

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

AGENDA

May 30, 2008

8:00 a.m.	Call to Order Introduction of Committee	Chair, ODAC
	Conflict of Interest Statement	Nicole Vesely, Pharm.D. Designated Federal Official, ODAC
8:10 a.m.	ODAC Member Appreciation	Richard Pazdur, M.D., Director, Office of Oncology Drug Products (OODP), Office of New Drugs (OND), CDER, FDA

On May 30, 2008, the committee will discuss new drug application (NDA) 022-291, proposed trade name PROMACTA (eltrombopag olamine), GlaxoSmithKline, proposed indication for the short-term treatment of previously-treated patients with chronic idiopathic thrombocytopenic purpura (ITP) to increase platelet counts and reduce or prevent bleeding..

8:15 a.m.	<u>Sponsor Presentation</u>	GlaxoSmithKline
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9:00 a.m.	<u>FDA Presentation</u>	
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9:45 a.m.	Questions to the Presenters	
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10:15 a.m.	<i>Break</i>	
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10:30 a.m.	Open Public Hearing	
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11:30 a.m.	Questions to ODAC and ODAC Discussion	
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12:30 p.m.	Adjourn	
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