June 10, 2013

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2013-N-0377

The undersigned organizations hereby submit these comments in the above-designated docket, which solicits comments on the collection of health documents created during the period June 22, 2009 through December 31, 2009 pursuant to Section 904 of the Food, Drug and Cosmetic Act as amended by the Family Smoking Prevention and Tobacco Control Act of 2009 ("the Act").

Section 904 creates two sets of requirements for production of documents by tobacco product manufacturers to FDA: section 904(a)(4) requires production of documents developed after June 22, 2009 relating to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives. The statute requires manufacturers to submit all such documents to FDA whether or nor FDA specifically requests them.

The second set of requirements, contained in section 904(b)(1)-(3), applies to three sets of documents: (a) documents relating to health toxicological, behavioral, or physiologic effects of current or future tobacco products and developed on or before June 22, 2009; (b) documents developed either before or after June 22, 2009 "relating to research activities, and research findings. . .possessed by the manufacturer. . .related to the issue of whether a reduction in risk to health from tobacco products can occur upon the employment of technology available or known to the manufacturer. . .or (c) relating to marketing research involving the use of tobacco products or marketing practices and the effectiveness of such practices used by tobacco product manufacturers." Manufacturers are required to submit all documents within these categories to FDA upon FDA's request.

It is extremely important for FDA to have comprehensive information about all of these categories in order for it to fulfill its regulatory function. Documents comprehended by these categories are highly relevant to (1) the development of potential

product standards under Section 907; (2) determinations of substantial equivalence under Sections 910 and 905(j); (3) determinations as to new product applications under Section 910; (4) determinations as to modified risk tobacco products with regard to Section 911; and (5) determinations as to potential restrictions on marketing under Section 906. Moreover, as discussed at length in our recently submitted comments on good manufacturing practices, documents relating to marketing research on the use of tobacco products will demonstrate that the results of marketing research on the use of tobacco products determine the outcome of business decisions regardless of the health effects of such decisions.[1] Products with the greatest sensory appeal to the targeted market are those that are marketed and promoted, regardless of the public health consequences.

In order for FDA to exercise its regulatory authorities effectively, FDA must be as knowledgeable as possible about all research regarding the health effects of tobacco products, including having information about all research conducted by the manufacturers and research not undertaken by the manufacturers. Having comprehensive information from the manufacturers regarding their research is an essential element.

Moreover, FDA must also have comprehensive information regarding the reasons why manufacturers have failed to employ readily available technologies that would substantially reduce the levels of toxicants in tobacco products. For example, although technology has been available for more than 15 years to greatly reduce the levels of TSNAs in cigarettes and smokeless tobacco, few if any manufacturers of tobacco products sold in the United States have used such technologies and consumers have unnecessarily been exposed to high levels of such toxicants. Similarly, although the technology has existed to greatly reduce the toxicant levels in smokeless tobacco (technology that has been employed for many years in Sweden), nearly all smokeless tobacco sold in the United States has toxicant levels far in excess of the levels achieved in Sweden. Available documentation cited in our comments on good manufacturing practice demonstrates that the reason for these failures is that manufacturers have placed a higher priority on developing and marketing products that are most appealing to the targeted consumer base than on developing and marketing products that limit consumers' exposure to risk. Section 904 requires manufacturers to submit many of the documents that would more fully expose these policies and gives FDA authority to require submission of all documentation relevant to such policies.

To date, however, we do not know if FDA has required manufacturers to provide FDA the information <u>they are required</u> by the statute to submit and has taken few if any steps to require submission of information FDA is authorized to require. According to information in the notice, it appears that the only documents submitted pursuant to section 904(a)(4) is information created between June 23, 2009 and December 31, 2009. FDA has evidently not required documents created in the three-and-one-half years since December 31, 2009 to have been submitted—despite the fact that submission of such documents is both required by statute and highly pertinent to the exercise of FDA's

[1] Comments of certain of the undersigned organizations in Docket No. FDA-2013-N-0227, 78 F.R. 16824 (March 19, 2013).

central regulatory authorities. FDA has a statutory obligation to establish a mechanism to ensure that this information is provided to the agency on an ongoing, real time basis.

Moreover, it does not appear that FDA has made use of its authority under any section of Section 904(b) to require production of documents created before June 22, 2009 that may have important implications for the development or enforcement of regulatory policy. The failure to require production of such documents is not consistent with the development of sound regulatory policies.

The notice in this docket ignores all these problems and focuses on an extremely narrow set of technical issues. The notice invites comment on a number of topics. In response to this invitation, it is the view of the undersigned organizations that collection of all the information either required to be submitted under Section 904(a)(4), or required to be submitted pursuant to FDA request under Section 904(b), is necessary for FDA to fulfill its regulatory functions under sections 905(j), 906, 907, 910, and 911 of the Act and that its submission and analysis will materially assist the formulation of regulatory policy.

One need only look at the amount of previously unknown information revealed and the effect of the disclosures of the tobacco industry documents produced in the state litigation in the late 1990s to see the importance of document disclosure. The value of these documents to researchers and regulators in understanding decision making by the tobacco industry cannot be overstated. Effective regulation will require full production and analysis of all documents subject to sections 904(b)(4) and 904(c).

It is understandable that FDA would need to set priorities for what information it requests first under Section 904(b) so that it is not overwhelmed with information, but it should set a schedule for receiving all of the information potentially relevant to its authority so that over the course of a reasonable period of time (no more than 2 years) it obtains all of the information called for by Section 904(b). As the documents obtained by the state attorneys general demonstrate, there is a wealth of important information that is still relevant today in documents that go back to the 1960s.

Among the priorities should be any documents on the role of substances of concern related to their impact on toxicity, addictiveness or impact on youth initiation, such as NNN and NNK, acetaldehyde, ammonia, benzo[a]pyrene, particle size, nicotine, polonium-210, acrolein, pH, leveulinic acid, lead, cadmium, arsenic – whenever the research was conducted. Internal marketing research should also be a priority both as FDA evaluates modified risk claim applications and as FDA assesses the role of certain forms of marketing, certain marketing claims or the placement of marketing on matters such as youth initiation or consumer understanding of risk. Furthermore, such documents will reveal the manner in which health considerations were or were not considered in decision making regarding product design and marketing.

Moreover, FDA should not restrict the requirement for submission to those created within a short time period. The fact that—four years after the enactment of the

Act—the only documentation submitted covers a mere six-month period is evidence that this authority has been inadequately used.

Nor should documentation created before June 22, 2009 be exempted from submission. FDA has the resources to develop an effective program for receipt and analysis of this data and implementation of such a program should be a priority. Given the industry's record of obfuscation and deceit, there can be no substitute for production of all industry documentation that could be material to the exercise of FDA's authority. Moreover, given the huge public health problem that tobacco use represents and the likelihood that effective regulation could ameliorate this problem, the benefits of full document production substantially outweigh the burdens of production imposed on the manufacturers who created the problem.

It is important for FDA to make effective enforcement of its document production authority a real priority. Doing so will create a firmer foundation for the exercise of its regulatory authority in numerous areas.

We strongly urge FDA to develop, promptly and effectively, a program to require production and analysis of all documentation required to be produced under section 904(a)(4) or within the authority of FDA to request under section 904(b) in order to inform the development of regulatory policy and facilitate an understanding by the regulatory authority of the way the tobacco industry has chosen to design and market its deadly products.

Respectfully submitted,

American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco-Free Kids
Legacy
Tobacco Control Legal Consortium