Version 5, August 9, 2023
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AGENDA

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

Thursday, September 28, 2023

8:45 - 9:00

Welcome and Overview

Brenda Stodart, PharmD, BCGP, RAC-US
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 and Research (CDER) | FDA

9:00 – 9:15

Keynote

Jill Furman
Director
Office of Compliance (OC)
CDER | FDA

Your SBIA Host

Forest "Ray" Ford, Jr., PharmD, BCPS
CAPT, USPHS, *Pharmacist*
SBIA | DDI | OCOMM | CDER | FDA

Thursday, September 28, 2023

9:15 – 10:00

Registering Your Drug Manufacturing Establishment Using CDER Direct

Topics include:

- CDER Direct Establishment Registration Demo
- Using the Appropriate Business Operation(s) and Business Qualifier(s)
- Registration Renewals, Updates, and Deregistration
- US Agents and Official Contacts

Regie Samuel
Technical Information Specialist
Drug Registration and Listing Branch (DRLB)
Division of Labeling, Registration and Unapproved Drugs (DLRUD)
Office of Unapproved Drugs and Labeling Compliance (OUDLC)
Office of Compliance (OC)
CDER | FDA

Jose Cabrera
Information Technology Specialist
DRLB | DLRUD | OUDLC | OC | CDER | FDA

10:00 – 10:45

Requesting a Labeler Code from FDA

Topics include:

- CDER Direct Labeler Code Request Demo
- Who Will be Assigned a Labeler Code and Who Won't
- Labeler Code Inactivation and Reactivation
- Updates, Mergers and Acquisitions

Soo Jin Park
LCDR, USPHS
Regulatory Officer
DRLB | DLRUD | OUDLC | OC | CDER | FDA

Laurie Simonds, GWCPM
Technical Information Specialist
DRLB | DLRUD | OUDLC | OC | CDER | FDA

Lalnunpuii Huber
Technical Information Specialist
DRLB | DLRUD | OUDLC | OC | CDER | FDA

10:45 – 11:00: BREAK

11:00 – 12:00

Listing Your Drug Using CDER Direct

Topics include demonstrations of:

- CDER Direct Drug Listing Demo
- Listing a Combination Product
- Strength Conversion in Drug Listing
- Listing Updates and Delisting
- Blanket No Change Certification

Troy Cu
Technical Information Specialist
DRLB | DLRUD | OUDLC | OC | CDER | FDA

Leyla Rahjou-Esfandiary
Lead Consumer Safety Officer
DRLB | DLRUD | OUDLC | OC | CDER | FDA

Yogesh Paruthi
Consumer Safety Officer
DRLB | DLRUD | OUDLC | OC | CDER | FDA

Vikas Arora
Pharmacist

DRLB | DLRUD | OUDLC | OC | CDER | FDA

Thursday, September 28, 2023

12:00 – 12:15

503B Registration and Product Reporting Using CDER Direct

Topics include:

- Demo
- Updates

Huascar Batista
Senior Advisor
Office of Compounding Quality and Compliance (OCQO)
Office of Compliance (OC) | CDER | FDA

12:15 – 12:45

Q&A Panel

All Speakers

12:45 – 1:40: LUNCH BREAK

1:40 – 1:45

SBIA Welcome Back & CE Reminders

Forest "Ray" Ford, Jr., PharmD, BCPS
CAPT, USPHS, *Pharmacist*
SBIA | DDI | OCOMM | CDER

1:45 – 2:00

OMUFA Updates

Yajun (Jason) Tu, PharmD, PhD
LCDR, USPHS
Program Management Officer
Policy and Operations Branch (POB)
Division of User Fee Management (DUFM)
Office of Management (OM) | CDER | FDA

2:00 – 2:30

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 | OC | CDER | FDA

Julian Chun
Pharmacist
DRLB | DLRUD | OUDLC | OC | CDER | FDA

Soo Jin Park
LCDR, USPHS
Regulatory Officer
DRLB | DLRUD | OUDLC | OC | CDER | FDA

Thursday, September 28, 2023

2:30 – 3:15

Registration and Listing Compliance Program

Topics include:

- Untitled Letters and Warning Letters
- Data Inactivation
- Data Removals and Flags
- Downstream Effects

Tasneem Hussain
Pharmacist
DRLB | DLRUD | OUDLC | OC | CDER | FDA

Vikas Arora
Pharmacist
DRLB | DLRUD | OUDLC | OC | CDER | FDA

Leyla Rahjou-Esfandiary
Branch Chief
DRLB | DLRUD | OUDLC | OC | CDER | FDA

3:15 – 3:30: BREAK

3:30 – 3:45

Recent Automated Validation Rules

Lalnunpuii Huber
Technical Information Specialist
DRLB | DLRUD | OUDLC | OC | CDER | FDA

3:45 – 4:15

Case Studies

Julian Chun
Pharmacist
DRLB | DLRUD | OUDLC | OC | CDER | FDA

4:15 – 4:40

Q&A Panel

All Speakers

4:40 – 4:45

SBIA Closing

Forest "Ray" Ford, Jr., PharmD, BCPS
CAPT, USPHS, *Pharmacist*
SBIA | DDI | OCOMM | CDER

4:45 - ADJOURN