FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Endocrinologic and Metabolic Drugs Advisory Committee
Holiday Inn Silver Spring
8777 Georgia Avenue, Silver Spring, MD

AGENDA
September 8, 2005

The committee will discuss new drug application (NDA) 21-868, proposed trade name Exubera (insulin recombinant deoxyribonucleic acid (rDNA) origin powder for oral inhalation), 1 milligram (mg) and 3 mg powder for inhalation, Pfizer, Inc., for the treatment of adult patients with diabetes mellitus

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8:00	Call to Order and Introductions	**Paul D. Woolf, M.D.** (Acting) Chair Endocrinologic and Metabolic Drugs Advisory Committee
	Conflict of Interest Statement	**LCDR Cathy Groupe, B.S.N.** Executive Secretary Endocrinologic and Metabolic Drugs Advisory Committee
8:10	Welcome	**David Orloff, M.D.** Director FDA/CDER Division Metabolic and Endocrine Drug Products
	Sponsor Presentation **<u>Pfizer Global Research and Development:</u>**	
8:15	Introduction	**Neville Jackson, M.D.** Full Development Team Leader, EXUBERA Pfizer Global Research and Development
	Overview of Clinical Program	**Anne Cropp, Pharm.D.** Global Clinical Leader, EXUBERA Pfizer Global Research and Development
	Medical Needs	**William Cefalu, M.D.** Professor and Chief, Department of Nutrition and Chronic Diseases Pennington Biomedical Research Center, LSU
	Benefit and Managing the Risk	**Neville Jackson, M.D.** Pfizer Global Research and Development
9:45		Committee Discussion
10:00		**Break**

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AGENDA (Continued)
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FDA Review Division Presentation:

10:15	Clinical Efficacy and Non-Pulmonary Safety Review	**Karen M. Mahoney, M.D.** Medical Officer FDA/CDER Division Metabolic and Endocrine Drug Products
10:45	Statistical Review and Evaluation	**Joy D. Mele, M.S.** Statistician FDA/CDER Office of Pharmacoepidemiology and Statistical Science
11:00	Clinical Pharmacology and Biopharmaceutics Review	**Sayed (Sam) Al Habet, R.Ph., Ph.D.** Senior Clinical Pharmacologist/Reviewer FDA/CDER Office of Clinical Pharmacology and Biopharmaceutics
11:20	Clinical Pulmonary Safety	**Sally Seymour, M.D.** Medical Officer FDA/CDER Division of Pulmonary and Allergy Drug Products
12:00		**Lunch**
1:00		**Open Public Hearing**
2:30		**Committee Discussion**
3:00		**Break**
3:15		**Committee Discussion and Questions**
5:00		**Adjournment**