FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Endocrinologic and Metabolic Drugs Advisory Committee Meeting
Crowne Plaza Hotel, Silver Spring, Maryland
October 21, 2008

AGENDA
OPEN SESSION

The committee will discuss the safety and efficacy of biologic license application (BLA) 125291, MYOZYME (alglucosidase alfa), Genzyme Corp., for the treatment of late onset Pompe disease.

11:40 a.m. – 11:50 a.m.	Call to Order (Open Session) Introduction of Committee	**Kenneth Burman, M.D.** (Acting) Committee Chair Endocrinologic and Metabolic Drugs Advisory Committee
11:50 a.m. – 11:55 a.m.	Conflict of Interest Statement	**Paul Tran, R.Ph.** Designated Federal Official, EMDAC
11:55 a.m. – 12:00 p.m.	Open Session Introductory Remarks	**Donna Griebel, M.D.** Division Director Division of Gastroenterology Products (DGP) CDER, FDA
12:00 p.m. – 12:45 p.m.	Genzyme Presentation	**TBD**
12:45 p.m. – 1:30 p.m.	FDA Presentation	**Lynne Yao, M.D.** Lead Medical Officer DGP CDER, FDA
1:30 p.m. – 2:30 p.m.	Open Public Hearing (OPH) Session	
2:30 p.m. – 5:00 p.m.	Open Session Questions and Discussion	
5:00 p.m.	Adjourn	