CDC Response to Public Comments
Received from Altria Client Services (ALCS) on behalf of Philip Morris USA, Inc. (PM USA)
Federal Register Notice Volume 77, No. 37, pp. 11126-11127, "List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products," OMB No. 0920-0210.

1. ALCS comments addressed 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 and nicotine reporting.

2. CDC/OSH's response to ALCS is as follows:

   - The Federal Cigarette Labeling and Advertising Act (FCLAA), Public Law 89–92, requires annually of CDC's Office on Smoking and Health (OSH) to collect, store, and analyze the list of ingredients added to tobacco in the manufacture of cigarettes. The Ingredient Report must include all additives and flavors.

   - FCLAA requires, by March 31 each year, each person who manufacturers, packages, and/or imports to report a list of all ingredients added to tobacco in the manufacture of cigarettes during the previous calendar year.

   - Upon review and validation of each submitted annual report CDC/OSH provides the manufacturer, packager and/or importer a Certificate of Compliance; which is required for entities to be lawfully allowed to sell cigarettes in the U.S.

   - In June 2010, 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 subbrand."

   - The Act requires that manufacturers to provide an ingredient listing under the following circumstances: (1) prior to new cigarette brand style; (2) prior to increasing or adding a new ingredient to an existing cigarette brand style; (3) eliminating or decreasing an additive to an existing cigarette brand style; (4) adding or increasing an additive designated as not harmful by FDA to an existing cigarette brand style.

   - Currently the tobacco industry is required to provide State Attorney General's (SAG) the HHS Certificate of Compliance in order to sell their tobacco products in the United States. The FSPTCA does not supply the tobacco industry with annual compliance, but rather inspects and gives compliance to retailers, not manufacturers, packagers and importers. .

   - If ALCS's request is permitted, the tobacco industry cannot provide the SAG's offices accurate certifications, thus the tobacco industry will not be allowed to sell their tobacco products in the US.

Given the above, while similarities do exist in the nature of the information collected, key differences in the scope and detail of the information make these collections non-duplicative. Aligning the programmatic collection and sharing of information will improve the overall utility of data collected. This will allow the agencies to verify the reliability and accuracy of the data, given CDC's year-by-year program and ability to serve as an annual quality assurance check for FDA monitoring of cigarette changes by manufacturers.

It would be beneficial if the Secretary would grant both HHS agencies the ability to share information received under the FCLAA and FSPTCA legislations.