

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
Oncologic Drugs Advisory Committee

AGENDA

December 16, 2008

8:00 a.m.	Call to Order Introduction of Committee	Acting Chair, ODAC
	Conflict of Interest Statement	Nicole Vesely, Pharm.D. Designated Federal Official, ODAC

The committee will discuss biologic license application (BLA) 125084, trade name ERBITUX (cetuximab), ImClone Systems, Incorporated, and BLA 125147, trade name VECTIBIX (panitumumab), Amgen, Incorporated, in the context of K-ras as a predictive and/or prognostic biomarker in oncology drug development.

8:10 a.m.	Opening Remarks
8:15 a.m.	<u>FDA Presentation</u>
8:30 a.m.	<u>Sponsor Presentation</u>
9:00 a.m.	<u>Sponsor Presentation</u>
9:30 a.m.	<u>FDA Presentation</u>
10:15 a.m.	<i>Break</i>
10:30 a.m.	Questions to the Presenters
11:30 a.m.	Open Public Hearing
12:30 p.m.	<i>Lunch</i>
1:30 p.m.	Questions to ODAC and ODAC Discussion
3:00 p.m.	<i>Break</i>
3:15 p.m.	Questions to ODAC and ODAC Discussion
4:00 p.m.	Adjourn