Response to Public Comments to Federal Register Notice (FRN) Volume 78 No. 211 pp. 65233-65324 Questions and Comments Regarding "Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S." OMB No. 0920-0338

Altria Client Services (ALCS) on behalf of Philip Morris USA, Inc. (PM USA) submits these comments regarding the above Federal Register Notice ("the Notice"). The Notice asks whether ongoing collection by the Centers for Disease Control and Preventions is "necessary for the proper performance of the functions of the agency". We do not believe this collection 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 CDC not to extend similar 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.

ALCS comments addressed two topics:

- Congress empowered FDA with broad authority to collect information and regulate smokeless tobacco ingredients and nicotine content.
- HHS should avoid costly and burdensome requirements by instructing CDC to eliminate dual reporting requirements.

CDC/OSH proposed response to ALCS on behalf of PM USA is as follows:

The Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA)requires annually that CDC's Office on Smoking and Health (OSH) collect, store, and analyze the list of ingredients added to tobacco in the manufacture of smokeless tobacco products. The Ingredient Report must include all additives and flavors. Please note this is an "annual" requirement.

In June 2010, the Family Smoking Prevention and Tobacco Control Act (FSPTCA) required manufacturers and importers to provide FDA within six months of enactment of the FSPTCA "a listing of 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 sub-brand." FDA collected their data in 2009. No other ingredient submission is required unless there is a change in the product.

CDC does believe the FCLAA collection is necessary because it is a statutory requirement and collects tobacco products data yearly. FDA does not collect smokeless tobacco ingredients and nicotine content on an annual basis and therefore cannot collect the ingredient information data required by FCLAA.

In addition, under the Tobacco Control Act, user fees collected by FDA may only be used for the purpose of paying the costs of the activities for FDA to regulate tobacco products. FDA cannot use these funds for any other activity. The Tobacco Control Act does not include authority for FDA to provide tobacco manufacturers, importers and packagers with a Certificate of Compliance that allows them to be in compliance with State requirements for selling tobacco products, and/or to be imported in the United States. States as well as Customs rely upon CDC Certification in order to allow tobacco companies to import and sell their products in the U.S.

The three statutes authorizing CDC and FDA to collect this information would have to be substantially revised to allow the collection of all required product ingredient information by only one of the two

agencies. In light of the potential benefits to sharing information, CDC and FDA will continue to discuss opportunities for programmatic collaborations to enhance the overall utility of both HHS' and FDA's tobacco industry reporting requirements.