October 11, 2016

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

Re: Docket No. FDA-2009-D-0600-0015

Ladies and Gentlemen:

The undersigned organizations submit these comments on the revised draft guidance in the above-designated docket.

Section 904(a)(4) of the Tobacco Control Act requires manufacturers to submit to FDA "all documents developed after June 22, 2009 that relate to the health, toxicological, behavioral or physiologic effect of current or future tobacco products, the constituents (including smoke constituents), ingredients, components and additives." The documents required to be produced pursuant to this provision provide evidence to inform the primary mission of FDA under the TCA: to protect the public health from the adverse health consequences caused by tobacco products.

However, FDA has not followed either the spirit or the letter of this provision with regard to cigarettes, smokeless tobacco and roll-your-own tobacco by failing to require that tobacco product manufacturers produce any documents created after December 31, 2009. In 2010 FDA proposed to collect documents created between June 22, 2009 and December 31, 2009. 75 Fed. Reg. 20606 (April 20, 2010). However, FDA never required production of such documents created after that date.

In April, 2013 FDA stated that it was "in the process of revising the April 2010 guidance and invited public comment on, inter alia, "whether the proposed collection of information is necessary for the proper performance of FDA's functions." 78 Fed. Reg. 21379 (April 10, 2013). In response, the undersigned organizations submitted comments stating that the statute requires production of all such documents for all periods subsequent to June 22, 2009 and urging FDA not to truncate this obligation to documents created before December 31, 2009. That comment

stated, "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." Comment filed on June 13, 2013 in Docket No. 2013-N-0377 (attached hereto). That comment described in detail why provision of this information was not only required by the statute, but was essential to FDA's performance of its statutory duties. On August 14, 2010, FDA issued another notice acknowledging that the statute "sets out an ongoing requirement and once again stating that "FDA is in the process of revising the April 2010 guidance to specify the timing of subsequent submissions." 78 Fed. Reg. 49528 (August 14, 2013). Despite this statement, FDA has not required the production of any subsequently created documents. Thus, by its inaction, FDA has effectively nullified section 904(a)(4).

In this draft guidance, FDA proposes similarly to nullify this requirement with regard to the tobacco products subjected to FDA jurisdiction by the deeming rule. FDA states that it will seek production only of documents created during the six-month period between June 22, 2009 and December 31, 2009. Draft Guidance at p. 13 It is difficult to understand how doing so could be consistent with FDA's obligation to protect the public health. In the deeming rule, FDA concluded that regulation was necessary precisely to learn more about the potential health effects of the deemed products. As the FDA stated in the text accompanying the deeming rule, "the Agency has concluded, based on scientific data, that the newly deemed products should be regulated due to their potential for public harm and *regulation is necessary to learn more about that potential.*" 81 Fed. Reg. at 28973 Documents in the files of e-cigarette manufacturers concerning the health effects of e-cigarettes are potentially important sources of such information. Moreover, if no such documents exist that fact in itself would be revealing. Given that the large majority of e-cigarette products currently marketed were not on the market before December 31, 2009, if potentially useful documents exist, the strong likelihood is that they were created after December 31, 2009. The limitations imposed by FDA virtually guarantee that few, if any, useful documents will be produced and that FDA will be denied important information that the statute requires manufacturers to provide. Remarkably, the guidance document provides no rationale for effectively writing section 904(a)(4) out of the statute.

FDA may believe that it will receive such information from manufacturers with regard to products for which new product applications or substantial equivalence applications are filed. However, because FDA has given manufacturers of the deemed products lengthy compliance periods before applications must be submitted, those documents may not be forthcoming until February 8, 2018 for substantial equivalence applications and August 8, 2018 for new product applications. Moreover, even if such information were provided in the application process no health documents would be required to be produced for products as to which manufacturers do not file applications even though those products could be causing great harm to public health right now. For example, if a manufacturer decided not to file a new product application for a product because the product was producing adverse health effects, provision of information about such adverse health effects could provide significant information that would justify strong

regulatory action to protect the public from those adverse effects. Yet under the policy announced in this guidance, no such health documents would be produced.

In short, there does not appear to be a defensible rationale for the distinction created in this guidance or for nullifying the statutory obligation of manufacturers to produce documents relating to the health effects of their products for all periods except an arbitrarily chosen six-month period in 2009. We urge FDA to rescind this guidance and to enforce section 904(a)(4) as it was written. Indeed, we believe the law requires nothing less – and for good reason.

Respectfully submitted,

American Cancer Society Cancer Action Network
American Heart Association
American Lung Association
Campaign for Tobacco-Free Kids
Truth Initiative