



direct.fda.gov

Annual Reporting using CDER Direct: Technical Tips for Wholesale Drug Distributors and Third-Party Logistics Providers



Part I

- Background
- CDER Direct Refresher

Part II

- Reporting Jan-Mar
- Adding & Deleting Licenses
- Withdraw Submission
- Going Out of Business
- Doing Business As (DBA)
- Street Address Confidential

Part III

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- Contact Information



Background

The Drug Supply Chain Security Act (DSCSA) requires prescription drug Wholesale Distributors (WDDs) and Third-Party Logistics Providers (3PLs) to report State licensure and other information to the FDA **annually**. This presentation provides an overview of CDER Direct, information on how WDDs and 3PLs can use CDER Direct to resubmit, and answers to some frequently asked questions.

- January 1st March 31st each year
- CDER Direct is available to report information
- Some information is made public
- If you are just learning about reporting or would like additional information about reporting requirements, please visit:

http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm423749.htm



CDER Direct Refresher

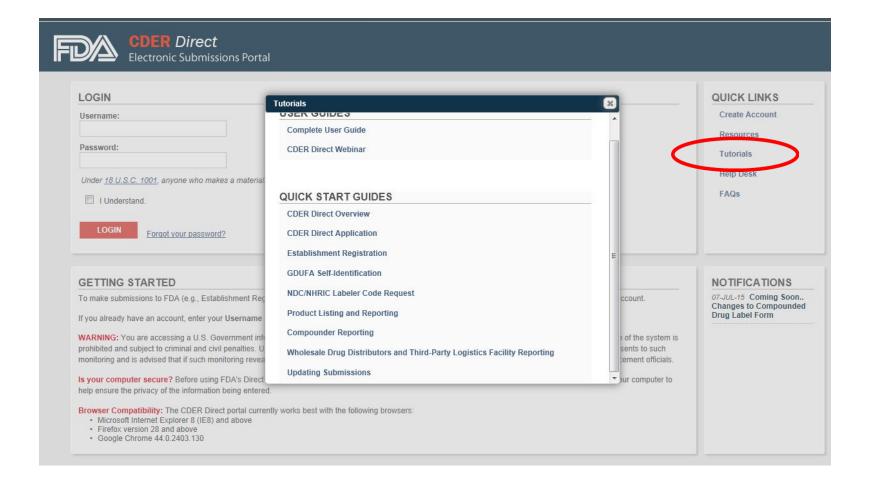
CDER Direct is a web based tool for reporting annually to FDA.

Steps to report include:

- Obtain a CDER Direct Account
- Choose WDD/3PL entry form
- Enter information, save, and submit
- Status e-mail
- Public database update



Tutorials available at CDER Direct portal

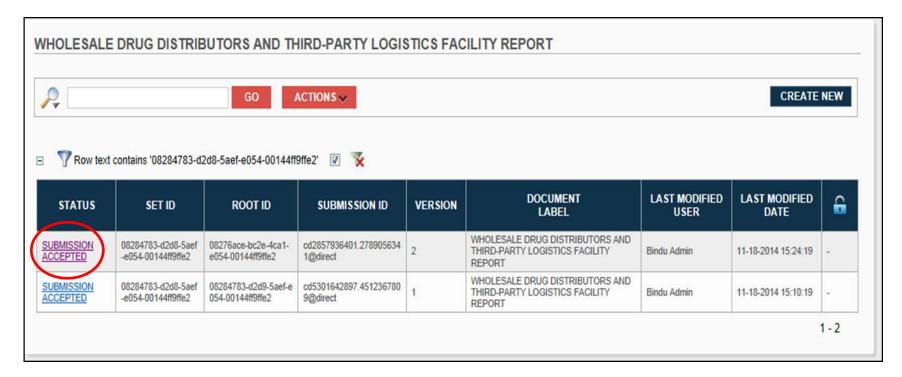




How to Resubmit

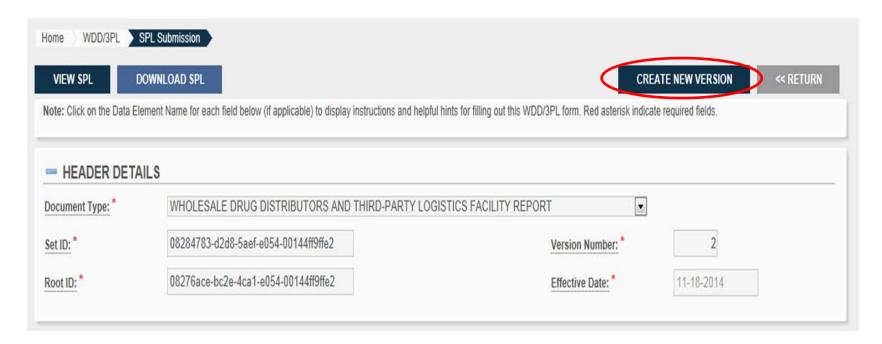
- Log into CDER Direct Account
- Open last accepted submission
- Create new version





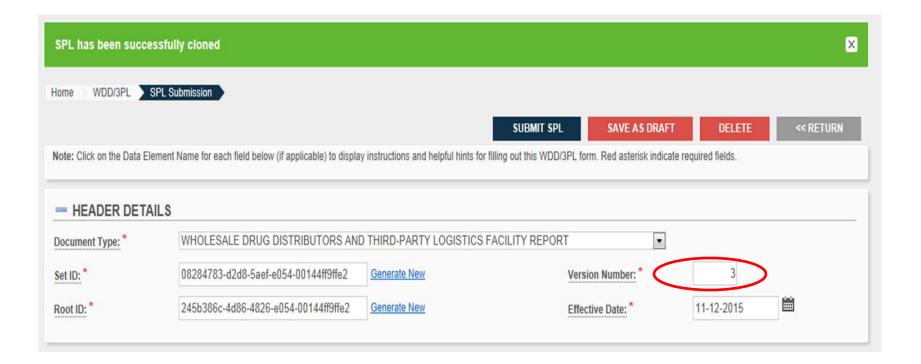
- Log into CDER Direct Account
- Go to last "Submission Accepted" and open it





- Click "Create New Version"





- A new version will be auto-generated
- Click "Submit SPL" to submit with no changes



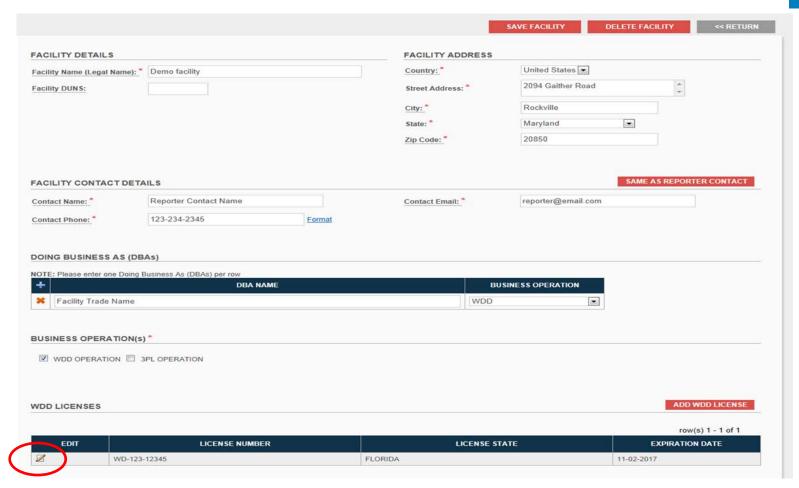
How to Resubmit <u>with</u> Changes: Update Facility Information Update License Expiration Dates



Document Type: *	WHOLESALE DRUG DISTR	BUTORS AND THIRD-PARTY LOGIS	STICS FACILITY REPORT	•	
Set ID: *	08284783-d2d8-5aef-e054-0	0144ff9ffe2 <u>Generate New</u>	Version Number: *	3	
Root ID: *	245b386c-4d86-4826-e054-0	0144ff9ffe2 Generate New	Effective Date: *	11-12-2015	ä
REPORTER DETAI	LS				
Reporter Organization Name:	* Reporter Name				
Reporter Organization DUNS	* 123423423				
REPORTER CONTACT PE	ERSON DETAILS				
Contact Person Name: *	Reporter Contact Name				
Contact Person Email: *	reporter@email.com				
Contact Person Phone: *	123-234-2345	Format			
- FACILITIES					ADD FACILITY
					row(s) 1 - 1 of 1
F	ACILITY DUNS	FACILITY NAME	FACILITY CITY	FACILITY	STATE
	-	emo facility	Rockville	MD	

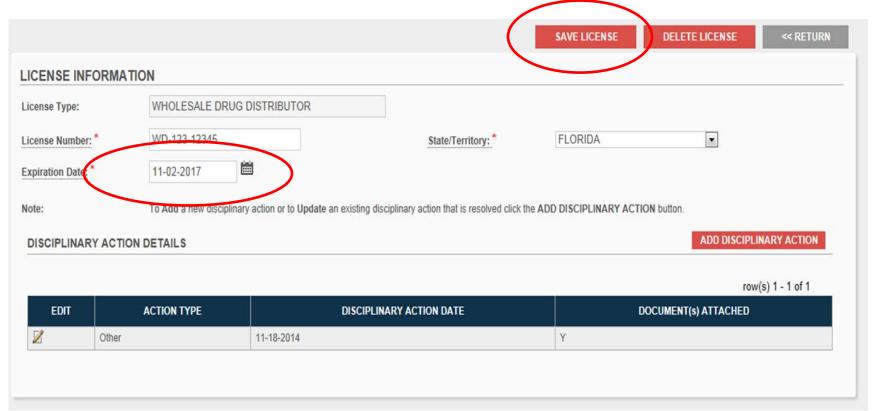
- Click on edit pencil to make changes to that facility





- Update facility information
- Click pencil of license to be updated





- Change expiration date
- Click "Save License"

- Submit SPL



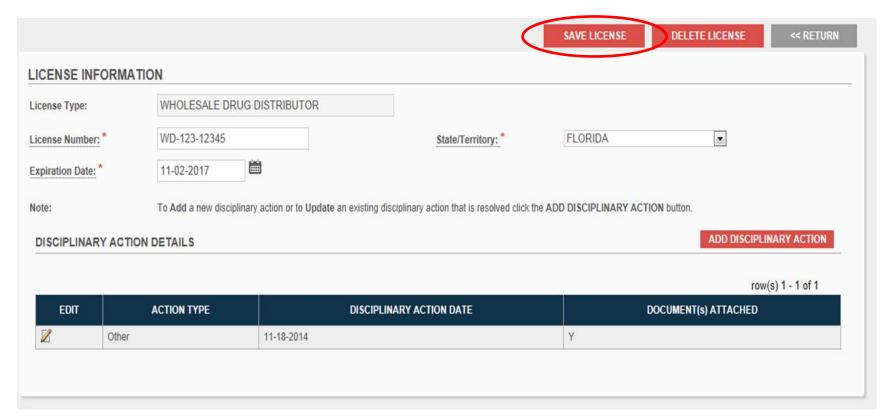
How to Resubmit with Changes: Adding New Licenses Deleting Licenses



ACILITY DETAILS			FACILITY ADDRESS		
Facility Name (Legal Name): Demo facility		Country: United States			
	me): Demo facility		Street Address: *	2094 Gaither Road	
Facility DUNS:					Ç
			City: *	Rockville	
			State: *	Maryland	
			Zip Code: *	20850	
ACILITY CONTACT	DETAILS				SAME AS REPORTER CONTACT
Contact Name: *	Reporter Contact Name		Contact Email: *	reporter@email.com	
Contact Phone: *	123-234-2345	Format			
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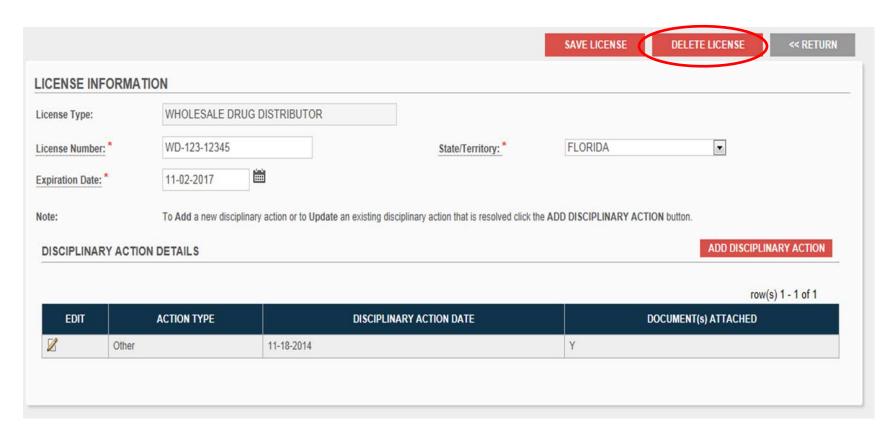
- Click "Add License"





- Add license information
- Click "Save License" when finished



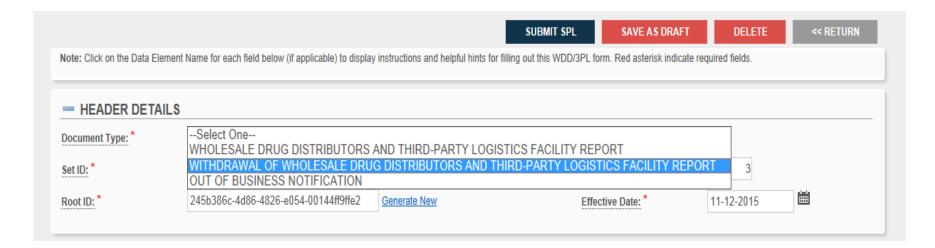


- To delete license: click "Delete License"



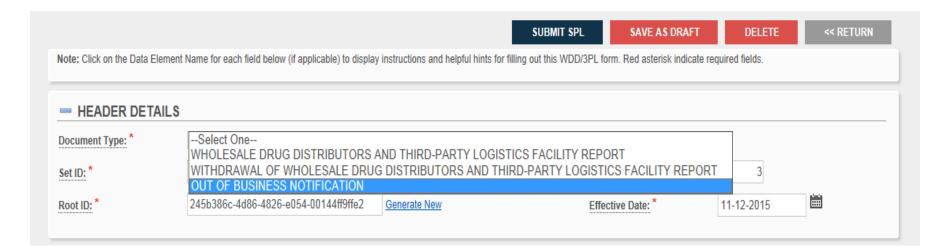
New Features: How to Eliminate All Facilities How to Report "Going Out of Business"





- Select "Withdrawal of Wholesale Drug Distributor and Third-Party Logistics Facility Report"
- Submit the SPL



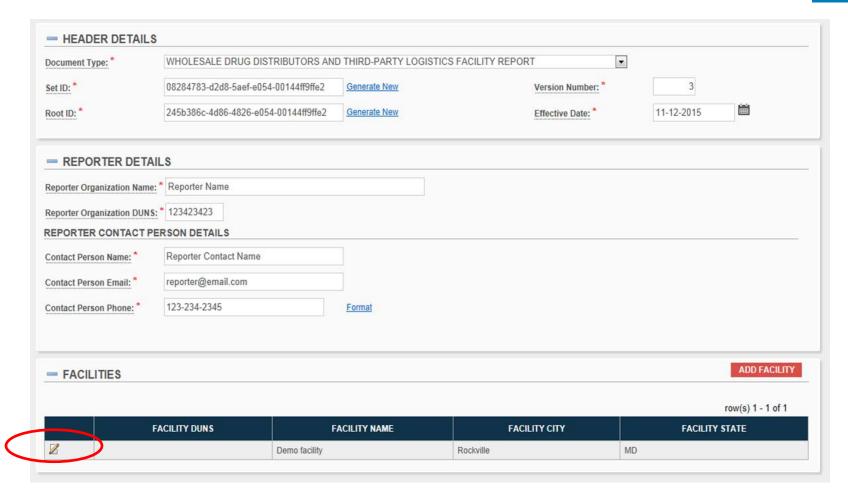


- Select "Out of Business Notification"
- Submit the SPL



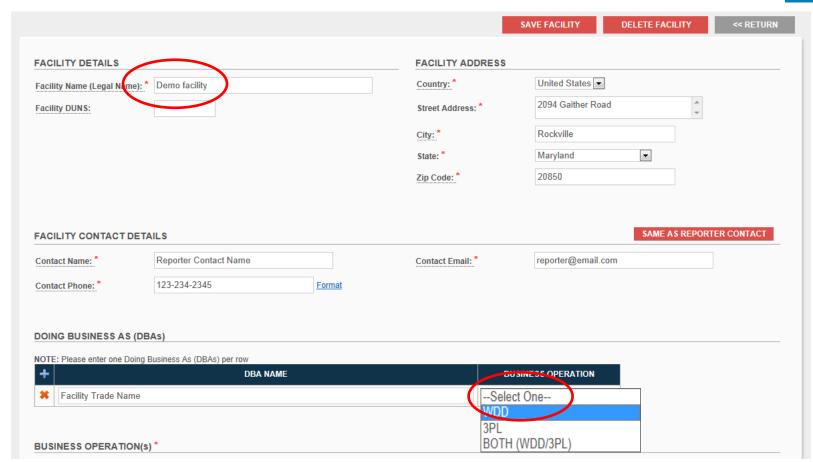
New Features: How to Enter Doing Business As (DBAs)





- Click on edit pencil to make changes to that facility



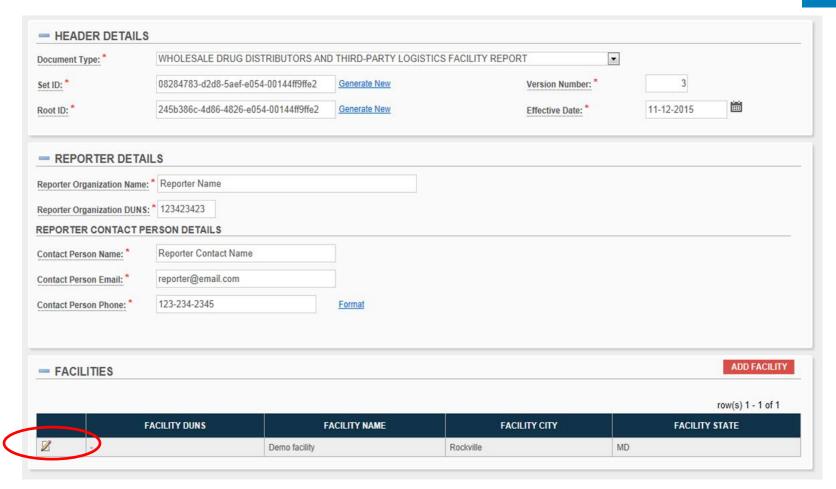


- Enter facility DBA name
- Select corresponding business operation



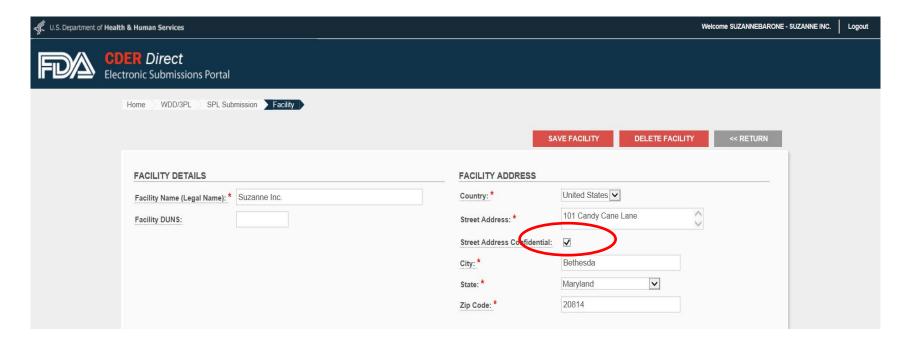
New Features: Street Address Confidential





- Click on edit pencil to make changes to that facility





- Check Street Address Confidential box
- Click "Save Facility"





Do I need to update my expired licenses <u>outside</u> of the reporting timeframe?

Reporting is <u>not</u> required outside of the reporting period of **January 1st** - **March 31st** <u>except</u> to report going out of business or disciplinary actions. We do request that companies correct errors in the submission. Since the data is public, a company may want to update expired licenses outside of the reporting period.



Can I make changes at any time?

Yes, CDER Direct is always available to make corrections.

I added or updated my information, when should it appear in the public database?

The updated information should appear in the public database on the next business day <u>after</u> the submission is accepted depending on the time of day.



Why can't I change my submission?

It is not possible to change an accepted submission.

In order to add additional information or correct information, follow these steps:

- 1. Log into CDER Direct account
- 2. Choose the last Submission Accepted and open it
- 3. Click on Create New Version (the version number should increase by
- 1). The form will now be active.
- 4. Add or correct the information, save and resubmit



Where do I get more information?

Log on to CDER Direct: direct.fda.gov

- IE version 8 and above
- Firefox version 28 and above
- Chrome version 44.0.2403.130

Help Desk: CDERdirect@fda.hhs.gov

Inquires: WDD3PLRequirements@fda.hhs.gov

