Altria
Altria Client Services

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Centers for Disease Control and Prevention
Attn: Mr. LeRoy Richardson
1600 Clifton Road
MS D-74
Atlanta, Georgia 30333

Re: FR Doc. 2013 – 25799 (October 31, 2013) – Comments on the "List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products."

Altria Client Services ("ALCS"), on behalf of Philip Morris USA ("PM USA"),[1] submits these comments regarding the above referenced Federal Register Notice ("the Notice"). The Notice asks whether ongoing collection by the Centers for Disease Control and Prevention ("CDC") of information on ingredients added to tobacco in the manufacture of cigarettes is "necessary for the proper performance of the functions of the agency." We do not believe this collection of information is necessary.

Because the Food and Drug Administration ("FDA") has the authority to and does collect extensive ingredient information from tobacco product manufacturers, the Department of Health and Human Services ("HHS") should instruct the CDC not to extend similar and burdensome reporting requirements detailed in the Notice. Instead, HHS should ***centralize*** ingredient-reporting requirements with FDA, the agency empowered with broad regulatory authority over tobacco products.

Our comments address two points:

- Congress empowered FDA with broad authority to collect information about cigarette ingredients and to regulate their use.
- HHS should avoid costly and burdensome requirements by instructing CDC to eliminate dual reporting requirements.

[1] PM USA is a wholly-owned subsidiary of Altria Group, Inc. ("Altria"). ALCS provides certain services, including regulatory affairs, to the Altria family of companies. "We" and "our" are used throughout to refer to PM USA.

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A. Congress empowered FDA with broad authority to collect information about cigarette ingredients and to regulate their use.

Since 1985, the Federal Cigarette Labeling and Advertising Act ("FCLAA") has required that cigarette manufacturers, packagers, and importers report certain ingredient information annually to the Secretary of HHS.[2] HHS delegated responsibility for collecting and protecting the ingredient information to the CDC.[3] The annual reports include a cumulative list of all ingredients added to tobacco in the manufacture of all brands of cigarettes during the prior year, with no quantitative information on a brand style basis. Each year, PM USA complies with this reporting requirement. Since 2000, at CDC's request, the major U.S. manufacturers, including PM USA, have voluntarily provided additional information in the annual reports.[4]

The Family Smoking Prevention and Tobacco Control Act ("FSPTCA") created new and more detailed ingredient-reporting obligations for tobacco product manufacturers that far exceed the FCLAA ingredient reporting requirements. For example, Section 904(a)(1) of the Federal Food, Drug and Cosmetic Act ("FDCA") required manufacturers and importers to provide FDA, within six months of enactment of the FSPTCA, "a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand." PM USA complied with that obligation in June 2010.

Importantly, FDA's authority to use the information it collects for regulatory purposes far exceeds that of CDC under FCLAA.[5] The FSPTCA empowers FDA to take direct regulatory actions related to cigarette ingredients, including establishing product standards, pursuant to its authority under Section 907.

Manufacturers and importers are required to provide FDA with ongoing cigarette ingredient reporting. Sections 904(c)(1), 904(c)(2) and 904(c)(3) require that cigarette manufacturers provide FDA an ingredient listing by brand style under any of the following circumstances:

1) 90 days prior to introducing a new cigarette brand style;
2) 90 days prior to increasing or adding a new ingredient to an existing brand style;
3) within 60 days of eliminating or decreasing an additive to an existing cigarette brand style; and,
4) within 60 days of adding or increasing an additive designated as not harmful by FDA to an existing cigarette brand style.

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[2] 15 USC § 1335A(a).

[3] *See* 50 Fed. Reg. Notice 9617 (December 3, 1985).

[4] This additional voluntary information includes applicable regulatory citations; ingredient function and chemical identification numbers.

[5] The FCLAA contemplated use of the less-extensive ingredient information is much more limited in scope. FCLAA authorized HHS to report to Congress, when HHS deems appropriate, a summary of research and proposed research on the health effects of ingredients added to tobacco and the findings of such research; information pertaining to any ingredient that HHS judges to pose a health risk to cigarette smokers; and any other information that it determines to be in the public interest. 15 USC § 1335A(b). HHS did not expressly delegate that reporting authority to CDC.

Section 910 of the FDCA also requires manufacturers to provide FDA ingredient information as part of FDA's pre-market review of a new or modified tobacco product and FDA also collects such information as part of its review of substantial equivalence reports submitted by manufacturers under Section 905(j). FDA makes market authorization determinations based, in part, on the ingredient information provided by manufacturers. FDA can regulate the ingredients in specific tobacco products through its pre-market authorization process. Section 904(b) also gives FDA the authority to require manufacturers to provide documents relating to, among other topics, ingredients, components and additives. FDA has used this authority to require manufacturers to provide such information.

B. HHS should avoid costly and overly burdensome requirements by instructing CDC to eliminate dual reporting requirements.

Given the extent of ingredient and product information manufacturers are required to provide to FDA, we encourage HHS to end CDC's reporting requirements and instead rely on the more extensive information provided to FDA. This makes sense for two reasons.

First, such action aligns squarely with President Obama's commitment to improving regulation and regulatory review. In an Executive Order, the President recognized that:

> Some sectors and industries face a significant number of regulatory requirements, some of which may be redundant, inconsistent, or overlapping. Greater coordination across agencies could reduce these requirements, thus reducing costs and simplifying and harmonizing rules. In developing regulatory actions and identifying appropriate approaches, each agency shall attempt to promote such coordination, simplification, and harmonization.[6]

The dual ingredient reporting requirements are exactly the type of "overlapping" regulatory requirements that need to be addressed. Eliminating the dual reporting requirements will reduce the overall administrative burden for CDC and manufacturers. For example, CDC would not expend its resources reviewing and certifying annual ingredient submissions. Centralization of responsibilities in one agency should lead to efficiencies in several activities such as handling, certifying, reviewing, and protecting the information. Manufacturers would avoid providing different levels of cigarette ingredient information to multiple federal entities.

Second, centralizing these reporting requirements would not deprive CDC of information "necessary for the proper performance of the functions of the agency." FDA could, subject to certain provisions,[7] upon request provide the cigarette ingredient reports to CDC. CDC would benefit because it would receive information that is more detailed than the ingredient information it currently receives, while eliminating its burden associated with collecting, reviewing and certifying current CDC ingredient submissions.

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[6] *See* Executive Order 13563 (January 18, 2011).

[7] These provisions would include applicable protections of confidential information, including the requirements of Section 906 (c) of the FSPTCA and the confidentiality provisions of 21 CFR, Part 20.

For these compelling reasons, we believe HHS should instruct CDC to eliminate the dual ingredient reporting requirement detailed in the Notice. Rather, HHS should centralize all tobacco-related ingredient information collecting responsibilities with FDA.

We have on several occasions requested an opportunity to discuss with CDC the issues raised in this letter.[8] We again extend a request to discuss how eliminating this dual reporting requirement will reduce burdens on CDC and more efficiently centralize ingredient information in FDA.

Sincerely,

James E. Dillard III

cc: Mitchell Zeller, J.D., Director, Center for Tobacco Products

[8] *See* letter from Gary R. Ruth, Senior Vice President, PM USA , to Timothy A. McAfee, M.D., M.P.H., March 11, 2011, Philip Morris USA Inc. *Cigarette Products Ingredient Disclosure Report as of December 31, 2010*, letter from James E. Dillard, Senior Vice President, ALCS Regulatory Affairs, to Timothy A, McAfee, M.D., M.P.H., March 2012, Philip Morris USA Inc. *Cigarette Products Ingredient Disclosure Report as of December 31, 2011,* letter from James E. Dillard, Senior Vice President, ALCS Regulatory Affairs, to Timothy A, McAfee, M.D., M.P.H., March 2013, Philip Morris USA Inc. *Cigarette Products Ingredient Disclosure Report as of December 31, 2012.* To date, we have not received a reply.