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

Re: FDA Docket No. FDA-2013-N-1588

The Campaign for Tobacco-Free Kids ("TFK") submits these comments in the above-designated docket concerning the collection of information with regard to applications submitted pursuant to section 905(j)(iii) of the Food, Drug and Cosmetic Act (21 USC § 387(e)(j)(iii)) for applications for exemptions from the substantial equivalence requirements for "minor modifications" of tobacco products. FDA sought public comments for a proposed rule on this subject in Docket No. FDA-2010-D-0646 and TFK submitted comments therein on March 22, 2011. Those comments are incorporated by reference in this comment. After receiving comments on the proposed rule, FDA issued a final rule on July 5, 2011 76 Fed. Reg. 38961-75, 21 CFR 1107.1.

The requirements for information to be submitted in connection with such an application are set forth in 21 CFR 1107.1. The Tobacco Control Act (the "Act") provided for premarket review of any modifications in tobacco products marketed on February 15, 2007 and provided several different pathways for such review. No such premarket review had been required prior to the Act and manufacturers had been free to modify their product in any way without prior notice or approval and without disclosing any such modifications to the public. The most recent Report of the Surgeon General, issued in January 2014, describes the result of these practices. As detailed in the Report, products made without premarket review resulted in cigarettes today that are both more addictive and more deadly than cigarettes in 1964. Because of changes in the design and composition of the product, smokers today have a substantially higher risk of lung cancer than they had in 1964. These results counsel against the creation of any shortcuts that would permit modifications of tobacco products without premarket review.

The statutory scope of modifications of a tobacco product eligible for classification as "minor modifications" (and therefore subject to the least rigorous premarket review) is

appropriately narrow. The statute limits "minor modifications" to changes in the level of an additive. Moreover, such an exemption may be granted only if FDA finds that "a [substantial equivalence] report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health" and that "an exemption [from the substantial equivalence reporting requirements] is otherwise appropriate." Given the limited experience FDA has had considering such modifications, FDA has correctly been unwilling to create blanket categories of modifications that would be entitled to treatment as "minor modifications." FDA should continue on its current course of requiring individual applications for each such proposed modification. Although such a requirement will result in more applications than would occur if a blanket exemption were issued, there is no justification for a blanket exemption. Moreover, the importance of meaningful premarket review in protecting the public health constitutes ample justification for continuation of this policy.

We are concerned that the information FDA proposes to require from manufacturers seeking such an exemption is inadequate to support a finding that a substantial equivalence report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health. Proposed alterations of a product that could be eligible for designation as "minor modifications" should, at an absolute minimum, require a statement of the precise amount of the additive in the predicate product and the precise amount in the product that is the subject of the minor modification application. Furthermore, the manufacturer should provide an explanation, supported by evidence, as to why the proposed change in the level of the additive would not increase either (1) the toxicity, (2) the addictiveness, or (3) the likelihood that non-smokers would start using the product and that the proposed change would not diminish cessation.

FDA's experience in reviewing substantial equivalence applications has demonstrated that manufacturers frequently provide inadequate information in support of their applications and that FDA must often insist on provision of additional information before it can consider such an application. There is no reason to believe that manufacturers would perform any better in the submission of applications for exemptions from such applications. It would be a major mistake for FDA to create a process that enables manufacturers to avoid provision of sufficient information merely upon their assertion that the modification is "minor." The industry's long record of deception, coupled with the manifest inadequacy of most of the substantial equivalence applications submitted, demonstrates the danger of relying on conclusory statements by the applicants. FDA should require precise quantification of the additive in question and scientific evidence in support of the assertion that the change in the level is "appropriate for the protection of the public health."

The Surgeon General's Report's findings are also a reminder that changes that seem "minor" can produce long-term harmful results. It is also a reminder that because the tobacco industry has not previously been required to provide data when it made changes to its products or assess the health impact of those changes, in most situations FDA will not have the evidence

needed to be certain that a change won't produce an increased risk of disease, addictiveness or make the product more appealing to non-smokers.

Moreover, FDA should establish procedures to prevent successive "minor modifications" to the same product which cumulatively would not be appropriate for the protection of the public health.

In establishing ground rules for "minor modification" applications, FDA should bear in mind that what manufacturers are seeking is an exemption from requirements that are themselves weaker than the requirements generally applicable to product modifications under the statute; that the product at issue is lethal; that tobacco product manufacturers have a long history of altering their products in ways that make them more lethal, more addictive, more likely to increase initiation and discourage cessation and hiding or misrepresenting the results of such alterations; and that, given the opportunity to establish substantial equivalence tobacco product manufacturers have generally failed to provide sufficient information in their applications. Given these considerations, FDA's should establish requirements sufficient to ensure that manufacturers cannot exploit this narrow exception at the expense of public health.

Respectfully Submitted,

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