Response to Public Comments to Federal Register Notice (FRN) Volume 77 No. 41, pp. 12595-12596 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

1. **jeanpublic1@gmail.com "Don't need this anymore"**

   OMB-Comments (CDC) has deemed this comment as a non-substantive comment and replied with CDC's standard response.

2. **Altria Client Services(ALCS) on behalf of Philip Morris USA, Inc. (PM USA) please see Attachments 11 & 12**

   ALCS comments addressed 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.

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

   - CSTHEA Public Law 99–252 requires annually of CDC's Office on Smoking and Health (OSH) to collect, store, and analyze the list of ingredients added to cigarettes and smokeless tobacco products.

   - CSTHEA 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 smokeless tobacco products with a specification of the quantity of nicotine contained in each product

   - 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 tobacco products 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.

   - FSPTCA does not collect smokeless tobacco ingredient and nicotine data on an annual basis, therefore, not providing State and local entities with accurate and sufficient data, in protecting the public's health concerns.

   - The Act requires that manufacturers to provide an ingredient listing under the following circumstances: (1) prior to new brand style; (2) prior to changing an existing brand style of smokeless tobacco product(s); (3) adding or increasing an additive as part of premarket review of a new or modified brand style.

   - FSPTCA act does not meet the requirements of selling tobacco products in the U. S. The Act does not provide States with compliance, instead, inspects and gives compliance to retailers, not manufacturers, packagers and importers.

- If ALCS's request is permitted, the state and local tobacco control programs will not have full disclosure to accurate tobacco product data and would depend upon year(s) old information.

- CSTHEA provides manufacturers, packagers and importers with required certification to import and sell tobacco products in the U.S.

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 tobacco product changes by manufacturers.

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