Export Notification and Recordkeeping Requirements

OMB Control Number 0910-0482
Revision

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

FDA is requesting approval from the Office of Management and Budget (OMB) of an information collection requirement in "Exports: Notification and Recordkeeping Requirements"--21 CFR 1.101, which pertains to the exportation of unapproved new drugs, biologics, devices, animal drugs, food, cosmetics, and tobacco products that may not be sold in the United States. FDA's Office of International Programs (OIP) works with governments, industry and academia in foreign countries, as well as with multilateral organizations, to help assure that food and medical products exported to the United States meet U.S. standards.

The Tobacco Control Act was enacted on June 22, 2009, and amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by granting the Food and Drug Administration (FDA) with the authority to regulate tobacco products (Public Law 11-31; 123 Stat. 1776). The enactment of the Tobacco Control Act by Congress ensured that FDA had the authority to provide effective oversight and to impose appropriate regulatory controls on the tobacco industry.

On March 30, 2012, OMB approved "Further Amendments to General Regulations of the Food and Drug Administration To Incorporate Tobacco Products", OMB Control No. 0910-0690, which amended, among other sections, title 21 of the Code of Federal Regulations, Section 1.101 to incorporate tobacco products. These amendments reflect the Agency's authority over tobacco products under the FD&C Act and added "tobacco products" to the list of products covered under § 1.21(a) and (c) (1) (21 CFR 1.21(a) and 21 CFR 1.21(c) (1)) and § 1.101 (a) and (b) (21 CFR 1.101(a) and 21 CFR 1.101(b)).

The FDA is issued a final rule to deem products meeting the statutory definition of "tobacco product" to be subject to the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C Act provides FDA authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco, and any other tobacco products that the Agency by regulation deems to be subject to the law. This final rule extends the Agency's "tobacco product" authorities to all other categories of products that meet the statutory definition of "tobacco product" in the FD&C Act, except accessories of such newly deemed tobacco products. This final rule also prohibits the sale of "covered tobacco products" to individuals under the age of 18 and requires the display of health warnings on cigarette tobacco, roll-your own tobacco, and covered tobacco product packages and in advertisements. The rule also provides that manufacturers, distributors, importers, and retailers are responsible for ensuring that the covered tobacco

products (in addition to cigarettes and smokeless tobacco) they manufacture, label, advertise, package, distribute, import, sell, or otherwise hold for sale comply with all applicable requirements. FDA is taking this action to reduce the death and disease from tobacco products.

This information is needed to reflect the Agency's regulatory authority over exported products under the FD&C Act.

21 CFR 1.101(b) – Recordkeeping Requirements for human drugs, biological products, devices, animal drugs, foods, cosmetics, and tobacco products exported under or subject to section 801(3)(1) of the FD&C Act.

This provision requires persons who export human drugs, biologics, devices, animal drugs, foods, 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. In brief, the provision requires exporters to keep records demonstrating that the exported product: (1) Meets with the foreign purchaser's specifications; (2) does not conflict with the laws of the foreign country; (3) is labeled on the outside of the shipping package that it is intended for export; and (4) is not sold or offered for sale in the United States. These are the four criteria in Section 801(e) (1) of the FD&C Act, although the regulation suggests these four criteria could be met by submitting other documentation. For example, to show that an exported product does not conflict with the laws of the foreign country, the regulation allows FDA to accept 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.

21 CFR 1.101(c) – Additional recordkeeping requirements for partially processed biological products exported under section 351(h) of the PHS Act.

This provision requires additional records for persons exporting partially processed biologics pursuant to Section 351(h) of the Public Health Service Act (PHS). This would consist of records showing that the product is, in fact, a partially processed biologic and manufactured in accordance with good manufacturing practices, distribution records, and labeling that is to accompany the exported product.

21 CFR 1.101(d) – Notification requirements for drugs, biological products, and devices exported under section 802 of the FD&C Act.

This provision requires persons exporting a human drug, biologic, or device under Section 802 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to notify FDA (as required by Section 802(g) of the FD&C Act). In general, the regulation requires the notification to identify the product being exported (e.g., name, description, and, in some cases, country of destination) and specifies where the notification should be sent. These notifications are sent only for an initial export; subsequent exports of the same product to the same destination (or, in the case of certain countries identified in Section 802(b) of the FD&C Act, to any of those countries) would not result in a notification to FDA.

21 CFR 1.101(e) – Recordkeeping requirements for products subject to section 802(g) of the FD&C Act.

This regulation requires persons exporting any product under Section 802 of the FD&C Act to maintain records regarding the exported products and the countries to which they were exported. This provision implements Section 802(g) of the FD&C Act. Records would be kept for the same time period as good manufacturing practice records.

2. Purpose and Use of the Information Collection

FDA will use the information to determine whether an exporter has complied with the export requirements in the FD&C Act and the Public Health Service (PHS) Act and, in situations where FDA is required by law to notify an appropriate health official in a foreign country, to determine where a product was exported (so that the Agency can provide notice to the foreign country). For example, records identifying the foreign countries receiving the exported product and notifications to FDA identifying importing countries will enable FDA to carry out its statutory obligations to consult with the appropriate foreign government officials in the event of an imminent hazard or other violations specified in the FD&C Act.

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 currently regulated FDA products not intended for sale in the United States.

3. Use of Improved Information Technology and Burden Reduction

The collection of information neither requires nor prohibits the use of automated, electronic, mechanical, or other technological collection techniques. Respondents may submit their notifications electronically or on paper. 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 90% of the respondents and recordkeepers for this collection of information will use current technology to submit reports and create and maintain their records.

4. Efforts to Identify Duplication and Use of Similar Information

Under the FDA Export Reform and Enhancement Act, FDA is the only Agency responsible for the export of unapproved or otherwise violative drugs, devices, food and color additives, cosmetics, dietary supplements, blood and blood products, tissues and tobacco products. In particular, the maintenance of records relating to the export of tobacco products pertains only to documents developed after June 22, 2009. Records created for this collection of information which relate to tobacco products will not be duplicate documents. Therefore, no duplication of data for this collection of information exists.

5. Impact on Small Businesses or Other Small Entities

Respondents to this collection of information include manufacturers, distributors, and other persons who export products currently regulated by FDA, which are not intended for sale in the United States, a portion of whom may be small businesses. All exporters are expected to create reports and maintain records demonstrating that the exported products 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. FDA believes this collection of information does not fall disproportionately upon small businesses.

6. Consequences of Collecting the Information Less Frequently

Respondents to this collection of information will respond by submitting reports or creating and maintaining records on an occasional basis. Failure to maintain records would impair a firm's ability to show, and FDA's ability to determine, that exportation of a particular drug product complied with all statutory requirements. For exports under Section 802 of the FD&C Act, failure to maintain records would also be contrary to law.

Failure to provide the notifications would be contrary to law and would impair FDA's ability to carry out its statutory obligations to notify foreign countries if an exported product presents an imminent hazard, has been refused approval by FDA, or otherwise violates the conditions for export.

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

There are no special circumstances for this collection of information.

The recordkeeping and reporting requirements are consistent with the guidelines in 5 CFR 1320.5. The records required under the regulation would be retained, in accordance with good manufacturing practice requirements for the product, (which results in a record retention period of three years or less, depending on the product).

The regulation does not require notifications to occur more frequently than the quarterly basis described in 1320.5(d) (2) (i) nor does it require multiple copies of the notification.

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

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the FEDERAL REGISTER of April 25, 2014 (79 FR 23142). FDA has responded to the comments received in the preamble to the final rule, and the

supporting statement for the Deeming information collections under OMB control number 0910-0768

9. Explanation of Any Payment or Gift to Respondents

FDA will not provide any payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The information that would be collected under this regulation would be subject to the safeguards under 21 CFR Part 20 of the Freedom of Information Act.

11. Justification for Sensitive Questions

No questions of a sensitive nature are asked.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The Estimated Annual Reporting Burden total hours for Non-Tobacco are 150,825 hours.

The Agency estimated the number of respondents and burden hours associated with the reporting and recordkeeping requirements in § 1.101 by reviewing past Agency records, using Agency expert resources, conferring with another Federal agency who has experience and information regarding tobacco product exports, and by consulting with industry sources. For example, the estimated number of respondents and total annual responses in §§ 1.101(b) and 1.101(e) were derived from the number of export certificates manufacturers have requested from FDA, and the estimated hours per response reflect revised estimates derived from actual data received from exporters who must report or maintain records for this collection of information.

Existing Burden

Table 1 - Estimated Annual Reporting Burden

21 CFR, Section 801	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total hours
1.101(d) (Non-Tobacco) (CBER)	5	193	965	15	14,475

1,101(d) (Non-Tobacco) (CDER)	5	180	900	15	13,500
1.101(d) (Non-Tobacco) (CDRH)	63	130	8,190	15	122,850
Total	73		10,055		150,825

The total estimated reporting burden is comprised of non-tobacco reporting to three of FDA's Centers (the Center for Biologics Evaluation and Research [CBER], the Center for Drug Evaluation and Research [CDER], and the Center for Devices and Radiological Health [CDRH].) The total estimated burden is 150,825 hours, which is 14,475 hours (CBER) plus 13,500 hours (CBER) plus 122,850 hours (CDRH). These estimates were calculated based on FDA's actual experience and submissions submitted by respondents previously. Based on the same experience, FDA now estimates that the total number of reporting respondents will be 73.

Existing Burden

Table 2 – Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Record-keepers	No. Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
1.101 (b), (c), (e) (Non-Tobacco) (CBER, CDER, and CDRH)	320	3	960	22	21,120
1.101(b) Office of International Programs Only (Non-Tobacco)	1	189	189	22	4,158
1.101(b) (Tobacco Products)	158	3	474	22	10,428
Total					35,706

New Deeming Burden

Table 3.--Estimated Annual Recordkeeping Burden[1]

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours
21 CFR 1.101(b):					
Cigar Manufacturers (Large and Small)	57	3	171	22	3,762
Pipe and Waterpipe Tobacco Manufacturers	37	3	111	22	2,442
Other Tobacco, E-Cigarettes, and Nicotine Product Manufacturers (ENDS)	93	3	279	22	6,138
Exports: Notification and Recordkeeping Requirements					0

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

[2] At publication of the proposed rule, the burden for these activities were under OMB control number 0910-0690. The burden has since been transferred to OMB control number 0910-0482

New Final Recordkeeping Burden

Table 4 – Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Record-keepers	No. Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours
1.101 (b), (c), (e) (Non-Tobacco) (CBER, CDER, and CDRH)	320	3	960	22	21,120
1.101(b) Office of International Programs Only (Non-Tobacco)	1	189	189	22	4,158
1.101(b) (currently regulated Tobacco Products)	345	3	1,035	22	22,770
Total					0

In Table 4, FDA estimates the annual recordkeeping hourly burden to CBER, CDER, and CDRH recordkeepers of non-tobacco products to be 21,120 hours (300 recordkeepers times 3 average annual responses times 22 hours). FDA estimates the annual hourly recordkeeping burden to the Office of Commissioners Office of International Programs (OIP) recordkeepers to be 4,158 hours (1 recordkeeper times 189 responses times 22 hours). FDA also estimates the **new** annual hourly recordkeeping burden to CTP recordkeepers to be 22,770 hours (345 recordkeepers times 3 responses times 22 hours). Total recordkeeping burden, therefore, is 48,048 hours. This estimate is based on the average number of hours expected to create and maintain a single record, and was determined by the Agency's current estimates of respondent recordkeeping burden needed to respond to this collection of information.

The hours include 1) Non-tobacco, 2) Office of International Programs (OIP) and 3) Tobacco

collections. The addition of OIP and CTP to FDA's recordkeeping estimates has increased the recordkeeping estimates due to capturing OIP and CTP recordkeeping information and tracking the data collection of information for export notifications

With regard to tobacco product recordkeeping, FDA now estimates that 345 currently regulated establishments could be involved in the exporting of tobacco products under §1.101(b), and each establishment may have to maintain records up to 3 times per year, at a total of 22 hours per record-keeper. The agency therefore estimates that 22,770 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.

For the new burden added per the deeming final rule, 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 that have experience and information regarding tobacco product exporters. FDA estimates that 187 establishments (50 percent of all the tobacco manufacturers listed in the collection of information under OMB Control Number 0910-0046 in this document who manufacture cigars, pipe tobacco, waterpipe, other tobacco products, and ENDS) could be involved in the exporting of all tobacco products annually. Based on previous recordkeeping estimates for the exporter's reporting burden in this OMB Control Number 0910-0482, "Export Notification and Recordkeeping Requirements"), each establishment will maintain an average of three records per year, and it will take each recordkeeper an average of 22 hours per recordkeeper to maintain each record. The Agency estimates 12,342 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.

12b. Annualized Cost Burden Estimate

FDA estimates the annual reporting burden cost to exporters of Non-Tobacco product to be $1,005,500 (i.e, Total Annual Reporting Responses of 10,055 multiplied by $100). FDA estimates the annual recordkeeping burden cost to exporters of non-tobacco products to be $114,900, which is the estimated total annual number of records (960 records for CBER, CDER, and CDRH plus 189 records for OIP, or 1,149 records) multiplied by $100 per record. This cost is based on the average cost expected to create and maintain a single a single record, and was determined by the Agency's current estimates of respondent costs to respond to this collection of information.

FDA estimates the recordkeeping cost to exporters of tobacco products to be $47,400, which is the number of records estimated (474) for each respondent multiplied by $100 per record. This cost is based on the average cost expected to create and maintain a single record, and was determined by the Agency's current estimates of respondent costs to respond to this collection of information.

The total burden cost is expected to be $1,167,800, which is $1,005,500 plus $114,900 plus $47,400.

Table 3 – Estimated Annual Burden Cost

Type of Respondent	Total Number of Reports and/or Records	Cost Per Report or Record	Total Annual Respondent Costs

Non-Tobacco - Exporters Filing/ Reporting 1.101 (d)	10,055	$100	$1,005,500
Non-Tobacco - Exporters Recordkeeping and 1.101 (b)(c)(e)	1,149	$100	$114,900
Exporters of Tobacco Products Maintaining Records/Recordkeeping 1.101(b)	1,035	$100	$103,500
Total			0

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

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

14. Annualized Cost to the Federal Government

The total number of reports and records are 12,239. FDA estimates that an average federal employee full time equivalent hourly wage to review these reports and records is $ 43.00 per hour and the program will require one hour reviewing each record or report by one GS-13 employee in the Washington metropolitan area. Therefore, the total annualized government cost for this collection of information is expected to be $526,277, which is $43.00 hourly FTE wage rate multiplied by 12,239 records and reports.

15. Explanation for Program Changes or Adjustments

The new collections of information under this control number were previously submitted to OMB at the proposed rule stage under the deeming rule information collection (0910-0768). After discussions with OMB about the final rule submission, it was decided that the collections associated with existing control numbers would be submitted under their respective approvals.

The estimated total annual hourly burden for this collection of information is expected to be 198,873 hours, which is an increase of 12,342 hours from the currently OMB approved burden. Recordkeeping burden is expected to increase by 12,342 hours, from 35,706 to 48,048 hours due to the addition of recordkeeping requirements in section § 1.101(b) for the Center for Tobacco Products.

This increase is a result of FDA extending the Agency's "tobacco product" authorities in the FD&C Act to all other categories of products that meet the statutory definition of "tobacco product" in the FD&C Act, except accessories of such newly deemed tobacco products.

Exporters of Tobacco Products Maintaining Records/Recordkeeping 1.101(b)	No. recordkeepers	Total Annual records	Hours Per Response	Total Hours
Tobacco (Existing)	158	474	22	10,428

Tobacco (Deeming)	187	561	22	12,342
New Total Tobacco	345	1,035	22	0

16. for Tabulation and Publication and Project Time Schedule

Information collected under this requirement will not be published.

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

The Agency does not seek an exemption from displaying the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There ae no exceptions to the certification.