ATTACHMENT 9B

**Text of CDC correspondence sent in response to public comment submitted for Document Entitled "Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S"**

This letter is in response to two public comments submitted by Altria Client Services LLC on behalf of Philip Morris USA, Inc., Sherman Group Holdings LLC and its subsidiaries, and U.S. Smokeless Tobacco Company LLC. The comments dated October 19, 2018 were submitted in response to CDC's Federal Register Notices: 1) "*List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products"* (OMB No. 0920-0210), and; 2) *"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).

The comments suggest that there are duplicative reporting requirements across the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) and state that all reporting requirements should be centralized under FDA. The information collected by CDC is Congressionally-mandated by the Federal Cigarette Labeling and Advertising Act (FCLAA) and the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA). The information collected by FDA is Congressionally-mandated by the Federal Food, Drug, and Cosmetic Act (FDCA) as amended by the Family Smoking Prevention and Tobacco Control Act (TCA).

While there is some overlap in the data collected, FCLAA and CSTHEA contain requirements that differ from the statutory requirements for submission of information in the FDCA. For instance, FCLAA and CSTHEA require ingredients to be provided annually whereas the FDCA only mandates annual submissions detailing lists of products, but not ingredients. FDCA only requires submission of ingredients prior to a tobacco product's delivery for introduction into commerce and thereafter if certain changes are made to such product.

Further, FCLAA and CSTHEA allow for the list submission of ingredients in a way that does not identify the company that uses the ingredients or the brand of cigarettes or smokeless tobacco containing the ingredients. The FDCA, on the other hand, requires submission of all ingredients by quantity, brand, and sub-brand. FCLAA and CSTHEA also contain specific requirements concerning written procedures assuring confidentiality, physical possession of information, as well as storage requirements. The FDCA does not require that level of specificity.

CDC and FDA continue to discuss ways to avoid duplication. However, at present, in order to meet the Congressional mandates it remains necessary that the separate data collections occur.