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]

BILLING CODE 4165–15–P

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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