

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

AGENDA
August 7, 2002

Holiday Inn, 8120 Wisconsin Avenue, Bethesda, MD

Topic: Clinical trial design issues in the development of products for the treatment of chronic hepatitis B infection

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| 8:00 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 |
| 8:15 a.m. | Opening Remarks | Jeffrey Murray, M.D., M.P.H. Deputy Director Division of Antiviral Drug Products FDA |
| 8:30 a.m. | Natural History and Clinical Virology of Hepatitis B | Jay H. Hoofnagle, M.D. NIDDK/NIH |
| 9:15 a.m. | Treatment of Chronic Hepatitis B | Anna S. F. Lok, M.D. University of Michigan Medical Center |
| 10:00 a.m. | Break | |
| 10:30 a.m. | Pharmaceutical Development Issues for Hepatitis B | Nathaniel A. Brown, M.D. Senior Vice President Hepatitis Clinical Research Idenix Pharmaceuticals |
| 11:00 a.m. | Surrogate Endpoints for Hepatitis B Trials | Greg Soon, Ph.D. Statistical Team Leader Division of Antiviral Drug Products FDA |
| 12:00 p.m. | Lunch | |
| 1:00 p.m. | Open Public Hearing | Lee Crooks – Hepatitis B Foundation Gilead Sciences, Inc. |
| 2:00 p.m. | Charge to the Committee/Questions/Discussion | |
| 5:00 p.m. | Adjourn | |

