OMB INFORMATION COLLECTION
Supporting Statement
Bar Code Label Requirement for Human Drug Products and Blood

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

As discussed in the proposed rule and the final rule, FDA conducted a public meeting to discuss the rulemaking. In addition, numerous comments were received on the proposal and were discussed in the final rule. In the Federal Register of November 6, 2009 (74 FR 57495), FDA announced an opportunity for public comment on this information collection. 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

Most of the information collection burden resulting from the final rule, as calculated in Table 1 of the final rule (69 FR at 9149), was a one-time burden that should not occur after the rule's compliance date of April 26, 2006. However, as explained below before Table 1, parties may continue to seek an exemption from the bar code requirement under certain circumstances. A description of the information collection burden as estimated in the final rule and the reasons why that burden was a one-time burden follows:

- For prescription drugs (including prescription biologics and vaccines) and OTC drugs subject to the bar code requirement, the final rule indicated that there are 1,447 establishments that would be affected by the bar code requirement, and that there are approximately 89,800 separate, identifiable product packages subject to the requirement. Half of the packages (45,000) need redesigned labels to comply with the bar code requirement because they did not currently use coded NDC numbers. The annual frequency of reports under § 201.25 and § 610.67 was 31.1 (45,000 package labels requiring a bar code/1,447 establishments = 31.09 packages per establishment, rounded up to 31.1). The final rule estimated that the number of hours per response to redesign a package label to include bar coded information to comply with the requirement was

approximately 24 hours. Therefore, the total burden hours for § 201.25 and § 610.67 was estimated in the final rule to be 1,080,000 hours (45,000 packages x 24 hours per package label = 1,080,000 hours).

We are not requesting that this burden be extended by OMB because the label redesign had to be completed by the final rule's compliance date of April 26, 2006. In addition, § 201.57(c)(17) (iii) ("How supplied/storage and handling") requires that the labeling for drugs include appropriate information to facilitate identification of the drug. The information collection burden in § 201.57 is approved by OMB under OMB Control Number 0910-0572.

• Concerning the requirement in § 601.121(c)(13) to include machine-readable information on blood and blood components, the final rule estimated 981 blood and plasma establishments. The final rule also estimated that approximately 13.9 million blood donations are collected annually. The final rule estimated that each blood donation yields approximately three blood components, and that the frequency of responses is approximately 41.7 million occurrences (13.9 million blood donations x 3 blood components), divided by 981 establishments, or 42,507.645 occurances per establishment, rounded up to 42,507.7. The final rule estimated that it takes one minute per machine-readable information, thus resulting in an annual reporting burden of 695,000 hours ((41.7 million reports x one minute per report) /60 minutes per hour = 695,000 hours).

We are not requesting that this burden be extended by OMB because the label redesign had to be completed by the rule's compliance date of April 26, 2006.

• Because FDA would have bar code information for drugs subject to a new drug application or abbreviated new drug application to be reported through an annual report, the final rule affected the reporting burden associated with 21 CFR 314.81(b)(2)(iii). Section 314.81(b)(2)(iii) requires the submission of an annual report containing a representative sample of package labels and a summary of labeling changes (or, if no changes have been made, a statement to that effect) since the previous report. Here, the bar code resulted in a labeling change. Similarly, minor label changes for blood and blood products are reported as part of an annual report, as described in 21 CFR 601.12(f)(3). The final rule explained that for prescription drugs whose label changes are reported in an annual report pursuant to § 314.81, there are approximately 1,447 establishments reporting, and, under § 601.12(f)(3), there are 211 licensed blood and blood component manufacturers. There are 89,800 separate, identifiable product packages that must comply with the requirement. These packages account for 8,576 separate and distinct products (each product is marketed in an average of 10.47 packaging variations). This means that the annual frequency of reports is 5.9 (8,576 products subject to annual reports/1,447 registered establishments = 5.92 products per registered establishment, rounded down to 5.9). For § 601.12(f)(3), the final rule estimated 211 products. The final rule estimated that the addition of a bar code to a label would necessitate a simple statement in the annual report declaring that the bar code has been added, and the final rule estimated one minute for such statements per label. Each product=s annual report included labels for all packaging variations. The total reporting burden was estimated to be 1,496.67 hours ((8,576 reports x 10.47 labels (or one label per packaging variation)

per report x one minute per report)/60 minutes per hour = 1,496.67 hours), rounded up to 1,497 hours (and 3.5 hours for § 601.12(f)(3)).

Because the compliance date for the final rule is April 26, 2006, there should be no additional statements pertaining to the bar code labeling change in annual reports after 2006. Similarly, minor label changes for blood and blood products are reported as part of an annual report, as described in 21 CFR 601.12(f)(3), and, because the compliance date for the final rule is April 26, 2006, there should be no additional statements pertaining to the bar code labeling change in annual reports after 2006.

• Parties may continue to seek an exemption from the bar code requirement under certain, limited circumstances. Section 201.25(d) (21 CFR 201.25(d)) requires submission of a written request for an exemption and describes the contents of such requests. The final rule estimated 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
201.25(d)	2	1	2	24	48
Total					48

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

Costs –
We estimate the annualized cost to respondents to be $3600. We base this figure on the total burden hours (48) multiplied by an hourly wage of $75 for pharmaceutical/biological industries professionals.

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

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

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

As explained under item 12 above, most of the information collection burden resulting from the final rule, as calculated in Table 1 of the final rule (69 FR at 9149), was a one-time burden that does not occur after the rule's compliance date of April 26, 2006.

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

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

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PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the supporting statement, and any additional documentation to: Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

1. Agency/Subagency originating request	2. OMB control number	b. [ ] None
FDA	a. 0910 - 0537	

3. Type of information collection (*check one*)

a. [ ] New Collection

b. [ ] Revision of a currently approved collection

c. [x] Extension of a currently approved collection

d. [ ] Reinstatement, without change, of a previously approved collection for which approval has expired

e. [ ] Reinstatement, with change, of a previously approved collection for which approval has expired

f. [ ] Existing collection in use without an OMB control number

For b-f, note Item A2 of Supporting Statement instructions

4. Type of review requested (*check one*)
a. [x] Regular submission
b. [ ] Emergency - Approval requested by at close of comment period
c. [ ] Delegated

5. Small entities
Will this information collection have a significant economic impact on a substantial number of small entities? [ ] Yes [x] No

6. Requested expiration date
a. [X] Three years from approval date b. [ ] Other Specify:____/__

7. Title Bar Code Label Requirement for Human Drug Products and Blood

8. Agency form number(s) (*if applicable*)

9. Keywords human drugs label

10. Abstract 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 Bloodthat 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.

11. Affected public (*Mark primary with "P" and all others that apply with "x")*
a. ___ Individuals or households d. ___ Farms
b. _x__ Business or other for-profit e. ___ Federal Government
c. ___Not-for-profit institutions f. ___ State, Local or Tribal Government

12. Obligation to respond (*check one*)
a. [ ] Voluntary- (guidance document)
b. [x] Required to obtain or retain benefits
c. [Mandatory

13. Annual recordkeeping and reporting burden
a. Number of respondents 2 _____
b. Total annual responses 2 _____
1. Percentage of these responses collected electronically all could be
c. Total annual hours requested 48
d. Current OMB inventory 48 ___
e. Difference
f. Explanation of difference
1. Program change _____
2. Adjustment See item 15 in Supporting Statement
_____

14. Annual reporting and recordkeeping cost burden *(in thousands of dollars)*
a. Total annualized capital/startup costs 0
b. Total annual costs (O&M) 0
c. Total annualized cost requested 0
d. Current OMB inventory 0
e. Difference 0
f. Explanation of difference
1. Program change _____
2. Adjustment _____

15. Purpose of information collection (*Mark primary with "P" and all others that apply with "X"*)
a. __ Application for benefits e.__ Program planning or management
b. __ Program evaluation f.__ Research
c. __ General purpose statistics g. x Regulatory or compliance
d. __ Audit

16. Frequency of recordkeeping or reporting *(check all that apply)*
a. [ ] Recordkeeping b. [ ] Third party disclosure
c. [x] Reporting
1. [x] On occasion 2. [ ] Weekly 3. [ ] Monthly
4. [ ] Quarterly 5. [ ] Semi-annually 6. [x] Annually
7. [ ] Biennially 8. [x] Other (describe) one-time

17. Statistical methods
Does this information collection employ statistical methods
[ ] Yes [x] No

18. Agency Contact (person who can best answer questions regarding the content of this submission)

Name: _____

Phone: _____

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