

(BECS) as they relate to inventory control. The public workshop has been planned in partnership with the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health, America's Blood Centers, and AABB. This public workshop will include presentations and panel discussions by experts knowledgeable in this field from government Agencies and industry.

**Date and Time:** The public workshop will be held on September 13, 2011, from 8:30 a.m. to 5 p.m.

**Location:** The public workshop will be held at the Universities at Shady Grove Conference Center, 9630 Gudelsky Dr., Rockville, MD 20850-5820, 301-738-6000.

**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](mailto:rhonda.dawson@fda.hhs.gov).

**Registration:** Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone, and fax numbers) to Rhonda Dawson (see *Contact Person*) by September 1, 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:** QREs refer to the inadvertent release of blood or blood components either before completion of testing and determination that all other criteria affecting the safety, purity, or potency of the product have been met, or despite findings that would render the blood or blood components unsuitable for release. Although QREs that result in the distribution of blood or blood components are required to be reported to FDA as biologic product deviation reports (BPDRs), the amount of information provided in BPDRs varies and often represents a summary of information rather than a detailed description and analysis of the problem. Thus, the root causes of QREs are not known with certainty. Further, the rates of QREs are also not known with certainty, and actions necessary to correct and prevent them are unclear.

There has been a recent focus on QREs related to the release of units with incomplete or absent testing for transfusion-transmitted infectious

diseases. On June 10 and 11, 2010, the HHS Advisory Committee on Blood Safety and Availability (the Committee) met to discuss the current FDA blood donor deferral policy on men who have sex with other men. While the Committee recommended that the current deferral policy not be changed at the present time, it found the current policy to be suboptimal in permitting some potentially high risk donations while preventing some low risk donations. The Committee made a number of recommendations and indicated that HHS should take action to investigate and reduce the risk of QREs in blood collection establishments.

This public workshop will serve as a forum for discussion of QREs and provide FDA and industry with information necessary to reduce the rates of QREs. The public workshop presentations and panel discussions will: (1) Review recent BPDR data to better determine the root causes for QREs and identify activities that could address those causes; (2) evaluate the use of 510(k) cleared BECS or implementation of BECS performance standards in reducing the rate of QREs; and (3) explore other potential strategies to address QREs. The public workshop will conclude with a summary of the issues discussed.

**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., Rockville, MD 20857.

Dated: July 13, 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]**

### Effects of Ischemia Reperfusion Injury on Outcomes in Kidney Transplantation; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

### **ACTION:** Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop to discuss the effects of ischemia/reperfusion injury (IRI) on outcomes in kidney transplantation. This public workshop is intended to obtain information from health care providers, academia, and industry on various aspects of the pathophysiology, clinical management, and outcomes following IRI. The meeting will include a discussion of animal models, devices, and clinical trial design. The input from this public workshop will help in developing topics for further discussion and may serve to inform recommendations on clinical trial design for products for the mitigation of IRI and/or for the prophylaxis and/or treatment of delayed graft function (DGF) and related conditions in kidney transplant recipients.

**Date and Time:** The public workshop will be held on September 8, 2011, from 9 a.m. to 6 p.m. and on September 9, 2011, from 8 a.m. to 3 p.m.

**Location:** The public workshop will be held at the Crowne Plaza, 8777 Georgia Ave., Silver Spring, MD 20910, 301-589-0800. Seating is available only on a first-come-first-served basis.

**Contact Persons:** Christine Moser or Ramou Mauer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6209, Silver Spring, MD 20993-0002, 301-796-1300 or 301-796-1600.

**Registration:** Registration is free for the public workshop. Interested parties are encouraged to register early because space is limited. Seating will be available on a first-come-first-served basis. To register electronically, e-mail registration information (including name, title, firm name, address, telephone, and fax number) to [IRIworkshop@fda.hhs.gov](mailto:IRIworkshop@fda.hhs.gov). Persons without access to the Internet can call Christine Moser, 301-796-1300, or Ramou Mauer, 301-796-1600, to register.

Persons needing a sign language interpreter or other special accommodations should notify Christine Moser or Ramou Mauer (see *Contact Persons*) at least 7 days in advance.

**SUPPLEMENTARY INFORMATION:** FDA is announcing a public workshop regarding effects of IRI on outcome in kidney transplantation and medical product development for the prevention and/or treatment of DGF in kidney transplant recipients. This public workshop will include scientific discussion on the following topics:

- Pathophysiology and contributing factors to IRI,
- Downstream measures of response to IRI,
- Current management strategies and outcomes in patients with DGF,
- Animal models in IRI and DGF,
- Device issues related to DGF, and
- Clinical trial issues related to the recipient in development of medical products for the management of DGF and related conditions in kidney transplantation.

The Agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

**Transcripts:** Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management

(HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, Rm. 6-30, Rockville, MD 20857.

Transcripts will also be available on the Internet at <http://www.fda.gov/Drugs/NewsEvents/ucm206132.htm> approximately 45 days after the workshop.

Dated: July 13, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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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

##### Correction

In notice document 2011-16127 appearing on page 37821 in the issue of Tuesday, June 28, 2011, make the following correction:

In the table on page 37821, in column one, row three, "4353" should read "2353." A corrected table should appear as set forth below.

The annual estimate of burden is as follows:

Respondents	Number of respondents	Number of responses/respondent	Average hours per response	Total burden hours
Survey respondents .....	2000	1	.166	332
Screened households .....	2353	1	.016	38
<b>Total .....</b>	<b>2353</b>	.....	.....	<b>370</b>

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, e-mail [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Reports Clearance Officer at (301) 443-1129.

*Comments are invited on:* (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

#### Proposed Project: Maternal and Child Health Services Title V Block Grant Program Guidance and Forms for the Title V Application/Annual Report (OMB No. 0915-0172)—[Revision]

The Health Resources and Services Administration (HRSA) proposes to revise the *Maternal and Child Health Services Title V Block Grant Program—Guidance and Forms for the Application/Annual Report*. The guidance is used annually by the 50 states and 9 jurisdictions in making application for Block Grants under Title V of the Social Security Act and in preparing the required annual report. The proposed revisions follow and build on extensive consultation received from a workgroup convened to provide

suggestions to improve the guidance and forms.

The changes in this edition of the Maternal and Child Health Services Title V Block Grant Program Guidance and Forms for the Title V Application/Annual Report include the following proposed revisions: (1) The requirements for reporting on the health status indicators and health systems capacity indicators were rewritten to reduce the reporting burden to the states; (2) instructions for completing Form 7, Number of Individuals Served, have been clarified to assist states in more accurately estimating the number of individuals who receive Title V services; (3) a resource tool has been added to assist states in assessing the level of family participation in Children with Special Health Care Needs Programs (Form 13); and (4) the detail sheets for the performance measures, outcome measures, health systems capacity indicators and health status indicators have been updated with corresponding Healthy People 2020 Objectives. In addition, efficiencies through use of the electronic application are identified for states to reduce their efforts in completing the application.

The estimated average annual burden is as follows: