

CDER Direct: A New SPL Authoring Tool from FDA

*Paul Loebach, Lead Operations Research Analyst, Team Lead
Drug Registration And Listing System
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration*

CDERDirect URL: <https://direct.fda.gov>

What is CDER Direct?

- Web Based Electronic Registration and Listing Submissions
 - User Friendly data Entry Forms
 - Perform initial Validations
 - Creates and saves the SPL Submission
 - Submit to FDA for internal Processing
 - No SSL certificates needed
 - No ESG Account needed
 - Provide the FDA Response to the User

Why CDER Direct?

- Thousands of small firms do not have IT departments or specialists.
 - Many small companies assign non-technical Regulatory Affairs, MDs, new hires, etc... to do the dirty work of creating/maintaining Webtrader accounts and creating submitting SPL.
 - Some are forced to hire consultants to meet regulatory deadlines. (good for the consultants 😊)
- Lots of extra email traffic through the 3 SPL helpdesks: ESGHelpdesk, SPL, and eDRLS.
 - eDRLS@fda.hhs.gov gets 1000+ emails a month with a spike at the end of the year for re-registration.

Why CDER Direct?

- FDA's Xforms, although very successful, can be intimidating to the untrained eye and does not offer a lot of help text.
 - **CDER Direct** offers a more data entry form style of interface.
 - There is more help text available when populating the fields, and many validation error messages have been reworded to be more descriptive.
 - **CDER Direct** offers a submission status so you know when an SPL has made it through both the ESG and SPL Validation.
 - **CDER Direct** will not replace Xforms for those who are partial to XForms, or need it for document types not available in CDERDirect. FDA will continue to offer both.

CDER Direct: Account Creation

- Create Account with CDER Direct
 - Account Activation
 - Email is sent to user to activate Account
 - Password and Security Questions are setup
 - The user has Administrator Privileges
 - User can then create Sub-Accounts
 - Ability to grant Administrator / User access

CDER Direct: SPL Forms

- SPL Forms
 - Currently available:
 - Labeler Code Request/Update
 - Establishment Registration
 - Human Prescription Drug Label
 - Human OTC Drug Label
 - GDUFA Self ID
 - Future expansion to include other submissions

CDER Direct: Login Page

U.S. Department of Health & Human Services

FDA **CDER Direct**
Electronic Submissions Portal

LOGIN

Username:

Password:

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

I Understand.

[LOGIN](#) [Forgot your password?](#)

QUICK LINKS

- [Create Account](#)
- [FAQs](#)
- [Resources](#)
- [Tutorials](#)
- [Help Desk](#)

GETTING STARTED

To make submissions to FDA (e.g., Establishment Registration, Product Listing and Self-ID, etc.) you must first create an account. [Click here](#) to create a new account.

If you already have an account, enter your **Username** and **Password**.

WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording. Anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

Is your computer secure? Before using FDA's Direct system, FDA strongly encourages you to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

NOTIFICATIONS

Sep 18, 2013 **eDirect initiative kick-off**
The FDA has begun work on the electronic submissions portal, eDirect, to aid the industry with online submissions. The new portal...

Oct 17, 2013 **eDirect Architecture**
The portal's architecture has been completed as of Oct 17, 2013. The team is rapidly working on getting the system design completed...

Nov 22, 2013 **eDirect's Look 'n' Feel**
The portal's theme will be quickly redesigned to match FDA's latest theme developed for www.fda.gov. This would bring in consistency...

FDA [FDA Home](#) | [Browser Requirements](#) | [FAQs](#) | [Resources](#) | [Tutorials](#) | [Help Desk](#)
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CDER Direct: Activate Account

ACTIVATE ACCOUNT

Username must be at least 8 characters and no more than 32 characters. It can consist of any combination of capital and lowercase letters, numbers, a period, or an underscore ("_").

Username: *

Password must be at least 10 characters and no more than 32 characters. It must include a capital letter, a lowercase letter, a number, and a special character.

Password: *

Confirm Password: *

Select and answer security questions. If you forget your password, you will need to provide this information. [Show Answers](#)

Security Question 1: * --Select One--

Security Answer 1: *

Security Question 2: * --Select One--

Security Answer 2: *

Security Question 3: * --Select One--

Security Answer 3: *

SUBMIT

CANCEL

CDER Direct: Dashboard – All Submissions

Home

SUBMISSIONS

- NDC Labeler Code Request
- Establishment Registration
- GDUFA Self-Identification

MANAGE ACCOUNT

- Edit User Profile
- Manage Users

ALL SUBMISSIONS

GO
ACTIONS ▾

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE
AWAITING ACCEPTANCE	f2dc6c82-db2b-2468-e044-00144ffaa30a	f32e14dd-b256-6ebf-e044-00144ffaa30a	cd9072581364.3172649085@direct	3	NDC LABELER CODE REQUEST	Jane Doe	26-MAR-2014 18:19:02
DRAFT	f5884a77-08a7-476a-e044-00144ffaa30a	f5884a77-08a8-476a-e044-00144ffaa30a	-	1	ESTABLISHMENT REGISTRATION	Jane Doe	26-MAR-2014 17:22:25
SUBMISSION SUCCESSFUL	f3f58480-b65e-74f4-e044-00144ffaa30a	f3f58480-b65f-74f4-e044-00144ffaa30a	cd2153768490.2795610843@direct	1	ESTABLISHMENT REGISTRATION	Jane Doe	18-MAR-2014 15:02:16
SUBMISSION SUCCESSFUL	f4461a3a-a4c9-3551-e044-00144ffaa30a	f4461a3a-a4ca-3551-e044-00144ffaa30a	cd8532764901.4872951603@direct	1	GENERIC DRUG FACILITY IDENTIFICATION SUBMISSION	Jane Doe	18-MAR-2014 15:02:16

CDER Direct: NDC Labeler Code Request

Home > Labeler Code Requests > SPL Submission

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

HEADER DETAILS

Document Type: * NDC LABELER CODE REQUEST

Set ID: * f24e6a62-88f2-5f57-e044-00144ffaa30a [Generate New](#)

Root ID: * f24e6a62-88f3-5f57-e044-00144ffaa30a [Generate New](#)

Version Number: * 1

Effective Date: * 02-13-2014

LABELER DETAILS

Labeler Name: * Adesi Company

Labeler DUNS: * 123456789

Labeler Code:

CONTACT DETAILS

Contact Name: * Suprana Dias

Contact Email: * siprana.dias@adesi.com

Contact Phone: * 91-000-2222222 [Format](#)

Phone Extension:

CONTACT ADDRESS

Country: * India

Street Address: * 3400 Thandlam St.

City: * Hyderabad

State/Province: Tirupati

Postal Code: 111 111

CDER Direct Support

- CDERDirect URL: <https://direct.fda.gov>
- CDERDirect Helpdesk Support: CDERDirect@fda.hhs.gov
- eDRLS Helpdesk: edrls@fda.hhs.gov

Thank you

Paul Loebach

FDA/CDER/Office of Compliance

Paul.loebach@fda.hhs.gov

eDRLS@fda.hhs.gov

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