

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

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| 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 |
| | BLA 125036, alefacept, Biogen, Inc. - indicated for the treatment of patients with chronic plaque psoriasis who are candidates for phototherapy or systemic therapy. | |
| | Introduction | Ezio Bonvini, M.D. Division of Monoclonal Antibodies Office of Therapeutics Research and Review Center for Biologics Evaluation and Research FDA |
| 8:45 | Sponsor Presentation | Biogen, Inc. |
| | Overview: | Burt Adelman, MD Executive Vice President Research and Development |
| | Clinical Experience: | Akshay K. Vaishnav, MD, PhD Director, Medical Research |
| | Alefacept Risk Benefit Profile: | Mark Lebwohl, MD Chairman, Professor of Dermatology Mount Sinai School of Medicine |
| 10:15 | FDA Presentation | 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 | |
| 2:30 | Committee Discussion and Vote | |
| 5:00 | Adjourn | |