

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Anti-Infective Drugs Advisory Committee Meeting
Advisory Committee Conference Room,
5630 Fishers Lane, Room 1066
Rockville, Maryland
December 3, 2008

TENTATIVE AGENDA
OPEN SESSION

The committee will discuss new drug application (NDA) 22-268, artemether 20 mg/lumefantrine 120 mg, sponsored by Novartis Pharmaceuticals Corporation, for the proposed indication of treatment of acute, uncomplicated malaria infection due to *Plasmodium falciparum* or mixed infections including *P. falciparum*.

8:00 to 8:15 am	Call to Order Executive Secretary for Committee
8:15 to 8:30 am	Welcome & Introductory Remarks Renata Albrecht, M.D., Director, Division of Special Pathogen and Transplant Products
8:30 to 10:00 am	Novartis Presentation of NDA 22-268
10:00 to 10:15 am	Questions from the Committee to Novartis
10:15 to 10:30 am	BREAK
10:30 to 11:30 am	FDA Presentation of NDA 22-268 Elizabeth O'Shaughnessy, M.D., Medical Officer, DSPTP, OAP Sue Lim, M.D., Medical Officer, DSPTP, OAP
11:30 am to 12:30 pm	OPEN PUBLIC HEARING
12:30 to 1:30 pm	LUNCH
1:30 to 2:00 pm	Questions from the Committee to FDA and Novartis
2:00 to 2:15 pm	Charge to the Committee Edward Cox, M.D., M.P.H. Director, Office of Antimicrobial Products
2:15 to 5:00 pm	Committee Discussion and Answer Questions
5:00 pm	ADJOURN