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Altria Client Services

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

Re: **Docket No. FDA–2014–N–0189 (RIN 0910-AG38) (79 Fed. Reg. 23142) (April 25, 2014) -- Comments on "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products"**

Altria Client Services, Inc. ("ALCS"), on behalf of Philip Morris USA, Inc. ("PM USA"),[1] appreciates the opportunity to comment on the Food and Drug Administration's ("FDA") Notice of Proposed Rulemaking ("Proposed Rule") on the deeming of tobacco products subject to the Federal Food, Drug, and Cosmetic Act ("FDCA"), as amended by the Family Smoking Prevention and Tobacco Control Act ("FSPTCA").[2]

Both cigarette tobacco and roll-your-own tobacco currently are subject to the FDCA, as amended by the FSPTCA, but neither carries a federally mandated health warning. We believe that cigarette tobacco and roll-your-own tobacco should bear the same health warnings as cigarettes.

FDA's Proposed Rule includes the following definitions, which are identical to those added to the FDCA by the FSPTCA:

> *Cigarette tobacco* means any product that consists of loose tobacco that is *intended for use by consumers in a cigarette.* Unless otherwise stated, the requirements applicable to cigarettes under this chapter also apply to cigarette tobacco.[3]

[1] PM USA is a wholly-owned subsidiary of Altria Group, Inc. ("Altria"). ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" and "our" are used throughout to refer to PM USA.
[2] 79 Fed. Reg. 23142 (April 25, 2014).
[3] 79 Fed. Reg. 23203 (emphasis added).

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> *Roll-your-own tobacco* means any tobacco product, which, because of its appearance, type, packaging, or labeling, is suitable for use and likely to be offered to, or purchased by, consumers *as tobacco for making cigarettes*.[4]

The difference between the two defined tobacco product categories is not obvious. Both comprise tobacco purchased to make cigarettes.

In its Proposed Rule, FDA would require the display of the following health warning on cigarette tobacco and roll-your-own tobacco product packages and in advertisements: "WARNING: This product contains nicotine derived from tobacco. Nicotine is an addictive chemical."[5] FDA does not propose that these products bear the four warnings currently required by the Federal Cigarette Labeling and Advertising Act ("FCLAA") for cigarettes.[6]

FDA explained that its rationale for requiring the proposed warning is "to help consumers better understand and appreciate the addictiveness of tobacco product use by adding warnings on packages and in advertisements for all covered tobacco products and those products not already requiring a health warning under Federal law or regulation (i.e., cigarette tobacco and roll-your-own tobacco)."[7] FDA noted that it "is taking this action to address the public health concerns associated with the use of tobacco products"[8] and observed that "the requirements of this subsection would not apply to tobacco products for which health warnings are already required by law or regulation. Specifically, health warnings for cigarette packages are already required by section 4(a) of FCLAA (15 U.S.C. 1333(a))."[9] Inexplicably, FDA then proposes a different warning for cigarette tobacco, despite defining its intended use and the intended use of roll-your-own tobacco for making cigarettes, and despite noting in the cigarette tobacco definition that "[u]nless otherwise stated, the requirements applicable to cigarettes under this chapter also apply to cigarette tobacco." The Proposed Rule does "otherwise state," but without providing FDA's rationale.

Cigarettes and the loose tobacco used for making cigarettes, whether defined as "cigarette tobacco" or "roll-your-own tobacco," are within the same tobacco product category. Warnings should, as a matter of principle and policy, be uniform for all products in the same tobacco product category. Tobacco products in the same category can differ in numerous respects. But when the science and evidence identifies a health risk common to all products in the category, health warnings addressing that risk should convey a uniform message. The presence of non-uniform, inconsistent, or conflicting warnings for tobacco products in the same category will confuse consumers and could erroneously signal a difference in health risk among the products. Congress wanted to prevent consumer confusion about differences in risk among tobacco products within the same tobacco product category. That was a primary reason why Congress

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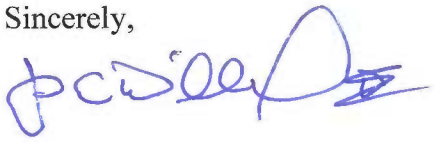
[4] 79 Fed. Reg. 23204 (emphasis added).
[5] 79 Fed. Reg. 23162.
[6] *See* 15 U.S.C. § 1333.
[7] 79 Fed. Reg. 23166.
[8] 79 Fed. Reg. 23142.
[9] 79 Fed. Reg. 23179.

prohibited manufacturers from making modified risk claims absent an FDA determination that certain requirements were satisfied.[10]

FDA should act to prevent consumer confusion by requiring all tobacco products in the same category to include uniform warnings for risks that are common to all in the category and should work to harmonize applicable warning requirements. In this instance, FDA should conform the proposed health warnings for cigarette tobacco and roll-your-own tobacco with the currently federally mandated health warnings for cigarettes required by section 4(a) of FCLAA (15 U.S.C. 1333(a)) and with health warnings that FDA mandates for cigarettes in the future. Compliance with FDA's warning requirement should satisfy the warnings required by Section 903(a)(8) of the FSPTCA.

We appreciate the opportunity to submit this comment and hope FDA will consider it in developing its final rule.

Sincerely,



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[10] *See* FSPTCA § 911.