Bar Code Label Requirement for Human Drug Products and Biological Products

OMB Control No. 0910-0537
Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

In the Federal Register of February 26, 2004 (69 FR 9120), FDA issued a final rule entitled "*Bar Code Label Requirement for Human Drug Products and Blood*" that requires human drug product and biological product labels to have bar codes. Specifically, the rule requires bar codes on most human prescription drug products and on over-the-counter (OTC) drug products that are dispensed pursuant to an order and commonly used in health care facilities. The rule also requires machine-readable information on blood and blood components. For human prescription drug products and OTC drug products that are dispensed pursuant to an order and commonly used in health care facilities, the bar code must contain the NDC number for the product. For blood and blood components, the rule specifies the minimum contents of the label in a format that is machine-readable and approved for use by the Director, Center for Biologics Evaluation and Research. We believe the rule helps to reduce the number of medication errors in hospitals and other health care settings by allowing health care 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.

While most of the information collection burdens created by the final rule have now been incorporated into currently approved information collections supporting the applicable regulations, respondents to the collection may continue to seek an exemption from the bar code label requirement under 21 CFR 201.25(d). Section 201.25(d) requires submission of a written request for an exemption and describes the information that must be included in such a request. Accordingly, we are requesting OMB approval of the information collection provisions under 21 CFR 201.25(d).

2. Purpose and Use of the Information Collection

FDA will use information from respondents to determine whether an exemption from the bar code labeling requirements may be granted to respondent.

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

We are unaware of any duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

While the information collection applies to small and large businesses alike, FDA provides small business and industry assistance to respondents through the Center for Drug Evaluation and Research (CDER) and through the Division of Manufacturers Assistance and Training component in the Center for Biologics Evaluation and Research (CBER).

6. Consequences of Collecting the Information Less Frequently

Information collection occurs only upon respondent request for agency action.

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

There are no special circumstances for this collection of information.

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 December 15, 2015. No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

Records that may be reviewed during FDA inspections are subject to FDA regulations in 21 CFR Part 20. Confidential commercial information is protected from disclosure under FOIA in accordance with section 552(a) and (b) (5 U.S.C. 552(a) and (b)) and by part 20. To the extent that § 20.64 applies, we will honor the confidentiality of any data in investigation records compiled for law enforcement purposes.

11. Justification for Sensitive Questions

The information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Hour Burden and Costs

12a. Annualized Hour Burden Estimate

FDA estimates it receives 2 exemption requests annually and that each exemption request requires 24 hours to complete. This results in an annual reporting burden of 48 hours, as reflected in Table 1 below.

Table 1 – Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	Responses per Respondent	Total Annual Responses	Burden per Response	Total Hours
Exemption from bar code requirement; 201.25(d)	2	1	2	24	48

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

Because of the small number of exemption requests filed under the regulation and because the activity may be performed in conjunction with associated product review activities, we estimate no annual cost to the Federal government.

15. Explanation for Program Changes or Adjustments

The burden for the information collection is unchanged.

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 Submission

There are no exceptions to the certification.