Version 5, October 5, 2020
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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 – 9:20

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

9:20 – 10:10

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

10:10 - 10:30: BREAK

Thursday, October 8, 2020

10:30 – 11:45

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

11:45 - 12:45 LUNCH BREAK

12:45 – 2:25

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

2:25 - 2:40: BREAK

2:40 – 3:15

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

3:15 – 4:55

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

Thursday, October 8, 2020

4:55 – 5:00

Closing Remarks

Paul Loebach

5:00 p.m. - ADJOURN