Tobacco Product Standard on Flavored Cigarettes

0910-0647

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Public Law 111-31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FFDCA) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

FDA is requesting an extension for the OMB approval of the information collection pertaining to section 907(a)(1)(A) of the FFDCA, as amended by the Tobacco Control Act, which provides a general tobacco standard special rule for cigarettes that becomes effective on September 22, 2009. This special rule for cigarettes states in part that:

> "…a cigarette or any of its component parts (including the tobacco, filter, or paper) shall not contain, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice, including strawberry, grape, orange, clove, cinnamon, pineapple, vanilla, coconut, licorice, cocoa, chocolate, cherry, or coffee, that is a characterizing flavor of the tobacco product or tobacco smoke.

FDA issued a letter on September 14, 2009, to remind regulated industry that as of that date, all manufacturers, distributors, and retailers must be in compliance with section 907(a)(1)(A), and that any cigarette or any of its component parts that contain an artificial or natural flavor (other than tobacco or menthol) or a herb or spice that is a characterizing flavor of the tobacco product is deemed adulterated under section 902 of the FFDCA, as amended. Manufacturers, distributors, or retailers who sell adulterated cigarettes are in violation of the FFDCA and subject to an enforcement action.

As part of our enforcement strategy, FDA created a Tobacco Call Center (with a toll-free number: 1-877-CTP-1373) to accept information from the public about violations of the cigarette flavor ban. Callers are able to report violations of the flavor ban and FDA will conduct targeted follow-up investigation based on information received. When callers report a violation, the caller will be asked for certain information: name, caller contact information, purchase date, description of the tobacco product, and address of the retail outlet or Internet address where the violative product was viewed. FDA has developed a form that will be used to solicit this information from the caller (FDA Form 3734). Additionally, this form will be posted on FDA's Internet and information may be submitted by filling out

the form on-line (or the public can request a copy of Form 3734 by contacting the Center for Tobacco Products). Others may simply choose to send a letter to FDA with their information. In summary, the public will be able to report information regarding possible violations of the flavor ban through the following methods:

- Calling the Tobacco Call Center using a toll-free number;
- Using a fill-able form found on FDA's website; and
- Sending a letter to FDA's Center for Tobacco Products.

2. Purpose and Use of the Information Collection

The form posted on-line and used by the Tobacco Call Center to gather information on reported violations asks for the following information:

1. Name of the caller and call-back/contact information;
2. Whether the caller purchased the tobacco product;
3. Description of the tobacco product, including the lot number on the package, if available;
4. Date the tobacco product was seen in the retail outlet, name and address of the retail outlet, and the location of tobacco product in the retail outlet (or in the case of Internet sales, the Internet address (URL)).

This is an existing collection of information. The information collected from the caller will assist FDA in its investigation of violative firms and violative flavored cigarettes.

FDA included the information on how to report information about possible violations in a Federal Register notice reminding regulated industry of the effective date of the ban on flavored cigarettes (September 25, 2009; 74 FR 48974). FDA also included this information in the following outreach materials:

- Letter to our tobacco control partners announcing the flavored cigarette ban and soliciting information on possible violations,
- Press release that announces the effective date of the flavored cigarette ban,
- Flavored tobacco products fact sheet, and
- Flavored tobacco products parental advisory.

3. Use of Improved Information Technology and Burden Reduction

Information on reported violations is being solicited using the Tobacco Call Center (telephone) and the Internet. The public may also choose to mail a letter to FDA with their information.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only Federal agency that is soliciting information regarding violations of section 907(a)(1)(A) of the FFDCA. Maine is the first and only state to ban the sale of

certain flavored tobacco products and therefore, it is conceivable that reported violation information could be provided about the same retail outlet/tobacco product on the federal and state level. It also could be possible that more than one individual could submit a report against the same retail outlet/same tobacco product. Multiple reported violations, however, may be indicative of continued violations and patterns of violation of the cigarette flavor ban and therefore, duplicative information would be useful in our enforcement efforts.

5. Impact on Small Businesses or Other Small Entities

There is no special burden placed on small businesses by this information collection. Anyone is able to submit a report to FDA.

6. Consequences of Collecting the Information Less Frequently

Without the ability to collect information on violations of the cigarette flavor ban, FDA will be hindered in its enforcement efforts. The Tobacco Control Act was enacted just 3 months prior to the effective date of the cigarette flavor ban. FDA is currently in the process of building the staff, resources, and state/local partnerships needed to enforce the provisions of the Tobacco Control Act. Therefore, the assistance of the public in reporting violations of the cigarette flavor ban is an important piece of FDA's enforcement strategy.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This section is not applicable.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

FDA received one comment in response to the 60-day notice soliciting public comment on the extension of OMB approval for this information collection generally supporting "the extension of this collection of information regarding the enforcement of the cigarette flavor ban and submits that the extension of data collection is critical to the 'proper performance of FDA's functions' and that it will have great 'practical utility'."

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide for any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

The person contacting the Tobacco Call Center is not required to provide his/her name or contact information. Similarly, the form posted on the Internet does not require the name and contact information fields to be completed in order to submit the form electronically. To the extent that 21 CFR 20.64 applies, FDA will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

11. Justification for Sensitive Questions

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

FDA did not receive any comments on the burden hours and costs in response to the 60-day notice soliciting public comment on the extension of OMB approval for this information collection. However, FDA is adjusting the estimate of the number of respondents based on current reporting experience.

FDA estimates the burden for this information collection as follows:

12a. *Hour Burden Estimate*

Table 1.--Estimated Annual Reporting Burden					
Activity and form FDA 3734	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Minutes per Response	Total Hours
Reporting violations of section 907(a)(1)(A) of the FFDCA	170	1	170	10 (0.167 hours)	28

Reporting Burden

FDA continues to estimate that submitting the information (by phone, Internet, or mail) will take 10 minutes. Since the cigarette flavor ban went into effect about four months ago, FDA has received approximately 100 reports via the Internet or email. Judging from this rate of reporting, FDA is decreasing our estimate of the number of respondents. The agency now estimates that approximately 170 reports will be submitted annually by phone, Internet, and mail combined. Since the flavor ban has been in effect for four months, FDA expects the rate of calls and reports received to decrease even further.

12b. *Reporting Cost Burden Estimate*

Since the Tobacco Call Center will have a toll-free telephone number, there is no cost to report a violation of the flavored cigarette ban via telephone. There is no cost burden associated with reporting a violation using the Internet. The postage stamp expense is described in item 13 below as a capital cost.

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

The capital costs associated with this collection pertain to the postage cost for mailing a letter containing the reported violation information. FDA estimates the capital cost to submit a report via mail to be $0.88. This estimate is based upon 2 responses (1% of 170 total responses) being submitted via U.S. first class mail and the cost of a first class postage stamp at $ 0.44.

14. Annualized Cost to the Federal Government

FDA's internal assessment estimates that the cost for processing a violation report is $19.00 per report. The total annual responses (table 1) are estimated at 170 responses per year. Thus, $19.00 x 170 responses = $3,230.00 per year.

15. Explanation for Program Changes or Adjustments

The decrease in burden estimate (an adjustment) is based on the number of complaints the agency has received.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans to publish data from this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are not seeking approval to not display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the certification statement were identified.