

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

**AGENDA**  
March 19, 2002

Holiday Inn, Two Montgomery Village Avenue, Gaithersburg, MD

NDA 21-245, Picovir™ (pleconaril), ViroPharma Incorporated, proposed for treatment of acute picornaviral upper respiratory illness (common cold) in adults

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.	<b>Introduction/Opening Remarks</b>	Debra B. Birnkrant, M.D. Director Division of Antiviral Drug Products FDA
8:30 a.m.	<b>Sponsor Presentation</b>	ViroPharma, Incorporated
	Introduction	Mark McKinlay, Ph.D. Vice President Research and Development
	Impact of the Common Cold	Frederick G. Hayden, M.D. University of Virginia School of Medicine
	A New Option for Treating Colds	Mark McKinlay, Ph.D.
	Clinical Efficacy and Safety	Ellen C. Cooper, M.D., M.P.H. Vice President Clinical and Regulatory Affairs
	Benefit/Risk	Ellen C. Cooper, M.D., M.P.H.
9:30 a.m.	<b>FDA Presentation</b>	Russ Fleischer, PA-C, M.P.H. Senior Clinical Analyst Division of Antiviral Drug Products
		Thomas Hammerstrom, Ph.D. Statistical Reviewer Division of Antiviral Drug Products
10:30 a.m.	Break	

- 10:45 a.m.      Questions to the Presenters
- 12:00 p.m.     Lunch
- 1:00 p.m.      Open Public Hearing
- 2:00 p.m.      Questions to the Committee/Discussion
- 5:00 p.m.      Adjourn