

FDA-Industry GDUFA II Reauthorization Meeting - Small Business Subgroup
December 18, 2015: 9:30am – 12:00pm
FDA White Oak Campus, Silver Spring, MD
Building 75, Room 5600

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 further discussed possible approaches to providing small businesses fee relief, including application fee and facility fee relief. FDA and Industry compared the administrative burdens to potential benefits to different segments of Industry. FDA and Industry also discussed that the Agency would need increased resources in order to administer a fee relief program.