COMMENT SUBMITTED IN RESPONSE TO FDA ON PROPOSED COLLECTION OF INFORMATION REGARDING EXEMPTIONS FROM SUBSTANTIAL EQUIVALENCE REQUIREMENTS FOR TOBACCO PRODUCTS

Docket No. FDA-2013-N-1588

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I'm submitting these comments in response to FDA's notice concerning the proposed collection of information regarding exemptions from substantial equivalence requirements for tobacco products (i.e., Docket No. FDA-2013-N-1588).

The FDA rule establishing procedures for tobacco companies to request exemptions from the substantial equivalence requirements of the Family Smoking Prevention and Tobacco Control Act needs to be evaluated carefully since it potentially has created a loophole that gives tobacco companies an opportunity to alter their products in ways that could impact smoking behavior in ways to promote appeal, addiction, and or toxicity by claiming that modifications are "minor" and insignificant. Any modification to a tobacco product and its packaging, even those claimed to be minor, can be significant in terms of how it impacts smoking behavior.

In the past, modifications to tobacco products were made routinely by manufacturers without any notification to consumers or regulatory agencies(1). For example, between 1954 and 1983 RJ Reynolds documented over 80 modifications to its Winston King Size brand, including multiple changes in tobacco blend, filter length, paper, casings and top dressing(2). In 1979, RJ Reynolds added ammonia to its G7 recon tobacco. Internal business records reveal that the addition of ammonia made cigarettes more attractive, appealing, and potentially more addictive. None of these modifications were revealed to consumers or government regulators, although the effects of these modifications were monitored by manufacturers and their effects on smoking behavior and sales carefully tracked.

While the proposed collection of information on product modifications is necessary, it is not sufficient for FDA to properly meet its mandated responsibility to protect the public health. The public health requirement of the Family Smoking Prevention and Tobacco Control Act (FSPTCA) requires that in reaching its determination that a tobacco product may be exempt from the substantial equivalence reporting requirements, FDA must determine not only that the product modification would be a "minor modification," but also that a 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 is otherwise appropriate. It is essential for FDA to exercise this authority and require as much information as is necessary to make a determination that will protect the public health.

This mandate is different than FDA's regulatory authority over drugs and medical devices, which requires FDA to strike an appropriate balance between the public's need to get fast access to potentially life-saving medications and the need to ensure that those products are

safe and effective, FDA's regulatory authority over tobacco products is intended to protect the public from those very products, since they are known to be lethal if used as directed.

Although the final rule provides that an exemption request must contain a detailed explanation of the purpose for the modification and a detailed description of the modification, including whether the modification involves adding or deleting a tobacco additive, or increasing or decreasing the quantity of the existing tobacco additive, it does not explicitly require exemption requests to include statements, supported by scientific evidence, indicating the exact amount of the additives contained in the predicate product and the exact amount of the additives contained in the modified product together with compelling evidence from adequately powered studies to demonstrate that these changes do not increase health risks to individual consumers or the population as a whole.

The FDA should require this level of detail and specificity. By requiring this specificity, FDA would be better able to make an independent determination about whether the modification is indeed "minor" and whether the modified product would be appropriate for the protection of public health. Moreover, the FDA should set a small limit on the number of "minor modification" exemptions it will permit for any one product and its successor products. Without such a limit, a manufacturer could over time request a string of "minor" modifications that, taken together, would in effect be introducing a new product thus circumventing the requirement that manufacturers have for introducing new products.

Also, the manufacturer's claim that a proposed product modification is "minor" should be viewed with suspicion, given the actions of the companies. For example, recent evidence shows that product modifications made by manufacturers to their products over the past 50 years have increased the risks of smoking despite arguments by manufacturers to the contrary(3). FDA must require manufacturers to produce substantial evidence about whether a proposed product modification, be it to the blend, additives, engineering, and/or packaging does not increase the tobacco product's appeal, abused liability, and/or toxicity. It is not sufficient to merely accept the manufacturer's certification that a product modification is inconsequential. If needed, the FDA should be prepared at the expense of the manufacturer to obtain independent confirmation that a proposed "minor modification" is truly insignificant in terms of public health impact to ensure that the public's health is protected as provided in the rule.

Finally, modifications to a product need to be tracked and reevaluated overtime to ensure that unintended effects are not observed at a later time. For example, when Philip Morris introduced Marlboro Lights in 1972 with its white filter tipping paper and filter vents, it was a product intended for adult females, yet over the course of a decade became the bestselling cigarette among teenagers(4).

Unless the FDA is exceptionally careful, allowing substantial equivalence exemptions for seemingly "minor" modifications could open up a huge loophole that would undermine meaningful product regulation.

1. Wayne GF, Connolly GN. Regulatory assessment of brand changes in the commercial tobacco product market. Tobacco control. 2009;18(4):302-9. Epub 2009/06/17. doi: 10.1136/tc.2009.030502. PubMed PMID: 19528042.
2. History of product changes: Winston KS (1954-1983) and Winston Lights KS (1974-1983) [Internet]. RJ Reynolds. 1983 [cited February 17, 2014].
3. Thun MJ, Carter BD, Feskanich D, Freedman ND, Prentice R, Lopez AD, et al. 50-year trends in smoking-related mortality in the United States. The New England journal of medicine. 2013;368(4):351-64. Epub 2013/01/25. doi: 10.1056/NEJMsa1211127. PubMed PMID: 23343064; PubMed Central PMCID: PMC3632080.
4. Cummings KM, Hyland A, Bansal MA, Giovino GA. What do Marlboro Lights smokers know about low-tar cigarettes? Nicotine & tobacco research : official journal of the Society for Research on Nicotine and Tobacco. 2004;6 Suppl 3:S323-32. Epub 2005/04/01. PubMed PMID: 15799595.