

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

***Endocrinologic and Metabolic Drugs Advisory Committee Meeting
July 9, 2003***

Holiday Inn, Versailles Ballroom, Bethesda, MD

DRAFT AGENDA

8:30 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, M.H.A., NP-C Executive Secretary, EMDAC
8:45 a.m.	Welcome and Introductory Comments	David Orloff, M.D. Director Division of Metabolic and Endocrine Drug Products, FDA

**NDA 21-366 Crestor® (rosuvastatin calcium) tablets, AstraZeneca Pharmaceuticals agent for
iPR Pharmaceuticals, Inc.**

Proposed for the indication of treatment of hypercholesterolemia and mixed dyslipidemia

9:15 a.m.	<u>Sponsor Presentation</u>	
	Introduction and Regulatory Overview	Mark S. Eliason, M.Sc. Director, Regulatory Affairs AstraZeneca
	Clinical Development Efficacy Overview	James W. Blasetto, M.D., M.P.H. Senior Medical Director AstraZeneca
	Clinical Development Safety Overview	Howard G. Hutchinson, M.D. Vice President, Clinical Research AstraZeneca

**Endocrinologic and Metabolic Drugs Advisory Committee
Meeting
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Agenda (cont.)**

Sponsor Presentation Cont.

The Role of Rosuvastatin in the
Treatment of Hyperlipidemia

Daniel J. Rader, M.D.
Associate Program Director
University of Pennsylvania

10:30 – 10:45 a.m. Break

10:45 – 11:15 a.m. Committee Discussions

11:15a.m. **FDA Presentation**

Efficacy

Joy Mele, M.S.
Statistical Reviewer
Division of Biometrics II
Office of Biostatistics, FDA

Safety and Dosing

William Lubas, M.D.
Medical Officer
Division of Metabolic and Endocrine
Drug Products, FDA

11:45 – 12:30 p.m. Questions from the Committee

12:30 – 1:30 p.m. Lunch

1:30 – 2:30 p.m. Open Public Hearing

2:30 – 2:45p.m. Charge to the Committee

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

2:45 – 3:30 p.m. Committee Discussions/Questions

3:30 – 3:45 p.m. Break

3:45 – 4:45 p.m. Committee Discussions/Questions/Review

5:00 p.m. Adjournment