4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0873]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Bar Code Label Requirement for Human Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0537. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A-12M, 11601 Landsdown Street, North Bethesda, MD 20852, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Bar Code Label Requirement for Human Drug Products and Blood; OMB Control No. 0910-0537 – Extension

In the Federal Register of February 26, 2004 (69 FR 9120), FDA issued a final rule 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 under 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 under 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 § 201.25(d) (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. 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 1.

In the Federal Register of December 15, 2015 (80 FR 77637) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Average Burden Per Response	Total Hours
201.25(d)	2	1	2	24	48

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

Dated: July 13, 2016.

Leslie Kux,
Associate Commissioner for Policy.
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