



August 5, 2010

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
RM. 1061  
Rockville, MD 20852

Re: Docket No. FDA-2010-D-0276

Ladies and Gentlemen:

The American Cancer Society Cancer Action Network, American Heart Association, American Legacy Foundation, American Lung Association and the Campaign for Tobacco-Free Kids submit these comments on FDA's Guidance for Industry on Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco Products and its Letter to Retailers regarding such rotation plans.

### **Background**

Section 204 of the Family Smoking Prevention and Tobacco Control Act amends Section 3 of the Comprehensive Smokeless Tobacco Health Education Act of 1986 ("the Smokeless Tobacco Act") to (1) prescribe a new set of warning labels for smokeless tobacco products and advertisements for such products, (2) make changes in the requirements for the display of such products, and (3) transfer responsibility for administering the rotational warning plans applicable to such products and advertisements from the Federal Trade Commission to the FDA. The Act requires new warning labels to begin to rotate on June 22, 2010 and prohibits any manufacturer from introducing any smokeless tobacco product into domestic commerce unless its packaging complies with Section 3 of the Smokeless Tobacco Act.

The guidance and the Letter to Retailers issued by the FDA allows smokeless tobacco manufacturers, distributors, or retailers who have submitted a plan by July 22, 2010 to market such products without prior approval by the FDA provided they are in compliance with all the requirements of Section 3 of the Smokeless Tobacco Act other than the requirement that such plan have received the prior approval of the FDA. Pursuant to this policy, such companies are required to be in compliance with all requirements of Section 204 relating to size, formatting, location and use of the required warning statements and must have submitted a rotational plan to the FDA by July 22, 2010.

The apparent purpose of this guidance is to provide an interim enforcement policy pending adoption of a regulatory regime that will require *prior* approval of rotational warning plans by the FDA as a condition of introducing such products into domestic commerce. This guidance contemplates the implementation of a revised enforcement policy within a

reasonable time after July 22, 2010 that will govern the submission and approval of such plans and require such approval prior to continued introduction of such products into domestic commerce as required by the statute.

## **Comments**

*Importance of warning labels on packages and advertising of smokeless products.* The requirement of effective warning labels is an important public health policy—and a statutory requirement—both with respect to cigarettes and smokeless tobacco products. It is especially important that the new warning labels on smokeless tobacco products be as effective as possible because smokeless use has been increasing significantly both overall and among youth. For example, national snuff tobacco sales have risen significantly in the past several years, increasing by 18.5% from 2005 to 2009.<sup>1</sup> In addition, the National Youth Risk Behavior Survey found that in 2009, 15.0%<sup>2</sup> of U.S. high school boys currently use smokeless tobacco products – a 12% increase from 2007.<sup>3</sup> And in states such as Wyoming and Kentucky, about one in four high school boys use smokeless tobacco.<sup>4</sup> Moreover, the major tobacco companies have sharply increased their investments in smokeless tobacco and have begun marketing a range of new smokeless tobacco products, such as Marlboro and Camel Snus and Camel Orbs, Sticks and Strips. It is also likely that consumer awareness and understanding of the risks associated with the use of smokeless tobacco products is even lower than consumers' inadequate awareness and understanding with respect to cigarettes.

*Recognition that the warning labels required by Section 204 are only a minimum.* Section 204 requires FDA to ensure that warning labels on smokeless tobacco products meet certain minimum standards. The legislation gives FDA authority to require different text, larger letters, larger labels and graphic depictions of the dangers of smokeless tobacco products. FDA should recognize that the program it will be implementing is one designed to ensure that warning labels provide an appropriate level of information to consumers and potential consumers in a format that will communicate such information effectively and that the minimum standards established in Section 204 may or may not be sufficient to accomplish the required goal. Further evaluation is necessary to determine if indeed these minimum standards meet the required goal. FDA should not assume that the minimum requirements established in the statute are sufficient and should, from the outset, consider not only what is required to meet these minimum requirements, but also what additional requirements, consistent with the statute, would best inform consumers of the risks associated with the use of smokeless tobacco products and serve the purposes and goals set forth in the Tobacco Control Act.

*Publication of submitted plans.* Since submission of a plan to the FDA by July 22, 2010 is a condition of the applicability of the policy, FDA should promptly make available on its website, as soon as possible after July 22, 2010, the full text of all plans submitted so as to ensure that all stakeholders are aware which products and brands are potentially eligible for the benefits

of the policy. Publication of such plans will also permit stakeholders to provide comments to the FDA on the adequacy of proposed plans to meet the statutory requirements. In addition, publication of such plans will facilitate enforcement of the statutory prohibition on brands for which no such plan has been submitted.

*Compliance of submitted plans with substantive statutory requirements and submission of samples for each brand.* The announced policy requires companies submitting such plans to comply with all requirements relating to size, formatting, location and use of the required warning statements. The statute sets forth the requirements for these elements with sufficient clarity to enable companies subject to the regulation to meet such requirements. However, in light of the wide variety of packages of smokeless tobacco, it is essential for FDA to require that samples of each brand's packaging be submitted together with the plan. This requirement should apply both for eligibility for the interim plan and for any permanent protocol for submission and approval of rotation plans. It is also important for FDA to require submission of actual packages as a condition of eligibility for the interim policy in order to ensure that the integrity of the warning label will not be compromised when the package is opened.

*Elaboration of the meaning of "principal display panels."* The statutory requirement that the warning label appear on the two "principal display panels" of the packaging may require elaboration. This is true particularly because the requirement for packaging displays on two surfaces is a new requirement that did not exist under the prior statutory regime. Regulations or guidance containing such elaboration should make clear that with regard to a circular container with flat top and bottom, the outer surface encircling the side of the container is clearly a "principal display panel." It is likely that the top of the container would be the second "principal display panel," provided the top is not removable and the warning label would not be obscured in the intended use.

Where ambiguity exists as to what the two "principal display panels" of a container are, the FDA should be prepared to provide a prompt determination regarding the adequacy of the labeling. Furthermore, such determinations should be made publicly available in order to maximize the effectiveness of policy guidance to all stakeholders.

*Requirement that packs depicted in advertisements bear warning labels.* FDA should specify that packs may not be depicted in advertisements unless the packs depicted bear warning labels. This requirement is independent of the requirement that the advertisement itself bear a warning label. It is important for warning labels to be seen as an integral part of the total package offered to the consumer and the depiction of packs without such labels would be inconsistent with this goal.

*Requirements for labeling on packaging and subpackaging.* It is conceivable that smokeless tobacco products may be packaged in a manner such that individually wrapped packages are included in a larger package. FDA should promulgate regulations that make it clear

that warning labels are required on both the outer and the inner packages. Furthermore, there should be a requirement that warnings on inner packages should be randomized so that not all such packages contain the same warning. These requirements should apply both for eligibility for the interim program and in regulations promulgated to establish conditions for approval of such plans.

*Rotation plans.* The statute expands the number of required warnings to four. The listing of four separate warnings is a recognition of two significant policy considerations: (1) it is important for consumers to be made aware of each distinct danger presented by the product; and (2) the rotation of warnings helps to prevent warnings from being considered so routine as to constitute “background noise” that can be disregarded. Rotation of the messages – both on packaging and in advertising- is essential for these policies to be served.

*Deadline for promulgation of regulations and establishment of a requirement of prior approval.* The Smokeless Tobacco Act, as amended by Section 204 of the Tobacco Control Act, contemplates a regulatory structure in which *prior* approval of a rotational warning plan is a condition for introduction of smokeless tobacco products into domestic commerce. The FDA should have called for the submission of such plans in time to put them into effect on June 22, 2010, but the interim policy announced by the FDA is a reasonable accommodation to the fact that regulations governing the submission and approval of such plans have not been put into effect. Nonetheless, it is reasonable only if the FDA acts promptly to limit the period in which such policy will be in effect by promptly promulgating an appropriate regulatory structure. That the FTC has had a regulatory structure in place, albeit under statutory requirements that differ from the requirements contained in Section 204 of the Tobacco Control Act, should simplify the FDA’s task and limit the period during which the interim policy is in effect.

*Requirements for rotation of warnings on products.* Both with respect to warning labels on packages and on advertising, the statute requires rotation plans to ensure, to the maximum possible extent, at any time that every potential consumer of a brand or viewer of an advertisement will have an equal likelihood of seeing each of the warning labels. Thus, arrangements provided for in the plan should ensure equal exposure of each of the warnings, separately for each brand and brand style, in each geographic location and in every time period. Thus, a rotation plan should not be approved unless FDA is satisfied that, for example, consumers of every subbrand of Brand X in any neighborhood at any point in time will be equally likely to encounter each of the four warnings both on the Brand X packages and in any Brand X ads at retail outlets or other locations. In the formulation of requirements for approval of rotational plans, FDA should examine the regulations previously promulgated and enforced by the FTC and consult with FTC personnel experienced in enforcing these regulations to determine what modifications to the policies previously applied are necessary to meet these requirements.

*Monitoring of compliance with rotation plans.* FDA should develop an effective regulatory policy to monitor compliance with rotation plans to ensure (1) that the compliance plan is being followed and (2) that the plan has the effect in practice of producing approximately equal exposure of each of the warnings on all packaging and advertising of smokeless tobacco products in accordance with the statutory purpose. As part of its inspection of retail point of sale displays and advertising, FDA and its state contractors should verify that smokeless tobacco product labeling and advertising is in compliance with applicable requirements.

*Evaluation of the effectiveness of the warnings and consideration of alternative warning labels.* It is important for FDA not only to establish an effective regulatory framework for warning labels on smokeless tobacco product packaging and advertising, but also to test the effectiveness of such warnings in practice on a continuing basis. The FDA should continuously evaluate the impact of consumer warnings on consumer behavior and determine what types of warnings are the most effective to reach consumers and inform them regarding the health hazards of tobacco use. Accomplishment of this goal will require an ongoing program to permit FDA to evaluate whether the required labeling is accomplishing its purpose and whether modifications in labeling could improve effectiveness. It is likely, for example, that changes in the text of the warning labels will be necessary to ensure that consumers are provided with newly developed information or with messages that are found more likely to communicate clearly the dangers of the product or to inform consumers of the availability of assistance in cessation. Indeed, some of the key reasons behind the rotation requirements also support periodic changes to the content and format of the warning labels, as well, to prevent them from becoming ignored "background noise." Section 205(a) of the Tobacco Control Act gives the FDA authority to require changes in the text of the warning labels, changes in the type size and area of packaging and advertising covered, as well as to require graphic depiction of the dangers of smokeless tobacco products "if the Secretary finds that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products."

Such graphic warnings have been required in other countries and studies indicate that such warnings are effective at informing smokers about the health hazards of smoking and in reducing the use of tobacco products.<sup>5</sup> FDA should develop a means not only to evaluate the level of public understanding of the risks associated with the use of smokeless tobacco products following the promulgation of the minimum standards for warning labels set forth in Section 204, but also of the level of understanding of such risks that would be produced by larger warnings, different messages, and graphic depictions. We urge FDA to initiate a systematic examination of these issues as early as possible.

Sincerely,



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President  
American Cancer Society Cancer Action Network



Nancy Brown  
Chief Executive Officer  
American Heart Association



Cheryl Heaton  
President and Chief Executive Officer  
American Legacy Foundation



Charles D. Connor  
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Matthew L. Myers  
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<sup>1</sup> U.S. Alcohol and Tobacco Tax and Trade Bureau, Tobacco Statistics.

<sup>2</sup> Centers for Disease Control and Prevention (CDC), “Youth Risk Behavior Surveillance—United States, 2009,” *Morbidity and Mortality Weekly Report (MMWR) Surveillance Summaries* 59(SS-5), June 4, 2010, <http://www.cdc.gov/mmwr/pdf/ss/ss5905.pdf>.

<sup>3</sup> Centers for Disease Control and Prevention (CDC), “Youth Risk Behavior Surveillance—United States, 2007,” *Morbidity and Mortality Weekly Report (MMWR) Surveillance Summaries* 57(SS-4), June 6, 2008 <http://www.cdc.gov/mmwr/pdf/ss/ss5704.pdf>.

<sup>4</sup> Centers for Disease Control and Prevention (CDC), “Youth Risk Behavior Surveillance—United States, 2009,” *Morbidity and Mortality Weekly Report (MMWR) Surveillance Summaries* 59(SS-5), June 4, 2010, <http://www.cdc.gov/mmwr/pdf/ss/ss5905.pdf>.

<sup>5</sup> See, e.g., Borland R, et al., “How reactions to cigarette packet health warnings influence quitting: findings from the ITC Four-Country survey,” *Addiction*, February, 2009. Hammond, D., et al., “Text and graphic warnings on cigarette packages: Findings from the international tobacco control four country study,” *American Journal of Preventive Medicine*. 32(3):202-9, March 2007. Nascimento BE, et al., “Avoidance of smoking: the impact of warning labels in Brazil. *Tobacco Control*. 2008 Dec;17(6):405-9. Hammond, D., et al., “Graphic Canadian warning labels and adverse outcomes: evidence from Canadian smokers,” *American Journal of Public Health* 94 (8), 2004. Hammond, D., et al., “Impact of the graphic Canadian warning labels on adult smoking behaviour.” *Tobacco Control*, Vol. 12, No. 4, p.391-395., December 2003. White, V et al., “Do graphic warning labels have an impact on adolescents’ smoking-related beliefs and behaviors?” *Addiction* 103(9): 1562-71, September, 2008. Hammond D., et al., “Effectiveness of cigarette warning labels in informing smokers about the risks of smoking: Findings from the International Tobacco Control (ITC) Four Country Survey,” *Tobacco Control*. 2006 Jun;15 Suppl 3:iii19-25.