



CDER *Direct*

Electronic Submissions Portal

**CDER Direct –
Wholesale Drug Distributors and
Third Party Logistics Facility
Report (WDD/3PL)**

Helpful Hints

- To get access to the form:
 - Create a CDER Direct account or if you already have an account, log in as an Administrator
 - Click on Edit Profile on the left hand side
 - Check the box next to the WDD/3PL Document Type

WDD/3PL

FORM ACCESS

Labeler Code Request/Activation

NDC/NHRIC LABELER CODE REQUEST

Establishment Annual Registration

ESTABLISHMENT REGISTRATION

GDUFA Facility Self-Identification

GENERIC DRUG FACILITY IDENTIFICATION SUBMISSION

WDD/3PL

WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT

Product Listings

- BLANKET NO CHANGES CERTIFICATION OF
- BULK INGREDIENT
- CELLULAR THERAPY
- DRUG FOR FURTHER PROCESSING
- HUMAN COMPOUNDED DRUG LABEL
- HUMAN OTC DRUG LABEL
- HUMAN PRESCRIPTION DRUG LABEL
- NON-STANDARDIZED ALLERGENIC LABEL
- PLASMA DERIVATIVE
- STANDARDIZED ALLERGENIC
- VACCINE LABEL

SUBMIT

CANCEL

CDER Direct: direct.fda.gov

WDD/3PL



CDER Direct

Electronic Submissions Portal

Home

WDD/3PL

SUBMISSIONS

NDC Labeler Code Request


Establishment Registration

GDUFA Self-Identification

Product Listing and Reporting

WDD/3PL

WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT



None

Click here to begin new registration

CDER Direct: direct.fda.gov

WDD/3PL



CDER Direct

Electronic Submissions Portal

SUBMISSIONS

NDC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

Product Listing and Reporting

WDD/3PL

CREATE NEW WDD/3PL

- Create a new WDD/3PL using a blank form
- Import an existing WDD/3PL SPL

Note: To update an existing submission, click on Cancel and select a submission with the status SUBMISSION ACCEPTED from the table in the prior page / Dashboard.

CONTINUE

CANCEL

Click here to create a new SPL

Click here to upload previously created SPL

CDER Direct: direct.fda.gov

WDD/3PL

Home > WDD/3PL > SPL Submission

SUBMIT SPL

SAVE AS DRAFT

DELETE

<< RETURN

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

HEADER DETAILS

<u>Document Type:</u> *	WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT ▾		
<u>Set ID:</u> *	<input type="text" value="08611985-4ea2-4892-e054-00144ff8a759"/> Generate New	<u>Version Number:</u> *	<input type="text" value="1"/>
<u>Root ID:</u> *	<input type="text" value="08611985-4ea3-4892-e054-00144ff8a759"/> Generate New	<u>Effective Date:</u> *	<input type="text" value="11-21-2014"/> 

WDD/3PL

REPORTER DETAILS

Reporter Organization Name: * Reporter Name

Reporter Organization DUNS: * 123456789

REPORTER CONTACT PERSON DETAILS

Contact Person Name: * John Doe

Contact Person Email: * John.Doe@gmail.com

Contact Person Phone: * 1-233-123-1231

[Format](#)

Phone Extension: 234

WDD/3PL

REPORTER CONTACT PERSON DETAILS

Contact Person Name: *

John Doe

Contact Person Email: *

john.doe@email.com

Contact Person Phone: *

222-222-2222

[Format](#)

FACILITIES

None

Click here to add a
facility

 [ADD FACILITY](#)

WDD/3PL

SAVE FACILITY

<< RETURN

FACILITY DETAILS

Facility Name (Legal Name): * XYZ Company

Facility DUNS: 999999999

FACILITY ADDRESS

Country: * United States ▼

Street Address: *

123 Road St.

City: *

Silver Spring

State: *

Maryland ▼

Zip Code: *

20852

WDD/3PL

DOING BUSINESS AS (DBAs)

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

+	DBA NAME	BUSINESS OPERATION OF DBA
✖		--Select One--
		--Select One--
		WDD
		3PL
		BOTH (WDD/3PL)

Click on the “+” button to add multiple DBA names

FACILITY CONTACT DETAILS

Contact Name: *

Contact Email: *

Contact Phone: * [Format](#)

Phone Extension:

REPORTER CONTACT

WDD/3PL

Click here to automatically fill out the Facility Contact Details if they are the same as the Reporter ContactDetails

FACILITY CONTACT DETAILS

SAME AS REPORTER CONTACT

Contact Name:*

Contact Email:*

Contact Phone:*

[Format](#)

Phone Extension:

BUSINESS OPERATION(S) OF FACILITY*

WDD OPERATION 3PL OPERATION

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WDD/3PL

BUSINESS OPERATION(S) OF FACILITY *

WDD OPERATION 3PL OPERATION

Click here to add a
WDD license



WDD LICENSES

ADD WDD LICENSE

SWITCH TO 3PL LICENSE

Enter wholesale distributor licenses.

Only enter DEA registration or state controlled-substance license if there is a significant disciplinary action.

Click here to add a 3PL
license



3PL LICENSES

ADD 3PL LICENSE

SWITCH TO WDD LICENSE

Enter 3PL licenses.

Only enter DEA registration or state controlled-substance license if there is a significant disciplinary action.


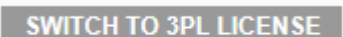
Helpful Hints

□ Business Operations

- Wholesale Drug Distribution (WDD)
 - *to indicate WDD as facility business operation, allows entry of WDD State License information*
- Third Party Logistics (3PL)
 - *to indicate 3PL as facility business operation, allows entry 3PL State License information, if available*

Helpful Hints

□ Business Operations

- If user enters a WDD License by mistake under the 3PL Business Operation, the user can switch the license to WDD License by clicking on 
- If user enters a 3PL License by mistake under the WDD Business Operation, the user can switch the license to 3PL License by clicking on 

Helpful Hints

□ Business Operations

- If one facility (at one address) performs both business operations (WDD and 3PL), do not enter the facility twice. Choose both business operations for the facility located at the same address.

WDD/3PL

Check here to indicate if this is a controlled substance license

SAVE LICENSE

DELETE LICENSE

<< RETURN

LICENSE INFORMATION

License Type: WHOLESALE DRUG DISTRIBUTOR

Controlled-substance license or permit:

License Number: * 12345b36

Issuer: * MARYLAND

Expiration Date: * 11-16-2017

State/Territory MARYLAND

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

None

ADD DISCIPLINARY ACTION

Click here to Add Disciplinary Action

WDD/3PL



CDER Direct
Electronic Submissions Portal

Home > WDD/3PL > SPL Submission > Facility > License

SAVE LICENSE

DELETE LICENSE

<< RETURN

LICENSE INFORMATION

License Type:

License Number: *

Expiration Date: *

Note:

DISCIPLINARY ACTION

None

Message from webpage



You must enter a disciplinary action associated with this controlled substances license.

OK

Controlled-substance license or permit:

Issuer: *

-Select State-

State/Territory

on that is resolved click the ADD DISCIPLINARY ACTION button.

ADD DISCIPLINARY ACTION

CDER Direct: direct.fda.gov

WDD/3PL

SAVE ACTION

<< RETURN

ACTION DETAILS

Action Type: *

-- Select Action --
-- Select Action --
Revoked
Suspended
Other
Resolved

Issuing Date: *



RELEVANT DOCUMENTS

Note:

Upload relevant documents related to disciplinary action in pdf form only. Browse for document then click **Add Document** button. The file should be named -.pdf

Document:

Browse...

ADD DOCUMENT

Click here to save Disciplinary Action information before returning to the previous screen

Click here to add a WDD Disciplinary Action Document, in pdf form only

WDD/3PL

Home > WDD/3PL > SPL Submission > Facility > License

Click here to save License information before returning to the previous screen

SAVE LICENSE

DELETE LICENSE

<< RETURN

LICENSE INFORMATION

License Type:

WHOLESALE DRUG DISTRIBUTOR

Controlled-substance license or permit:

License Number: *

00000000

Issuer: *

OHIO

Expiration Date: *

06-30-2018



State/Territory

OHIO

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
	Resolved	10-26-2017	Y

Helpful Hints

- *Note: To resolve a Disciplinary Action, please 'Add Disciplinary Action' and select 'Resolved' for Action Type*
- *Note: The process for adding License Information and Disciplinary Actions for 3PL is the same as it is for WDD. To avoid confusion screenshots from only one of these actions have been included here.*

WDD/3PL

License saved. X

Home > WDD/3PL > SPL Submission > Facility

SAVE FACILITY

DELETE FACILITY

<< RETURN

FACILITY DETAILS

Facility Name: *

XYZ Company

Facility DUNS:

999999999

FACILITY ADDRESS

Country: *

United States

Street Address: *

123 Road St.

City: *

Silver Spring

State: *

Maryland

Zip Code: *

20852

Click here to save Facility information
before returning to the previous screen

CDER Direct: direct.fda.gov

WDD/3PL

Facility saved. X

Home > WDD/3PL > SPL Submission

SUBMIT SPL

SAVE AS DRAFT

DELETE

<< RETURN

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

Please 'Save As Draft'
before Submitting SPL

— HEADER DETAILS

Document Type: *

WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT ▾

Set ID: *

08611985-4ea2-4892-e054-00144ff8a759

[Generate New](#)

Version Number: *

1

Root ID: *

08611985-4ea3-4892-e054-00144ff8a759

[Generate New](#)

Effective Date: *

11-21-2014



Helpful Hints

- To revise a previously submitted WDD/3PL SPL, please create a new version. You **cannot** edit an already submitted version.
- More information can be found in the 'Updating Successful Submissions' quick guide and the 'Complete User's Guide.'

Where do I get more information?

Log on to CDER Direct:

direct.fda.gov

Compatible with the following
browsers:

- Microsoft Edge
- Safari 10.0.1 and above
- Firefox version 28 and above
- Google Chrome

Help Desk: CDERdirect@fda.hhs.gov

WDD3PLRequirements@fda.hhs.gov