FURTHER AMENDMENTS TO GENERAL REGULATIONS OF THE FOOD AND DRUG ADMINISTRATION TO INCORPORATE TOBACCO PRODUCTS

FINAL RULE

0910-0690
RIN 0910-AG60

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Tobacco Control Act was enacted on June 22, 2009, amending the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and providing FDA with the authority to regulate tobacco products (Public Law 11-31; 123 Stat. 1776). In enacting the Tobacco Control Act, Congress sought to ensure that FDA had authority to provide effective oversight and to impose appropriate regulatory controls on the tobacco industry. In order to effectuate these purposes, FDA is amending several provisions of its general regulations to reflect the Agency's new authority and mandate regarding tobacco products to amend certain of its general regulations to include tobacco products, where appropriate, in light of FDA's authority to regulate these products under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). With these amendments, tobacco products will be subject to the same general requirements that apply to other FDA-regulated products.

Abstract

FDA is amending title 21 of the Code of Federal Regulations (CFR), to reflect the Agency's authority over tobacco products under the Tobacco Control Act. FDA is adding "tobacco products" to the list of products covered by § 1.21(a) and (c)(1) (21 CFR 1.21(a) and (c)(1)) and § 1.101(a) and (b) (21 CFR 1.101(a) and (b)). The agency also is revising the definition of "product" in § 7.3(f) (21 CFR 7.3(f)) to include tobacco products; and revising § 16.1(b) (21 CFR 16.1(b)) to add provisions from the Tobacco Control Act that allow for hearings.

Section 1.101(b) - One collection of information subject to the Paperwork Reduction Act of 1995 is located in section 1.101(b). Section 1.101 outlines the notification and recordkeeping requirements for exports of FDA-regulated products. Section 1.101(b) states that persons exporting an article under section 801(e)(1) of the FD&C Act or an article otherwise subject to section 801(e)(1) of the Act shall maintain records demonstrating that the product meets the requirements of section 801(e)(1) of the Act. The records shall be maintained for the same period of time as required for records subject to good manufacturing practice or quality systems regulations applicable to the product, and shall be made available to FDA upon request, during an inspection for

review and copying by FDA. The records must demonstrate that the product meets the foreign purchaser's specifications, and demonstrate that the product does not conflict with the laws of the importing country. The records should also show that the product is labeled on the outside of the shipping package that it is intended for export, and should show that the product is not sold or offered for sale in the United States. Because section 103(l) of the Tobacco Control Act specifically amends section 801 of the FD&C Act to include "tobacco products" on the list of FDA-regulated products that may be exported under this section, this final rule amends § 1.101(b) to indicate that tobacco products exported under section 801(e)(1) of the FD&C Act also would be subject to the recordkeeping requirements of this regulation.

This information is needed to reflect the Agency's regulatory authority over tobacco products under the Tobacco Control Act.

This information collection is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

This is a new collection of information for FDA. The amendments ensure tobacco manufacturers adhere to the regulations that apply to other FDA-regulated products, where appropriate. The rule requires persons who export human drugs, biologics, devices, animal drugs, cosmetics, and tobacco products that may not be sold in the United States to maintain records demonstrating their compliance with the requirements in section 801(e)(1) of the FD&C Act. Section 801(e)(1) requires exporters to keep records demonstrating that the exported product meets with the foreign purchaser's specifications; does not conflict with the laws of the foreign country; is labeled on the outside of the shipping package that is intended for export; and is not sold or offered for sale in the United States. These criteria also could be met by maintaining other documentation, such as letters from a foreign government Agency or notarized certifications from a responsible company official in the United States stating that the exported product does not conflict with the laws of the foreign country.

Respondents to this collection of information include manufacturers, distributors, and other persons from the private sector in business and other for-profit institutions who export tobacco products not intended for sale in the United States.

3. Use of Improved Information Technology and Burden Reduction

This collection of information requires respondents to maintain records documenting that the exported product meets certain criteria and is not sold or offered for sale in the United States. While FDA does not mandate the use of technology to create or maintain records, it does encourage the use of technology such as office suite computer software to create and maintain these records. FDA estimates that over 90% of respondents will use current technology to create and maintain their records.

4. Efforts to Identify Duplication and Use of Similar Information

The maintenance of records relating to the export of tobacco products pertains only to documents developed after June 22, 2009; therefore, the records created for this information collection will not be duplicate documents.

5. Impact on Small Businesses or Other Small Entities

Respondents to this collection of information include manufacturers, distributors, and other persons who export tobacco products not intended for sale in the United States, a portion of whom may be small businesses. All exporters are expected to maintain records demonstrating that the exported product meets with the foreign purchaser's specifications; does not conflict with the laws of the foreign country; is labeled on the outside of the shipping package that is intended for export; and is not sold or offered for sale in the United States. This information collection does not fall disproportionately upon small businesses.

6. Consequences of Collecting the Information Less Frequently

Information relating to this rule is not collected, and there are no legal obstacles to reduce the burden. Respondents to the collection of information in the rule are expected to maintain records regarding exported products, and no submission of information to FDA is required.

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

This section is not applicable. There are no special circumstances for this collection of information.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of April 14, 2011 (76 FR 20901). FDA received several comments, however they were not PRA related.

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

This section is not applicable. Persons affected by this collection of information must maintain records, and are not required to submit that information to FDA.

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 estimates the burden for this information collection as follows:

12a. *Hour Burden Estimate*

Table 1.--Estimated Annual Recordkeeping Burden[1]

Exporters of Tobacco Products					
21 CFR Section	**No. of Recordkeepers**	**Annual Frequency of Recordkeeping**	**Total Annual Records**	**Hours per Recordkeeper**	**Total Hours**
1.101(b)	158	3	474	22	10,428

The Agency has estimated the number of respondents and burden hours associated with the recordkeeping requirements by reviewing Agency records and using Agency expert resources, and conferring with another federal Agency with experience and information regarding tobacco product exporters. FDA estimates that between 30 and 158 establishments could be involved in the exporting of tobacco products and, based on previous recordkeeping estimates in OMB control number 0910-0482, "Export Notification and Recordkeeping Requirements," each establishment may have to maintain records up to 3 times per year, at a total of 22 hours per recordkeeper. The agency estimates between 1,980 and 10,428 burden hours will be needed for tobacco product exporters to create and maintain records demonstrating compliance with section 801(e)(1) of the FD&C Act. Therefore, to be conservative, FDA estimates that 158 respondents will require approximately 10,428 hours to comply with the requirements of section 801(e)(1) of the FD&C Act.

12b. *Recordkeeping Cost Burden Estimate*

FDA estimates the recordkeeping cost to respondents to be $374,991, which is the number of hours estimated (10,428) for each person who creates and maintains records multiplied by $35.96 per hour ($17.98 per hour plus benefits and overhead), an average wage rate which is based on a 2,080 annual work hours and at an annual salary rate of $74,797. This health care professional salary rate includes salary, benefits, overhead, technical staff, support staff, etc. This annual rate was determined by the Agency's current estimates of staff expenses.

Table 2. -- Estimated Annual Recordkeeping Cost Exporters of Tobacco Products			
Type of Recordkeeper	**Total Burden Hours**	**Hourly Wage Rate**	**Total Recordkeeping Costs**
Exporters of Tobacco Products	10,428	$35.96	$374,991

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

There are no annualized costs to the Federal government for the recordkeeping involved in this collection of information.

15. Explanation for Program Changes or Adjustments

    This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

    There is no possibility that the recordkeeping associated with this collection of information will be published, tabulated or manipulated (i.e., the results will be summarized, segmented, or altered). This includes hard copies and publication on the Internet.

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

    FDA is 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.