



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

- FAQs
- 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 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/DrugSupplyC hainSecurityAct/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

LOGIN	Tutorials		QUICK LINKS
Username:	Complete User Guide		Create Account
Password:			Resources
Password.	CDER Direct Webinar		Tutorials
Under 18 U.S.C. 1001, anyone who makes a material			Help Desk
I Understand	QUICK START GUIDES		FAQs
	CDER Direct Overview		
LOGIN Forgot your password?	CDER Direct Application		
	Establishment Registration	=	
	GDUFA Self-Identification		
GETTING STARTED	NDC/NHRIC Labeler Code Request	· · · · · · · · · · · · · · · · · · ·	NOTIFICATIONS
To make submissions to FDA (e.g., Establishment Reg	Product Listing and Reporting	ccount.	07-JUL-15 Coming Soon Changes to Compounde
If you already have an account, enter your Username			Drug Label Form
WARNING: You are accessing a U.S. Government info	Compounder Reporting	e of the system is	
prohibited and subject to criminal and civil penalties. U monitoring and is advised that if such monitoring revea	Wholesale Drug Distributors and Third-Party Logistics Facility Reporting	sents to such cement officials.	
Is your computer secure? Before using FDA's Direct.	Updating Submissions	▼ pur computer to	
help ensure the privacy of the information being entered.		jui computer to	



# **How to Resubmit**

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

#### WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT R **CREATE NEW** GO **ACTIONS** V W Row text contains '08284783-d2d8-5aef-e054-00144ff9ffe2' V 🏹 Ξ DOCUMENT LAST MODIFIED LAST MODIFIED -**STATUS** SET ID **ROOT ID** VERSION SUBMISSION ID LABEL USER DATE WHOLESALE DRUG DISTRIBUTORS AND SUBMISSION 08284783-d2d8-5aef 08276ace-bc2e-4ca1cd2857936401.278905634 2 THIRD-PARTY LOGISTICS FACILITY Bindu Admin 11-18-2014 15:24:19 ACCEPTED -e054-00144ff9ffe2 e054-00144ff9ffe2 1@direct REPORT WHOLESALE DRUG DISTRIBUTORS AND SUBMISSION 08284783-d2d8-5aef 08284783-d2d9-5aef-e cd5301642897.451236780 THIRD-PARTY LOGISTICS FACILITY Bindu Admin 11-18-2014 15:10:19 ACCEPTED -e054-00144ff9ffe2 054-00144ff9ffe2 9@direct REPORT 1-2

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

VIEW SPL D	OWNLOAD SPL	CRE	EATE NEW VERSION 🔰 « RETUR
te: Click on the Data Ele	ement Name for each field below (if applicable) to display instructions and helpful	hints for filling out this WDD/3PL form. Red asterisk indica	ate required fields.
HEADER DETA	ILS		
	WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGI	STICS FACILITY REPORT	
HEADER DETA ocument Type: * et ID: *		STICS FACILITY REPORT	2

- Click "Create New Version"



SPL has been success	fully cloned			×
Home WDD/3PL SP	L Submission			
			SUBMIT SPL SAVE AS DRAFT DELETE << R	ETURN
Note: Click on the Data Elem	ent Name for each field below (if applicable) to displa	y instructions and helpful hints for t	filling out this WDD/3PL form. Red asterisk indicate required fields.	
- HEADER DETAIL	.s			
Document Type: *	WHOLESALE DRUG DISTRIBUTORS AND	O THIRD-PARTY LOGISTICS F	ACILITY 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	

- 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

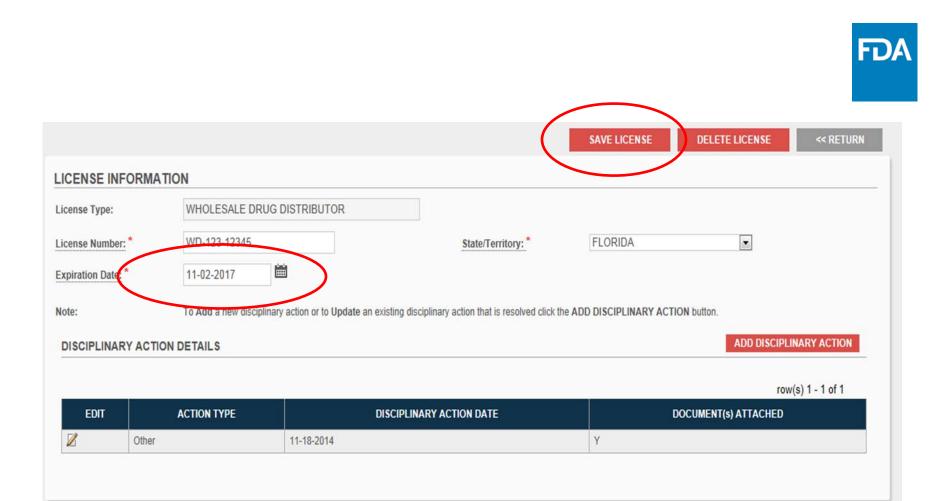
Document Type: *	WHOLESALE DRUG DISTRIBUTORS AN	D THIRD-PARTY LOGISTI	CS FACILITY REPORT	•
Set ID: *	08284783-d2d8-5aef-e054-00144ff9ffe2	Generate New	Version Number: *	3
Root ID: *	245b386c-4d86-4826-e054-00144ff9ffe2	Generate New	Effective Date: *	11-12-2015
- REPORTER DETAIL	.\$			
Reporter Organization Name: *	Reporter Name			
Reporter Organization DUNS: *	123423423			
REPORTER CONTACT PER	RSON DETAILS			
Contact Person Name: *	Reporter Contact Name			
Contact Person Email: *	reporter@email.com			
Contact Person Phone: *	123-234-2345	Format		
- FACILITIES				ADD FACIL
				row(s) 1 - 1 of
	CILITY DUNS	ACILITY NAME	FACILITY CITY	FACILITY STATE

- Click on edit pencil to make changes to that facility

	DA
-	

			SAVE FACILITY DE	LETE FACILITY	<< RETUR
ACILITY DETAILS		FACILITY ADDRE	SS		
acility Name (Legal Name)	Demo facility	Country: *	United States 💌		
acility DUNS:		Street Address: *	2094 Gaither Road	÷.	
		City: *	Rockville		
		State: *	Maryland		
		Zip Code: *	20850		
ACILITY CONTACT DE	TAILS			SAME AS REPORTE	R CONTACT
ontact Name: *	Reporter Contact Name	Contact Email: *	reporter@email.com		
ontact Phone:	123-234-2345 Format				
DTE: Please enter one Doin	ng Business As (DBAs) per row DBA NAME		BUSINESS OPERATION		
Facility Trade Name	Ê.	W	DD		
USINESS OPERATION	i(s) *				
WDD OPERATION	3PL OPERATION				
DD LICENSES				ADD W	DD LICENSE
EDIT	LICENSE NUMBER	LICEN	SE STATE	row(s	) 1 - 1 of 1 DATE
and the second				11-02-2017	
WD-1	23-12345	FLORIDA		11-02	2-2017

- 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

	7A T

				SAVE FACILITY	DELETE FACILITY	<< RETURI
ACILITY DETAILS			FACILITY ADDRESS			
acility Name (Legal Name):	Demo facility		Country: *	United States 💌		
acility DUNS:			Street Address: *	2094 Gaither Road	÷.	
			City: *	Rockville		
			State: *	Maryland		
			Zip Code: *	20850		
ACILITY CONTACT DET					SAME AS REPOR	TER CONTACT
ontact Name: *	Reporter Contact Name		Contact Email: *	reporter@email.com	m	
ontact Phone: *	123-234-2345	Format				
OTE: Please enter one Doing	Business As (DBAs) per row DBA NAME		E	BUSINESS OPERATION		
Facility Trade Name			WDD		6	
USINESS OPERATION(S	;) *					
WDD OPERATION	3PL OPERATION					
					400	
DD LICENSES					ADD	WODLICENSE
						WDD LICENSE
					row	wDD LICENSE
EDIT WD-123	LICENSE NUMBER		LICENSE	STATE	EXPIRATIO	v(s) 1 - 1 of 1

- Click "Add License"



			(	SAVE LICENSE	DELETE LICENSE << RETUR
ICENSE INF	ORMATION				
icense Type:	WHOLESALE	DRUG DISTRIBUTOR			
icense Number:	* WD-123-1234	5	State/Territory: *	FLORIDA	•
	* 44.00.0047				
Expiration Date:	* 11-02-2017				
Expiration Date:			ng disciplinary action that is resolved click	the ADD DISCIPLINARY ACT	FION button.
Note:			ng disciplinary action that is resolved click	the ADD DISCIPLINARY ACT	FION button. ADD DISCIPLINARY ACTION
Note:	To Add a new di		ng disciplinary action that is resolved click	the ADD DISCIPLINARY ACT	
Note:	To Add a new di	sciplinary action or to Update an existi	ng disciplinary action that is resolved click		ADD DISCIPLINARY ACTION

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



				SAVE LICENSE	DELETE LICENSE << RETU
CENSE INF	ORMATION				
ense Type:	WHOLESALE D	ORUG DISTRIBUTOR			
cense Number	* WD-123-12345		State/Territory: *	FLORIDA	
piration Date:	* 11-02-2017	i			
ote:	To Add a new disc	ciplinary action or to Update an existing	disciplinary action that is resolved click t	he ADD DISCIPLINARY ACTIO	N button
DISCIPLINAR	Y ACTION DETAILS				ADD DISCIPLINARY ACTION
DISCIPLINAR	ACTION DETAILS	DISCI	PLINARY ACTION DATE		

### - 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 Ele	ement Name for each field below (if applicable) to display	instructions and helpful hints for f	illing out this WDD/3PL for	m. Red asterisk indicate re	quired fields.	
- HEADER DETA	ILS					
Document Type: *	Select One WHOLESALE DRUG DISTRIBUTORS	AND THIRD-PARTY LOGIS	TICS FACILITY REP	ORT		
Set ID: *	WITHDRAWAL OF WHOLESALE DRU OUT OF BUSINESS NOTIFICATION	G DISTRIBUTORS AND TH	IRD-PARTY LOGIST	ICS FACILITY REPOR	RT 3	
Root ID: *	245b386c-4d86-4826-e054-00144ff9ffe2	Generate New	Effec	tive Date: *	11-12-2015	
		_				

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

- Submit the SPL





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 DETA	ILS				
Document Type: *	Select One WHOLESALE DRUG DISTRIBUTORS /	AND THIRD-PARTY LOGIS	TICS FACILITY REPORT		
Set ID: *	WITHDRAWAL OF WHOLESALE DRUG	G DISTRIBUTORS AND TH	IRD-PARTY LOGISTICS FACILITY REPO	DRT 3	
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)

F	ACILITY DUNS	FACILITY NAME	FACILITY CITY	FACILITY	STATE
					row(s) 1 - 1 of 1
FACILITIES					ADD FACILIT
Contact Person Phone: *	123-234-2345	Format			
Contact Person Email: *	reporter@email.com				
Contact Person Name: *	Reporter Contact Name				
REPORTER CONTACT PE	RSON DETAILS				
Reporter Organization DUNS	* 123423423				
eporter Organization Name:	* Reporter Name				
REPORTER DETA	LS				
Root ID: *	245b386c-4d86-4826-e054	-00144ff9ffe2 <u>Generate New</u>	Effective Date: *	11-12-2015	Ē
Set ID: *	08284783-d2d8-5aef-e054		Version Number: *	3	100
ocument Type: *			72		
Do num ant Tunas	WHOLESALE DDUC DIST	<b>RIBUTORS AND THIRD-PARTY LO</b>	CISTICS EACH ITY DEDODT		

### - Click on edit pencil to make changes to that facility



			SAVE FACILITY	DELETE FACILITY	<< RETURN
FACILITY DETAILS	$\frown$	FACILITY ADDRESS	6		
Facility Name (Legal Num	e):* Demo facility	Country: *	United States -	]	
Facility DUNS:		Street Address: *	2094 Gaither Ro	ad 🔶	
		City: *	Rockville		
		State: *	Maryland	•	
		Zip Code: *	20850		
FACILITY CONTACT D	ETAILS			SAME AS REPOR	TER CONTACT
Contact Name: *	Reporter Contact Name	Contact Email: *	reporter@email.	com	]
Contact Phone: *	123-234-2345 Format				
DOING BUSINESS AS	(DBAs)				
NOTE: Please enter one Do	ng Business As (DBAs) per row				
+	DBA NAME		BUSINESS OPERATION		
Facility Trade Name			lect One		
		3PL			
BUSINESS OPERATIO	N(s) *		TH (WDD/3PL)		

- Enter facility DBA name
- Select corresponding business operation



# New Features: Street Address Confidential

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 DETAIL	S				
Reporter Organization Name: *	Reporter Name				
Reporter Organization DUNS: *	123423423				
REPORTER CONTACT PER	SON DETAILS				
Contact Person Name: *	Reporter Contact Name				
Contact Person Email: *	reporter@email.com				
Contact Person Phone: *	123-234-2345	Format			
- FACILITIES				ADD FACIL	
				row(s) 1 - 1 of	
	CILITY DUNS F	ACILITY NAME	FACILITY CITY	FACILITY STATE	

- Click on edit pencil to make changes to that facility



🖑 U.S. Department of	Health & Human Services			Welcome SUZANNEBARONE - SUZANNE INC.	Logout
FD/A	CDER Direct Electronic Submissions Portal				
	Home WDD/3PL SPL Submission Facility				
		Sa	VE FACILITY DELETE FACILITY	<pre>&lt;&lt; RETURN</pre>	
			DELETETAGETT	SK RETOKN	
	FACILITY DETAILS	FACILITY ADDRESS			
	Facility Name (Legal Name): * Suzanne Inc.	Country: *	United States		
	Facility DUNS:	Street Address: *	101 Candy Cane Lane	0	
		Street Address Confidential:			
		City: *	Bethesda		
		State: *	Maryland 🗸		
		Zip Code: *	20814		

- 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 1<sup>st</sup> -March 31<sup>st</sup> <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.



# **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 <u>after</u> 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: <u>direct.fda.gov</u>

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

Help Desk: <u>CDERdirect@fda.hhs.gov</u>

Inquires: <u>WDD3PLRequirements@fda.hhs.gov</u>

