The New 21 CFR 207 and What You Need to Know

Leyla Rahjou-Esfandiary, Pharm. D.
FDA/ CDER/ OC

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

October 2017

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

  – 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

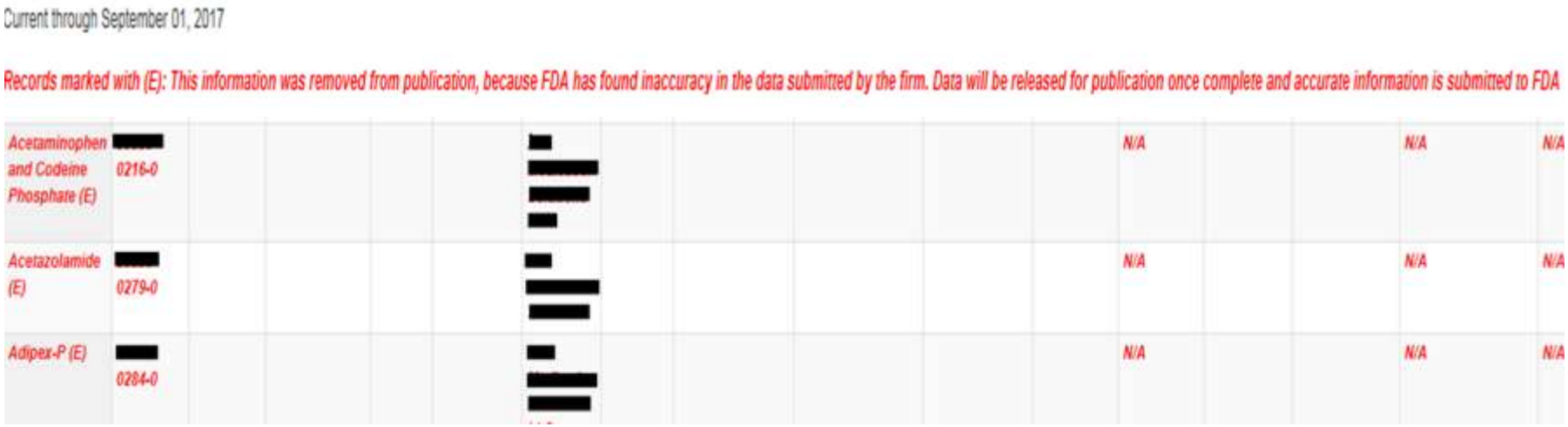
Submission Tools

- 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!

Registration and Listing Compliance Program

- Compliance cases and deficiency letters
- NDC Directory and DECRS data removal
  - Removal statement



Current through September 01, 2017

Records marked with (E): This information was removed from publication, because FDA has found inaccuracy in the data submitted by the firm. Data will be released for publication once complete and accurate information is submitted to FDA

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

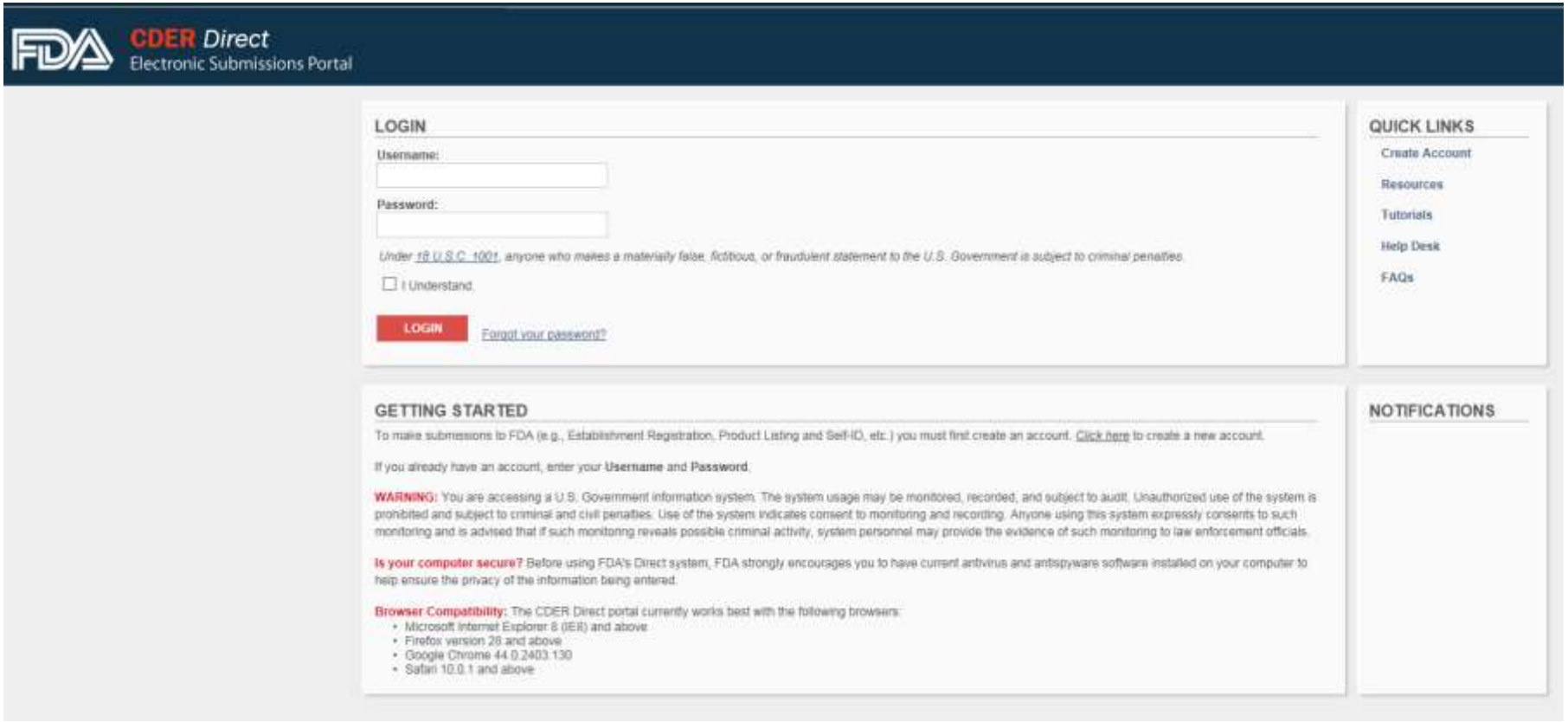
If an NDC is included in an open compliance case, it cannot be certified until the case is closed!

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



Questions?

Leyla.Rahjou-Esfandiary@fda.hhs.gov

eDRLS@fda.hhs.gov