

**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**

***AGENDA***

8:30 a.m.	Call to Order and Introductions	Glenn Braunstein, M.D. Chair, Endocrinologic and Metabolic Drugs Advisory Committee, EMDAC
	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

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**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

9:00 a.m.	<b><u>Sponsor Presentation</u></b>	
	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

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Agenda (cont.)**

**Sponsor Presentation (Cont.)**

The Role of Rosuvastatin in the  
Treatment of Hyperlipidemia

Daniel J. Rader, M.D.  
Associate Professor of Medicine  
University of Pennsylvania

10:30 a.m. Break

10:45 a.m. Questions from the Committee

11:15 a.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 p.m. Questions from the Committee

12:30 p.m. Lunch

1:30 p.m. Open Public Hearing

2:30 p.m. Charge to the Committee

David Orloff, M.D.

2:45 p.m. Committee Discussions/Questions

3:30 p.m. Break

3:45 p.m. Committee Discussions/Questions/Summary

5:00 p.m. Adjournment