Establishment De-Registration

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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
DEMO of CDER Direct

https://direct.fda.gov
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
Thank You for De-Registering!

Contact Us:

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