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February 13, 2012

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

VIA ELECTRONIC SUBMISSION

**Re: Experimental Study on the Public Display of Lists of Harmful and Potentially Harmful Tobacco Constituents (Docket No. FDA-2011-N-0867)**

Dear Sir or Madam:

Lorillard Tobacco Company (Lorillard) submits these comments in response to Food and Drug Administration's (FDA) notice of request for comments on the proposed Experimental Study on the Public Display of Lists of Harmful and Potentially Harmful Tobacco Constituents (the Experimental Study), issued on December 14, 2011 (the Notice).<sup>1</sup>

Under Section 904(d)(1) of the Family Smoking Prevention and Tobacco Control Act (the Act),<sup>2</sup> FDA is required to publish the list of harmful and potentially harmful constituents in tobacco products (HPHCs)<sup>3</sup> in a format that is understandable and not misleading to a lay person.<sup>4</sup> FDA has stated its intent to conduct the Experimental Study "to help inform decisions about how to implement section 904(d)(1) of the FD&C Act and to provide information about how consumers understand information about HPHCs."<sup>5</sup>

Lorillard supports FDA's efforts to evaluate how the public may perceive and understand a list of HPHCs. Lorillard also appreciates how difficult it will be to assess what information about HPHCs will be meaningful to the public and how that information will be best communicated. Many agencies, including FDA, have expressed concern regarding whether information provided to the public will be enlightening or whether it will be uninformative or misleading. An

<sup>1</sup> 76 Fed. Reg. 240 (Dec. 14, 2011).

<sup>2</sup> Pub. L. No. 111-31, 123 Stat. 1776 (2009).

<sup>3</sup> Lorillard incorporates by reference its submissions to the Meeting of the Tobacco Products Constituents Subcommittee, Briefing Regarding Constituents, June 8-9, 2010, and Meeting of the Tobacco Products Scientific Advisory Committee, Background Information Regarding Constituents, August 30, 2010, (both available at <http://www.fda.gov>) and the response of Philip Morris USA, Inc. and U.S. Smokeless Tobacco Company, R.J. Reynolds Tobacco Company, on behalf of itself, American Snuff Company, LLC and Santa Fe Natural Tobacco Company, Inc. and Constituents in Tobacco Products and Tobacco Smoke," October 11, 2011 (available at <http://www.regulations.gov>).

<sup>4</sup> The Act at 904(d).

<sup>5</sup> 76 Fed. Reg. 240,

appraisal of the public's understanding of information regarding HPHCs is particularly challenging.

For example, in 1994, an expert committee was convened to "...review and make recommendations on the accuracy and appropriateness of the Federal Trade Commission's method for determining the relative 'tar' and nicotine content of cigarettes."<sup>6</sup> One of the questions the committee was asked to consider was "[s]hould constituents other than tar, nicotine, and carbon monoxide be added to the protocol?" In response to this question, the committee stated:

"The committee recommends that to avoid confusing smokers, no smoke constituents other than tar, nicotine, and carbon monoxide be measured and published at the present time. Smokers should be informed of the presence of other hazardous smoke constituents with each package and with all advertisements. These constituents should be classified by toxic effects."<sup>7</sup>

A second question considered was "[d]oes the FTC protocol provide information useful to smokers in making decisions about their health?" The committee's response was:

"The available data suggest that smokers misunderstand the FTC test data. This underscores the need for an extensive public education effort."<sup>8</sup>

Although the laboratory methods and the statutory requirements for measurement and reporting of smoke constituents have evolved since 1994, these concerns about potential consumer confusion over quantitative HPHC information remain.

In 2008, the Federal Trade Commission (FTC) withdrew its guidance that it is generally not a violation of the FTC Act to make factual statements of the tar and nicotine yields of cigarettes when statements of such yields are supported by testing conducted pursuant to the Cambridge Filter Method (also referred to as the FTC Test Method).<sup>9</sup> In its proposal to rescind its guidance, the FTC stated:

"Given the serious limitations of the existing test method, the Commission's rationale for its 1966 guidance generally permitting factual tar and nicotine statements based on this methodology no longer appears valid. The Commission is concerned that statements based on the Cambridge Filter Method may be confusing or misleading to consumers who believe they will get proportionately less of the harmful substances from cigarette smoke by smoking relatively lower yield cigarettes than from higher-yield cigarettes."<sup>10</sup>

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<sup>6</sup> NCI Tobacco and Tobacco Control Monograph 7: The FTC Cigarette Test Method for Determining Tar, Nicotine, and Carbon Monoxide Yields of U.S. Cigarettes (NCI Monograph 7, Forward at v., available at <http://cancercontrol.cancer.gov/tcrb/monographs/7/index.html>

<sup>7</sup> NCI Monograph 7, Forward at vi.

<sup>8</sup> NCI Monograph 7, Forward at vi.

<sup>9</sup> 73 Fed. Reg. 236 (December 8, 2008).

<sup>10</sup> 73 Fed. Reg. 135 (July 14, 2008).

FTC's continued concern was present despite the fact that only tar, nicotine and carbon monoxide measurements were being published, using the most comprehensively validated and standardized testing methods available for cigarette smoke constituents. Other public health organizations have expressed similar concerns.<sup>11</sup> The likelihood of the public's misinterpretation of and confusion regarding HPHCs and any potentially associated health risks is many times greater. The confusion is likely to be compounded by the fact that many of the tobacco constituents on the HPHC list have complicated chemical names and are unfamiliar to the public.

Virtually every researcher who has evaluated tobacco constituents has acknowledged the complexity of the scientific issues surrounding their measurement and association with potential health risks. Lorillard urges the FDA to include questions in the Experimental Survey that will allow assessment of whether the message being conveyed by the information contained in any HPHC list is clear and understandable for people with varied linguistic and educational levels. Lorillard encourages the FDA to design the Experimental Survey to allow assessment of:

- Consumers' abilities to comprehend a long list of HPHCs, names of which will include substances with commonly used chemical names and those which are referred to by only chemical formulas, most of which will not be familiar to consumers
- Consumers' abilities to comprehend the required quantitative terminology (e.g., nanograms, micrograms, milligrams)
- The potential of providing everyday examples of the occurrence of the listed HPHCs or of their quantities to facilitate consumer comprehension of the uniqueness and magnitude of tobacco-related exposures, insofar as these are known
- Consumers' ability to understand the limitations of contemporary methods of analysis in characterizing one cigarette as significantly different from another
- Whether and why specific groups of consumers may be more or less interested in receiving quantitative HPHC information than others may be
- The reasons why consumers may have interest in HPHCs, and how they intend to apply the information in brand variant choice or decisions about continuing tobacco use

Because the Notice provided only a brief summary of the goals of the Experimental Survey rather than the substance of the actual survey questions, Lorillard also urges the FDA to publish

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<sup>11</sup> *E.g.*, the WHO Scientific Advisory Committee on Tobacco Product Regulation (SACTob) had earlier expressed concerns about consumers' ability to understand numerical smoke constituent yield information, and concluded that "[t]ar, nicotine and CO numerical ratings based upon current ISO/FTC methods and presented in numerical form on cigarette packages and in advertising as numerical values are misleading and should not be displayed." Other public health bodies have advanced similar concerns. SACTob, 2002. Conclusions and recommendations on health claims derived from ISO/FTC method to measuring cigarette yield, available at [http://www.who.int/tobacco/global\\_interaction/tobreg/oslo\\_2002\\_iso/en/index.html](http://www.who.int/tobacco/global_interaction/tobreg/oslo_2002_iso/en/index.html)

for comment the actual questionnaire for the Experimental Survey, as well as detailed information on the methodology to be used to determine participants and to conduct the survey.

FDA should also consider whether the information on HPHCs, as presented, will have unintended, adverse consequences for the public. An evaluation of the unintended consequences of the information published should extend beyond an assessment of the effect of the HPHC information on “initiation of tobacco use, motivation and confidence to quit tobacco use, risk perceptions about tobacco use, and emotional reactivity” as outlined in the Notice. FDA should also consider the extent to which the public will be confused or misled by the information in the HPHC list when making decisions regarding the use of tobacco products. For example, a recently reported nationally representative survey found that smokers who believe that FDA regulation includes cigarette safety assessments reported a number of significant differences in perceived smoking risks relative to those who do not harbor that belief.<sup>12</sup> The provision of HPHC information may be interpreted by some smokers as an FDA assessment of the relative safety of different cigarettes whether or not that is FDA’s intent.

Lorillard respectfully reminds FDA that the imposition of HPHC yield reporting requirements and the accompanying public disclosures required by the Act are likely to promote additional confusion among consumers prior to the establishment of sound analytical chemistry methods that have been fully validated among the various laboratories which may perform analyses of HPHCs. In addition to the lack of validated and standardized methods, many of the tobacco constituents on the HPHC list recommended by the Tobacco Products Constituents Subcommittee of the Tobacco Products Scientific Advisory Committee (TPSAC) simply do not have sufficiently robust methods of analysis to permit meaningful comparisons among products. The inter-laboratory and day-to-day variability that characterizes currently available smoking and analytical methods for most HPHCs on the list recommended by TPSAC exceeds the ranges of brand-to-brand variation in smoke yields determined by any such methods known to contemporary science.

In addition, the potential requirement for use of multiple laboratory smoking protocols, e.g. the use of both the ISO and Canadian Intense (CI) protocols, is likely to introduce additional confusion by doubling the number of measurement values of HPHCs presented to consumers. The ISO and CI protocols differ dramatically with respect to puff volume and frequency. The CI protocol further requires complete occlusion of the filter ventilation holes which are elements of the design of some cigarettes. The elimination of this design element has been shown to differentially affect the yield of some HPHCs among brands and will entirely eliminate some differences among brands. Consumers who may wish to compare HPHC yields of different cigarettes would be best served when presented with data generated using a single smoking protocol.

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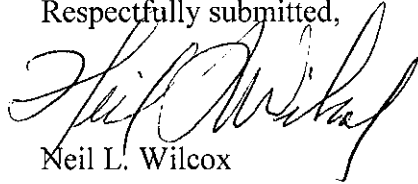
<sup>12</sup>Kauffman, A.R., *et al.* (2011), Food and Drug Administration Evaluation and Cigarette Smoking Risk Perceptions. *Am J Health Behav.* 35(6):766-776.

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Lorillard appreciates the opportunity to provide these brief comments on the Experimental Survey. Lorillard would also appreciate an opportunity to provide more detailed comments on the actual questionnaire and methodology to be used.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Neil L. Wilcox", written in a cursive style.

Neil L. Wilcox