnings on packaging or quarterly rotate warnings on advertisements in accordance with an FDA-approved plan under section 4 of the FCLAA and this proposed part must maintain a copy of the FDA-approved plan (approved under proposed § 1141.10(g)(3)). This copy (or record) of such FDA-approved plan must be available for inspection and copying by officers or employees of FDA. This proposed subsection would require that the record(s) be retained for a period of not less than 4 years from the date of FDA's approval of the plan.

Table 6.--Estimated Annual Recordkeeping Burden ¹

Plan Records	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Records	59	1.5	89	3	267
Total					267

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that 59 recordkeepers will keep a total of about 89 records at 2 hours per record for a total of 267 hours. As stated previously, these estimates are based on FDA's experience with information collections for other tobacco product plans (i.e., smokeless OMB control number 0910-0671 and cigars OMB control number 0910-0768). Based on our estimates for the submission of initial plans and supplements (that all respondents will submit initial plans and about half of respondents will submit supplements), we estimate that each recordkeeper will keep an average of 1.5 records.

FDA estimates that the total burden for this information collection is 11,367 hours (11,100 reporting + 267 recordkeeping).

FDA believes that the proposed required warnings for cigarette packages and cigarette advertisements in proposed § 1141.10 are not subject to review by OMB under the PRA because they do not constitute a "collection of information" under that statute (44 U.S.C. 3501-3520). Rather, these labeling statements are a "public disclosure" of information originally supplied by the Federal Government to the recipient for the purpose of "disclosure to the public" (5 CFR 1320.3(c)(2)).

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB or emailed to oir_submission@omb.eop.gov (see ADDRESSES). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the *Federal Register*.

XV. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132 and seek input from State and local officials on potential federalism impacts of the proposed regulation. Section 4(a) of the Executive Order requires agencies to "construe...a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute." This rule is being proposed under section 4 of the FCLAA, as amended by the Tobacco Control Act, and sections 701, 704, 903, 905(g), and 909 of the FD&C Act, as amended by the Tobacco Control Act. Federal law includes an express preemption provision that preempts any requirement, except pursuant to the Tobacco Control Act, for a "statement relating to smoking and health, other than the statement required by section 4 of [FCLAA],...on any cigarette package." Section 5(a) of the FCLAA. It also includes an express preemption provision that preempts any "requirement or prohibition based on smoking and health...imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of [FCLAA]," which includes section 4 of the FCLAA. Section 5(b) of the FCLAA. However, section 5(b) of the FCLAA does not preempt any State or local statutes and regulations based on smoking and health, that take effect after June 22, 2009, imposing specific bans or restrictions on the time, place, and manner, but not content, of the advertising or promotion of any cigarettes. Section 5(c) of the FCLAA.

In addition, section 916(a)(2) of the FD&C Act (21 U.S.C. 387p) expressly preempts any state or local requirement which is different from, or in addition to, any requirement under

Chapter IX of the FD&C Act relating to, among other things, misbranding and labeling. This express preemption provision, however, does not apply to requirements relating to among other things the sale, distribution, access to, or the advertising and promotion of tobacco products.

XVI. Consultation and Coordination with Indian Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The Agency solicits comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

XVII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

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*220. Preliminary Regulatory Impact Analysis; Initial Regulatory Flexibility Analysis; Unfunded Mandates Reform Act Analysis, Required Warnings for Cigarette Packages and Advertisements; Proposed Rule.

Advertising, Incorporation by reference, Labeling, Packaging and containers, Tobacco, 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, the Food and Drug Administration proposes to revise 21 CFR part 1141 to read as follows:

PART 1141--REQUIRED WARNINGS FOR CIGARETTE PACKAGES AND
ADVERTISEMENTS

Subpart A--General Provisions

Sec.

1141.1 Scope.

1141.3 Definitions.

1141.5 Incorporation by reference.

Subpart B--Required Warnings for Cigarette Packages and Advertisements

1141.10 Required warnings.

1141.12 Misbranding of cigarettes.

Authority: 15 U.S.C. 1333; 21 U.S.C. 371, 374, 387c, 387e, 387i; Secs. 201 and 202, Pub. L. 111-31, 123 Stat. 1776.

Subpart A--General Provisions

§ 1141.1 Scope.

(a) This part sets forth the requirements for the display of required warnings on cigarette packages and in advertisements for cigarettes.

(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 will not be in violation of § 1141.10 for packaging that:

(1) Contains a warning;

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

(3) Is not altered by the retailer in a way that is material to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1333) or this part.

(d) Section 1141.10(d) applies to a cigarette retailer only if that retailer is responsible for or directs the warnings required under § 1141.10 for advertising. However, this paragraph (d) does not relieve a retailer of liability if the retailer displays, in a location open to the public, an advertisement that does not contain a warning or has been altered by the retailer in a way that is material to the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act or this part.

§ 1141.3 Definitions.

For 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, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

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

Manufacturer means any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette product; or imports any cigarette that is intended for sale or distribution to consumers in the United States.

Package or *packaging* 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.

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.

§ 1141.5 Incorporation by reference.

(a) Certain material titled "Required Cigarette Health Warnings," appearing in § 1141.10, is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at U.S. Food and Drug Administration, Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available from the source listed in paragraph (b) of this section. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fedreg.legal@nara.gov or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

(b) Center for Tobacco Products, U.S. Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993; 1-888-463-6332.

(1) "Required Cigarette Health Warnings"

(2) [Reserved]

Subpart B--Required Warnings for Cigarette Packages and Advertisements

§ 1141.10 Required warnings.

(a) A required warning must include the following:

(1) One of the following textual warning label statements:

(i) WARNING: Tobacco smoke can harm your children.

(ii) WARNING: Tobacco smoke causes fatal lung disease in nonsmokers.

(iii) WARNING: Smoking causes age-related macular degeneration, which can lead to blindness.

(iv) WARNING: Smoking causes type 2 diabetes, which raises blood sugar.

(v) WARNING: Smoking reduces blood flow to the limbs, which can require amputation.

(vi) WARNING: Smoking causes cataracts, which can lead to blindness.

(vii) WARNING: Smoking causes bladder cancer, which can lead to bloody urine.

(viii) WARNING: Smoking reduces blood flow, which can cause erectile dysfunction.

(ix) WARNING: Smoking causes head and neck cancer.

(x) WARNING: Smoking can cause heart disease and strokes by clogging arteries.

(xi) WARNING: Smoking during pregnancy stunts fetal growth.

(xii) WARNING: Smoking causes COPD, a lung disease that can be fatal.

(2) A color graphic to accompany the textual warning label statement.

(b) Each required warning, comprising a combination of a textual warning label statement and its accompanying color graphic, must be obtained and accurately reproduced as specified from the electronic files contained in "Required Cigarette Health Warnings," which is incorporated by reference at § 1141.5.

(c) It is unlawful for any person to manufacture, package, sell, offer to sell, distribute, or import for sale or distribution within the United States any cigarettes unless the package of which bears a required warning in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.

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

(2) The required warning must comprise at least the top 50 percent of the front and rear panels; provided, however, that on cigarette cartons, the required warning must be located on the left side of the front and rear panels of the carton and must comprise at least the left 50 percent of these panels.

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

(d) It is unlawful for any manufacturer, distributor, or retailer of cigarettes to advertise or cause to be advertised within the United States any cigarette unless each advertisement bears a required warning in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.

(1) For print advertisements and other advertisements with a visual component (including, for example, advertisements on signs, retail displays, internet web pages, digital platforms, mobile applications, and email correspondence), the required warning must appear directly on the advertisement.

(2) The required warning must comprise at least 20 percent of the area of the advertisement in a conspicuous and prominent format and location at the top of each advertisement within the trim area, if any.

(3) The text in each required warning must be in the English language, except as follows:

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

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

(4) For English-language and Spanish-language warnings, each required warning must be obtained from the electronic files contained in "Required Cigarette Health Warnings," which is incorporated by reference at § 1141.5, and must be accurately reproduced as specified in "Required Cigarette Health Warnings."

(5) For non-English-language warnings, other than Spanish-language warnings, each required warning must be obtained from the electronic files contained in "Required Cigarette Health Warnings," which is incorporated by reference at § 1141.5, and must be accurately reproduced as specified in "Required Cigarette Health Warnings," including the substitution and insertion of a true and accurate translation of the textual warning label statement in place of the English language version. The inserted textual warning label statement must comply with the requirements of section 4 of the Federal Cigarette Labeling and Advertising Act, including area and other formatting requirements, and this part.

(e) The required warnings must be indelibly printed on or permanently affixed to the package or advertisement. These 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.

(f) No person may manufacture, package, sell, offer for sale, distribute, or import for sale or distribution within the United States cigarettes whose packages or advertisements are not in compliance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part, except as provided by § 1141.1(c) and (d).

(g)(1) *Random display.* The required warnings for packages specified in paragraph (a) of this section must be randomly displayed in each 12-month period, 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 in accordance with a plan submitted by the tobacco product manufacturer, distributor, or retailer to, and approved by, the Food and Drug Administration.

(2) *Rotation.* The required warnings for advertisements specified in paragraph (a) of this section must be rotated quarterly in alternating sequence in advertisements for each brand of cigarettes in accordance with a plan submitted by the tobacco product manufacturer, distributor, retailer to, and approved by, the Food and Drug Administration.

(3) *Review.* The Food and Drug Administration will review each plan submitted under this section and approve it if the plan:

(i) Will provide for the equal distribution and display on packaging and the rotation required in advertising under this subsection; and

(ii) Assures that all of the labels required under this section will be displayed by the tobacco product manufacturer, distributor, or retailer at the same time.

(4) *Record retention.* Each tobacco product manufacturer required to randomly and equally display and distribute warnings on packaging or rotate warnings in advertisements in accordance with an FDA-approved plan under section 4 of the Federal Cigarette Labeling and Advertising Act and this part must maintain a copy of such FDA-approved plan and make it available for inspection and copying by officers or employees duly designated by the Secretary of Health and Human Services. The FDA-approved plan must be retained while in effect and for a period of not less than 4 years from the date it was last in effect.

§ 1141.12 Misbranding of Cigarettes.

(a) A cigarette will be deemed to be misbranded under section 903(a)(1) of the Federal Food, Drug, and Cosmetic Act if its package does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part. A cigarette will be deemed to be misbranded under section 903(a)(7)(A) of the Federal Food, Drug, and Cosmetic Act if its advertising does not bear one of the required warnings in accordance with section 4 of the Federal Cigarette Labeling and Advertising Act and this part.

(b) A cigarette advertisement and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor 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 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 other descriptive printed matter 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 and this part.

Dated: July 24, 2019.

Norman E. Sharpless,

Acting Commissioner of Food and Drugs.

Dated: August 9, 2019.

Eric D. Hargan,

Deputy Secretary,

Department of Health and Human Services.

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