CDER Small Business and Industry Assistance (SBIA)

FDA U.S. FOOD & DRUG ADMINISTRATION

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
The Event Page on SBIAevents.com

Add to Your Calendar

FDA Acronyms & Abbreviations - CDER Guidance Documents

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

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