

April 1, 2013

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

Re: Docket No. FDA-2012-N-1032 – Smokeless Tobacco Warning Statements

To Whom It May Concern:

On behalf of our 157,000 members, we are pleased to comment on what changes to the smokeless tobacco product warnings, if any, would promote greater public understanding of the risks associated with the use of smokeless tobacco products. We offer these comments in response to your Federal Register notice of January 29, 2013 (78 FR 6056).

Section 204 of the Family Smoking Prevention and Tobacco Control Act (15 U.S.C. 4402) requires smokeless tobacco product packages (and advertising) to bear one of four health warning statements. The four required warning statements are:

- “WARNING: This product can cause mouth cancer.”
- “WARNING: This product can cause gum disease and tooth loss.”
- “WARNING: This product is not a safe alternative to cigarettes.”
- “WARNING: Smokeless tobacco is addictive.”

In terms of helping the public understand the risks associated with using smokeless tobacco products, these health warning statements are sufficient. They are clear, concise and scientifically sound. They leave no doubt that smokeless tobacco can cause mouth cancer, gum disease and tooth loss. They leave no doubt that smokeless tobacco is highly addictive and is not a safe alternative to cigarettes. Above all, they are consistent with the wide body of scientific literature on the health effects of smokeless tobacco use.

In addition to these statutory warning statements, section 205(a) of the Tobacco Control Act authorizes the FDA to require other health warning statements if the agency “finds that such a change would promote greater public understanding of the risks associated with the use of smokeless tobacco products” (15 U.S.C. 4402(d)). If and when the FDA chooses to exercise that authority, we urge you to refrain from approving any statements suggesting that smokeless tobacco products are somehow “safer” than cigarettes.

As a matter of public health, we have become increasingly alarmed by attempts to market smokeless tobacco products as a healthier (or less harmful) alternative to cigarettes. Smokeless tobacco is not a healthy alternative to cigarette smoking; both products pose health risks. Suggesting one product is somehow “safer” than the other dilutes that vital public health message.

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Compared with cigarettes, smokeless tobacco products are less likely to cause lung cancer, but they are associated with oral (mouth) and pharyngeal (throat) cancers, as well as cancers of the stomach and pancreas.<sup>1,2,3,4</sup> These cancers progress rapidly and are frequently deadly.

Additionally, smokeless tobacco is considered a “gateway drug” that can lead users to a lifetime of cigarette smoking.<sup>5,6,7,8</sup> Among persons who had used both smokeless tobacco and cigarettes in their lifetime, 31.8 percent started using smokeless tobacco first.<sup>9</sup> Researchers have found that adolescent boys who use smokeless tobacco products are highly likely to become cigarette smokers within four years.<sup>10</sup>

Smokeless tobacco is not a healthy alternative to cigarette smoking; both products pose health risks. Suggesting one product is somehow “safer” than the other would only confuse the public’s understanding of the risks associated smokeless tobacco use.

We appreciate the opportunity to comment on what changes to the smokeless tobacco product warnings, if any, would promote greater public understanding of the risks associated with the use of smokeless tobacco products. If you have any questions, please contact Mr. Robert J. Burns at 202-789-5176 or burnsr@ada.org.

Sincerely,

/s/

/s/

Robert A. Faiella, D.M.D., M.M.Sc.  
President

Kathleen T. O’Loughlin, D.M.D., M.P.H.  
Executive Director

RAF:KTO:rjb

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<sup>1</sup> World Health Organization, International Agency for Research on Cancer, “Smokeless Tobacco and some Tobacco-specific N-Nitrosamines. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans 89(2007)”, <http://monographs.iarc.fr/ENG/Monographs/vol89/index.php>, accessed September 25, 2009.

<sup>2</sup> “The S.T.O.P. Guide (The Smokeless Tobacco Outreach and Prevention Guide): A Comprehensive Directory of Smokeless Tobacco Prevention and Cessation Resources,” Applied Behavioral Science Press, 1997.

<sup>3</sup> D. Hatsukami and H. Severson, “Oral Spit Tobacco: Addiction, Prevention and Treatment,” *Nicotine and Tobacco Research* 1:21-44, 1999.

<sup>4</sup> “The Smokeless Tobacco Outreach and Prevention Guide,” Applied Behavioral Science Press, 1997.

<sup>5</sup> Institute for Social Research, The University of Michigan, “Monitoring the Future,” <http://monitoringthefuture.org/pressreleases/00cigpr.pdf>.

<sup>6</sup> American Academy of Pediatrics, “Things You Should Know about Smokeless Tobacco,” <http://www.aap.org/advocacy/chmchew2.htm>.

<sup>7</sup> CDC, “Is smokeless tobacco safer than cigarettes?,” *SGR4Kids*, [www.cdc.gov/tobacco/sgr/sgr4kids/smokless.htm](http://www.cdc.gov/tobacco/sgr/sgr4kids/smokless.htm).

<sup>8</sup> H.H. Severson, K.K. Forrester, and A. Biglan, “Use of smokeless tobacco is a risk factor for cigarette smoking,” *Nicotine Tob Res.* 2007 Dec;9(12):1331-7.

<sup>9</sup> Substance Abuse and Mental Health Services Administration, Office of Applied Studies, “The NSDUH Report: Smokeless Tobacco Use, Initiation, and Relationship to Cigarette Smoking: 2002 to 2007,” Rockville, MD.

<sup>10</sup> S. Tomar, “Is use of smokeless tobacco a risk factor for cigarette smoking? The U.S. experience,” *Nicotine & Tobacco Research* 5(4):561-569, August 2003.