

Export Notification and Recordkeeping Requirements  
OMB Control Number 0910-0482  
Supporting Statement

A. Justification

1. Circumstances Necessitating Information Collection

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 (Tab A) 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.

The estimated information collection for the regulation is 43,214 hours, of which 23,426 hours would be attributed to a regulatory burden and 19,788 hours attributed to a statutory burden.

21 CFR 1.101(d) - Reporting

This provision requires persons exporting a human drug, biologic, or device under section 802 of the Federal Food, Drug, and Cosmetic Act (the act) to notify FDA (as required by section 802(g) of the act) (Tab B). 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 act, to any of those countries) would not result in a notification to FDA.

21 CFR 1.101(b) - Recordkeeping

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) (Tab C) of the 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 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(e) - Recordkeeping

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

#### 21 CFR 1.101(c) - Recordkeeping

This provision requires additional records for persons exporting partially processed biologics pursuant to section 351(h) of the Public Health Service Act (Tab D). 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.

#### 2. How, by Whom, and for What Purpose Information Used

FDA will use the information in the records to determine whether an exporter has complied with the export requirements in the act and the Public Health Service 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 act.

#### 3. Consideration of Information Technology

The collection of information neither requires nor prohibits the use of automated, electronic, mechanical, or other technological collection techniques.

#### 4. Efforts to Identify Duplication and Similar Information Already Available

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. Small Business

FDA has revised the final rule so that the information that would be requested by the rule is the minimum amount of information necessary. Thus, no methods were required to minimize any impact.

#### 6. Consequences of Less Frequent Information Collection and Technical or Legal Obstacles

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 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. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

The recordkeeping and reporting requirements are consistent with the guidelines in 5 CFR 1320.5(d)(2). 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 3 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. Consultation 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.

In accordance with 5 CFR 1320.8(d), a 60-day notice for public comment on the information collection provisions was published in the *Federal Register* of December 27, 2004, (69 FR 77255) (Tab E). No comments were received from the public.

9. Payment or Gift to Respondents

FDA did not provide any payment or gifts to respondents.

10. Confidentiality of Information

The information that would be collected under this regulation would be subject to the safeguards under the Freedom of Information Act and FDA's public information regulations in 21 CFR Part 20.

11. Sensitive Questions

No questions of a sensitive nature are asked.

12. Estimates of Burden Hours and Explanation

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 number of respondents, total annual responses, and burden hours in § 1.101(c) are based on FDA estimates. The estimated number of respondents, total annual responses, and 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.

#### Estimated Annual Recordkeeping and Reporting Burden

21 CFR Section	No. of Respondents or Recordkeepers	Annual Frequency per Response or Record	Total Annual Responses or Records	Hours per Response or Record	Total Hours
1.101 (d, e)	419	2.8	1164	17	19,788
Subtotal Statutory					19,788
1.101(b, c)	324	2.8	901	26	23,426
Subtotal Regulatory					23,426
Total					43,214

(There are no capital costs or operating and maintenance costs associated with this collection.)

#### 13. Annual Cost to Respondents

There are no total capital or start-up costs or service due to the minimal nature of the recordkeeping and reporting requirements. 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 act should, as part of their normal course of business, already be retaining records to show their compliance with that section. Consultations with industry sources concerning similar records indicate that the estimated average cost of maintaining records would be \$ 100.00 per record.

For the reporting cost, this, too, would consist of the cost of the notifications to FDA and the wages associated with generating those notifications. The cost of the notifications should be small given the minimal content requirements for such notifications.

14. Annual Cost to the Government

The annualized cost to the federal government is estimated to range between \$55,342 to \$99,279. The first figure is based on the following calculations and assumptions: (a) the program will require one hour per record or report for one GS-13 employee in the Washington metropolitan area; (b) the employee's hourly wage is \$ 26.80 per hour; and (c) the total number of records and reports is 2,065. So, \$ 26.80 per record or report \* 2,065 records and reports = \$ 55,342. The actual cost to the federal government may be less because the information to be reported under proposed § 1.101(d) is quite minimal (ex., name and description of product being exported and identification of the country to which it was exported) and should be reviewed quickly. These costs may decrease further if, after more records and reports are reviewed or received, the agency determines that these functions can be performed by less senior employees.

Alternatively, if one uses an estimate of \$100,000 per full-time equivalent (FTE) employee and multiplies that figure by a percentage of a FTE that would be devoted to the records and reports, the cost to the federal government is  $\$100,000 * (2,065 \text{ hrs.} / 2,080 \text{ hrs. for a full FTE year}) = \$100,000 * 0.99279 \text{ FTE} = \$99,279$ .

15. Changes in Burden

Due to an increase in the number of respondents, as well as the amount of time needed to prepare a response, the total burden hours increased from OMB's current inventory of 31,106 to 43,214.

16. Statistical Reporting

Information collected under this requirement will not be published.

17. Exemption for Display of Expiration Date

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

18. Exemption to Certification Statement

The agency is not requesting any exemption from the certification statement identified in Item 19 of form OMB Form 83-I.