Altria
Altria Client Services

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December 24, 2013

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

Re: FR Doc. 2013 – 25860 (October 31, 2013) – Comments on the "Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S."

Altria Client Services ("ALCS"), on behalf of Philip Morris USA ("PM USA") and U.S. Smokeless Tobacco Company LLC ("USSTC"),[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 related to ingredients and nicotine in smokeless tobacco 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 and nicotine content information from tobacco product manufacturers, the Department of Health and Human Services ("HHS") should instruct the CDC not to extend the similar reporting requirements detailed in the Notice. Instead, HHS should ***centralize*** ingredient and nicotine content 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 and regulate smokeless tobacco ingredients and nicotine content.

[1] PM USA and USSTC are wholly-owned subsidiaries 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 and USSTC.

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

A. Congress empowered FDA with broad authority to collect information and regulate smokeless tobacco ingredients and nicotine content.

The Comprehensive Smokeless Tobacco Health Education Act of 1986 ("CSTHEA") requires smokeless tobacco manufacturers, packagers, and importers to report certain ingredient information annually to the Secretary of HHS.[2] HHS delegated responsibility for collecting and protecting the ingredient and nicotine reporting information to the CDC.[3] Each annual report includes a composite listing of all of the ingredients added to tobacco in the manufacture of all brands of smokeless tobacco during the prior year, with no quantitative information on a brand style basis. USSTC has complied with the CSTHEA ingredient reporting requirements since they became effective in 1991. PM USA has complied with the annual reporting requirement since it began manufacturing smokeless tobacco products in 2006.

CSTHEA also requires manufacturers, packagers, and importers of smokeless tobacco products to report annually on the specific quantity of nicotine in their products by submitting data on total nicotine, un-ionized nicotine, total moisture, and pH. The annual nicotine reports specify the quantity of nicotine contained in smokeless tobacco products manufactured during the previous calendar year. CDC developed a uniform analytical protocol that consists of standard laboratory methods to measure nicotine, moisture, and pH in smokeless tobacco products, and an equation to calculate un-ionized nicotine.[4] Manufacturers, packagers, and importers must submit their annual nicotine report in accordance with the specifications set forth in the protocol. The CSTHEA nicotine reporting requirements became effective in 1994. Both USSTC and PM USA comply with the CSTHEA requirements.

The Family Smoking Prevention and Tobacco Control Act ("FSPTCA") created several new and more detailed ingredient and nicotine reporting obligations for smokeless tobacco product manufacturers. The new reporting requirements far exceed the CSTHEA ingredient and nicotine 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." USSTC and PM USA complied with this obligation in June 2010.

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[2] 15 USC § 4403(a).
[3] *See* 59 Fed Reg. Notice 4717 (February 1, 1994).
[4] *See* 64 Fed. Reg. Notice 14,085 (March 23, 1999) and 74 Fed. Reg. Notice 712 (January 7, 2009).

Importantly, FDA's authority to use the information it collects for regulatory purposes far exceeds that of CDC under CSTHEA.[5] The FSPTCA empowers FDA to take direct regulatory actions related to smokeless tobacco ingredients and nicotine content, including establishing product standards.

Ingredient reporting to FDA is an ongoing obligation. Sections 904(c)(1), 904(c)(2) and 904(c)(3) require that manufacturers provide FDA an ingredient listing by brand style under any of the following circumstances:

1) 90 days prior to introducing a new tobacco product 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 brand style; and,
4) within 60 days of adding or increasing an additive designated as not harmful by FDA to an existing brand style.

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. The FSPTCA also contains several provisions that establish nicotine reporting obligations for smokeless tobacco manufacturers and importers. Section 904(a)(2) empowers FDA to require the submission of "a description of the content, delivery, and form of nicotine in each tobacco product measured in milligrams of nicotine in accordance with regulations promulgated by the Secretary in accordance with section 4(e) of the Federal Cigarette Labeling and Advertising Act."

Section 904(a)(3) establishes the requirement to report a listing of constituents "identified by the Secretary as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product, by brand and by quantity in each brand and subbrand." On March 30, 2012, FDA published its list of Harmful and Potentially Harmful Constituents ("HPHC") in tobacco products and tobacco smoke along with Draft Guidance on testing and reporting against the list. For each smokeless tobacco product brand style, FDA required testing and reporting by September 22, 2012, of nine specified constituents, including nicotine. In its March 2012 Draft Guidance for Industry, FDA stated that "[f]or smokeless tobacco products, FDA recommends that you use the CDC method to calculate free nicotine (74 FR 712, January 7, 2009)."[6] HHS indicated that future reporting requirements would be announced in December

[5] The CSTHEA contemplated use of the less-extensive ingredient information is much more limited in scope. CSTHEA 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 in the manufacture of smokeless tobacco products and the findings of such research; information pertaining to any ingredient that HHS judges to pose a health risk to users of smokeless tobacco; and any other information that HHS determines to be in the public interest. 15 USC § 4403(b). HHS did not expressly delegate that reporting authority to CDC.

[6] Draft Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act at 9.

2013.[7] In Guidance, FDA has also requested the inclusion of constituent data in substantial equivalence reports submitted under Section 905(j).

FDA's ability to obtain detailed product information is not limited to the above referenced sections. FDA has the authority under Section 904(b) 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 burdensome requirements by instructing CDC to eliminate dual ingredient and nicotine reporting requirements.

Given the extent of ingredient and nicotine content 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.[8]

Dual ingredient and nicotine reporting requirements are exactly the type of "redundant" and "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 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 ingredient and nicotine content 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,[9] upon request provide the smokeless tobacco ingredient and nicotine 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 and nicotine submissions.

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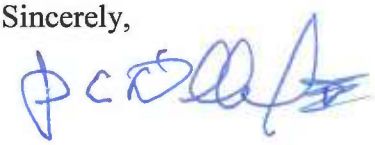
[7] *See* HHS Semiannual Regulatory Agenda July 2013.
[8] *See* Executive Order 13563 (January 18, 2011).
[9] These provisions would include applicable protections of confidential information, including the requirements of Section 906 (c) of the FSPTCA and the confidentiality provisions of 21 CFR, Part 20.

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

We have on several occasions offered to discuss with CDC the issues raised in this letter.[10] We again extend a request to discuss how eliminating this dual reporting requirement will reduce burdens on CDC and more efficiently centralize ingredient and nicotine information in FDA.

Sincerely,



James E. Dillard III

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

[10] *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. Smokeless Tobacco 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 21, 2012, *Philip Morris USA Inc. Smokeless Tobacco Products Ingredients 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 27, 2013, *Philip Morris USA Inc. Smokeless Tobacco Products Ingredients Disclosure Report as of December 31, 2012;* letter from Mary A. Gordon, Vice President, Manufacturing, U.S. Smokeless Tobacco Manufacturing Company to Timothy A. McAfee M.D., M.P.H., March 15, 2011, *U.S. Smokeless Tobacco Manufacturing Company Smokeless Tobacco 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 21, 2012, *U.S. Smokeless Tobacco Manufacturing Company Smokeless Tobacco Products Ingredient Disclosure Report as of December 31, 2011*; and letter from James E. Dillard, Senior Vice President, ALCS Regulatory Affairs, to Timothy A. McAfee, M.D., M.P.H., March 27, 2013, *U.S. Smokeless Tobacco Manufacturing Company Smokeless Tobacco Products Ingredient Disclosure Report as of December 31, 2012.* To date, we have not received a reply.