

CDER Small Business and Industry Assistance (SBIA)  
**2019 CDER PRESCRIPTION DRUG LABELING CONFERENCE**

COLLEGE PARK, MD or ONLINE

**DECEMBER  
4-5**

Version 5, November 27, 2019  
 (use link below to check for updates)

For files and resources, please visit  
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## AGENDA

[\(Jump to Day Two\)](#)

**Day One: Wednesday, December 4, 2019** (all sessions include panel discussions)

**7:30 a.m. Registration Opens**

**8:20 - 8:35: Administrative Announcements**

**Jeff Kelly**

**8:35 - 8:45**

**Welcome**

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

**8:45 - 8:55**

**Introduction to the Conference**

**Eric Brodsky**  
*Associate Director, Labeling Policy Team (LPT)  
 Office of New Drug Policy (ONDP)  
 Office of New Drugs (OND) | CDER*

**8:55 - 9:40**

**Voluntary PLR Conversions and Updating Prescribing Information**

**Eric Brodsky**  
*Associate Director  
 LPT | ONDP | OND | CDER*

**Day One: Wednesday, December 4, 2019** (all sessions include panel discussions)

**9:40 – 10:40**

**Indications and Usage Section of Labeling Draft Guidance and Drug Abuse and Dependence Section of Labeling Draft Guidance**

**Iris Masucci**  
*Special Assistant for Labeling*  
Office of Medical Policy (OMP) | CDER

**10:40 - 11:05: BREAK**

**11:05 – 12:05**

**Adverse Reaction Information in Prescribing Information**

**Jeanne Herndon**  
*Clinical Advisor for Labeling*  
LPT | ONDP | OND | CDER

**12:05 - 1:20 p.m. LUNCH & NETWORKING - On your own. Click [HERE](#) for onsite dining options**

**1:20 – 1:55**

**Pediatric Information In Prescribing Information**

**Eric Brodsky**  
*Associate Director*  
LPT | ONDP | OND | CDER

**1:55 – 2:40**

**The Pregnancy and Lactation Labeling Rule: Four Years In — What's next?**

**Miriam Dinatale**  
*Team Leader*  
Maternal Health Team (MHT)  
Division of Pediatric and Maternal Health (DPMH)  
OND | CDER

**Kristie Baisden**  
*Medical Officer*  
MHT | DPMH | OND | CDER

**2:40 – 3:30**

**Labeling Case Study: Transformation of an Indication**

**Ann Marie Trentacosti**  
*Medical Lead*  
LPT | ONDP | OND | CDER

**3:30 - 3:50**

**Panel Questions & Discussion**

**Eric Brodsky, Miriam Dinatale, Kristie Baisden, Ann Marie Trentacosti, and Tamara Johnson**  
*Team Leader*  
MHT | DPMH | OND | CDER

**3:50 - 4:10: BREAK**

**Day One: Wednesday, December 4, 2019** (all sessions include panel discussions)

**4:10 – 4:35**

**Labeling Finalization – Recommendations for Final Check of Labeling Format and Appearance in the Prescribing Information**

**John Gallagher**  
*Science Policy Analyst*  
LPT | ONDP | OND | CDER

**4:35 – 5:00**

**Improving the Accuracy of Structured Product Labeling Submissions: “The Missing LOINC”**

**Farrokh Sohrabi**  
*Clinical Advisor for Labeling*  
LPT | ONDP | OND | CDER

**5:00 – 5:15**

**Panel Questions & Discussion**

**John Gallagher and Farrokh Sohrabi**

**5:15 p.m. - DAY ONE ADJOURN**

**5:30 - 6:30 PM: NETWORKING OPPORTUNITY**

Onsite attendees are invited to gather at [THE HOTEL's Lobby Bar](#) to continue the conversation with fellow attendees.



**Day Two: Thursday, December 5, 2019** (all sessions include panel discussions)

**8:00 a.m. Registration Opens**

**8:45 - 8:55: Administrative Announcements**

**Jeff Kelly**

**8:55 - 9:00**

**Welcome**

**Forest "Ray" Ford, Jr.**  
DDI | OCOMM | CDER

**9:00 – 9:30**

**Labeling for Biological Products**

**Ruby (Chi-Ann) Wu**  
*Captain, U.S. Public Health Service, Labeling Reviewer*  
Office of Therapeutic Biologics and Biosimilars (OTBB)  
OND | CDER

**Jessica Greenbaum**  
*Regulatory Counsel*  
OTBB | OND | CDER

**9:30 – 10:15**

**A Recipe for Clinical Pharmacology Information in Labeling That is Easy to Digest**

**Joseph Grillo**  
*Associate Director of Labeling and Health Communication*  
Office of Clinical Pharmacology (OCP)  
Office of Translational Sciences (OTS) | CDER

and joining for the panel: **Mongthuong Tran**  
*Labeling Reviewer and Health Communication Specialist*  
OCP | OTS | CDER

**10:15 - 10:35: BREAK**

**10:35 – 11:20**

**Instructions for Use Draft Guidance**

**Morgan Walker**  
*Lieutenant Commander, United States Public Health Service*  
*Senior Patient Labeling Reviewer*  
Division of Medical Policy Programs (DMPP)  
Office of Medical Policy Initiatives (OMPI) | OMP | CDER

and joining for the panel: **Bryon Pearsall**  
*Division Director*  
DMPP | OMPI | OMP | CDER

**LaShawn Griffiths**  
*Associate Director for Patient Labeling*  
DMPP | OMPI | OMP | CDER

**11:20 - 12:35 p.m. LUNCH & NETWORKING - On your own. Click [HERE](#) for onsite dining options**

**Day Two: Thursday, December 5, 2019** (all sessions include panel discussions)

**12:35 – 1:05**

**Product Title and Initial U.S. Approval in Highlights of Prescribing Information Draft Guidance**

**Debra Beitzell**

*Clinical Advisor for Labeling*  
LPT | ONDP | OND | CDER

**1:05 – 1:35**

**Drug Product Nomenclature**

**Jibril Abdus-Samad**

*Lieutenant Commander, United States Public Health Service*  
*Policy Lead, Compendial Operations and Standards Staff*  
Office of Policy for Pharmaceutical Quality (OPPQ)  
Office of Pharmaceutical Quality (OPQ) | CDER

**1:35 – 1:55**

**Panel Questions & Discussion**

**Debra Beitzell and Jibril Abdus-Samad**

**1:55 – 2:15: BREAK**

**2:15 – 2:45**

**Safety Considerations for Container Labels and Carton Labeling to Minimize Medication Errors**

**Chi-Ming (Alice) Tu**

*Lieutenant commander, United States Public Health Service*  
*Team Leader*  
Division of Medication Error Prevention and Analysis (DMEPA)  
Office of Medication Error Prevention and Risk Management (OMEPRM)  
Office of Surveillance and Epidemiology (OSE) | CDER

**2:45 – 3:15**

**Improving Consistency of Information Between the Prescribing Information and Carton/Container Labeling**

**Eric Brodsky**

*Associate Director*  
LPT | ONDP | OND | CDER

**3:15 – 3:30**

**Panel Questions & Discussion**

**Chi-Ming (Alice) Tu and Eric Brodsky**

**3:30 – 3:35**

**Closing Remarks**

**Eric Brodsky**

*Associate Director*  
LPT | ONDP | OND | CDER

**3:35 PM: ADJOURN**