

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Oncologic Drugs Advisory Committee
PROPOSED AGENDA

May 3, 2004:

8:00 a.m.	Call to Order Introduction of Committee	ODAC Chair
	Conflict of Interest Statement	Johanna Clifford, M.S., RN, Executive Secretary, ODAC

The committee will discuss New Drug Application (NDA) 21-649, Genasense™ (oblimersen sodium) Genta, Incorporated, proposed indication for use in combination with DTIC DOME® (dacarbazine), Bayer Pharmaceuticals Corporation, proposed for the treatment of patients with advanced malignant melanoma.

8:10 a.m.	Opening Remarks
8:15 a.m.	<u>Sponsor Presentation</u>
9:00 a.m.	<u>FDA Presentation</u>
10:00	Break
10:15 a.m.	Open Public Hearing
10:45 a.m.	<i>Committee Discussion</i>
12:00 p.m.	<i>Lunch</i>

The committee will discuss NDA 21-661, RSR 13 Injection (efaproxiral sodium) Allos Therapeutics Inc., proposed indication for use as an adjunct to whole brain radiation therapy in the treatment of brain metastases from primary breast cancer.

12:45	<u>Sponsor Presentation</u>
1:30 p.m.	<u>FDA Presentation</u>
2:45 p.m.	Open Public Hearing
3:15 p.m.	Break
3:30 p.m.	Committee Discussion
5:00 p.m.	Adjourn

May 4, 2004:

8:00 a.m.	Call to Order Introduction of Committee	ODAC Chair
	Conflict of Interest Statement	Johanna Clifford, M.S., RN, Executive Secretary,

ODAC

The committee will discuss safety concerns associated with Aranesp (darbepoetin alfa) Amgen, Inc., and Procrit (epoetin alfa) Ortho Biotech, L.P., both of which are indicated for the treatment of anemia associated with cancer chemotherapy.

8:10 a.m.	Opening Remarks
8:15 a.m.	<u>Sponsor Presentations</u>
9:30 a.m.	<u>FDA Presentation</u>
10:00 a.m.	Break
10:15 a.m.	Open Public Hearing
10:45 a.m.	Committee Discussion
12:00 p.m.	<i>Lunch</i>

The Committee will discuss colo-rectal cancer endpoints as a follow up to the November 2003 FDA Workshop.

12:45 p.m.	Introduction of Committee	ODAC Chair
	Conflict of Interest Statement	Johanna Clifford, M.S., RN, Executive Secretary, ODAC
1:00 p.m.	FDA Presentation	
1:20 p.m.	Presentation	
1:50 p.m.	Presentation	
2:30 p.m.	Open Public Hearing	
3:00 p.m.	Break	
3:15 p.m.	Committee Discussion	
5:00 p.m.	Adjourn	