

## 2019 ELECTRONIC DRUG REGISTRATION AND LISTING USING CDER DIRECT



**OCT 22**

The Hotel  
College Park, MD

Version 4, October 9, 2019  
(use link below to check for updates)

For files and resources, please visit  
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# AGENDA

Tuesday, October 22, 2019

8:00 a.m. Registration Opens

8:50 - 9:00: Administrative Announcements

Jeff Kelly

9:00 - 9:05

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)*

9:05 - 9:10

Welcome from CDER's Office of Compliance

**Rosemary Cook**  
*Director, Office of Program and Regulatory Operations  
Office of Compliance (OC) | CDER*

Tuesday, October 22, 2019

9:10 – 9:30

**Keynote from the Drug Registration and Listing Staff**

**Paul Loebach**

*Director*

Drug Registration and Listing Staff (DRLS) | CDER

9:30 – 10:20

**Establishment Registration and Labeler Code Requests**

The basics of registration and labeler code requests, common errors to avoid, and things to remember each year.

**Don Duggan**

*Lead Consumer Safety Officer*

**Puii Huber**

*Technical Information Specialist*

Drug Registration and Listing Staff (DRLS) | CDER

10:20 - 10:40: BREAK

10:40 – 11:30

**NDC Reservation, Drug Listing, 503B Compounded Product Reporting**

Learn the basics of reserving an NDC, listing a drug, and reporting a compounded product, plus common errors to avoid and things to remember each year.

**David Mazyck**

*Consumer Safety Officer*

**Troy Cu**

*Technical Information Specialist*

**Soo Jin Park**

*Regulatory Officer*

Drug Registration and Listing Staff (DRLS) | CDER

11:30 – 12:00

**Onsite Helpdesk Time**

For in-person participants only. DRLS Helpdesk Staff will be available to help you register and update your listings.

12:00 - 1:00 p.m. LUNCH & NETWORKING - On your own. Click [HERE](#) for onsite dining options

1:00 – 1:50

**Listing Certification and Inactivation**

As announced via Federal Register notice, FDA has begun to remove older non-compliant listings. Receive valuable information about the annual listing requirement, how to avoid inactivation of your listings, and what to do if a drug listing is inactivated.

**Regie Samuel**

*Technical Information Specialist*

**Leyla Rahjou Esfandiary**

*Lead Consumer Safety Officer*

Drug Registration and Listing Staff (DRLS) | CDER

1:50 - 2:10: BREAK

**2:10 – 3:00**

### Compliance Program and Case Study

Find out how the DRLS staff handles errors that it finds in the data.

**Tasneem Hussain**

*Pharmacist*

**Julian Chun**

*Pharmacist*

Drug Registration and Listing Staff (DRLS) | CDER

**3:00 - 3:20: BREAK**

**3:20 – 4:00**

### DRLS Town Hall

An opportunity to pose questions and join an open discussion with DRLS staff. To prepare for the discussion, consider these questions:

1. Are there Specific Registration and Listing (R&L) regulatory topics you would like FDA to address in future?
2. Are there specific aspects of the R&L process that you have difficulty with and would like FDA to provide more training on?
3. Are there other methods/modes of delivery you think would be effective for R&L outreach?
4. What other professional groups and associations are you a member of that would benefit from R&L outreach?

**4:00 – 4:05**

### Closing

**Paul Loebach**

*Director*

Drug Registration and Listing Staff (DRLS) | CDER

**4:05 p.m. - ADJOURN**

**4:05 – 4:30**

### Onsite Helpdesk Time

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