

**Food and Drug Administration  
Center for Drug Evaluation and Research**

**Dermatologic and Ophthalmic Drugs Advisory Committee**

Kennedy Ballroom  
Holiday Inn  
8777 Georgia Avenue  
Silver Spring, Maryland

**Agenda**

**May 23, 2002**

8:30	Call to Order and Opening Remarks	Lynn Drake, M.D. Acting Chair, DODAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Acting Executive Secretary, DODAC
	<b>BLA 125036, alefacept, Biogen, Inc.</b> - indicated for the treatment of patients with chronic plaque psoriasis who are candidates for phototherapy or systemic therapy.	
	<b>Introduction</b>	Ezio Bonvini, M.D. Division of Monoclonal Antibodies Office of Therapeutics Research and Review Center for Biologics Evaluation and Research FDA
8:45	<b>Sponsor Presentation</b>	Biogen, Inc.
	Overview:	Burt Adelman, MD Executive Vice President Research and Development
	Clinical Experience:	Akshay K. Vaishnav, MD, PhD Director, Medical Research
	Clinical Safety:	Gloria Vigliani, MD Vice President, Medical Research
	Alefacept Risk Benefit Profile:	Mark Lebwohl, MD Chairman, Professor of Dermatology Mount Sinai School of Medicine
10:15	<b>FDA Presentation</b>	Louis Marzella, M.D., Ph.D. Division of Clinical Trial Design and Analysis OTRR, CBER, FDA
11:15	Break	

11:30 Questions from the Committee

12:30 Lunch

1:30 Open Public Hearing

Gail M. Zimmerman - National Psoriasis Foundation

Diane Lewis - National Psoriasis Foundation

Maryellen Crawford - National Psoriasis Foundation

Sean Morton - National Psoriasis Foundation

Alan Menter, M.D. – Psoriasis Specialists Patient Advocacy Group

2:30 Committee Discussion and Vote

5:00 Adjourn