

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

Endocrinologic and Metabolic Drugs Advisory Committee

Holiday Inn
8170 Wisconsin Avenue
Bethesda, Maryland

Agenda

January 13-15, 2003

8:00	Call to Order and Opening Remarks	Thomas Aoki, M.D. Acting Chair, EMDAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Acting Executive Secretary, EMDAC

BL 103979, Fabrazyme™ (agalsidase beta), Genzyme Corporation
- proposed for the treatment of Fabry's disease

8:10	Introduction	CBER
8:15	Sponsor Presentation	Genzyme Corporation
9:15	Questions from the Committee	
9:45	Break	
10:00	FDA Presentation	
11:00	Questions from the Committee	
11:30	Open Public Hearing	
12:30	Lunch	
1:30	Committee Discussion and Vote	
5:00	Estimated Time of Adjournment	

January 14, 2003

8:00	Call to Order and Opening Remarks	Thomas Aoki, M.D. Acting Chair, EMDAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Acting Executive Secretary, EMDAC

BL 103977, Replagal™ (agalsidase alfa) - Transkaryotic Therapies, Inc.
- proposed for the treatment of Fabry's disease

8:10	Introduction	CBER
8:15	Sponsor Presentation	Transkaryotic Therapies, Inc.
9:15	Questions from the Committee	
9:45	Break	
10:00	FDA Presentation	
11:00	Questions from the Committee	
11:30	Open Public Hearing	
12:30	Lunch	
1:30	Committee Discussion and Vote	
5:00	Estimated Time of Adjournment	

January 15, 2003

8:00	Call to Order and Opening Remarks	Thomas Aoki, M.D. Acting Chair, EMDAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Acting Executive Secretary, EMDAC

BL 125058, Aldurazyme™ (laronidase), BioMarin Pharmaceutical Inc.
-proposed for the treatment of mucopolysaccharidosis

8:10	Introduction	CBER
8:15	Sponsor Presentation	BioMarin Pharmaceutical Inc.
9:15	Questions from the Committee	
9:45	Break	
10:00	FDA Presentation	
11:00	Questions from the Committee	
11:30	Open Public Hearing	
12:30	Lunch	
1:30	Committee Discussion and Vote	
5:00	Estimated Time of Adjournment	