

Expenses Section of the Program Eligibility Guidelines.

Any payment permitted under this authority must not violate section 301 of the National Organ Transplant Act of 1984, which makes it “unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.” 42 U.S.C. 274e(a). Certain expenses are excluded from the scope of valuable consideration, including “expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.” 42 U.S.C. 274e(c)(2). As the Secretary considers rulemaking, she will consider this criminal prohibition in evaluating which expenses are appropriate for reimbursement under this Program.

HRSA is seeking public comment as to whether the Secretary should initiate rulemaking to allow reimbursement under this Program for specific incidental nonmedical expenses and concerning which incidental nonmedical expenses should be included in such rulemaking.

Dated: December 29, 2009.

Mary K. Wakefield,
Administrator.

[FR Doc. E9-31312 Filed 1-5-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0525]

Guidance for Industry on New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products,” dated December 2009. As part of the Medical Device User Fee Amendments of 2007 (MDUFA) Commitment for the Performance Goals and Procedures commitment letter, FDA agreed to publish guidance for medical imaging devices for use with imaging contrast agents or radiopharmaceuticals. FDA intends this guidance to assist developers of medical imaging devices

and imaging drug/biological products that provide image contrast enhancement. The final guidance announced in this document fulfills FDA’s commitment to issue guidance called for by the commitment letter. The guidance supercedes the draft guidance of the same title dated September 30, 2008.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Patricia Y. Love, Office of Combination Products (HFG-3), Office of the Commissioner, Food and Drug Administration, 15800 Crabbs Branch Way, Rockville, MD 20855, 301-427-1934.

SUPPLEMENTARY INFORMATION:

I. Background

As part of the Medical Device User Fee Amendments of 2007 (MDUFA) Commitment for the Performance Goals and Procedures, Item I.N of the September 27, 2007, commitment letter, FDA agreed to publish draft guidance by September 30, 2008, for medical imaging devices for use with imaging contrast agents or radiopharmaceuticals. Further, the agreement stated that the “draft guidance will be published by the end of FY 2008, and will be subject to a 90-day comment period. FDA will issue a final guidance within one year of the close of the public comment period.” The draft guidance was dated September 30, 2008 (73 FR 58604, October 7, 2008); the comment period closed on January 5, 2009. FDA held meetings with imaging industry stakeholders in July 2008 and August 2009. The final guidance announced in this document fulfills FDA’s commitment to issue final guidance called for by the commitment letter. The guidance supercedes the draft guidance

of the same title dated September 30, 2008.

FDA is announcing the availability of guidance for industry entitled “New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products.” FDA intends this guidance to assist developers of medical imaging devices and imaging drug/biological products that provide image contrast enhancement. Particularly, this guidance focuses on the following topics: (1) When the imaging device developers may add certain new imaging contrast indications to their device for use with already approved imaging drugs without a need for a modification of the drug labeling, (2) when the imaging drug developers may add certain new imaging contrast indications to their drug for use with already approved imaging devices without a need for a modification of the device labeling, and (3) what type of marketing submission(s) imaging drug or imaging device developers should submit to FDA to request approval/clearance to add a new imaging contrast indication. FDA intends for the recommendations in this guidance to promote timely and effective review of, and consistent and appropriate regulation and labeling for imaging drugs and devices.

FDA notes that during the comment period, certain topics identified in the docket were beyond the scope of the guidance document. These comments included requests for guidance on developing specific medical imaging indications (e.g., myocardial perfusion or breast cancer imaging) and offered suggestions for the type of acceptable data. FDA will consider whether separate guidance would be appropriate.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the agency’s current thinking on “New Contrast Imaging Indication Considerations for Devices and Approved Drug and Biological Products”. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 807 have been approved under

OMB control number 0910-0120. The collections of information in 21 CFR 814 have been approved under OMB control number 0910-0231. The collections of information in 21 CFR 314 have been approved under OMB control number 0910-0001.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/RegulatoryInformation/Guidances/ucm122047.htm> or <http://www.regulations.gov>.

Dated: December 30, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-31307 Filed 1-5-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of Meeting; National Commission on Children and Disasters

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of meeting.

DATES: The meeting will be held on Tuesday, February 2, 2010, from 9:30 a.m. to 3:30 p.m.

ADDRESSES: The meeting will be held at the Administration for Children and Families, 901 D Street, SW., Washington, DC 20024. To attend either in person or via teleconference, please register by 5 p.m. Eastern Time, January 28, 2010. To register, please e-mail jacqueline.haye@acf.hhs.gov with "Meeting Registration" in the subject line, or call (202) 205-9560.

Registration must include your name, affiliation, and phone number. If you require a sign language interpreter or other special assistance, please call Jacqueline Haye at (202) 205-9560 or e-

mail jacqueline.haye@acf.hhs.gov as soon as possible and no later than 5 p.m. Eastern Time, January 19, 2010.

Agenda: The Commission will discuss: (1) Outcomes from the Commission's Long-Term Disaster Recovery Workshop on February 1, 2010; (2) A National resource center on children and disasters; and (3) Plans for future work of the Commission.

Written comments may be submitted electronically to roberta.lavin@acf.hhs.gov with "Public Comment" in the subject line. The Commission recommends that you include your name, mailing address and an e-mail address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment, and it allows the Commission to contact you if further information on the substance of the comment is needed or if your comment cannot be read due to technical difficulties. The Commission's policy is that the Commission will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment placed in the official record.

The Commission will provide an opportunity for public comments during the public meeting on February 2, 2010. Those wishing to speak will be limited to three minutes each; speakers are encouraged to submit their remarks in writing in advance to ensure their comment is received in case there is inadequate time for all comments to be heard on February 2, 2010.

Additional Information: Contact Roberta Lavin, Office of Human Services Emergency Preparedness and Response, e-mail roberta.lavin@acf.hhs.gov or (202) 401-9306.

SUPPLEMENTARY INFORMATION: The National Commission on Children and Disasters is an independent Commission that shall conduct a comprehensive study to examine and assess the needs of children as they relate to preparation for, response to, and recovery from all hazards, building upon the evaluations of other entities and avoiding unnecessary duplication by reviewing the findings, conclusions, and recommendations of these entities. The Commission shall then submit a report to the President and the Congress on the Commission's independent and specific findings, conclusions, and recommendations to address the needs of children as they relate to preparation for, response to, and recovery from all hazards, including major disasters and emergencies.

Dated: December 28, 2009.

David A. Hansell,

Principal Deputy Assistant Secretary for Children and Families.

[FR Doc. E9-31393 Filed 1-5-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

Anesthetic and Life Support Drugs Advisory Committee; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Anesthetic and Life Support Drugs Advisory Committee scheduled for January 28, 2010, is cancelled. This meeting was announced in the **Federal Register** of December 8, 2009 (74 FR 64702). This meeting has been cancelled to allow time for the FDA to review new information that is relevant to the benefit risk balance for the proposed new indication. The agency intends to continue evaluating the application and, as needed, will announce future meeting dates in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Kalyani Bhatt, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, email: Kalyani.Bhatt@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512529. Please call the Information Line for up-to-date information on this meeting.

Dated: December 30, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-31306 Filed 1-5-10; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: E-Verify Data Collection Survey, New Information Collection; Comment Request

ACTION: 60-Day Notice of Information Collection Under Review: E-Verify Data