

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DDM

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For K. LEDESMA

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 March 3, 2005, from 8 a.m. to 5 p.m. and March 4, 2005, from 8 a.m. to 1 p.m.

Location: Hilton, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Johanna M. Clifford, 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, e-mail: cliffordj@cder.fda.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.

Agenda: On March 3, 2005, the committee will do the following: (1) Discuss new drug application (NDA) 21-115, COMBIDEX (ferumoxtran-10), Advanced Magnetics, Inc., proposed indication for intravenous administration

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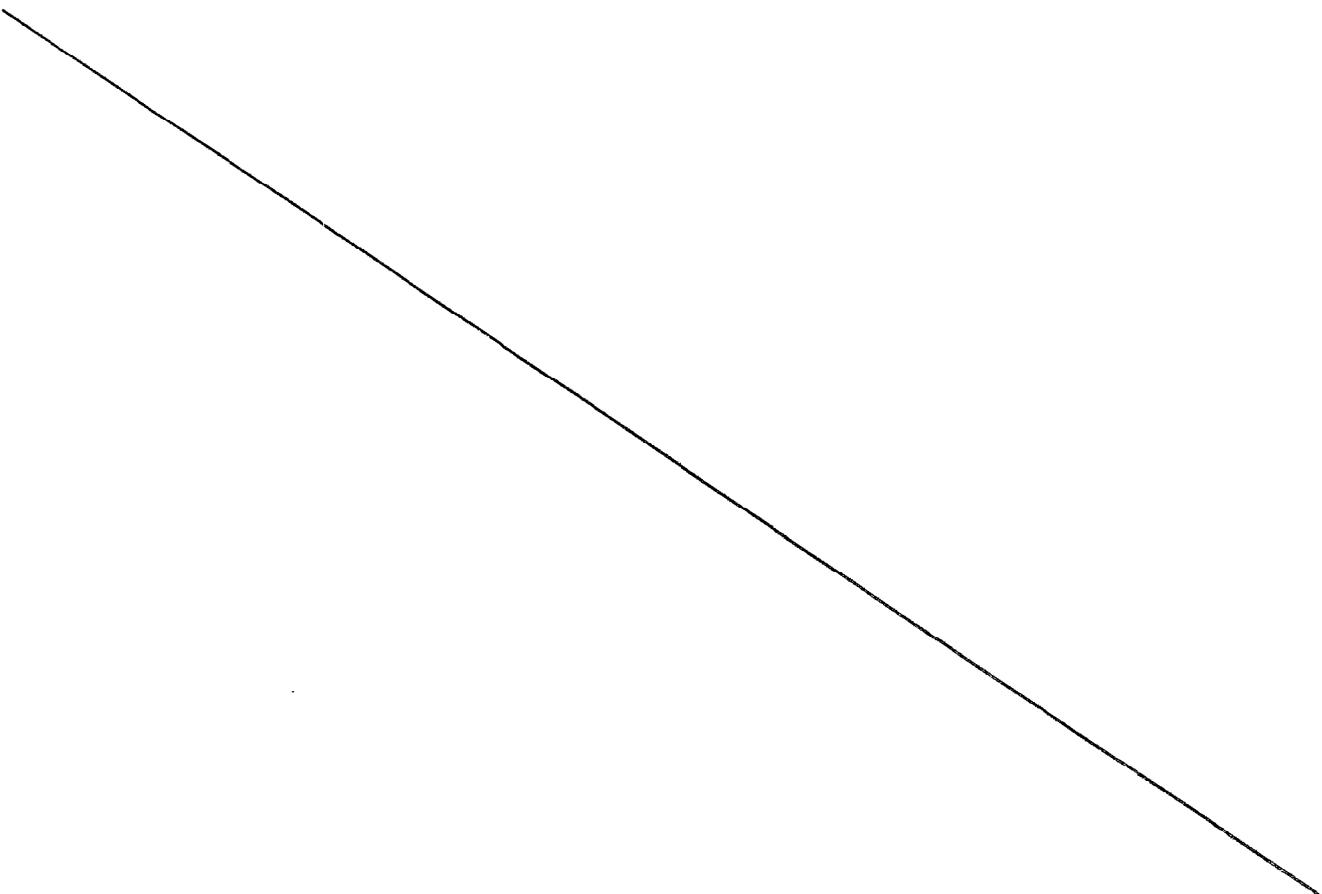
as a magnetic resonance imaging contrast agent to assist in the differentiation of metastatic and nonmetastatic lymph nodes in patients with confirmed primary cancer who are at risk for lymph node metastases, and (2) discuss prostate cancer endpoints as a followup to the June 2004 FDA workshop. On March 4, 2005, the committee will do the following: (1) Discuss the results of a confirmatory trial for NDA 21-399, IRESSA (gefitinib) AstraZeneca Pharmaceuticals LP, for the treatment of patients with locally advanced or metastatic nonsmall cell lung cancer after failure of both platinum-based and docetaxel chemotherapies, and (2) discuss safety concerns, specifically osteonecrosis of the jaw (ONJ), associated with two bisphosphonates, NDA 21-223, ZOMETA (zoledronic acid) Injection and AREDIA (pamidronate disodium for injection), both from Novartis Pharmaceuticals Corp. ZOMETA is indicated for the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed after treatment with at least one hormonal therapy. It is also approved for hypercalcemia of malignancy. AREDIA is indicated, in conjunction with standard antineoplastic therapy, for the treatment of osteolytic bone metastases of breast cancer and osteolytic lesions of multiple myeloma. It is also indicated for the treatment of moderate or severe hypercalcemia associated with malignancy, and treatment of patients with moderate to severe Paget's disease of bone.

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 by February 28, 2005. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 2:30 p.m. to 3 p.m. on March 3, 2005, and between

approximately 10:30 a.m. to 11 a.m. on March 4, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 28, 2005, 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.

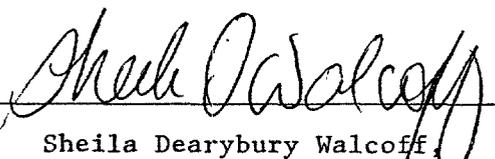
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

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 Trevelin Prysock at 301-827-7001, at least 7 days in advance of the meeting.



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

Dated: 1-27-05
January 27, 2005.



Sheila Dearybury Walcott,
Associate Commissioner for External Relations.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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