

**FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)
ANTIVIRAL DRUGS ADVISORY COMMITTEE
Hilton Hotel, Maryland Room, Silver Spring, MD**

October 19-20, 2006

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	Kenneth Sherman, M.D., Ph.D. Acting Chair, Antiviral Drugs Advisory Committee
	Introduction of Committee	
	Conflict of Interest Statement	Cicely C. Reese, Pharm.D. Designated Federal Officer
8: 15 a.m.	FDA Introductory Remarks Hepatitis C: Perspective on Drug Development Issues	Debra Birnkrant, M.D. Director, Division of Antiviral Products, CDER, FDA
8: 30 a.m.	Hepatitis C Epidemiology, Natural History, Impact, and Viral Kinetics	Kenneth E. Sherman, M.D., Ph.D. Gould Professor of Medicine, Director, Division of Digestive Diseases University of Cincinnati Medical Center Cincinnati, Ohio
9: 00 a.m.	Clinical Experience: Difficulties in Trial Design for Therapeutic Products to Treat Chronic HCV Infection	John M. Vierling, M.D., F.A.C.P. Professor of Medicine and Surgery Director of Baylor Liver Health Chief of Hepatology Baylor College of Medicine Houston, Texas
9: 30a.m.	Community Perspective	Jules Levin Executive Director/Founder National AIDS Treatment Advocacy Project (NATAP)
10: 00 a.m.	Break	
10: 30 a.m.	Summary of Industry Responses and Regulatory Perspective	William Tauber, M.D. Medical Officer, Division of Antiviral Products, CDER, 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
4:00 p.m. **Adjournment**

October 20, 2006

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