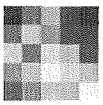

Altria
Altria Client Services

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. 11,126 (February 24, 2012) – Comments on the "List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products"

Altria Client Services ("ALCS") Inc., on behalf of Philip Morris USA Inc. ("PM USA"),[1] submits these comments on the above-captioned notice (the "Federal Register Notice").

The Comprehensive Smoking Education Act of 1984 ("CSEA") amended the Federal Cigarette Labeling and Advertising Act ("FCLAA") to require that "[e]ach person who manufactures, packages, or imports cigarettes shall annually provide the Secretary [of Health and Human Services ("HHS")] a list of the ingredients added to tobacco in the manufacture of cigarettes which does not identify the company which uses the ingredients or the brand of cigarettes which contain the ingredients."[2] HHS delegated responsibility for implementing FCLAA's ingredient 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 on ingredients to the FDA by manufacturers and importers of cigarettes and other tobacco products.[3] In the Act, Congress recognized that FDA is the federal agency with "the scientific expertise needed to implement effectively all provisions of the FSPTCA."[4]

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[1] PM USA is a wholly-owned subsidiary 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.

[2] *See* 15 U.S.C. 1335a(a).

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

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

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

Our comments will address three topics:

- Cigarette ingredient reporting to CDC under FCLAA and related voluntary submissions;
- Cigarette ingredient reporting to FDA under the FSPTCA and related requirements; and
- CDC should urge HHS to eliminate duplicative cigarette ingredient reporting.

I. Cigarette Ingredient Reporting to CDC Under FCLAA and Related Voluntary Submissions

FCLAA requires that cigarette manufacturers, packagers, and importers report certain ingredient information annually. The FCLAA amendment became effective in 1985, and PM USA has since complied with the annual cigarette ingredient reporting requirements.

Each annual report includes a cumulative listing of all of the 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. The annual report 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.

The major United States manufacturers have also voluntarily provided additional information to CDC with its annual report since 2000 pursuant to a request from CDC.[7] For ingredients included in the statutory composite list, this supplemental information also includes: applicable regulatory citations; ingredient function; chemical identification numbers; examples of food products in which the ingredient naturally occurs or is used; and where applicable, associated maximum use levels and annual poundage of the ingredient on a cumulative basis. PM USA provides the voluntary information in conjunction with its annual statutory report.

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[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. Cigarette 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, *Philip Morris USA Inc. Cigarette Products Ingredient Disclosure Report as of December 31, 2011*. To date, we have not received a reply.

[6] 77 Fed. Reg. Notice 12,595 (March 1, 2012) also solicits comments on ingredient and nicotine reporting to CDC for smokeless tobacco products. ALCS will separately submit comments in response to that notice.

[7] Beginning in 2000, Covington & Burling provided CDC the annual voluntary cigarette ingredient reporting on behalf of several cigarette manufacturers, including PM USA. *See* attached letter from Clausen Ely, Jr., to Michael E. Eriksen, Director, Office of Smoking and Health, February 4, 2000 . Since 2004, PM USA has provided directly to CDC the annual voluntary cigarette ingredient reporting. *See* attached letter from Richard P. Solana, Vice President, Worldwide Scientific Affairs, to Ms. Rosemarie Henson, Director, CDC, March 25, 2004. Currently, ALCS provides this information to CDC on behalf of PM USA.

II. Cigarette Ingredient Reporting to FDA Under the FSPTCA and Related Requirements

The FSPTCA created several new and more detailed cigarette ingredient reporting obligations, as well as other ingredient-related requirements for manufacturers and importers.

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 provided FDA this initial ingredient submission in June 2010, for all cigarettes marketed by PM USA as of June 22, 2009.

Second, manufacturers and importers must provide FDA ongoing cigarette 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 cigarette brand style; (2) 90 days prior to increasing or adding a new ingredient to an existing cigarette 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.[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.

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

In addition to the brand-specific cigarette ingredient 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."[11] As requested by FDA, PM USA has provided the Agency documents and information.

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[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).

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

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

Lastly, FDA has the authority under the FSPTCA to promulgate performance standards for cigarettes, including for ingredients.[12]

III. CDC Should Urge HHS to Eliminate Duplicative Cigarette Ingredient Reporting

We believe continued collection of annual ingredient information by CDC is no longer necessary in light of FDA's broad regulatory authority over cigarettes pursuant to the FSPTCA. We urge CDC to recommend to HHS that it delegate the ingredient 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 FCLAA. 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 cigarette ingredient reporting requirements under FCLAA are less extensive.

Second, the FSPTCA provides FDA the authority to take direct regulatory actions related to cigarette ingredients. As described above, the FSPTCA provides FDA broad regulatory authority to regulate ingredients in cigarettes. This includes taking regulatory action on individual products or on all cigarettes through the adoption of product standards.[13]

Third, eliminating manufacturer ingredient reporting to CDC reduces the overall administrative burden for manufacturers and CDC. It would reduce the burden associated with manufacturers providing different cigarette ingredient reports to multiple federal entities and preclude the need for CDC resources to review the annual ingredient submissions and provide certificates of compliance.[14] If it is helpful to either HHS or CDC, FDA could provide cigarette ingredient reports to HHS or CDC on an annual or more frequent basis.[15]

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

[13] In contrast, CDC's regulatory authority is more limited. Like FDA, CDC has authority to receive and analyze information about ingredients. CDC does not, however, have the authority to take direct regulatory action related to specific products or ingredients. Specifically, FCLAA provides that HHS may use the annual cigarette ingredient 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 cigarettes and the findings of such research; information pertaining to any ingredient that it judges to pose a health risk to cigarette smokers; and any other information which it determines to be in the public interest. *See* 15 U.S.C. 1335a(b)(1).

[14] 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."

[15] 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.

* * * * *

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

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February 4, 2000

CONFIDENTIAL

VIA FEDERAL EXPRESS

Michael E. Eriksen, Sc.D.
Director
Office on Smoking and Health
National Center for Chronic Disease
Prevention and Health Promotion
Department of Health and Human Services
4770 Buford Highway, N.E.
Atlanta, GA 30341-3724

Dear Dr. Eriksen:

As agreed at our meeting on November 17, 1999, this will provide a further written response to your letter of May 28, 1999, describe our clients' offer for voluntary submission of ingredient data, and follow-up on other topics discussed at our meeting.

In your May 28 letter, you requested that our clients voluntarily submit to your Office, on a brand specific basis, the identity, function and level in the finished product of each ingredient added to tobacco in the manufacture of cigarettes. As explained in my letter to you of September 21, 1999 and during our meeting on November 17, the identity and quantity of ingredients used in individual cigarette brands is extremely valuable trade secret information that is closely guarded by each of the companies and protected from disclosure to competitors and third parties. In particular, the flavor formulas for cigarette products are highly valuable trade secrets that give each brand its distinctive flavor, taste and aroma.

We submitted to your Office, on December 7, 1999, the functions and maximum use levels ("MUL's"), together with other information, for all of the ingredients added to tobacco in the manufacture of cigarettes, including flavorants, on the composite list submitted to your Office on behalf of our clients in March 1999. As in the past, we requested that this information be treated as confidential by your Office.

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http://legacy.library.ucsf.edu/tid/lkp90g00/pdf

As discussed at our meeting on November 17, our clients also are prepared voluntarily to disclose to HHS, on a brand specific basis in descending order of predominance by weight, the ingredients added to tobacco in the manufacture of cigarettes except for ingredients used solely for the purpose of flavoring. This form of disclosure is consistent with the ingredient disclosures required for food products. In our view, this information, along with the quantitative data that we provided on December 7, 1999, will provide HHS with the necessary information to perform a safety evaluation and will protect the companies' valuable trade secrets. As discussed at our meeting, an assessment that assumes maximum exposures can be made for any flavor or combination of flavors through use of the MUL's and, as noted below, the companies are prepared to provide available test data and literature reviews for any ingredient(s) with respect to which your Office has a specific issue.

In your May 28, 1999 letter, you also requested the analytical methods used to measure ingredients in cigarettes. As explained at our meeting, analytical methods are not available for many of the ingredients, particularly flavors added at low levels in the manufacture of cigarettes. Individual companies, however, have developed their own analytical methods. Because these methods are for each company's internal use, they have not been published or peer-reviewed. The companies agreed to provide your Office with available analytical methods for ingredients in cigarettes, and two companies (Philip Morris and R.J. Reynolds) have already done so. As we discussed with Shelley Langguth, our clients do not claim trade secret status for these analytical methods and have no objection to your staff sharing the methods within HHS. However, because the methods have not been validated or peer reviewed, our clients have asked that the methods not be published or distributed outside the Agency, and it is our understanding that this arrangement is acceptable to you.

The final request in your May 28, 1999 letter was for "chemistry or toxicology testing or literature review results" for each ingredient. During our November 17 meeting, we discussed the significant burdens that would be involved in responding to this broad request, and you agreed that a large undifferentiated data submission would not necessarily be helpful to your Office. In view of these concerns, you stated that your Office would be willing to provide the companies with a narrower request relating to specific ingredients or test types in which you have a particular interest.

This will also confirm the following additional points discussed at our meeting.

(1) The companies are prepared, at your request, to arrange for representatives from your Office to view the manufacturing process at one or more of the companies' facilities with particular reference to the use and control of ingredients.

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(2) We will provide you with information concerning the results of the Massachusetts benchmarking study after submission of the final report to Dr. Connolly of the Massachusetts Department of Public Health. The benchmarking study is designed to establish the relationships between smoke constituent yields of cigarettes and specified parameters. The study is scheduled to be completed during the first quarter of 2000.

(3) The companies have commissioned the creation of a database of substances approved or prohibited for addition to tobacco in the manufacture of cigarettes in countries with cigarette ingredient regulatory schemes. This database will be provided to your Office as soon as it is finalized. It is anticipated that the database will be completed in the coming year.

(4) The companies are prepared, at your request, to schedule a presentation for your staff regarding the effect on nicotine delivery, including the concept of "vapor phase" nicotine, of the use of ammonia compounds, levulinic acid and any other ingredients identified by you. In this regard, we are enclosing for your information a recent publication by Philip Morris entitled "Form of Nicotine in Tobacco. Thermal Transfer of Nicotine and Nicotine Acid Salts to Nicotine in the Gas Phase," J. Agric. Food Chem. 47:5133-5145 (1999).

(5) The companies will provide you with updated white papers on major cigarette ingredients as they become available.

(6) The companies will compile and submit to your Office in the near future the same type of data on nontobacco materials used in cigarette products as voluntarily submitted to your Office in the past.

(7) The companies will make an annual voluntary submission to your Office of composite ingredient information of the type provided in the past (i.e., MUL's, functions, regulatory citations, poundage, natural occurrence in food) at the same time as submission of the statutory list at the end of March or as soon thereafter as possible.

(8) The companies will prepare for submission to your Office a summary of tobacco ingredient disclosure laws in foreign countries.

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We appreciated the opportunity to meet with you and your staff in Atlanta and the companies look forward to continued cooperation with your Office on ingredient matters.

Respectfully submitted,

Clausen Ely, Jr.

Enclosure

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March 25, 2004

VIA COURIER

Ms. Rosemarie Henson
Director
CDC/NCCDPHP
Office on Smoking and Health (K 50)
4770 Buford Highway, N.E.
Atlanta, Georgia 30341-3724

Re: 2004 Voluntary Submission Regarding Cigarette Ingredients

Dear Ms. Henson:

Beneath this cover, please find the additional information regarding cigarette ingredients that various cigarette manufacturers voluntarily agreed annually to provide your Office. See Letter from Clausen Ely to former Director Eriksen at 3 (Feb. 4, 2000) (memorializing agreement of certain manufacturers to "make an annual voluntary submission to your Office of composite ingredient information of the type provided in the past"). In keeping with the 2000 agreement, Philip Morris USA's voluntary submission (hereinafter "Spreadsheet Data") provides, for each ingredient:

(1) The associated Chemical Abstract Services Registry Number, if any;

(2) The associated Flavor & Extract Manufacturers Association identification number, if any;

(3) The associated FDA Food Additive Regulation, if any;

(4) The associated maximum use levels (MULs), where applicable;

(5) The total annual pounds used in production (poundage), where applicable;

(6) The ingredient's function; and,

(7) Examples of food products in which the ingredient is used or naturally occurs.

The Spreadsheet Data is presented according to the same three categories employed in the statutorily mandated ingredient list. See Letter from Dr. Richard P. Solana to Director Henson (March 25, 2004) (explaining the three categories of Philip Morris USA's ingredient list).

MUL and poundage information is provided only for ingredients added to cigarettes (whether domestic or export) that are manufactured by Philip Morris USA. Additionally, in light of its decision to submit information on its own behalf, Philip Morris USA is providing your Office with poundage information for any ingredient used in an amount exceeding 10,000 pounds during 2003.

http://legacy.library.ucsf.edu/tid/yqm86a00/pdf

Due to the trade secret and commercially sensitive nature of certain information contained in this submission, Philip Morris USA respectfully requests that your Office continue to maintain the confidentiality of the Spreadsheet Data. See Letter from Director Eriksen to Joseph K. Doss (July 22, 1996) ("As is the case for all other information submitted on tobacco additives, the Office on Smoking and Health will maintain the confidentiality of this [Spreadsheet Data] pursuant to 15 U.S.C. 1335a(b)(2)").

To confirm that your office has received Philip Morris USA's voluntary submission of Spreadsheet Data, please sign the enclosed Certification and return this document in the enclosed overnight envelope.

Philip Morris USA is prepared to make available one or more of its employees to discuss any additional ingredient matters with respect to which your office has a particular interest.

Sincerely,

http://legacy.library.ucsf.edu/tid/yqm86a00/pdf