



# Complex Product Workshop

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## Workshop Disclaimer

- The opinions and conclusions expressed in this workshop are the viewpoints of the speaker(s) and do not necessarily reflect the official position of the U.S. Food and Drug Administration.

# Complex Generic Products in GDUFA II

- Complex active ingredients
  - Complex mixtures of APIs, polymeric compounds, peptides
- Complex formulations
  - Liposomes, suspensions, emulsions, gels
- Complex routes of delivery
  - Locally acting such as dermatological and inhalational drugs
- Complex dosage forms
  - Long acting injectables, implantable drugs
- Complex drug-device combination products
  - Transdermals, metered dose inhalers (MDIs)
- Other products where complexity or uncertainty concerning the approval pathway or other alternative approach would benefit from early scientific engagement



# Complex Product Workshop Logistics

1:30 PM – Salon B/D

Introduction

Markham Luke

Podium Keynote

Rob Lionberger

Pre-ANDA – Interacting with FDA

Kris Andre

1:55 PM - Breakout Session Descriptions

2:25 PM – End Main Room Session – Go to Breakouts



## Workshop Logistics 2

2:30 PM—Breakout Sessions – Hands-on Role Play for Pre-ANDA

– Group 1 – Salon B/D – Liposomal Ophthalmologic Suspension

– Group 2 – Salon A – Orally Inhaled Drug-Device Combination Product

– Group 3 – Brookside – Topical Dermatologic Cream

Each session will include

a) Crafting a meeting package – what to include

b) How to write good questions to ask FDA

c) Simulated pre-ANDA meeting

4:20 PM—End of Breakout Sessions



# Workshop Logistics 3

4:25 PM – Salon B/D

Report back from each of the Breakout Sessions

4:55 PM – Closing Remarks – Rob Lionberger and Jeff Jiang

Course Evaluations

5:00 PM – End of Workshop



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