

FDA-Industry GDUFA II Reauthorization Meeting - Small Business Subgroup  
December 1, 2015: 2:00pm – 5:00pm  
FDA White Oak Campus, Silver Spring, MD  
Building 75, Room 6600

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**Purpose:**

Kickoff meeting for Small Business sub-group. Set sub-group goals and expectations.

**Participants:**

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

**Discussion of small business working group goals**

FDA and Industry representatives discussed the objectives of the working group in that Congress directed all stakeholders to consider relief for small businesses during the GDUFA reauthorization process. This subgroup will discuss potential options and present them back to the GDUFA II negotiators.

**Discussion of generic drug small business landscape**

The sub-group discussed the generic drug landscape including how to define a small business within the industry. It was noted that possible solutions should be easy to operationalize and that relief for one segment of the industry would require increased fees from all others.

**Discussion of next steps and upcoming meetings**

The sub-group has scheduled additional meetings. At the next meeting, Industry has agreed to propose potential options for small business relief.