FOOD AND DRUG ADMINISTRATION (FDA)

Joint Meeting of the Pulmonary-Allergy Drugs Advisory Committee (PADAC), Drug Safety and Risk Management Advisory Committee (DSaRM), and the Pediatric Advisory Committee (PAC)

Hilton Washington, DC/Rockville
1750 Rockville Pike, Rockville, MD

December 10-11, 2008

AGENDA

The committees will discuss the benefit risk assessment of long acting beta-2 adrenergic agonists for the treatment of asthma in adults and children.

December 10, 2008

8:30 a.m.	Call to Order Introduction of Committees	Erik Swenson, M.D. Acting Chair, PADAC Marsha Rappley, M.D. Co-Chair, PAC
	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 Allergy Products, Center for Drug Evaluation and Research (CDER), FDA Henry Francis, M.D. Deputy Director, Office of Surveillance and Epidemiology, CDER, FDA
9:00 a.m.	Recent Advances in Asthma Treatment	Robert Lemanske, Jr., M.D. Professor of Pediatric Medicine, University of Wisconsin
	FDA Presentations	
9:45 a.m.	Background and Regulatory Approval History of Long Acting Beta2 Agonists	Sally Seymour, M.D. Deputy Director for Safety, Division of Pulmonary and Allergy Products, CDER, FDA
10:35 a.m.	Clarification/questions	

10:45 a.m.	Break	
11:00 a.m.	Background on Long Acting Beta2 Agonists Safety Issues	Andy Mosholder, M.D. Medical Officer, Division of Epidemiology, CDER, FDA
11:45 a.m.	Meta-analysis of Data Summarizing the Risks of Long Acting Beta2 Agonists	Mark Levenson, Ph.D. Mathematical Statistician Division of Biometrics, CDER, FDA
12:15 p.m.	Lunch	
1:15 pm.	Clarification/questions	
1:30 p.m.	Benefits in the Context of Risks of Long Acting Beta2 Agonists	Ann McMahon, M.D. Acting Director, Division of Pharmacovigilance II CDER, FDA
1:55 p.m.	Public Health Considerations of Benefits and Risks with LABAs	David Graham, M.D. Associate Director for Science and Medicine, Office of Surveillance and Epidemiology, CDER, FDA
2:35 p.m.	Clarification/questions	
2:50 p.m.	Benefits in the Context of Risks of Long Acting Beta2 Agonists- Division of Pulmonary and Allergy Products Perspective	Badrul Chowdhury, M.D., Ph.D. Director, Division of Pulmonary and Allergy Products, CDER, FDA
3:40 p.m.	Break	
	Sponsors Presentations	
3:50 p.m.	Overview of Asthma and Guidelines for the Diagnosis and Management of Asthma	Stuart Stoloff, M.D. Clnical Professor of Family and Community Medicine, University of Nevada
4:10 p.m.	Benefit Risk Assessment of Salmeterol for the Treatment of Asthma in Adults and Children	C. Elaine Jones, Ph.D. Vice President, Respiratory Regulatory Affairs, GlaxoSmithKline

		Katherine Knobil, M.D. Vice President, Respiratory Medicines Development Center, GlaxoSmithKline
4:45 p.m.	Introduction and Regulatory History of Foradil	Mathias Hukkelhoven, Ph.D., Senior Vice President, Global Head of Drug Regulatory Affairs, Novartis
	Efficacy and Safety of Foradil	Linda Armstrong, M.D., Executive Medical Director, Clinical Development and Medical Affairs, Novartis
5:20 p.m.	Benefits and Risks of AstraZeneca Formoterol-containing Products	Catherine Bonuccelli, M.D. Vice President, Development Projects, Symbicort, AstraZeneca
		Tomas Andersson, M.D., Ph.D. Medical Science Director, Symbicort, AstraZeneca
		Kevin Carroll, MSc Vice President, Statistics and Chief Statistician, AstraZeneca
5:55 p.m.	*Adjournment for December 10, to resume at 8:30 a.m. on December 11*	

December 11, 2008

8:30 a.m.	Call to Order Introduction of Committees	Erik Swenson, M.D. Acting Chair, PADAC
		Marsha Rappley, M.D. Co-Chair, PAC
	Conflict of Interest Statement	Kristine Khuc, Pharm.D. Designated Federal Official, PADAC
8:45 a.m.	Opening Remarks	Ann McMahon, M.D. Acting Director, Division Of Pharmacovigilance II, CDER, FDA
		M. Dianne Murphy, M.D. Director, Office of Pediatric Therapeutics, Office of the Commissioner, FDA

8:50 a.m.	Open Public Hearing	
9:30 a.m.	Clarification/questions to FDA and Sponsors	
10:45 a.m.	Break	
11:00 a.m.	FDA Division of Pulmonary-Allergy Drug Products Summary Remarks	Badrul Chowdhury, M.D., Ph.D. Director, Division of Pulmonary and Allergy Products, CDER, FDA
11:10 a.m.	FDA Office of Surveillance and Epidemiology Summary Remarks and Questions to the Committees	Ann McMahon, M.D. Acting Director, Division of Pharmacovigilance II, CDER, FDA
11:15 a.m.	Committee Discussion	
12:15 p.m.	Lunch	
1:15 p.m.	Committee resumes Discussion/Vote	
4:00 p.m.	Adjournment	