

**FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH  
Endocrinologic and Metabolic Drugs Advisory Committee Meeting  
The Inn and Conference Center, University of Maryland University College  
3501 University Boulevard East, Adelphi, MD  
May 27, 2010**

**DRAFT AGENDA**

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The committee will discuss the safety and efficacy of a new drug application (NDA) for EGRIFTA (tesamorelin acetate) sterile lyophilized powder for injection, NDA 22-505, Theratechnologies, Inc. The proposed indication for EGRIFTA in this application is to induce and maintain a reduction of excess visceral abdominal fat in HIV-infected patients with lipodystrophy.

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8:00 a.m.– 8:05 a.m.	Call to Order and Introductions	<b>Committee Chair</b> Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC)
8:05 a.m. – 8:15 a.m.	Conflict of Interest Statement	<b>Paul Tran, R.Ph</b> Designated Federal Official EMDAC
8:15 a.m. – 8:30 a.m.	Introduction/Background	FDA
8:30 a.m. – 9:45 a.m.	Sponsor Presentation	<b>Theratechnologies, Inc.</b>
9:45 a.m. – 10:00 a.m.	Clarifying Questions from the Committee to Sponsor	
10:00 a.m. – 10:15 a.m.	<b>Break</b>	
10:15 a.m. – 11:30 a.m.	FDA Presentation	<b>FDA</b>
11:30 a.m. – 12:00 p.m.	Clarifying Questions from the Committee to FDA	
12:00 p.m. – 1:00 p.m.	<b>Lunch</b>	
1:00 p.m. – 2:00 p.m.	Open Public Hearing Session	
2:00 p.m. – 2:30 p.m.	Questions from Committee to Sponsor and FDA	
2:30 p.m. – 2:45 p.m.	<b>Break</b>	
2:45 p.m. – 5:00 p.m.	Discussion/Questions to the Committee	
5:00 p.m.	<b>Adjournment</b>	