

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE (AIDAC) MEETING

AGENDA
July 10, 2002

Marriott Washingtonian Center, Grand Ballroom, 9751 Washingtonian Blvd., Gaithersburg, MD

NDA 21-242, Artesunate Rectal Capsules, World Health Organization, proposed for the initial management of acute malaria in patients who cannot take medication by mouth and for whom parenteral treatment is not available

8:30 a.m.	Call to Order	L. Barth Reller, M.D. Chair, AIDAC
	Introduction of Committee	
	Conflict of Interest Statement	Tara P. Turner, Pharm.D. Executive Secretary, AIDAC
8:40 a.m.	Opening Remarks	Renata Albrecht, M.D. Acting Director Division of Special Pathogen and Immunologic Drug Products, FDA
8:45 a.m.	Sponsor Presentation	World Health Organization (WHO) Dr. Melba Gomes Special Programme for Research & Training in Tropical Diseases World Health Organization Geneva, Switzerland Professor Nicholas White Director, Wellcome Trust Faculty of Tropical Medicine Mahidol University Bangkok, Thailand Professor Peter Folb Director, WHO Collaborating Centre for Drug Policy Cape Town, South Africa Professor Fred Binka School of Public Health University of Ghana Legon, Ghana
10:15 a.m.	Break	

10:30 a.m.	FDA Presentation	Leonard Sacks, MB.B.Ch. Medical Reviewer Division of Special Pathogen and Immunologic Drug Products, FDA Ruthanna Davi, M.S. Statistical Reviewer Office of Pharmacoepidemiology and Statistical Science, FDA Rosemary Johann-Liang, M.D. Medical Reviewer Division of Special Pathogen and Immunologic Drug Products, FDA Renata Albrecht, M.D. Acting Director Division of Special Pathogen and Immunologic Drug Products, FDA
11:45 a.m.	Lunch	
1:00 p.m.	Open Public Hearing Swissmedic	
1:45 p.m.	Charge to the Committee	Mark Goldberger, M.D., M.P.H. Director Office of Drug Evaluation IV FDA
2:00 p.m.	Committee Discussion	
3:30 p.m.	Break	
3:45 p.m.	Continued Discussion and Vote	
5:00 p.m.	Adjourn	