



**CDER** *Direct*

Electronic Submissions Portal

[direct.fda.gov](https://direct.fda.gov)

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

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- **CDER Direct** Refresher

## Part II

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- Adding & Deleting Licenses
- Withdraw Submission
- Going Out of Business
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# 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 1<sup>st</sup> – March 31<sup>st</sup>** 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

**WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT**

GO
ACTIONS ▾
CREATE NEW

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
<a href="#">SUBMISSION ACCEPTED</a>	08284783-d2d8-5aef-e054-00144ff9fe2	08276ace-bc2e-4ca1-e054-00144ff9fe2	cd2857936401.2789056341@direct	2	WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT	Bindu Admin	11-18-2014 15:24:19	-
<a href="#">SUBMISSION ACCEPTED</a>	08284783-d2d8-5aef-e054-00144ff9fe2	08284783-d2d9-5aef-e054-00144ff9fe2	cd5301642897.4512367809@direct	1	WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT	Bindu Admin	11-18-2014 15:10:19	-

1 - 2

- Log into **CDER Direct** Account
- Go to last “Submission Accepted” and open it

Home > WDD/3PL > SPL Submission

[VIEW SPL](#)
[DOWNLOAD SPL](#)
[CREATE NEW VERSION](#)
[<< RETURN](#)

Note: Click on the Data Element Name for each field below (if applicable) to display instructions and helpful hints for filling out this WDD/3PL form. Red asterisk indicate required fields.

**— HEADER DETAILS**

<u>Document Type:</u> *	<input type="text" value="WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT"/>		
<u>Set ID:</u> *	<input type="text" value="08284783-d2d8-5aef-e054-00144ff9fe2"/>	<u>Version Number:</u> *	<input type="text" value="2"/>
<u>Root ID:</u> *	<input type="text" value="08276ace-bc2e-4ca1-e054-00144ff9fe2"/>	<u>Effective Date:</u> *	<input type="text" value="11-18-2014"/>

- Click “Create New Version”



SPL has been successfully cloned X

Home > WDD/3PL > **SPL Submission**

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

Note: Click on the Data Element Name for each field below (if applicable) to display instructions and helpful hints for filling out this WDD/3PL form. Red asterisk indicate required fields.

**— HEADER DETAILS**

Document Type: *	WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT	
Set ID: *	08284783-d2d8-5aef-e054-00144ff9fe2 <a href="#">Generate New</a>	Version Number: * <span style="border: 2px solid red; border-radius: 50%; padding: 2px;">3</span>
Root ID: *	245b386c-4d86-4826-e054-00144ff9fe2 <a href="#">Generate New</a>	Effective Date: * 11-12-2015

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



***How to Resubmit with Changes:  
Update Facility Information  
Update License Expiration Dates***

**HEADER DETAILS**

Document Type: \* WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT

Set ID: \* 08284783-d2d8-5aef-e054-00144ff9ffe2 [Generate New](#) Version Number: \* 3

Root ID: \* 245b386c-4d86-4826-e054-00144ff9ffe2 [Generate New](#) Effective Date: \* 11-12-2015

**REPORTER DETAILS**

Reporter Organization Name: \* Reporter Name

Reporter Organization DUNS: \* 123423423

**REPORTER CONTACT PERSON 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

	FACILITY DUNS	FACILITY NAME	FACILITY CITY	FACILITY STATE
		Demo facility	Rockville	MD

- Click on edit pencil to make changes to that facility

[SAVE FACILITY](#) [DELETE FACILITY](#) [<< RETURN](#)

---

**FACILITY DETAILS**

Facility Name (Legal Name):\* Demo facility  
Facility DUNS:

**FACILITY ADDRESS**

Country:\* United States  
Street Address:\* 2094 Gaither Road  
City:\* Rockville  
State:\* Maryland  
Zip Code:\* 20850

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**FACILITY 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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**DOING BUSINESS AS (DBAs)**

NOTE: Please enter one Doing Business As (DBAs) per row

	DBA NAME	BUSINESS OPERATION
	Facility Trade Name	WDD

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**BUSINESS OPERATION(s)\***

WDD OPERATION  3PL OPERATION

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**WDD LICENSES** [ADD WDD LICENSE](#)

row(s) 1 - 1 of 1

EDIT	LICENSE NUMBER	LICENSE STATE	EXPIRATION DATE
	WD-123-12345	FLORIDA	11-02-2017

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

**SAVE LICENSE** **DELETE LICENSE** << RETURN

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**LICENSE INFORMATION**

License Type:

License Number: \*  State/Territory: \*

Expiration Date: \*

Note: To Add a new disciplinary action or to Update an existing disciplinary action that is resolved click the **ADD DISCIPLINARY ACTION** button.

**DISCIPLINARY ACTION DETAILS** **ADD DISCIPLINARY ACTION**

row(s) 1 - 1 of 1

EDIT	ACTION TYPE	DISCIPLINARY ACTION DATE	DOCUMENT(s) ATTACHED
	Other	11-18-2014	Y

- Change expiration date
- Click "Save License"
- Submit SPL



# ***How to Resubmit with Changes: Adding New Licenses Deleting Licenses***

[SAVE FACILITY](#) [DELETE FACILITY](#) [<< RETURN](#)

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**FACILITY DETAILS**

Facility Name (Legal Name):\*

Facility DUNS:

**FACILITY ADDRESS**

Country:\*

Street Address:\*

City:\*

State:\*

Zip Code:\*

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**FACILITY CONTACT DETAILS** [SAME AS REPORTER CONTACT](#)

Contact Name:\*

Contact Email:\*

Contact Phone:\*  [Format](#)

---

**DOING BUSINESS AS (DBAs)**

NOTE: Please enter one Doing Business As (DBAs) per row

	DBA NAME	BUSINESS OPERATION
	<input type="text" value="Facility Trade Name"/>	<input type="text" value="WDD"/>

---

**BUSINESS OPERATION(s) \***

WDD OPERATION  3PL OPERATION

---

**WDD LICENSES** [ADD WDD LICENSE](#)

row(s) 1 - 1 of 1

EDIT	LICENSE NUMBER	LICENSE STATE	EXPIRATION DATE
	WD-123-12345	FLORIDA	11-02-2017

- Click "Add License"

**SAVE LICENSE** **DELETE LICENSE** << RETURN

---

**LICENSE INFORMATION**

License Type:

License Number: \*  State/Territory: \*

Expiration Date: \*

Note: To Add a new disciplinary action or to Update an existing disciplinary action that is resolved click the ADD DISCIPLINARY ACTION button.

**ADD DISCIPLINARY ACTION**

---

row(s) 1 - 1 of 1

EDIT	ACTION TYPE	DISCIPLINARY ACTION DATE	DOCUMENT(S) ATTACHED
	Other	11-18-2014	Y

- Add license information
- Click “Save License” when finished



[SAVE LICENSE](#) [DELETE LICENSE](#) [<< RETURN](#)

### LICENSE INFORMATION

License Type:

License Number:  State/Territory:

Expiration Date:

Note: To Add a new disciplinary action or to Update an existing disciplinary action that is resolved click the ADD DISCIPLINARY ACTION button.

[ADD DISCIPLINARY ACTION](#)

### DISCIPLINARY ACTION DETAILS

row(s) 1 - 1 of 1

EDIT	ACTION TYPE	DISCIPLINARY ACTION DATE	DOCUMENT(s) ATTACHED
	Other	11-18-2014	Y

- To delete license: click “Delete License”




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

[SUBMIT SPL](#) [SAVE AS DRAFT](#) [DELETE](#) [<< RETURN](#)

**Note:** Click on the Data Element Name for each field below (if applicable) to display instructions and helpful hints for filling out this WDD/3PL form. Red asterisk indicate required fields.

**— HEADER DETAILS**

<b>Document Type:</b> *	--Select One-- WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT <b>WITHDRAWAL OF WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT</b> OUT OF BUSINESS NOTIFICATION		
<b>Set ID:</b> *			3
<b>Root ID:</b> *	245b386c-4d86-4826-e054-00144ff9ffe2 <a href="#">Generate New</a>	<b>Effective Date:</b> *	11-12-2015 

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

SUBMIT SPL

SAVE AS DRAFT

DELETE

<< RETURN

Note: Click on the Data Element Name for each field below (if applicable) to display instructions and helpful hints for filling out this WDD/3PL form. Red asterisk indicate required fields.

— HEADER DETAILS

Document Type: \*

--Select One--  
WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT  
WITHDRAWAL OF WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT  
**OUT OF BUSINESS NOTIFICATION**

3

Set ID: \*

Root ID: \*

245b386c-4d86-4826-e054-00144ff9ffe2

[Generate New](#)

Effective Date: \*

11-12-2015



- Select “Out of Business Notification”
- Submit the SPL



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

**HEADER DETAILS**

Document Type: \*

Set ID: \*  [Generate New](#) Version Number: \*

Root ID: \*  [Generate New](#) Effective Date: \*

**REPORTER DETAILS**

Reporter Organization Name: \*

Reporter Organization DUNS: \*

**REPORTER CONTACT PERSON DETAILS**

Contact Person Name: \*

Contact Person Email: \*

Contact Person Phone: \*  [Format](#)

**FACILITIES** [ADD FACILITY](#)

row(s) 1 - 1 of 1

	FACILITY DUNS	FACILITY NAME	FACILITY CITY	FACILITY STATE
		Demo facility	Rockville	MD

- Click on edit pencil to make changes to that facility

**SAVE FACILITY**   **DELETE FACILITY**   << RETURN

---

**FACILITY DETAILS**

Facility Name (Legal Name): \*

Facility DUNS:

**FACILITY ADDRESS**

Country: \*

Street Address: \*

City: \*

State: \*

Zip Code: \*

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**FACILITY CONTACT DETAILS** **SAME AS REPORTER CONTACT**

Contact Name: \*       Contact Email: \*

Contact Phone: \*  [Format](#)

---

**DOING BUSINESS AS (DBAs)**

NOTE: Please enter one Doing Business As (DBAs) per row

	DBA NAME	BUSINESS OPERATION
	<input type="text" value="Facility Trade Name"/>	<input type="text" value="--Select One--"/>

BUSINESS OPERATION(s) \*

- Enter facility DBA name
- Select corresponding business operation



# ***New Features: Street Address Confidential***



**HEADER DETAILS**

Document Type: \* WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT

Set ID: \* 08284783-d2d8-5aef-e054-00144ff9ffe2 [Generate New](#) Version Number: \* 3

Root ID: \* 245b386c-4d86-4826-e054-00144ff9ffe2 [Generate New](#) Effective Date: \* 11-12-2015

**REPORTER DETAILS**

Reporter Organization Name: \* Reporter Name

Reporter Organization DUNS: \* 123423423

**REPORTER CONTACT PERSON 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

	FACILITY DUNS	FACILITY NAME	FACILITY CITY	FACILITY STATE
		Demo facility	Rockville	MD

- Click on edit pencil to make changes to that facility

[SAVE FACILITY](#) [DELETE FACILITY](#) [<< RETURN](#)

**FACILITY DETAILS**

Facility Name (Legal Name):\*   
Facility DUNS:

**FACILITY ADDRESS**

Country:\*   
Street Address:\*   
Street Address Confidential:   
City:\*   
State:\*   
Zip Code:\*

- Check Street Address Confidential box
- Click “Save Facility”



# *FAQs*



## FAQs

**Do I need to update my expired licenses outside of the reporting timeframe?**

Reporting is not required outside of the reporting period of **January 1<sup>st</sup> - March 31<sup>st</sup>** except 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.



## FAQs

### **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 after the submission is accepted depending on the time of day.

# FAQs

## 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](http://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](mailto:CDERdirect@fda.hhs.gov)

Inquires: [WDD3PLRequirements@fda.hhs.gov](mailto:WDD3PLRequirements@fda.hhs.gov)

