

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
ANTIVIRAL DRUGS ADVISORY COMMITTEE (AVAC) MEETING

AGENDA
November 14, 2002

Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD

BLA 125061, peginterferon alfa-2a in combination with ribavirin, NDA 21-511, Hoffmann-La Roche, Inc.,
proposed for treatment of chronic hepatitis C

8:30 a.m.	Call to Order	Roy M. Gulick, M.D., M.P.H. Chair, AVAC
	Introduction of Committee	
	Conflict of Interest Statement	Tara P. Turner, Pharm.D. Executive Secretary, AVAC
8:40 a.m.	Introduction	Karen D. Weiss, M.D. Director Division of Clinical Trial Design and Analysis FDA Emanuel F. Petricoin, III, Ph.D. Division of Therapeutic Proteins FDA
9:00 a.m.	Sponsor Presentation	Hoffmann-La Roche, Inc.
	Introduction	Dr. Candice Teuber Group Director Regulatory Affairs
	Overview of Pegasys-Copegus Development Program	Dr. Joseph Hoffman V.P. & Group Leader Virology and Transplantation
	Efficacy	Dr. Frank Duff Clinical Leader
	Safety	Dr. Jonathan Solsky Director, Drug Safety and Risk Management
	Conclusions	Dr. Joseph Hoffman
10:30 a.m.	Break	

- | | | |
|------------|--|--|
| 10:45 a.m. | FDA Presentation | William Tauber, M.D.
Medical Officer
Division of Clinical Trial Design and
Analysis |
| 11:45 a.m. | Questions to the Presenters | |
| 12:30 p.m. | Lunch | |
| 1:30 p.m. | Open Public Hearing | |
| 2:30 p.m. | Charge to the Committee/Questions/Discussion | |
| 4:00 p.m. | Adjourn | |