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Altria Client Services

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Via Electronic Submission
https://www.reginfo.gov/public/do/PRAMain

Re: Food and Drug Administration [Docket No. FDA–2012–D–0429] Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Meetings With Industry and Investigators on the Research and Development of Tobacco Products

Altria Client Services LLC ("ALCS"), on behalf of Philip Morris USA Inc. ("PM USA"), U.S. Smokeless Tobacco Company LLC ("USSTC"), and Helix Innovations LLC ("Helix"),[1] submits these comments to the U.S. Food and Drug Administration ("FDA" or "Agency") in response to the above captioned Information Collection Request ("Request").

FDA and other public health authorities agree that there is a broad "continuum of risk" among tobacco products, with cigarettes at the highest end of that spectrum and complete cessation at the lowest end.[2] In fact, when the FDA announced its Comprehensive Plan in 2017, then-FDA Commissioner Gottlieb stated FDA policy should be used as a vehicle to "move addicted smokers down that continuum of risk to these less harmful [innovative] products."[3] We agree.

Our vision is to responsibly lead the transition of adult smokers to a smoke-free future. We are working to expand awareness and availability of our smoke-free product portfolio by seeking FDA authorization to market and communicate the relative risk of these products.

The success of the Tobacco Control Act and tobacco harm reduction hinges on a regulatory framework that allows manufacturers to provide adult tobacco consumers (21+) with potentially reduced-risk tobacco products and communicate accurate health information about them. An important part of implementing an effective regulatory framework must include meaningful opportunities for manufacturers and FDA to engage in an active and productive dialogue about innovative new products that could move smokers who can't or won't quit tobacco use down the continuum of risk.

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[1] PM USA and USSTC are wholly-owned subsidiaries of Altria Group, Inc. ("Altria"). Helix is a majority-owned subsidiary of Altria Enterprises II LLC, which is a wholly-owned subsidiary of Altria. PM USA manufactures cigarettes and is licensed to sell and distribute IQOS® and HeatSticks® in the United States. USSTC manufactures smokeless tobacco products and oral tobacco-derived nicotine products. Helix manufactures oral tobacco-derived nicotine products. ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" and "our" are used throughout to refer to PM USA, USSTC, and Helix.

[2] "… we must acknowledge that there's a continuum of risk for nicotine delivery. That continuum ranges from combustible cigarettes at one end, to medicinal nicotine products at the other." Remarks by Scott Gottlieb, M.D., Protecting American Families: Comprehensive Approach to Nicotine and Tobacco. July 28, 2017. Available at https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017

[3] *Id*.

Pre-application meetings between industry and the Center for Tobacco Products ("CTP") about the research and development of tobacco products are a critical part of this process. Such early engagement can facilitate a more efficient and transparent application review process – and thereby advance tobacco harm reduction – by proactively identifying any key issues to be addressed before a manufacturer submits a product application. In the more than 10 years since FDA first issued guidance for meetings about the research and development of tobacco products ("Guidance"),[4] we have gained significant experience with these types of meetings. We offer some ideas below to improve the efficiency and effectiveness of these meetings for both manufacturers and FDA.[5]

First, meetings between FDA and tobacco product manufacturers could be more constructive. While the Guidance describes very specific meeting request and response procedures, we found that these prescribed procedures do not allow for the types of interactive conversations needed to inform research and product development of innovative tobacco products in what is still an evolving regulatory area. In our experience, meeting requests may be denied because the questions posed are considered too exploratory or not specific to the development or marketing of an individual tobacco product. We, however, find this to be a critical moment in the product development process, in which the decisions made will ultimately define the subject of future product applications. Instead, FDA should grant meetings to discuss questions related to products in early phases of product development and research. Indeed, meetings between a tobacco manufacturer and their regulator should facilitate constructive dialogue that could lead to better products and applications that meet CTP's expectations.[6] Ultimately, this could result in a more efficient product review process for both industry and CTP.

Second, effective interactions between CTP and manufacturers during early-stage product development support the Agency's public health mandate to reduce the negative health effects of tobacco use.[7] Ongoing and timely engagement between industry and FDA will help manufacturers submit well-informed product applications that in turn will reduce the need for CTP resources, questions during the review process, application review time, and even enforcement action. Such a process would also encourage industry to continue to invest in innovations that can reduce the harms of smoking.

Third, manufacturers and CTP can work together to navigate some of the novel regulatory questions that may emerge in the development of innovative smoke-free products by considering the approach used with the Emerging Technology Program ("ETP").[8] "Established in 2014, ETP is a collaborative program where industry representatives can meet with Emerging Technology Team (ETT) members to discuss, identify, and resolve potential technical and regulatory issues regarding the development and implementation of a novel technology prior to filing a regulatory submission."[9] One of the goals of ETP is to try and avoid "delays while novel regulatory challenges are considered."[10] We urge FDA to look to

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[4] Meetings with Industry and Investigators on the Research and Development of Tobacco Products (Revised*) Guidance for Industry and Investigators. Updated June 2020. Available at https://www.fda.gov/media/83420/download

[5] The Request focuses its scope on Research and Development; however, we believe there are similar opportunities to improve the meeting process for pending product applications and we urge FDA to consider these ideas in that context as well.

[6] When "meetings" are granted we have found that they may consist of only a one-way written response. We believe that a dialogue that allows conversation between a manufacturer and FDA would be more constructive for both manufacturers and FDA.

[7] FDA, About the Center for Tobacco Products (CTP). Available at https://www.fda.gov/tobacco-products/about-center-tobacco-products-ctp

[8] ETP is part of FDA's Center for Drug Evaluation and Research. *See* FDA, Emerging Technology Program. Available at https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/emerging-technology-program

[9] *Id.*

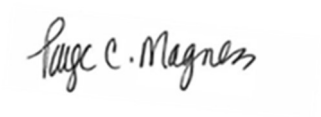
[10] *Id.*

the ETT model for ways to "encourage[] development of innovative tobacco products"[11] that support tobacco harm reduction.

Finally, meetings between industry and CTP during research and development can advance manufacturing processes and product testing methodologies, improve the quality of documentation in pre-market tobacco applications, and support industry compliance. The Center for Drug Evaluation and Research guidance on Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization[12] states that meeting opportunities will enable the participants and FDA to discuss "product or manufacturing design and development issues"[13] including those for which "the Agency has limited review or inspection experience."[14] Tobacco product developers, manufacturers and potentially CTP staff would similarly benefit from a discussion on the risk assessment and mitigation strategies, manufacturing control strategies, quality documentation and qualification of novel manufacturing processes that may one day expand from pilot to commercial scale. CTP should consider how this type of engagement could be applied to support innovative smoke-free products.

We appreciate the opportunity to share these comments and would welcome the opportunity to discuss this further.

Sincerely,



[11] FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death. July 27, 2017. Available at https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death

[12] FDA, Advancement of Emerging Technology Applications for Pharmaceutical Innovation and Modernization Guidance for Industry, September 2017. Available at https://www.fda.gov/files/drugs/published/Advancement-of-Emerging-Technology-Applications-for-Pharmaceutical-Innovation-and-Modernization-Guidance-for-Industry.pdf

[13] *Id*. at 3.

[14] *Id*. at 4.