OMB INFORMATION COLLECTION
Supporting Statement
Bar Code Label Requirement for Human Drug Products and Blood
(0910-0537)

Terms of Clearance: None

A. Justification

1. Circumstances Making the Collection of Information Necessary

In the Federal Register of February 26, 2004 (69 FR 9120), FDA issued a new rule entitled "Bar Code Label Requirement for Human Drug Products and Blood" that required human drug product and biological product labels to have bar codes. The bar code for such products (other than blood and blood components) must contain the National Drug Code (NDC) number in a linear bar code. The rule is intended to help reduce the number of medication errors in hospitals and other health care settings by allowing healthcare professionals to use bar code scanning equipment to verify that the right drug, in the right dose and right route of administration, is being given to the right patient at the right time. The proposal also required the use of machine-readable information on blood and blood component container labels.

The information collection requirements in the final rule "Bar Code Label Requirement for Human Drug Products and Blood" were as follows. For the reasons explained in section 12 below, most of these were one-time burdens that are not expected to occur after the rule's compliance date of April 26, 2006. In addition, some of the information collection burden estimated in the final rule is now covered in other OMB approved packages.

21 CFR 201.25 and 610.67 - Reporting

This provision required a linear bar code on prescription drug products and over-the-counter drugs that are dispensed pursuant to an order and commonly used in hospitals. The bar code must contain, at a minimum, the drug's NDC number. For biological products (other than blood), the linear bar code requirement applies through 21 CFR 610.67.

21 CFR 314.81(b)(2)(iii) - Reporting

Although the final rule does not contain a new reporting requirement expressly for the bar code, the bar code represents a change to the product label. Minor labeling changes for certain drug products are reported to FDA under 21 CFR 314.81(b)(2)(iii).

21 CFR 601.12(f)(3) - Reporting

Although the final rule does not contain a new reporting requirement for the machine-readable information on blood and blood component labels, the information represents a change to the product label. Minor labeling changes for blood and blood components are reported to FDA under 21 CFR 601.12(f)(3).

21 CFR 606.121(c)(13) - Reporting

This provision specifies the minimum contents of machine-readable information (such as a unique facility identifier, lot number relating to the donor, and product code) for blood and blood components.

2. Purpose and Use of the Information Collection

The bar code and machine-readable information is used by hospitals to ensure that the right product (including the right dose and right route of administration for the product) is reaching the right patient at the right time.

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.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only federal agency responsible for approving drug products for human use and for regulating blood and blood components. Therefore, no duplication of data exists.

5. Impact on Small Businesses or Other Small Entities

The rule was not expected to have a significant economic impact on a substantial number of small entities. For example, the Analysis of Impacts in the rule suggested that the economic impact on small packagers would be $240 per entity, compared against an average annual revenue of $1.7 million per small entity, so the cost would be less than 0.1 percent of annual revenues. As another example, the analysis suggested that the cost to small manufacturers would be $1,800 per entity, compared against an average annual revenue of $26.6 million per small entity, so that the cost to small manufacturers would be less than 0.1 percent of annual revenues.

6. Consequences of Collecting the Information Less Frequently

Failure to submit the bar code or machine-readable information would impair a hospital's ability to determine whether the right drug, blood, or blood component is reaching the right patient. Failure to submit the reports regarding label changes would hinder FDA's ability to ensure that it has the latest product label.

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

The reporting requirement is consistent with the guidelines in 5 CFR 1320.5(d)(2). The rule does not require reports to occur more frequently than the quarterly basis described in § 1320.5(d)(2)(i) nor would it require multiple copies of the report.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the FEDERAL REGISTER of 8/17/12 (77 FR 49818). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

FDA did not provide any payment or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

To the extent that the information provided in a report regarding labeling changes is confidential commercial information or trade secret information, that information is protected against public disclosure to the extent required by law and FDA regulations. Thus, an assurance of confidentiality (beyond those already existing in federal law and FDA regulations) is unnecessary.

11. Justification for Sensitive Questions

No questions of a sensitive nature are asked.

12. Estimates of Annualized Hour Burden and Costs

12a. Annualized Hour Burden Estimate

FDA estimates that we may receive 40 exemption requests annually. Based on the number of exemption requests submitted during 2004 and 2005, we estimate that approximately 2 waiver requests may be submitted annually, and that each exemption request will require 24 hours to complete. This would result in an annual reporting burden of 48 hours.

The estimated annual reporting burden for this request for OMB approval is as follows:

Table 1.--Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
Bar Code Label Requirements -	2	1	2	24	48

201.25(d)					

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

12b. Annualized Cost Burden Estimates

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Pharmaceutical/Biological	48	$75.00	3,600

13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers

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

14. Annualized Cost to the Federal Government

We estimate the annualized cost to the federal government associated with reviewing the exemption requests to be negligible.

15. Explanation for Program Changes or Adjustments

There are no program changes or adjustments to the information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

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. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.