Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma; Final Rule

0910-NEW
SUPPORTING STATEMENT

## A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting Office of Management and Budget (OMB) approval of the information collection requirements contained in the final rule amending 21 CFR Part 606. These requirements are listed below.

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| 21 CFR 606.121(c)(11) | Disclosure | 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 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) and § 640.65(b). |
| 21 CFR 606.121(e)(2)(i) | Disclosure | Requires that the product labels of certain red blood cells must include the type of additive solution with which the product was prepared. |

FDA is issuing these 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 (FD&C Act) (21 U.S.C. 321, 331, 351-353, 355, 360, 360j, 371, and 374). Under these provisions of the PHS Act and the FD&C 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.

The labeling regulations implement FDA's statutory authority to ensure the safety, purity, and potency of blood and blood components. These labeling requirements are intended to help prevent the transmission of communicable disease and to ensure that blood and blood components are safe, pure, potent, and properly labeled.

This collection of information is not related to the American Recovery and Reinvestment Act of 2009 (ARRA).

2. Purpose and Use of the Information Collection

   The requirements under §§ 606.121(c)(11) and 606.121(e)(2)(i) will facilitate the use of a labeling system using machine-readable information that will 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 intended to help ensure the continued safety of the blood supply and facilitate consistency in labeling.
3. Use of Improved Information Technology and Burden Reduction

   Manufacturers may use any appropriate information technology to develop and distribute the required labeling. FDA is not aware of any improved information technology that could be used to reduce the burden.
4. Efforts to Identify Duplication and Use of Similar Information

   FDA is the only agency that requires this information. The required information is not available from any other source.
5. Impact on Small Businesses or Other Small Entities

   This collection of information applies to small as well as large facilities. Although FDA must apply the statutory and regulatory requirements equally among all enterprises, FDA does provide special help to small businesses. The Center for Biologics Evaluation and Research, Office of Communication, Outreach and Development, Division of Manufacturers Assistance and Training, provides assistance to small businesses subject to FDA's regulatory requirements.
6. Consequences of Collecting the Information Less Frequently

   Less frequent collection of information or other methods of reducing the frequency of information would not ensure that the products are safe, pure, potent, and properly labeled, or provide the information needed to help prevent the transmission of communicable disease by blood and blood components.
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 December 30, 2011 (76 FR 82300) that was corrected on February 8, 2012 (77 FR 6566). No comments were received.
9. Explanation of Any Payment or Gift to Respondents

   No payment or gift was provided to respondents.
10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received by FDA would be consistent with the Freedom of Information Act (FOIA) and the FDA's published regulations of "Public Information" under 21 CFR Part 20.

11. Justification for Sensitive Questions

Questions of a sensitive nature are not applicable to this information collection.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

Respondents to this collection of information are manufacturers of blood and blood components, and blood derivatives. 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.

12b. Annualized Cost Burden Estimate

There is no estimated annual cost burden associated with this collection of information.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

There are no estimated annual costs to the Federal Government associated with this collection of information.

15. Explanation for Program Changes or Adjustments

Program changes or adjustments are not applicable as this is the first submission for the final rule.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

17. Reason(s) Display of Expiration Date is Inappropriate

FDA is not seeking approval to exempt display of the expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.