December 26, 2013

Via email omb@cdc.gov

Re: Proposed Data Collections Submitted for Public Comment and Recommendations: List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products; Annual Submission of the Ingredients Added to, and the Quantity of Nicotine Contained in, Smokeless Tobacco Manufactured, Imported, or Packaged in the U.S., Request for Comments (OMB Nos. 0920-0210, 0920-0338)

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). CITMA is a trade coalition group that represents small tobacco product manufacturers (STPMs), defined in the Federal Food, Drug, and Cosmetic Act (FFDCA) as domestic tobacco manufacturers and importers that employ fewer than 350 people each. 21 U.S.C. § 387(16).

In particular, CDC requested comment on:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;
(b) The accuracy of the agency's estimate of the burden of the proposed collection of information;
(c) Ways to enhance the quality, utility, and clarity of the information to be collected; and
(d) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

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.

CDC's Information Collection

The Comprehensive Smoking Education Act of 1984 (CSEA) requires each person who manufactures, packages, or imports cigarettes to provide the Secretary of HHS with a general list of ingredients added to tobacco in the manufacture of cigarettes. *See* 15 U.S.C. § 1335a(a). HHS has delegated responsibility for implementing the CSEA's ingredient reporting requirements to CDC's Office on Smoking and Health (OSH). CDC requires the ingredient report to be submitted by chemical name and CAS number. Ingredient reports must be filed with CDC annually.

The Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA) likewise requires each person who manufactures, packages, or imports smokeless tobacco products to provide the Secretary of HHS with a general list of ingredients added to tobacco in the manufacture of smokeless tobacco products. *See* 15 U.S.C. § 4403(a)(1)(A). The CSTHEA further requires submission of the quantity of nicotine contained in each smokeless tobacco product. *See* 15 U.S.C. § 4403(a)(1)(B). As with cigarettes, HHS has delegated responsibility for implementing the required information collection to CDC's OSH. Respondents are required to meet reporting guidelines and to submit the ingredient report by chemical name and CAS Registration Number. Ingredient reports must be filed annually.

FDA's Information Collection

*Ingredient Lists*

Section 904(a)(1) of the FFDCA requires each tobacco product manufacturer or importer, or agent thereof, to submit a listing of all ingredients, including tobacco, substances, compounds, and additives that are 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. For tobacco products on the market as of June 22, 2009, the list of ingredients was first required to be submitted by December 22, 2009. For tobacco products not on the market as of June 22, 2009, section 904(c)(1) requires that the list of ingredients be submitted at least 90 days prior to delivery for introduction into interstate commerce. Section 904(c) also requires submission of information whenever any additive, or the quantity of any additive, is changed.

FDA has issued detailed guidance on the information that must be included in the list of ingredients, as well as the level of detail required in the submission. *See* Guidance for Industry: Listing of Ingredients in Tobacco Products (Nov. 2009) (attached). For example, ingredients that are single chemical substances that may be purchased or prepared in-house and purified must be identified by unique scientific name or code, such as the FDA Unique Ingredient Identifiers (UNII) code, Chemical Abstract Service (CAS) number, or International Union of Pure and Applied Chemistry (IUPAC) name. FDA also requires identification of the quality of the ingredient, any internal identification number, and the expected function. FDA's guidance provides extensive advice on how manufacturers and importers should report required information for leaf tobacco, complex purchased ingredients, and reaction products. FDA thus collects information on cigarette and smokeless ingredients that it could easily share with CDC.

*HPHC Reporting*

Section 904(a)(3) of the FFDCA requires each tobacco product manufacturer or importer to report to FDA "all constituents, including smoke constituents, identified by [FDA] as harmful or potentially harmful to health in each tobacco product, and as applicable in the smoke of each tobacco product." For tobacco products that were not on the market on June 22, 2009, section 904(c)(1) requires that these reports be submitted to FDA at least 90 days before the product is delivered for introduction into interstate commerce.

FDA issued a draft guidance document that expressed the agency's intent to require reporting of an abbreviated list of HPHCs, which includes nicotine levels for both cigarettes and smokeless tobacco products. *See* Draft Guidance for Industry: Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act (March 2012) (attached). FDA recommends 20 replicates for the determination of quantities of nicotine in cigarette smoke and seven replicates for the determination of nicotine in smokeless tobacco. FDA also specifically recommends use of the CDC method to calculate nicotine levels in smokeless tobacco products and therefore should receive nicotine content data that will satisfy CDC requirements. If FDA and CDC coordinate, manufacturers and importers could provide to FDA the nicotine subset of HPHC data in an electronic format that FDA may then convert for sharing with and appropriate use by CDC, without the need for duplicative recordkeeping or regulatory submissions.

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.

Thank you for your consideration of the foregoing comments. Please do not hesitate to contact me should you require additional information.

Respectfully Submitted,

Kevin Altman
Consultant, CITMA