

United States Food and Drug Administration

Export Notification and Recordkeeping Requirements (21 CFR 1.101)

OMB Control No. 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. Sections 801 and 802 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381 and 21 U.S.C. 382) charge the Secretary of Health and Human Services, through FDA, with the responsibility of helping to ensure that exports of unapproved new drugs, biologics, devices, animal drugs, food, cosmetics, and tobacco products that are not to be sold in the United States meet the requirements of the country to which the product is to be exported. The respondents to this information collection are exporters who have notified FDA of their intent to export unapproved products that may not be sold or offered for sale in domestic commerce in the United States as allowed under section 801(e) of the FD&C Act.

The notification and recordkeeping requirements are 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.

Respondents to this collection of information maintain records demonstrating their compliance with the requirements in 21 CFR 1.101. 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.

We therefore request extension of OMB approval for the information collection requirements 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 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. In accordance with the requirements, records shall be made available to FDA upon request during an inspection for

review and copying.

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.

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

We published a 60-day notice inviting public comment on the information collection in the *Federal Register* of January 25, 2022 (87 FR 3811). 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

Respondents to the information collection are exporters of products that may not be sold in the United States and are regulated by FDA's Center for Drug Evaluation and Research (CDER); Center for Biologics Evaluation and Research (CBER); Center for Devices and Radiological Health (CDRH); Center for Veterinary Medicine (CVM); Center for Food Safety and Applied Nutrition (CFSAN); and Center for Tobacco Products. Respondents to this collection of information maintain records demonstrating their compliance with the requirements in 21 CFR 1.101.

In general, the notification identifies the product being exported (e.g., name, description, and in some cases, country of destination) and specifies where the notifications were sent. These notifications are sent only for an initial export. Subsequent exports of the same product to the same destination or to certain countries identified in section 802(b) of the FD&C Act would not result in a notification to FDA.

We estimate a total of 5,985 annual burden hours for reporting and a total of 39,094 annual burden hours for recordkeeping, as reflected in Tables 1 and 2, respectively, below.

Table 1.—Estimated Annual Reporting Burden¹

21 CFR Section	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total hours
1.101(d) (CBER)	4	35	140	15	2,100
1.101(d) (CDER)	3	57	171	15	2,565
1.101(d) (CDRH)	22	4	88	15	1,230
TOTAL			399		5,985

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

Table 2.—Estimated Annual Recordkeeping Burden¹

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)	181	4.12	746	22	16,412
1.101(b) Office of International Programs only	1	65	65	22	1,430
1.101(b) (currently regulated Tobacco Products)	322	3	966	22	21,252
TOTAL			1,777		39,094

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

Based on a review of Agency data, we decreased our estimate by 24,251 burden hours. This decrease reflects an overall downward trend in the number of export certification requests across programs and commodities. The estimate for tobacco products remains steady.

12b. Annualized Cost Burden Estimate

The estimated annual cost to respondents is \$1,517,154.03.

Table 3 – Estimated Annual Burden Cost

Activity	Total Burden Hours	Hourly Wage Rate	Total Annual Respondent Cost
Export reports	5,985	\$51.85	\$310,322.25
Export recordkeeping	39,094	\$30.87	\$1,206,831.78
TOTAL	45,079	-	\$1,517,154.03

The reporting cost estimate is based on an average pay rate of \$51.85 per hour. This average is based on the salaries of an executive, a manager, and a clerical support worker who are involved in export reporting or providing any other information necessary. The recordkeeping cost estimate is based on an average pay rate of \$30.87 for a clerical support worker involved in recordkeeping. The salary estimates include fringe benefits.

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or 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 (2,176) 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 2022 (\$51.18).

(https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/22Tables/html/DCB_h.aspx) This results in a total of \$111,368 (rounded to the nearest whole dollar) (\$51.18 x 2,176 = \$111,367.68).

15. Explanation for Program Changes or Adjustments

Based on a review of Agency data, we decreased our estimate by 24,251 burden hours. This decrease reflects an overall downward trend in the number of export certification requests across programs and commodities. The estimate for tobacco products remains steady.

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

FDA is not requesting an exemption from display of the OMB expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.