

Establishment Registration Renewal, Updates, and De-Registration

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Electronic Drug Registration and Listing Using CDER DIRECT September 28, 2023

Learning Objectives



- Determine when to update your Establishment Registration
- Create and submit an updated Establishment Registration



When to Update Your Registration



- Annual registration renewal to be submitted between Oct. 1 and Dec. 31
- Expedited updates to be provided within 30 days of a change
 - Closing or selling an establishment (De-Registration / Out of Business Notification)
 - Changing an establishment's name or physical address
 - Changing the name, mailing address, telephone number, or email address of the official contact or the United States agent.

Document Types for Establishment Registration



- Establishment Registration
- No Change Notification
- Establishment De-Registration
- Out of Business Notification

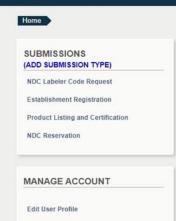




https://direct.fda.gov

LIVE DEMO on CDER Direct





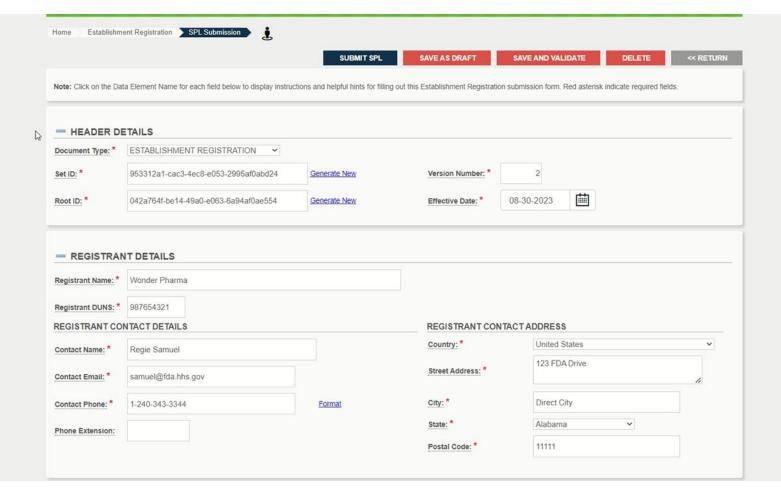
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Challenge Question



If I submitted my establishment re-registration on September 30, 2023, until what date is my registration current?

- A. October 1, 2023
- B. September 30, 2024
- C. December 31, 2023
- D. December 31, 2024



Thank You for Re-Registering and De-Registering! **Contact Us:**

eDRLS@fda.hhs.gov