4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0827]

Agency Information Collection Activities; Proposed Collection; Comment Request; Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on certain labeling requirements for blood and blood components, including Source Plasma. These requirements will facilitate the use of a labeling system using machine-readable information that would be acceptable as a system for labeling blood and blood components, and the use of new labeling systems that may be developed in the future. Additionally, these requirements are issued to help ensure the continued safety of the blood supply and facilitate consistency in labeling.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the

Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. This document solicits comments on certain labeling requirements for blood and blood components, including Source Plasma, finalized as part of a rule FDA is publishing elsewhere in this Federal Register entitled "Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma."

Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma--(OMB Control Number 0910-NEW)

FDA is finalizing the labeling requirements for blood or blood components intended for use in transfusion or for further manufacture pursuant to the provisions of the Public Health Service Act (PHS Act) (42 U.S.C. 262-264), and the drugs, devices, and general administrative provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351-353, 355, 360, 360j, 371, and 374). Under these provisions of the PHS Act and the Federal Food, Drug, and Cosmetic Act, we have the authority to issue and enforce regulations designed to ensure that biological products are safe, pure, potent, and properly labeled, and to prevent the introduction, transmission, and spread of communicable disease.

Under this rulemaking, FDA is consolidating the regulations related to labeling blood and blood components. Regulations for labeling of blood and blood components will be consolidated into § 606.121 (Container label) (21 CFR 606.121) and 21 CFR 606.122 (Circular of information). This notice solicits comments on the information collection associated with § 606.121(c)(11) (21 CFR 606.121(c)(11)) which requires that if the product is intended for further manufacturing use, a statement listing the results of all the tests for communicable disease agents required under § 610.40 (21 CFR 610.40) for which the donation has been tested and found negative must be on the container label; except that the label for Source Plasma is not required to list the negative results of serological syphilis testing under § 610.40(i) (21 CFR 610.40(i)) and § 640.65(b) (21 CFR 640.65(b)). In addition, this notice also solicits comments on the information collection associated with § 606.121(e)(2)(i) (21 CFR 606.121(e)(2)(i)) which requires that the product labels of certain red blood cells must include the type of additive solution with which the product was prepared.

The Agency believes the rule amendments and the information collection provisions under § 606.121(c)(11) and § 606.121(e)(2)(i) in the final rule are part of usual and customary business practice and do not create any new burden for respondent.

The collection of information requirements under §§ 606.121 and 606.122 are approved under OMB control number 0910-0116; and those in 21 CFR 640.70 have been approved under OMB control number 0910-0338. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: December 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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