

(National Institutes of Health), Center for Biologics, Evaluation and Research (Food and Drug Administration), a discussion on causation, and an update from the IOM on the project to review adverse effects of vaccines. Agenda items are subject to change as priorities dictate.

Public Comments: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Kay Cook, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857 or e-mail: kcCook@hrsa.gov. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period. These persons will be allocated time as it permits.

FOR FURTHER INFORMATION CONTACT:

Anyone requiring information regarding the ACCV should contact Kay Cook, DVIC, HSB, HRSA, Room 11C-26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443-6593 or e-mail: kcCook@hrsa.gov.

Dated: August 4, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9-19109 Filed 8-10-09; 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, September 15, 2009, 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, September 11, 2009. To register, please e-mail capelt@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 Carol Apelt at (202) 205-4618 as soon as possible and no later than 5 p.m., Eastern Time, September 1, 2009.

Agenda: The Commission will hear reports from four subcommittees: (1) Pediatric Medical Care Subcommittee; (2) Education, Child Welfare, and Juvenile Justice Subcommittee; (3) Evacuation, Transportation and Housing Subcommittee; and (4) Human Services Recovery Subcommittee. The Commission will also deliberate and vote on its Interim Report to the President and Congress.

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 email 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 your 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 September 15, 2009. 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 September 15, 2009.

Additional Information: Contact Roberta Lavin, Office of Human Services Emergency Preparedness and Response, e-mail roberta.lavin@acf.hhs.gov or phone (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 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: August 3, 2009.

David A. Hansell,

Acting Assistant Secretary for Children and Families.

[FR Doc. E9-19157 Filed 8-10-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Advisory Council on Blood Stem Cell Transplantation.

Date and Times: September 21, 2009, 8:30 a.m. to 4:30 p.m.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, Maryland 20814.

Status: The meeting will be open to the public.

Purpose: Pursuant to Public Law 109-129, 42 U.S.C. 274k (section 379 of the Public Health Service Act, as amended) the Advisory Council on Blood Stem Cell Transplantation (ACBSCT) advises the Secretary of HHS and the Administrator, HRSA, on matters related to the activities of the C.W. Bill Young Cell Transplantation Program (Program) and the National Cord Blood Inventory (NCBI) Program.

Agenda:

The Council will hear reports from three ACBSCT Work Groups: Informed Consent, Access to Transplantation, and Cord Blood Collections. The Council also will hear presentations and discussions on the following topics: Induced pluripotent stem cells and adult stem cells, National Marrow Donor Program Infrastructure Summit, Radiation Injury Treatment Network, and trends in post-transplant survival. Agenda items are subject to change as priorities indicate.

After the presentations and Council discussions, members of the public will have an opportunity to provide comments. Because of the Council's full agenda and the timeframe in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACBSCT meeting. Meeting summary notes will be made available on the HRSA's Program Web site at http://bloodcell.transplant.hrsa.gov/ABOUT/Advisory_Council/index.html.

The draft meeting agenda and a registration form will be available on or about August 21, 2009, on the HRSA's Program Web site at http://bloodcell.transplant.hrsa.gov/ABOUT/Advisory_Council/index.html.

The completed registration form should be submitted by facsimile to Professional and Scientific Associates (PSA), the logistical support contractor for the meeting, at fax number (703) 234-1701 ATTN: Rebecca Pascoe. Registration can also be completed electronically at <https://www.team-psa.com/dot/fall2009/acbsct>. Individuals without access to the Internet who wish to register may call Rebecca Pascoe with PSA at (703) 234-1747.

FOR FURTHER INFORMATION CONTACT:

Remy Aronoff, Executive Secretary, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 12-105, Rockville, Maryland 20857; telephone (301) 443-3264.

Dated: August 4, 2009.

Alexandra Huttinger,

Director, Division of Policy Review and Coordination.

[FR Doc. E9-19110 Filed 8-10-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 1, 2009, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/ Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301-589-5200.

Contact Person: Nicole Vesely, 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, 301-827-6793, FAX: 301-827-6776, e-mail: nicole.vesely@fda.hhs.gov, or FDA

Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the following topics: (1) Supplemental new drug application (sNDA) 021-673/S-009, CLOLAR (clofarabine) Injection for intravenous use, Genzyme Corp., proposed indication for the treatment of previously untreated adults aged 60 years or older with acute myeloid leukemia with at least one unfavorable baseline prognostic factor and (2) new drug application (NDA) 022-489, proposed trade name ONRIGIN (laromustine) Injection, Vion Pharmaceuticals, Inc., proposed indication for remission induction therapy for patients 60 years or older with de novo poor-risk acute myeloid leukemia (AML).

CLOLAR (clofarabine) Injection for intravenous use has a new proposed indication for treatment of AML in previously untreated adults aged 60 years or older with at least one medical or health factor that increases the risk of an unfavorable outcome. Laromustine Injection, with the proposed trade name ONRIGIN, has a proposed use for "remission induction therapy" for AML. This is an initial approach to AML treatment designed to induce, or bring about, remission (reduction or disappearance) of leukemia in patients 60 years or older with de novo, or first occurrence, AML designated as "poor-risk," or more likely to have a poor outcome.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views,

orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before August 25, 2009. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:15 a.m. and between approximately 3:30 p.m. and 4 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 25, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 26, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Nicole Vesely at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 3, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9-19108 Filed 8-10-09; 8:45 am]

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