FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)
ANTIVIRAL DRUGS ADVISORY COMMITTEE
Hilton Hotel, The Maryland Room, Silver Spring, MD
8:00 a.m. – 4:00 p.m.
October 19, 2006

DRAFT AGENDA

Presentations, discussion, and questions will focus on clinical trial design issues in the development of products for the treatment of chronic hepatitis C infection. This meeting is being convened in response to the growing number of products in development for this indication. The primary objectives for the committee deliberations are to discuss issues relating to the identification of appropriate control arms, populations for study, endpoints, and long-term follow-up.

8: 00 a.m.	Call to Order and Opening Remarks	
	Introduction of Committee	
	Conflict of Interest Statement	Cicely C. Reese, Pharm.D. Designated Federal Officer
8: 15 a.m.	FDA Introductory Remarks	Debra Birnkrant, M.D. Director, Division of Antiviral Products, CDER, FDA
8: 30 a.m.	Viral Kinetics: RVR, EVR, SVR and Durability of Response	
9: 00 a.m.	Clinical Experience: Difficulties in Trial Design	
9: 30a.m.	Community Perspective	
10: 00 a.m.	**Break**	
10: 30 a.m.	Summary of Industry Reponses and Regulatory Perspective	William Tauber, M..D. Medical Officer Division of Antiviral Products, FDA
11: 30 a.m.	Questions / Clarifications	
12: 00 p.m.	**Lunch**	
1: 00 p.m.	Open Public Hearing	
2: 00 p.m.	Questions / Discussion / Charge to the Committee	
4:00 p.m.	**Adjournment**	