

# FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

*Oncologic Drugs Advisory Committee (ODAC)*

## DRAFT AGENDA

April 12, 2011

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*On April 12, 2011, during the morning session, the committee will discuss supplemental new drug application (sNDA) 022334/S-009, trade name AFINITOR (everolimus) tablets, application submitted by Novartis Pharmaceuticals Corp. The proposed indication (use) for this product is for the treatment of patients with advanced neuroendocrine tumors (NET) of pancreatic origin.*

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8:00 a.m.	Call to Order Introduction of Committee	Chair, ODAC
	Conflict of Interest Statement	<b>Caleb Briggs, Pharm.D.</b> Designated Federal Officer, ODAC
8:15 a.m.	<b><u>Sponsor Presentation</u></b>	<b>Novartis Pharmaceuticals Corp.</b>
9:00 a.m.	<b><u>FDA Presentation</u></b>	
9:45 a.m.	<i>Break</i>	
10:00 a.m.	Questions to Presenters	
10:30 a.m.	Open Public Hearing	
11:00 a.m.	Questions to the ODAC and ODAC Discussion	
12:00 p.m.	<i>Lunch</i>	

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## **DRAFT AGENDA** (continued)

April 12, 2011

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*During the afternoon session, the committee will discuss sNDA 021938/S-013, trade name SUTENT (sunitinib malate) capsules, application submitted by C.P. Pharmaceuticals International C.V., represented by Pfizer, Inc. (authorized U.S. agent). The proposed indication (use) for this product is for the treatment of unresectable pancreatic neuroendocrine tumors (PNET).*

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1:00 p.m.	Call to Order Introduction of Committee	Chair, ODAC
	Conflict of Interest Statement	<b>Caleb Briggs, Pharm.D.</b> Designated Federal Officer, ODAC
1:15 p.m.	<b><u>Sponsor Presentation</u></b>	<b>Pfizer, Inc.</b>
2:00 p.m.	<b><u>FDA Presentation</u></b>	
2:45 p.m.	<i>Break</i>	
3:00 p.m.	Questions to Presenters	
3:30 p.m.	Open Public Hearing	
4:00 p.m.	Questions to the ODAC and ODAC Discussion	
5:00 p.m.	<i>Adjourn</i>	