SMARTT
COALITION

February 18, 2014

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

Re: Docket No. FDA-2013-N-1588: Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Product, Exemptions From Substantial Equivalence Requirements

Dear Sir or Madam:

The Small Manufacturers Association for the Reasonable Treatment of Tobacco ("SMARTT") submits the following comments in response to the Proposed Agency Information Collection Comment Request ("Proposed Collection") for the above-referenced docket seeking information related to the requirements for Exemptions From Substantial Equivalence Requirements for tobacco products. SMARTT is a coalition of Subsequent Participating Manufacturers to the multi-state Master Settlement Agreement who share issues of common concern with respect to the ongoing implementation of the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), as amended by the Family Smoking Prevention and Tobacco Control Act (the "Tobacco Control Act"). We appreciate this opportunity to comment on the Proposed Collection as part of our continuing efforts to assist the U.S. Food and Drug Administration's ("FDA's" or the "Agency's") Center for Tobacco Products ("CTP") in the effective and efficient implementation of the Act.

With respect to the Proposed Collection, FDA solicits comments and information on the following four (4) topics: (i) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility, (ii) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used, (iii) ways to enhance the quality, utility, and clarity of the information to be collected, and (iv) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.[1] SMARTT's comments herein touch upon all of these topics, with particular emphasis on the latter three topics listed above.

[1] 78 Fed. Reg. 76838, 76839 (Dec. 19, 2013).

Background

The Tobacco Control Act amended the FDCA to authorize FDA to regulate the manufacture, marketing, and distribution of tobacco products in order to protect the public health and reduce tobacco use by minors. Toward this end, the Tobacco Control Act requires that all "new tobacco products" be submitted to FDA for premarket review and approval prior to commercialization in the United States. The FDCA, as amended, outlines three distinct premarket review pathways for tobacco products, including submission of a report under FDCA Section 910 (Premarket Tobacco Product Application), a report under FDCA Section 905(j) ("Substantial Equivalence Report"), or in lieu of the latter, a request for exemption from substantial equivalence requirements under FDCA Section 905(j)(3) ("Minor Modification Exemption Request" or "MME Request").

FDA may exempt a new tobacco product from the substantial equivalence requirements under the Minor Modification Exemption if FDA determines the following about the proposed modification to the product's additives[2]:

- (1) the modification is a minor modification of a tobacco product that can be sold under the Act;
- (2) a report demonstrating substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and
- (3) an exemption is otherwise appropriate.[3]

In addition to the statutory criteria set forth above, it is also FDA's position that an MME Request is only appropriate for new tobacco products that result from minor modifications to the additives *in a manufacturer's own legally marketed tobacco products.*[4]

FDA Underestimates the Burden of the Proposed Collection

FDA has issued a final rule, codified at 21 CFR § 1107.1, (the "Final Rule" or the "Rule") to establish the procedures for making a Minor Modification Exemption Request. Under the Rule, an MME Request is an electronic submission which must contain the manufacturer's address and contact information; identification of the tobacco product(s); a detailed explanation of the purpose of the modification; a detailed description of the modification; a detailed explanation of why the modification is "minor"; a detailed explanation

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2 An "additive" is defined as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any tobacco product (including any substances intended for use as a flavoring or coloring or in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding), except that such term does not include tobacco or a pesticide chemical residue in or on raw tobacco or a pesticide chemical. FDCA § 900(1), 21 U.S.C. § 387(1).

3 FDCA § 905(j)(3)(A), 21 U.S.C. § 387e(j)(3)(A).

4 21 C.F.R. § 1107.1(b).

of why a Substantial Equivalence Report is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of the public health; a certification summarizing the supporting evidence and providing a rationale for why the modification does not increase the appeal of the product for use by minors, its toxicity, addictiveness, or abuse liability; other information justifying an exemption; and an environmental assessment prepared in accordance with FDA regulations at 21 CFR § 25.40.

In the preamble to the Final Rule, the Agency explained that an MME Request is intended to be the least burdensome approach for introducing new or modified tobacco products to the market. Specifically, FDA stated that it does "not expect an exemption request will be as lengthy or detailed as a 905(j) substantial equivalence report"[5] and that "the overall exemption pathway to market will be less burdensome than the substantial equivalence or premarket application pathways to market."[6] In calculating the burden of preparing an MME submission, FDA reported that it would require 12 hours to prepare an MME Request, an additional 12 hours to prepare the accompanying environmental assessment, and an average of 3 hours to prepare a response to an FDA request for additional information.[7]

SMARTT respectfully suggests that FDA's estimated burden significantly underestimates the amount of time that it actually takes manufacturers to prepare all aspects of an MME submission. In our experience, SMARTT would estimate the burden of preparing a complete MME submission as 300 total hours as set forth below:

Activity	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Burden per Response	Total Hours
21 CFR 1107.1(b): Preparation of MME Request	500	1	500	190	95,000
21 CFR 1107.1(c): Preparation of additional information	500	2	1,000	95	95,000
21 CFR 25.40: Preparation of environmental assessment[8]	500	1	500	12	6,000

5 Tobacco Products, Exemptions From Substantial Equivalence Requirements, 76 Fed. Reg. 38961, 38963 (Jul. 5, 2011).

6 *Id.* at 38965.

7 *Id.* at 38971. SMARTT believes it would be helpful for FDA to provide more insight as to how the Agency arrived at its respective estimates, as this would shed useful light on the kind of information the Agency expects to collect.

8 SMARTT acknowledges that FDA recently issued a proposed rule to amend its NEPA implementing regulations and provide categorical exclusions for certain actions related to MME Reports and other premarket submissions. *See* National Environmental Policy Act: Environmental Assessments for Tobacco

21 USC 905(j)(1)(A)(ii): Preparation of required report for granted exemptions	500	1	500	3	1,500

As shown in the chart above, SMARTT further asserts that FDA has underestimated the number of responses per respondent with regard to the requirements of 21 CFR Section 1107.1(c). In SMARTT's experience, FDA's MME review process typically generates at least two Advice/Information Request letters: namely, one letter during the Agency's Administrative Review of the submission and a second letter during FDA's Substantive Review.[9] SMARTT believes that a lack of substantive guidance from FDA about MME submissions has increased FDA's need to issue, and industry's need to respond to, these Advice/Information Request letters. We believe that the MME review process could be made less burdensome if CTP provided the industry with greater clarity on the *substance* of, and not merely the *process* for, obtaining the requested exemption. Our recommended approach would also be more consistent with the aims of the Paperwork Reduction Act of 1995[10], Executive Order 13610[11], and the Obama Administration's "high priority" of "eliminating unjustified regulatory requirements, including unjustified reporting and paperwork burdens."[12]

FDA Can Enhance the Quality, Utility, and Clarity of the Information Collected

In our view, the Final Rule did very little to clarify the meaning of a "minor" modification and did not go far enough in addressing manufacturers' needs to engage in certain modifications that Congress contemplated when establishing this statutory premarket pathway in the first instance. Additionally, the Final Rule did not (and to date, CTP has not) provided the industry with explicit guidance regarding the "detailed" explanations and descriptions that an MME Request must contain. In short, CTP has promulgated no regulations, issued no guidance documents, and hosted no webinars which contain meaningful discussion of the *substantive* requirements which must be met in order to obtain FDA approval of an MME Request. Indeed, in the preamble to the Final Rule, CTP acknowledged that "there may still be some uncertainty on the part of manufacturers about . . . how much supporting evidence will be required as the

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Products; Categorical Exclusions 79 Fed. Reg. 3742 (Jan. 23, 2014). If and when such a final rule takes effect, it could change, and very well reduce, the amount of time it takes to prepare an environmental assessment.

9 This aspect of the MME review process is very similar to the process CTP uses in the review of Substantial Equivalence Reports under Section 905(j) of the Act, except that this second phase is called a Scientific Review in the latter context.

10 44 U.S.C. §§ 3501-3520.

11 Exec. Order No. 13610, Identifying and Reducing Regulatory Burdens, 77 Fed. Reg. 28469 (May 10, 2012).

12 Office of Mgmt. & Budget, Exec. Office of the President, OMB Memorandum for the Heads of Executive Departments and Agencies, Reducing Reporting and Paperwork Burdens (2012), available at http://www.whitehouse.gov/sites/default/files/omb/inforeg/memos/reducing-reporting-and-paperwork-burdens.pdf (last accessed Feb. 18, 2014).

basis for an exemption."[13] SMARTT posits that this uncertainty negatively impacts the quality, utility, and clarity of information in MME submissions, and that CTP leaves the industry with no choice but to make relatively uninformed guesses as to what information may be required. This inefficient approach unnecessarily increases the Proposed Collection's burden on both Agency and industry resources.

According to CTP, industry submitted approximately 60 MME Requests between September 2011 and December 2013.[14] SMARTT understands that FDA has not approved or denied a single such MME Request to date, and that at least 22 such submissions have received Refusal to Accept Letters ("RFAs") from the Agency.[15] SMARTT asserts that the relatively high proportion of RFAs issued—amounting to at least one-third (1/3) of all MME submissions reported to date—supports our position that FDA has not provided sufficient clarity to inform industry's MME submissions.

In sum, SMARTT believes that FDA's approach has frustrated Congress's intent to provide tobacco product manufacturers with a third viable pathway to market. Instead, and similar to the Agency's review of Substantial Equivalence Reports, FDA has subjected yet another category of premarket submissions to a protracted, ill-defined review process that is devoid of any meaningful Agency timelines or other performance measures.

FDA Can Minimize the Burden of the Collection on Respondents

There are several ways that FDA can minimize the Proposed Collection's burden on respondents. First, SMARTT encourages the Agency to use the experience it has acquired in the past two years of reviewing MME submissions to provide the substantive guidance necessary to streamline industry's preparation, and CTP's review, of MME Requests.

Second, we encourage CTP to provide a workable definition of what constitutes a "minor" modification to a tobacco product from a technical perspective.[16] For example, we would propose that one such minor modification arises when (i) it is necessary to alter an additive to ensure consistency, (ii) the manufacturer intends to make an equivalent product across the product's characteristics (i.e., there is no intent to alter the product), and (iii) the manufacturer demonstrates that the modification is functionally equivalent in the resulting new product (e.g., release criteria remain within pre-established manufacturing, testing, and other

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13 76 Fed. Reg. at 38972.

14 FDA, FDA-TRACK CTP Office of Science Dashboard, Total number of product submissions received or filed in the month, available at http://www.accessdata.fda.gov/FDATrack/track?program=ctp&id=CTP-OS-total-product-submissions-received&fy=all (last accessed February 14, 2014).

15 FDA, CTP Tobacco Product Marketing Orders, available at http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm339928.htm (last accessed February 14, 2014).

16 SMARTT notes that various other FDA centers have provided their respective industries with important technical guidance that may help to inform CTP's efforts in this regard. For example, the Center for Drug Evaluation and Research (CDER) has issued a guidance titled *Changes to an Approved NDA or ANDA* which, among other things, distinguishes between certain "major changes" and "minor changes" that can be made to an approved drug product.

tolerances). The foregoing definition, and various others that the Agency may recognize, would serve as useful gating features to help reduce the underutilization of the MME pathway—or the corresponding waste of industry and CTP resources in preparing and reviewing submissions under the lengthier, alternative premarket pathways—for products which Congress and FDA both agree should rather be subject to more efficient, less burdensome premarket review. Moreover, SMARTT believes that providing this much-needed definitional clarity (i) would likely reduce the number of RFAs and additional information requests with which both industry and CTP have to contend and (ii) would permit CTP to better effectuate its public health mission by focusing on what should be at the center of MME review, namely whether a Substantial Equivalence Report is necessary to ensure that the modified tobacco product is appropriate for the protection of the public health.

Finally, we encourage the Agency to facilitate a more robust dialogue about how best to inform industry of the kinds of modifications which have been determined to be minor. As CTP knows, the Final Rule does not provide a mechanism for public disclosure of such information. In the preamble to the Rule, FDA suggested that "one option might be to create a public database of exemption determinations that may help inform manufacturers when preparing exemption requests" and that "the other option would be for FDA to issue guidance in Question and Answer form which could be updated with new information on a regular basis."[17] SMARTT believes that these and other options could potentially help reduce the burden of preparing an MME submission which is acceptable to FDA, so we encourage the Agency to establish an appropriate forum for obtaining industry feedback on these options and any attendant concerns about public disclosure.

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We thank you in advance for your consideration of our recommendations, and appreciate this opportunity to share our perspectives with the Agency once again. We look forward to continuing to assist FDA in its efforts to protect the public health through reasonable regulation devoid of unnecessary burdens on either the Agency or regulated industry.

Respectfully,

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[17] 76 Fed. Reg. at 38964.

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