Export Notification and Recordkeeping Requirements
OMB Control Number 0910-0482
SUPPORTING STATEMENT

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, and cosmetics that may not be sold in the United States.

21 CFR 1.101(b) – Recordkeeping Requirements for human drugs, biological products, devices, animal drugs, foods, and cosmetics 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, and cosmetics 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.

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 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.

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.

4. Efforts to Identify Duplication and Use of Similar Information

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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, and tissues. Therefore, no duplication of data exists.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

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

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

The Agency consulted individuals in the industry who are experienced in export matters to estimate the amount of time and cost needed for export matters and to prepare the notifications and records that would be required under the regulation. Consultations with industry sources concerning similar records indicate that the estimated average cost of maintaining records would be $ 100.00 per record.

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of December 6, 2010, (75 FR 75677) to which one comment was received. The commenter stated that the agency has been unable to make proper use of the information we are already authorized to collect and urged that the regulation be declined. The commenter did not make any recommendations on how to improve the utility of the information. Also, FDA will not make any changes to the regulation at this time.

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 total estimated annual burden hours for this information collection is 39,120.

The Agency estimated the number of respondents and burden hours associated with the reporting and recordkeeping requirements by reviewing past Agency records, and by consulting industry sources. For example, the estimated number of respondents and total annual responses in §§ 1.101(b) and 1.101(e) are derived from the number of export certificates manufacturers have requested from FDA, and the estimated hours per response reflect revised estimates supplied by comments to the proposed rule. The No. of Respondents, No. of Responses per Respondent, Total Annual Responses, and Average Burden Hours in § 1.101(c) are based on FDA estimates. The estimated No. Respondents, No. of Responses per Respondent, Total Annual Respondents, and Average Burden Hours in §1.101(d) are based on the number of export notifications FDA has received and FDA and industry estimates of the burden hours.

Additionally, Section 801(e)(1) of the act has remained essentially unchanged for decades, so firms exporting drugs, devices, and other FDA-regulated products subject to Section 801(e)(1) of the FD&C Act should, as part of their normal course of business, already be retaining records to show their compliance with that section.

Table 1 - Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
1.101(d)	400	3	1,200	15	18,000

Table 2 – Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Record-keepers	No. Records per Recordkeeper	Total Annual Records	Average Burden Hours per Recordkeeping	Total Hours
1.101 (b), (c), (e)	320	3	960	22	21,120

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Number of Reports and/or Records	Cost Per Report or Record	Total Annual Respondent Costs
Exporters filing reports and keeping records	2,160	$100	$216,000

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

There are no total capital or start-up costs or service due to the minimal nature of the recordkeeping and reporting requirements.

14. Annualized Cost to the Federal Government

The annualized cost to the Federal government is estimated to be $82,166.40. The program will require one hour to review each record or report by one GS-13 employee in the Washington metropolitan area. The employee's hourly wage is $ 38.04 per hour and the total number of records and reports is 2,160. Therefore, $ 38.04 per record or report multiplied by 2,160 records and reports = $ 82,166.40.

15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments to report.

16. Plans 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

N/A.