

James E. Dillard III Senior Vice President Regulatory Affairs

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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 ("FTC") in the Federal Register on August 13, 2014, with respect to proposed information requests to tobacco manufacturers. This response is regarding FTC's proposal to continue making information requests for average cigarette tar, nicotine and carbon monoxide ratings, and its request for comments on whether FTC should expand the information requests to once again require testing and reporting of "tar," nicotine and carbon monoxide yields.

In comments on FTC's 2011 proposal to extend making information requests through January 31, 2015, ALCS noted:

[T]he FTC rescinded its guidance [that factual statements of cigarette "tar" and nicotine yields based on the Cambridge Method generally do not violate the FTC Act] in December 2008 and Congress enacted the Family Smoking

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 Letter from James E. Dillard to Donald S. Clark of Dec. 21, 2011, "Tobacco Reports: Paperwork Comment," FTC File No P054507.

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"). 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." The FTC had previously repeatedly recommended that Congress transfer authority for cigarette testing to one of the public health agencies.

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 is superfluous.⁵

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. Thereafter, manufacturers are required to test and report to FDA the HPHCs and their quantities in each brand and sub-brand. 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. 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."

In its most recent response to FTC compulsory process and transmission of data including constituent data for each cigarette brand style "for which they are available," PM USA explained why the FTC collection is superfluous:

On March 30, 2012, FDA published its list of [HPHCs] in tobacco products and tobacco smoke and required testing and reporting of the constituents by September 22, 2012. PM USA conducted testing and submitted the required HPHC data, which included nicotine and CO, by the deadline . . . While tar was not included in the HPHC data required by FDA, PM USA tested for tar in its process for testing for the HPHC data. 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.").

⁵FTC requests for other product attributes (e.g., cigarette length) similarly duplicate what PM USA provides to FDA. ⁶ FSPTCA, Section 904(a)(3), 21 U.S.C. §387d(a)(3).

⁷ FSPTCA, Section 904(d)(1) and (2), 21 U.S.C. §387d(d)(1) and (2). See, Report to Congress, Progress and Effectiveness of the Implementation of the Family Smoking Prevention and Tobacco Control Act, U.S. Department of Health and Human Services Food and Drug Administration, May 23, 2013.

⁸ FSPTCA, Section 915(b)(1), 21 U.S.C. §387o(b)(1).

⁹ July 8, 2014 transmittal from Shira D. Modell, FTC Division of Advertising Practices, for Order to File Special Report for Calendar Year 2013.

October 28, 2013, transmittal from Denise F. Keane for response to Order to File Special Report; FTC File No. P114508.

Given the fact that Congress placed primary authority and responsibility for smoke constituent testing, reporting, research and communication in FDA, PM USA respectfully submits that FTC should no longer request that the manufacturers report cigarette smoke constituent data for each brand style "for which they are available." PM USA further submits that FTC should certainly not expand its future requests for cigarette smoke constituent data to include generation and reporting of such smoke constituent data specifically for FTC.

If FTC nonetheless decides to continue and even expand its requests for information, FTC should request cigarette smoke constituent data from all industry members and provide ample time to supply the requested information. It would be inequitable to impose that supplemental burden only on the major manufacturers and doing so would result in an incomplete data set.

Sincerely,

James E. Dillard III

¹¹ July 8, 2014, transmittal from Shira D. Modell, FTC Division of Advertising Practices, for Order to File Special Report for Calendar Year 2013.