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	**Janice Dutcher, M.D.** 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. The discussion at this meeting will focus on general considerations for clinical trial designs involving the use of diagnostic tests and conducting retrospective analyses.

8:10 a.m.	Opening Remarks	**Richard Pazdur, M.D.** Director, Office of Oncology Drug Products (OODP), Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**FDA Presentation** Regulatory History	**Ruthann Giusti, M.D.** Medical Officer, Division of Biologic Oncology Products, OODP, OND, CDER, FDA
8:30 a.m.	**Sponsor Presentation** Role of K-ras Mutation Status In Optimizing Selection of Colorectal Cancer Patients for Treatment with Erbitux® (Cetuximab)	**ImClone Systems Inc.** **Hagop Youssoufian, M.D.** Senior Vice President, Clinical Research and Development ImClone Systems, a wholly-owned subsidiary of Eli Lilly and Company
9:00 a.m.	**Sponsor Presentation** Introduction and Overview	**Amgen, Inc.** **Paul Eisenberg, M.D., MPH**, Senior Vice President, Global Regulatory Affairs & Safety, Amgen Inc.
	KRAS as a Predictive Biomarker for Vectibix®(panitumumab) Monotherapy	**David Reese, M.D.,** Executive Director, Global Clinical Development, Amgen Inc.
9:30 a.m.	**FDA Presentation** Prospective vs. Non-Prospective Design in Companion Drug/Diagnostic Studies	**Robert Becker, Jr., M.D., Ph.D.** Chief Medical Officer, Office of In Vitro Diagnostics (OIVD), CDRH
	Some Considerations for Statistical Design, Analysis, and Interpretation for Biomarker Classifier Based Clinical Trials in Establishing Efficacy in Support of Regulatory Marketing and Promotional Claims	**Robert O'Neill, Ph.D.** Director, Office of Biostatistics (OB), Office of Translational Sciences (OTS), CDER, FDA

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(continued)

10:30 a.m.	*Break*
10:45 a.m.	Questions to the Presenters
11:30 a.m.	Open Public Hearing
12:30 p.m.	*Lunch*
1:30 p.m.	Questions to ODAC and ODAC Discussion
3:00 p.m.	*Break*
3:15 p.m.	Questions to ODAC and ODAC Discussion
4:00 p.m.	Adjourn