

Lorillard, Inc.

Ronald S. Milstein
Senior Vice President,
Legal and External Affairs,
General Counsel and Secretary

(336) 335-7718
Fax (336) 335-7707

February 18, 2010

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

Re: Use of Tobacco Marketing Descriptors to Convey Modified Risk (FDA-2010-N-0020)

Dear Sir or Madam:

Lorillard Tobacco Company (Lorillard) appreciates FDA's solicitation of public comments in order to develop guidance that will help tobacco product manufacturers understand the meaning of the term "similar descriptors" in § 911(b)(2)(A)(ii) of the Food, Drug and Cosmetic Act (FDCA). However, the notice suggests that FDA may be contemplating an overbroad approach that prohibits no misleading, constitutionally protected product information.

I. The Role of Colors, Images and Descriptors in Tobacco Product Branding

Tobacco companies, like manufacturers of any other legal product, must be able to communicate information about their products to adult consumers. All major tobacco companies offer consumers multiple brands and sub brands, each of which provides consumers with unique attributes. Consumers select products according to their own taste preferences and generally have strong brand loyalty. As with any consumer product, consumers need to be able to distinguish among brands and sub brands in order to obtain their preferred product.

Any distinguishing visual feature of product packaging, labeling or advertising – whether it is a letter, number, color, logo, word, or other descriptor – could conceivably be characterized as conveying information about that product in comparison to similar products, including the

potential health risks of the product. But distinguishing visual characteristics alone do not demonstrate that the manufacturer is attempting to mislead consumers or convey a message about the health or risk of products. Nor do they mean that consumers are purchasing a product based on a mistaken impression about the product's health risks. Instead, product branding, colors, logos, and other descriptors are intended to promote brand awareness and allow consumers to purchase products with the attributes they prefer.

Lorillard has traditionally used different colors, logos, and branding to distinguish among brands and sub brands that each provide consumers with a unique taste experience. None of these features are intended to imply that any brand or sub brand is a reduced risk product. Rather, these features are necessary to communicate the taste and attributes of the cigarette to consumers. Banning distinguishing features in tobacco packaging, labeling and advertising would result in consumer confusion, with no countervailing improvement in the public health.

II. The Constitution Limits FDA's Authority to Restrict Product Descriptors

Commercial speech is protected by the First Amendment to the Constitution, as it "not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information." *Central Hudson Gas & Electric Corp v. Public Service Commission*, 447 U.S. 557, 563 (1980). This principle applies no less to commercial expression regarding tobacco products than to any other product that is legal for adults. *See Lorillard v. Reilly*, 533 U.S. 525, 564 (2001) ("tobacco retailers and manufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information about tobacco products."). Thus, a United States District Court recently decided in the case of *Commonwealth Brands, Inc. et al v. United States* that the ban on using color or graphics in most tobacco labeling and advertising, which was to be instituted soon by the Family Smoking Prevention and Tobacco Control Act (FSPTCA), is unconstitutional.

If the First Amendment means anything, it means that the government cannot simply declare categories of communication illegal without a compelling justification. There is no public health justification for depriving adult consumers of needed information about the brand

and attributes of tobacco products that they wish to purchase. If color and graphics cannot be banished from advertising, despite narrow exceptions for advertising in “adult-only” venues, then certainly color cannot be banished from product packaging.

Moreover, the Government may not restrict commercial speech based on the mere perception or possibility that consumers might be misled. *See Ibanez v. Florida Department of Business & Prof. Regulation*, 512 U.S. 136, 146 (1994) (“If the protections afforded commercial speech are to retain their force, we cannot allow rote invocation of the words ‘potentially misleading’ to supplant the [Government’s] burden to demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.”) (internal citations omitted); *Washington Legal Found. v. Henney*, 56 F. Supp. 2d 81, 85 (D.D.C. 1999) (“The FDA may not restrict speech based on its perception that the speech could, may, or might mislead.”) FDA must demonstrate empirical evidence that a descriptor is misleading and that disclaimers cannot correct for this potential. *See Pearson v. Thompson*, 141 F. Supp.2d 105, 112 (D.D.C. 2001) (Pearson III) (FDA “must demonstrate with empirical evidence that disclaimers ... would bewilder consumers and fail to correct for deceptiveness.”).

To the extent that there is any concern that a particular color implicitly communicates something about a tobacco product’s risk, there are other means for FDA to address this potential misimpression. For example, Lorillard has long placed on each pack of its “Light” cigarettes the following statement: “**Light cigarettes do not present a reduced risk of harm.**” In the near future, Lorillard will place a similar statement (without the term “light”) on every pack of cigarettes – regardless of brand or subbrand. Disclaimers such as this are demonstratively less burdensome means for achieving the government’s goal of ensuring that consumers are not misled regarding the relative risks of tobacco products by colors or other descriptors.

Attempts to define *some* colors as impermissible would also fail constitutional review because it would “provide only ineffective or remote support for the government’s purpose.” *Central Hudson* at 564. The notice suggests that FDA might consider banning “colors like white, silver or pastels,” yet there is no clear line between white and ivory, silver and gray, or between pastels and non-pastels. If FDA were to devise some definition of forbidden colors that

avoided unconstitutional vagueness, there would still be a spectrum of permissible colors that consumers might perceive as representing varied risk. Attempts to define permissible and impermissible colors would be an indirect and ineffective means for correcting any misperceptions of color, thus failing to demonstrate “a reasonable fit between the means and ends of the regulatory scheme” as required by *Central Hudson*. See also *Lorillard v. Reilly* at 564-567 (striking down prohibitions on outdoor advertising within 1,000 feet of a school or playground and indoor advertising less than 5 feet above the ground as insufficiently tailored to protect communication with adults while preventing advertising targeted at children).

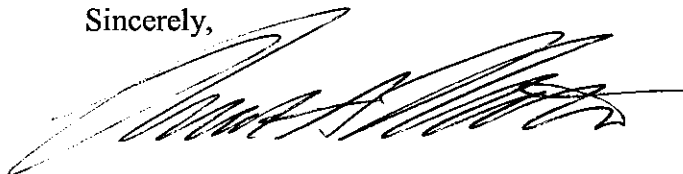
Finally, a ban on colors on packaging would exceed FDA’s authority and violate Congressional intent. FDCA § 900(2) defines “brand” as “a variety of tobacco product distinguished by the tobacco used, tar content, nicotine content, flavoring used, size, filtration, packaging, logo, registered trademark, brand name, *identifiable pattern of colors*, or any combination of such attributes.” In addition, the 1996 Rule that FDA must repromulgate pursuant to Section 102(a) of FSPTCA expressly provides that companies can continue to use colors in packaging. 21 C.F.R. § 897.30(c). Thus, Congress clearly intended that color would continue to play a prominent role in the packaging and branding of cigarette products after FSPTCA was enacted.

III. Conclusion

There may always be some who allege that any distinguishing visual feature on a tobacco product implicitly conveys health risk information about that product. However, product packaging for all types of products, including tobacco products, is designed to differentiate products and to enable consumers to quickly identify the products with the attributes they prefer. Tobacco product manufacturers use a variety of packaging attributes, including color and logos, to communicate the different tastes and characteristics of products to their consumers. Consumers must be able to distinguish among brands and subbrands. This is why other countries that have banned words such as “light” that imply modified risk, including Europe and Canada, continue to permit the use of package color and other taste descriptors.

The FSPTCA provides that “light,” “mild,” and “low,” imply a lower health risk, and therefore may not be used on tobacco product packaging unless their modified risk claims have received preapproval from FDA. Lorillard is prepared to fully comply with these limitations. But FSPTCA does not – and should not – be used to give FDA unlimited authority to ban any type of speech it wants. Lorillard has a constitutional right to communicate with its customers, and consumers have a right to receive such information.

Sincerely,

A handwritten signature in black ink, appearing to read 'Ronald S. Milstein', written in a cursive style.

Ronald S. Milstein