

# **The New 21 CFR 207 and What You Need to Know**

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CDER SBIA Extended Webinar: Electronic Drug  
Registration & Listing Using CDER Direct

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# Poll Question

**How many registrations or listing SPLs have you submitted to FDA?**

☐ Over 500

☐ 100-499

☐ 1-99

☐ 0



# Overview of the Day

- New 207
- CDER Direct Submissions; Requirements and Live Demo
  - Establishment Registration
  - Labeler Code Request
  - Drug Listing
- Listing Certification
- 503B Product Reporting; Requirements and Live Demo
- In person questions and consultations

# Establishment Registration and Drug Listing Requirements



- Included in Section 510 of the Food, Drug and Cosmetic Act

<https://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/html/USCODE-2010-title21-chap9-subchapV-partA-sec360.htm>

- Outlined in 21 CFR Part 207

[https://www.ecfr.gov/cgi-bin/text-idx?SID=fa8d7e9c3c27e094261bf903b897eb6e&mc=true&node=pt21.4.207&rgn=div5#se21.4.207\\_117](https://www.ecfr.gov/cgi-bin/text-idx?SID=fa8d7e9c3c27e094261bf903b897eb6e&mc=true&node=pt21.4.207&rgn=div5#se21.4.207_117)

- Revised in August 2016
- Effective date of November 2016
- Most compliance dates of November 2017

# Definitions – What's New?

- Active Pharmaceutical Ingredient
- Finished and unfinished drug product
- Importer
- Manufacture (separated from relabel, repack, salvage)
- Outsourcing facility
- Private label distribution
- Registrant

# Establishment Registration

## What's New?



- Electronic submission
- Registration update window (October-December) consistent with FDASIA
- Business type: “Recover” to “Salvage”
- UFI for establishment registration
- Requirements for official contacts, U.S. agents and importers

# Labeler Code Request and NDC

## What's New?



- Labeler code inactivation
- NDC proposed by labeler and assigned by FDA
- NDC reservation
- Clarification of new NDC requirements for previously listed drugs
  - Physical characteristics
  - Intended use
- Possible misbranding charges for NDC assignment to non-drugs

# Labeler Code Request and NDC

## What's **OLD**?



- NDC is currently a **10 digit** code!
- NDC has 3 segments
  - Labeler code
  - Product code
  - Package code
- Current NDC configurations:
  - 4-4-2
  - 5-3-2
  - 5-4-1



# Drug Listing – What’s New?



- Electronic Submission
- No change certification
- Inclusion of inactive ingredients
- PLD and CMO drug listing clarification
- Introduction of “Source NDC” for repackaged drugs
- Inclusion of lot number for salvaged drugs
- Inclusion of DMF for unfinished drugs



# Submission Tools

- SPL authoring softwares
  - FDA
    - CDER Direct
    - Xform
  - Non-FDA
    - Other commercial softwares

**Whatever the submission tool and method, the data must be complete and accurate!**

- Current through September 01, 2017

Acetaminophen and Codeine Phosphate (E)	0216-0									N/A			N/A	N/A
Acetazolamide (E)	0279-0									N/A			N/A	N/A
Adipex-P (E)	0284-0									N/A			N/A	N/A



# Deficiency Letters

- Attempt to notify the firm of the deficiency
- 30 days to fix the data
- Many need manual overrides
- Start the process early!

**Make sure your establishment registration and labeler contact information are up-to-date!**



# Compliance Program – What's New?

- DailyMed data removal
- NSDE data removal
- Validation of NDCs for certification against open compliance cases

**If an NDC is included in an open compliance case, it cannot be certified until the case is closed!**

# Takeaway

- **You are making a difference!**
  - Electronic prescribing
  - Adverse event reporting
  - GMP inspections
  - Drug importation
  - Supply chain management
  - Reimbursement
  - And many more....

# CDER Direct

<https://direct.fda.gov>

## LOGIN

Username:

Password:

*Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.*

☐ I Understand.

**LOGIN**

[Forgot your password?](#)

## QUICK LINKS

[Create Account](#)

[Resources](#)

[Tutorials](#)

[Help Desk](#)

[FAQs](#)

## GETTING STARTED

To make submissions to FDA (e.g., Establishment Registration, Product Listing and Self-ID, etc.) you must first create an account. [Click here](#) to create a new account.

If you already have an account, enter your Username and Password.

**WARNING:** You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording. Anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

**Is your computer secure?** Before using FDA's Direct system, FDA strongly encourages you to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

**Browser Compatibility:** The CDER Direct portal currently works best with the following browsers:

- Microsoft Internet Explorer 8 (IE8) and above
- Firefox version 28 and above
- Google Chrome 44.0.2403.130
- Safari 10.0.1 and above

## NOTIFICATIONS

# Questions?

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