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Altria Client Services

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October 6, 2017

Mr. Donald S. Clark
Federal Trade Commission
Office of the Secretary
Suite CC–5610 (Annex J)
600 Pennsylvania Avenue NW.
Washington, DC 20580

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

Dear Mr. Clark:

On behalf of Philip Morris USA Inc. ("PM USA") and U.S. Smokeless Tobacco Company ("USSTC"), Altria Client Services ("ALCS")[1] submits this letter in response to the Comment Request published by the Federal Trade Commission ("FTC") in the Federal Register on August 10, 2017, with respect to information requests to cigarette and smokeless tobacco manufacturers.

ALCS believes that the FTC's proposed information collection is no longer necessary in light of the Food and Drug Administration's ("FDA's") extensive, active regulatory authority over tobacco products under the Family Smoking Prevention and Tobacco Control Act ("FSPTCA" or "Act").[2] Prior to enactment of the Act, FTC's oversight of the tobacco industry was limited to product advertising and promotion. FTC annually would collect information in order to publish periodic reports on cigarette and smokeless tobacco product sales and marketing expenditures.[3] In 2009, Congress established a comprehensive framework for tobacco product regulation that vested broad authority in FDA to regulate the manufacture, marketing, sale and distribution of tobacco products. In doing so, Congress recognized that "[n]either the FTC nor any other

[1] PM USA and USSTC are wholly owned subsidiaries of Altria Group, Inc. ("Altria"). Altria Client Services LLC provides certain services, including regulatory affairs, research and development, and regulatory sciences to the Altria family of companies.
[2] Pub. L. 111-31 (June 22, 2009), codified primarily at 21 U.S.C. § 387 *et seq.*
[3] *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) (concluding that FDA did not have the authority to regulate tobacco products absent further action by Congress).

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Federal agency except the FDA possesses the scientific expertise needed to implement effectively all provisions of the FSPTCA."[4]

Since the FSPTCA took effect, FDA has issued numerous regulations, orders and guidance documents addressing product labeling and marketing, and has collected a broad range of information from tobacco manufacturers, including product lists, labels, and advertisements. For example, manufacturers must submit to FDA all labeling for tobacco products, along with a representative sampling of advertisements, and, on request by FDA, all advertisements for a particular tobacco product.[5] Manufacturers must provide biannual reports listing new products, discontinued products, and products back in production.[6] Manufacturers must also test and submit information on ingredients, compounds, additives, harmful or potentially harmful constituents, and also submit documents relating to health, toxicological, behavioral, or psychologic effects of current or future tobacco products.[7]

FDA has used this information to actively enforce the requirements of the Act. FDA has monitored promotional activities, taken enforcement actions, tracked tobacco product ingredient and constituent levels, and proposed product requirements.[8] FDA is implementing a plan that it developed to enforce restrictions on promotion and advertising of cigarettes to youth, as required by the FSPTCA.[9]

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[4] FSPTCA Section 2(45). FTC itself recommended that Congress transfer authority for cigarette testing to a "science-based public health agenc[y]." Prepared statement of Commissioner William E. Kovacic Before the Committee on Commerce, Science and Transportation, United States Senate (Nov. 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] FSPTCA Section 905(i)(1), 21 U.S.C. § 387e(i)(1). The FSPTCA transferred primary authority over the labeling of cigarettes and smokeless tobacco products from FTC to FDA, including authority for approving warning statement rotation plans. FSPTCA Section 201 (amending 15 U.S.C. § 1333(c)(2)); FSPTCA Section 204 (amending 15 U.S.C. § 4402(b)(3)(C)); *see also* FTC, Memorandum to Potential Cigarette Manufacturers and Importers (Mar. 21, 2011), https://www.ftc.gov/public-statements/2011/03/memorandum-potential-cigarette-manufacturers-importers; FTC, Per Congress, FTC Rescinds Regulations on Smokeless Tobacco, Authority to Move to HHS (Sep. 24, 2010), https://www.ftc.gov/news-events/press-releases/2010/09/congress-ftc-rescinds-regulations-smokeless-tobacco-authority.

[6] FSPTCA Section 905(i)(3), 21 U.S.C. § 387e(i)(3).

[7] FSPTCA Section 904(a)(4), 21 U.S.C. § 387d(a)(4).

[8] *See, e.g.*, FDA, Proposed Tobacco Product Standard for N-nitrosonornicotine Level in Finished Smokeless Tobacco Products (Jan. 2017), https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm537091.htm; FDA, FDA's New Plan for Tobacco and Nicotine Regulation (July 28, 2017), https://www.fda.gov/tobaccoproducts/newsevents/ucm568425.htm (discussing FDA's intent to establish a tobacco product standard for nicotine content in cigarettes); FDA, FDA Enforcement Statistics Summary Fiscal Year 2016, https://www.fda.gov/downloads/ICECI/EnforcementActions/UCM540606.pdf; FDA, Warning Letter to ITG Brands, LLC (Aug. 27, 2015), https://www.fda.gov/iceci/enforcementactions/warningletters/2015/ucm459779.htm (addressing cigarette advertising and marketing practices).

[9] *See* FDA, Enforcement Action Plan for Promotion and Advertising Restrictions (Oct. 2010), https://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM227882.pdf.

FDA has taken these steps in the context of significantly declining smoking rates.[10] Nevertheless, to the extent warranted in the future, FDA has the authority to require tobacco product manufacturers to submit additional information to FDA, including financial information relating to marketing practices, and to promulgate additional regulations regarding advertising and promotion of tobacco products.[11]

In light of the authority Congress has given to FDA and the regulatory actions FDA has taken to date, FTC's proposed information requests are now superfluous. In addition to being unnecessary in light of FDA's activities, the requests impose unnecessary burdens and costs on manufacturers. That is contrary to executive policy requiring FTC to alleviate unnecessary regulatory burdens and consider the impact of its activities on regulated parties.[12]

FTC's most recent information requests illustrate these concerns. FTC continues to ask PM USA for information about the average cigarette tar, nicotine and carbon monoxide yields of its cigarettes, even though PM USA already conducted testing and submitted the required harmful and potentially harmful constituent data to FDA.[13] FTC also continues to ask PM USA and USSTC for data on their sales and marketing expenditures. For decades, the companies have complied with those requests without objection. But now, rather than curtail those requests to eliminate needless burdens, FTC has expanded the requests to seek information on expenditures from parent companies that do not sell or advertise tobacco products.[14] These most recent requests seek not only information that the companies already produce to FDA, but also

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[10] *See* Centers for Disease Control and Prevention (CDC), Current Cigarette Smoking Among Adults in the United States (Dec. 1, 2016), https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm; CDC, Morbidity and Mortality Weekly Report (MMWR), Tobacco Use Among Middle and High School Students – United States, 2000-2009 (Aug. 27, 2010), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5933a2.htm; FDA, Youth Tobacco Use: Results from the 2016 National Youth Tobacco Survey (Sep. 20, 2017), https://www.fda.gov/TobaccoProducts/PublicHealthEducation/ProtectingKidsfromTobacco/ucm405173.htm.

[11] *See* FSPTCA Section 904(b)(3) (financial information relating to marketing practices); Section 906(d) (regulations restricting the advertising and promotion of tobacco products); Section 920(b) (regulations for the establishment and maintenance of records).

[12] *See, e.g.*, Executive Order, Presidential Executive Order on Enforcing the Regulatory Reform Agenda (Feb. 24, 2017), https://www.whitehouse.gov/the-press-office/2017/02/24/presidential-executive-order-enforcing-regulatory-reform-agenda; Executive Order, Presidential Executive Order on Reducing Regulation and Controlling Regulatory Costs (Jan. 30, 2017), https://www.whitehouse.gov/the-press-office/2017/01/30/presidential-executive-order-reducing-regulation-and-controlling.

[13] *See* FDA, Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List (April 2012), https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm297786.htm; FDA Notice, Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 12,501 (Mar. 9, 2016). For this reason, ALCS has previously noted that FTC should no longer ask manufacturers to report cigarette smoke constituent data. Letter from James E. Dillard to Donald S. Clark of Oct. 14, 2014, "Tobacco Reports: Paperwork Comment," FTC File No. P054507; Letter from James E. Dillard to Donald S. Clark of Dec. 21, 2011, "Tobacco Reports: Paperwork Comment," FTC File No. P054507.

[14] *See* FTC, Order To File Special Report To Collect Information Concerning Sales and Practices and Methods of Advertising and Promotion of Cigarettes Employed In the United States During Calendar Year 2016 (Generic Text Version) (May 2017), https://www.ftc.gov/reports/order-file-special-report-collect-information-concerning-sales-practices-methods-0.

information unrelated to the advertising and promotion of tobacco products.[15] Not only is this overbroad but it is also to no avail. FTC does not have broad regulatory authority over tobacco products. FDA, as the agency with authority, should be collecting the information it requires.

In sum, given that Congress placed primary authority and responsibility for tobacco product labeling, advertisements, testing, reporting, research and communication in FDA, ALCS respectfully requests that the FTC reduce the burden of duplicative reporting obligations on cigarette and smokeless tobacco manufacturers by ceasing the proposed information requests.

Sincerely,

[15] *See id.* at 6-8 (seeking information already submitted to FDA, such as (a) cigarette design data, including cigarette length, style, flavor, and filter type; (b) constituent data, including nicotine, carbon monoxide, and tar; (c) lists of cigarettes first sold or discontinued in 2016; and (d) lists of other product information, including brand varieties, pack size, and package type).