Activity Outline
Electronic Drug Registration and Listing Using CDER Direct
October 22, 2019
The Hotel at the University of Maryland 7777 Baltimore Ave, College Park, MD 20740

Activity Coordinator
Lisa Misevicz
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Description

As the registration renewal and drug listing recertification period approaches, this event will educate and assist participants with the registration and listing process using CDER Direct. Attendees will be able to observe the step by step process of submissions and be able to ask questions. Presentations will also discuss establishment registration, product listing, top 10 errors when submitting, compliance cases, listing recertification, labeler code request, National Drug Code reservation, DRLS compliance program, and 503B product reporting for compounding outsourcing facilities.

References

- Section 360 of 21 U.S.C: https://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/html/USCODE-2010-title21-chap9-subchapV-partA-sec360.htm
- Chapter 21 of Code of Federal Regulations Part 207: https://www.ecfr.gov/cgi-bin/text-idx?SID=fa8d7e9c3c27e094261bf903b897eb6e&mc=true&node=pt21.4.207&rgn=div5
- Electronic Drug Registration and Listing Instruction: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/ucm078801.htm
- Guidance for Industry: Providing Regulatory Submission in Electronic Format – Drug Establishment Registration and Drug Listing: https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072339.pdf

Learning Objectives

- Describe drug establishment registration and drug listing requirements under Food, Drug and Cosmetic Act
- List all the available free tools through FDA to submit registration and listing information
- List all the required data for drug establishment registration with FDA
- List all the required data for drug listing with FDA

Target Audience
This activity is intended for physicians, pharmacists, and nurses.

Agenda
Day 1 October 22, 2019

Time	Topic	Speaker
9:00 - 9:05 AM	Overview	Brenda Stodart, PharmD, BCGP, RAC-US
9:05 - 9:10 AM	Keynote from CDER Office of Program and Regulatory Operations	Rosemary Cook, MBA
9:10 - 9:30 AM	Keynote from Drug Registration and Listing Director	Paul Loebach
9:30 - 10:20 AM	Establishment Registration and Labeler Code Requests	Donovan Duggan, MBA Lalnunpuii Huber
10:20 - 10:40 AM	*Break*	
10:40 - 11:30 AM	NDC Reservation, Drug Listing, Compounded Product Reporting	Soo Park, PharmD Troy Cu David Mazyck

11:30 - 12:00 PM	Helpdesk Time - DRLS Staff Helps with Registration and Updating Listings	Paul Loebach Donovan Duggan, MBA Lalnunpuii Huber Soo Park, PharmD Troy Cu Leyla Rahjou-Esfandiary Regie Samuel *Not offered for CE*
12:00 - 1:00 PM	*Lunch*	
1:00 - 1:50 PM	Listing Certification and Inactivation	Leyla Rahjou-Esfandiary Regie Samuel
1:50 - 2:10 PM	*Break*	
2:10 - 3:00 PM	Compliance Program and Case Study	Julian Chun TASNEEM HUSSAIN, Pharm. D
3:00 - 3:20 PM	*Break*	
3:20 - 4:00 PM	Town Hall Interactive Discussion: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?	Paul Loebach Donovan Duggan, MBA Lalnunpuii Huber Soo Park, PharmD Troy Cu David Mazyck Leyla Rahjou-Esfandiary Regie Samuel Julian Chun TASNEEM HUSSAIN, Pharm. D
4:00 - 4:05 PM	Closing Remarks	Paul Loebach
4:05 - 4:30 PM	Helpdesk Time - DRLS Staff Helps with Registration and Updating Listings	Donovan Duggan, MBA Lalnunpuii Huber Soo Park, PharmD Troy Cu David Mazyck Leyla Rahjou-Esfandiary Regie Samuel Julian Chun TASNEEM HUSSAIN, Pharm. D *Not offered for CE*

Continuing Education Accreditation

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This activity was planned by and for the healthcare team, and learners will receive 4.50 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 4.50 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-19-082-L04-P for 4.50 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 4.50 contact hour(s).

Requirements for Receiving CE Credit

Physicians, pharmacists, nurses, and those claiming non-physician CME: participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Pharmacists will need their NABP e-profile ID number as well as their DOB in MMDD format in order to claim CE credit.

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit.Physicians and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 10 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Chun, Julian, Pharmacist, FDA - nothing to disclose
- Cook, Rosemary, MBA, Director, Office of Program and Regulatory Operations, FDA/CDER/OC/OPRO - nothing to disclose
- Cu, Troy, Technical Information Specialist, FDA - nothing to disclose
- Duggan, Donovan, MBA, Lead Consumer Safety Officer, CDER/OC/OPRO/DRLS - nothing to disclose
- HUSSAIN, TASNEEM, Pharm. D, Pharmacist, FDA - nothing to disclose
- Huber, Lalnunpuii, Technical Information Specialist, FDA - nothing to disclose
- Loebach, Paul, Supv Operations Research Analyst, FDA/CDER/OC - nothing to disclose
- Mazyck, David, Consumer Safety Officer, FDA/ CDER/ OC/OPRO/DRLS - nothing to disclose
- Park, Soo, PharmD, Senior Regulaory Officer, FDA/CDER/OC/OPRO - nothing to disclose
- Rahjou-Esfandiary, Leyla, Lead CSO, FDA - nothing to disclose
- Samuel, Regie, Technical Information Specialist, Food and Drug Administration - nothing to disclose
- Stodart, Brenda, PharmD, BCGP, RAC-US, Program Director, FDA - nothing to disclose

Planning Committee

- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Kleppinger, Cynthia, MD, Medical Officer, FDA - nothing to disclose
- Loebach, Paul, Supv Operations Research Analyst, FDA/CDER/OC - nothing to disclose
- Rahjou-Esfandiary, Leyla, Lead CSO, FDA - nothing to disclose

CE Consultation and Accreditation Team

- Lisa Thompson, MSHA, MBA, CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
  Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to

- Giroux, Virginia, MSN, FNP-BC, Associate Director for Accreditation, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Registration Fee and Refunds
Registration is complimentary, therefore refunds are not applicable.

Requirements for Certificate of Completion (Non CE)
Must attend 90% of the activity.