CDER Direct – GDUFA Self-Identification

GDUFA Self-Identification

CDER *Direct*
Electronic Submissions Portal

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SUBMISSIONS

NDC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

GDUFA FACILITY SELF-IDENTIFICATION

GO | ACTIONS | CREATE NEW

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	

Click here to begin new registration

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GDUFA Self-Identification

CREATE NEW GDUFA FACILITY SELF-IDENTIFICATION

○ Create New GDUFA Self-Identification using a blank form

○ Import an existing GDUFA Self-Identification SPL

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

CONTINUE   CANCEL

Click here to create SPL from scratch

Click here to upload previously created SPL

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SAVE AS DRAFT   **<< RETURN**

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

HEADER DETAILS

Document Type: *   GENERIC DRUG FACILITY IDENTIFICATION SUBMISSION
                    --Select One--
                    GENERIC DRUG FACILITY IDENTIFICATION SUBMISSION

Set ID: *   Version Number: *   1

Root ID: *   01260df0-39d1-0c16-e054-00144ffa2cc4   Generate New   Effective Date: *   08-21-2014

Please select the Self-ID form

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REGISTRANT DETAILS

Registrant Name: * [Registrant Company]

Registrant DUNS: * [123456789]

REGISTRANT CONTACT DETAILS

Contact Name: * [John Doe]

Contact Email: * [john.doe@gmail.com]

Contact Phone: * [222-222-2222]   Format

Phone Extension: [ ]

Contact Fax: [ ]

REGISTRANT CONTACT ADDRESS

Country: * [United States ▼]

Street Address: * [1234 Street]

City: * [Rockville]

State: * [Maryland ▼]

Postal Code: [ ]

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GDUFA Self-Identification

REGISTRANT CONTACT DETAILS

Contact Name: * John Doe

Contact Email: * john.doe@gmail.com

Contact Phone: * 222-222-2222   Format

Phone Extension:

Contact Fax:

REGISTRANT CONTACT ADDRESS

Country: * United States

Street Address: * 1234 Street

City: * Rockville

State: * Maryland

Postal Code:

FACILITIES   ADD FACILITY

Click here to add a facility

None

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Note: This is the contact information for the
Facility, not the Registrant

FACILITY CONTACT DETAILS

Contact Name: * Jane Doe

Contact Email: * jane.doe@gmail.com

Contact Phone: * 333-333-3333   Format

Phone Extension:

Contact Fax:

FACILITY CONTACT ADDRESS

Country: * United States

Street Address: * 444 Street

City: * Silver Spring

State: * Maryland

Postal Code:

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BUSINESS OPERATIONS

Note: Enter the one or more drug manufacturing and processing operations performed at the facility. Click on + button to select multiple business operations.

+	BUSINESS OPERATION	QUALIFIER
✖	--Select One-- ▼	--Select One-- ▼

--Select One--
API/FDF ANALYTICAL TESTING
FDF MANUFACTURE
CLINICAL BIOEQUIVALENCE OR BIOAVAILABILITY STUDY
IN VITRO BIOEQUIVALENCE OR BIOANALYTICAL TESTING
REPACK
API MANUFACTURE
PACK
POSITRON EMISSION TOMOGRAPHY DRUG PRODUCTION

Click on the "+" button to select multiple business operations.

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More than one Business Operation Qualifier can be entered for the Business Operations: FDF Manufacture and PACK.

BUSINESS OPERATIONS

Note: Enter the one or more drug manufacturing and processing operations performed at the facility. Click on + button to select multiple business operations.

+	BUSINESS OPERATION	QUALIFIER
✖	FDF MANUFACTURE ▾	CONTRACT MANUFACTURING ▾
✖	FDF MANUFACTURE ▾	MANUFACTURES NON-GENERICS ▾
		--Select One--
		CONTRACT MANUFACTURING
		MANUFACTURES NON-GENERICS

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

SAVE FACILITY   DELETE FACILITY   << RETURN

FACILITY DETAILS

Facility Name: * XYZ Drug Company

Facility DUNS: * 888888888

Facility FEI: * 1234566549

FACILITY ADDRESS

Country: * United States

Street Address: * 123 Road

City: * Silver Spring

State: * Maryland

Postal Code:

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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: <u>CDERdirect@fda.hhs.gov</u>
eDRLS Helpdesk: <u>edrls@fda.hhs.gov</u>

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