

FDA-Industry GDUFA II Reauthorization Meeting - Small Business Subgroup  
January 5, 2016: 2:00pm – 5:00pm  
FDA White Oak Campus, Silver Spring, MD  
Building 75, Room 6600

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**Purpose:**

Discuss potential relief options for small businesses.

**Participants:**

FDA

Mike Jones	CDER
Rob Berlin	OC
Kirk Kerr	CDER
Carter Beach	CDER
Thomas Henry	OC
Lucie Yang	CDER
Gisa Perez	CDER

Industry

Lisa Tan	GPhA
David Gaugh	GPhA
Alan Nicholls	BPTF
Tom Thorpe	PBOA
Keith Webber	GPhA

**Discussion**

FDA and Industry discussed the subgroup's considerations and prepared to report to the full negotiation session on January 6.