From: Burroughs, Kennya L. (CDC/OD/OADS) **On Behalf Of** OMB-Comments (CDC)
Sent: Monday, March 05, 2012 9:46 AM
To: Macaluso, Renita (CDC/ONDIEH/NCCDPHP)
Subject: FW: dont need this anymore

One non-substantive comment received. CDC's standard response was sent.

From: usacitizen1 usacitizen1 [mailto:usacitizen1@live.com]
Sent: Thursday, March 01, 2012 2:31 PM
To: kimberly.lane@cdc.gov; OMB-Comments (CDC); oira_submission@omb.eop.gov; rush.holt@mail.house.gov; americanvoices@mail.house.gov; speakerboehner@mail.house.gov; sf.nancy@mail.house.gov; comments@whitehouse.gov; info@taxpayer.net; media@cagw.org; info@theteaparty.org
Subject: FW: dont need this anymore

the taxpayers say this needs to be sunset. there is no need to fund this old, antique project anymore. those who use this crap know it is unhealthful. there is no need for fat cat high paid govt employees to work on this anymore. we simply do not need it. if it that unhealthful, stop the sale of it. the us govt is allowing it to be sold, so leave it alone. stop penalizing american taxpaeyrs to colelct unnneeded unnecessary information on this. the cost to employe the fat cat bureaucrats collecting this information is through the roof. american taxpaeyrs wants smaller, cheaper govt, and we dont need to collect information about every last thing goin on on earth. this is an example of completely unnecessary collection of information and useless taxes to be paid by americans. i dont think american taxpayers should be bamboozled into paying for any health risks of those too stupid to have gotten the message by now. the message has been out there for many many years. you smoke you die. stop hitting the taxpayers on the wallet for this message. you are making general taxpayers suffer the consequences. those who use this crap should be suffering the conseequences.
jean public

Date: Thu, 1 Mar 2012 10:39:19 -0500
Subject: dont need this anymore
From: jeanpublic1@gmail.com
To: usacitizen1@live.com

[Federal Register Volume 77, Number 41 (Thursday, March 1, 2012)]
[Notices]
[Pages 12595-12596]
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[FR Doc No: 2012-4950]

Altria
Altria Client Services

James E. Dillard III
Senior Vice President
Regulatory Affairs

April 23, 2012

Ms. Kimberly Lane
CDC Reports Clearance Officer
1600 Clifton Road, MS D-74
Atlanta, Georgia 30333

Re: 77 Fed. Reg. 12,595 (March 1, 2012) – 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") Inc., 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").

The Comprehensive Smokeless Tobacco Health Education Act of 1986 ("CSTHEA") requires "[e]ach person who manufactures, packages, or imports smokeless tobacco products shall annually provide the Secretary [of Health and Human Services ("HHS")] a list of the ingredients added to tobacco in the manufacture of smokeless tobacco products which does not identify the company which uses the ingredients or the brand of smokeless tobacco which contains the ingredients."[2] CSTHEA further requires submission of the quantity of nicotine contained in each smokeless tobacco product. HHS delegated responsibility for implementing CSTHEA's ingredient and nicotine reporting requirements to the Centers for Disease Control and Prevention ("CDC") Office of Smoking and Health.

The 2009 Family Smoking Prevention and Tobacco Control Act ("FSPTCA" or "Act") vested authority over tobacco products with the Food and Drug Administration ("FDA"). The FSPTCA requires, among other things, comprehensive reporting of ingredients and nicotine to FDA.[3] In

[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* 15 U.S.C. 4403(a).

[3] *See* 21 U.S.C.

the Act, Congress recognized that FDA is the federal agency with the scientific expertise needed to implement effectively all provisions of the FSPTCA."[4]

We previously requested an opportunity to discuss with CDC the potential to gain efficiencies by eliminating now duplicative ingredient reporting obligations.[5] We take this current opportunity to share our perspectives.[6]

Our comments will address three topics:

- Smokeless tobacco ingredient and nicotine reporting to CDC under CSTHEA;
- Smokeless tobacco ingredient and nicotine reporting to FDA under the FSPTCA and related requirements; and
- CDC should urge HHS to eliminate duplicative smokeless tobacco ingredient and nicotine reporting.

I. Smokeless Tobacco Ingredient and Nicotine Reporting to CDC Under CSTHEA

CSTHEA requires smokeless tobacco manufacturers, packagers, and importers to report certain ingredient information annually. The CSTHEA ingredient reporting requirements became effective in 1991, and USSTC has since complied with annual smokeless tobacco ingredient reporting. PM USA began manufacturing smokeless tobacco products in 2006 and has complied with the annual reporting requirements since that time. 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.

CSTHEA additionally requires manufacturers, packagers, and importers of smokeless tobacco products to annually report on the specific quantity of nicotine in these products by submitting data on total nicotine, unionized nicotine, total moisture, and pH. The annual nicotine report specifies 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

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[4] *See* 21 U.S.C. 387 note, Sec. 2(45).

[5] *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 Ingredient Disclosure Report as of December 31, 2011*; 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*; and 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*. To date, we have not received a reply.

[6] 77 Fed. Reg. Notice 11,126 (February 24, 2012) also solicits comments on ingredient reporting to CDC for cigarettes. ALCS will separately submit comments in response to that notice.

products, and an equation to calculate un–ionized nicotine.[7] Manufacturers, packagers, and importers must submit their annual nicotine report according to the specifications set forth in the protocol. The CSTHEA nicotine reporting requirements became effective in 1994, and USSTC has since complied with annual smokeless tobacco nicotine reporting. PM USA has complied with the annual nicotine reporting requirements since 2006, when it began to manufacture smokeless tobacco products.

The annual ingredient and nicotine reports must be submitted to CDC by March 31st of each year. Following review and verification of each annual report, CDC provides the manufacturer, packager, or importer a written certificate of compliance.

II. Smokeless Tobacco Ingredient and Nicotine Reporting to FDA Under the FSPTCA and Related Requirements

The FSPTCA created several new and more detailed requirements for disclosure of smokeless tobacco ingredient and nicotine information to FDA.

First, Section 904(a)(1) requires 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." In accordance with guidance issued by FDA,[8] PM USA and USSTC each provided FDA initial ingredient submissions in June 2010, for all smokeless tobacco products marketed as of June 22, 2009.

Second, manufacturers and importers must provide FDA ongoing smokeless tobacco ingredient reporting. Subsequent to the initial ingredient submission, 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 smokeless tobacco brand style; (2) 90 days prior to increasing or adding a new ingredient to an existing smokeless tobacco brand style; (3) within 60 days of eliminating or decreasing an additive to an existing smokeless tobacco brand style; and (4) within 60 days of adding or increasing an additive designated as not harmful by FDA to an existing smokeless tobacco brand style.[9]

Third, Section 910 of the FSPTCA requires manufacturers to provide FDA ingredient information as part of FDA's premarket review of a new or modified brand style.

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[7] *See* 64 Fed. Reg. Notice 14,085 (March 23, 1999), available at: http://www.gpo.gov/fdsys/pkg/FR-1999-03-23/html/99-7022.htm and 74 Fed. Reg. Notice 712 (January 7, 2009), available at: http://www.gpo.gov/fdsys/pkg/FR-2009-01-07/html/E9-19.htm.

[8] *See Final Guidance for Industry: Listing of Ingredients in Tobacco Products*, November 2009, available at: http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM192053.pdf.

[9] To date, FDA has not designated any additives as "not harmful" pursuant to Section 904(c)(3).

Subsequent to its initial ingredient submissions in June 2010, PM USA and USSTC have provided FDA with ingredient disclosures under Section 904(c) and other relevant provisions of the FSPTCA, as applicable.[10]

The FSPTCA also contains several provisions that establish nicotine reporting obligations for smokeless tobacco manufacturers and importers. First, Section 904(a)(2) requires 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." To date, FDA has not promulgated these regulations.

Section 904(a)(3) also 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" beginning three years after enactment of the FSPTCA. On March 30, 2012, FDA published a list of constituents that included nicotine.[11] Manufacturers must report against this list and the associated draft guidance recommends that manufacturers use the current CDC protocol to calculate and report total and free nicotine.[12]

In guidance, FDA has requested the inclusion of constituent data in substantial equivalence reports submitted under Section 905(j).[13] Prior to the issuance of the March 30, 2012, constituent list, PM USA and USSTC voluntarily provided FDA a comparison of the nicotine values between the new smokeless tobacco product and its predicate in its 905(j) submissions, using nicotine data generated and reported to the CDC in these submissions.

In addition to the brand-specific smokeless tobacco ingredient and nicotine reporting, the FSPTCA also requires manufacturers to submit upon request of FDA "[a]ny or all documents (including underlying scientific information) relating to research activities, and research findings, conducted, supported, or possessed by the manufacturer (or agents thereof) on the health, toxicological, behavioral, or physiologic effects of tobacco products and their constituents (including smoke constituents), ingredients, components, and additives."[14] As requested by FDA, PM USA has provided the Agency documents and information.

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[10] PM USA and USSTC also have voluntarily provided FDA the smokeless tobacco product portfolio maximum use level as of February 15, 2007, for all ingredients disclosed in its 905(j) substantial equivalence reports.

[11] *See* 77 Fed. Reg. Notice 20,030 (April 3, 2012), available at: https://federalregister.gov/a/2012-7766.

[12] *See 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*, March 2012, available at: http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm297752.htm

[13] *See Guidance for Industry and FDA Staff: Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products*, January 5, 2011, available at: http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM239021.pdf

[14] *See* Section 904(b)(1).

Lastly, FDA has the authority under the FSPTCA to promulgate performance standards for smokeless tobacco, including for ingredients or constituents.[15]

III. CDC Should Urge HHS to Eliminate Duplicative Smokeless Tobacco Ingredient and Nicotine Reporting

We believe continued collection of annual ingredient and nicotine information by CDC is no longer necessary in light of FDA's broad regulatory authority over smokeless tobacco products pursuant to the FSPTCA. We urge CDC to recommend to HHS that it delegate the ingredient and nicotine related responsibilities previously assigned to CDC exclusively to FDA. We believe this is appropriate for three reasons.

First, the type and extent of ingredient information that manufacturers are required to provide to FDA under the FSPTCA exceeds the information manufacturers are required to provide CDC pursuant to CSTHEA.[16] As described above, the FSPTCA requires manufacturers to provide quantitative ingredient information on a per-brand style basis either before or soon after any commercial change. In addition, the FSPTCA requires manufacturers to provide ingredient information as part of a new premarket tobacco product application. The annual smokeless tobacco ingredient reporting requirements under FCLAA are less extensive.

Second, the FSPTCA provides FDA the authority to take direct regulatory actions related to smokeless tobacco ingredients and constituents. As described above, the FSPTCA provides FDA broad regulatory authority to regulate ingredients and constituents in smokeless tobacco. This includes taking regulatory action on individual products or on all smokeless tobacco products through the adoption of product standards.[17]

Third, eliminating manufacturer ingredient and nicotine reporting to CDC reduces the overall administrative burden for manufacturers and CDC. It would reduce the burden associated with manufacturers providing different smokeless tobacco ingredient and nicotine reports to multiple federal entities and preclude the need for CDC resources to review the annual ingredient and nicotine submissions and provide certificates of compliance.[18] If it is helpful to either HHS or

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[15] *See* Section 907 generally and Section 907(a)(4)(B)(i) in particular.

[16] The smokeless tobacco nicotine reporting requirements under the FSPTCA and FCLAA are fundamentally the same; as such, HHS could appropriately delegate them solely to FDA.

[17] In contrast, CDC's regulatory authority is more limited. Like FDA, CDC has authority to receive and analyze information about ingredients and nicotine. CDC does not, however, have the authority to take direct regulatory action related to specific products, ingredients or nicotine. Specifically, FCLAA provides that HHS may use the annual smokeless tobacco ingredient and nicotine reports to provide information to Congress, such as: 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 it judges to pose a health risk to users of smokeless tobacco; and any other information which it determines to be in the public interest. *See* 15 U.S.C. 4403(b)(1).

[18] This is consistent with Executive Order 13563: "Sec. 3. Integration and Innovation. 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."

CDC, FDA could provide smokeless tobacco ingredient and nicotine reports to HHS or CDC on an annual or more frequent basis.[19]

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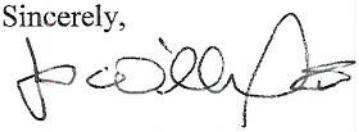
We appreciate the opportunity to submit these comments and ask CDC to carefully consider them. We also reiterate our request for an opportunity to meet and discuss our recommendations with CDC.

Sincerely,



James E. Dillard III

cc: Dr. Lawrence Deyton, U.S. Food and Drug Administration, Center for Tobacco Products

Ms. Kathleen Sebelius, U.S. Department of Health and Human Services

[19] Of course, any such disclosures between FDA, CDC and HHS are subject to the applicable protections of such confidential information, including the requirements of Section 906(c) of the FSPTCA and the confidentiality provisions of 21 CFR, Part 20.