

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)**

***Endocrinologic and Metabolic Drugs Advisory Committee Meeting
June 10, 2003***

Holiday Inn, Versailles Ballroom, Bethesda, Maryland

AGENDA

8:30 – 8:45 a.m.	Call to Order and Introductions	Glenn Braunstein, M.D. Chair, Endocrinologic and Metabolic Drugs Advisory Committee
	Conflict of Interest Statement	Dornette Spell-LeSane, A.N.P., M.H.A. Executive Secretary, EMDAC
8:45 – 9:00 a.m.	Welcome and Introductory Comments	David Orloff, M.D. Division of Metabolic and Endocrine Drug Products, FDA

sNDA 19-640/S-033, Humatrope® (somatropin [rDNA origin] for injection), Eli Lilly and Company

Proposed for the indication of non-growth hormone deficient short stature

9:00 a.m.	<u>Sponsor Presentation</u>	
	Introduction	Gregory Enas, Ph.D. Director, US Regulatory Affairs Eli Lilly and Company
	Rationale for treatment	Raymond Hintz, M.D. Professor of Pediatrics Stanford University Medical Center
	Efficacy	Gordon Cutler, M.D. Director, Growth and Recovery Research and Clinical Investigation Eli Lilly and Company
	Safety	Charmian Quigley, M.B.B.S. Senior Clinical Research Physician Endocrinology Eli Lilly and Company

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Agenda (cont.)

Sponsor Presentation (cont.)

Benefit-Risk Assessment
and Risk Management Plan

Charmian Quigley, M.B.B.S.

Concluding Statements

Margaret MacGillivray, M.D.
Professor of Pediatrics
University of Buffalo
Pediatric Endocrinologist
School of Medicine & Biomedical Sciences
Children's Hospital Buffalo

10:45 – 10:55 a.m.

Break

10:55 – 11:30 a.m.

Committee Discussions

11:30 – 12:00 p.m.

Presentation

Harvey John Guyda, B.Sc. (Med), M.D., FRCPC
Professor, Department of Pediatrics
McGill University

12:00 – 12:30 p.m.

Committee Discussion

12:30 – 1:30 p.m.

Lunch

1:30 – 2:30 p.m.

Open Public Hearing

2:30 – 2:45 p.m.

Charge to the Committee

David Orloff, M.D.
Division Director
Metabolic and Endocrine Drug Products
FDA

2:45 – 3:45 p.m.

Committee Discussion/Questions

Break

Committee Discussion/Questions/Summary

5:00 p.m.

Adjournment