UNITED STATES FOOD & DRUG ADMINISTRATION

Export Notification and
Recordkeeping Requirements (21 CFR 1.101)

OMB Control Number 0910-0482

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency, us or we) regulations pertaining to notifications and records required for human drug, biological product, device, animal drug, food, cosmetic, and tobacco product exports under sections 801 or 802 of the Federal Food, Drug, and Cosmetic Act or (FFDCA or the act) (21 U.S.C. 381 and 382), or section 351 of the Public Health Service Act (PHS) (42 U.S.C. 262). The notification and recordkeeping is codified at 21 CFR 1.101. As set forth in the regulations, exporters must keep records demonstrating that exported products:

(1) meet with the foreign purchaser's specifications;
(2) do not conflict with the laws of the foreign country;
(3) are labeled on the outside of the shipping package that it is intended for export; and
(4) are not sold or offered for sale in the United States.

Although tobacco products are not currently subject to notification requirements, recordkeeping elements are applicable to all FDA-regulated products and are enumerated in the regulations. In accordance with the requirements, records shall be made available to FDA upon request during an inspection for review and copying.

We therefore request extension of OMB approval for the information collection provisions found in 21 CFR 1.101, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

We use the information collection to determine compliance with export requirements prescribed in the FFDCA and the Public Health Service (PHS) Act. The information collection also allows us to comply with notification requirements to foreign health officials pertaining to product exports should we become aware of imminent hazards or other violations specified in the act.

Description of Respondents: Respondents to the collection of information include manufacturers, distributors, and other persons from the private sector in business and other for-profit institutions who export FDA-regulated 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 we do 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. We estimate 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

We are unaware of duplicative information collection. Under the FDA Export Reform and Enhancement Act, FDA is solely 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. Upon review of our ICR inventory, however, we intend to consolidate burden associated with Form FDA 766 entitled, "*Application for Authorization to Relabel or to Perform Other Action of the Federal Food, Drug, And Cosmetic Act And Other Related Acts*," (currently approved under OMB Control No. 0910-0025) into the instant ICR. Although Form FDA 766 supports requests to relabel and/or recondition all FDA-regulated articles and applies to *import* activities, the regulation is related to others covered in subpart E of our General Enforcement Regulations and we believe, therefore, its burden is more appropriately accounted for in this collection. The remaining regulations found in subpart E pertain to conduct during official FDA administrative actions and are therefore excluded from review under the PRA pursuant to 5 CFR 1320.4(a)(2).

5. Impact on Small Businesses or Other Small Entities

Respondents to this collection of information may include small businesses. However, all exporters are expected to create reports and maintain records demonstrating that their exported products meet with the foreign purchaser's specifications; do not conflict with the laws of the foreign country; are labeled on the outside of the shipping package that is intended for export; and are not sold or offered for sale in the United States. We do not believe these requirements impose undue burden on small entities. At the same time, we provide assistance and resources to small businesses in complying with FDA regulatory requirements, available from our website at www.fda.gov.

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 demonstrate, and our ability to determine, whether exportation of a particular regulated product complies with statutory requirements. For exports under Section 802 of the act, failure to maintain records would also be contrary to law.

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 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

In accordance with 5 CFR 1320.8(d), we published a 60-day notice inviting public comment on the information collection in the Federal Register of February 15, 2019 (84 FR 4473). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No gifts or payments are provided to respondents to the information collection.

10. Assurance of Confidentiality Provided to Respondents

This ICR is not collecting personally identifiable information (PII) or other data of a personal nature. Rather, the information collection pertains to the exportation of unapproved new drugs, biologics, devices, animal drugs, food, cosmetics, and tobacco products. In consultation with our Privacy Office, we have therefore concluded that a Privacy Act Statement is not applicable to the information collection. At the same time, information collected is subject to the safeguards under the Freedom of Information Act and FDA's related regulations at 21 CFR Part 20.

11. Justification for Sensitive Questions

No questions of a sensitive nature are included in the information collection.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

We estimate a total of 22,800 annual burden hours for reporting and a total of 46,530 annual burden hours for recordkeeping, as reflected in Tables 1 and 2, respectively, below.

Table 1.—Estimated Annual Reporting Burden[1]

21 CFR Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total hours
1.101(d) (CBER)	5	92	460	15	6,900
1.101(d) (CDER)	5	180	900	15	13,500
1.101(d) (CDRH)	160	1	160	15	2,400
TOTAL			1,520		22,800

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

The estimated burden figures are based on our experience with the information collection, along with informal communication with other Federal agencies and industry sources. As a result, we reduced the estimated number of notifications attributable to CBER by 505 responses and 7,575 hours, which corresponds with a reduction in notifications received over the past few years. Also, upon a reevaluation of available data, we adjusted estimates associated with CDRH notifications resulting in a reduction of 8,030 responses and 120,450 hours, finding that our previous figures had been over-estimated.

Table 2.—Estimated Annual Recordkeeping Burden[1]

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping (in hours)	Total Hours
1.101 (b), (c), (e) (CBER, CDER, CDRH, CFSAN, and CVM)	320	3	960	22	21,120
1.101(b) Office of International Programs only	1	189	189	22	4,158
1.101(b) (currently regulated Tobacco Products)	322	3	966	22	21,252
TOTAL			2,115		46,530

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

Similarly, these figures are based on our experience with the information collection. Our estimate of burden associated with CTP recordkeeping reflects a reduction of 69 responses and 1,518 burden hours. This adjustment is based on reporting summaries by the Alcohol and Tobacco Tax and Trade Bureau.

12b. Annualized Cost Burden Estimate

Assuming a cost of $100 per report and multiplying this figure by the total number of annual records (1,520), we estimate $152,000 in annual reporting costs to exporters of non-tobacco products. Similarly, assuming a cost of $100 per record and multiplying this figure by the number of non-tobacco records (1,149) and tobacco records (966), we estimate $114,900 and $96,600 in annual recordkeeping costs, respectively. Cumulatively, the total estimated cost is $363,500.

Table 3 – Estimated Annual Burden Cost

Type of Respondent	Total No. of Reports/Records	Cost Per Report/Record	Total Annual Respondent Cost
Non-tobacco export reports	1,520	$100	$152,000
Non-tobacco export recordkeeping	1,149	$100	$114,900
Tobacco export recordkeeping	966	$100	$96,600
TOTAL			$363,500

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

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

14. Annualized Cost to the Federal Government

To calculate costs to the Federal Government, we multiplied the total number of reports and records (3,635) by an average hourly wage rate for a full-time Federal employee (GS-13/1) in the Washington Metropolitan Area, using OPM pay schedules for 2019 ($46.46). (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/19Tables/html/DCB_h.aspx) This results in a total of $168,882 (rounded to the nearest whole dollar) ($46.46 x 3,635 = $168,882.10).

15. Explanation for Program Changes or Adjustments

The information collection reflects adjustments in our estimated burden. Cumulatively these adjustments result in an overall reduction to the information collection by **8,604** annual responses and **129,543** burden hours. The majority of this reduction results from correcting previous over-estimating associated with CDRH export notifications, however we discuss this more fully at *Question 12* in conjunction with our burden tables. Also, as discussed in more detail in *Question 4*, we intend to modify the collection to incorporate submissions via Form FDA 766. Currently, burden for the form is accounted for under OMB Control No. 0910-0025, however we believe this is an inadvertent oversight. Upon our extension/renewal of OMB Control No. 0910-0025 (expiring July 31, 2020) we will give notice and invite public comment regarding our proposal to include the form as part of the instant information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

We have no such plans for the information collection.

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

Display the OMB expiration date as required by 5 CFR 1320.5 is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.