For files and resources, please visit
The Event Page on SBIAevents.com

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

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Presenter(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:10 – 9:30</td>
<td><strong>Keynote from the Drug Registration and Listing Staff</strong></td>
<td>Paul Loebach, Director Drug Registration and Listing Staff (DRLS)</td>
</tr>
<tr>
<td>9:30 – 10:20</td>
<td><strong>Establishment Registration and Labeler Code Requests</strong></td>
<td>Don Duggan, Lead Consumer Safety Officer, Puii Huber, Technical Information Specialist, Drug Registration and Listing Staff (DRLS)</td>
</tr>
<tr>
<td></td>
<td><strong>Break</strong></td>
<td></td>
</tr>
<tr>
<td>10:20 – 10:40</td>
<td><strong>Break</strong></td>
<td></td>
</tr>
<tr>
<td>10:40 – 11:30</td>
<td><strong>NDC Reservation, Drug Listing, 503B Compounded Product Reporting</strong></td>
<td>David Mazyck, Consumer Safety Officer, Troy Cu, Technical Information Specialist, Soo Jin Park, Regulatory Officer, Drug Registration and Listing Staff (DRLS)</td>
</tr>
<tr>
<td>11:30 – 12:00</td>
<td><strong>Onsite Helpdesk Time</strong></td>
<td>For in-person participants only. DRLS Helpdesk Staff will be available to help you register and update your listings.</td>
</tr>
<tr>
<td>12:00 – 1:00 p.m.</td>
<td><strong>LUNCH &amp; NETWORKING</strong> - On your own. Click HERE for onsite dining options</td>
<td></td>
</tr>
<tr>
<td>1:00 – 1:50</td>
<td><strong>Listing Certification and Inactivation</strong></td>
<td>Regie Samuel, Technical Information Specialist, Leyla Rahjou Esfandiary, Lead Consumer Safety Officer, Drug Registration and Listing Staff (DRLS)</td>
</tr>
<tr>
<td>1:50 – 2:10</td>
<td><strong>Break</strong></td>
<td></td>
</tr>
</tbody>
</table>
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
**Onsite Helpdesk Time**
For in-person participants only. DRLS Helpdesk Staff will be available to help you register and update your listings.