

FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Gastrointestinal Drugs Advisory Committee (GIDAC)
Hilton Washington, DC/Silver Spring
May 19, 2009
DRAFT Agenda

OPEN SESSION

The committee will discuss the safety and efficacy of new drug application (NDA) 21-761, Sanvar (vapreotide acetate) Intravenous Injection, Debiovision, Inc., for the proposed indication as an adjunctive therapy to endoscopic intervention for the control of acute esophageal bleeding as a result of portal hypertension.

8:00 a.m. - 8:15 a.m.	Call to Order Introduction of Committee	Lin Chang, M.D. Acting Chair
	Conflict of Interest Statement	Kristine Khuc, Pharm.D. Designated Federal Official
8:15 a.m. - 8:25 a.m.	FDA Opening Remarks	
8:25 a.m. - 9:55 a.m.	Presentation from Sponsor	
9:55 a.m. - 10:15 a.m.	Committee Questions to Sponsor	
10:15 a.m. - 10:30 a.m.	Break	
10:30 a.m. - 12:00 p.m.	Presentation from FDA	
12:00 p.m. - 12:15 p.m.	Committee Questions to FDA	
12:15 p.m. - 1:00 p.m.	Lunch Break	
1:00 p.m. - 2:00 p.m.	Open Public Hearing (OPH) Session	
2:00 p.m. - 3:00 p.m.	Advisory Committee Discussion and Voting	
3:00 p.m. - 3:15 p.m.	Break	
3:15 p.m. - 5:00 p.m.	Resume Advisory Committee Discussion and Voting	
5:00 p.m.	Adjourn	