

**FDA-Industry GDUFA Reauthorization Meeting**  
**February 18, 2021, 10:00 am – 2:00 pm**  
**Virtual Meeting**

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**Purpose**

To continue negotiations to reauthorize GDUFA (GDUFA III).

**Participants**

FDA

Carter Beach	CDER
Donald Beers	OC/OCC
Lisa Berry	CDER
Ashley Boam	CDER
Joshua Brown	OC/OCC
Jacqueline Corrigan-Curay	CDER
Alonza Cruse	ORA
Robert Lionberger	CDER
Susan Rosencrance	CDER
Bethany Rue	CDER
Edward Sherwood	CDER
Maryll Toufanian	CDER

Industry

John DiLoreto	BPTF
David Gaugh	AAM
Karin Hessler	AAM
Kiran Krishnan	AAM (Apotex)
Brian McCormick	AAM (Teva)
Lisa Parks	AAM
Gil Roth	PBOA
Cornell Stamoran	PBOA (Catalent)
Molly Ventrelli	AAM (Fresenius-Kabi)

FDA Supporting Staff

Tiana Barnes, Dat Doan, Andrew Fine, Tawni Schwemer, Scott Vehovic

**Discussion**

Industry provided response to some of FDA's proposals on inspections and continued to seek clarification on specific issues to the remaining inspection proposals.

FDA and Industry discussed using business days instead of calendar days for certain goal dates.

Industry and FDA began discussions to clarify needs and identify opportunities for continued enhancements to the Inactive Ingredient Database. This will be a continuing discussion in upcoming meetings.

Industry continued to seek clarification related to proposals to set a sound foundation for continued programmatic success.

**Next Meeting**

The next negotiation meeting will either be Thursday, February 25, 2021 or Thursday, March 4, 2021.