

CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE (SBIA)

# WEBINARS

[www.fda.gov/CDERSBIALearn](http://www.fda.gov/CDERSBIALearn)

Version 4, November 1, 2023

## Navigating Complex Waters: A Deep Dive into FDA Drug Interactions Guidances and Resources December 12 & 13, 2023

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### AGENDA

All times are Eastern (UTC-5)

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#### Day One: Tuesday, December 12, 2023

12:00 – 12:10

##### SBIA Welcome and Overview

**Forest "Ray" Ford, Jr., PharmD, BCPS**

*Captain, United States Public Health Service  
Pharmacist, Small Business, and Industry Assistance (SBIA)  
Division of Drug Information (DDI) | Office of Communications (OCOMM)  
Center for Drug Evaluation and Research (CDER) | FDA*

12:10 – 12:20

##### Overview

**Rajanikanth Madabushi**

*Associate Director | Guidance & Policy Team  
Office of Clinical Pharmacology (OCP)  
Office of Translational Sciences (OTS)  
| CDER | FDA*

12:20 – 12:40

##### Health Communications for Optimal Drug Therapy: Examples of Drugs That Interact with CYP Enzymes & Transporter Systems

**Joseph A. Grillo**

*Associate Director | Labeling and Health Communication Team  
OCP | OTS | CDER | FDA*

12:40 – 1:00

##### Q&A Panel

**Rajanikanth Madabushi, Joseph A. Grillo**

*and  
Xinning Yang  
Policy Lead | Guidance & Policy Team  
OCP | OTS | CDER | FDA*

## Day One: Tuesday, December 12, 2023

1:00 – 1:25

### Clinical Drug Interaction Studies with Combined Oral Contraceptives

**Yanhui Lu**

*Team Lead* | Division of Cardiometabolic and Endocrine  
Pharmacology (DCEP)  
OCP | OTS | CDER | FDA

**Li Li**

*Senior Clinical Pharmacologist*  
DCEP | OCP | OTS | CDER

1:25 – 1:55

### Q&A Panel

**Yanhui Lu, Li Li, Xinning Yang**  
and

**Gerald D Willett**

*Lead Physician*  
Division of Urology, Obstetrics, and Gynecology (DUOG)  
Office of Rare Diseases, Pediatrics, Urologic and Reproductive  
Medicine (ORPURN)  
Office of New Drugs (OND) | CDER | FDA

1:55 – 2:00

### Day One Closing

**Forest "Ray" Ford, Jr., PharmD, BCPS**

*CAPT, USPHS, Pharmacist*  
SBIA | DDI | OCOMM | CDER

2:00: ADJOURN DAY ONE

## Day Two: Wednesday, December 13, 2023

1:00 – 1:10

### SBIA Welcome and Overview

**Forest "Ray" Ford, Jr., PharmD, BCPS**

*Captain*, United States Public Health Service  
*Pharmacist*, Small Business, and Industry Assistance (SBIA)  
Division of Drug Information (DDI) | Office of Communications (OCOMM)  
Center for Drug Evaluation and Research (CDER) | FDA

1:10 – 1:30

### Evaluation of Gastric pH Change-mediated DDIs with Acid-reducing Agents

**Xinning Yang**

*Policy Lead* | Guidance & Policy Team  
Office of Clinical Pharmacology  
Office of Translational Sciences (OTS) CDER | FDA

**Anuradha Ramamoorthy**

*Policy Lead* | Guidance & Policy Team OCP | OTS | CDER | FDA

1:30– 2:00

### Q&A Panel

**Xinning Yang, Anuradha Ramamoorthy**

And

**Fang Wu**

*Senior Pharmacologist* | Division of Quantitative Methods and Modeling (DQMM)  
Office of Research and Standards (ORS)  
Office of Generic Drugs (OGD) | CDER | FDA

**Insook Kim**

*Master Scientist*  
Division of Inflammation and Immune Pharmacology (DIIP)  
OCP | OTS | CDER | FDA

2:00 – 2:25

### Drug-Drug Interaction Assessment for Therapeutic Proteins

**Lin Zhou**

*Senior Clinical Pharmacologist*  
Division of Cardiometabolic and Endocrine Pharmacology (DCEP)  
OCP | OTS | CDER | FDA

**Raajan Naik**

*Policy Analyst* | Guidance & Policy Team  
OCP | OTS | CDER | FDA

**2:25 – 2:55**

**Q&A Panel**

**Lin Zhou, Raajan Naik**  
and

**Elimika Pfuma Fletcher**  
*Policy Lead* | Guidance & Policy Team | OCP | OTS | CDER | FDA

**Xiaofei Wang**  
*Pharmacologist* | Division of Clinical Evaluation General Medicine (DCEGM)  
Office of Therapeutic Products (OTP)  
Center for Biologics Evaluation and Research (CBER)

**2:55 – 3:00**

**SBIA/Webinar Closing**

**Forest "Ray" Ford, Jr., PharmD, BCPS**  
*CAPT, USPHS, Pharmacist*  
SBIA | DDI | OCOMM | CDER

**3:00: ADJOURN DAY TWO**