Center for Regulatory Effectiveness

Suite 500
1601 Connecticut Avenue, N.W.
Washington, D.C. 20009
Tel: (202) 265-2383 Fax: (202) 939-6969
secretary1@mbsdc.com www.TheCRE.com

February 7, 2011

VIA FAX AND ELECTRONIC MAIL

Attn: FDA Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Re: Docket No. FDA-2010-N-0646—Paper Work Reduction Act Comments on Tobacco Products, Exemptions from Substantial Equivalence Requirements.

RIN: 0910-AG39

Dear Sir or Madam:

The Center for Regulatory Effectiveness (CRE) is pleased to submit these comments to the Office of Information and Regulatory Affairs (OIRA) regarding the Food and Drug Administration's (FDA) proposed rule for Exemptions from Substantial Equivalence Requirements for Tobacco Products and the associated problems with the information collection request (ICR). The proposed rule is not compliant with the Paperwork Reduction Act (PRA), because there is no objective basis for the estimate of the burden, there is no practical utility for the information collected, and there is no plan for the efficient and effective use of the information to be collected. CRE recommends that the FDA cure the PRA defects by providing a more accurate and detailed estimate of the burden, details of the actual practical utility of the information to be collected, and provide a plan for efficient and effective use of the collected information.

I. ***There is no Objective Basis for the Estimate of the Burden***

For an information collection request, the agency must provide a "specific, objectively supported estimate of burden, which shall include, in the case of an existing collection of information, an evaluation of the burden that has been imposed by such collection."[1] In addition, information collection requests must comply with OMB data quality guidelines.[2] Data quality guidelines require that data used by agencies must be objective.[3] "Objectivity involves a focus on ensuring accurate, reliable, and unbiased information. In a…financial, or statistical context, the original and supporting data shall be developed, using sound statistical and research methods."[4] The data "shall include a ***high degree of transparency about data and methods*** to facilitate the reproducibility of such information by qualified third parties."[5]

In the proposed rule, the FDA estimates that it will require 360 hours for a manufacturer to prepare an exemption request to the substantial equivalence requirements. This unsupported estimate of the burden violates the PRA on two grounds: (1) there is no basis for the estimate and (2) it is an inaccurate estimate.

First, the FDA does not provide any basis for its estimate of 360 hours to prepare an exemption request or for the additional 50 hours to comply with the FDA's additional requests for information. Without any support, the FDA's estimate of the burden fails to provide the high degree of transparency about data and methods required by the Data Quality Act and the PRA. In addition, it is evident that the estimate lacks any basis, because the substantial equivalence process is also estimated to take 360 hours.[6] If the exemption process is intended to reduce the

---

1 31 U.S.C. 1320.8(a)(4)

2 John D. Graham, *Memorandum for the President's Management Council*, p. 12, June 10, 2002 (In this light, we note that each agency is already required to demonstrate the practical utility of a proposed collection of information in its PRA submission, i.e., for draft information collections designed to gather information that the agency plans to disseminate. Thus, we think it important that each agency should declare in its guidelines that it will demonstrate in its PRA clearance packages that each such draft information collection will result in information that will be collected, maintained, and used in a way consistent with the OMB and agency information quality standards. It is important that we make use of the PRA clearance process to help improve the quality of information that agencies collect and disseminate. Thus, OMB will approve only those information collections that are likely to obtain data that will comply with the OMB and agency information quality guidelines) available at http://www.whitehouse.gov/sites/default/files/omb/assets/omb/inforeg/iqg_comments.pdf.

3 Office of Management and Budget, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication*, p. 8, available at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=2002_register&docid=R2-59-filed.pdf.

4 *Id*. at 9.

5 *Id*. at 10 (emphasis added).

6 76 Fed. Reg. 411, January 24, 2011.

submission costs for manufacturers, then why does the FDA estimate that the exemption process will impose the same burdens as the substantial equivalence submission process?

Second, even if there is an ample basis for the estimate, the estimate does not accurately reflect the actual burden on manufacturers. The proposed rule imposes a much greater burden on manufacturers than the estimated 360 hours to prepare the exemption request. The proposed rule requires that the exemption request be submitted with:

> supporting documentation and contain the manufacturer's address and contact information; a ***detailed explanation*** of the purpose for modification; a ***detailed description*** of the modification, including whether the modification involves adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive; a ***detailed explanation*** of why the modification is considered a minor modification of a tobacco product that can be sold under the FD&C Act***; a detailed explanation*** of why a report intended to demonstrate substantial equivalence is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for the protection of public health; a certification by a responsible official of the company, such as the chief executive officer, summarizing the supporting evidence and providing the rationale for the official's determination that the modification ***will not increase the product's toxicity, addictiveness, or appeal to or use by minors***; and other information justifying an exemption."[7]

These very detailed requirements for the exemption request will require much greater resources and impose a much greater burden on manufacturers than the FDA estimates. Requiring a certification from an official, such as a CEO, that the minor modification "will not increase the product's toxicity, addictiveness, or appeal to use by minors" requires substantial testing and resources. The burden is further amplified by the lack of definitional guidance provided by the FDA for the terms "toxicity," "addictiveness," and "appeal to use by minors."

Thus, the FDA's unsupported estimate of 360 hours to respond to the exemption requests violates both the PRA and the Data Quality Act. Accordingly, in order for OMB to approve this ICR, the FDA must provide some support for its estimated burden of 360 hours to prepare an exemption request. CRE has requested specific details about the basis for the estimate, and as of this date, the FDA has failed to provide any additional information on how it concluded an estimate of 360 hours.

II. ***There is no Practical Utility for the Information Collection***

[7] 74 Fed. Reg. 737 at 739, January 6, 2011.

In order to collect information in compliance with the PRA, an agency "shall demonstrate that it has taken every reasonable step to ensure that the proposed collection of information… (iii) has practical utility."[8] "Practical utility" is "actual, not merely theoretical or potential, usefulness of information to or for an agency, taking into account its accuracy, validity, adequacy, and reliability."[9] "Practical utility is also the agency's ability to process the information it collects…in a useful and timely fashion."[10] For the information collection request to be approved, the agency must demonstrate "actual timely use for the information to carry out its functions."[11]

Under the proposed rule, the FDA states that "the main effect of this proposed rule would be a potential reduction in the costs of introducing new tobacco products compared with" the pre-market application process and the substantial equivalence process.[12] However, the FDA does not indicate how the exemption process will reduce costs, because the "substantial equivalence report requirements are not yet being enforced [and the] FDA does not attempt to estimate the cost of preparing a 905(j) report that includes the demonstration of substantial equivalence."[13] Furthermore, the FDA acknowledges that under the proposed rule, "there may be uncertainty on the part of manufacturers as to what kinds of product modifications may be granted an exemption and how much supporting evidence will be required as the basis for an exemption."[14] The FDA admits that the overall submissions costs for the exemption process could be larger than the submission costs from the substantial equivalence process itself.[15]

Under the proposed rule, the FDA states that the purpose of the exemption process is to reduce the regulatory costs of introducing new tobacco products into the market, relative to the premarket application process and the substantial equivalence process. However, the burdens of the exemption process are so significant that the FDA admits the exemption process could increase the overall submission costs. The PRA requires that the information collected be "actual, not merely theoretical or potential, usefulness of information to or for an agency." Here the FDA fails to satisfy this core requirement of the PRA where the cost savings for the exemption process are merely theoretical. Thus, the exemption process under the proposed rule

---

8 31 U.S.C. 1320.5(d)(1)(iii).
9 31 U.S.C. 1320.3(l).
10 *Id.*
11 *Id.*
12 74 Fed. Reg. 737 at 739, January 6, 2011.
13 *Id*. at 741.
14 *Id.*
15 *Id.*

violates the PRA where the FDA has failed to demonstrate the practical utility of the information collected.

III. ***There is no Plan for the Efficient and Effective Use of the Collected Information***

To properly collect information an agency must have, "a plan for the efficient and effective management and use of the information to be collected, including necessary resources."[16] Under the proposed rule, the FDA does not have any plan for the efficient and effective use of the information to be collected. Specifically, the FDA does not provide any details on when the agency will seek additional information from the manufacturers or what type of information it will require. This uncertainty increases the burden on the manufacturer while determining whether it will be less costly to prepare an exemption request. Furthermore, the FDA admits that there is "uncertainty on the part manufacturers as to what kinds of product modifications may be granted an exemption and how much supporting evidence will be required as the basis for an exemption." This lack of planning and heightened uncertainty for the information collection is the very thing the PRA is aimed to prevent.

Thus, the FDA's lack of a plan for the information to be collected violates the PRA. The FDA must provide OMB and the public with a much more detailed plan on how the collected information will be used efficient and effectively.

IV. ***Conclusion***

CRE appreciates the opportunity to highlight the deficiencies in the FDA's ICR concerning the substantial equivalence exemption process. CRE requests that the FDA cure these defects by providing a detailed basis of its estimated burden, outlining the practical utility of the information collected, and creating a plan for the effective use of the information. If you need further information regarding any issue discussed in this comment letter, please do not hesitate to contact me at secretary1@mbsdc.com or (202) 265-2383.

Respectfully submitted,

Jim Tozzi
Member, Board of Advisors

[16] 31 U.S.C. 1320.8