Establishment De-Registration

Vikas Arora
Health Science Project Manager
OC/OPRO
CDER | US FDA

Electronic Drug Registration and Listing Using CDER DIRECT
October 13, 2021

Overview

- Why is De-Registration Important?
- When to De-Register?
- What are the De-Registration SPL Document Types?
- What to do after De-Registration?
- Demonstration in CDER Direct
- Challenge Question

Why is De-Registration Important?

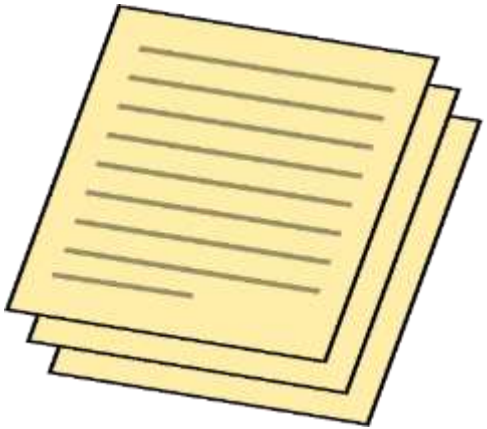
- Preserve integrity and accuracy of the system when establishments are no longer manufacturing drugs
- Assists the agency in conducting mission critical activities
  - Database is relied upon for many programs
    - Internal – Inspection planning, Post marketing surveillance, Recalls, Monitoring drug shortages, etc.
    - External – Reimbursement, Prescribing, Supply Chain
- Alerts business partners when there are changes

When to De-Register?

- Annual registration renewal period: Oct-Dec
- 21 CFR 207.29 states that expedited registration updates to be provided within 30 calendar days of a change
  - Closing or selling of an establishment when no longer manufacturing drug products

What are the SPL Documents to De-Register Establishments?

- Establishment De-Registration SPL
- Out of Business Notification SPL



Establishment De-Registration SPL

- De-Register if the establishment(s) is/are no longer manufacturing drug products for commercial distribution in the US
- May still manufacture non-drug products
  - Check possible registration requirements with other FDA centers

Out of Business Notification SPL

- Firm/establishment is no longer in business

Multiple Establishments

- Multiple establishments on one Registration SPL:
  - Establishment De-Registration or Out of Business Notification SPL will de-register all establishments.
  - To de-register one or any fewer than all establishments, drop the de-registered establishment(s) in a new version of the SPL.

What to do after De-Registration?

- Drug listing updates
  - All affected listing SPLs must be revised
  - Discontinued, if no longer manufactured
    - Enter **future** end marketing date to allow for existing supply to be exhausted
  - Updated to include a new manufacturing establishment, if drug remains in the market
- Labeler code updates
  - If an establishment no longer manufactures drugs or goes out of business, labeler code should be inactivated

https://direct.fda.gov

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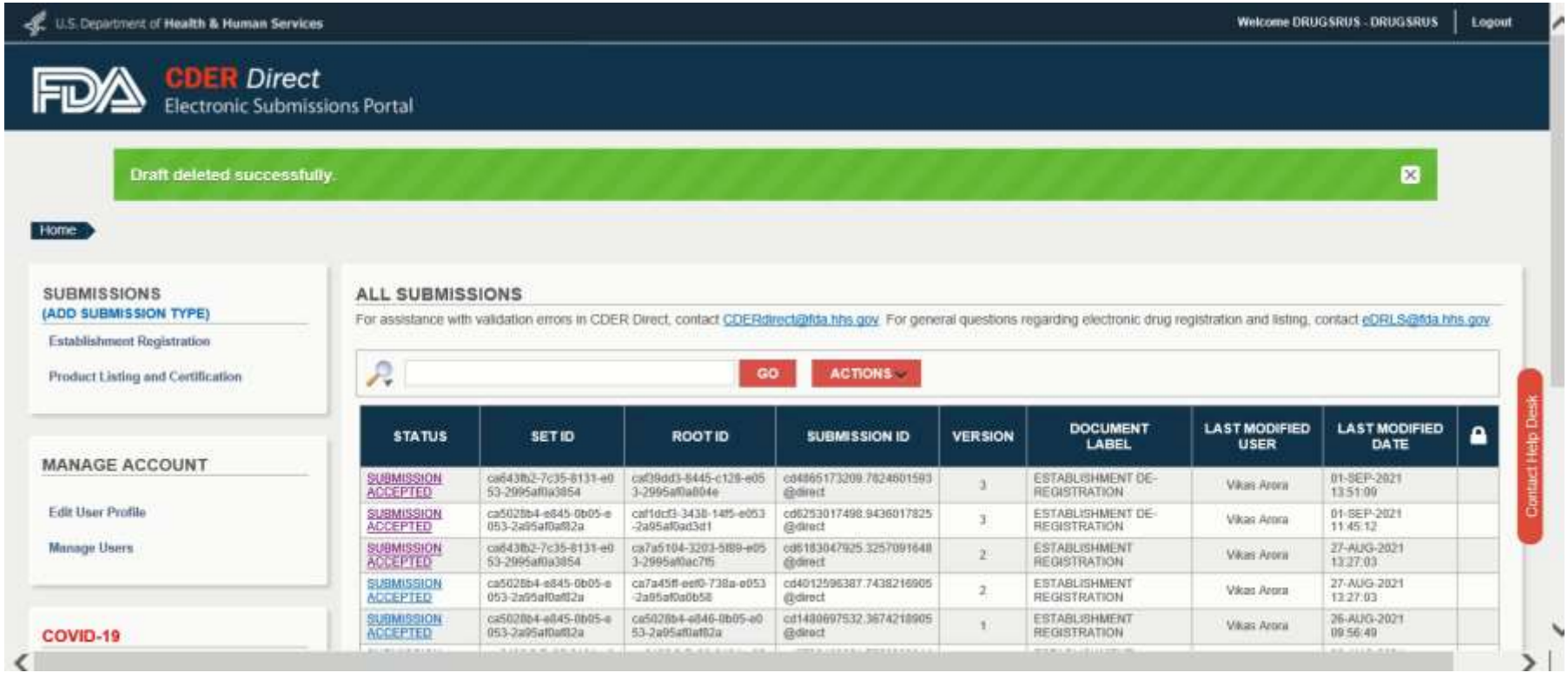
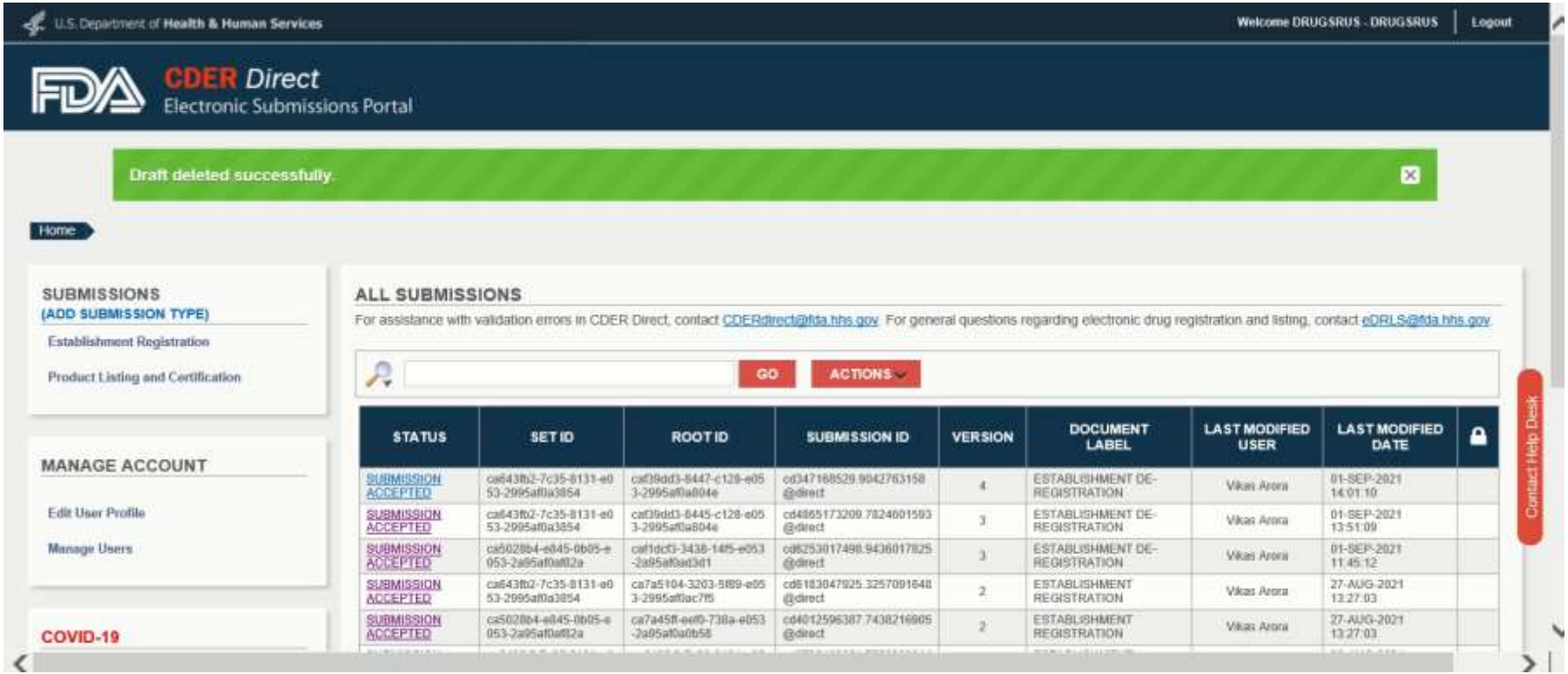
De-Registration Demonstration



De-Registration Demonstration (cont'd)



Challenge Question

A manufacturing establishment which was manufacturing hand sanitizers in response to the pandemic, stops production. Within how many days should it De-Register with FDA?

A. Same day

B. 14 days

C. 30 days

D. Between October and December

Summary

- De-register in a timely manner!
  - Simple and quick process
  - Alerts the agency and others of the removal of establishment(s) and change in business status
- Report all required updates to FDA
  - Establishment De-Registration vs. Out of Business Notification
  - Drug listing
  - Labeler code

U.S. FOOD & DRUG ADMINISTRATION

Thank You for De-Registering!

Contact Us:

eDRLS@fda.hhs.gov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