

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, IRB inspections, electronic record requirements, and investigator initiated research. Topics for discussion include the following: (1) What FDA Expects in a Pharmaceutical Clinical Trial; (2) Adverse Event Reporting—Science, Regulation, Error, and Safety; (3) Part 11 Compliance—Electronic Signatures; (4) Informed Consent Regulations; (5) IRB Regulations and FDA Inspections; (6) Keeping Informed and Working Together; (7) FDA Conduct of Clinical Investigator Inspections; (8) Meetings With FDA: Why, When, and How; (9) Investigator Initiated Research; (10) Medical Device Aspects of Clinical Research; (11) Working With FDA's Center for Biologics Evaluation and Research; (12) The Inspection is Over—What Happens Next? Possible FDA Compliance Actions; (13) Ethical Issues in Subject Enrollment; (14) Medical Device Aspects of Clinical Research; (15) Are We There Yet? An Overview of the FDA GCP Program.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the quality of FDA-regulated drugs and devices. The public workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The public workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121) as outreach activities by Government Agencies to small businesses.

Dated: August 10, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Hemoglobin Standards and Maintaining Adequate Iron Stores in Blood Donors; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled: “Hemoglobin Standards and Maintaining Adequate Iron Stores in Blood Donors.” The purpose of this public workshop is to discuss blood donor hemoglobin and hematocrit qualification standards in the United States, its impact on donor safety and blood availability, and potential measures to maintain adequate iron stores in blood donors. The public workshop has been planned in partnership with the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health, the National Heart, Lung and Blood Institute, America's Blood Centers, AABB, and the Plasma Protein Therapeutics Association. This public workshop will include presentations and panel discussions by experts knowledgeable in the field from academic institutions, government agencies, and industry.

Dates and Times: The public workshop will be held on November 8, 2011, from 8 a.m. to 5:30 p.m. and November 9, 2011, from 8 a.m. to 3 p.m.

Location: The public workshop will be held at the Natcher Conference Center, Main Auditorium, Building 45, National Institutes of Health, 45 Center Dr., Bethesda, MD 20892.

Contact Person: Rhonda Dawson, Center for Biologics Evaluation and Research (HFM–302), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6129, FAX: 301–827–2843, e-mail: rhonda.dawson@fda.hhs.gov.

Registration: Mail, fax, or email your registration information (including name, title, firm name, address, telephone and fax numbers) to Rhonda Dawson (see *Contact Person*) by October 14, 2011. There is no registration fee for the public workshop. Early registration is recommended because seating is limited. Registration on the day of the public workshop will be provided on a space available basis beginning at 7:30 a.m.

If you need special accommodations due to a disability, please contact

Rhonda Dawson (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

Under FDA's current regulations, allogeneic blood donors must have a hemoglobin level of no less than 12.5 grams of hemoglobin per 100 milliliters of blood or a hematocrit value of 38 percent prior to donation (21 CFR 640.3(b)(3) and 640.63(c)(3)). Hemoglobin and hematocrit measurements are typically obtained from a small sample of blood drawn from a finger or vein. New technologies that potentially allow for less invasive, faster, and more convenient methods of measuring blood donor hemoglobin and hematocrit levels are being studied. A low donor hemoglobin and hematocrit level is the most common reason that prospective blood donors, particularly women, are deferred.

Allogeneic donors of a unit of red blood cells generally may not donate more than once in an 8 week period to ensure recovery of their red blood cells and iron stores (21 CFR 640.3). Nonetheless, some donors, especially repeat and premenopausal female donors, can develop iron deficiency, with or without anemia, from blood donation. Improved understanding of iron loss in blood donors may help reduce donor deferrals due to low hemoglobin and hematocrit levels and reduce iron deficiency that can result from blood donation. Different strategies to minimize iron deficiency in blood donors (e.g., testing for iron stores, adjusting the donation interval, or providing iron replacement) have been explored in the past. Changes in qualifying hemoglobin levels have been discussed in various forums for both men and women to bring these levels into closer concordance with population norms. However, the potential risks and benefits of these strategies require further discussion.

This public workshop will serve as a forum for discussion of hemoglobin and hematocrit donation standards, current methods for hemoglobin measurement, iron loss and iron measurement methods in blood donors, and strategies to maintain adequate donor iron stores. The first day of the public workshop will include presentations and panel discussions on the following topics: (1) Hemoglobin standards for blood donors in the United States; (2) studies of hemoglobin distribution and deferral patterns in blood donors; and (3) measurement of hemoglobin and hematocrit and iron levels in blood donors. The second day of the public workshop will include a discussion of the following topics: (1) Iron

metabolism, iron stores and iron deficiency in blood donors; and (2) potential methods to maintain adequate iron stores in blood donors, including adjustment of the interdonation interval, iron measurement and iron replacement.

Transcripts: Please be advised that as soon as possible after a transcript of the public workshop is available, it will be accessible on the Internet at: <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/default.htm>. Transcripts of the public workshop may also be requested in writing from the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

Dated: August 10, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011-20861 Filed 8-16-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget (OMB), in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, e-mail paperwork@hrsa.gov or call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Health Education Assistance Loan (HEAL) Program: Lender's Application for Insurance Claim Form and Request for Collection Assistance Form (OMB No. 0915-0036)—Extension

The clearance request is for an extension of two forms that are currently approved by OMB. HEAL lenders use the Lenders Application for Insurance Claim to request payment from the Federal Government for federally insured loans lost due to borrowers' death, disability, bankruptcy, or default. The Request for Collection Assistance form is used by HEAL lenders to request federal assistance with the collection of delinquent payments from HEAL borrowers. The annual estimate of burden is as follows:

Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Lender's Application for Insurance Claim Form 510	13	28	364	0.50	182
Request for Collection Assistance Form 513 ..	13	445	5,785	0.17	983
Total Burden	26	1,165

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to the desk officer for HRSA, either by e-mail to OIRA_submission@omb.eop.gov or by fax to 202-395-6974. Please direct all correspondence to the "attention of the desk officer for HRSA."

Dated: August 11, 2011.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2011-20999 Filed 8-16-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; National Institutes of Health Construction Grants

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for public comment on proposed data

collection projects, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: National Institutes of Health Construction Grants 42 CFR Part 52b (Final Rule). *Type of Information Collection Request:* Extension of OMB Control No. 0925-0424, expiration date 10/31/2011. *Need and Use of the Information Collection:* This request is for OMB review and approval of a renewal for the information collection and recordkeeping requirements contained in the regulation codified at 42 CFR part 52b. The purpose of the regulation is to govern the awarding and administration of grants awarded by NIH and its components for construction of new buildings and the alteration, renovation, remodeling, improvement, expansion, and repair of existing buildings, including the provision of equipment necessary to make the buildings (or applicable part of the buildings) suitable for the purpose for which it was constructed. In terms of reporting

requirements: Section 52b.9(b) of the regulation requires the transfer of a facility which is sold or transferred, or owner of a facility, the use of which has changed, to provide written notice of the sale, transfer or change within 30 days. Section 52b.10(f) requires a grantee to submit an approved copy of the construction schedule prior to the start of construction. Section 52b.10(g) requires a grantee to provide daily construction logs and monthly status reports upon request at the job site. Section 52b.11(b) requires applicants for a project involving the acquisition of existing facilities to provide the estimated cost of the project, cost of the acquisition of existing facilities, and cost of remodeling, renovating, or altering facilities to serve the purposes for which they are acquired. In terms of recordkeeping requirements: Section 52b.10(g) requires grantees to maintain daily construction logs and monthly status reports at the job site. *Frequency of Response:* On occasion. *Affected Public:* Non-profit organizations and Federal agencies. *Type of respondents:* Grantees. The estimated respondent burden is as follows: