Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) Cardiovascular and Renal Drugs Advisory Committee

February 3, 2009

Hilton Washington DC/Silver Spring, Maryland Ballroom 8727 Colesville Road, Silver Spring MD

Agenda

8:00 a.m. Call to Order

Introduction of Committee

Marvin A. Konstam, M.D

Acting Chair

Conflict of Interest Statement

Elaine Ferguson, M.S.,R.Ph.

Designated Federal Official, CRDAC

The committee will discuss new drug application (NDA) 22-307, prasugrel hydrochloride film coated oral tablets, 5 milligrams (mg) and 10 mg, for the proposed indication for use in acute coronary syndrome.

8:05 a.m. FDA Opening Remarks Norman Stockbridge, M.D.

Director, Cardiovascular and Renal Drug

Products, CDER

8:15 a.m. **Sponsor Presentations**

Introduction J. Anthony Ware, MD

Vice President, Lilly Research Laboratories Diabetes, Cardiovascular, and Acute Care

Platform

Unmet Medical Need Eugene Braunwald, M.D.

Hersey Distinguished Professor of Theory and Practice of Medicine, Harvard Medical School Chairman, TIMI Study Group, Brigham and

Women's Hospital

Dosing Considerations Jeffrey Riesmeyer, M.D.

Medical Fellow, Cardiovascular Medicine

Eli Lilly and Company

Benefit-Risk (TRITON-TIMI 38) Elliott M. Antman, M.D.

Professor of Medicine, Harvard Medical School

Senior Investigator, TIMI

Director of Samuel A. Levine Cardiac Unit,

Brigham and Women's Hospitals

Special Topics William Macias, M.D., Ph.D.

Senior Medical Director, Cardiovascular Acute

Care

Eli Lilly and Company

Closing Remarks Eugene Braunwald, M.D.

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9:45 a.m. Questions to presenters

10:15 a.m. **Break**

10:30 a.m. FDA Presentation Ellis F. Unger, M.D.

Deputy Director

Division of Cardiovascular and Renal Products

Office of Drug Evaluation-I
Office of New Drugs

CDER, FDA

11:30 a.m. Questions to presenters

12:00 <u>Lunch</u>

1:00 p.m. Open Public Hearing

2:00 p.m. Discussion of questions to

committee

3:30 p.m. **Break**

3:45 p.m. Discussion of questions to

committee (continued)

5:00 p.m. Adjourn