

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

AGENDA

March 12, 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: biologic license application (BLA) 125268, proposed trade name NPLATE (romiplostim), Amgen Inc., proposed indication for the treatment of thrombocytopenia in adults with chronic immune (idiopathic) thrombocytopenia purpura (ITP) who are nonsplenectomized and have had an inadequate response or are intolerant to corticosteroids and/or immunoglobulins; or patients who are splenectomized and have an inadequate response to splenectomy.

Opening Remarks

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

FDA Presentation

Sponsor Presentation

FDA Presentation

Questions to the Presenters

12:15 p.m. Lunch

1:00 p.m. Open Public Hearing

2:00 p.m. Questions to the ODAC and ODAC Discussion

4:00 p.m. Adjourn