FOOD AND DRUG ADMINISTRATION (FDA)

Pulmonary-Allergy Drugs Advisory Committee (PADAC)

Hilton Washington, DC/Gaithersburg
620 Perry Parkway, Gaithersburg, MD

February 4, 2009

AGENDA

The committee will discuss biologic license application (BLA) #125277, KALBITOR, ecallantide injection by Dyax Corp., for the treatment of acute attacks of hereditary angioedema.

8:30 a.m.	Call to Order Introduction of Committee	William Calhoun, M.D. Acting Chair
	Conflict of Interest Statement	Kristine Khuc, Pharm.D. Designated Federal Official, PADAC
8:45 a.m.	Opening Remarks	Badrul Chowdhury, M.D., Ph.D. Director, Division of Pulmonary and Allergy Products Center for Drug Evaluation and Research (CDER) FDA
	Sponsor Presentation	
9:00 a.m.	Introduction and Overview	William Pullman, M.D., Ph.D. Executive Vice President of Clinical Development and Medical Affairs, Dyax Corp.
	Clinical Efficacy and Safety	Patrick Horn, M.D., Ph.D. Vice President of Clinical Development and Medical Affairs, Dyax Corp.
	Safe-Use Conditions	William Pullman, M.D., Ph.D. Executive Vice President of Clinical Development and Medical Affairs, Dyax Corp.

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-Agenda cont.-

	Clinical Perspective	Marc Riedl, M.D., M.S. Clinical Immunology and Allergy, UCLA David Geffen School of Medicine
	Concluding Remarks	William Pullman, M.D., Ph.D. Executive Vice President of Clinical Development and Medical Affairs, Dyax Corp.
10:00 a.m.	Questions for clarification	
10:15 a.m.	Break	
	FDA Presentation	
10:30 a.m.	Clinical Overview of Ecallantide for the Treatment of Acute Attacks of Hereditary Angioedema	Susan Limb, M.D. Medical Officer, Division of Pulmonary and Allergy Products CDER, FDA
	Statistical Considerations	Dongmei Liu, Ph.D. Statistical Reviewer, Office of Biostatistics CDER, FDA
11:45 a.m.	Questions for clarification	
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Charge and questions to the Committee Committee discussion/vote	
3:45 p.m.	Break	
4:00 p.m.	Committee discussion/vote	
5:00 p.m.	Adjournment	