



September 10, 2009

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

RE: Docket Number FDA-2009-N-0294

To Whom It May Concern:

The Family Smoking Prevention and Tobacco Control Act prohibits the introduction into the marketplace of tobacco products advertised or labeled as offering reduced health risks unless an order has been issued by the Food and Drug Administration (FDA) permitting the marketing of the product. Included among such modified risk products are those for which the label, labeling, or advertising uses the descriptors "light," "low," "mild," or similar terms. Accordingly, twelve months after the date of enactment of the law, tobacco manufacturers and others will be prohibited from using descriptors, such as "light", "mild", "low" or "other similar descriptors" in the label, labeling or advertising without an order from the FDA because of the scientific evidence that these products do not reduce the risk of disease.

The purpose of this letter is to make sure FDA is aware of how tobacco manufacturers have responded to descriptor bans in other countries and take steps to ensure that the intent of the ban – to stop manufacturers from misleading consumers – is met. The Agency has clear authority under Section 911 of the law to address these actions by the companies to continue to mislead consumers once they are no longer permitted to use these misleading descriptors.

The United States is not the first country to ban the use of these types of descriptors because of the evidence that these descriptors are misleading. The evidence demonstrates that all too often consumers interpret these descriptors as indicating that products associated with these terms are less hazardous than other tobacco products or that switching to products associated with these terms will reduce a tobacco user's risk of disease. The science is clear that this is not the case and that these terms and the marketing of products using them has convinced many smokers to switch rather than quit.

Indeed, in the Findings Section of the Family Smoking Prevention and Tobacco Control Act, Congress noted that the National Cancer Institute has found "many smokers mistakenly believe that 'low tar' and 'light' cigarettes cause fewer health

problems than other cigarettes” and that these “mistaken beliefs ... can reduce the motivation to quit smoking entirely and thereby lead to disease and death.”

Thus, the goal of the congressionally mandated ban on the use of descriptors such as “light”, “mild” and “low” is to break the link between the false and misleading beliefs created by the tobacco industry that certain brands are less harmful than other cigarettes and the connection to the specific brands to which they have been associated.

More than forty countries ban descriptors like “light” and “mild.” Experience from these countries shows that the tobacco industry has used the time period between the date of the enactment of the legislation and the date of implementation of the ban to link in the minds of consumers the same mental association and health-based message conveyed by the soon to be banned descriptors to other cues. As a result, by the time the prohibited descriptors were actually removed, these other cues conveyed the same mental association.

Industry documents also reveal that the companies know how to convey less harm without explicit use of these descriptors, as exemplified by the following quote from a Philip Morris document, cited by Hammond and Parkinson¹, regarding lower deliver products (e.g., those with lower tar and/or nicotine ratings):

“Lower delivery products tend to be featured in blue packs. Indeed, as one moves down the delivery sector, then the closer to white a pack tends to become. This is because white is generally held to convey a clean, healthy association.”

The recent study by Hammond and Parkinson and another similar study² have also found that consumers react to words, colors, shading, and images or references to filters in evaluating the relative risk of tobacco products. In addition to terms like “light” and “mild,” packs using terms such as “smooth” or “silver,” those with a lighter blue shade versus a darker blue shade, those with a white symbol versus a gray symbol, and those with the words and picture of a charcoal filter were all deemed to have lower health risks by large majorities of respondents.

It is no surprise then, that around the world, companies have replaced forbidden descriptors with other terms, symbols, or images to convey the same information. These efforts include using alternative terms not explicitly banned, using colors or shading, and using numbers. Examples include replacing the term “light” with “smooth” and “gold” (UK), removing the term light and replacing it with the letter “L” and the word for “clear” (Italy), and replacing the term “Super Lights” with “8 mg”

¹ Hammond, D. and Parkinson, C., “The impact of cigarette package design on perceptions of risk,” *Journal of Public Health* 31(3):345-53, Epub 2009. <http://jpubhealth.oxfordjournals.org/cgi/content/full/31/3/345>

² Hammond, D., et al., “Cigarette pack design and perceptions of risk among UK adults and youth,” *The European Journal of Public Health* doi:10.1093/eurpub/ckp122. Advance Access published online on September 2, 2009. <http://eurpub.oxfordjournals.org/cgi/content/abstract/ckp122v1>

(China). These are just a few of the many examples of pack changes. In addition some websites do the translation for the smoker – with the color of the packaging and the name of the color on display and the term “light” in parentheses --

<http://2000cigs.com/camel.html>

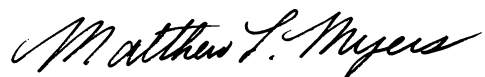
In the U.S., Pall Mall ran magazine advertising to highlight the new colors of its light and ultra light versions prior to passage of the Family Smoking Prevention and Tobacco Control Act. Similarly, new versions of Salem have been seen with the terms “ultra light” and “light” removed and replaced with different shades of green in the packaging and use of the terms “gold” and “silver.”

Given these examples and the tobacco industry’s long history of circumventing restrictions placed on it, it is important that the FDA act early and strongly to prevent the companies from finding alternative ways to deceive consumers into falsely thinking that some products are less harmful than others. These actions should include:

- Issuing guidance on the descriptor ban that include putting the tobacco companies and others on notice that FDA will be closely monitoring labeling and packaging changes for any evidence that the companies are continuing to mislead consumers and will consider such actions as violations of the law.
- Conducting a review of practices tobacco companies have undertaken in countries with similar restrictions and studies of the impact of those practices.
- Conducting surveillance in the U.S. to determine what practices are being undertaken in anticipation of the ban on descriptors.
- Ensuring that consumer testing is conducted to determine how consumers respond to the use of new terms, images, colors, etc.
- Making sure that the intent of the descriptor ban – stopping the companies from misleading consumers about the relative harm of tobacco products – is met.

We urge the FDA to use its new authority to prevent the tobacco companies from continuing to mislead consumers about the risks of products previously labeled and/or marketed as “light,” “low,” or “mild.”

Sincerely,



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