



November 8, 2011

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

RE: Docket No. FDA-2011-D-0480

To whom it may concern:

The undersigned public health groups appreciate the opportunity to submit these comments on FDA's Draft Guidance for Industry on the Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products.

### **Background and the Importance of Rotating Warning Labels**

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) amended both the Federal Cigarette Labeling and Advertising Act (FCLAA) and the Smokeless Tobacco Health Education Act (Smokeless Tobacco Act). New health warnings on the labels of both cigarettes and smokeless products are now required by law. Before selling these products in the U.S. market, those involved in the manufacture, packaging, sale, distribution or importation of cigarettes or smokeless tobacco products must have Food and Drug Administration (FDA) approval of a plan that ensures that the nine cigarette warnings and the four smokeless tobacco warnings are:

- Randomly displayed in each 12 month period on each brand of the product;
- Randomly displayed in as equal a number of times as is possible on each brand of the product; and
- Randomly distributed in all areas of the United States in which the product is marketed

These rotation requirements in the statute are important, as a way to maintain the effectiveness of the warnings and help stave off "wearout".<sup>1</sup> Numerous studies in the field of advertising have demonstrated that advertisements and other marketing lose their effectiveness over time, a phenomenon known as "wearout". Ensuring a random and frequent rotation of the warnings may help lengthen the warnings' effectiveness, and allow FDA time to monitor and evaluate these warnings, in order to determine if it is necessary to introduce new warning texts or graphics.

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<sup>1</sup> J. Walter Thompson, et al., *Planning for Wearout: An Advertiser's Guide to Evaluating Campaign Needs in the Americas*, Marketing Beyond Cultures and Borders, May 1999.

### **The Need for Regulation on the Rotation Plans**

In light of the important role of rotation plans in maintaining the effectiveness of warning labels, FDA should issue regulations regarding the rotation plans, including how they will enforce those plans. Currently, no rules have been promulgated regarding the submission of rotational warning plans for either smokeless tobacco products or cigarettes. While at this time the Final Rule for cigarette warning labels has not yet gone into effect, that rule specifically did not address the warning label rotation plans required by the statute. Meanwhile, the new required warning labels and the plans for rotating the warnings for smokeless products have been in effect since June 22, 2010. We are disappointed to note that FDA has not been enforcing the requirement that an approved warning label rotation plan for smokeless tobacco products be in place before products are sold in the marketplace. We strongly urge FDA to issue rules regarding these rotation plan requirements for both cigarettes and smokeless products as soon as possible. Timely issuance of a rule for smokeless tobacco products is particularly important since those rotation plans have not been enforced for more than one year.

We note that a just-issued preliminary injunction has stayed implementation of the graphic warning labels for cigarettes. Nonetheless, there remains an important need for a rotation plan for when the labels go into effect, in order to reduce “wearout”. While a final Guidance from FDA on this issue can provide some assistance in assuring that the rotation plans are both submitted and enforced, Guidances do not carry the force of law. While it appears that the FDA has consulted the Federal Trade Commission (FTC) regulations for warning label rotation plans in devising this Guidance, it is important that FDA draft regulations to reflect statutory changes made by the Tobacco Control Act regarding the jurisdiction and implementation of rotation plans for warning labels. These regulations will help ensure that the most effective warnings about the health effects of using smokeless tobacco and/or cigarettes are reaching those who use these products, and those who may consider using them.

### **Public Availability of Plans**

As the undersigned groups previously recommended in comments regarding the Enforcement Policy Concerning Rotational Warning Plans for Smokeless Tobacco Products issued by FDA in June 2010 (Docket No. FDA-2010-D-0176), FDA should post approved plans on its website as soon as possible after approval. Additionally, the full text of all plans should be made public so that stakeholders are aware of which brands and products are impacted by the plans, and can comment on whether the plans meet the statutory requirements. Further, publication of the plans may be helpful in enforcing this requirement for brands for which no plan has been submitted.

### **Require samples of all brand packaging and advertising**

While FDA has *requested* as part of rotation plan submissions, representative samples of packages and advertisements with each of the warnings, we encourage FDA to *require* samples of each brand, and size of package or advertisement for each brand. This is important to ensure that the warning labels themselves meet all the statutory requirements and ensure that packaging or advertisement design does not damage, obscure or otherwise render the warnings unreadable when either displayed or opened. Secondly, it is important to have samples in order for FDA to evaluate the effectiveness of the proposed rotation plan.

This is especially important for packaging and sub-packaging of cartons of cigarettes or packages of multiple tins of smokeless tobacco. As is indicated by the statute, and reiterated according to FDA’s Frequently Asked Questions about the warning labels for cigarettes, the

warning labels are required on the packaging of individual packs as well as the carton packages. This should also apply to packages of multiple tins of smokeless tobacco. FDA should reiterate this in the Guidance and any subsequent regulations, and samples of cartons or packages of smokeless tobacco as well as individual packages of cigarettes or smokeless tobacco should be required.

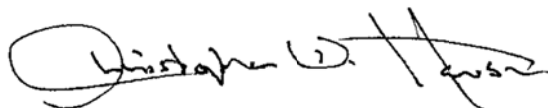
### **Enforcement and Evaluation of the Rotation Plan**

FDA should implement an enforcement policy to ensure that rotation plans approved by FDA are being followed. It is critical to the success of the warning labels that FDA monitor compliance with the rotation plan. As we have suggested in previous comments, FDA and its state contractors should verify the compliance of the rotation plans, as part of the inspection of retail point of sale displays and advertising.

In addition, we strongly recommend that FDA implement an evaluation system to track the effectiveness of the warning labels. FDA must also evaluate the effectiveness of and compliance with the warning label rotation plans. As the body of evidence on the effectiveness of warning labels grows, it is important that warning labels reflect the most recent science – and the rotation plans should as well.

In conclusion, we are pleased that FDA has issued a Guidance regarding rotation of warning labels for cigarettes as early as it has, in preparation for the Final Rule regarding Warning Labels for Cigarettes to go into effect, but encourage FDA to issue regulations regarding the rotation plans as well. At the same time, we are disappointed in the delay in enforcing the requirement that FDA approve warning label rotation plans before smokeless tobacco products are sold in the marketplace. We offer our expertise and assistance to FDA to ensure the regulations for the rotation plans are issued as soon as possible, as well as ensuring that plans are adhered to and in compliance with the statutory requirements.

Sincerely,



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Nancy A. Brown, CEO  
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