

Establishment Registration Renewal, Updates, and De-Registration

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OC/OU DLC/DRLB

CDER | US FDA

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

A blue, rounded rectangular button with a white play icon on the right side. The word "REGISTER" is written in white, bold, uppercase letters on the left side of the button.

REGISTER

<https://direct.fda.gov>

LIVE DEMO
on
CDER Direct

Home

SUBMISSIONS

[\(ADD SUBMISSION TYPE\)](#)

NDC Labeler Code Request

Establishment Registration

Product Listing and Certification

NDC Reservation

MANAGE ACCOUNT

Edit User Profile

Manage Users

ALL SUBMISSIONS

For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic drug registration and listing, contact eDRLS@fda.hhs.gov.

GO
ACTIONS ▾

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
SUBMISSION ACCEPTED	953312a1-cac3-4ec8-e053-2995af0abd24	cd28a52e-c5c7-bf7e-e053-2995af0adb9a	cd913478265.6180392457@direct	1	ESTABLISHMENT REGISTRATION	Regle Samuel	30-AUG-2023 15:31:34	🔒
SUBMISSION ACCEPTED	835fa90e-d5b9-25c0-e053-2a91ab0abc1e	835fa90e-d5ba-25c0-e053-2a91ab0abc1e	cd8604952731.2074859163@direct	1	ESTABLISHMENT REGISTRATION	Regle Samuel	01-OCT-2018 11:55:10	

1 - 2

SUBMIT SPL **SAVE AS DRAFT** **SAVE AND VALIDATE** **DELETE** << RETURN

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Establishment Registration submission form. Red asterisk indicate required fields.

— HEADER DETAILS

Document Type: *	ESTABLISHMENT REGISTRATION	
Set ID: *	953312a1-cac3-4ec8-e053-2995af0abd24	Generate New
Version Number: *	2	
Root ID: *	042a764f-be14-49a0-e063-6a94af0ae554	Generate New
Effective Date: *	08-30-2023	

— REGISTRANT DETAILS

Registrant Name: *	Wonder Pharma
Registrant DUNS: *	987654321

REGISTRANT CONTACT DETAILS

Contact Name: *	Regie Samuel	
Contact Email: *	samuel@fda.hhs.gov	
Contact Phone: *	1-240-343-3344	Format
Phone Extension:		

REGISTRANT CONTACT ADDRESS

Country: *	United States
Street Address: *	123 FDA Drive
City: *	Direct City
State: *	Alabama
Postal Code: *	11111



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



**U.S. FOOD & DRUG
ADMINISTRATION**

Thank You for Re-Registering and De-Registering!

Contact Us:

eDRLS@fda.hhs.gov