

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

Conflict of Interest Statement

Nicole Vesely, PharmD
Designated Federal Official, ODAC

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), PROCRT (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.

8:10 a.m. Opening Remarks

8:15 a.m. **FDA Presentation**

Sponsor Presentation

FDA Summary/Wrap-Up

Questions to the Presenters

12:00 a.m. *Lunch*

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