Letter to Philip Morris USA, Inc., Marketing Marlboro Lights Cigarettes with an Onsert

Food and Drug Administration
Center for Tobacco Products
9200 Corporate Boulevard
Rockville MD 20850-3229

June 17, 2010

Denise F. Keane
Executive Vice President
and General Counsel
Altria Group, Inc.
6601 W. Broad Street
Richmond, Virginia 23230

Dear Ms. Keane:

The Food and Drug Administration (FDA) is aware that Philip Morris USA, Inc., is marketing its Marlboro Lights cigarettes with an onsert, which we understand is currently attached to individual packs of Marlboro Lights cigarettes sold to consumers. The onserts include the following statements:

- YOUR MARLBORO LIGHTS PACK IS CHANGING.
- BUT YOUR CIGARETTE STAYS THE SAME.
- IN THE FUTURE, ASK FOR 'MARLBORO IN THE GOLD PACK.'

Under section 911 of the Federal Food, Drug, and Cosmetic Act (FFDCA or the Act) (21 U.S.C. § 387k), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31), no person may introduce or deliver for introduction into interstate commerce any modified risk tobacco product without an FDA order in effect under section 911(g) of the FFDCA (21 U.S.C. § 387k(g)). A "modified risk tobacco product" includes, among other things, a tobacco product where the product's label, labeling or advertising uses the descriptors "light," "mild," or "low," or similar descriptors. FFDCA § 911(b)(2) (21 U.S.C. § 387k(b)(2)).

The provision regarding use of "light," "mild," or "low," or similar descriptors takes effect on June 22, 2010, with respect to the manufacture of tobacco products for sale or distribution. *Id*. at § 911(b)(3) (21 U.S.C. § 387k(b)(3)). Manufacturers, however, may no longer introduce any such products into domestic commerce on or after July 22, 2010, irrespective of the date of manufacture. *Id*. After the effective date, the introduction of any tobacco product using "light," "mild," "low," or similar descriptors into interstate commerce, without an FDA order in effect under section 911(g) (21 U.S.C. § 387k(g)), is a prohibited act. *Id*. at §§ 301(a) & (pp) (21 U.S.C. §§ 331(a) & (pp)). Such products also are adulterated under section 902(8) of the FFDCA (21 U.S.C. § 387b(8)).

In enacting the Tobacco Control Act, Congress found that "many smokers mistakenly believe that 'low tar' and 'light' cigarettes cause fewer health problems than other cigarettes." Tobacco Control Act § 2(38). FDA is concerned that the statements included in the onserts attached to the individual packs of Marlboro Lights may perpetuate the mistaken beliefs associated with your "light" cigarettes when marketed as Marlboro in the gold pack. By stating that only the packaging is changing, but the cigarettes will stay the same, the onsert suggests that Marlboro in the gold pack will have the same characteristics as Marlboro Lights, including any mistaken attributes associated with the "light" cigarettes.

Although the onsert includes some disclaimer language, Congress found that disclaimers have been ineffective in eliminating mistaken beliefs regarding "low tar" and "light" cigarettes. Tobacco Control Act §§ 2(41) and (42). We are concerned that the disclaimers in your onsert would likewise be ineffective in mitigating any potential mistaken beliefs that may be perpetuated by your onsert.

In light of these concerns, FDA requests and therefore you are to submit, in accordance with section 904(b) of the FFDCA (21 U.S.C. § 387d(b)), the following documents in your possession, custody, or control, including documents in the possession of any agents of Philip Morris:

1. All documents referring or relating to any onsert or other written materials for dissemination to consumers concerning the marketing or sale of Marlboro in the gold pack or any change in the packaging of Marlboro Lights, including all materials about market strategies, themes, concepts, creative recommendations, and dissemination strategies or plans.
2. All documents referring or relating to marketing research, regardless of whether qualitative, empirical, or otherwise, concerning Marlboro in the gold pack, including the onserts provided with the Marlboro Lights packs. Such documents include, but are not limited to, any documents relating to:

a. consumers' concerns, beliefs, perceptions, understandings, thoughts or impressions about:

i. the marketing or sale of Marlboro in the gold pack;
ii. any onsert included on or with Marlboro Light packages;

iii. any other materials for dissemination to consumers concerning the marketing of Marlboro in the gold pack;
iv. any correlations between the color or word "gold" and taste, the yields of tar, nicotine, or other tobacco constituents, or health risk or product harm;

b. messages, communications, or beliefs intended to be conveyed about the marketing or sale of Marlboro in the gold pack or any onserts included on or with Marlboro Light packages or other written materials for dissemination to consumers concerning the marketing or sale of Marlboro in the gold pack.

3. All documents referring or relating to any written materials disseminated to any distributor or retailer concerning messages or communications these distributors or retailers should convey to consumers concerning the marketing or sale of Marlboro in the gold pack or any onsert included on or with Marlboro Lights packages.

For purposes of these requests, the word "documents" shall include all non-identical written, typed, printed, transcribed, taped, recorded, filmed, computer-stored, or graphic materials, including but not limited to correspondence, memoranda, reports, electronic communications and any attachments thereto, charts, tabulations, images, or graphs.

All documents requested above are to be received by the Center for Tobacco Products (CTP) no later than July 30, 2010. If you anticipate difficulties with this document production, please contact CTP within 15 days of receipt of this letter so that we may assist you in resolving any technical difficulties you may have and facilitate compliance with the above timeline.

The failure to provide information requested by FDA in accordance with section 904(b) of the Act is a violation of the Act and subject to regulatory and enforcement action by FDA. FFDCA §§ 301(q)(1)(B) & 903(a)(10)(A) (21 U.S.C. §§ 331(q)(1)(B) & 387c(a)(10)(A)).

Consistent with applicable statutes and regulations, the confidentiality of trade secret and confidential commercial information submitted to FDA pursuant to this request will be preserved.

We encourage you to submit your response in an electronic format on CD-ROM or DVD. Please see the enclosed document for guidance in preparing your electronic submission to FDA.

Your submission should be prominently identified with the label [FDA 06-2010 – Onsert Request] and sent to the following address:

Center for Tobacco Products
Food and Drug Administration
Attn: Document Control Center

9200 Corporate Boulevard
Rockville, Maryland 20850

We look forward to your prompt response. If you have questions regarding this document request, please contact:

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Sincerely,
/s/
Lawrence R. Deyton, M.S.P.H., M.D.
Director, Center for Tobacco Products