Food and Drug Administration
Center for Drug Evaluation and Research
Dermatologic and Ophthalmic Drugs Advisory Committee
Holiday Inn, Montgomery Village Avenue, Gaithersburg, Maryland
September 9, 2003

Draft Agenda

BLA - STN # 125075/0, Efalizumab, (Raptiva) by Genentech, Inc. to be used in the treatment of adult patients with moderate to severe plaque psoriasis

8:30	Call to Order and Opening Remarks	Robert S. Stern, M.D.
	Conflict of Interest Statement	Kimberly L. Topper, M.S.
8:50	Introduction to Efalizumab	Steven Kozlowski, M.D.
9:00	Genentech Presentation	
	Introduction	Michelle Rohrer, Ph.D.
	Moderate to Severe Psoriasis – The Unmet Need	Mark G. Lebwohl, M.D.
	Mechanism of Action and Dose Determination	Charles Johnson, M.B., Ch.B.
	Efficacy	Lee Kaiser, Ph.D.
	Safety	Richard Chin, M.D.
	Raptiva Benefit: Risk Profile	Charles Johnson, M.B., Ch.B.
10:00	Committee Discussion	
10:30	Break	
10:45	FDA Presentation Review of Efficacy and Safety Results	Elektra Papadopoulos, M.D.
11:45	Committee Discussion	
12:15	Lunch	
1:15	Open Public Hearing	
2:15	Committee Discussion	
3:15	Break	
3:30	Questions	
5:30	Adjourn	