



Small Business and Industry Assistance Electronic Drug Registration and Listing (eDRLS) Using CDER Direct 2024



Version 1, June 24, 2024
(use link below to check for updates)

For files and resources, please visit
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AGENDA

All times are Eastern (UTC-5)
[View Start Time on World Clock](#)

Thursday, September 12, 2024

8:45 - 9:00

Welcome and Overview

Brenda Stodart, PharmD, BCGP, RAC-US

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

9:00 – 9:15

Keynote

Matthew Lash, JD

*Deputy Director
Office of Compliance (OC)
CDER | FDA*

Your SBIA Host

Nora Lim, PharmD, BCPS

*Lieutenant Commander | USPHS | Pharmacist
SBIA | DDI | OCOMM | CDER | FDA*

Thursday, September 12, 2024

9:15 – 10:30

Registering Your Drug Manufacturing Establishment Using CDER Direct

Topics include:

- CDER Direct Establishment Registration Demo
- Establishment Registration Highlights
- Complying with Establishment Registration Requirements

Regie Samuel

Technical Information Specialist

Drug Registration and Listing Branch (DRLB)

Division of Labeling, Registration, and Unapproved Drugs (DLRUD)

Office of Unapproved Drugs & Labeling Compliance (OUDLC)

CDER | FDA

Jose Cabrera

Technical Information Specialist

DRLB | DLRUD | OUDLC | CDER | FDA

Tasneem Hussain, PharmD

Consumer Safety Officer

DRLB | DLRUD | OUDLC | CDER | FDA

10:30 – 10:45: BREAK

10:45 - 11:30

Requesting a Labeler Code from FDA

Puii Huber

Technical Information Specialist

DRLB | DLRUD | OUDLC | CDER | FDA

Laurie Simonds, GWCPM

Technical Information Specialist

DRLB | DLRUD | OUDLC | CDER | FDA

Jeffrey Trunzo, RPh, MBA

Consumer Safety Officer

DRLB | DLRUD | OUDLC | CDER | FDA

11:30 - 12:00

Q&A Panel

All Speakers

12:00 – 1:00: LUNCH BREAK

Thursday, September 12, 2024

1:00 – 2:30

Listing Your Drug Using CDER Direct

Topics include:

- CDER Direct Drug Listing Demo
- Listing Updates and Blanket No Change Certification Demo
- Drug Listing Highlights
- Complying with Drug Listing Requirements

Troy Cu

Technical Information Specialist

DRLB | DLRUD | OUDLC | CDER | FDA

Yogesh Paruthi, PharmD

Consumer Safety Officer

DRLB | DLRUD | OUDLC | CDER | FDA

Vikas Arora, PharmD

Consumer Safety Officer

DRLB | DLRUD | OUDLC | CDER | FDA

Tasneem Hussain, PharmD

Consumer Safety Officer

DRLB | DLRUD | OUDLC | CDER | FDA

2:30 – 3:00

National Drug Code

Topics include:

- NDC Reservation
- Future Format of the National Drug Code
- NDC Assignment to Drugs

David Mazyck

Consumer Safety Officer

DRLB | DLRUD | OUDLC | CDER | FDA

Leyla Rahjou-Esfandiary, PharmD

Branch Chief

DRLB | DLRUD | OUDLC | CDER | FDA

Soo Jin Park, PharmD, MS

Lieutenant Commander | USPHS | Regulatory Officer

DRLB | DLRUD | OUDLC | CDER | FDA

3:00 – 3:15: BREAK

Thursday, September 12, 2024

3:15 – 3:45

Recent Updates

Topics include:

- OTC Drug Listing Updates and Validation
- Drug Amount Reporting for Listed Drugs
- Who Should Not Register or List

Leyla Rahjou-Esfandiary, PharmD

Branch Chief

DRLB | DLRUD | OUDLC | CDER | FDA

Obinna Ugwu-Oju, MS

Division Director

Office of Pharmaceutical Quality (OPQ)

Office of Quality Surveillance (OSI)

CDER | FDA

Yogesh Paruthi, PharmD

Consumer Safety Officer

DRLB | DLRUD | OUDLC | CDER | FDA

3:45 – 4:15

Case Studies

Julian Chun, PharmD, MBA

Consumer Safety Officer

DRLB | DLRUD | OUDLC | OC | CDER | FDA

4:15 – 4:40

Q&A Panel

All Speakers

4:40 – 4:45

SBIA Closing

Nora Lim, PharmD, BCPS

Lieutenant Commander | USPHS | Pharmacist

SBIA | DDI | OCOMM | CDER | FDA

4:45 - ADJOURN