

FDA-Industry GDUFA II Reauthorization Meeting - Small Business Subgroup  
December 10, 2015: 9:30am – 12:00pm  
FDA White Oak Campus, Silver Spring, MD  
Building 75, Room 5600

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**Purpose:**

Discuss potential relief options for small businesses.

**Participants:**

<u>FDA</u>		<u>Industry</u>	
Mike Jones	CDER	Lisa Tan	GPhA
Rob Berlin	OC	David Gaugh	GPhA
Kirk Kerr	CDER	Alan Nicholls	BPTF
Carter Beach	CDER	Tom Thorpe	PBOA
Thomas Henry	OC		
Lucie Yang	CDER		
Gisa Perez	CDER		

**Defining small business**

FDA and Industry continued to discuss how to define a small business using, for example, number of employees or revenue. FDA and Industry also discussed the possibility of having different definitions for manufacturers and ANDA applicants.

**Potential small business relief**

FDA and Industry discussed possible approaches to providing small businesses fee relief, including application fee and facility fee relief.