

# FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

*Oncologic Drugs Advisory Committee*

## AGENDA

March 13, 2008

8:00 a.m.	Call to Order Introduction of Committee	<b>Joanne Mortimer, M.D.</b> Acting Chair, ODAC
	Conflict of Interest Statement	<b>Nicole Vesely, Pharm.D.</b> Designated Federal Official, ODAC

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*The committee will discuss the cumulative data, including recent study results, on the risks of erythropoiesis-stimulating agents when administered to patients with cancer. Agents to be discussed include Aranesp (darbepoetin alfa), Epogen (epoetin alfa), Procrit (epoetin alfa, Amgen, Inc.), and Mircera (methoxypolyethylene glycol-epoetin beta, Hoffman-La Roche Inc.). This is a follow-up to the May 10, 2007, Oncologic Drugs Advisory Committee Meeting.*

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8:15 a.m.	<b><u>Sponsor Presentation</u></b> Introduction	<b><u>Amgen, Inc.</u></b> Paul Eisenberg, M.D., MPH Global Regulatory Affairs and Safety, Amgen Inc.
	Background Information	William Hait, M.D., Ph.D. Oncology&Hematology R&D, Ortho Biotech Oncology
	Benefits:Risk of ESAs	Tom Lillie, M.D., Ph.D. Global Development, Amgen Inc.
	Risk Minimization	Adrian Thomas, M.D. Global Safety and Benefit:Risk Management J&J Pharmaceutical Group
	Proposed Label Revisions and Summary	Paul Eisenberg, M.D., MPH Global Regulatory Affairs and Safety, Amgen Inc.
9:45	<i>Break</i>	
10:00 a.m.	<b><u>FDA Presentation</u></b> ESAs for Chemotherapy Induced Anemia & Management of Risks	<b>Vinni Juneja, M.D.</b> Medical Officer, Division of Biologic Oncology Products, OODP, OND, CDER, FDA
11:00 a.m.	Questions to the Presenters	
12:00 a.m.	<i>Lunch</i>	

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(continued)

- 1:00 p.m.           Open Public Hearing
- 2:00 p.m.           Questions to the ODAC and ODAC Discussion
- 2:45 p.m.                     *Break*
- 3:00 p.m.           Questions to the ODAC and ODAC Discussion
- 4:00 p.m.           Adjourn