

Response to Public Comments to Federal Register Notice (FRN) Volume 78 No. 211 pp. 65234-65325 Questions and Comments Regarding “List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products” OMB No. 0920-0210 and “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.

Coalition of Independent Tobacco Manufacturers of America:

The Coalition of Independent Tobacco Manufacturers of America (CITMA) respectfully submits these comments in response to the Centers for Disease Control and Prevention’s (CDC’s) invitation to submit comments relating to the information collection for the following proposed projects: (1) List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products (OMB No. 0920-0210, exp. 2/28/2014) 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, exp. 2/28/2014).

Each of the CDC’s information collections are duplicative of the Food and Drug Administration’s (FDA’s) collection of tobacco product ingredient lists and reports on the quantities of harmful and potentially harmful constituents (HPHCs) in tobacco products. Both CDC and FDA are part of the Department of Health and Human Services (HHS) and through a formal inter-agency Memorandum of Understanding (MOU) could easily share this information without requiring manufacturers and importers to submit the information multiple times. Thus, the collection by CDC of information relating to ingredients in cigarettes and ingredients and nicotine in smokeless tobacco is not necessary for the proper performance of the CDC’s functions and will not have practical utility.

CITMA’s Recommendation:

FDA’s collection of information under the FFDCa covers all of the information collected by CDC under the CSEA and CSTHEA, but in substantially greater detail. Moreover, FDA requires the submission of such information at least 90 days prior to delivery of a new tobacco product into interstate commerce and each time any additive, or the quantity of any additive, is changed. In light of FDA’s active regulation of these tobacco products, in particular enforcement of section 904 of the FFDCa, CDC’s proposed collection of information is duplicative, lacks practical utility, and is a waste of government and industry resources. Thus, to minimize the burden on respondents and the agencies, CITMA recommends that CDC enter into an MOU with FDA with respect to these information collections. The agencies should work together to ensure that FDA receives cigarette and smokeless ingredient and smokeless tobacco nicotine content listings in a format that can be converted for sharing with and use by CDC consistent with its statutory mandates.

CDC/OSH Response:

The Federal Cigarette Labeling and Advertising Act (FCLAA), Public Law 89–92; The Comprehensive Smoking Education Act of 1984 (CSEA); and 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 tobacco products. The Ingredient Reports 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 tobacco ingredients on an annual basis and therefore cannot satisfy the requirements of the FCLAA statute.

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.