UNITED STATES FOOD & DRUG ADMINISTRATION

Bar Code Label Requirement for Human Drug Products and Biological Products

OMB Control No. 0910-0537

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency, us or we) regulations. In the Federal Register of February 26, 2004 (69 FR 9120), we issued a regulation requiring human drug product and biological product labels to have bar codes. Specifically, the 21 CFR part 201.25 regulations require bar codes on most human prescription drug products and on over-the-counter (OTC) drug products that are dispensed under an order and commonly used in health care facilities. It also requires machine-readable information on blood and blood components. For human prescription drug products and OTC drug products that are dispensed under an order and commonly used in health care facilities, the bar code must contain the national drug code number for the product. For blood and blood components, the regulation 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 (CBER). The regulations are intended 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.

Although most of the information collections created by the regulation have now been incorporated in OMB approved information collections supporting the applicable regulations, respondents to the collection may continue to seek an exemption from the bar code label requirement under § 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 § 201.25(d).

2. Purpose and Use of the Information Collection

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

Although the information collection applies to small and large businesses alike, we provide 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 FDA action.

7. Special Circumstances Relating to the Guidelines of 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 November 1, 2018 (83 FR 54930). No comments were received that pertained to this ICR burden.

9. Explanation of Any Payment or Gift to Respondents

FDA has not provided and has no intention to provide any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

We have reviewed this information collection to identify any potential risks to the privacy of individuals whose information may be handled by or on behalf of FDA and to ensure appropriate handling of information that may require privacy protection under the Privacy Act. In this case, this information collection does not involve solicitation or collection of personally identifiable information (PII) by or on behalf of FDA/CDER. Specifically, FDA/CDER does not intend to collect personally identifiable information (PII) and will not maintain records subject to the Privacy Act or otherwise operate a Privacy Act System of Records in relation to this specific collection.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature associated with the information collection.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Section 201.25(d) requires respondents to submit a written request for an exemption and describes the information that must be included in such a request. Based on the number of exemption requests we have received previously, we estimate that approximately 2 exemption requests will be submitted annually and that each exemption request will require 24 hours to complete. This results in an annual reporting burden of 48 hours, as reflected below in table .

We estimate the burden of this collection of information as follows:

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
21 CFR 201.25(d)	2	1	2	24	48

12b. Annualized Cost Burden Estimate

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 Costs to Respondents and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

Costs to the Federal government are absorbed through existing resource allocations covering review of product labeling.

15. Explanation for Program Changes or Adjustments

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.