



February 18, 2010

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-2010-N-0020

To Whom It May Concern:

In September, we submitted a letter to the FDA (attached) outlining issues the agency should address regarding the ban on misleading descriptors that goes into effect June 22, 2010. We continue to believe these issues are very important and urge FDA's consideration of them. Actions by some of the tobacco companies since that submission only reinforce the need for FDA to monitor closely how the companies are reacting to the descriptor ban and how those actions are perceived by consumers.

For example, Philip Morris has produced a document that constitutes labeling under the Family Smoking Prevention and Tobacco Control Act (the "Act") and translates for retailers the terms "light" and "low" into new colored packaging (*e.g.*, "Marlboro Lights" are now color-coded as the "Marlboro Gold Pack"). (see attached). This is a pattern that has been seen elsewhere and is now emerging in the United States. With few exceptions, lighter shades have been used to designate cigarette brands previously labeled light or low tar. For example, light blue/gold/silver have been routinely used outside the United States for brands previously labeled light or ultra-light, just as we are now seeing with Marlboro, Camel and many other brands in the United States. Full flavored are in red or dark colors. Lights are most often gold or a shade of blue (See <http://www.fastcompany.com/blog/lucas-conley/advertising-branding-and-marketing/smoke-and-mirrors-smoke-signals-tobacco-two-ste>). It is not a coincidence, and it is consistent with the industry documents we note in our September letter.

In our view, the use of this type of labeling violates Section 911(b)(2)(A)(ii), which prohibits "labels" or "labeling" from using "the descriptors 'light', 'mild', or 'low' or similar descriptors." This labeling makes clear that the new color-coded packaging by Philip Morris (and other cigarette manufacturers who are likely to follow suit) is designed to communicate visually what the Act prohibits from being stated directly (*i.e.*, that the products are "light", "low" or "mild"). The plain language of the Act does not permit manufacturers to use any method that explicitly or implicitly attempts to circumvent the restrictions in Sections 911(b)(2)(A)(i)(I) and (b)(2)(A)(ii), including color coding.

Section 911(b)(2)(A)(i)(I) prohibits "label, labeling or advertising of which represents explicitly or *implicitly* that the tobacco product . . . is less harmful than one or more other commercially marketed tobacco products." Color cues that translate to "light," "low," or "mild" implicitly

communicate that the product is less harmful than others. Similarly, the Act prohibits the use of “similar descriptors” to “light,” “low,” and “mild.” Colors that translate directly to those terms qualify as “similar descriptors” under the Act, as they are simply color representations of the very terms that are banned.

It is imperative that FDA look closely at these types of practices, as it appears that manufacturers are using the new colored packaging to communicate to smokers that the “light” and “low” products are still available and are less harmful than others, without proof of reduced harm to the overall public health.

It will also be important for FDA to examine how retailers communicate with consumers who ask for the brands that are no longer available after the ban. If retailers, either on their own or upon instruction from the companies, communicate that the replacement products are the same as the “light,” “low,” or “mild” products, the light and low deception will only continue.

The FDA should issue guidance to the tobacco companies that, as they begin to distribute the new brands, they should communicate to retailers that retailers must not tell consumers the new brands are the same as the “light”, “low,” and “mild” products or are any less harmful than other brands. They should explain to retailers the reason for the ban – that the government has concluded that light cigarettes and others with similar descriptors have resulted in no benefit to smokers.

We believe there are several actions FDA should consider taking to monitor actions around the ban and their impact on consumers, as well as to educate consumers on the issue.

- As outlined in our earlier letter, the tobacco companies might take a variety of actions in response to the ban. FDA should require the companies to disclose to FDA what they are doing in place of each brand with a banned descriptor, along with any research they have conducted on the impact of these changes.
- FDA should consider conducting surveillance at the point-of-sale to monitor how the newly packaged products are being marketed and sold. This could be done as part of contracts with states to do compliance checks regarding sales to youth. It could involve simple observational studies, as well as mystery shopper studies to determine what retailers communicate to customers who ask for those brands no longer available.
- The FDA should consider a public education campaign to inform smokers about why the change is being made – that there are no benefits to smoking lights/low tar, that the new packaging does nothing to change that, and that the best thing to do is quit. Any such campaign should be based on consumer testing to make sure the messages are communicated effectively.

The ban on misleading descriptors is an important step forward in beginning to reverse the deception of light and low tar cigarettes and the untold damage it has inflicted on public health.

Vigilant monitoring and strong enforcement of this critical provision of the legislation is essential to fulfill the potential of the descriptor ban.

Sincerely,



Matthew L. Myers
President
Campaign for Tobacco-Free Kids



Nancy Brown
Chief Executive Officer
American Heart Association



Molly A. Daniels
Interim President
American Cancer Society Cancer Action
Network



Charles D. Connor
President and Chief Executive Officer
American Lung Association



Cheryl Healton
President and Chief Executive Officer
Legacy



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,



Matthew L. Myers
President
Campaign for Tobacco-Free Kids



Daniel E. Smith
President
American Cancer Society Cancer Action Network



Nancy Brown
Chief Executive Officer
American Heart Association



Charles D. Connor
President and Chief Executive Officer
American Lung Association



Cheryl Heaton
President and Chief Executive Officer
American Legacy Foundation

Old Pack

Marlboro Lights
 Marlboro Lights 100's
 Marlboro Lights 25's
 Marlboro Medium
 Marlboro Medium 100's
 Marlboro Menthol Lights
 Marlboro Menthol Lights 100's
 Marlboro Menthol Milds
 Marlboro Menthol Milds 100's
 Marlboro Menthol Ultra Lights
 Marlboro Menthol Ultra Lights 100's
 Marlboro Seventy-Twos
 Marlboro Seventy-Twos Menthol (Blue)
 Marlboro Seventy-Twos Menthol (Green)
 Marlboro Seventy-Twos Lights
 Marlboro Seventy-Twos Ultra Lights
 Marlboro Ultra Lights
 Marlboro Ultra Lights 100's

New Pack Identifier

Marlboro Gold Pack
 Marlboro Gold Pack 100's
 Marlboro Gold Pack 25's
 Marlboro Red Label
 Marlboro Red Label 100's
 Marlboro Menthol Gold Pack
 Marlboro Menthol Gold Pack 100's
 Marlboro Menthol Blue Pack
 Marlboro Menthol Blue Pack 100's
 Marlboro Menthol Silver Pack
 Marlboro Menthol Silver Pack 100's
 Marlboro 72's
 Marlboro 72's Blue Pack
 Marlboro 72's Green Pack
 Marlboro 72's Gold Pack
 Marlboro 72's Silver Pack
 Marlboro Silver Pack
 Marlboro Silver Pack 100's

New Pack Available In

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The following packings will remain unchanged:

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|-------------------|------------------------|---|--|
| Marlboro* | Marlboro Menthol 100's | Marlboro Blend No. 54 100's | Marlboro Special Blend (Gold Pack) 100's |
| Marlboro 100's* | Marlboro Smooth | Marlboro Special Blend (Red Pack) | Marlboro Virginia Blend |
| Marlboro 25's | Marlboro Smooth 100's | Marlboro Special Blend (Red Pack) 100's | Marlboro Virginia Blend 100's |
| Marlboro Menthol* | Marlboro Blend No. 54 | Marlboro Special Blend (Gold Pack) | Marlboro Blend No. 27* |

*Available in Box and Soft Pack