FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research
Oncologic Drugs Advisory Committee
AGENDA

May 3, 2004:

8:00 a.m.	Call to Order Introduction of Committee	Donna Przepiorka, M.D., Ph.D Chair, ODAC
	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	Richard Pazdur, M.D., Division Director Division of Oncology Drug Products, FDA
8:15 a.m.	**Sponsor Presentation**	
	Introduction	Loretta M. Itri, M.D.
	Melanoma Overview	John M. Kirkwood, M.D.
	Study GM301	Loretta M. Itri, M.D.
	Clinical Benefit Summary	Frank Haluska, M.D., Ph. D.
9:00 a.m.	**FDA Presentation**	Robert Kane, M.D. &.Peiling Yang, Ph.D. Division of Oncology Drug Products, FDA
9:45 a.m.	*Questions from the Committee*	
10:00	Break	
10:15 a.m.	Open Public Hearing	
10:45 a.m.	*Committee Discussion*	
12:00 p.m.	*Lunch*	

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	**Sponsor Presentation**	
	Introduction	Pablo J. Cagnoni, M.D., Vice President, Clinical Therapeutics
	Brain Metastases	John H. Suh, M.D., Clinical Director, Radiation Oncology Cleveland Clinic Foundation, Cleveland, OH
	The Science of RSR: Drug Design Rational, Mechanism of Action, and Initial Translation into the Clinic	Brian D. Kavanaugh, M.D., M.P.H., Dept. of Radiation Oncology, Anschutz Comprehensive Cancer Center, Univ. of Colorado
	Clinical Efficacy Safety Profile of Efapoxiral (RSR13)	Pablo J. Cagnoni, M.D.
	Conclusions	Dr. Paul Bunn, M.D. Paul Bunn, M.D. Professor and Director University of Colorado Cancer Center
1:30 p.m.	**FDA Presentation**	Kevin Ridenhour, M.D. & Rajeshwari Sridhara, Ph.D Division of Oncology Drug Products, FDA
2:15 p.m.	Open Public Hearing	
2:45 p.m.	Subgroup Analyses in Clinical Trials	Stephen George, Ph.D., Director Biostatistics and Information Systems Duke University Medical Center
3:15 p.m.	Break	
5:00 p.m.	Adjourn	

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May 4, 2004:

8:00 a.m.	Call to Order Introduction of Committee	Bruce Cheson M.D., Acting Chair, ODAC
	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) Johnson & Johnson, Ltd., both of which are indicated for the treatment of anemia associated with cancer chemotherapy.

8:10 a.m.	Opening Remarks	Patricia Keegan, M.D., Director Division of Therapeutic Biological Oncology Products, FDA
	Sponsor Presentations	
8:15 a.m.	NeoRecorman (epoetin beta)	Hoffman-La Roche, Ltd.
8:30 a.m.	***Johnson & Johnson, Ltd.*** Introduction	Robert DeLap, M.D., Ph.D., Vice President Global Regulatory Affairs
	Evaluation of Studies	Peter Bowers, M.D., Senior Director, Clinical Team Leader EPO, Drug Development
	Future Clinical Data	Martine George, M.D. Vice President, Hematology & Oncology Clinical Research and Global Development
9:00 a.m.	***Amgen, Inc.*** Introduction	Dawn Viveash, M.D., Vice President, Regulatory Affairs & Safety
	Aranesp Properties, Pre-Clinical Observations & EPO Receptor Biology	Glenn Begley, M.D., Ph.D., Vice President, Hematology Research
	Aranesp Clinical Observations & Pharmacovigilance Program Conclusions	David Parkinson, M.D. Vice President, Oncology Clinical Dev.
9:30 a.m.	**FDA Presentation**	Harvey Luksenburg, M.D., Medical Officer Division of Therapeutic Biological Oncology Products, FDA
10:15 a.m.	Break	
10:30 a.m.	Open Public Hearing	
10:45 a.m.	Committee Discussion	
12:00 p.m.	Lunch	

12:45 p.m.	Introduction of Committee	David Kelsen, M.D, Acting Chair, ODAC
	Conflict of Interest Statement	Johanna Clifford, M.S., RN, Executive Secretary, ODAC

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

12:55 p.m.	Opening Remarks	Richard Pazdur, M.D., Director Division of Oncology Drug Products, FDA
1:00 p.m.	Regulatory Background and Past FDA Approvals in Colorectal cancer	Amna Ibrahim, M.D., Medical Officer Division of Oncology Drug Products, FDA
1:20 p.m.	Synopsis of FDA Colorectal Cancer Endpoints Workshop	Michael O'Connell, M.D., Director Division of Medical Oncology Allegheny General Hospital, Pittsburgh, PA
1:50 p.m.	Disease-Free Survival (DFS) vs. Overall Survival (OS) as a Primary Endpoint for Adjuvant Colon Cancer Studies	Daniel Sargent, Ph.D., Director, Cancer Center Statistics Mayo Clinic Cancer Center, Rochester, MN
2:30 p.m.	Open Public Hearing	
3:00 p.m.	Break	
3:15 p.m.	Committee Discussion	
5:00 p.m.	Adjourn	