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Mr. Donald S. Clark
Federal Trade Commission
Office of the Secretary
Room H-113 (Annex J)
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Re: Tobacco Reports: Paperwork Comment, FTC File No. P054507

Dear Mr. Clark:

On behalf of Philip Morris USA, Inc. ("PM USA"), Altria Client Services ("ALCS") submits this letter in response to the Comment Request published by the Federal Trade Commission ("the FTC") in the Federal Register on November 25, 2011, with respect to proposed information requests to tobacco manufacturers.[1] This response is regarding the FTC's proposal to continue making information requests for average cigarette tar, nicotine and carbon monoxide ratings.

In comments on the FTC's 2008 proposal to extend making information requests through January 31, 2012, PM USA stated that "[i]f the FTC were to rescind its guidance that factual statements of cigarette tar and nicotine yields based on the Cambridge Method generally do not violate the FTC Act, PM USA would question the FTC's need to continue collecting such information."[2] In fact, the FTC rescinded its guidance in December 2008 and Congress enacted the Family Smoking Prevention and Tobacco Control Act ("FSPTCA") in 2009 to establish a comprehensive framework for tobacco regulation that vested authority in the Food and Drug Administration ("FDA").

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[1] PM USA is a wholly-owned subsidiary of Altria Group, Inc. Altria Client Services ("ALCS") is making this submission on behalf of PM USA. ALCS provides certain services, including regulatory affairs, to the Altria family of companies.

[2] *See* http://www.ftc.gov/os/comments/tobaccoreportspra/537030-00001.pdf

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In doing so, Congress recognized that "[n]either the FTC nor any other Federal agency except the FDA possesses the scientific expertise needed to implement effectively all provisions of the FSPTCA."[3] The FTC had previously repeatedly recommended that Congress transfer authority for cigarette testing to one of the public health agencies.[4]

In its November 25, 2011 Comment Request, FTC states that it "believes it is important to continue collecting [cigarette tar, nicotine and carbon monoxide] data, which researchers and policymakers use to track trends over time."[5] In light of the authority Congress has given FDA regarding constituent testing, reporting and disclosure to the public, and the rescinding by FTC of its guidance, further collection by FTC of smoke constituent data will soon be superfluous.[6]

FSPTCA Section 904, for example, requires FDA to establish a list of all constituents, including smoke constituents, identified by FDA as harmful or potentially harmful to health ("HPHCs") in each tobacco product by brand and by quantity in each brand and sub-brand.[7] Thereafter, manufacturers will be required to test and report to FDA the HPHCs and their quantities in each brand and sub-brand.[8] FDA is also required to publish the list of HPHCs "in a format that is understandable and not misleading to a lay person" and to submit a report to Congress on research into consumer understanding of HPHCs, and to recommend whether annual publication of the HPHC list should be continued or modified.[9] Finally, FSPTCA Section 915(a) requires FDA to promulgate regulations that "require testing and reporting of . . . smoke constituents, by brand and sub-brand that [FDA] determines should be tested to protect the public health."[10]

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[3] FSPTCA, Section 2(45).

[4] *See*, e.g., Prepared statement of William E. Kovacic, a Commissioner at the FTC Before the Committee on Commerce, Science and Transportation, United States Senate November 13, 2007. ("[I]n its July 1999 'Report to Congress for 1997 . . .' the FTC recommended that Congress consider giving authority over cigarette testing to one of the federal government's science-based public health agencies. The FTC renewed that recommendation in 2003 in testimony before Congress, and the FTC reiterates that recommendation again today").

[5] 76 Fed. Reg. 47187, 47188, n.1.

[6] FTC requests for other product attributes (e.g., cigarette length) will similarly duplicate what PM USA provides to FDA.

[7] FSPTCA, Section 904(e), 21 U.S.C. §387d(e). Establishment of the HPHC list is well under way, with FDA recently requesting public comment on its proposed list. See "Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke" 76 Fed. Reg. 50226 (August 12, 2011).

[8] FSPTCA, Section 904(a)(3), 21 U.S.C. §387d(a)(3).

[9] FSPTCA, Section 904(d)(1) and (2), 21 U.S.C. §387d(d)(1) and (2).

[10] FSPTCA, Section 915(b)(1), 21 U.S.C. §387o(b)(1).

FDA has recommended use of the FTC/ISO method for testing and reporting cigarette smoke constituent data, which will allow for the continued tracking of trends over time. [11]

PM USA respectfully requests that the FTC reduce the burden of duplicative reporting obligations on cigarette manufacturers by ceasing to require reporting of cigarette smoke constituent data once FDA acts to do so.

Sincerely,

James E. Dillard III

[11] See "Draft Guidance for Industry: Applications for Premarket Review of New Tobacco Products" at p. 17 (September, 2011). The Constituents Subcommittee of FDA's Tobacco Products Scientific Advisory Committee ("TPSAC") had recommended that FDA adopt the FTC/ISO method for testing and reporting of constituents on the HPHC list because its historical use permits trend analysis over time – precisely the justification cited by FTC for continuing to request such information from cigarette manufacturers. See July 7, 2010 Transcript of the Tobacco Products Constituents Subcommittee of the TPSAC at 145, 158.