



**CDER SMALL BUSINESS AND INDUSTRY ASSISTANCE**  
**ELECTRONIC DRUG REGISTRATION AND**  
**LISTING USING CDER DIRECT**

VIA WEBCAST  
[www.fda.gov/CDERSBIA](http://www.fda.gov/CDERSBIA)

**OCT 8, 2020**

Version 4, September 16, 2020  
 (use link below to check for updates)

For files and resources, please visit  
[The Event Page on SBIAevents.com](https://www.fda.gov/CDERSBIA)

[Add to Your Calendar](#)

# AGENDA

All times are Eastern (EDT UTC-4)

[View Start Time on World Clock](#)

**Thursday, October 8, 2020**

**8:40 - 9:00**

**Welcome and Overview**

**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)

**9:00 – 9:30**

**Keynote: eDRLS and the COVID-19 National Health Emergency**

**Paul Loebach**  
*Director*  
 Drug Registration and Listing Staff (DRLS)  
 Office of Program and Regulatory Operations (OPRO) | CDER

**9:30 – 10:45**

**Labeler Code Request**

Topics include:

- How to submit a Labeler Request SPL using CDER Direct
- How to update an existing Labeler Code Request SPL
- Why a labeler code is inactivated by FDA?
- Top Dos and Don'ts
- **Q&A session with speakers**

**Don Duggan**  
*Team Lead, Helpdesk Operations Team*  
**Puii Huber**  
*Technical Information Specialist*  
 DRLS | OPRO | CDER

**10:45 - 11:00: BREAK**

Thursday, October 8, 2020

11:00 – 12:15

**Establishment Registration**

Topics include:

- How to submit a registration SPL using CDER Direct
- Establishment registration renewal
- Establishment De-registration
- US Agents and Importer requirements for foreign establishments
- How to use DECRS
- Top Dos and Don'ts
- **Q&A session with speakers**

**Regie Samuel**  
*Technical Information Specialist*

**Leyla Rahjou Esfandiary**  
*Lead Consumer Safety Officer*

**Vikas Arora**  
*Pharmacist*

**Tasneem Hussain**  
*Pharmacist*

DRLS | OPRO | CDER

12:15 - 1:15 LUNCH BREAK

1:15 – 2:45

**Drug Listing**

Topics include:

- How to reserve an NDC prior to drug listing
- How to submit a Drug Listing SPL using CDER Direct
- How to update an existing Drug Listing SPL, including discounting a drug
- How to certify drug listing
- How to use the NDC Directory
- Top Dos and Don'ts
- **Q&A session with speakers**

**David Mazyck**  
*Consumer Safety Officer*

**Troy Cu**  
*Technical Information Specialist*

**Puii Huber**  
*Technical Information Specialist*

**Tasneem Hussain**  
*Pharmacist*

DRLS | OPRO | CDER

2:45 - 3:00: BREAK

3:00 – 3:30

**503B Compounder Product Reporting using CDER Direct**

Topics include:

- How to submit a Product Reporting SPL using CDER Direct
- Top Dos and Don'ts
- Q&A Session with Speakers

**Soo Jin Park**  
*LCDR, USPHS  
Regulatory Officer*

DRLS | OPRO | CDER

3:30 – 5:00

**Establishment Registration and Drug Listing Compliance Program**

Topics include:

- Compliance case process and manual overrides
- Case Study of a violation
- FDA's Drug Listing Inactivation Project
- Top Dos and Don'ts
- **Q&A session with speakers**

**Julian Chun**  
*Pharmacist*

**Leyla Rahjou Esfandiary**  
*Lead Consumer Safety Officer*

DRLS | OPRO | CDER

5:00 p.m. - ADJOURN