

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention (CDC)

#### Request for Nominations of Candidates To Serve on the Advisory Committee on Breast Cancer in Young Women (ACBCYW)

The CDC is soliciting nominations for membership on the ACBCYW. The Committee provides advice and guidance to the Secretary, HHS; the Assistant Secretary for Health; and the Director, CDC, regarding the formative research, development, implementation and evaluation of evidence-based activities designed to prevent breast cancer (particularly among those at heightened risk) and promote the early detection and support of young women who develop the disease. The advice provided by the Committee will assist in ensuring scientific quality, timeliness, utility, and dissemination of credible appropriate messages and resource materials.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishments of the committee's objectives. The Secretary, HHS, acting through the Director, CDC, shall appoint to the advisory committee nominees with expertise in breast cancer, disease prevention, early detection, diagnosis, public health, social marketing, genetic screening and counseling, treatment, rehabilitation, palliative care, and survivorship in young women, or in related disciplines with a specific focus on young women. Members may be invited to serve for up to four years. The next cycle of selection of candidates will begin in the winter of 2012, for selection of potential nominees to replace members whose terms will end on October 15, 2012 and October 15, 2013 respectively.

Selection of members is based on candidates' qualifications to contribute to the accomplishment of ACBCYW objectives <http://www.cdc.gov/maso/FACM/facmACBCYW.htm>. The U.S. Department of Health and Human Services will give close attention to equitable geographic distribution and to minority and female representation so long as the effectiveness of the Committee is not impaired. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens, and

cannot be full-time employees of the U.S. Government.

Candidates should submit the following items:

- Current curriculum vitae or resume, including complete contact information (name, affiliation, mailing address, telephone numbers, fax number, email address);
- A 150 word biography for the nominee;
- At least one letter of recommendation from a person(s) not employed by the U.S. Department of Health and Human Services. Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by HHS.

Nominations should be submitted (postmarked or received) by January 25, 2012.

- *Electronic submission:* You may submit nominations, including attachments, electronically to [acbcyw@cdc.gov](mailto:acbcyw@cdc.gov).
- *Regular, Express or Overnight Mail:* Written nominations may be submitted to the following addressee only: Temeika L. Fairley, Ph.D., c/o ACBCYW Designated Federal Officer, CDC, 4770 Buford Highway NE., Mailstop K-52, Atlanta, Georgia 30341.

Telephone and facsimile submissions cannot be accepted. Nominations may be submitted by the candidate or by the person/organization recommending the candidate.

Candidates invited to serve will be asked to submit the "Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the Centers for Disease Control and Prevention." This form allows CDC to determine whether there is a statutory conflict between that person's public responsibilities as a Special Government Employee and private interests and activities, or the appearance of a lack of impartiality, as defined by Federal regulation. The form may be viewed and downloaded at [http://www.usoge.gov/forms/oge450\\_pdf/oge450\\_accessible.pdf](http://www.usoge.gov/forms/oge450_pdf/oge450_accessible.pdf). This form should not be submitted as part of the nomination.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and the Agency for Toxic Substances and Disease Registry.

Dated: December 23, 2011.

**Ronald Ergle,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

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## 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 February 28, 2012.

**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:** Juanmanuel Vilela, Office of

Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, (301) 796-7651, [Juanmanuel.vilela@fda.hhs.gov](mailto:Juanmanuel.vilela@fda.hhs.gov).

**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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**BILLING CODE 4160-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2011-N-0619]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices: Humanitarian Use Devices**

**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 January 30, 2012.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0332. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, (301) 796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@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.

**Medical Devices: Humanitarian Use Devices—(OMB Control Number 0910-0332)—Extension**

This collection of information implements the humanitarian use device (HUD) provision of section 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(m)) and subpart H, part 814 (21 CFR part 814). Under section 520(m) of