

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

DRAFT Agenda

8:00 a.m.	Call to Order Introduction of Committee	Marvin 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.	<u>Sponsor Presentations</u>	
9:45 a.m.	Questions to presenters	
10:30 a.m.	<u>Break</u>	
10:45 a.m.	<u>FDA Presentations</u>	Ellis Unger, M.D. Deputy Division Director, Cardiovascular and Renal Drug Products, CDER
12:00	<u>Lunch</u>	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Questions to presenters	
3:30 p.m.	<u>Break</u>	
3:45 p.m.	Discussion of questions to committee (continued)	
5:00 p.m.	Adjourn	