April 3, 2015

Mitchell Zeller
Director, Center for Tobacco Products
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: Docket No. FDA-2011-D-0147

Dear Director Zeller:

The undersigned organizations, all of which have submitted extensive comments in various dockets on substantial equivalence, write to express concerns regarding the guidance issued by FDA on March 4, 2015 in the above-designated docket.[i]

The new guidance creates a new pathway to market for two very narrowly defined sets of products:

- Products as to which the only change is a change in the product's name or labeling and
- Products as to which the only change is a change in quantity.

For both classes of products, the pathway would apply because they have "the same characteristics."

It is our understanding that the "Same Characteristics SE" pathway only applies in the two situations described above. A manufacturer could not use the "Same Characteristics SE" pathway if any change whatsoever has been made to the product itself, such as a change in the ingredients, constituents, smoke constituents or any other component of the product, because the product would not have the "same characteristics" as the predicate product.

As an example of what might qualify for the new pathway, we are aware that some manufacturers may fabricate private label cigarettes that carry several different labels but that are manufactured to identical specifications on the same machines and using all the same components and ingredients and using the same design. Assuming the cigarettes are actually manufactured in accordance with the same specifications, we understand that under the new guidance such cigarettes could qualify for the new pathway as having the "same characteristics" but that if any change was made to the product itself such cigarettes would not qualify.

1) Our first concern is to assure that FDA's stated intention—to permit a pathway to market only for products that are exactly the same in every respect as the predicate product—is accurate, understood

by all stakeholders and that mechanisms are in place to insure that it is actually accomplished. We are concerned that it is possible that the tobacco industry could interpret the scope of the "Same Characteristics SE" pathway more broadly and we urge the FDA to clarify to all stakeholders that our understanding is correct.

2) We also remain concerned about whether the self-certification mechanism in the new Guidance is sufficient to guarantee that FDA knows fully and exactly what is in the product subject to the application. The self-certification can accomplish that goal only if the manufacturer certifies that the product is "identical in every respect" to a predicate product for which the manufacturer has already provided the FDA the same information fully and completely. During the Webinar held by FDA on March 24, 2105, Christi Starke, the Associate Director of Science Policy of the Office of Science of CTP, indicated that such a certification was FDA's intent but we are concerned that the new Guidance document needs to be clearer on that point.

Under the new guidance, a manufacturer could allege that its product has the "same characteristics" as a predicate product even if the predicate product is the subject of a provisional substantial equivalence application that has not yet been acted on. Furthermore, the guidance would allow the manufacturer to market its product based on this self-certification.

As FDA has made clear many times, many substantial equivalence applications have been found to lack complete information about the new product or the predicate product. In fact, more than 86 percent of the substantial equivalence applications resolved to date have either been denied or withdrawn by the manufacturer. Unless the provisional application that can serve as the predicate product under the new guidance contains complete information with respect to each and every characteristic, it cannot be shown that the new product has all the "same characteristics" as the predicate product.

3) In addition, there is no statutory basis for such provisionally marketed product to serve as a predicate product. The statute does not permit FDA to base a decision to allow a product to be marketed where the predicate product has not been reviewed by FDA and for products for which incomplete information has been provided or where the manufacturer has not even alleged that the underlying product has the same characteristics as a product marketed on February 15, 2007.

4) We have concerns about what information will be made public regarding products that will be marketed while Same Characteristics SE applications are pending. It is important for such products to be publicly identified at or before the time they are marketed. FDA's policy of refusing to identify products that are the subject of SE applications should not be extended to this new category of applications. Because such applications contain no information about the actual characteristics of the products there is no risk that information regarded as confidential could be disclosed.

5) As we noted in our prior comments, we also remain concerned about the consequences of FDA's response to question 17, indicating that FDA "does not intend to enforce the requirements of sections 910 and 905(j) for tobacco blending changes required to address the natural variation of tobacco. . .in order to maintain a consistent product." Despite the limitation in the sentence that "blending changes that are intended to alter the chemical or perception properties of the new product (e.g., nicotine level, pH,

smoothness, harshness, etc.)" must be reported, we believe that making the availability of the exception depend on the manufacturer's intention is not appropriate for the protection of the public health. As we have pointed out in previous comments, blending changes that have the actual effect of altering the chemical or perception properties of the new product should not be permitted in the absence of prior FDA review regardless of the manufacturer's intention.[ii] For example, a blending change that results in higher nicotine content or higher TSNA content could have significant public health consequences. The existence of this exemption becomes even more troubling when such products can serve as predicate products. Under this provision, the "characteristics" of either a predicate product or a new product—insofar as such characteristics are determined by blending changes—need not be fixed but may change depending on a manufacturer's intention.

We would appreciate the opportunity to meet with you to discuss these concerns and to work constructively with you to address them. We will contact your office to set up a meeting.

Sincerely,

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

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[i] Comments on substantial equivalence of Campaign for Tobacco-Free Kids, et al., in Docket No. FDA-2010-D-0635 (March 22, 2011); Docket No. FDA-2011-D-0147 (November 8, 2011); Docket No. 2013-N-1588 (January 28, 2013); Comments on substantial equivalence of Campaign for Tobacco-Free Kids Docket No. FDA-2013-N-1588 (February 18, 2014 and February 25, 2014); Comments on new products of Campaign for Tobacco-Free Kids, et al., in Docket No. FDA-2011-D-0212 (December 27, 2011).

[ii] In addition to our comments in dockets directly concerning substantial equivalence, we believe comments that we filed on Good Manufacturing Practices in Docket No. FDA-2013-N-0227 are highly relevant, a copy of which is attached hereto. In those comments, we responded to contentions by tobacco product manufacturers that FDA's policy of not objecting to tobacco blending changes intended to maintain a consistent product permitted manufacturers to make such changes without notifying or seeking authorization from FDA regardless of the effects of such changes on the public health. We argued that if a blending change intended to produce consistency in sensory experience comes at the expense of an increase in exposure to carcinogens, the resulting product should not fall within this exception. (see comments, pp. 6-10) It is important for FDA to clarify the scope of its response to question 17.