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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1140

[Docket No. FDA-1995-N-0259] (formerly Docket No. 1995N-0253)
RIN 0910-AG33

Regulations Restricting the Sale and Distribution of Cigarettes
and Smokeless Tobacco To Protect Children and Adolescents

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reissuing a final rule restricting the sale, distribution, and use of cigarettes and smokeless tobacco. As required by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), FDA is issuing a final rule that is identical to the provisions of the final rule on cigarettes and smokeless tobacco published by FDA in 1996, with certain required exceptions. The rule prohibits the sale of cigarettes and smokeless tobacco to individuals under the age of 18 and imposes specific marketing, labeling, and advertising requirements. Elsewhere in this issue of the Federal Register, FDA is issuing an advance notice of proposed rulemaking to obtain information related to the regulation of outdoor advertising of cigarettes and smokeless tobacco.

DATES: This rule is effective June 22, 2010.

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- I. Background

The Tobacco Control Act was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act (act) and providing FDA with the authority to regulate tobacco products (Public Law 111-31; 123 Stat. 1776). Section 102 of the Tobacco Control Act requires FDA to publish a final rule regarding cigarettes and smokeless tobacco identical in its provisions to the regulation issued by FDA in 1996 (61 FR 44396, August 28, 1996) (1996 final rule), with certain specified exceptions.

In enacting the Tobacco Control Act, Congress made extensive legislative findings regarding the lethal and addictive nature of tobacco products, including that tobacco use is the foremost preventable cause of premature death in the United States (section 2(13) of the Tobacco Control Act; 61 FR 44398). Tobacco use causes more than 400,000 deaths each year (section 2(13) of the Tobacco Control Act). Moreover, advertising, marketing, and promotion of tobacco products have been ``especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth'' (section 2(15) of the Tobacco Control Act). The use of tobacco products is a ``pediatric disease'' and an effective program to address this disease must include restrictions on youth access and restrictions on labeling and advertising to help reduce the appeal of tobacco products to young people (section 2(1), (30) of the Tobacco Control Act; 60 FR 41314 at 41315; August 11, 1995).

As Congress recognized, the 1996 final rule was ``the longest rulemaking proceeding in [FDA] history,'' with 700,000 comments received in the course of the rulemaking (Congressional Record, S6407, June 10, 2009, Statement of Senator Kennedy). ``[I]t makes no sense to require FDA to reinvent the wheel by conducting a new multiyear rulemaking process on the same issues * * * this legislation will give the youth access and advertising restrictions already developed by FDA the force of law'' (Congressional Record, S6407, June 10, 2009, Statement of Senator Kennedy). Both the 1996 final rule and the 1995 proposed rule (60 FR 41314) included extensive discussions of the scientific information available at that time and the final rule included FDA's responses to the more than 700,000 comments on the proposed rule (61 FR 44396).

II. Overview of the Final Rule

Consistent with the requirements of section 102 of the Tobacco Control Act, this rule prohibits the sale of cigarettes and smokeless tobacco to any person under age 18 and imposes restrictions on marketing, labeling, and advertising. The rule requires retailers to verify a purchaser's age by photographic identification; prohibits free samples of cigarettes and prohibits free samples of smokeless tobacco, except in qualified adult-only facilities; prohibits the sale of cigarettes and smokeless tobacco products through vending machines and self-service displays, except in facilities where individuals under the age of 18 are not present or permitted at any time; limits the advertising and labeling to which children and adolescents are exposed to a black-and-white, text-only format \1\; prohibits the sale or distribution of brand-identified promotional nontobacco items such as hats and tee shirts; and prohibits sponsorship of sporting and other events, teams, and entries in a brand name of a tobacco product, but permits such sponsorship in a corporate name.

\1\ As discussed later in this section II, this provision is the subject of an injunction issued by the United States District Court for the Western District of Kentucky (Commonwealth Brands, Inc. v. United States, No. 1:09-CV-117-M (W.D. Ky. Jan. 4, 2010)).

As required by section 102(a)(2) of the Tobacco Control Act, this final rule includes the following changes to the provisions of the 1996

final rule:

Strikes subpart C--Labels and Sec. 897.32(c) (section 102(a)(2)(B));

Replaces the definitions of ``cigarette,' ' ``cigarette tobacco,' ' and ``smokeless tobacco' ' with the definitions of those terms included in the Tobacco Control Act (section 102(a)(2)(C));

Inserts the phrase ``or roll-your-own paper' ' in 21 CFR 1140.34(a) (formerly Sec. 897.34(a) of the 1996 final rule) (section 102(a)(2)(D)); and

Reflects the language in section 102(a)(2)(G) of the Tobacco Control Act in 21 CFR 1140.16(d) (formerly Sec. 897.16(d) of the 1996 final rule.

FDA has also changed the section numbers of the codified provisions to reflect the rule's codification at part 1140 (21 CFR part 1140) (the 1996 final rule codified the provisions at part 897, a part used for device regulations, because the products were regulated as devices at that time), made conforming edits, such as corrections to paragraph numbering, to Sec. 1140.16(d), and updated the address in Sec. 1140.30(a)(2). In addition, the rule reflects the following considerations.

Section 21 CFR 1140.16(a)--Under this final rule, manufacturers may not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product unless the trade or brand name was on both the tobacco product and a nontobacco product sold in the United States on January 1, 1995. FDA is aware of concerns regarding this provision and is considering what changes, if any, would be appropriate.

Section 21 CFR 1140.30(b)--Consistent with section 102(a)(2)(E) of the Tobacco Control Act, FDA has carefully considered whether this section (formerly Sec. 897.30(b)) should be modified in light of governing First Amendment case law, including the decision of the Supreme Court of the United States in *Lorillard Tobacco Co. v. Reilly* (Lorillard) (533 U.S. 525 (2001)). FDA has determined that it is appropriate in light of governing First Amendment case law to solicit additional information regarding outdoor advertising in order to determine what modifications to this section, if any, are appropriate. Accordingly, elsewhere in this Federal Register, FDA is publishing an advance notice of proposed rulemaking (ANPR) requesting comments and information on outdoor advertising. By issuing this ANPR, the Agency will obtain comments and data, research, or other information that may have developed since the 1996 issuance of Sec. 897.30(b). This will enable the Agency to implement a regulatory approach to outdoor advertising that reflects careful consideration of the U.S. Supreme Court's decision in *Lorillard*, the other provisions of the Tobacco Control Act, and other developments and information, such as the Master Settlement Agreement between the State Attorneys General and the tobacco industry, that have occurred since the original publication of the 1996 final rule. FDA intends to use the information submitted in response to this advance notice of proposed rulemaking, along with information in the existing record and other information developed since the publication of the 1996 final rule, to inform its regulation of outdoor advertising of cigarettes and smokeless tobacco. Accordingly, FDA has reserved former Sec. 897.30(b), which is now renumbered as Sec. 1140.30(b), in this final rule.

Section 21 CFR 1140.32(a)--The United States District Court for the Western District of Kentucky recently issued an order granting the plaintiffs' motion for an order enjoining FDA from enforcing against them section Sec. 1140.32(a) (formerly Sec. 897.32(a) of the 1996 final rule), scheduled to go into effect on June 22, 2010. (Commonwealth

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Brands, Inc. v. United States, No. 1:09-CV-117-M (W.D. Ky. Jan. 4, 2010)). The government has noticed an appeal from the final judgment

entered in that case on March 8, 2010.

III. Scientific Information That Has Become Available Since the Publication of the 1996 Final Rule

In developing its proposed rule (60 FR 41314, August 11, 1995) and the 1996 final rule, FDA carefully considered the scientific reviews and information available at that time. Although not required to do so by the Tobacco Control Act, FDA reviewed scientific information that has become available since publication of the 1996 final rule and found that, consistent with the evidence in the record for the 1996 final rule, the provisions continue to be overwhelmingly supported by extensive studies on continued youth access to tobacco products, the targeted marketing of tobacco products to youth, and the immense public health harm that results. Following is an overview of some of the scientific information that has become available since the 1996 final rule.

A. Access

The 2008 National Survey on Drug Use and Health found that the number of persons aged 12 or older who smoked cigarettes for the first time within the past 12 months was 2.4 million in 2008, which was significantly higher than the estimate for 2002 (1.9 million), 2003 (2.0 million), and 2004 (2.1 million).² In 2008, every day, nearly 4,000 youth aged 12 to 17 became new cigarette smokers.³ Approximately 85 percent of persons who ever tried a cigarette did so by age 18.⁴ In addition, the number of persons aged 12 or older initiating use of smokeless tobacco was 1.4 million in 2008 and a little less than half (47.4 percent) were under age 18 when they first used smokeless tobacco.⁵ The President's Cancer Panel identified youth as a population group "particularly vulnerable to tobacco initiation, continued use, and consequent diseases caused by tobacco use" and reported that the "younger people are when they begin to smoke, the more likely they are to be adult smokers."⁶ Based on 2009 data from the Monitoring the Future survey, past-month cigarette smoking rates among 8th, 10th, and 12th grade students declined only slightly from 2007 to 2009, at a much slower pace than observed previously, while significant increases occurred from 2005 to 2009 in past-month use of smokeless tobacco among 10th and 12th grade students.⁷

² Substance Abuse and Mental Health Services Administration, "Results from the 2008 National Survey on Drug Use and Health: National Findings," p. 60, Office of Applied Studies, NSDUH Series H-34, DHHS Publication No. SMA 09-4434, Rockville, MD, 2009. (<http://www.oas.samhsa.gov/nsduh/2k8nsduh/2k8Results.cfm>). (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

³ Id.

⁴ Memorandum from the Centers for Disease Control to the Food and Drug Administration, February 3, 2010.

⁵ Substance Abuse and Mental Health Services Administration, "Results from the 2008 National Survey on Drug Use and Health: National Findings," p. 62, Office of Applied Studies, NSDUH Series H-34, DHHS Publication No. SMA 09-4434, Rockville, MD, 2009.

⁶ President's Cancer Panel, "Promoting Healthy Lifestyles," p. 64, U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, 2007 (<http://deainfo.nci.nih.gov/ADVISORY/pcp/pcp07rpt/pcp07rpt.pdf>).

⁷ Johnston, L.D., P.M. O'Malley, J.G. Bachman, et al., "Smoking continues gradual decline among U.S. teens, smokeless tobacco threatens a comeback" (press release), University of

Michigan News Service, December 14, 2009 (<http://www.monitoringthefuture.org/data/09data.html#2009data-cigs>).

Cigarette sources include social and commercial sources (e.g., gas stations, convenience stores). Despite state laws prohibiting the sale of cigarettes to youth, many middle school and high school students continue to report that cigarettes are easy to obtain.\8\ One study found that minors were 2.2 times more successful when attempting to buy a smokeless tobacco product than when trying to buy cigarettes.\9\ Age verification data indicate that minors are able to purchase cigarettes and other tobacco products from stores without age verification.\10,11\ In addition, youth continue to have some access to ``loosies'' (defined as less than a full pack of cigarettes).\12,13\

\8\ Id.

\9\ Clark, P.I., S.L. Natanblut, C.L. Schmitt, et al., ``Factors Associated With Tobacco Sales to Minors: Lessons Learned From the FDA Compliance Checks,' ' Journal of American Medical Association; 284(6), pp.729-734, 2000.

\10\ Centers for Disease Control and Prevention (CDC), ``Tobacco Use, Access, and Exposure to Tobacco in Media Among Middle and High School Students, United States, 2004,' ' MMWR Highlights, April 1, 2005 (http://www.cdc.gov/tobacco/data_statistics/mmwrs/byyear/2005/mm5412a1/highlights.htm).

\11\ Jones S.E., D.J. Sharp, C.G. Husten, et al., ``Cigarette acquisition and proof of age among U.S. high school students who smoke,' ' Tobacco Control, 11(1), pp. 20-25, 2002.

\12\ Johnston L.D., P.M. O'Malley, Y.M. Terry-McElrath, ``Methods, Locations, and Ease of Cigarette Access for American Youth, 1997-2002,' ' American Journal of Preventive Medicine; 27(4), pp. 267-276, 2004.

\13\ Clegg Smith, K., F. Stillman, L. Bone, et al., ``Buying and Selling `Loosies' in Baltimore: The Informal Exchange of Cigarettes in the Community Context,' ' Journal of Urban Health, 84(4), pp.494-507, 2007.

Youth access restrictions and enforcement of these laws continue to be identified as important interventions for preventing tobacco use among adolescents.\14,15,16,17\ One national study found that increases in state retailer compliance with state laws against selling tobacco products to minors were associated with decreases in daily cigarette smoking rates among 10th grade students.\18\ States have universally adopted youth access restrictions in light of the Synar Amendment (Public Law 102-321), which is aimed at decreasing youth access to tobacco, and most states have made considerable progress in achieving the goal of reducing retailer violation rates in random inspections to 20 percent or less.\19,20\ In 2008, the national average retailer violation rate (tobacco sales to minors) was 9.9 percent.\21\ This was the lowest retailer violation rate in Synar's 12-year history. However, the Synar Amendment focuses on only one aspect of tobacco control: Reducing youth access to tobacco products through retail sources. Although important, reduction of youth access to tobacco products is generally recognized as only one aspect of an effective multi-component approach to reduce youth tobacco initiation and use, which should also include efforts to limit tobacco industry marketing and smoking restrictions.\22,23\ Moreover,

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data indicate many teens still report access to cigarettes and smokeless tobacco through commercial and/or social sources even in communities with strong enforcement of youth access laws.\24,25,26,27\

\14\ National Institutes of Health, ``NIH State-of-the-Science Conference Statement on Tobacco Use: Prevention, Cessation and Controls,' ' 2006 (<http://consensus.nih.gov/2006/2006TobaccoSOS029html.htm>).

\15\ Substance Abuse and Mental Health Services Administration: Center for Substance Abuse Prevention: Division of State Programs, ``FFY 2008 Annual Synar Reports: Youth Tobacco Sales,' ' 2008 (<http://prevention.samhsa.gov/tobacco/synarreportfy2008.pdf>).

\16\ Stead, L.F., T. Lancaster, ``Interventions for preventing tobacco sales to minors (Review),' ' Cochrane Database of Systematic Reviews, Issue 1, Article No. CD001497, 2005.

\17\ Restricting minors' access to tobacco products, Guide to Community Preventive Services, 2009, (<http://www.thecommunityguide.org/Tobacco/restrictingaccess/index.html>).

\18\ DiFranza J.R., J.A. Savageau, K.E. Fletcher, ``Enforcement of underage sales laws as a predictor of daily smoking among adolescents--a national study,' ' BioMed Central Public Health, 9:107, pp. 1-7, 2009.

\19\ DiFranza J.R., G.F. Dussault, ``The federal initiative to halt the sale of tobacco to children--the Synar Amendment, 1992-2000: lessons learned,' ' Tobacco Control, 14(2), pp. 93-98, 2005.

\20\ Substance Abuse and Mental Health Services Administration: Center for Substance Abuse Prevention: Division of State Programs, ``FFY 2008 Annual Synar Reports: Youth Tobacco Sales,' ' 2008 (<http://prevention.samhsa.gov/tobacco/synarreportfy2008.pdf>).

\21\ Id.

\22\ National Institutes of Health, ``NIH State-of-the-Science Conference Statement on Tobacco Use: Prevention, Cessation and Controls,' ' 2006, (<http://consensus.nih.gov/2006/2006TobaccoSOS029html.htm>).

\23\ Institute of Medicine (IOM) of the National Academies, ``Ending the Tobacco Problem: A Blueprint for the Nation,' ' (2007 IOM Report), 2007 (<http://www.iom.edu/Reports/2007/Ending-the-Tobacco-Problem-A-Blueprint-for-the-Nation.aspx>).

\24\ Johnston, L.D., P.M. O'Malley, J.G. Bachman, et al., ``Smoking continues gradual decline among U.S. teens, smokeless tobacco threatens a comeback`` (press release). University of Michigan News Service, December 14, 2009 (<http://www.monitoringthefuture.org/data/09data.html#2009data-cigs>).

\25\ Clark, P.I., S.L. Natanblut, C.L. Schmitt, et al., ``Factors Associated With Tobacco Sales to Minors: Lessons Learned From the FDA Compliance Checks,' ' Journal of American Medical Association; 284(6), pp.729-734, 2000.

\26\ Johnston L.D., P.M. O'Malley, Y.M. Terry-McElrath, ``Methods, Locations, and Ease of Cigarette Access for American Youth, 1997-2002,' ' American Journal of Preventive Medicine; 27(4), pp. 267-276, 2004.

\27\ DiFranza J.R., M. Coleman, ``Sources of tobacco for youths in communities with strong enforcement of youth access laws,' ' Tobacco Control, 10, pp. 323-328, 2001.

B. Marketing

In 2006, the U.S. tobacco industry spent \$12.5 billion on advertising and promoting cigarettes and another \$354 million on advertising and promoting smokeless tobacco products.\28,29\ Combined advertising and promotion expenditures for cigarettes and smokeless tobacco in 2006 amounted to \$35 million a day. ``As direct advertising channels have become increasingly restricted by policy interventions on both the domestic and global levels, promotional expenditures for tobacco continue to increase in areas such as point-of-purchase displays, promotional allowances, and viral, or `stealth,' marketing.' '

\30\ Sponsorship expenditures, including sponsorship of sports teams and athletes, were \$30.6 million in 2005.\31,32\ Price discounts accounted for 74 percent of total cigarette marketing expenditures in 2006 (\$9.2 billion), with the broader category of promotional allowances (which includes price discounts) accounting for 81 percent of these expenditures (\$10.6 billion).\33\ The largest category of advertising and promotion for smokeless tobacco products in 2006 was price discounts, which accounted for 58 percent of total spending (\$204 million).\34\ The broader category of promotional allowances (which includes price discounts) accounted for 61 percent of total spending (\$216 million).\35\ In comparison, as a general matter, ``the assessment of State tobacco control funding indicates little progress in the past year toward the level needed for effective, comprehensive state tobacco control efforts, as recommended by the Centers for Disease Control and Prevention'' and is ``miniscule'' compared to the amount tobacco companies spend on marketing.\36\

\28\ Federal Trade Commission, ``Federal Trade Commission Cigarette Report for 2006,'' 2009 (<http://www.ftc.gov/os/2009/08/090812cigarettereport.pdf>).

\29\ Federal Trade Commission, ``Federal Trade Commission Smokeless Tobacco Report for the Year 2006,'' 2009 (<http://www.ftc.gov/os/2009/08/090812smokelesstobaccoreport.pdf>).

\30\ National Cancer Institute, ``The Role of the Media in Promoting and Reducing Tobacco Use,'' NCI Tobacco Control Monograph Series, Monograph 19, pp. 7-8, NIH Publication No. 07-6242, 2008 (<http://cancercontrol.cancer.gov/TCRB/monographs/19/index.html>).

\31\ Federal Trade Commission, ``Federal Trade Commission Cigarette Report for 2004 and 2005,'' 2007 (<http://www.ftc.gov/reports/tobacco/2007cigarette2004-2005.pdf>).

\32\ National Cancer Institute, ``The Role of the Media in Promoting and Reducing Tobacco Use,'' NCI Tobacco Control Monograph Series, Monograph 19, pp. 154-55, 180, NIH Publication No. 07-6242, 2008 (<http://cancercontrol.cancer.gov/TCRB/monographs/19/index.html>).

\33\ Federal Trade Commission, ``Federal Trade Commission Cigarette Report for 2006,'' 2009 (<http://www.ftc.gov/os/2009/08/090812cigarettereport.pdf>).

\34\ Federal Trade Commission, ``Federal Trade Commission Smokeless Tobacco Report for the Year 2006,'' 2009 (<http://www.ftc.gov/os/2009/08/090812smokelesstobaccoreport.pdf>).

\35\ Id.

\36\ President's Cancer Panel 2007-2008 Annual Report, ``Maximizing Our Nation's Investment in Cancer: Three Crucial Actions for America's Health,'' U.S. Department of Health and Human Services, National Institutes of Health, National Cancer Institute, p. 54, 2008 (<http://deainfo.nci.nih.gov/advisory/pcp/pcp07-08rpt/pcp07-08rpt.pdf>).

NCI Monograph 19--In 2008, the Department of Health and Human Services (HHS) U.S. National Cancer Institute (NCI) published its 19th monograph in the Tobacco Control Monograph Series, The Role of the Media in Promoting and Reducing Tobacco Use (Monograph 19). Monograph 19 is a ``comprehensive distillation of the scientific literature on media communications in tobacco promotion and tobacco control.'' \37\ In examining tobacco advertising, Monograph 19 stated that ``tobacco advertising forms part of an integrated marketing communications strategy combining sponsorship, brand merchandising, brand stretching, packaging, point-of-sale promotions, and product placement.'' \38\ The major conclusions of Monograph 19 included the following: (1) Cigarettes are one of the most heavily marketed products in the United States; (2) the targeting of various population groups, including youth and young adults, ``has been strategically important to the tobacco

industry''; and (3) the weight of the evidence demonstrates a causal relationship between tobacco advertising and promotion and increased tobacco use.\39\ With respect to marketing of tobacco to children and adolescents, Monograph 19 concluded, among other things, that: (1) Tobacco advertising targets the psychological needs of adolescents (e.g., popularity) and ``adolescents who believe that smoking can satisfy their psychological needs, or whose desired image of themselves is similar to their image of smokers, are more likely to smoke cigarettes''; and (2) even brief exposure to tobacco advertising influences adolescents' intentions to smoke.\40\

\37\ National Cancer Institute, ``The Role of the Media in Promoting and Reducing Tobacco Use,'' NCI Tobacco Control Monograph Series, Monograph 19, p. xvii, NIH Publication No. 07-6242, 2008 (<http://cancercontrol.cancer.gov/TCRB/monographs/19/index.html>).

\38\ Id., p. 7.

\39\ Id., pp. 11-12.

\40\ Id., pp. 280-281.

Monograph 19 reviewed studies and literature related to point of sale advertising, use of promotional items in marketing, restrictions on the use of color in labeling and advertising, and tobacco industry sponsorship of sporting and other events. Monograph 19 stated that ``cigarette advertising and promotion are heavy in volume and high in visibility at the point of sale, particularly in convenience stores.'' \41\ Further, point of purchase retail settings and bars have become important sites of promotion.\42,43,44,45,46,47\ The tobacco industry has also directed more resources toward public relations activities, personal selling, direct marketing campaigns, internet

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advertising, package design, and trademark diversification.\48,49,50\

\41\ Id., pp.132, 133.

\42\ Id., p. 84.

\43\ Feighery, E. C., K.M. Ribisl, N. Schleicher, R.E. Lee, et al. , ``Cigarette advertising and promotional strategies in retail outlets: results of a statewide survey in California,'' Tobacco Control 10(1), pp. 184-88, 2001.

\44\ Katz, S.K., A.M. Lavack, ``Tobacco related bar promotions: insights from tobacco industry documents,'' Tobacco Control 11, Suppl. 1: i92-i101, 2002.

\45\ Sepe, E., P.M. Ling, S.A. Glantz, ``Smooth Moves: Bar and Nightclub Tobacco Promotions That Target Young Adults,'' American Journal of Public Health vol. 92 (3), pp. 414-19, 2002.

\46\ Dewhirst, T, ``POP goes the power wall? Taking aim at tobacco promotional strategies utilised at retail,'' Tobacco Control vol. 13(3), pp. 209-10, 2004.

\47\ Institute of Medicine (IOM) of the National Academies, ``Ending the Tobacco Problem: A Blueprint for the Nation,'' (2007 IOM Report), Appendix L, L-5, 2007. <http://www.iom.edu/Reports/2007/Ending-the-Tobacco-Problem-A-Blueprint-for-the-Nation.aspx>.

\48\ Freeman, B., S. Chapman, ``Open source marketing: Camel cigarette brand marketing in the `Web 2.0' world,'' Tobacco Control, 18, pp. 212-217, 2009.

\49\ Hamilton, W.L., D.M. Turner-Bowker, C.C. Celebucki, et al., ``Cigarette advertising in magazines: the tobacco industry response to the Master Settlement Agreement and to public pressure,'' Tobacco Control 11 Suppl. pp. ii54-ii58, 2002.

\50\ National Cancer Institute, ``The Role of the Media in Promoting and Reducing Tobacco Use,'' NCI Tobacco Control Monograph

Series, Monograph 19, p. 84, NIH Publication No. 07-6242, 2008,
<http://cancercontrol.cancer.gov/TCRB/monographs/19/index.html>.

Monograph 19 also contained an extensive discussion of the colors and symbols associated with cigarette brands and found that colors and symbols can be used in ways that facilitate the circumvention of tobacco advertising restrictions.\51\ Monograph 19 found that the ``brand image of most tobacco products represents the end result of a multifaceted marketing effort involving brand identity * * * and the use of color. The development, enhancement, and reinforcement of this brand imagery are primary objectives of tobacco promotion.''\52\

\51\ Id., p. 85.

\52\ Id., p. 87.

Other Information--In addition to Monograph 19's comprehensive discussion of the many studies and reviews related to youth access and tobacco industry marketing to youth, other recent reports and documents also reflect the need to address these issues. In 2007 the Institute of Medicine of the National Academies issued a report entitled ``Ending the Tobacco Problem: A Blueprint for the Nation'' (2007 IOM report). In discussing factors that have slowed reductions in tobacco use initiation and kept the annual rate of cessation among smokers fairly low, the 2007 IOM report noted ``First and foremost, tobacco products are highly addictive because they contain nicotine, one of the most addictive substances used by humans. Nicotine's addictive power thus poses significant challenges to smoking cessation efforts at both the individual and the population levels. Second, factors such as distorted risk and harm perceptions, which are associated with the initiation and maintenance of tobacco use among young smokers, pose a continuing obstacle for prevention and control strategies.''\53\

\53\ Institute of Medicine (IOM) of the National Academies, ``Ending the Tobacco Problem: A Blueprint for the Nation,''\54\ (2007 IOM Report), p. 77, 2007. <http://www.iom.edu/Reports/2007/Ending-the-Tobacco-Problem-A-Blueprint-for-the-Nation.aspx>.

With respect to adolescent cigarette smoking, the 2007 IOM report stated that ``research suggests that adolescents misperceive the magnitude of smoking harms and the addictive properties of tobacco and fail to appreciate the long-term dangers of smoking, especially when they apply the dangers to their own behavior. When taken together with the general tendencies of adolescents to take a short-term perspective and to given [sic] substantial weight to peer influences, they tend to unduly discount the risks and overstate the benefits of smoking. These distorted risk perceptions are associated with adolescents' decisions to initiate tobacco use, a decision that they will later regret.''\54\ Moreover, ``[t]he evidence clearly shows that youth exposure to images that create a positive association with smoking is associated with a higher likelihood of smoking'' and ``prevailing scientific opinion regards the relationship between promotional exposures and smoking to be a causal one.''\55\ The 2007 IOM report recommended a two-pronged strategy for reducing tobacco use in the United States. The first prong would strengthen traditional tobacco control measures, including restricting youth access within the context of a comprehensive approach, and the second prong would increase the Federal presence in tobacco control, including Federal regulation over tobacco industry products and marketing.\56\

\54\ Id., p. 93.

\55\ Id., pp. 322-323.

\56\ Id., pp.154, 272.

In 2003, the World Health Organization's Framework Convention on Tobacco Control (FCTC) opened for signature, and has since been signed by the United States and ratified by 168 countries. The FCTC was developed in response to the global ``tobacco epidemic'' and is aimed at reducing the supply and demand for tobacco. The core demand reduction provisions include articles aimed at tobacco labeling, advertising, promotion, and sponsorship, including provisions that these be accompanied by health or other appropriate warnings.\57\ The core supply reduction provisions include provisions aimed at sales to minors. The FCTC's preamble includes language reflecting concerns ``about the escalation in smoking and other forms of tobacco consumption by children and adolescents worldwide, particularly smoking at increasingly early ages'' and ``the impact of all forms of advertising, promotion and sponsorship aimed at encouraging the use of tobacco products.''\58\

\57\ World Health Organization, ``WHO Framework Convention on Tobacco Control,''\ Geneva: World Health Organization, 2003, http://www.who.int/fctc/text_download/en/index.html.

\58\ Id., pp. 1-2.

In enacting the Tobacco Control Act, Congress found, among other things, that the use of tobacco products is a pediatric disease, virtually all new users of tobacco products are under the minimum legal age to purchase such products, children are exposed to substantial and unavoidable tobacco advertising that leads to favorable beliefs about tobacco use and are more influenced by tobacco marketing than are adults, and that tobacco company documents indicate that young people are an important and often crucial segment of the tobacco market (section 2(1), (4), (20), (23), (24)) of the Tobacco Control Act). In addition, Congress found that reducing the use of tobacco by minors by 50 percent would prevent well over 10,000,000 of today's children from becoming regular, daily smokers, saving over 3,000,000 of them from premature death due to tobacco-induced disease (section 2(14) of the Tobacco Control Act). Accordingly, Congress directed FDA to reissue provisions contained in its 1996 final rule that restrict youth access to tobacco products and target the advertising practices used by the industry to recruit children and adolescents (section 2(30), (31)).

IV. Legal Authority

Section 102 of the Tobacco Control Act directs the Secretary to issue a final rule identical in its provisions to the final rule issued on August 28, 1996 (61 FR 44615 to 44618), with certain exceptions. Under section 102(a)(1)(B), the rule issued under this section is, ``deemed to be in compliance with all applicable provisions of chapter 5, title 5, United States Code, and all other provisions of law related to rulemaking procedures.''

V. Executive Order 12866

This rule has been determined to be economically significant for the purposes of Executive Order 12866 and, therefore, it has been reviewed by the Office of Management and Budget (OMB). Because section 102 of the Tobacco Control Act directs the Secretary to issue a final rule identical in its provisions to the final rule issued on August 28, 1996 (61 FR 44615 to 44618), OMB has not required a Regulatory Impact Analysis beyond that done at that time (see 61 FR 44568 to 44606).

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VI. Information Collection Provisions in the Final Rule

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The 1995 proposed rule provided a 90-day comment period (extended to 144 days in the Federal Register of October 16, 1995 (60 FR 53560)). The information collection provisions in the proposed rule were approved under OMB control number 0910-0312. FDA will be submitting the information collection provisions of the final rule to OMB for reinstatement. Prior to the effective date of this final rule, FDA will publish a notice in the Federal Register of OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule.

List of Subjects in 21 CFR Part 1140

Tobacco, Smoking, Advertising, Labeling.

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Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, chapter I of title 21 of the Code of Federal Regulations is amended by adding a new subchapter K, consisting of part 1140 to read as follows:

SUBCHAPTER K--TOBACCO PRODUCTS

PART 1140--CIGARETTES AND SMOKELESS TOBACCO

Subpart A--General Provisions

Sec.

1140.1 Scope.

1140.2 Purpose.

1140.3 Definitions.

Subpart B--Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age

1140.10 General responsibilities of manufacturers, distributors, and retailers.

1140.12 Additional responsibilities of manufacturers.

1140.14 Additional responsibilities of retailers.

1140.16 Conditions of manufacture, sale, and distribution.

Subpart C--[Reserved]

Subpart D--Labeling and Advertising

1140.30 Scope of permissible forms of labeling and advertising.

1140.32 Format and content requirements for labeling and advertising.

1140.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.

Authority: 21 U.S.C. 301 et seq., Sec. 102, Pub. L. 111-31, 123 Stat. 1776.

Subpart A--General Provisions

Sec. 1140.1 Scope.

(a) This part sets out the restrictions under the Federal Food, Drug, and Cosmetic Act (the act) on the sale, distribution, and use of cigarettes and smokeless tobacco that contain nicotine.

(b) The failure to comply with any applicable provision in this part in the sale, distribution, and use of cigarettes and smokeless tobacco renders the product misbranded under the act.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

Sec. 1140.2 Purpose.

The purpose of this part is to establish restrictions on the sale, distribution, and use of cigarettes and smokeless tobacco in order to reduce the number of children and adolescents who use these products, and to reduce the life-threatening consequences associated with tobacco use.

Sec. 1140.3 Definitions.

(a) Cigarette. (1) Means a product that:

(i) Is a tobacco product; and

(ii) Meets the definition of the term "cigarette" in section 3(1) of the Federal Cigarette Labeling and Advertising Act; and

(2) Includes tobacco, in any form, that is functional in the product, 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 or as roll-your-own tobacco.

(b) Cigarette tobacco means any product that consists of loose tobacco that is intended for use by consumers in a cigarette. Unless otherwise stated, the requirements applicable to cigarettes under this chapter shall also apply to cigarette tobacco.

(c) Distributor means any person who furthers the distribution of cigarettes or smokeless tobacco, whether domestic or imported, at any point from the original place of manufacture to the person who sells or distributes the product to individuals for personal consumption. Common carriers are not considered distributors for the purposes of this part.

(d) Manufacturer means any person, including any repacker and/or relabeler, who manufactures, fabricates, assembles, processes, or labels a finished cigarette or smokeless tobacco product.

(e) Nicotine means the chemical substance named 3-(1-Methyl-2-pyrrolidinyl)pyridine or C[10]H[14]N[2], including any salt or complex of nicotine.

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

(g) Point of sale means any location at which a consumer can purchase or otherwise obtain cigarettes or smokeless tobacco for personal consumption.

(h) Retailer means any person who sells cigarettes or smokeless tobacco to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under this part.

(i) Smokeless tobacco means any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity.

Subpart B--Prohibition of Sale and Distribution to Persons Younger Than 18 Years of Age

Sec. 1140.10 General responsibilities of manufacturers,

distributors, and retailers.

Each manufacturer, distributor, and retailer is responsible for ensuring that the cigarettes or smokeless tobacco it manufactures, labels, advertises, packages, distributes, sells, or otherwise holds for sale comply with all applicable requirements under this part.

Sec. 1140.12 Additional responsibilities of manufacturers.

In addition to the other responsibilities under this part, each manufacturer shall remove from each point of sale all self-service displays, advertising, labeling, and other items that the manufacturer owns that do not comply with the requirements under this part.

Sec. 1140.14 Additional responsibilities of retailers.

In addition to the other requirements under this part, each retailer is responsible for ensuring that all sales of cigarettes or smokeless tobacco to any person comply with the following requirements:

(a) No retailer may sell cigarettes or smokeless tobacco to any person younger than 18 years of age;

(b) (1) Except as otherwise provided in Sec. 1140.16(c)(2)(i) and in paragraph (b)(2) of this section, each retailer shall verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age;

(2) No such verification is required for any person over the age of 26;

(c) Except as otherwise provided in Sec. 1140.16(c)(2)(ii), a retailer may sell cigarettes or smokeless tobacco only in a direct, face-to-face exchange without

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the assistance of any electronic or mechanical device (such as a vending machine);

(d) No retailer may break or otherwise open any cigarette or smokeless tobacco package to sell or distribute individual cigarettes or a number of unpackage cigarettes that is smaller than the quantity in the minimum cigarette package size defined in Sec. 1140.16(b), or any quantity of cigarette tobacco or smokeless tobacco that is smaller than the smallest package distributed by the manufacturer for individual consumer use; and

(e) Each retailer shall ensure that all self-service displays, advertising, labeling, and other items, that are located in the retailer's establishment and that do not comply with the requirements of this part, are removed or are brought into compliance with the requirements under this part.

Sec. 1140.16 Conditions of manufacture, sale, and distribution.

(a) Restriction on product names. A manufacturer shall not use a trade or brand name of a nontobacco product as the trade or brand name for a cigarette or smokeless tobacco product, except for a tobacco product whose trade or brand name was on both a tobacco product and a nontobacco product that were sold in the United States on January 1, 1995.

(b) Minimum cigarette package size. Except as otherwise provided under this section, no manufacturer, distributor, or retailer may sell or cause to be sold, or distribute or cause to be distributed, any cigarette package that contains fewer than 20 cigarettes.

(c) Vending machines, self-service displays, mail-order sales, and

other ``impersonal'' modes of sale. (1) Except as otherwise provided under this section, a retailer may sell cigarettes and smokeless tobacco only in a direct, face-to-face exchange between the retailer and the consumer. Examples of methods of sale that are not permitted include vending machines and self-service displays.

(2) Exceptions. The following methods of sale are permitted:

(i) Mail-order sales, excluding mail-order redemption of coupons and distribution of free samples through the mail; and

(ii) Vending machines (including vending machines that sell packaged, single cigarettes) and self-service displays that are located in facilities where the retailer ensures that no person younger than 18 years of age is present, or permitted to enter, at any time.

(d) (1) Except as provided in paragraph (d) (2) of this section, no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of cigarettes, smokeless tobacco, or other tobacco products (as such term is defined in section 201 of the Federal Food, Drug, and Cosmetic Act).

(2) (i) Paragraph (d) (1) of this section does not prohibit a manufacturer, distributor, or retailer from distributing or causing to be distributed free samples of smokeless tobacco in a qualified adult-only facility.

(ii) Paragraph (d) (2) of this section does not affect the authority of a State or local government to prohibit or otherwise restrict the distribution of free samples of smokeless tobacco.

(iii) For purposes of paragraph (d) of this section, the term ``qualified adult-only facility'' means a facility or restricted area that:

(A) Requires each person present to provide to a law enforcement officer (whether on or off duty) or to a security guard licensed by a governmental entity government-issued identification showing a photograph and at least the minimum age established by applicable law for the purchase of smokeless tobacco;

(B) Does not sell, serve, or distribute alcohol;

(C) Is not located adjacent to or immediately across from (in any direction) a space that is used primarily for youth-oriented marketing, promotional, or other activities;

(D) Is a temporary structure constructed, designated, and operated as a distinct enclosed area for the purpose of distributing free samples of smokeless tobacco in accordance with this paragraph (d) (2) of this section;

(E) Is enclosed by a barrier that:

(1) Is constructed of, or covered with, an opaque material (except for entrances and exits);

(2) Extends from no more than 12 inches above the ground or floor (which area at the bottom of the barrier must be covered with material that restricts visibility but may allow airflow) to at least 8 feet above the ground or floor (or to the ceiling); and

(3) Prevents persons outside the qualified adult-only facility from seeing into the qualified adult-only facility, unless they make unreasonable efforts to do so; and

(F) Does not display on its exterior:

(1) Any tobacco product advertising;

(2) A brand name other than in conjunction with words for an area or enclosure to identify an adult-only facility; or

(3) Any combination of words that would imply to a reasonable observer that the manufacturer, distributor, or retailer has a sponsorship that would violate Sec. 1140.34(c).

(iv) Distribution of samples of smokeless tobacco under paragraph (d) (2) of this section permitted to be taken out of the qualified adult-only facility shall be limited to one package per adult consumer containing no more than 0.53 ounces (15 grams) of smokeless tobacco. If such package of smokeless tobacco contains individual portions of smokeless tobacco, the individual portions of smokeless tobacco shall not exceed eight individual portions, and the collective weight of such individual portions shall not exceed 0.53 ounces (15 grams). Any

manufacturer, distributor, or retailer who distributes or causes to be distributed free samples also shall take reasonable steps to ensure that the amounts in this paragraph (d)(2)(iv) are limited to one such package per adult consumer per day.

(3) Notwithstanding paragraph (d)(2) of this section, no manufacturer, distributor, or retailer may distribute or cause to be distributed any free samples of smokeless tobacco:

(i) To a sports team or entertainment group; or

(ii) At any football, basketball, baseball, soccer, or hockey event or any other sporting or entertainment event determined by the Secretary to be covered by paragraph (d)(3) of this section.

(4) The Secretary shall implement a program to ensure compliance with paragraph (d) of this section and submit a report to the Congress on such compliance not later than 18 months after the date of enactment of the Family Smoking Prevention and Tobacco Control Act.

(5) Nothing in paragraph (d) of this section shall be construed to authorize any person to distribute or cause to be distributed any sample of a tobacco product to any individual who has not attained the minimum age established by applicable law for the purchase of such product.

(e) Restrictions on labels, labeling, and advertising. No manufacturer, distributor, or retailer may sell or distribute, or cause to be sold or distributed, cigarettes or smokeless tobacco with labels, labeling, or advertising not in compliance with subpart D of this part, and other applicable requirements.

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Subpart C--[Reserved]

Subpart D--Labeling and Advertising

Sec. 1140.30 Scope of permissible forms of labeling and advertising.

(a)(1) A manufacturer, distributor, or retailer may, in accordance with this subpart D, disseminate or cause to be disseminated advertising or labeling which bears a cigarette or smokeless tobacco brand name (alone or in conjunction with any other word) or any other indicia of tobacco product identification, in newspapers; in magazines; in periodicals or other publications (whether periodic or limited distribution); on billboards, posters, and placards; in nonpoint-of-sale promotional material (including direct mail); in point-of-sale promotional material; and in audio or video formats delivered at a point-of-sale.

(2) A manufacturer, distributor, or retailer intending to disseminate, or to cause to be disseminated, advertising or labeling for cigarettes or smokeless tobacco in a medium that is not listed in paragraph (a)(1) of this section, shall notify the agency 30 days prior to the use of such medium. The notice shall describe the medium and discuss the extent to which the advertising or labeling may be seen by persons younger than 18 years of age. The manufacturer, distributor, or retailer shall send this notice to the Office of Compliance, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD, 20850-3229.

(b) [Reserved]

(c) This subpart D does not apply to cigarette or smokeless tobacco package labels.

Sec. 1140.32 Format and content requirements for labeling and advertising.

(a) Except as provided in paragraph (b) of this section, each manufacturer, distributor, and retailer advertising or causing to be

advertised, disseminating or causing to be disseminated, any labeling or advertising for cigarettes or smokeless tobacco shall use only black text on a white background. This section does not apply to advertising:

(1) In any facility where vending machines and self-service displays are permitted under this part, provided that the advertising is not visible from outside the facility and that it is affixed to a wall or fixture in the facility; or

(2) Appearing in any publication (whether periodic or limited distribution) that the manufacturer, distributor, or retailer demonstrates is an adult publication. For the purposes of this section, an adult publication is a newspaper, magazine, periodical, or other publication:

(i) Whose readers younger than 18 years of age constitute 15 percent or less of the total readership as measured by competent and reliable survey evidence; and

(ii) That is read by fewer than 2 million persons younger than 18 years of age as measured by competent and reliable survey evidence.

(b) Labeling and advertising in an audio or video format shall be limited as follows:

(1) Audio format shall be limited to words only with no music or sound effects.

(2) Video formats shall be limited to static black text only on a white background. Any audio with the video shall be limited to words only with no music or sound effects.

Sec. 1140.34 Sale and distribution of nontobacco items and services, gifts, and sponsorship of events.

(a) No manufacturer and no distributor of imported cigarettes or smokeless tobacco may market, license, distribute, sell, or cause to be marketed, licensed, distributed, or sold any item (other than cigarettes or smokeless tobacco or roll-your-own paper) or service, which bears the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

(b) No manufacturer, distributor, or retailer may offer or cause to be offered any gift or item (other than cigarettes or smokeless tobacco) to any person purchasing cigarettes or smokeless tobacco in consideration of the purchase thereof, or to any person in consideration of furnishing evidence, such as credits, proofs-of-purchase, or coupons, of such a purchase.

(c) No manufacturer, distributor, or retailer may sponsor or cause to be sponsored any athletic, musical, artistic, or other social or cultural event, or any entry or team in any event, in the brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco. Nothing in this paragraph prevents a manufacturer, distributor, or retailer from sponsoring or causing to be sponsored any athletic, musical, artistic, or other social or cultural event, or team or entry, in the name of the corporation which manufactures the tobacco product, provided that both the corporate name and the corporation were registered and in use in the United States prior to January 1, 1995, and that the corporate name does not include any brand name (alone or in conjunction with any other word), logo, symbol, motto, selling message, recognizable color or pattern of colors, or any other indicia of product identification identical or similar to, or identifiable with, those used for any brand of cigarettes or smokeless tobacco.

Dated: March 11, 2010.
Margaret A. Hamburg,

Commissioner of Food and Drugs.

Dated: March 11, 2010.
Kathleen Sebelius,
Secretary of Health and Human Services.
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