



**CDER** *Direct*

Electronic Submissions Portal

**CDER Direct –  
Establishment Registration  
No Change Notification**

# Establishment Registration – No Change Notification

 U.S. Department of Health & Human Services

 **CDER** Direct  
Electronic Submissions Portal

Step 1: Log into  
your CDER  
Direct Account

## LOGIN

Username:

Password:

*Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious*

I Understand.

**LOGIN**

[Forgot your password?](#)

CDER Direct: [direct.fda.gov](http://direct.fda.gov)

# Establishment Registration – No Change Notification

## SUBMISSIONS

[\(ADD SUBMISSION TYPE\)](#)

NDC/NHRC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

Product Listing and Certification

WDD/3PL

## ESTABLISHMENT REGISTRATION

For assistance with validation errors in CDER Direct, contact [CDERdirect@fda.hhs.gov](mailto:CDERdirect@fda.hhs.gov). For general questions regarding electronic drug registration and listing, co



**Step 2: Click on Establishment Registration**

GO

ACTIONS ▾

SEARCH ESTABLISHMENT

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME	DOCUMENT LABEL	DETAILS
<a href="#">SUBMISSION ACCEPTED</a>	04586534-ac2d-49b1-ba15-4e0c70ee63f3	8bd7f3da-2729-670b-e053-2a95af0aad1f	cd6517423908.285316947@direct	14	631055345	AMI Cosmetic Co.,Ltd.	ESTABLISHMENT REGISTRATION	<a href="#">DETAILS</a>
<a href="#">SUBMISSION ACCEPTED</a>	04586534-ac2d-49b1-ba15-4e0c70ee63f3	7fa87aa8-2965-5540-e053-2a91ab0a152e	cd529486713.9417560328@direct	13	631055345	AMI Cosmetic Co.,Ltd.	ESTABLISHMENT REGISTRATION	<a href="#">DETAILS</a>
<a href="#">DRAFT</a>	6cb99161-32ca-42ee-a4a8-6d1fb02df097	7758fc2d-481a-b7b5-e053-2a91ab0acf74	-	2	438636616	Fresenius Kabi IPS UM S.r.l.	ESTABLISHMENT REGISTRATION	<a href="#">DETAILS</a>

**Step 3: Open the previously submitted and accepted Establishment Registration**

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

# Establishment Registration – No Change Notification

Home > Establishment Registration > SPL Submission

VIEW SPL

DOWNLOAD SPL

CREATE NEW VERSION

**Note:** Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Establishment Registration submission form. Red asterisk indicate required field

Step 4: Click  
Create New  
Version

## HEADER DETAILS

Document Type: \* ESTABLISHMENT REGISTRATION

Set ID: \* a27c2e3e-b665-c8f3-7a8e-08f5fd7fe5d7 [Generate New](#)

Version Number: \* 27

Root ID: \* e935a701-0687-a6df-e053-2995af0a33e6 [Generate New](#)

Effective Date: \* 09-21-2022

## REGISTRANT DETAILS

Registrant Name: \* Drug Firm

Registrant DUNS: \* 012345678

REGISTRANT CONTACT DETAILS

REGISTRANT CONTACT ADDRESS

CDER Direct: [direct.fda.gov](http://direct.fda.gov)

# Establishment Registration – No Change Notification

Home > Establishment Registration > SPL Submission



Step 6: Submit SPL

SUBMIT SPL

SAVE AS DRAFT

SAVE AND VALIDATE

Note: Click on the [redacted] instructions and helpful hints for filling out this Establishment Registration submission form. Red asterisk in

## HEADER DETAILS

Document Type: \* ESTABLISHMENT REGISTRATION

Set ID: \* --Select One--

Root ID: \* ESTABLISHMENT REGISTRATION

ESTABLISHMENT DE-REGISTRATION

NO CHANGE NOTIFICATION

OUT OF BUSINESS NOTIFICATION

[Generate New](#)

Version Number: \* 27

[Generate New](#)

Effective Date: \* 09-21-2022

## REGISTRANT DETAILS

Registrant Name: \* Drug Firm

Registrant DUNS: \* 012345678

Step 5: Change the document type to No Change Notification

# Establishment Registration – Document Types

- Document Types
  - Establishment Registration
    - *to register or update your establishment(s) information*
  - No change notification
    - *each year when the information is updated, if there is no change*
  - Out of Business
    - *if the registrant goes out of business*
  - Establishment De-Registration
    - *de-register your establishment(s)*

# For more information

Log on to CDER Direct: [direct.fda.gov](https://direct.fda.gov)

The CDER Direct portal currently works best with the following browsers:

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

Help Desk: [CDERdirect@fda.hhs.gov](mailto:CDERdirect@fda.hhs.gov)