Altria
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-2011-N-0867 (76 Fed. Reg. 77,837) (Dec. 14, 2011) – Comments on the "Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study on the Public Display of Lists of Harmful and Potentially Harmful Tobacco Constituents"

Altria Client Services Inc. ("ALCS"), on behalf of Philip Morris USA Inc. ("PM USA") and U.S. Smokeless Tobacco Company LLC ("USSTC"),[1] submits these comments on the above-captioned notice (the "Federal Register Notice").

Section 904(e) of the Family Smoking Prevention and Tobacco Control Act ("FSPTCA" or "the Act") requires the FDA to establish a list, by April 2012, of all constituents identified by FDA as harmful or potentially harmful to health (the "HPHC List") in each tobacco product, by brand and by quantity in each brand and subbrand. Section 904(d)(1) of the Act requires the FDA to make publicly available, by April 2013, this HPHC list in a format "understandable and not misleading to a lay person." The Federal Register Notice states that the Agency plans to undertake a study to examine consumer perception of potential formats for the publicly available HPHC List (the "Experimental Study").

We previously submitted written comments to the Agency on implementation of the HPHC List under Section 904.[2] To date, however, the Agency has not addressed the issues raised in our

[1] PM USA and USSTC are wholly-owned subsidiaries of Altria Group, Inc. ALCS provides certain services, including regulatory affairs and regulatory health sciences, to the Altria family of companies. "We" and "our" are used throughout these comments to refer collectively to PM USA and USSTC.

[2] *See* ALCS comments dated May 27, 2011, September 8, 2010, and August 23, 2010; an ALCS presentation by Dr. Jane Lewis during an open public hearing at the August 30, 2010 Tobacco Product Scientific Advisory Committee meeting; industry comments submitted by ALCS, R.J. Reynolds Tobacco Company, and Lorillard Tobacco Company, dated October 11, 2011 (hereafter "October 2011 Comments"); and an industry presentation titled "Preliminary Information Concerning the Establishment of a List of Harmful and Potentially Harmful Tobacco Product Constituents" delivered at the June 8-9, 2010 Tobacco Product Constituents Subcommittee meeting.

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comments or the comments of others.[3] Further, the Federal Register Notice provides only limited information on the Experimental Study. Given this, it is difficult to comment fully on the Experimental Study.

Thus, our comments address three topics:

- Purpose and format of the HPHC List;
- Inherent limitations of the HPHC List data; and
- Methodological considerations for the Experimental Study.

I. Purpose and Format of the HPHC List

The Federal Register Notice does not articulate what purpose(s) the Agency seeks to achieve through its public display of the HPHC List under Section 904. The Federal Register Notice describes only the purpose of the Experimental Study, which will "evaluate the impact of different list formats on the public's ability to understand HPHC information, and to assess the potential for certain unintended consequences resulting from exposure to the lists." It does not state what context the Agency will provide the Experimental Study participants, including how it intends study participants to use the HPHC List.

The intended purpose of the public HPHC List should guide its format, both in terms of content and presentation. The Federal Register Notice does not provide the HPHC List formats that the Agency intends to assess in the Experimental Study. We request the Agency make the list formats available, including any context or other information that it will present to study participants, for public review and comment. Further, the Agency also should make available for public comment the format of the final HPHC List and how it intends to make this format available to the public, such as via a website or some other form of media.

We recommend that the Agency present the HPHC List in a standardized format that provides appropriate context for the data it contains. Specifically, the Agency should develop the list based on the standardized HPHC information that manufacturers will submit for each brand and subbrand pursuant to Section 904(e) and also include standardized explanations of the limitations of the data in each tobacco product category.

II. Inherent Limitations of the HPHC List Data

The methods used to generate the quantities of the designated constituents for the HPHC List have limitations. For example, manufacturers will use smoking machine methods to generate the HPHC data for cigarettes, roll-your-own and cigarette tobacco.[4] It is well known that such methods do not accurately reflect the wide range of human smoking behavior of individual

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[3] *See*, also, e.g., Lorillard comments dated August 30, 2010 and the May 30, 2010 *Update* (May/June 2011 Tobacco Regulation Issue): *Establishing an FDA List of Harmful and Potentially Harmful Tobacco Product Constituents*, Ogden, M. at pages 10-15. (http://www.nxtbook.com/ygsreprints/FDLI/g19403fdli_nxtbook/#/12).

[4] Consistent with our prior comments on the need for the Agency to establish a single, standardized regimen for smoking of cigarettes, we recommend that the Agency designate the International Organization for Standardization ("ISO") smoking regimen for machine smoking of roll-your-own and cigarette tobacco.

smokers such as variability in puff volume, puff duration and puff frequency.[5] Similarly, HPHC data for smokeless tobacco products derived from laboratory methods do not accurately reflect the wide range of human behavior of individual smokeless tobacco consumers, such as how long a person holds the product in their mouth or how large of a pinch of tobacco. In addition, constituent absorption, distribution, metabolism and excretion vary among individual tobacco product consumers.

Further, an HPHC List derived from non-standardized, non-validated methods will have limited utility, regardless of the format in which it is presented to consumers. As we commented previously, only properly validated and standardized measurement methodologies demonstrated to be fit-for-use and standardized across many laboratories can provide consistent and reliable constituent information. A wealth of scientific literature shows that without validated and standardized methods, tobacco product samples analyzed at multiple laboratories will vary even when using each individual laboratory's validated methods. This reality will make it difficult, if not impossible, for the Agency to provide the HPHC List in a consistent manner for each brand or subbrand as contemplated by Section 904(d)(1) or to use the data for other regulatory decisions.

We reiterate our request that the Agency undertake a collaborative effort to identify or develop the methods manufacturers use for constituent testing to establish the HPHC List and ensure those methods are validated within laboratories and standardized across laboratories.[6]

The relationships between constituent information generated by laboratory methods and human exposure remain complex. Even less well understood are the relationships between exposure to individual tobacco constituents and disease outcomes. In order to minimize potential misperceptions of the HPHC information, it is important that the Agency effectively convey these concepts and limitations to study participants and to the public when it publicizes the final HPHC List.

III. Methodological Considerations for the Experimental Study

The Federal Register Notice provides limited information on the proposed Experimental Study design. It is, therefore, difficult to provide feedback on the utility and methodological validity of the study. We request that the Agency make the detailed study design, including list formats and measures it intends to use, available to the public for review and comment. In the absence of this information, however, we offer the following considerations to the Agency:

First, we urge the Agency to modify the Experimental Study design and measures to sufficiently assess whether study respondents perceive different levels of risk based on presentation of an HPHC List. As described in the Federal Register Notice, the Experimental Study does not include a direct measure of this concept. In addition, we recommend the Agency include "no list" control groups in the Experimental Study. By including these components, the Agency could discern overall effects of exposure to any HPHC List among study participants, even if it does not observe significant differences between list formats.

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[5] In addition, roll-your-own cigarettes made by individual smokers can vary in terms of tobacco weight, density and selection of other design components such as paper.

[6] *See* October 2011 Comments at pg. 4.

Second, we ask the Agency to consider prioritizing the numerous communication concepts it plans to assess before conducting the Experimental Study. The Federal Register Notice describes thirteen[7] "concepts" for which the Agency will assess respondent understanding in reaction to various HPHC List formats. It seems unrealistic for a single list format to satisfy all of these measures equally. While the Federal Register Notice states "...we do not intend to imply that consumer understanding of all concepts is needed to comply with these requirements," it does not indicate whether the Agency believes certain of these concepts are more meaningful for evaluating consumer understanding. By establishing the prioritization up front, the Agency will be better positioned to evaluate study results and to communicate its rationale for final list selection in a clear, transparent manner.

Third, the Agency should clarify whether it intends to include smokeless tobacco brands and consumers in the Experimental Study. Based on the respondent samples described in the Federal Register Notice, the Experimental Study does not include smokeless tobacco users. However, the thirteen communication concepts present statements about "tobacco products," with one concept explicitly describing attributes associated with smokeless tobacco products.[8] If the Agency intends to include smokeless tobacco users in the Experimental Study, the Agency should consider whether respondents will view lists only within a single category (e.g., smokers viewing cigarette brands[9] only or smokeless tobacco users viewing smokeless tobacco brands only) or across different categories. Further, the Agency should consider whether to analyze smokeless tobacco user data separately from that of cigarette smoker data.

Fourth, we encourage the Agency to give additional consideration to certain respondent groups identified in the Federal Register Notice. For example, the Federal Register Notice mentions the planned inclusion of underage respondents in the Experimental Study, particularly former smokers and non-smokers. The Agency should carefully consider the utility of including underage non-smokers in the Experimental Study.

Lastly, we ask the Agency to define how it plans to measure "unintended consequences" in the Experimental Study. The Federal Register Notice states the Experimental Study will assess, "respondent's susceptibility to initiation of tobacco use, motivation and confidence to quit tobacco use, risk perceptions about tobacco use, and emotional reactivity." However, the Federal Register Notice provides no detail on how the Agency will evaluate these parameters.

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[7] The Federal Register Notice includes a total of thirteen concepts; however, it designates two concepts with the number (13).

[8] "(3) for smokeless products, many of the chemicals come from the tobacco leaf itself"

[9] It is unclear whether the Agency intends to address roll-your-own and cigarette tobacco as a discrete component of the study. If so, the same considerations as those for smokeless tobacco products and users apply.

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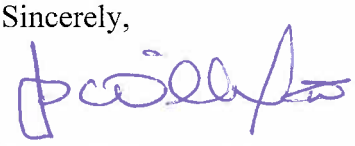
We appreciate the opportunity to submit these comments and urge the Agency to carefully consider them. We also ask the Agency to make available the full study protocol for public review and comment.

Sincerely,



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