

## Summary of CDC Response to Public Comment Received:

A public comment dated March 5, 2019 was submitted in response to the Office of Management and Budget's publication seeking comment on the annual collection of composite lists of ingredients added to tobacco in the manufacture of cigarette products (Docket No. CDC-2019-01322, "Agency Forms Undergoing Paperwork Reduction Act Review"). In summary, the public comment proposed three main points: 1) the current information collection regime is unnecessarily redundant; 2) HHS should delegate administration of the Federal Cigarette Labeling and Advertising Act (FCLAA)'s reporting requirement to FDA; and 3) the notice underestimates the burdens imposed by CDC's information collection request.

In response, CDC provides the following information:

The public comment submitted suggests that there are duplicative reporting requirements across the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) and states that all reporting requirements should be centralized under FDA. The information collected by CDC is Congressionally-mandated by 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 brand of smokeless tobacco which contains 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.

With regard to the estimated burden referenced in the OMB package, the burden estimate is based on experience with the information collection in the prior approval period. As before, the average burden per response has been estimated at 6.5 hours.