

U.S. Food and Drug Administration



USER'S GUIDE

to FDA Direct

July 2024

Table of Contents

1	FDA DIRECT	5
1.1	Overview	5
1.2	Account Types	5
1.2.1	CDER Direct Account	5
1.2.2	Cosmetics Direct Account	6
1.2.3	'Combined' Account – CDER Direct & Cosmetics Direct	6
2	ACCOUNTS	7
2.1	FDA Direct URL: https://direct.fda.gov/	7
2.2	Account Creation	7
2.3	Account Login	15
2.3.1	Forgot Password	17
2.4	Account Management	21
2.4.1	Edit Profile	23
2.5	Subaccounts	25
2.5.1	Creating A Subaccount:	25
2.5.2	Managing A Subaccount	27
3	SUBMISSION INFORMATION	29
3.1	Submission Options	29
3.2	Submission Statuses	32
3.3	Submission Header Information	33
3.4	Submission Help	33
4	COSMETIC REGISTRATION AND LISTING	36
4.1	Cosmetic Registration and Product Listing SPL	36
4.2	Document Types	37
4.2.1	Registration of Cosmetic Facility	37
4.2.2	Cosmetic Product Listing	38
4.3	Registering a New Cosmetic Product Facility	38
4.3.1	Save and Validate	48
4.3.2	Submit SPL to FDA	49
4.3.3	Submission Accepted	50
4.3.4	Submission Failed	51
4.3.5	Validation Failure	52
4.3.6	Amending Cosmetic Product Facility Registration	52
4.3.7	Amending Cosmetic Product Facility Cancellation	53
4.3.8	Biennial Cosmetic Product Facility Registration Renewal	54
4.3.9	Abbreviated Cosmetic Product Facility Registration	55

4.4 Cosmetics Product Listing	56
4.4.1 New Cosmetics Product Listing	56
4.4.2 Create a New Cosmetic Product Listing	57
4.4.3 Product(s), Ingredient(s), and Facility(ies)	68
4.4.3.1 Save and Validate	86
4.4.3.2 Submit SPL to FDA	87
4.4.3.3 Submission Accepted	88
4.4.3.4 Submission Failed	89
4.4.3.5 Validation Failure	89
4.4.4 Abbreviated Renewal Listing	90
4.4.5 Cosmetic – Update	91
4.4.5.1 Discontinue	92
4.4.5.2 Relist	97
4.5 Filters	99
4.5.1 Cosmetic Facility Registration	99
4.5.2 Cosmetic Product Listing	100
4.5.2.1 Filtering on Column Header	101
4.5.2.2 Search Product	102
4.5.2.3 Rows Per Page	103
5 DRUG REGISTRATION AND LISTING	104
5.1 Drug Establishment Registration SPL	104
5.1.1 Registering a New Drug Establishment	104
5.1.2 De-Registering a Drug Establishment	111
5.1.3 No Changes to Establishment Registration	112
5.2 Drug NDC Labeler Code Request	114
5.3 Drug NDC Reservation	119
5.4 Drug Product Listing and Certification	135
6 OUTSOURCING FACILITY REGISTRATION AND COMPOUNDED PRODUCT REPORTING	161
6.1 Outsourcing Facility Registration	161
6.1.1 Registering A New Outsourcing Facility	161
6.1.2 De-Registering An Outsourcing Facility	168
6.1.3 No Change To Outsourcing Facility Registration	169
6.2 Compounded Drug Reporting	170
7 WHOLESALE DRUG DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER REPORTS	193
7.1 WDD/3PL Facilities	204
7.2 WDD/3PL Licenses	206
8 GENERIC FACILITY GDUFA SELF-IDENTIFICATION	209
8.1 Generic Facility GDUFA Self-Identification	209
9 USEFUL INFO	216

9.1 Content of Labeling	216
9.1.1 Text Editing Tools	216
9.1.2 Adding and Deleting Footnotes	217
9.1.3 Links & Cross References	220
9.1.4 Sections and Subsections	223
9.2 Searching and Filtering	225
9.2.1 Search	225
9.2.2 Filters	229
9.2.2.1 Filtering on Column Header	229
9.2.3 Rows Per Page	231

1 FDA DIRECT

1.1 Overview

FDA Direct is the U.S. Food and Drug Administration's web-based and free *Structured Product Labeling* (SPL) authoring tool. Previously titled 'CDER Direct,' the newly upgraded FDA Direct platform now includes two modules: **CDER Direct** and **Cosmetics Direct**. Users can create separate accounts in CDER Direct or in Cosmetics Direct, or a single 'Combined' account that allows access to both CDER Direct submissions and Cosmetics Direct submissions.

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1993, requires that all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at <http://www.section508.gov/>.

1.2 Account Types

1.2.1 CDER Direct Account

CDER Direct can submit the following types of data directly to the FDA/CDER:

(Not to be used for CVM/CDRH registration and listing)

- Establishment Registration & Drug Listing
 - Establishment Registration
 - NDC Labeler Code Request
 - Drug Listing and Certification
 - NDC Reservation
- Outsourcing Facility Registration and Product Reporting
 - Outsourcing Drug Facility Registration
 - Compounded Drug Reporting
- DSCSA Annual Reporting

- Wholesale Drug Distributor and Third-Party Logistics (WDD/3PL) Provider Reports
- WDD/3PL Facilities
- WDD/3PL Licenses
- Generic Drug Self-Identification
 - Generic Facility GDUFA Self-Identification

1.2.2 Cosmetics Direct Account

Cosmetics Direct allows users to submit the following types of data directly to the FDA:

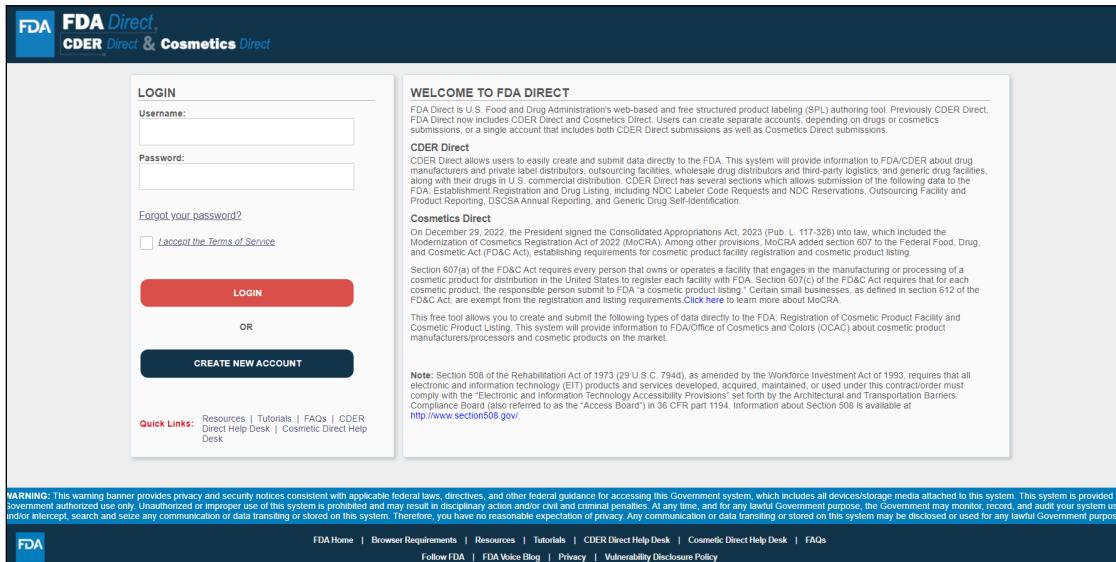
- Registration of Cosmetic Product Facility
- Cosmetic Product Listing

1.2.3 'Combined' Account – CDER Direct & Cosmetics Direct

Combined accounts have access to all CDER Direct and Cosmetics Direct submission types listed in Sections 1.2.1 and 1.2.2 above and should be used by companies that manufacture and/or distribute both drugs and cosmetics. For help with changing your account type, visit Section 2.4.1: Edit Profile.

2 ACCOUNTS

2.1 FDA Direct URL: <https://direct.fda.gov/>



At the bottom of the Login area, there are **Quick Links** that can provide you with further assistance on various topics:

- **Resources** - Links to the FDA's Structured Product Labeling Resources page, which includes an extensive list of SPL help documents and information.
- **Tutorials** - List of walkthrough documentation for various areas of FDA Direct (submissions, registration, etc.).
- **FAQs** - Frequently asked questions, searchable.
- **Help Desk** - Email contact for the CDER Direct and Cosmetics Direct helpdesks.

2.2 Account Creation

Follow these steps to create a new account:

1. Navigate to the FDA Direct main page at <https://direct.fda.gov/> and click **Create New Account**.

LOGIN

Username:

Password:

[Forgot your password?](#)

[I accept the Terms of Service](#)

LOGIN

OR

CREATE NEW ACCOUNT

Quick Links: [Resources](#) | [Tutorials](#) | [FAQs](#) | [CDER Direct Help Desk](#) | [Cosmetic Direct Help Desk](#)

2. Select your desired account type. This can be changed after account creation:

ORGANIZATION TYPE

What type of Account are you creating ? CDER Direct Cosmetics Direct Combined (CDER Direct and Cosmetics Direct)

There are three types of account that can be created on FDA Direct: CDER Direct, Cosmetics Direct, and a combined account (CDER Direct & Cosmetics Direct). A combined account is intended for companies that have both drugs and cosmetics submissions. A combined account streamlines both drugs and cosmetics submission requirements and saves time and effort. DUNS number is only a required field if you create a CDER Direct account or a combined account (CDER Direct and Cosmetics Direct). DUNS number is NOT required but requested if you create only a Cosmetics Direct account.

- **CDER Direct** – Select this option to register and list for human drugs or biological products. You will have access to drug-related submission forms such as *Establishment Registration and Drug Listing, Outsourcing Facility Registration and Product Reporting, DSCSA Annual Reporting, and Generic Drug Self-Identification*. A complete list of all forms will be shown upon selecting this option.
- **Cosmetics Direct** – Select this option to register cosmetic products only. You will have access to *Cosmetic Registration and Listing* submission forms. A complete list of all forms will be shown upon selecting this option.
- **Combined** – Full access to both Cosmetics Direct and CDER Direct submission forms. Select this option to register and list for both cosmetic and drug products. This account should be used by companies that manufacture/distribute both drugs and cosmetics. A complete list of all forms will be shown upon selecting this option.

3. Fill out your details in the fields that appear:

ORGANIZATION TYPE

What type of Account are you creating? CDER Direct Cosmetics Direct Combined (CDER Direct and Cosmetics Direct)

There are three types of account that can be created on FDA Direct: CDER Direct, Cosmetics Direct, and a combined account (CDER Direct & Cosmetics Direct). A combined account is intended for companies that have both drugs and cosmetics submissions. A combined account streamlines both drugs and cosmetics submission requirements and saves time and effort. DUNS number is only a required field if you create a CDER Direct account or a combined account (CDER Direct and Cosmetics Direct). DUNS number is NOT required but requested if you create only a Cosmetics Direct account.

ORGANIZATION INFORMATION

Name: *

DUNS: *

ORGANIZATION ADDRESS

Country: *

Street Address: *

City: *

State: *

Postal Code: *

CONTACT INFORMATION

First Name: *

Middle Name:

Last Name: *

Job Title:

Contact Email: *

CONTACT PHONE

Country Code: *

Phone Number: *

Phone Extension:

***The DUNS field is optional in Cosmetics Direct account creation only.**

4. A list of available submission forms will be automatically selected for you at the bottom of the page. If there are any unwanted submission forms in the list, de-select any of the boxes as desired:

FDA DIRECT (CDER DIRECT AND COSMETICS DIRECT)

With an FDA Direct account (CDER Direct and Cosmetics Direct), the following submissions can be made to the FDA. You can uncheck any submission types that are not needed.

ESTABLISHMENT REGISTRATION AND DRUG LISTING

- ESTABLISHMENT REGISTRATION
- NDC LABELER CODE REQUEST
- DRUG LISTING AND CERTIFICATION
 - BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING
 - BULK INGREDIENT
 - CELLULAR THERAPY
 - DRUG FOR FURTHER PROCESSING
 - HUMAN OTC DRUG LABEL
 - HUMAN PRESCRIPTION DRUG LABEL
 - NON-STANDARDIZED ALLERGENIC LABEL
 - PLASMA DERIVATIVE
 - STANDARDIZED ALLERGENIC
 - VACCINE LABEL
- NDC RESERVATION

COSMETIC REGISTRATION AND LISTING

- REGISTRATION OF COSMETIC PRODUCT FACILITY
- COSMETIC PRODUCT LISTING

DRUG REPORTING BY OUTSOURCING FACILITY

- OUTSOURCING FACILITY REGISTRATION
- COMPOUNDED DRUG REPORTING

DSCSA ANNUAL REPORTING

- WHOLESALE DRUG DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER REPORTS

GENERIC DRUG SELF-IDENTIFICATION

- GENERIC FACILITY GDFA SELF-IDENTIFICATION

5. Click the '*I have read and agree to the Terms and Conditions stated above*' checkbox at the end of the page. Then click 'Submit':

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 have read and agree to the Terms and Conditions stated above.

SUBMIT

CANCEL

6. An account activation email will be sent from FDADirect@fda.gov to the email address you used in Step 3. Activation links are valid for 48 hours. If your link has expired, you must re-do Steps 1-5 above.

***Activation email missing or delayed:** Check your spam/junk folder first. There may also be a slight delay for DUNS verification, if entered.

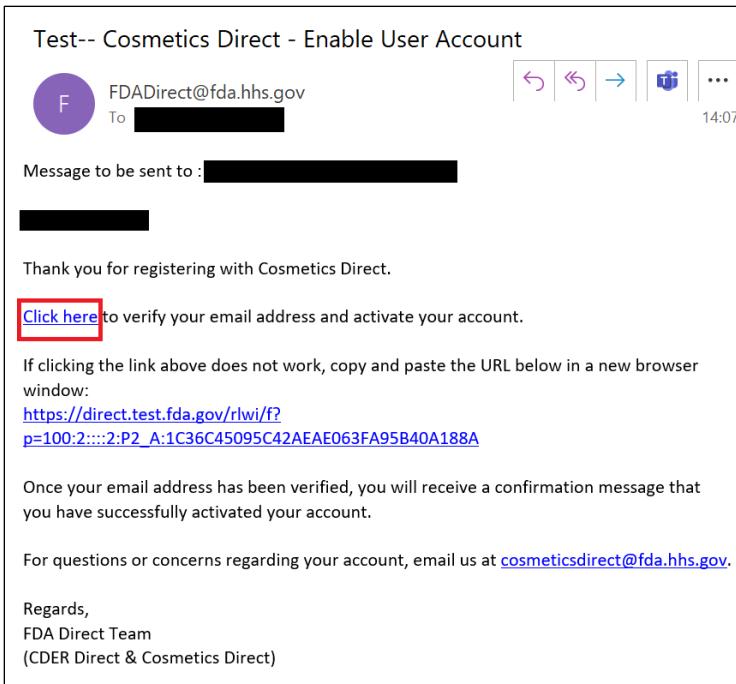
If you still have not received your activation email after 5-10 minutes, you can contact the Help Desk at:

- CDERDirect@fda.hhs.gov (CDER Direct, Combination accounts)

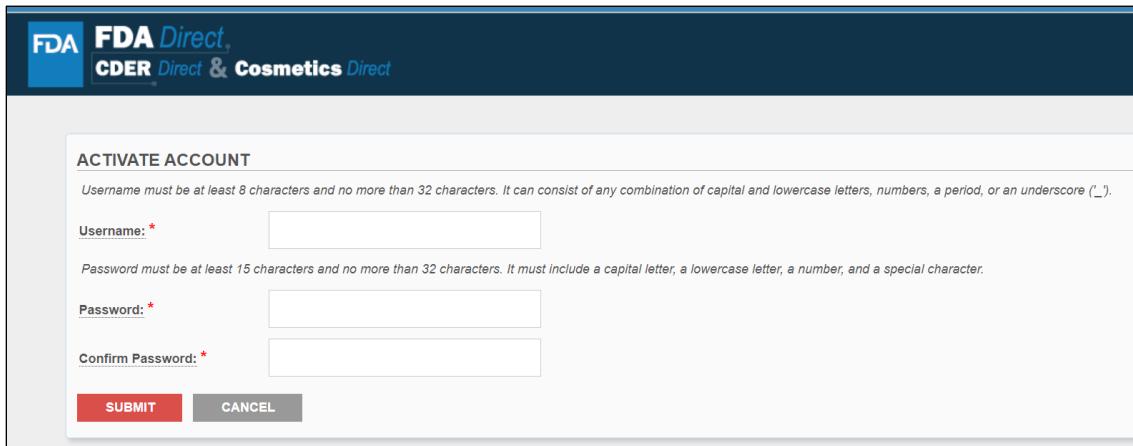
OR

- CosmeticsDirect@fda.hhs.gov (Cosmetics Direct accounts)

7. Click the link in the activation email:



8. The link will open the FDA Direct website in your browser. Enter your desired Username and Password:



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: *

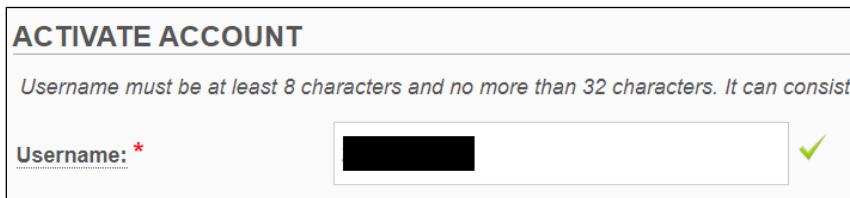
Confirm Password: *

SUBMIT CANCEL

Usernames must be within 8-32 characters in length. Passwords must be between 15-32 characters long, and include at least **one** of the following:

- Capital letter
- Lowercase letter
- Number
- Special character

A green checkmark will indicate that your username is acceptable:



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: *

9. Click 'Submit' when all information has been entered.
10. You will be redirected to the FDA Direct login page. A green banner at the top of the page will confirm your account activation. Enter your new username and password:

Your account has been activated. Login by entering your Username and the Password you selected.

LOGIN

Username:

Password:

[Forgot your password?](#)

[I accept the Terms of Service](#)

OR

WELCOME TO FDA DIRECT

FDA Direct is U.S. Food and Drug Administration's web-based and free system for manufacturers and private label distributors, outsourcing facilities, wholesalers, and their drugs in U.S. commercial distribution. CDER Direct has several submission types, including NDA, BLA, ANDA, PDUFA, and Generic Drug Self-Identification.

CDER Direct

CDER Direct allows users to easily create and submit data directly to the FDA. Submissions can be made by manufacturers and private label distributors, outsourcing facilities, wholesalers, and their drugs in U.S. commercial distribution. CDER Direct has several submission types, including NDA, BLA, ANDA, PDUFA, and Generic Drug Self-Identification.

Cosmetics Direct

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (H.R. 5373). This law includes the Modernization of Cosmetics Registration Act of 2022 (MoCRA). Among other provisions, MoCRA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishing requirements for cosmetic products.

Section 607(a) of the FD&C Act requires every person that owns or operates a facility that manufactures, packages, or holds a cosmetic product for distribution in the United States to register each facility with the FDA. The responsible person must submit to FDA a cosmetic product registration. Certain facilities, such as those that are exempt from the registration and listing requirements, are exempt from the registration and listing requirements.

This free tool allows you to create and submit the following types of data to the FDA: Establishment Registration, Drug Listing, and Cosmetic Product Listing. This system will provide information to FDA/Office of Cosmetic Product Registration and Cosmetic products on the market.

Note: Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by the Workforce Innovation and Opportunity Act of 2014 (WIOA) requires that electronic documents be accessible to people with disabilities. This system is designed to be accessible to people with disabilities.

11. Check the '*I accept the Terms of Service*' box and a warning banner will display. Then click '**I Agree**' to proceed.

This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes (1) this computer network, (2) all computers connected to this network, and (3) all devices and storage media attached to this network or to a computer on this network.

This system is provided for Government-authorized use only.

Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties.

Personal use of social media and networking sites on this system is limited as to not interfere with official work duties and is subject to monitoring.

By using this system, you understand and consent to the following: The Government may monitor, record, and audit your system usage, including usage of personal devices and email systems for official duties or to conduct HHS business. Therefore, you have no reasonable expectation of privacy regarding any communication or data transmitted or stored on this system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transmitted or stored on this system. Any communication or data transmitted or stored on this system may be disclosed or used for any lawful Government purpose.

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.

CLOSE **I AGREE**

Quick Links: Resources | Tutorials | FAQs | Direct Help Desk | Cosmetic Help Desk

12. The FDA uses **MFA (Multi-Factor Authentication)** for security verification. The 'Verify Email Address' screen below will only display once, immediately after your initial login to your new account:

***Click the pencil icon beside your email address to update your email address, or change it later in the Account Management settings (see Section 2.4)**

13. To retrieve your One-Time Passcode (OTP), check your email. If you still have not received a passcode after several minutes, click the 'Request New Passcode' link (shown above) to send another code, then check your email again.

Test-- FDA Direct - One-Time Passcode

FDADirect@fda.hhs.gov
To: [redacted]

Message to be sent to: [redacted]

Your one-time passcode (OTP) for FDA Direct is:

766796

If you do not recognize this request, we recommend you immediately change your password to protect your account from unauthorized access.

Regards,
FDA Direct Team
(CDER Direct & Cosmetics Direct)

Please do not reply to this email. This message was sent to you using an automated system.
It is not monitored for replies.

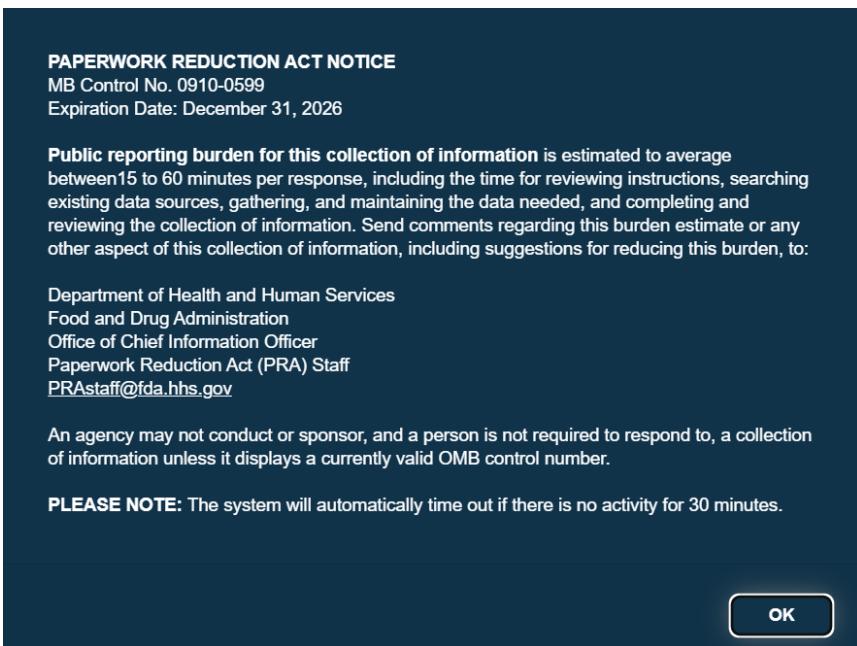
14. Enter the passcode from your email into the OTP field:

Contact Email: ✎ Select the F

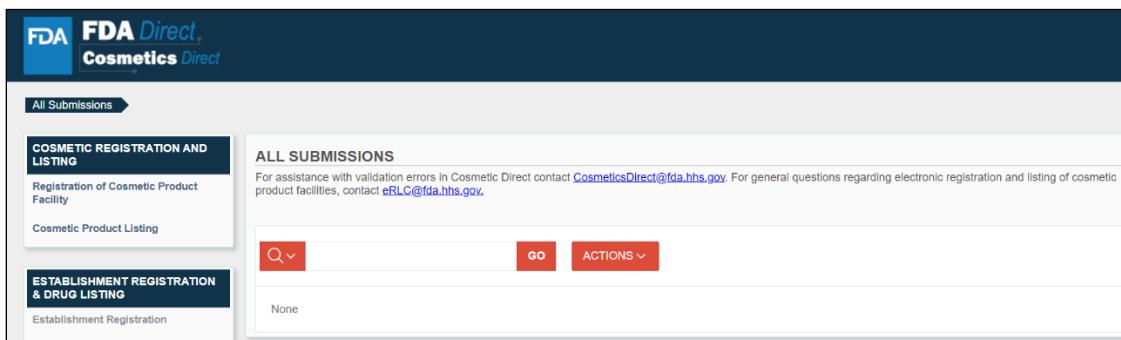
One-Time Passcode (OTP):

SUBMIT **CANCEL**

15. Click 'Submit.' If you have a Combined Account or a Cosmetics Direct account, a Paperwork Reduction Act notice will display. Click 'OK':



16. Once the main page displays, you now have access to your FDA Direct account. Continue to the next section for help with regular login and password recovery.

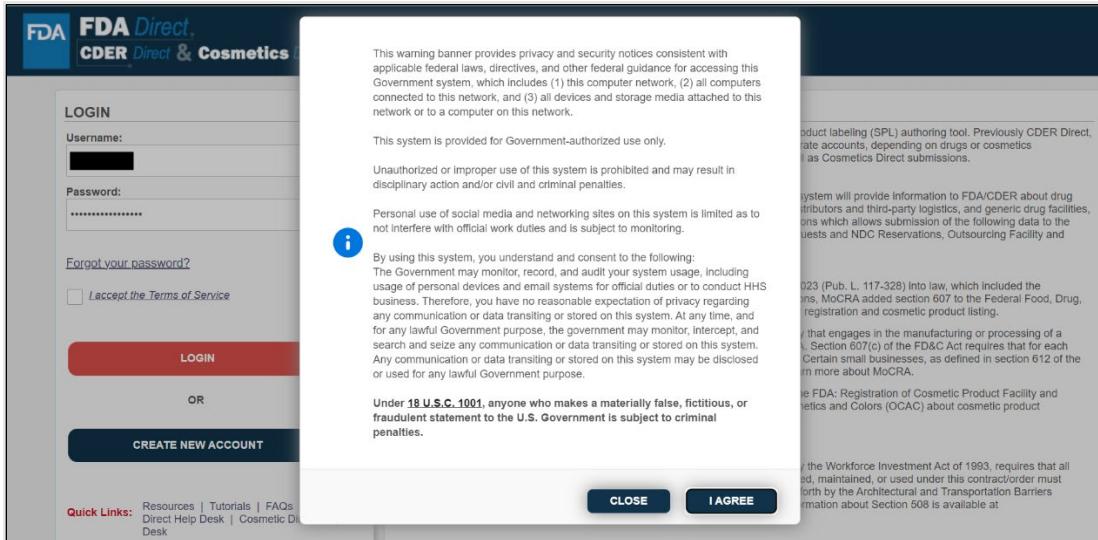


2.3 Account Login

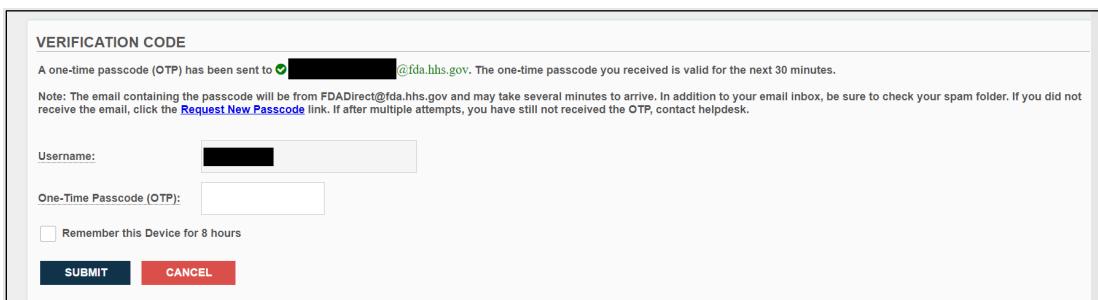
Once you have completed account activation in the steps above, you can return at any time to the FDA Direct homepage (<https://direct.fda.gov>).

To log in to FDA Direct and access your account:

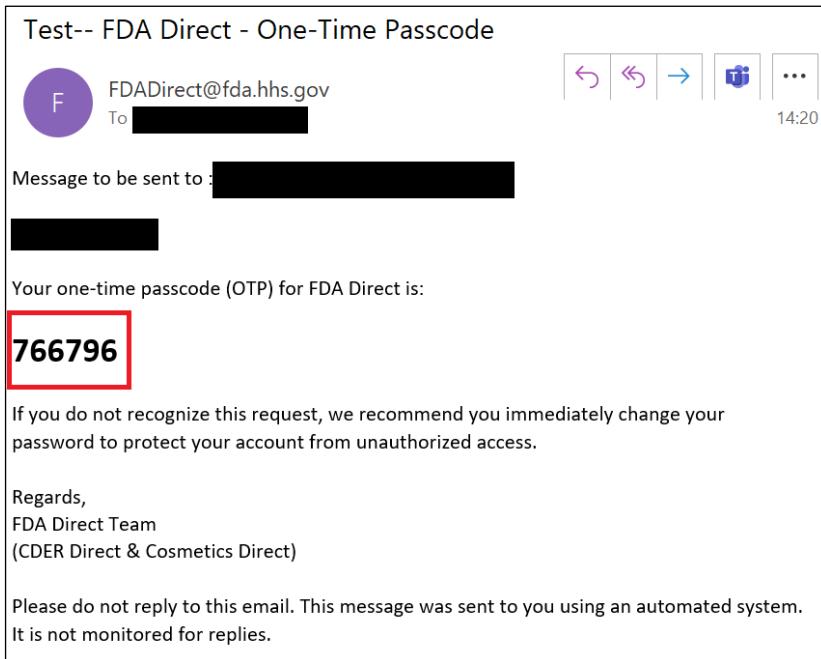
1. Enter your username and password.
2. Check the '*I accept the Terms of Service*' box and a warning banner will display. Then click '**I Agree**'.



3. Click the 'Login' button. If this is your **first time logging in for the day**, you will be redirected to the 'Verification Code' page:



4. Check your email for a One-Time Passcode (OTP). If you still have not received a passcode after several minutes, click the '**Request New Passcode**' link (shown above) and check your email again.



5. Enter the passcode from your email into the OTP field, then check the box '*Remember this device for 8 hours*':

The form has a label 'One-Time Passcode (OTP):' and a text input field containing '766796'. Below the input field is a checkbox labeled 'Remember this Device for 8 hours'. The 'SUBMIT' button is in a dark blue box, and the 'CANCEL' button is in a red box.

Clicking this box will prevent the verification step from appearing within an 8-hour timeframe. **If you do not check the box, you must re-do this verification step every single time you log in to FDA Direct!**

IMPORTANT: All accounts are subject to a **30-minute session timeout**. If you are inactive for longer than 30 minutes, you will automatically be logged out of FDA Direct.

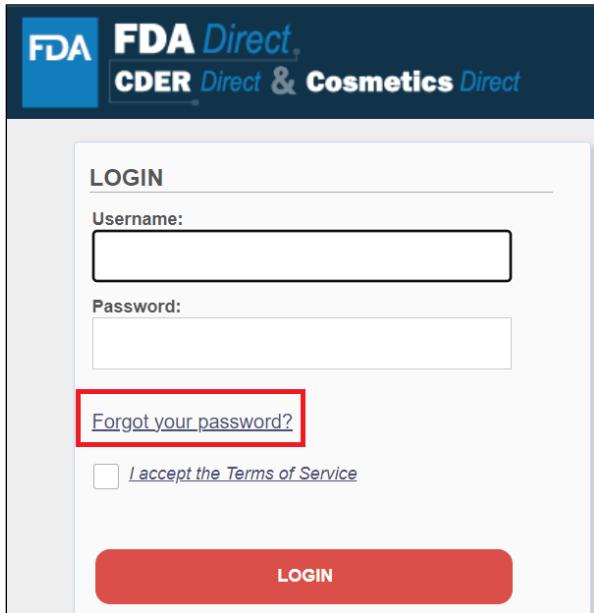
6. Click 'Submit.' You will then be taken to your account main page.
7. If you have a Cosmetics account or a Combined account, a Paperwork Reduction Act (PRA) banner will display. Click 'OK' to continue.

You are now logged in to your account.

2.3.1 Forgot Password

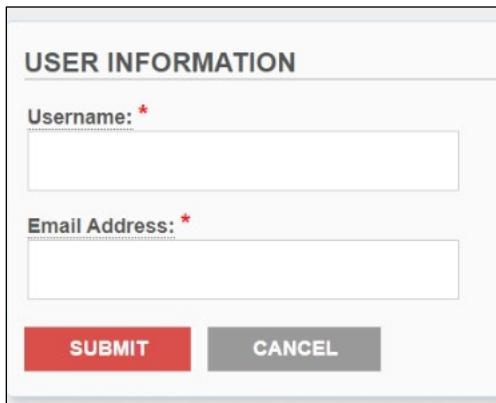
If you forgot your password, do the following:

1. Go to the FDA Direct homepage (<http://direct.fda.gov/>) and click 'Forgot Password':



The image shows the FDA Direct login interface. At the top, there is a blue header bar with the text 'FDA Direct' and 'CDER Direct & Cosmetics Direct'. Below this is a 'LOGIN' form. It contains two text input fields for 'Username' and 'Password', both of which are currently empty. Below these fields is a link 'Forgot your password?' which is highlighted with a red rectangular box. Underneath this link is a small checkbox followed by the text 'I accept the Terms of Service'. At the bottom of the form is a large red 'LOGIN' button.

2. Enter your username and your email address in the next page:



The image shows a 'USER INFORMATION' form. It has two text input fields: 'Username:' and 'Email Address:', both marked with a red asterisk to indicate they are required fields. Below these fields are two buttons: a red 'SUBMIT' button on the left and a grey 'CANCEL' button on the right.

IMPORTANT: If you do not remember one or both of these details, you must contact the Help Desk by returning to the FDA homepage and clicking one of the Help Desk links in the **Quick Links** section:

LOGIN

Username:

Password:

[Forgot your password?](#)

[I accept the Terms of Service](#)

LOGIN

OR

CREATE NEW ACCOUNT

Quick Links: [Resources](#) | [Tutorials](#) | [FAQs](#) | [CDER Direct Help Desk](#) | [Cosmetic Direct Help Desk](#)

3. On the 'Recover Account' page, you will be notified that a One-Time Passcode (OTP) has been emailed to the email address associated with your account:

User Information **Recover Account** Reset Password

RECOVER ACCOUNT

A one-time passcode (OTP) has been sent to [REDACTED]. The one-time passcode you received is valid for the next 30 minutes.

Note: The email containing the passcode will be from FDADirect@fda.hhs.gov and may take several minutes to arrive. In addition to your email inbox, be sure to check your spam folder. If you did not receive the email, click the [Request New Passcode](#) link. If after multiple attempts, you have still not received the OTP, contact helpdesk.

Username: * [REDACTED]

Email Address: * [REDACTED]

One-Time Passcode (OTP): [REDACTED]

SUBMIT **CANCEL**

4. Check your email address for the OTP. If you have not received an email after several minutes, you can click the '**Request New Passcode**' link (shown above) to send another code.

Test-- FDA Direct - One-Time Passcode

 FDADirect@fda.hhs.gov
To [REDACTED]  14:20

Message to be sent to : [REDACTED]
[REDACTED]

Your one-time passcode (OTP) for FDA Direct is:

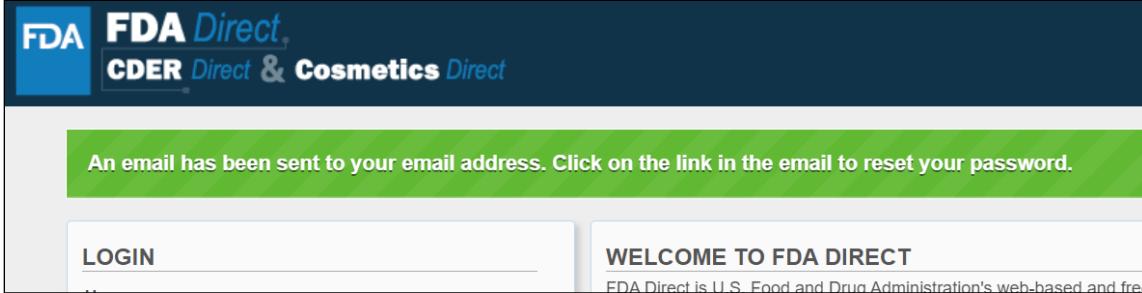
766796

If you do not recognize this request, we recommend you immediately change your password to protect your account from unauthorized access.

Regards,
FDA Direct Team
(CDER Direct & Cosmetics Direct)

Please do not reply to this email. This message was sent to you using an automated system.
It is not monitored for replies.

5. Enter the OTP and you will be returned to the FDA homepage with a confirmation notice:



The image shows the FDA Direct homepage. At the top, there is a dark blue header with the FDA logo and the text "FDA Direct" and "CDER Direct & Cosmetics Direct". Below the header, there is a green horizontal bar with the text "An email has been sent to your email address. Click on the link in the email to reset your password." In the center, there is a white "LOGIN" button. To the right of the button, there is a "WELCOME TO FDA DIRECT" message and a small note: "FDA Direct is U.S. Food and Drug Administration's web-based and free".

6. Check your email inbox for the reset email and click the link to reset your password:

Test-- Your Password Change Request

FDADirect@fda.hhs.gov
To [REDACTED] 20:46

Message to be sent to : [REDACTED]

Dear [REDACTED]

This email was sent because we received a request to change your password. If you did not request to change your password, please contact the appropriate Help Desk cderdirect@fda.hhs.gov (CDER Direct) or cosmeticsdirect@fda.hhs.gov (Cosmetics Direct).

To change your password, [Click here.](#)

If clicking the link above does not work, copy and paste the following URL in a new browser window:
https://direct.test.fda.gov/rlwi/f?p=100:4:::::P4_A:1C4E1BDB9A94815FE063FA95B40AC238

Regards,
 FDA Direct Team
 (CDER Direct & Cosmetics Direct)

Please do not reply to this email. This message was sent to you using an automated system. It is not monitored for replies.

7. Enter a new password in the 'Reset/Change Password' then click 'Save':

8. Another confirmation will display:

9. Log in with your username and your new password. The 'Verification Code' page will display:

VERIFICATION CODE

A one-time passcode (OTP) has been sent to [REDACTED].gov. The one-time passcode you received is valid for the next 30 minutes.

Note: The email containing the passcode will be from FDADirect@fda.hhs.gov and may take several minutes to arrive. In addition to your email inbox, be sure to check your spam folder. If you did not receive the email, click the [Request New Passcode](#) link. If after multiple attempts, you have still not received the OTP, contact helpdesk.

Username: [REDACTED]

One-Time Passcode (OTP): [REDACTED]

Remember this Device for 8 hours

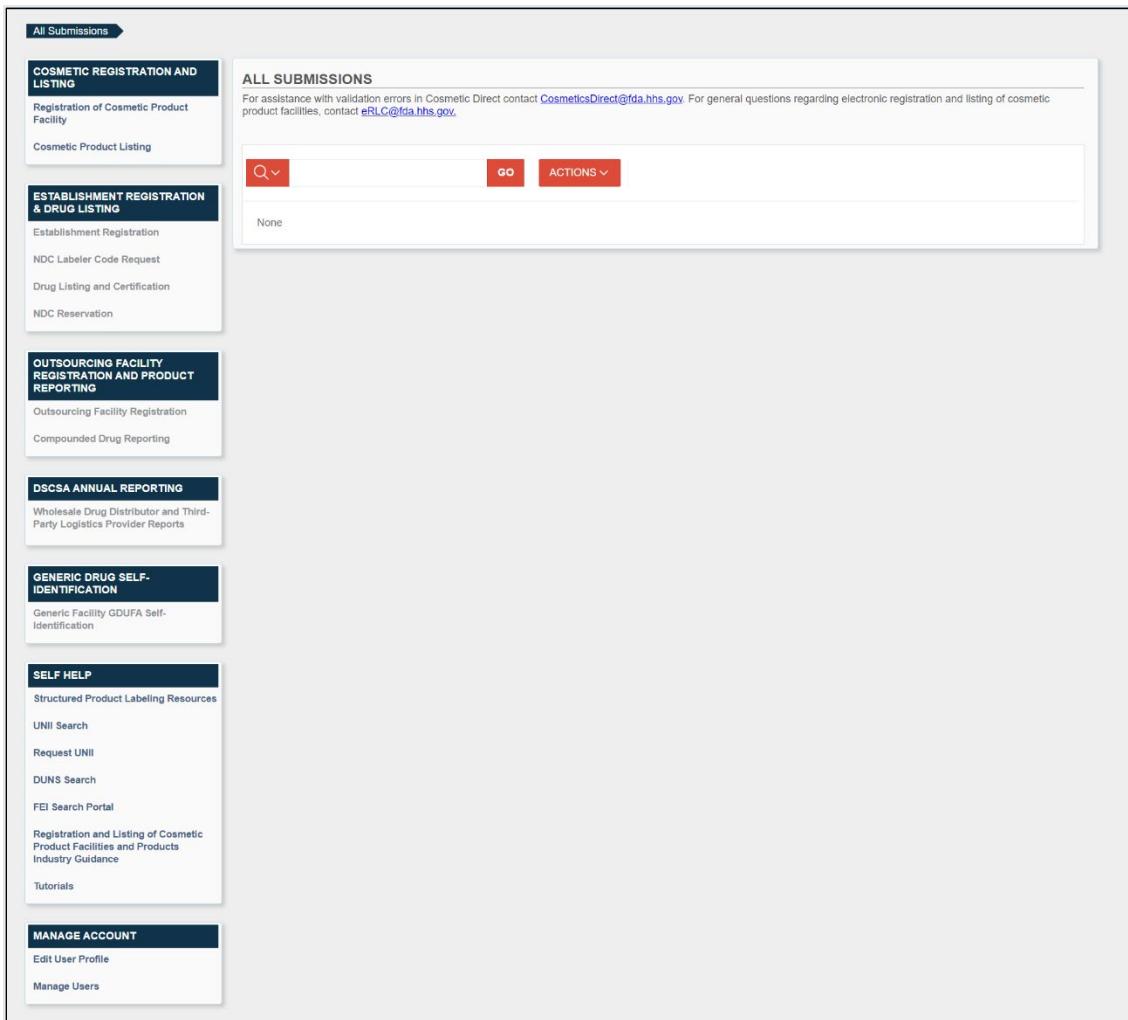
SUBMIT **CANCEL**

10. Check your email one last time for a One-Time Passcode. Enter the passcode from that email, check the '*Remember This Device For 8 Hours*' box, and finally click '**Submit**'.

You will now have access to your account.

2.4 Account Management

Your account main page will display each time you log in to FDA Direct:

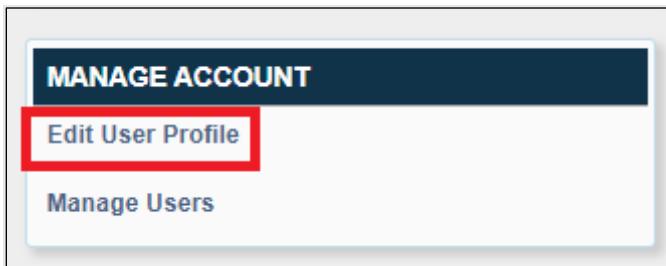


- The left menu displays all available submission forms in FDA Direct. Access to certain forms is limited based on both your account type (Cosmetic/CDER/Combined) and any de-selections made in Section 2.2: Account Creation. Greyed out areas of the menu indicate you do not have access to a particular form or group of forms.
- The '**Self Help**' section links to the [FEI Portal](#) (FEI number lookup), Dun & Bradstreet (DUNS number lookup), FDA Direct tutorials/user guides, and other useful information.
- The '**Manage Account**' section allows you to edit your profile (such as changing account type or account information) and manage your users.

2.4.1 Edit Profile

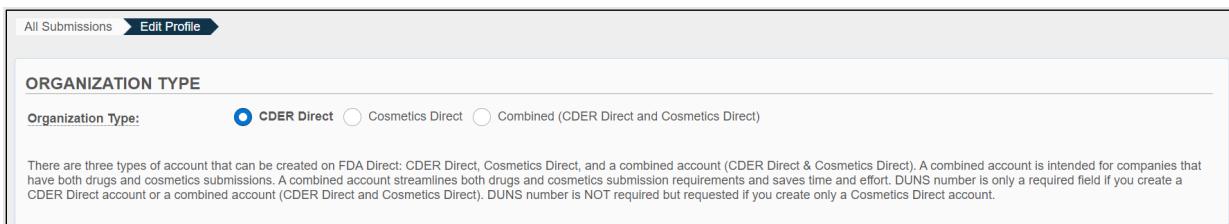
To change your account type (Cosmetics Direct, CDER Direct, or Combined) log in to FDA Direct.

Scroll down to the bottom of the page. Click '**Edit User Profile**' under the *Manage Account* section on the left side:



***The 'Manage Users' option only displays for certain account types. See Section 2.5: Subaccounts for more information.**

Select the desired account type:



***If you are converting from a Cosmetics Direct account to a CDER Direct or Combined account, you must enter a valid DUNS number to successfully switch accounts.**

You can modify the following in the next section:

- Contact Information
- Organization Information
- Account Password

All Submissions **Edit Profile**

ORGANIZATION TYPE

Organization Type: CDER Direct Cosmetics Direct Combined (CDER Direct and Cosmetics Direct)

There are three types of account that can be created on FDA Direct: CDER Direct, Cosmetics Direct, and a combined account (CDER Direct & Cosmetics Direct). A combined account is intended for companies that have both drugs and cosmetics submissions. A combined account streamlines both drugs and cosmetics submission requirements and saves time and effort. DUNS number is only a required field if you create a CDER Direct account or a combined account (CDER Direct and Cosmetics Direct). DUNS number is NOT required if you create only a Cosmetics Direct account.

CONTACT INFORMATION

First Name: * Amara

Middle Name:

Last Name: * Brown

Job Title:

Contact Email: * abrown@abc.com 

CONTACT PHONE

Country Code: * United States (+1)

Phone Number: * 1-123-123-4567

Extension:

ORGANIZATION INFORMATION

Name: * Company 123

DUNS: * 

ORGANIZATION ADDRESS

Country: * United States

Street Address: * 123 Lane

City: * City

State: * Maine

Postal Code: * 11111

CHANGE PASSWORD

Username: * 

Password: * [Change Password](#)

Finally, inspect your form accesses and check/uncheck form boxes as desired:

FDA DIRECT (CDER DIRECT AND COSMETIC DIRECT)

With an FDA Direct account (CDER Direct and Cosmetic Direct), the following submissions can be made to the FDA. You can uncheck any submission types that are not needed.

ESTABLISHMENT REGISTRATION AND DRUG LISTING

- ESTABLISHMENT REGISTRATION
- NDC LABELER CODE REQUEST
- DRUG LISTING AND CERTIFICATION
 - BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING
 - BULK INGREDIENT
 - CELLULAR THERAPY
 - DRUG FOR FURTHER PROCESSING
 - HUMAN OTC DRUG LABEL
 - HUMAN PRESCRIPTION DRUG LABEL
 - NON-STANDARDIZED ALLERGENIC LABEL
 - PLASMA DERIVATIVE
 - STANDARDIZED ALLERGENIC
 - VACCINE LABEL
- NDC RESERVATION

COSMETIC REGISTRATION AND LISTING

- REGISTRATION OF COSMETIC PRODUCT FACILITY
- COSMETIC PRODUCT LISTING

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING

- OUTSOURCING FACILITY REGISTRATION
- COMPOUNDED DRUG REPORTING

DSCSA ANNUAL REPORTING

- WHOLESALE DRUG DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER REPORTS

GENERIC DRUG SELF-IDENTIFICATION

- GENERIC FACILITY GDUFA SELF-IDENTIFICATION

SUBMIT **CANCEL**

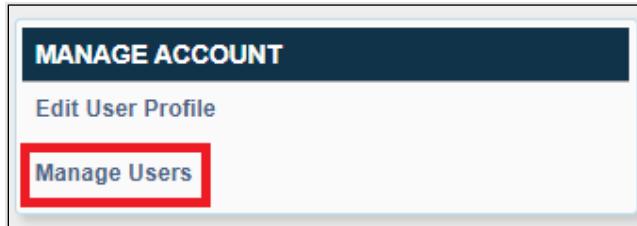
Click 'Submit' to finalize all changes made, or 'Cancel' to abandon your changes.

2.5 Subaccounts

If you are the first person to create an account for your organization, you are considered an 'Admin' user by default. **Only Admin users can create subaccounts, which are limited-access accounts for other users within your organization.** Subaccounts can be customized in a few ways:

- Form Access: Subaccounts can be limited to one or many submission forms.
- User Roles: Subaccounts can have either 'User' or 'Admin' roles.
- Status: Subaccounts can be inactivated by Admin users at any time. Inactivated accounts can also be reactivated.

Log in to FDA Direct. Scroll to the bottom of your account main page and select 'Manage Users' under the Section 2.4: Account Management section:

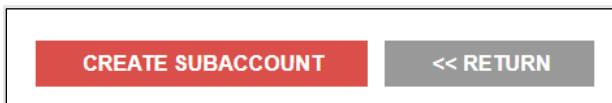


If you have already created subaccounts, they will display in a list. Otherwise, the page will be empty:



2.5.1 Creating A Subaccount:

1. Click the 'Create Subaccount' button



2. Enter all required fields for the subaccount user:

All Submissions Manage Users **Create / Edit User**

CONTACT INFORMATION

First Name: * User Role: * **USER** Country Code: * -Select Country Phone Code-

Middle Name: Job Title: Phone Number: *

Last Name: * Contact Email: * Extension:

3. Select the 'User Role' dropdown. This will determine whether the subaccount will have full access (Admin) or limited access (User).

User Role: * **USER**

Username: F

Job Title:

4. Select which forms the subaccount will have access to. This view will differ based on your organizational account type, which is modifiable in Section 2.4.1: Edit Profile. Click the form checkboxes then click 'Submit.'

CDER DIRECT ACCESS

With a CDER Direct account, the following submissions can be made to the FDA. You can uncheck any submission types that are not needed.

<input type="checkbox"/> ESTABLISHMENT REGISTRATION AND DRUG LISTING <ul style="list-style-type: none"> • ESTABLISHMENT REGISTRATION • NDC LABELER CODE REQUEST • DRUG LISTING AND CERTIFICATION <ul style="list-style-type: none"> • BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING • BULK INGREDIENT • CELLULAR THERAPY • DRUG FOR FURTHER PROCESSING • HUMAN OTC DRUG LABEL • HUMAN PRESCRIPTION DRUG LABEL • NON-STANDARDIZED ALLERGENIC LABEL • PLASMA DERIVATIVE • STANDARDIZED ALLERGENIC • VACCINE LABEL • NDC RESERVATION 	<input type="checkbox"/> OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING <ul style="list-style-type: none"> • OUTSOURCING FACILITY REGISTRATION • COMPOUNDED DRUG REPORTING
<input type="checkbox"/> DSCSA ANNUAL REPORTING <ul style="list-style-type: none"> • WHOLESALE DRUG DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER REPORTS 	<input type="checkbox"/> GENERIC DRUG SELF-IDENTIFICATION <ul style="list-style-type: none"> • GENERIC FACILITY GDUFA SELF-IDENTIFICATION

SUBMIT **CANCEL**

COSMETICS DIRECT ACCESS

With a COSMETICS Direct account, the following submissions can be made to the FDA.

<input checked="" type="checkbox"/> COSMETIC REGISTRATION AND LISTING <ul style="list-style-type: none"> • REGISTRATION OF COSMETIC PRODUCT FACILITY • COSMETIC PRODUCT LISTING

SUBMIT **CANCEL**

FDA DIRECT (CDER DIRECT AND COSMETICS DIRECT)

With an FDA Direct account (CDER Direct and Cosmetics Direct), the following submissions can be made to the FDA. You can uncheck any submission types that are not needed.

<input checked="" type="checkbox"/> ESTABLISHMENT REGISTRATION AND DRUG LISTING	<input checked="" type="checkbox"/> OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING
<ul style="list-style-type: none"> ESTABLISHMENT REGISTRATION NDC LABELER CODE REQUEST DRUG LISTING AND CERTIFICATION <ul style="list-style-type: none"> BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING BULK INGREDIENT CELLULAR THERAPY DRUG FOR FURTHER PROCESSING HUMAN OTC DRUG LABEL HUMAN PRESCRIPTION DRUG LABEL NON-STANDARDIZED ALLERGENIC LABEL PLASMA DERIVATIVE STANDARDIZED ALLERGENIC VACCINE LABEL NDC RESERVATION 	<ul style="list-style-type: none"> OUTSOURCING FACILITY REGISTRATION COMPOUNDED DRUG REPORTING
<input checked="" type="checkbox"/> COSMETIC REGISTRATION AND LISTING	<input checked="" type="checkbox"/> DSCSA ANNUAL REPORTING
<ul style="list-style-type: none"> REGISTRATION OF COSMETIC PRODUCT FACILITY COSMETIC PRODUCT LISTING 	<ul style="list-style-type: none"> WHOLESALE DRUG DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER REPORTS
<input type="button" value="SUBMIT"/> <input type="button" value="CANCEL"/>	

5. Subaccount creation confirmation will display at the top of the page, and the new user will be listed immediately:

Subaccount User has been created successfully.

All Submissions [Manage Users](#)

LIST OF USERS - CURCUMIN SOLUTIONS

	USERNAME	FIRST NAME	MIDDLE NAME	LAST NAME	ROLE	STATUS	EMAIL	PHONE
	-	Elif	D	Aydin	User	Pending	eda@lighthousellc.com	+90-90-111-111-11-11

6. An activation email is sent to the subaccount user's email. The *Username* field will remain empty until the account has been activated.

2.5.2 Managing A Subaccount

To edit a user's details, including their email and role, click the pencil icon to the far left of the user's entry:

	USERNAME	FIRST NAME	MIDDLE NAME	LAST NAME	ROLE	STATUS	EMAIL	PHONE
	-	Elif	D	Aydin	User	Pending	eda@lighthousellc.com	+90-90-111-111-11-11

You may edit the following information on this page:

- **Inactivate/Reactivate Account** - Select the ‘**Status**’ dropdown and choose ‘Inactive.’ To reactivate an inactive account, choose ‘Active.’ Inactivating an account will prevent the user from logging in and accessing organizational data. Subaccounts cannot be deleted.
- **User Roles** – Select the ‘**User Role**’ dropdown and choose either ‘Admin’ or ‘User.’ Admins have the ability to create and manage subaccounts, while Users do not.
- **Contact Information** – All fields are editable.
- **Form Access** – To limit users to specific forms, check or uncheck the boxes. Unchecked boxes will show as greyed out text on the subaccount user’s homepage and will not be clickable.

All Submissions Manage Users **Create / Edit User**

CONTACT INFORMATION

First Name: * User Role: * Country Code: *

Middle Name: Job Title: Phone Number: *

Last Name: * Contact Email: * Extension:

FORM ACCESS

With a COSMETICS Direct account, the following submissions can be made to the FDA.

COSMETIC REGISTRATION AND LISTING

- REGISTRATION OF COSMETIC PRODUCT FACILITY
- COSMETIC PRODUCT LISTING

CREATE USER **CANCEL**

Click ‘**Submit**’ to confirm changes.

3 SUBMISSION INFORMATION

Please read this section fully before starting a submission!

This section contains general submission information that applies to all account types (Combined, CDER Direct, Cosmetics Direct).

3.1 Submission Options

There are three ways in FDA Direct to submit information to the FDA:

1. Create a new submission via the standard SPL submission templates in FDA Direct.

Recommended if you have never submitted an establishment registration, product listing, etc. FDA Direct has several blank templates available for different types of submissions. See Sections 4 – 8 for walkthroughs based on specific submission types.

2. ‘Clone’ or copy a previously submitted FDA Direct SPL submission.

Recommended if you have previously submitted using one of the templates in FDA Direct and your submission was accepted by the FDA. An exact copy of your previous submission will be generated, and you can make updates as needed.

To clone a submission:

- Navigate to your account main page (by clicking the FDA logo at the top left of the page) and click and click on any submission with the **‘Submission Accepted’** status:

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL
SUBMISSION ACCEPTED	06fb25ba-b23c-92ab-e063-fb95b40a8a24	06fb25ba-b23d-92ab-e063-fb95b40a8a24	cd3879016452.2394681507@direct	1	WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT

- Click **‘Create New Version’** at the top of the page:

The screenshot shows a navigation bar with 'All Submissions', 'WDD/3PL', and 'SPL Submission'. Below the navigation are two buttons: 'VIEW SPL' and 'DOWNLOAD SPL'. At the bottom of the page, there is a note: '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.' To the right of the note is a large red rectangular box highlighting the 'CREATE NEW VERSION' button. To the right of the button is a 'RETURN' link.

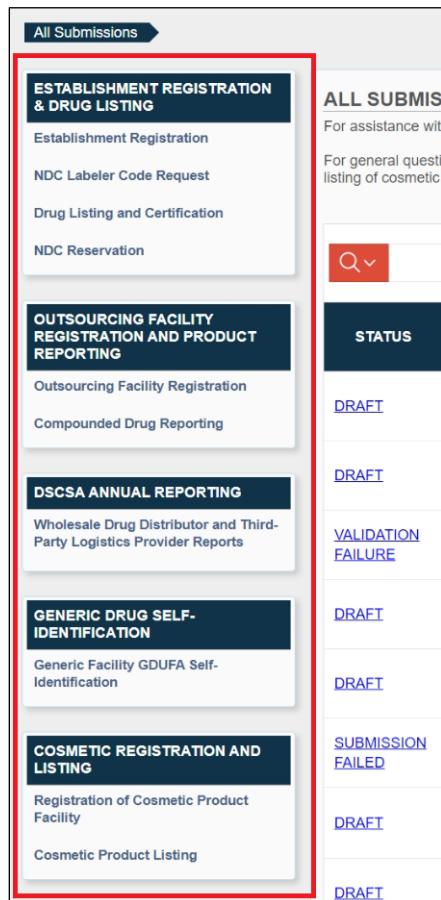
- Make any necessary changes, then return to the top and click **‘Submit.’**

3. Upload an FDA-accepted SPL submission file using a third-party tool.

Recommended if you already have a completed SPL submission file that is ready for submission to the FDA. The file must be in XML format and compressed into a zip file. Changes can be made to the file once it has been uploaded to FDA Direct.

To upload a completed file into FDA Direct:

- Select your submission category from the menu on the left:



- Click 'Create New/Upload File':

The screenshot shows the 'Establishment Registration' section of the CDR Direct interface. On the left, there are three main menu items: 'ESTABLISHMENT REGISTRATION & DRUG LISTING', 'OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING', and 'DSCSA ANNUAL REPORTING'. The 'ESTABLISHMENT REGISTRATION' section contains a detailed description of the registration process, including a list of requirements and a note about validation errors. At the bottom of this section is a table with columns: STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, REGISTRANT DUNS, REGISTRANT NAME, DOCUMENT LABEL, DETAILS, LAST MODIFIED USER, LAST MODIFIED DATE, and a lock icon. Overlaid on this table is a search bar with a magnifying glass icon, a 'GO' button, and a 'SEARCH ESTABLISHMENT' button. To the right of the search bar is a red box highlighting the 'CREATE NEW / UPLOAD FILE' button.

c. Select the 'Import an existing' option then click 'Continue':

The screenshot shows a dialog box titled 'CREATE NEW ESTABLISHMENT REGISTRATION'. It contains two radio button options: 'Create New Establishment Registration using a blank form' and 'Import an existing Establishment Registration SPL'. The 'Import an existing Establishment Registration SPL' option is selected and highlighted with a red box. Below the radio buttons is a note: '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.' At the bottom are 'CONTINUE' and 'CANCEL' buttons.

d. Click the upload area to select an SPL submission file from your computer, or drag the file from your computer onto this area:

The screenshot shows a dialog box titled 'UPLOAD ESTABLISHMENT REGISTRATION FILE'. It features a file input field with the placeholder text 'Establishment Registration File' and a small icon of a document with a magnifying glass. Below the input field is a note: 'Select a file or drop one here.' A red box highlights this file input area. At the bottom are 'UPLOAD' and 'CANCEL' buttons.

e. Once the file has been selected from your computer, click the 'Upload' button:

The screenshot shows the same 'UPLOAD ESTABLISHMENT REGISTRATION FILE' dialog box as the previous one, but now it displays the selected file name 'c7175e5b-8d18-7ed2-e053-0791b40ad884.zip' in the input field. A red box highlights the 'UPLOAD' button at the bottom of the dialog.

f. Your file will be ready for editing. Make any changes necessary.

For more information on editing existing data in your uploaded SPL submission file or how to add new details, skip to the appropriate walkthrough (Sections 4 – 8) of this guide.

3.2 Submission Statuses

Your submissions will always be in one of the following statuses:

- **Draft**: An in-progress submission that has been started but has not been sent to the FDA.
- **Awaiting Acceptance**: A submission that is sent but is pending approval/rejection by the FDA. Displays right after an SPL has been submitted. At this stage, the submission is viewable, but not editable.
- **Validation In Progress**: A submission that is being screened and pre-validated for potential errors prior to being sent to the FDA. This status will display after clicking 'Save And Validate,' and will typically last only a few minutes before changing to 'Validation Failure' or 'Ready For Submission.'
- **Ready For Submission**: A submission that has passed the initial screening and pre-validation check and is ready to be sent to the FDA. If you receive this status after clicking 'Save And Validate,' you must open your submission and click 'Submit' to complete the process.
- **Submission Accepted**: A submission that has been accepted by the FDA.
 - ***For NDC labeler code requests only***: If you did not enter the optional labeler details in an initial NDC Labeler Code Request submission, you will receive an email from the FDA to supply the data.
- **Submission Failed**: A submission that has not been accepted by the FDA's automated validations and has been rejected. You must open your submission to review error messages and update the data to correct them. Submit again and your submission will once again be in 'Awaiting Acceptance' Status.
- **Submission Override**: If you are unable to resolve a failed submission because you are correcting a previous error, the data may need to be manually loaded. A manual override request can be forwarded to the following email addresses:
 - spl@fda.hhs.gov for non-GDUFA related documents
 - CDEReFacility@fda.hhs.gov for GDUFA documents

A manual override is a lengthy process and may need approval from the respective FDA component before the data is loaded. If your request is granted, the file will be accepted by the FDA. A successfully overridden submission will change to the 'Submission Successful' status.

3.3 Submission Header Information

At the top of every submission is a pre-generated set of information:

HEADER DETAILS			
Document Type: *	HUMAN OTC DRUG LABEL	Version Number: *	1
Set ID: *	0ac4630f-6fa2-a749-e063-fa95b40a3a84	Generate New	Effective Date: *
Root ID: *	0ac4630f-6fa3-a749-e063-fa95b40a3a84	Generate New	11-22-2023 

1. Set ID: A 'Globally Unique Identifier' (GUID) that remains the same for each submission 'set,' which is a group of submission versions. When you submit a different version of a submission, the set ID stays the same through each new version.
2. Root ID: A GUID that is generated uniquely for every single submission. When you create a new submission, the root ID is always different (unlike the set ID).
3. Version Number: A number greater than zero that provides a sequence to the versions of the document. Any number can be inputted here, and the next version will automatically continue upward from that number (ex: 23, 24, 25, etc).
4. Effective Date: The date this form is created.

3.4 Submission Help

There are many ways to find assistance during the submission process:

1. Help Text/Tool Tips: You can click on the underlined title text beside every field in any FDA Direct submission. An informational box will display to help you understand what to enter into each field:

PRODUCT DATA ELEMENTS			
NDC Product Code: *	<input type="text"/>	Proprietary Name: *	<input type="text"/>
Non Proprietary Name: *	<input type="text"/>	Suffix:	<input type="text"/>
Dosage Form: *	<input type="text" value="-Select Dosage Form-"/> <div style="margin-top: 5px;"> -- Select DEA Schedule -- <input type="button" value="▼"/> </div>		
DEA Schedule:	<input type="button" value="-- Select DEA Schedule -- ▼"/>		

PRODUCT DATA ELEMENTS

NDC Product Code: *

Non Proprietary Name: *

Dosage Form: * -Select Dosa

NDC Product Code

The NDC is the official FDA 10-digit 3 segment number assigned to all drug products. It is different from the 11 digit alternate version of the NDC used by CMS and the payer industry. The NDC Product Code is the first 2 segments of the NDC. It is the 4 or 5 digit NDC Labeler Code assigned to the company whose name is on the label and the 3 or 4 digit product code segment of the NDC identifying the formulation and dosage form, separated by a hyphen. Before entering the NDC Product Code, make sure the leading zero added to any segment to create the 11 digit version has been removed.

Examples: 12345-678, 23456-7890, 0576-1234

2. **Tutorials/User Guide:** This User Guide provides complete and detailed information on all aspects of FDA Direct. It is recommended for first-time users of FDA Direct.

Tutorials will show you how to complete specific actions like creating an account or submitting a drug product listing. They are less detailed than this User Guide, and in slideshow format. Recommended for users familiar with FDA Direct who may want a quick refresher.

Both the User Guide and tutorials can be found in two places:

a. In the *Quick Links* section below the login area on the [FDA Direct homepage](#):

FDA Direct
CDER Direct & Cosmetics Direct

LOGIN

Username:

Password:

[Forgot your password?](#)

[I accept the Terms of Service](#)

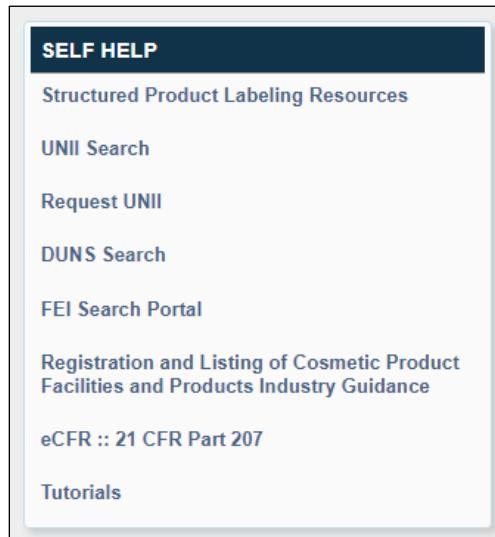
LOGIN

OR

CREATE NEW ACCOUNT

Quick Links: Resources | Tutorials | FAQs | CDER Direct Help Desk | Cosmetic Direct Help Desk

b. Under the *Self Help* section on the left menu (after you log in):



3. **Resources:** Useful links to official submission-related guidance, DUNS & FEI numbers, and so on.
4. **FAQs:** Answers to the most commonly asked questions about FDA Direct. You can use the keyword search bar at the top of the page to find a question related to your issue. The user guide, tutorials, and other helpful information can also be accessed from this page (right side menu).

SEARCH KEYWORDS

Search..

RESULTS

1. What are the different document types that can be submitted through the CDER DIRECT portal?
21 views | 0 | ★★★★☆ | DOCUMENT TYPES FORMS
The following document types are current... (Read more)
2. Can more than one person use a single login at the same time?
3 views | 0 | ★★★★★ | LOGIN
No. CDER DIRECT allows a person to login from... (Read more)
3. How can users be added to the Organization?
1 views | 0 | ★★★★★ | ADMINISTRATION USERS
Once a user has created an account with CDER DIRECT... (Read more)

Order By

Relevance

HELP

Contact Us

Resources

Tutorials

Help Desk

TAG CLOUD

Forms Standards Spi Register Wdd3pl Product
Listing Administration Browser Ndc Labeler
Code Userid Access Document
Types Ndc Labeler Code Request General
Product Labeling Account Setup Users Software
Establishment Registration Duns

5. **Help Desk:** If none of the above resources can help with a particular error or question, you may contact the Help Desk at either CDERDirect@fda.hhs.gov (CDER Direct, Combination accounts), or CosmeticsDirect@fda.hhs.gov (Cosmetics Direct accounts).

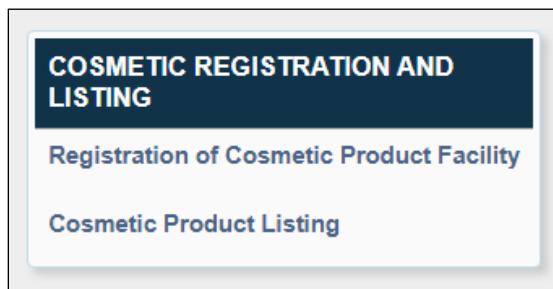
4 COSMETIC REGISTRATION AND LISTING

4.1 Cosmetic Registration and Product Listing SPL

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (Pub. L. 117-328) into law, which included the Modernization of Cosmetics Registration Act of 2022 (MoCRA). Among other provisions, MoCRA added section 607 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishing requirements for cosmetic product facility registration and cosmetic product listing.

Section 607(a) of the FD&C Act requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility with FDA. Section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person submit to FDA “a cosmetic product listing.” Certain small businesses, as defined in section 612 of the FD&C Act, are exempt from the registration and listing requirements. To learn more about MoCRA, visit <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022-mocra>.

This free tool allows you to create and submit the following types of data directly to the FDA: Registration of Cosmetic Product Facility and Cosmetic Product Listing. This system will provide information to FDA about cosmetic product manufacturers/processors and cosmetic products on the market.



The Cosmetic Registration and Listing SPL submission template can be used for the following purposes:

4.2 Document Types

4.2.1 Registration of Cosmetic Facility

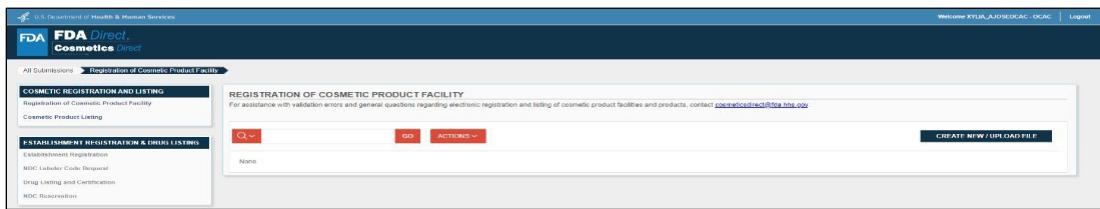
- **Cosmetic Facility Registration (INITIAL):** Every person that, on December 29, 2022, owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States must register each facility no later than December 29, 2023 (section 607(a)(1)(A) of the FD&C Act).
Every person that owns or operates a facility that first engages, after December 29, 2022, in manufacturing or processing of a cosmetic product for distribution in the United States, must register such facility within 60 days of first engaging in such activity or by February 27, 2024, whichever is later (section 607(a)(1)(B) of the FD&C Act).
 - **PLEASE NOTE:** Cosmetic Facility Registration (Initial) is preselected when entering the SPL application.
 - **Additional note:** On November 8, 2023, FDA issued a guidance for industry titled “Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing.” This guidance explains that FDA does not intend to enforce the requirements under section 607 of the FD&C Act related to cosmetic product facility registration until July 1, 2024.
- **Cosmetic Facility Registration (ABBREVIATED REGISTRATION RENEWAL):** FDA is providing for an abbreviated renewal of registrations when there have not been any updates to the registration since the most recent facility registration submission, as required under section 607(a)(4) of the FD&C Act.
- **Cosmetic Facility Registration (AMENDMENT):** Every person who is required to register must update their registration within 60 days of any changes to the information required for registration (section 607(a)(4) of the FD&C Act) (an “amended” registration). This includes any changes that result in cancellation of the registration.
- **Cosmetic Facility Registration (BIENNIAL REGISTRATION RENEWAL):** Every person who is required to register a facility must renew such registration biennially (i.e., every two years) (section 607(a)(2) of the FD&C Act).
- **Cosmetic Facility Registration (CANCELLATION):** Every person who is required to register must update their registration within 60 days of any changes to the information required for registration (section 607(a)(4) of the FD&C Act). This includes any changes that result in cancellation of the registration.

4.2.2 Cosmetic Product Listing

- **COSMETIC-(INITIAL):** The responsible person of a cosmetic product that is marketed on December 29, 2022, must submit a cosmetic product listing, or ensure such submission is made, not later than December 29, 2023, or for a cosmetic product that is first marketed after December 29, 2022, within 120 days of marketing such product in interstate commerce (section 607(c)(2) of the FD&C Act). Consistent with the approach for registration of a facility that starts manufacturing or processing cosmetic products after December 29, 2022 (section 607(a)(1)(B) of the FD&C Act), FDA expects the product listing for a cosmetic product to be submitted within 120 days after marketing the product, or within 120 days after December 29, 2023, whichever is later.
 - **PLEASE NOTE:** On November 8, 2023, FDA issued a guidance for industry titled “Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing.” This guidance explains that FDA does not intend to enforce the requirements under section 607 of the FD&C Act related to cosmetic product listing until **July 1, 2024**.
 - **PLEASE NOTE:** Cosmetic (Initial) is preselected when entering the SPL application form.
- **COSMETIC-ABBREVIATED RENEWAL:** FDA is providing for an abbreviated process for the renewal of any cosmetic product listing, as required under section 607(c)(3), for which there has been no change since the responsible person submitted the previous listing.
 - **PLEASE NOTE:** When making this selection an ALERT box will appear, “*By selecting this document type, you are certifying that no changes have been made to your product listing since the previous listing was submitted*”.
- **COSMETIC-UPDATE (CHANGES TO LISTING or DISCONTINUATION OF LISTING) (annual):**
The responsible person must provide any updates to such listing annually (CHANGES TO LISTING or DISCONTINUATION OF LISTING) (section 607(c)(5) of the FD&C Act). This includes an update that the product was discontinued.

4.3 Registering a New Cosmetic Product Facility

1. Log in to FDA Direct
2. Select ‘**Registration of Cosmetic Product Facility**’ under *Cosmetic Registration and Listing* section:



3. Click 'Create New/Upload File':

CREATE NEW / UPLOAD FILE

You will be given two options:

CREATE NEW REGISTRATION OF COSMETIC PRODUCT FACILITY

- Create a new Cosmetic Product Facility Registration using a blank form
- Import an existing Cosmetic Product Facility Registration 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

4. Select 'Create a new Cosmetic Product Facility Registration using a blank form' then click 'Continue':

CREATE NEW REGISTRATION OF COSMETIC PRODUCT FACILITY

- Create a new Cosmetic Product Facility Registration using a blank form
- Import an existing Cosmetic Product Facility Registration 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

5. A blank template will display with required fields marked with a red (*) and optional fields:

Document Type: * COSMETIC FACILITY REGISTRATION

Set ID: * 10e45b7f-e2b0-e571-e063-6a94af0a439c [Generate New](#) Version Number: * 1

Root ID: * 10e45b7f-e2b1-e571-e063-6a94af0a439c [Generate New](#) Effective Date: * 02-08-2024

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Registration of Cosmetic Product Facility submission form. A red asterisk (*) indicates a required field.

For assistance with validation errors and general questions regarding electronic registration and listing of cosmetic product facilities and products, contact cosmeticsdirect@fda.hhs.gov

6. Selecting the 'Save As Draft' button on the top right will save your work without submitting it. The 'Return' button will send you back to the main Establishment Registration SPL page without saving your changes.

SAVE AS DRAFT **<< RETURN**

7. Cosmetic Facility Registration (**INITIAL**) is preselected. The Set ID, Root ID, Version Number, and Effective Date fields will always auto-populate:

Document Type: * COSMETIC FACILITY REGISTRATION

Set ID: * 10e45b7f-e2b0-e571-e063-6a94af0a439c [Generate New](#) Version Number: * 1

Root ID: * 10e45b7f-e2b1-e571-e063-6a94af0a439c [Generate New](#) Effective Date: * 02-08-2024

Select words are underlined and provide definitions; select them to open the tool tip.

- a. **Set ID**: **This field is auto generated by the system.** The Set ID uniquely identifies a group of versions of an SPL submission. When an SPL submission changes, a new Root ID is assigned to the new SPL submission, but the Set ID in the original SPL submission also is used. The Set ID is a Globally Unique Identifier (GUID). A GUID is a string of numbers and lower- case letters generated using a specifically defined mathematical algorithm to ensure a very low probability of identical GUID used in the same system. An example is: 9aa9d2e6-6982-48e5-831d- dbe7c04a14ed.

b. **Root ID**^{*}: **This field is auto generated by the system.** The Root ID uniquely identifies a specific SPL file. Each new version of an SPL file has a new id root. The id root is a Globally Unique Identifier (GUID). A GUID is a string of numbers and lower-case letters generated using a specifically defined mathematical algorithm to ensure a very low probability of identical GUID used in the same system. An example is: 9aa9d2e6-6982-48e5-831d-dbe7c04a14ed.

c. **Version Number**^{*}: The Version Number gives sequential order to the different versions of an SPL submission. The version number is a whole number greater than zero, such as 6, 7, or 8. The version number is increased with each change to the SPL submission. Enter a number greater than zero (0) in the Version Number field.

d. **Effective Date**^{*}: The date the submission is created, users can modify it. However, the system will only use the actual registration date submitted to FDA. It also provides a date reference to the SPL version. Select the date by clicking on the calendar icon. Once an SPL has been submitted, this date cannot be edited by users.

8. Fill in all the blank fields in the Registrant Details and Facility Contact Details section:

REGISTRATION DETAILS

Is this a facility registration for a small business (optional registration)?: Yes No

Facility Name: *	<input type="text"/>	Facility Country: *	<input type="text"/> -Select Country-
Facility FEI Number: *	<input type="text"/>	Facility Street Address: *	<input type="text"/>
Facility D&B D-U-N-S Number:	<input type="text"/>	Facility City: *	<input type="text"/>
Parent Company Name (if applicable):	<input type="text"/>	Facility State or Province:	<input type="text"/>
		Facility Zip/Postal Code:	<input type="text"/>

a. **Is this a facility for a small business (optional registration) Yes or No:** (Optional) Indicate whether this registration is for a small business (optional registration) by selecting one of the options provided. Section 612 of the FD&C Act provides exemptions to certain small businesses from the requirements of section 607 (Registration and Product Listing). However, such exemptions from the requirements of section 607 of the FD&C Act do not apply to any responsible person or facility engaged in the manufacturing or processing of any of the following products listed in section 612(b) of the FD&C Act:

- **(1) Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual**
- **(2) Cosmetic products that are injected**

- (3) Cosmetic products that are intended for internal use
- (4) Cosmetic products that are intended to alter appearance for more than 24 hours under conditions of use that are customary or usual and removal by the consumer is not part of such conditions of use that are customary or usual.

b. Facility Name^{*}: Enter the complete name of the existing facility.

c. Facility FEI Number^{*}: Enter the existing 7 to 10-digit facility FEI number. The FEI number is a unique identifier assigned by the FDA to identify firms associated with FDA-regulated products. To facilitate the registration process, the owner or operator of a facility will need to obtain an FEI number before submitting the facility registration.

- To determine if an entity already has an FEI number, please refer to the [FEI Search Portal](#).
- If your firm does not have an FEI number assigned by FDA, see “[How can I request an FEI?](#)” at [FEI Search Portal](#).

d. Parent Company Name: (optional field) Enter the parent company's name if available.

e. Facility D&B D-U-N-S Number: (optional field) Enter the existing 9-digit facility DUNS number. Obtain a DUNS number: <https://www.dnb.com>

f. Name of the Owner and/or Operator of the Facility^{*}: Enter the facility owner's name and/or the name of the facility operator.

g. Facility Email^{*}: Enter the facility's email address.

h. Facility Phone Number^{*}: Enter the facility's phone number including the area or the country code. The format for Phone number should be <Country Code>-<Area Code>-<Subscriber Number>. For example, in the U.S. the phone number would be 1-999-9999999 or 1-999-999-9999

i. Facility Country^{*}: Select facility's country name where the facility is physically located.

j. Facility Street Address^{*}: Enter the complete information of the street where the facility is physically located.

k. Facility City^{*}: Enter the complete name of the city where the facility is physically located.

l. Facility State or Province: Enter the complete name of the state or province where the facility is physically located.

- m. Facility Zip/Postal Code: Enter the postal code or the zip code where the facility is physically located.

9. Fill in all the blank fields in the U.S. Agent Contact Information section (for foreign facilities):

US AGENT	
U.S. Agent Name (for foreign facilities): *	<input type="text"/>
U. S. Agent Email (If not available, enter "N/A") *	<input type="text"/>
	U.S. Agent Phone Number (Include Country/Area Code): *
	<input type="text"/>
	U.S. Agent Phone Extension:
	<input type="text"/>

- a. U.S. Agent Name (for foreign facilities) *: For foreign facilities, enter the business name of the U.S. agent.
- b. U.S. Agent Email (if not available, enter "N/A") *: For foreign facilities, enter the email address for the US agent contact person. If email address not available, enter N/A.
- c. U.S. Agent Phone Number (Include Country/Area Code) *: For foreign facilities, enter the U.S. agent telephone number including the country code and the area code. The format for Phone number should be <Area Code>-<Subscriber Number>. For example, in the U.S. the phone number would be 1-999-9999999 or 1-999-999-9999.
- d. U.S. Agent Phone Extension: (optional Field) For foreign facilities, enter U.S. agent phone extension, if any.

PLEASE NOTE: With respect to a foreign facility, a United States agent ("U.S. agent") is required for registration purposes. The U.S. agent is the person, which includes an individual or business entity, that resides in the U.S. or maintains a U.S. place of business and is physically present in the U.S. A U.S. agent should not be a mailbox, answering machine or service, or other place where an individual acting as the foreign facility's agent is not physically present.

10. To add multiple facility brand names to your SPL template, click the '**Add Brand Name**' button in *Facility Brand Names* section:

ADD BRAND NAME

11. A blank template titled *Brand Information* will display. Fill in the required fields and select all that apply.

BRAND INFORMATION

Brand Name of Cosmetic Products: *

Responsible Person (As listed on the label): *

Product Category Code(s) (Select all that apply): *

- (01) Baby products
- (02) Bath preparations
- (03) Eye makeup preparations (other than children's eye makeup preparations)
- (04) Children's eye makeup preparations
- (05) Fragrance preparations
- (06) Hair preparations (non-coloring)
- (07) Hair coloring preparations
- (08) Makeup preparations (not eye)(other than makeup preparations for children)
- (09) Makeup preparations for children (not eye)
- (10) Manicuring preparations
- (11) Oral products
- (12) Personal cleanliness
- (13) Shaving preparations
- (14) Skin care preparations (creams, lotions, powder, and sprays)
- (15) Suntan preparations
- (16) Tattoo preparations
- (17) Other preparations (i.e., those preparations that do not fit another category)

- a. **Brand Name of Cosmetic Product***: Enter brand names under which cosmetic products manufactured or processed in the facility are sold.
- b. **Responsible Person (As listed on the label)** *: Enter the responsible person name as it appears on the label.
- c. **Product Category Code(s) (Select all that apply)** *: Select the product category or categories for this brand name. Each main product category has a sub-product category. And some sub-product categories have sub-sub product categories, select the one that applies to this brand name. (i.e., leave-on or rinse-off).

12. Fill in all the blank fields in the Brand Information section.

13. Select the (+) of Product Category Code(s) and select all that apply:

- a. (01) - (16) are Main Product Categories

- (01) Baby products
 - (A) Baby shampoos
 - (B) Lotions, oils, powders, and creams
 - (C) Baby wipes
 - + (D) Other baby products
- (02) Bath preparations
 - (A) Bath oils, tablets, and salts
 - (B) Bubble baths
 - (C) Bath capsules
 - (D) Other bath preparations
- (03) Eye makeup preparations (other than children's eye makeup preparations)
 - (A) Eyebrow pencils
 - (B) Eyeliners
 - (C) Eye shadows
 - (D) Eye lotions
 - (E) Eye makeup removers
 - (F) False eyelashes
 - (G) Mascaras
 - (H) Eyelash and eyebrow adhesives, glues, and sealants
 - (I) Eyelash and eyebrow preparations (primers, conditioners, serums, fortifiers)
 - (J) Eyelash cleansers
 - (K) Other eye makeup preparations

b. (A) - (K) are Sub Product Categories. If that sub product category has a Sub-Subcategory, (+) can be selected to display the Sub-Subcategories (select if one or both apply; if none, leave unselected):

- Leave-on
- Rinse-off

- (06) Hair preparations (non-coloring)
 - (A) Hair conditioners
 - 1. Leave-on
 - 2. Rinse-off

14. Click 'SAVE BRAND', located at the top right of the page:

SAVE BRAND

15. The platform will return to the SPL Submission page with the verification banner 'Product brand saved.'

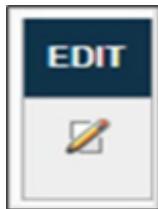
Product brand saved.

Under 'FACILITY BRAND NAMES' the inputted information will be present.

EDIT	BRAND NAME	RESPONSIBLE PERSON NAME	PRODUCT CATEGORY CODE(S)
	Company Name	Responsible Person (as listed on the label)	<ul style="list-style-type: none"> • (06) Hair preparations (non-coloring) - (b) Hair sprays (aerosol fixatives) • (06) Hair preparations (non-coloring) - (c) Hair straighteners • (06) Hair preparations (non-coloring) - (d) Rinse (non-coloring) • (06) Hair preparations (non-coloring) - (f) Shampoos (non-coloring) - 2. Rinse-off • (07) Hair coloring preparations - (a) Hair dyes and colors (all types requiring caution statement and patch test) • (07) Hair coloring preparations - (b) Hair tints • (07) Hair coloring preparations - (e) Hair color sprays (aerosol)

1 - 1

To edit the information, select the pencil icon under the 'EDIT' column.



16. To add more Brand Names, go to 'FACILITY BRAND NAMES' and select '**ADD BRAND NAME**'.
17. In the Confirmation Statement section, fill in the following blank fields:
 - a. **Date:** (Optional field) Enter today's date, two-digit month, two-digit day, and four-digit year.
 - b. **Name of Submitter:** (optional field) Enter the full name of the submitter.

CONFIRMATION STATEMENT

The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate. I agree to report changes to this information and renew as required under section 607 of the Federal Food, Drug and Cosmetic Act.

WARNING: A willfully false statement is a criminal offense, [U.S. Code, Title 18, Section 1001](#).

<input type="checkbox"/> I Agree	Date	<input type="text"/> 
Name of Submitter <input type="text"/>		

18. Click 'AGREE' after reading and understanding the confirmation statement:



19. If you would like to list additional contact information for an authorized agent, go to the '**Additional Contact Information For Authorized Agent**' section and fill in the following blanks:

ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

Additional Contact Name:	<input type="text"/>	Phone Number (Include Country/Area Code):	<input type="text"/>
Email:	<input type="text"/>	Phone Extension:	<input type="text"/>

- a. Additional Contact Name: (optional field) Enter an additional contact information for individuals associated with the registration.
- b. Email: (optional field) Provide the additional contact person's email address
- c. Phone Number (Include Country/Area Code): (optional field) Enter the additional contact person's phone number including the country code and the area code. The format for Phone number should be <Country Code>-<Area Code>-<Subscriber Number>. For example, in the U.S. the phone number would be 1-999-9999999 or 1-999-999-9999.
- d. Phone Extension: (optional field) Enter additional contact person's phone extension, if any.

20. Return to the top of the SPL Submission page where you can do the following:

SUBMIT SPL	SAVE AS DRAFT	SAVE AND VALIDATE	DELETE	<< RETURN
------------	---------------	-------------------	--------	-----------

- a. **'SUBMIT SPL'**
 - Submit SPL will send the submission to FDA for additional validation and processing.
- b. **'SAVE AS DRAFT'**
 - Save Draft button allows you to save your work, preserving your progress without submitting it to the FDA.
 - **PLEASE NOTE:** Click 'SAVE AS DRAFT' from any screen during the process of registering the cosmetic product facility. The system saves all the information you inputted and will bring you back to the homepage. The status column will be in 'DRAFT'.



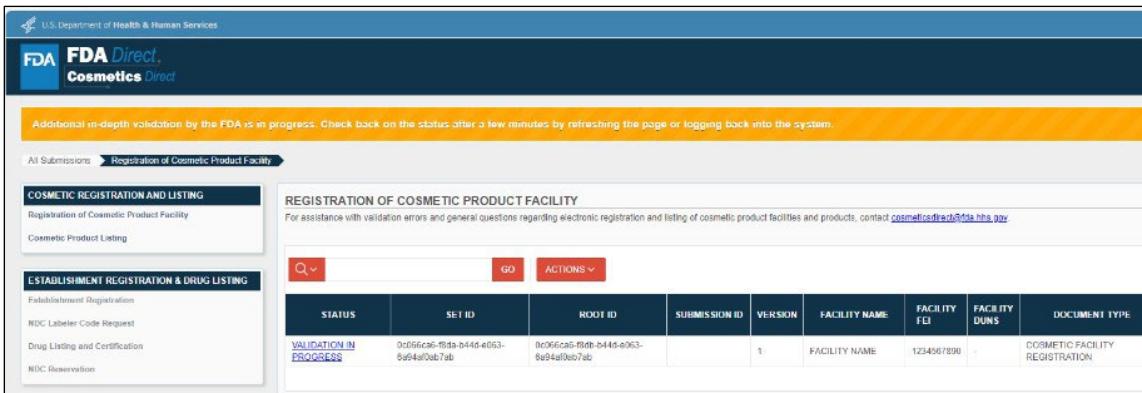
- c. **'SAVE AND VALIDATE'**
 - You can check your SPL for an initial validation before submitting to FDA. This option does not automatically submit your SPL to FDA, even if it passes the initial validation, but scans for certain errors prior to the actual submission.
- d. **'DELETE'**

- Delete will remove the submission from your account.

21. Click 'RETURN' at any time to return to the Registration of Cosmetic Product Facility main page.

4.3.1 Save and Validate

1. Click 'SAVE AND VALIDATE' if you want to check for errors within your SPL. To submit your SPL to FDA, skip to Section 4.3.2: Submit to FDA.
 - a. **PLEASE NOTE:** This option is only for an initial validation of your SPL before submitting to FDA. It does not automatically submit your SPL to FDA, even if it passes the initial validation, but scans for certain errors prior to the actual submission. To submit your data to the FDA, select "Submit SPL".
2. The Registration of Cosmetic Product Facility homepage will have the following details shown below. The status of your SPL will be in 'VALIDATION IN PROGRESS'. A yellow message will appear across your screen stating, "Additional in-depth validation by the FDA is in progress. Check back on the status after a few minutes by refreshing the page or logging back into the system."



The screenshot shows the FDA Direct Cosmetic Product Facility registration homepage. At the top, there is a yellow banner with the text: "Additional in-depth validation by the FDA is in progress. Check back on the status after a few minutes by refreshing the page or logging back into the system." Below the banner, the page title is "All Submissions > Registration of Cosmetic Product Facility". The main content area is titled "REGISTRATION OF COSMETIC PRODUCT FACILITY" with a sub-instruction: "For assistance with validation errors and general questions regarding electronic registration and listing of cosmetic product facilities and products, contact cosmetic.centre@fda.hhs.gov". Below this, there is a search bar with "GO" and "ACTIONS" buttons, and a table with columns: STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, FACILITY NAME, FACILITY FEI, FACILITY DUNS, and DOCUMENT TYPE. The first row in the table shows the status as "VALIDATION IN PROGRESS".

3. Once the system has completed validation, the status 'VALIDATION IN PROGRESS' will change to 'READY FOR SUBMISSION'.



The screenshot shows the FDA Direct Cosmetic Product Facility registration homepage after validation has completed. A green banner at the top says: "Click here to view submissions that have completed validation." Below the banner, the table from the previous screenshot now shows the status as "READY FOR SUBMISSION".

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT TYPE
READY FOR SUBMISSION	0c066ca6-f8da-b44d-e063-6a94af0ab7ab	0c066ca6-f8da-b44d-e063-6a94af0ab7ab	0c066ca6-f8da-b44d-e063-6a94af0ab7ab	1	FACILITY NAME	1234567890	-	COSMETIC FACILITY REGISTRATION

- a. If the system finds any errors, the status field will change to 'VALIDATION FAILURE', see Section 4.3.5: Validation Failure for additional details.

4. Click 'READY FOR SUBMISSION', the homepage will change to reflect the following:

- The system will generate a message stating that, '*This submission has passed the INITIAL VALIDATION but has NOT been ACTUALLY SUBMITTED TO FDA. Click ON "SUBMIT SPL" to SUBMIT.*'

4.3.2 Submit SPL to FDA

- Click 'SUBMIT SPL' if you are ready to submit your SPL to FDA.

SUBMIT SPL

- A green message will appear across your screen stating, "Your submission has been sent to FDA for additional validation and processing. Check the status of your submission after a few minutes by refreshing the page or logging back into the system. You will also receive an email from FDA when the processing is complete."

- The status field should read '**AWAITING ACCEPTANCE**'.



4.3.3 Submission Accepted

1. The status column will change to '**SUBMISSION ACCEPTED**' after the registration process has been successfully completed. A '**SUBMISSION ID**' will be generated automatically when an SPL is submitted to the FDA.

Please Note: A '**SUBMISSION ID**' does not always mean that the submission was in fact accepted by FDA. The '**Submission ID**' will also appear with '**Awaiting Acceptance**' and '**Submission Failure**'.

REGISTRATION OF COSMETIC PRODUCT FACILITY								
For assistance with validation errors and general questions regarding electronic registration and listing of cosmetic product facilities and products, contact cosmeticsdirect@fda.hhs.gov .								
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT TYPE
SUBMISSION ACCEPTED	0c066ca6-f8da-b44d-e063-6a94af0ab7ab	0c066ca6-f8db-b44d-e063-6a94af0ab7ab	cm1397680542.5304619872@direct	1	FACILITY NAME	1234567890	-	COSMETIC FACILITY REGISTRATION

2. Click on '**SUBMISSION ACCEPTED**' to **VIEW SPL** and **DOWNLOAD SPL**.
 - a. To clone and create a new version of your successfully submitted SPL, click '**CREATE A NEW VERSION**'

CREATE NEW VERSION

1. **PLEASE NOTE:** After selecting, your SPL will be successfully cloned and the ROOT ID, VERSION NUMBER, and EFFECTIVE DATE will change. All other fields will retain the same information from the initial successfully submitted SPL.

DOCUMENT TYPE DETAILS	
Document Type: *	COSMETIC FACILITY REGISTRATION
Set ID: *	0c066ca6-f8da-b44d-e063-6a94af0ab7ab
Root ID: *	0c06eb2a-30c9-7866-e063-6b94af0af38e
Generate New	Version Number: *
Generate New	Effective Date: *
	12-08-2023

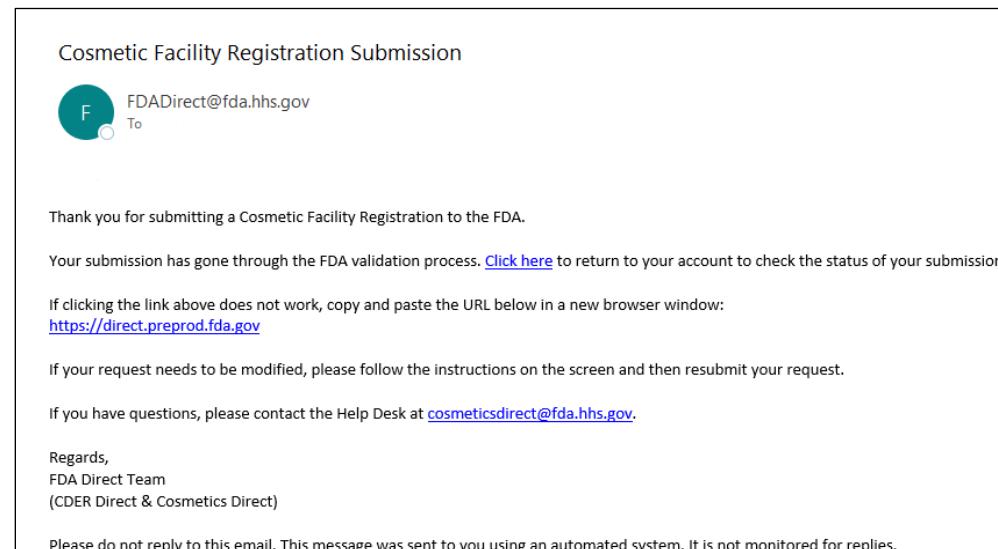
b. To view your SPL, click 'VIEW SPL'

VIEW SPL

c. To download your SPL for your records, click 'DOWNLOAD SPL'

DOWNLOAD SPL

d. When your submission has been validated by the FDA. You will receive an email to your account email address when the submission status changes.



e. A 'SUBMISSION ACCEPTED' status will appear in the status column of your SPL submission if it has been successfully submitted to the FDA. At this point, the process is finished and there is no further action needed unless you need to make any changes to your registration.

4.3.4 Submission Failed

1. If the status column changes to 'SUBMISSION FAILED', your submission has not passed the FDA's requirements and has been rejected.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL
SUBMISSION FAILED	0c066ca6-f3da-b44d-e063-6a94af0ab7ab	0c06eb2a-30c9-7866-e063-6b94af0af38e	cm6301528479.1247385960@direct	2	COSMETIC FACILITY REGISTRATION

a. You must open your submission at this stage to review error messages and update your submission to correct them.



b. Submit again and your submission will once again be '**AWAITING ACCEPTANCE**'.

2. If the status column changes to '**SUBMISSION ACCEPTED**', refer to Section 4.3.3: **Submission Accepted** for additional information.

4.3.5 Validation Failure

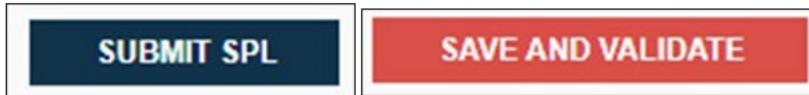
1. After clicking '**SAVE AND VALIDATE**', the registration of cosmetic product facility home page will have the following details as shown below. The status column will be in **VALIDATION IN PROGRESS**. However, if the system finds any errors the status will change to **VALIDATION FAILURE**.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT TYPE
VALIDATION FAILURE	0c066ca6-f8da-b44d-e063-6a94af0ab7ab	0c066ca6-f8db-b44d-e063-6a94af0ab7ab		1	FACILITY NAME	1234567890	-	COSMETIC FACILITY REGISTRATION

2. Click '**VALIDATION FAILURE**', the system will provide a list of errors that need to be fixed before submitting the SPL:



- a. After reviewing and fixing the errors, you can select '**SUBMIT SPL**' to resubmit or '**SAVE AND VALIDATE**' to check for any additional errors.



4.3.6 Amending Cosmetic Product Facility Registration

This document type should be selected if you are updating your registration within 60 days of any changes to the information required for registration (section 607(a)(4) of the FD&C Act)

1. Under Document Type, select '**COSMETIC PRODUCT FACILITY REGISTRATION – AMENDMENT**'.

DOCUMENT TYPE DETAILS

Document Type: *	COSMETIC FACILITY REGISTRATION
--Select One--	
Set ID: *	COSMETIC FACILITY REGISTRATION
Root ID: *	COSMETIC FACILITY REGISTRATION - ABBREVIATED RENEWAL
	COSMETIC FACILITY REGISTRATION - AMENDMENT
	COSMETIC FACILITY REGISTRATION - BIENNIAL RENEWAL
	COSMETIC FACILITY REGISTRATION - CANCELLATION

2. Repeat the steps in Section 4.3.3.
3. Refer to the steps in Section 4.3.2 for Submit to FDA instructions.

4.3.7 Amending Cosmetic Product Facility Cancellation

This document type should be selected if you are updating your registration within 60 days of any changes to the information required for registration (section 607(a)(4) of the FD&C Act) that result in cancellation of the registration.

1. Under Document Type, select '**COSMETIC PRODUCT FACILITY REGISTRATION – CANCELLATION**'.

DOCUMENT TYPE DETAILS

Document Type: *	COSMETIC FACILITY REGISTRATION - CANCELLATION
--Select One--	
Set ID: *	COSMETIC FACILITY REGISTRATION
Root ID: *	COSMETIC FACILITY REGISTRATION - ABBREVIATED RENEWAL
	COSMETIC FACILITY REGISTRATION - AMENDMENT
	COSMETIC FACILITY REGISTRATION - BIENNIAL RENEWAL
	COSMETIC FACILITY REGISTRATION - CANCELLATION

- a. **PLEASE NOTE:** The following message will appear, "By selecting this document type, any changes made to the submission will be lost and the submission details will be reverted to the previous submission." Select '**OK**':

By selecting this document type, any changes made to the submission will be lost and the submission details will be reverted to the previous submission.

OK

Cancel

2. After selecting 'OK', the fields for Registration Details, Confirmation Statement, and Additional Contact Information for Authorized Agent will be grayed out and can no longer undergo changes.
3. Click 'SUBMIT SPL' to submit your cancellation request to FDA.

SUBMIT SPL

4.3.8 Biennial Cosmetic Product Facility Registration Renewal

This document type should be selected to renew your registration biennially (i.e., every two years).

1. Under Document Type, select 'COSMETIC PRODUCT FACILITY REGISTRATION – BIENNIAL REGISTRATION RENEWAL'.

DOCUMENT TYPE DETAILS	
Document Type: *	COSMETIC FACILITY REGISTRATION - CANCELLATION
Set ID: *	--Select One-- COSMETIC FACILITY REGISTRATION COSMETIC FACILITY REGISTRATION - ABBREVIATED RENEWAL COSMETIC FACILITY REGISTRATION - AMENDMENT COSMETIC FACILITY REGISTRATION - BIENNIAL RENEWAL COSMETIC FACILITY REGISTRATION - CANCELLATION
Root ID: *	

2. Repeat the steps in Section 4.3.3.
3. Refer to the steps in Section 4.3.2 for Submit to FDA instructions.

4.3.9 Abbreviated Cosmetic Product Facility Registration

This document type should be selected if there have not been any updates to the registration since the most recent facility registration submission as required under section 607(a)(4) of the FD&C Act.

- Under Document Type, select '**COSMETIC PRODUCT FACILITY REGISTRATION – ABBREVIATED REGISTRATION RENEWAL**'.

DOCUMENT TYPE DETAILS

Document Type: *	COSMETIC FACILITY REGISTRATION - BIENNIAL RENEWAL
Set ID: *	--Select One--
Root ID: *	COSMETIC FACILITY REGISTRATION COSMETIC FACILITY REGISTRATION - ABBREVIATED RENEWAL COSMETIC FACILITY REGISTRATION - AMENDMENT COSMETIC FACILITY REGISTRATION - BIENNIAL RENEWAL COSMETIC FACILITY REGISTRATION - CANCELLATION

- PLEASE NOTE:** The following message will appear, "By selecting this document type, you are certifying that no changes have been made to your registration since the previous registration was submitted. Any changes made to the submission will be lost and the submission details will be reverted to the previous submission." Select, 'OK' to proceed.

By selecting this document type, you are certifying that no changes have been made to your registration since the previous registration was submitted. Any changes made to the submission will be lost and the submission details will be reverted to the previous submission.

OK
Cancel
- After selecting 'OK', the fields for Registration Details, Confirmation Statement, and Additional Contact Information for Authorized Agent will be grayed out and can no longer undergo changes.
- Click '**SUBMIT SPL**' to submit your request to FDA.

SUBMIT SPL

4.4 Cosmetics Product Listing

4.4.1 New Cosmetics Product Listing

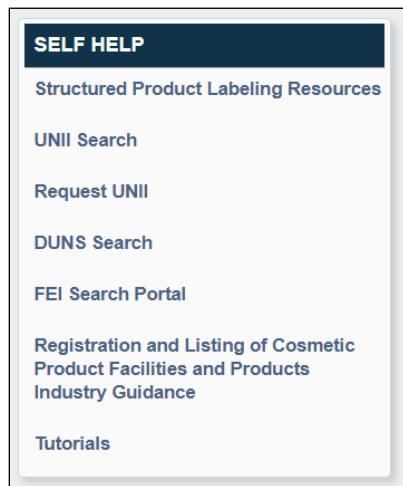
1. Log in to FDA Direct.
2. Select '**Cosmetic Product Listing**' under *Cosmetic Registration and Listing* section, on the left side of the FDA Direct menu.

STATUS	SET ID	ROOT ID
DRAFT	0a977e9a-3471-0b38-e063-fa95b40ac6b6	0a977e9a-3472-0b38
DRAFT	0a330707-7150-6d2c-e063-fb95b40a9540	0a330707-7151-6d2c

3. Navigate to the Cosmetic Product Listing Home Page AFTER selecting '**Cosmetic Product Listing**' under *Cosmetic Registration and Listing* section, on the left side of the FDA Direct menu. This will navigate the user to the **Cosmetic Product Listing Home Page**. The **Cosmetic Product Listing Home Page** will provide the ability to view all the previous product listing submissions based on the user's accessibility.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	RESPONSIBLE PERSON NAME	DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE	LOCK
--------	--------	---------	---------------	---------	---------------	-------------------------	---------	--------------------	--------------------	------

- a. Submission status: The status of each submission made to FDA. The status types are draft, validation in process, validation failure, ready for submission, and submission accepted.
- b. **Self-Help** box is also available at the bottom of the left side underneath all the submission boxes.



- This box contains articles and weblinks for additional information. It is also available on the FDA Direct home pages as well.

c. **Search bar** is available on the Cosmetic Product Listing home page.



- A user can search any previous submission or current submission by providing the Set ID, Root ID, or the submission ID number.

d. A product can be searched by select the **SEARCH PRODUCT** box next to **CREATE NEW/UPLOAD FILE**.



PLEASE NOTE: For assistance with validation errors in Cosmetic Direct contact cosmeticsdirect@fda.hhs.gov. For general questions regarding electronic registration and listing of cosmetic product facilities, contact eRLC@fda.hhs.gov.

e. Select '**CREATE NEW/UPLOAD FILE**' to begin the Cosmetics Product Listing submission process.



4.4.2 Create a New Cosmetic Product Listing

1. Click '**Create New/Upload File**':

CREATE NEW COSMETIC PRODUCT LISTING

Create a new Cosmetic Product Listing using a blank form
 Import an existing Cosmetic Product Listing

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 on the "CREATE NEW/UPLOAD FILE" button. This will open a new window where **you will be given two options: create a new/initial Cosmetic Product Listing or upload** an FDA-accepted SPL stored on your computer in a valid XML zip file. Importing an existing Cosmetic Product Listing SPL will be beneficial for bulk submission of multiple product listings under one submission.

SPL (Structured Product Labeling) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information.

- If you are '**Creating a New Cosmetic Product Listing using a blank form**', enter the required information. This includes:
 - The facility registration number (FEI) of each facility where the cosmetic product is manufactured or processed:
 - PLEASE NOTE:** The responsible person will need to obtain the relevant facility registration number(s) for each facility where its cosmetic products are manufactured or processed, because the facility registration number(s) is required for the product listing submission. If the facility is exempt from registration, for example because it is a small business, and has no facility registration number, then facility name/address can be provided instead.
 - The name and contact number of the responsible person and the name for the cosmetic product, as such name appears on the label.
 - The applicable cosmetic category or categories for the cosmetic product
 - A list of ingredients in the cosmetic product, including any fragrances, flavors, or colors, with each ingredient identified by the name, as required under section 701.3 of title 21, Code of Federal Regulations (or any successor regulations), or by the common or usual name of the ingredient.
 - The product listing number, if any previously assigned by the system.
 - Type of submission (initial, update to content (annual), abbreviated renewal).

b. Additional information can be provided, such as:

- Parent company name (if applicable)
- Type of business (as listed on the label), i.e., manufacturer, packer, or distributor.
- Image of the label (currently jpg files are accepted)
- Product webpage link
- Whether the cosmetic product is for professional use only
- Responsible person DUNS Number for address listed on product label.
- Unique Ingredient Identifiers (UNIIs)
 - **PLEASE NOTE:** For more information and to search for UNIIs please refer to the webpage at: <https://precision.fda.gov/uniisearch>. For UNII requests contact: FDA-SRS@fda.hhs.gov.
- Additional contact information for individuals associated with the listing.

c. If you are **uploading/importing an existing Cosmetic Product Listing SPL file** containing multiple product listings, make sure that the file is in the correct SPL format. This file may contain both the XML file and image (jpg) files, for bulk submission. Once the file has been uploaded, a user can **SAVE AND VALIDATE** to run a system validation check or **SUBMIT SPL**.

UPLOAD COSMETIC PRODUCT LISTING FILE

Cosmetic Product Listing File 
0a3d56b8-1955-9717-e063-eb95b30a2eb3.zip

Note: Please upload a zip file that contains the SPL file with the name as the root id followed by ".xml" and any associated image files that are referenced in the xml whose names end in 'jpg'.

UPLOAD **CANCEL**

3. Select '**Creating a New Cosmetic Product Listing using a blank form**' then click '**Continue**':

CREATE NEW COSMETIC PRODUCT LISTING

Create a new Cosmetic Product Listing using a blank form
 Import an existing Cosmetic Product Listing 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**

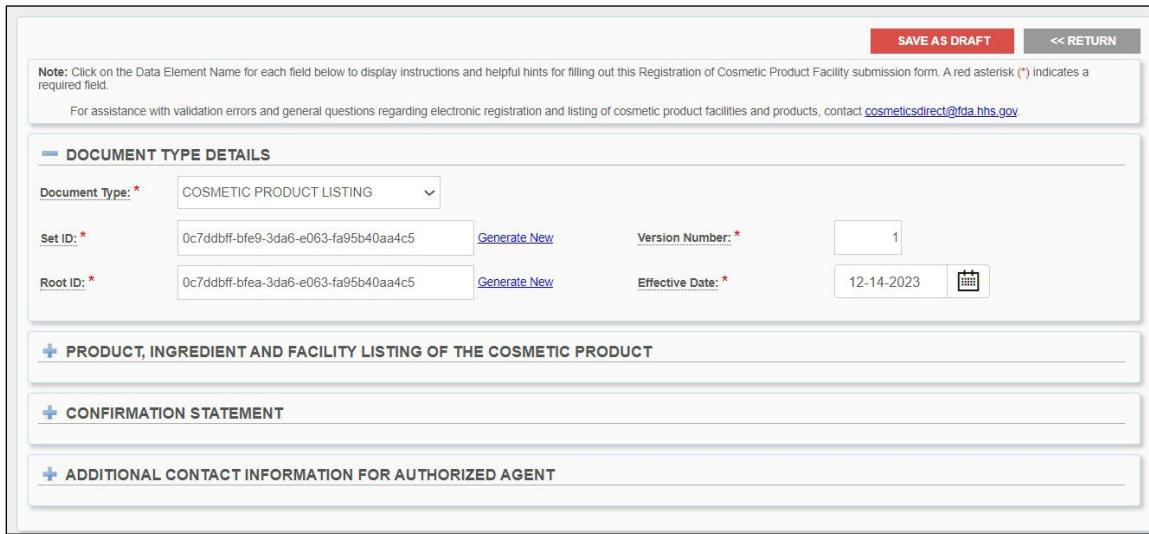
4. Navigate to the Create a New Cosmetics Product Listing using a blank form page. You can do this by clicking on the "Create an initial Cosmetic Product Listing using a blank form" option on the Create a New Product Listing or Upload an Existing File page.
 - a. This will allow users to create a new product listing for a cosmetic product using a blank form.
5. A **blank template** will display with **required and optional fields**, a red asterisk (*) indicates a required field throughout the submission process:

6. Enter the required information as indicated by red asterisk (*) throughout the submission process.
 - a. **PLEASE NOTE:** For assistance with validation errors in Cosmetic Direct contact CosmeticsDirect@fda.hhs.gov. For general questions regarding electronic registration and listing of cosmetic product facilities, contact eRLC@fda.hhs.gov.

7. A tour guide  is available to walk a user through the submission icon as shown below.

- a. **SUBMIT SPL:** Submit SPL will send the submission to FDA for additional validation and processing.
- b. **SAVE AS DRAFT:** Save Draft button allows you to save your work, preserving your progress without submitting it to the FDA.
- c. **SAVE AND VALIDATE:** You can check your SPL for an initial validation before submitting to FDA. This option does not automatically submit your SPL to FDA, even if it passes the initial validation, but scans for certain errors prior to the actual submission.

- d. **DELETE:** This will remove the submission from your account.
- e. **RETURN:** This will guide the user to Cosmetics Product Listing Submissions home page without saving your changes.
- 8. Select the '+' to open or '-' to close the **DOCUMENT TYPES** section of the **COSMETIC PRODUCT LISTING** to focus one section at a time, a red asterisk (*) indicates a required field throughout the submission process:  



DOCUMENT TYPE DETAILS

Document Type: * COSMETIC PRODUCT LISTING

Set ID: * 0c7ddbf-bfe9-3da6-e063-fa95b40aa4c5 [Generate New](#) Version Number: * 1

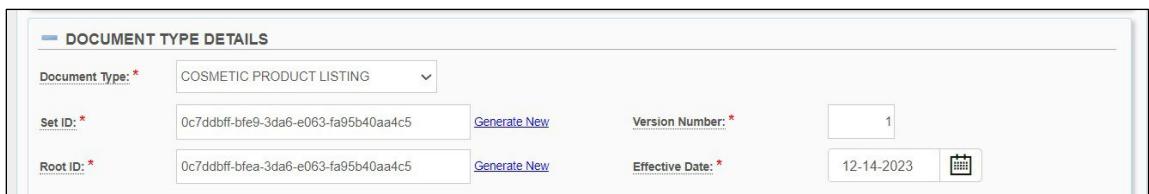
Root ID: * 0c7ddbf-bfea-3da6-e063-fa95b40aa4c5 [Generate New](#) Effective Date: * 12-14-2023 [Calendar](#)

PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT

CONFIRMATION STATEMENT

ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

- a. **PLEASE NOTE:** The **DOCUMENT TYPE** of the **DOCUMENT TYPE DETAILS** section is preselected to COSMETIC PRODUCT LISTING, which is the **(INITIAL)** submission. The **Set ID**, **Root ID**, **Version Number**, and **Effective Date** fields will always auto-populate for the **INITIAL SUBMISSION**:
- 9. Select “**DOCUMENT TYPE DETAILS**,” a red asterisk (*) indicates a required field throughout the submission process:



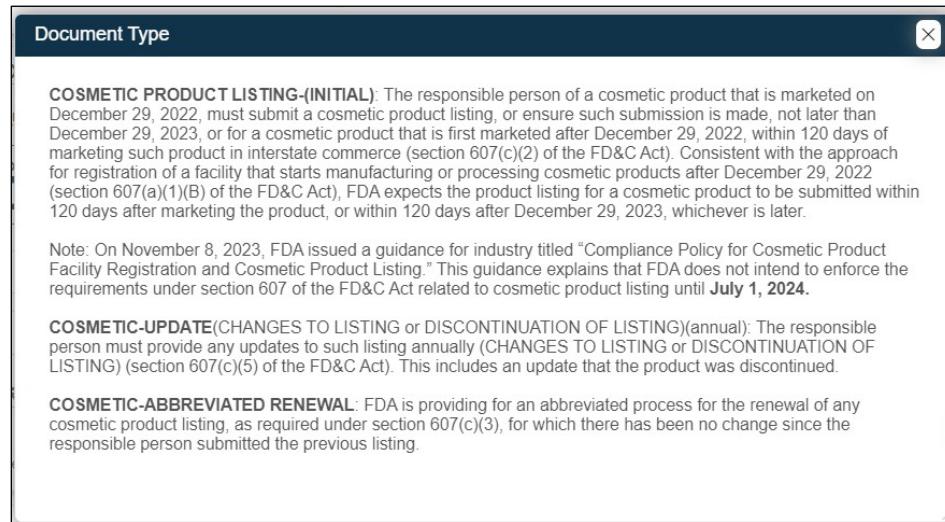
DOCUMENT TYPE DETAILS

Document Type: * COSMETIC PRODUCT LISTING

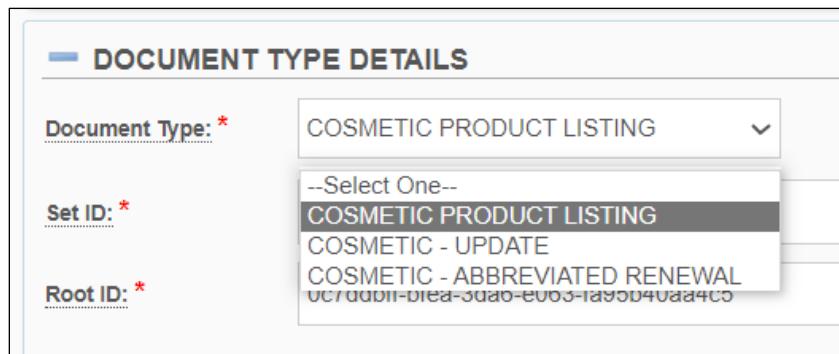
Set ID: * 0c7ddbf-bfe9-3da6-e063-fa95b40aa4c5 [Generate New](#) Version Number: * 1

Root ID: * 0c7ddbf-bfea-3da6-e063-fa95b40aa4c5 [Generate New](#) Effective Date: * 12-14-2023 [Calendar](#)

- a. **PLEASE NOTE:** By selecting the dotted underlined words throughout the system will pop up a tooltip with brief explanation/definitions, along with the link to the MoCRA guidance, as shown as an example below.



10. Select one of the '**DOCUMENT TYPE**' by selecting the drop-down icon, a red asterisk (*) indicates a required field throughout the submission process:



a. DOCUMENT TYPES INFORMATION*:

- **COSMETIC PRODUCT LISTING -(INITIAL):** The responsible person of a cosmetic product that is marketed on December 29, 2022, must submit a cosmetic product listing, or ensure such submission is made, not later than December 29, 2023, or for a cosmetic product that is first marketed after December 29, 2022, within 120 days of marketing such product in interstate commerce (section 607(c)(2) of the FD&C Act). Consistent with the approach for registration of a facility that starts manufacturing or processing cosmetic products after December 29, 2022 (section 607(a)(1)(B) of the FD&C Act), FDA expects the product listing for a cosmetic product to be submitted within 120 days after marketing the product, or within 120 days after December 29, 2023, whichever is later.

- **PLEASE NOTE:** On November 8, 2023, FDA issued a guidance for industry titled “Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing.” This guidance explains that FDA does not intend to enforce the requirements under section 607 of the FD&C Act related to cosmetic product listing until **July 1, 2024**.
- **PLEASE NOTE:** Cosmetic Product Listing (Initial) is preselected when entering the SPL application form.
- **COSMETIC-ABBREVIATED RENEWAL:** FDA is providing for an abbreviated process for the renewal of any cosmetic product listing, as required under section 607(c)(3), for which there has been no change since the responsible person submitted the previous listing.
 - **PLEASE NOTE:** When making this selection an ALERT box will appear, *“By selecting this document type, you are certifying that no changes have been made to your product listing since the previous listing was submitted”*.

By selecting this document type, you are certifying that no changes have been made to your Cosmetic Product Listing since the previous submission was submitted. Any changes made to the submission will be lost and the submission details will be reverted to the previous submission.

OK

Cancel

- **COSMETIC -UPDATE (CHANGES TO LISTING or DISCONTINUATION OF LISTING) (annual):** The responsible person must provide any updates to such listing annually (CHANGES TO LISTING or DISCONTINUATION OF LISTING) (section 607(c)(5) of the FD&C Act). This includes an update that the product was discontinued.
 - **PLEASE NOTE:** Selecting this document type will allow you to make changes to your submission. For more information visit: Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (FDA.gov)
- **Discontinue:** The discontinuation of cosmetic product listing feature provides responsible persons the option to discontinue cosmetic products previously listed in Cosmetics Direct that are no longer on the market.

- **Relist:** The relist feature provides responsible persons the option to relist cosmetic products that were previously discontinued in Cosmetics Direct.

11. The **Set ID, Root ID, Version Number, and Effective Date** fields will always auto-populate for the **INITIAL SUBMISSION ONLY**. When an SPL submission changes, a new Root ID is assigned to the new SPL submission along with a **NEW VERSION NUMBER**.

Set ID: *	0ae8f51f-68ca-38ff-e063-fa95b40ac758	Generate New	Version Number: *	1
Root ID: *	0ae8f51f-68cb-38ff-e063-fa95b40ac758	Generate New	Effective Date: *	11-24-2023 Calendar

- PLEASE NOTE:** Select words are underlined and provide definitions. Select each field and a tool tip will pop up with additional information related to that specific field.
- The other four elements under section one: Document Type Details
 - Set ID
 - Root ID
 - Version Number
 - Effective Date
- INFORMATION on the Four Elements:
 - **SET ID***: The Set ID uniquely identifies a group of versions of an SPL submission. When an SPL submission changes, a new Root ID is assigned to the new SPL submission, but the Set ID in the original SPL submission also is used. The Set ID is a Globally Unique Identifier (GUID). A GUID is a string of numbers and lower-case letters generated using a specifically defined mathematical algorithm to ensure a very low probability of identical GUID used in the same system. An example is: 9aa9d2e6-6982-48e5-831d-dbe7c04a14ed.

Set ID: *	0ae8f51f-68ca-38ff-e063-fa95b40ac758	Generate New
-----------	--------------------------------------	------------------------------

- **ROOT ID***: The Root ID uniquely identifies a specific SPL file. Each new version of an SPL file has a new id root. The id root is a Globally Unique Identifier (GUID). A GUID is a string of numbers and lower-case letters generated using a specifically defined mathematical algorithm to ensure a very low probability of identical GUID used in the same system. An example is: 9aa9d2e6-6982-48e5-831d-dbe7c04a14ed.

Root ID: *	0ae8f51f-68cb-38ff-e063-fa95b40ac758	Generate New
------------	--------------------------------------	------------------------------

- **VERSION NUMBER***: The Version Number gives sequential order to the different versions of an SPL submission. The version number is a whole number greater than zero, such as 6, 7, or 8. The version number is increased with each change to the SPL submission. Enter a number greater than zero (0) in the Version Number field.

Version Number: *	1
-------------------	---

- **EFFECTIVE DATE***: The date the submission is created, users can modify it. However, the system will only use the actual registration date submitted to FDA. It also provides a date reference to the SPL version. Select the date by clicking on the calendar icon. Once an SPL has been submitted, this date cannot be edited by users.

Effective Date: *	11-06-2023	
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12. Fill in all the blank fields in the **PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT** section, a red asterisk (*) indicates a required field throughout the submission process:

PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT	
Is this a product listing for a small business (optional product listing)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Responsible Person (as listed on label):	Type of Business: <input checked="" type="checkbox"/> MANUFACTURER <input type="checkbox"/> PACKER <input type="checkbox"/> DISTRIBUTOR
Responsible Person Name (as listed on label): *	Responsible Person Phone Number (Include Country/Area Code): *
Parent Company Name (if applicable):	Responsible Person D&B D-U-N-S Number for Address Listed on the Product Label:
PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)	
Add all required information by selecting ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES). ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)	

a. **PLEASE NOTE:** By selecting the dotted underlined words throughout the system will pop up a tooltip with brief explanation/definitions, along with the link to the Guidance for Industry: Registration and Listing of Cosmetic Product Facilities and Products (FDA.gov).

13. Fill in all the blank fields in the **RESPONSIBLE PERSON** section of the **PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT** section, a red asterisk (*) indicates a required field throughout the submission process:

PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT

Is this a product listing for a small business (optional product listing)?: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
Responsible Person (as listed on label):	Type of Business: <input checked="" type="checkbox"/> MANUFACTURER <input type="checkbox"/> PACKER <input type="checkbox"/> DISTRIBUTOR
Responsible Person Name (as listed on label): *	Responsible Person Phone Number (Include Country/Area Code): *
Parent Company Name (if applicable):	Responsible Person D&B D-U-N-S Number for Address Listed on the Product Label:

14. The elements toward the LEFT side of the webpage section of the PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT section, a red asterisk (*) indicates a required field throughout the submission process:

a. Is this product listing for a small business?: (optional) Indicate whether you are listing the product(s) for a small business by selecting one of the options provided.

- Section 612 of the FD&C Act provides exemptions to certain small businesses from the requirements of section 607 (Registration and Product Listing). However, such exemptions from the requirements of section 607 of the FD&C Act do not apply to any responsible person or facility engaged in the manufacturing or processing of any of the following products listed in section 612(b) of the FD&C Act:
 - Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual.
 - Cosmetic products that are injected.
 - Cosmetic products that are intended for internal use.
 - Cosmetic products that are intended to alter appearance for more than 24 hours under conditions of use that are customary or usual and removal by the consumer is not part of such conditions of use that are customary or usual.
- PLEASE NOTE:** For more information visit: Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)

Is this a product listing for a small business (optional product listing)?: Yes No

b. Responsible Person (as Listed on the label): (optional) The manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product.

- PLEASE NOTE:** ANY of the combination can be selected (one, none, or all).

Responsible Person (as listed on label):	Type of Business:
	<input type="checkbox"/> MANUFACTURER <input type="checkbox"/> PACKER <input type="checkbox"/> DISTRIBUTOR

c. Responsible Person Name (as Listed on the label) *: Enter the responsible person name as it appears on the label.

Responsible Person Name (as listed on label): *	
-------------------------------------------------------	--

d. Parent Company Name (if applicable): (optional) Enter the name of the parent company that is associated with this submission.

Parent Company Name (if applicable):	
-----------------------------------------	--

15. The elements toward the RIGHT side of the webpage section of the PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT section, a red asterisk (*) indicates a required field throughout the submission process:

a. Responsible Person Phone Number (Include Country /Area Code) *: Enter the responsible person's phone number including the area or the country code. The format for Phone number should be <Country Code>-<Area Code>-<Subscriber Number >For example, in the U.S. the phone number would be 1-999-9999999 or 1-999-999-9999

Responsible Person Phone Number (Include Country/Area Code): *	
----------------------------------------------------------------------	--

b. Responsible Person D&B D-U-N-S Number for Address Listed on the Product Label: (optional) Enter the existing 9- digit DUNS number of the address listed on the product label. Obtain a DUNS number: <https://www.dnb.com>

Responsible Person D&B D-U-N-S Number for Address Listed on the Product Label:	
-----------------------------------------------------------------------------------------	--

c. **PLEASE NOTE:** For more information on any of the fields ABOVE PLEASE visit: Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)

16. To add PRODUCT(S), INGREDIENT(S), AND FACILITY(IES) to your SPL template, click the 'ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)' button in the PRODUCT,

INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT section as shown below, a red asterisk (*) indicates a required field throughout the submission process:

ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)

PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)
ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)

17. A blank template titled *PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)* will display. Fill in the required fields and select all that apply, a red asterisk (*) indicates a required field throughout the submission process.

4.4.3 Product(s), Ingredient(s), and Facility(ies)

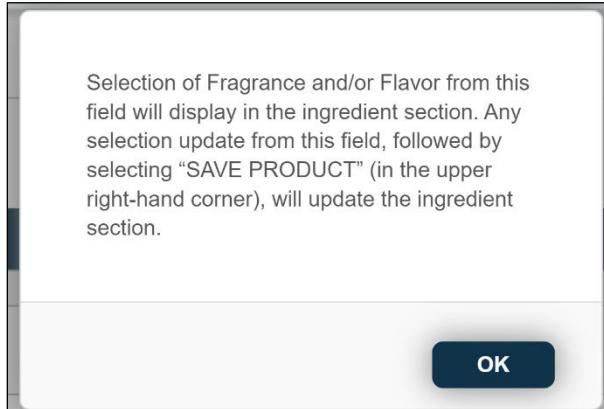
1. Fill in all the blank fields in the **COSMETIC PRODUCTS** section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section, a red asterisk (*) indicates a required field throughout the submission process:

The screenshot shows a web-based form for adding cosmetic product information. The main section is titled 'COSMETIC PRODUCTS' and includes fields for 'Cosmetic Product Listing Number', 'Product Name (As listed on label)*', 'Product Webpage Link', 'Fragrance or Flavor*', and 'Professional Use Only'. Below this section are four expandable sections indicated by a plus sign: 'PRODUCT CATEGORY CODE(S)', 'INGREDIENTS', 'LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED', and 'PRODUCT IMAGES'. At the top right of the form are 'SAVE PRODUCT' and '<< RETURN' buttons.

2. Select the '+' to open or '-' to close any sections.

PLEASE NOTE: By selecting the dotted underlined words throughout the system will pop up a tooltip with brief explanation/definitions, along with the link to the MoCRA guidance.

- Product Listing Number*: This 14-digit number will be generated by the system for each cosmetic product submission after acceptance. **PLEASE NOTE: THE PRODUCT LISTING NUMBER WILL BE GENERATED AFTER A SUBMISSION HAS BEEN ACCEPTED BY FDA.**

- b. Product Name (As Listed on Label)*: In the product name field, enter the *statement of identity*, as such name appears on the label. If the product names in the listing are not unique, then also include distinguishing information for identification purposes, for example brand name or a code that the responsible person uses to distinguish the product. Such information may also be included in addition to the product name even when product names in the listing are unique. If you believe certain distinguishing information is confidential, include that distinguishing information in parenthesis.
 - c. Product Webpage Link: (optional) Provide the webpage link of the product.
 - d. Fragrance or Flavor*: Select if the product contains fragrance, flavor, fragrance and flavor or N/A.
 - **PLEASE NOTE:** An INFORMATION BANNER will pop up when FRAGRANCE OR FLAVOR SELECTION is made, as shown below:
- 

Selection of Fragrance and/or Flavor from this field will display in the ingredient section. Any selection update from this field, followed by selecting "SAVE PRODUCT" (in the upper right-hand corner), will update the ingredient section.

OK
- e. Professional Use Only: (optional) Indicate whether this product is for professional use by selecting yes or no.
3. To add multiple **PRODUCT CATEGORY CODE(S)** section of the **PRODUCT(S)**, **INGREDIENT(S)**, AND **FACILITY(IES)** section, click the '**MANAGE CATEGORIES**' button in **Product Category Code(s)** section, as shown below. A red asterisk (*) indicates a required field throughout the submission process:


MANAGE CATEGORIES
4. A selection window titled *COSMETIC PRODUCT CATEGORIES* will display as shown below. Select all that apply.

PRODUCT CATEGORY CODE(S) (SELECT ALL THAT APPLY): *

Select the product category or categories for this product name. Each main product category has a sub-product category. A sub-product category can have sub-sub product category, select the one that applies to this product name. (e.g., leave-on or rinse-off). For more information visit: [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](https://www.fda.gov/cosmetics/registration-listing-cosmetic-product-facilities-and-products/cosmetic-product-categories-and-codes)

(01) Baby products
 (02) Bath preparations
 (03) Eye makeup preparations (other than children's eye makeup preparations)
 (04) Children's eye makeup preparations
 (05) Fragrance preparations
 (06) Hair preparations (non-coloring)
 (07) Hair coloring preparations
 (08) Makeup preparations (not eye)(other than makeup preparations for children)
 (09) Makeup preparations for children (not eye)
 (10) Manicuring preparations
 (11) Oral products
 (12) Personal cleanliness
 (13) Shaving preparations
 (14) Skin care preparations (creams, lotions, powder, and sprays)
 (15) Suntan preparations
 (16) Tattoo preparations
 (17) Other preparations (i.e., those preparations that do not fit another category)

a. **Product Category Code(s) ***: Select the product category or categories for this product name. Each main product category has a sub-product category. And some sub-product categories have sub-sub product category, select the one that applies to this product name. (e.g., leave-on or rinse-off). For example:

- (01) Baby products
 - (A) Baby shampoos
 - (B) Lotions, oils, powders, and creams
 - (C) Baby wipes
 - (D) Other baby products
 - 1. Leave-on
 - 2. Rinse-off

- (01) is considered a main product category (e.g. any section that begins with (#) are main product category).
- (A) to (D) are considered sub- product categories (e.g., any section that begins with (capital letter) are a sub-product category).
- 1. and 2. are considered a sub-sub product (e.g., any section that begins with a number that ends with a dot (.)) are a sub-sub product category).

b. **PLEASE NOTE:** For more information visit *Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)*:
<https://www.fda.gov/cosmetics/registration-listing-cosmetic-product-facilities-and-products/cosmetic-product-categories-and-codes>

c. **PLEASE NOTE:** Any combination can be selected, EXCEPT leave-on and rinse-off (one or the other may be selected). However, if sub-product category has been selected, then a sub-sub product category must be selected.

5. Once completed Click '**SAVE CATEGORIES**', located at the top right of the page:

SAVE CATEGORIES

6. After clicking '**SAVE CATEGORIES**' all the selection that was made on the previous page will be stated under the PRODUCT CATEGORY CODE(S) tab in the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section with a saved banner on the top of the page, as shown below:

PRODUCT CATEGORIES

- (01) Baby products - (D) Other baby products - 2. Rinse-off

MANAGE CATEGORIES

a. At this point, the option to '**DELETE**' this product tab on the upper right hand will appear along with '**SAVE PRODUCT**' and '**RETURN**' as shown below.

SAVE PRODUCT

DELETE

<< RETURN

Product categories saved.

All Submissions > Cosmetic Product Listing > Cosmetic Products > Product(s), Ingredient(s), and Facility(ies) >

SAVE PRODUCT

DELETE

<< RETURN

COSMETIC PRODUCTS

Cosmetic Product Listing Number:

Product Name (As listed on label):*

Product Webpage Link:

Fragrance or Flavor:*

-- Select --

Professional Use Only :

-- Select --

PRODUCT CATEGORY CODE(S)

MANAGE CATEGORIES

PRODUCT CATEGORIES

- (01) Baby products - (A) Baby shampoos
- (01) Baby products - (D) Other baby products - 1. Leave-on

1 - 1

7. To add **PRODUCT INGREDIENTS** section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section, click the '**MANAGE INGREDIENTS**' button in **INGREDIENTS**

section, as shown below. A red asterisk (*) indicates a required field throughout the submission process.

MANAGE INGREDIENTS

All Submissions | Cosmetic Product Listing | Cosmetic Products | Product(s), Ingredient(s), and Facility(ies) ►

COSMETIC PRODUCTS

Product Name:

Product Name
(As listed on label): *

Product Webpage Link:

Fragrance or Flavor: *

Professional Use Only:

PRODUCT CATEGORY CODE(S)

INGREDIENTS

Note that any update regarding Fragrance and/or Flavor made through the ingredient upload tool, will automatically update the above "Fragrance or Flavor" selection field in the previous section. **MANAGE INGREDIENTS**

LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

PRODUCT IMAGES

8. A blank template titled **COSMETIC INGREDIENTS** will display. Ingredients can be searched, added or uploaded, in the **INGREDIENTS** section. A red asterisk (*) indicates a required field throughout the submission process:

All Submissions | Cosmetic Product Listing | Cosmetic Products | Product(s), Ingredient(s), and Facility(ies) | Cosmetic Ingredients ►

INGREDIENTS

Note: Fill in all INGREDIENTS that are included in this product listing or upload a pre-filled ingredients file in the section below. Common, usual, or chemical name will auto populate as you type along with its UNII. If the ingredient does not auto-populate continue typing and select ADD. Ingredients can be re-ordered using drag and drop. Select an ingredient then move it into the new location.

Ingredient UNII-Name: * **ADD**

INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)	≡
<input checked="" type="checkbox"/>		1
<input checked="" type="checkbox"/>		

DOWNLOAD CURRENT INGREDIENT LIST

UPLOAD INGREDIENT FILE

Note: To download a template with the current ingredient list, select Download Current Ingredient List. Edit the ingredient list, if necessary, then upload the completed template to replace the previous ingredient list. UNII's should be entered in the first column and ingredient names in the second column. Please do not enter CAS numbers instead of UNII's. CAS numbers will not be recognized by the system.

Any update regarding Fragrance and/or Flavor made through the ingredient upload tool will automatically update the "Fragrance or Flavor" selection field in the previous section.

Drag and Drop Select a file or drop one here.

UPLOAD **CANCEL**

a. **PLEASE NOTE:** Selection on Fragrance and/or Flavor made in the previous section, on the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section, will be auto filled in the **INGREDIENTS** section. As an example, shown below:

COSMETIC PRODUCTS

Cosmetic Product Listing Number:	<input type="text"/>
Product Name (As listed on label): *	<input type="text"/>
Product Webpage Link:	<input type="text"/>
Fragrance or Flavor: *	<input type="text" value="Fragrance & Flavor"/>
Professional Use Only :	<input type="text" value="-- Select --"/>

All Submissions | Cosmetic Product Listing | Cosmetic Products | Product(s), Ingredient(s), and Facility(ies) | Cosmetic Ingredients

INGREDIENTS

Note: Fill in all INGREDIENTS that are included in this product listing or upload a pre-filled ingredients file in the section below. Common, usual, or chemical name will auto populate as you type along with its UNII. If the ingredient does not auto-populate continue typing and select ADD. Ingredients can be re-ordered using drag and drop. Select an ingredient then move it into the new location.

INGREDIENT UNII-Name: *	Search Ingredients	ADD
	FLAVOR	1
	FRAGRANCE	2

UPLOAD INGREDIENT FILE

Note: To download a template with the current ingredient list, select Download Current Ingredient List. Edit the ingredient list, if necessary, then upload the completed template to replace the previous ingredient list. UNII's should be entered in the first column and ingredient names in the second column. Please do not enter CAS numbers instead of UNII's. CAS numbers will not be recognized by the system.

Any update regarding Fragrance and/or Flavor made through the ingredient upload tool will automatically update the "Fragrance or Flavor" selection field in the previous section.

Drag and Drop

Select a file or drop one here.

UPLOAD CANCEL

DOWNLOAD CURRENT INGREDIENT LIST

9. Fill in all the ingredients that are included in this product (as listed on label). Common, usual, or chemical name will auto-populate as you type along with its UNII. If an ingredient does not auto-populate, continue typing and select **ADD**.

a. **PLEASE NOTE:**

- Adding UNII codes is optional.
- Ingredient(s) listed need to be in the same order as listed on the label.

- Each ingredient(s) needs to be entered separately.

An example is shown below:

INGREDIENTS

Note: Fill in all INGREDIENTS that are included in this product listing or upload a pre-filled ingredients file in UNII. If the ingredient does not auto-populate continue typing and select ADD. Ingredients can be re-ordered using drag and drop.

Ingredient UNII-Name: * **ADD**

INGREDI	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)
<input checked="" type="checkbox"/>	(059QF0KO0R) WATER
<input checked="" type="checkbox"/>	(5W66YHS8PH) WATER YAM
<input checked="" type="checkbox"/>	(63M8RYN44N) WATER O-15
<input checked="" type="checkbox"/>	(231473QB6R) WATERMELON
<input checked="" type="checkbox"/>	(K5877MW0LE) WATERCRESS
<input checked="" type="checkbox"/>	(7QV8F8BYNJ) WATER O-18
<input checked="" type="checkbox"/>	(0A4PW6CRAI) WATER BUFFALO
<input checked="" type="checkbox"/>	(267F5Y81NT) COCONUT WATER

UPLOAD INGREDIENTS

Note: To download a template list, UNIIs should be entered in the following order: INGREDIENT UNII, INGREDIENT NAME, INGREDIENT CODE(S), and INGREDIENT DESCRIPTION.

Any update regarding Fra

Drag and Drop

Select a file or drop

INGREDIENT UNII: 059QF0KO0R

INGREDIENTS

Note: Fill in all INGREDIENTS that are included in this product listing or upload a pre-filled ingredients file in the section below. Common, usual, or chemical name will auto-populate as you type along with its UNII. If the ingredient does not auto-populate continue typing and select ADD. Ingredients can be re-ordered using drag and drop. Select an ingredient then move it into the new location.

Ingredient UNII-Name: * **ADD**

INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)	
	FLAVOR	1
	FRAGRANCE	2
059QF0KO0R	WATER	3

SAVE INGREDIENTS **DELETE INGREDIENTS** **<< RETURN**

10. An ingredient can be deleted by selecting the X on the left-most column. As an example, shown below:

Ingredient UNII-Name: * Search Ingredients		
	INGREDIENT UNII CODE(S)	
✖	059QF0KO0R	WATER
		FLAVOR
		FRAGRANCE

a. **PLEASE NOTE:** Any update on **Fragrance and/or Flavor**, will have to go to the previous section, on the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section and make the changes as needed. Any changes made on the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section will regenerate it here on the ingredient list.

COSMETIC PRODUCTS

Cosmetic Product Listing Number:	<input type="text"/>
Product Name (As listed on label): *	<input type="text"/>
Product Webpage Link:	<input type="text"/>
Fragrance or Flavor: *	<input type="text" value="Fragrance & Flavor"/>
Professional Use Only :	<input type="text" value="-- Select --"/>

11. **Ingredients can be re-ordered using the drag and drop feature.** Select an ingredient then move it into the new location as shown below:

Ingredient UNII-Name: * Search Ingredients			ADD
	INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)	
✖	059QF0KO0R	FLAVOR	1
		WATER	3
		FRAGRANCE	2

Ingredient UNII-Name: * Search Ingredients			ADD
	INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)	
✖	059QF0KO0R	WATER	1
		FLAVOR	2
		FRAGRANCE	3

12. To download current ingredient list with its UNII CODE(S) from the **INGREDIENTS** section, click the '**DOWNLOAD CURRENT INGREDIENT LIST**', as shown below:

[DOWNLOAD CURRENT INGREDIENT LIST](#)

[SAVE INGREDIENTS](#) [DELETE INGREDIENTS](#) [<< RETURN](#)

INGREDIENTS

Note: Fill in all INGREDIENTS that are included in this product listing or upload a prefilled ingredients file in the section below. Common, usual, or chemical name will auto populate as you type along with its UNII. If the ingredient does not auto-populate continue typing and select ADD. Ingredients can be re-ordered using drag and drop. Select an ingredient then move it into the new location.

#	INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)	
1		FLAVOR	
2		FRAGRANCE	
3	059QF0KO0R	WATER	

[DOWNLOAD CURRENT INGREDIENT LIST](#)

UPLOAD INGREDIENT FILE

Note: To download a template with the current ingredient list, select Download Current Ingredient List. Edit the ingredient list, if necessary, then upload the completed template to replace the previous ingredient list. UNIIs should be entered in the first column and ingredient names in the second column. Please do not enter CAS numbers instead of UNIIs. CAS numbers will not be recognized by the system.

Any update regarding Fragrance and/or Flavor made through the ingredient upload tool will automatically update the "Fragrance or Flavor" selection field in the previous section.

Drag and Drop

Select a file or drop one here.

UPLOAD
CANCEL

a. It will download an EXCEL sheet prefilled with the current ingredient list, as shown below.

Clipboard		Font		Alignment	
B13		X	✓	fx	
	A			B	
1	INGREDIENT UNII CODE(S)			COMMON, USUAL OR CHEMICAL NAME	
2	059QF0KO0R			WATER	
3				FLAVOR	
4				FRAGRANCE	
5					
6					
7					

13. Edit the ingredient list, if necessary, then upload the completed template to replace the previous ingredient list. UNIIs should be entered in the first column and ingredient names in the second column.

a. **PLEASE NOTE: DO NOT enter CAS numbers instead of UNIIs. CAS numbers will not be recognized by the system.**

14. SAVE it on to the computer.

15. Upload the completed template to replace the previous ingredient list, by selecting the UPLOAD button underneath the DRAG AND DROP in the UPLOAD INGREDIENT FILE section. As shown below:

UPLOAD

CANCEL

[DOWNLOAD CURRENT INGREDIENT LIST](#)

UPLOAD INGREDIENT FILE

Note: To download a template with the current ingredient list, select Download Current Ingredient List. Edit the ingredient list, if necessary, then upload the completed template to replace the previous ingredient list. UNILs should be entered in the first column and ingredient names in the second column. Please do not enter CAS numbers instead of UNILs. CAS numbers will not be recognized by the system.

Any update regarding Fragrance and/or Flavor made through the ingredient upload tool will automatically update the "Fragrance or Flavor" selection field in the previous section.

Drag and Drop Select a file or drop one here.

UPLOAD

CANCEL

a. **PLEASE NOTE:** Any update regarding Fragrance and/or Flavor made through the ingredient upload tool, will automatically update the above "Fragrance or Flavor" selection field in the previous section.

16. Once all the **INGREDIENT(S)** are listed, select **SAVE INGREDIENTS**. If the user chooses to delete the ingredient's list, select **DELETE INGREDIENT**. By selecting RETURN, a warning banner will appear. As an example, shown below:

SAVE INGREDIENTS

DELETE INGREDIENTS

<< RETURN

All Submissions Cosmetic Product Listing Cosmetic Products Product(s), Ingredient(s), and Facility(ies) Cosmetic Ingredients

SAVE INGREDIENTS
DELETE INGREDIENTS
<< RETURN

INGREDIENTS

Note: Fill in all INGREDIENTS that are included in this product listing or upload a pre-filled ingredients file in the section below. Common, usual, or chemical name will auto populate as you type along with its UNIL. If the ingredient does not auto-populate continue typing and select ADD. Ingredients can be re-ordered using drag and drop. Select an ingredient then move it into the new location.

Ingredient UNI-Name: Search Ingredients
ADD

#	INGREDIENT UNI CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)	≡
1		FLAVOR	
2		FRAGRANCE	
3	059QF0KOOR	WATER	

[DOWNLOAD CURRENT INGREDIENT LIST](#)

UPLOAD INGREDIENT FILE

Note: To download a template with the current ingredient list, select Download Current Ingredient List. Edit the ingredient list, if necessary, then upload the completed template to replace the previous ingredient list. UNILs should be entered in the first column and ingredient names in the second column. Please do not enter CAS numbers instead of UNILs. CAS numbers will not be recognized by the system.

Any update regarding Fragrance and/or Flavor made through the ingredient upload tool will automatically update the "Fragrance or Flavor" selection field in the previous section.

Drag and Drop Select a file or drop one here.

77

To save your data, click Cancel and then click Save Ingredients.

Click OK to continue without saving.

OK

Cancel

17. After clicking '**SAVE INGREDIENTS**' all the INGREDIENTS that were listed on the previous page will be listed under the ingredients tab in the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section with a saved banner on the top of the page, as shown below:

Product Ingredients Saved.

All Submissions Cosmetic Product Listing Cosmetic Products **Product(s), Ingredient(s), and Facility(ies)**

SAVE PRODUCT **DELETE** **<< RETURN**

COSMETIC PRODUCTS

Cosmetic Product Listing Number:

Product Name (As listed on label): *

Product Webpage Link:

Fragrance or Flavor: *

Professional Use Only:

PRODUCT CATEGORY CODE(S)

INGREDIENTS

Note that any update regarding Fragrance and/or Flavor made through the ingredient upload tool, will automatically update the above "Fragrance or Flavor" selection field in the previous section.

MANAGE INGREDIENTS

INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)
	FLAVOR
	FRAGRANCE
059QF0KO0R	WATER

row(s) 1 - 3 of 3

18. To add the **LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED**, section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section, click the '**ADD FACILITY**' button in **LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED** section, as shown below. A red asterisk (*) indicates a required field throughout the submission process.

ADD FACILITY

19. Fill in all the blank fields in the **LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED** section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section, as shown below. A red asterisk (*) indicates a required field throughout the submission process:

- Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?*: Indicate by selecting one of the options, whether the facility where the product is manufactured or processed is exempt from registration (for example because it is a small business).
- SMALL BUSINESSES. — Under section 612(b) of the FD&C Act, regardless of their average gross annual sales, businesses that engage in the manufacturing or

processing of the following are not exempt from the registration and listing requirements:

- Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual;
- Cosmetic products that are injected;
- Cosmetic products that are intended for internal use; or
- Cosmetic products that are intended to alter appearance for more than 24 hours under conditions of use that are customary or usual and removal by the consumer is not part of such conditions of use that are customary or usual.

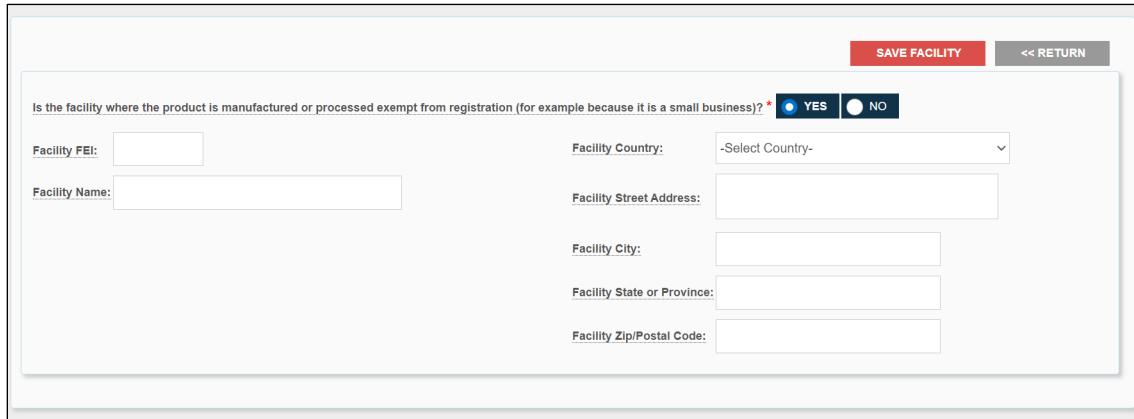
c. **Facility FEI:** Enter the existing 7 to 10-digit facility FEI number. The FEI number is a unique identifier assigned by the FDA to identify firms associated with FDA-regulated products. To facilitate the registration process, the owner or operator of a facility will need to obtain an FEI number before submitting the facility registration.

d. **PLEASE NOTE:** To determine if an entity already has an FEI number, please refer to the [FEI Search Portal](#). If your firm does not have an FEI number assigned by FDA, see [How can I request an FEI?](#) at [FEI Search Portal](#)

- **Facility Name:** Enter the complete name of the existing facility.
- **Facility country:** Select facility's country name where the facility is physically located.
- **Facility Street Address:** Enter the complete information of the street where the facility is physically located.
- **Facility City:** Enter the complete name of the city where the facility is physically located.
- **Facility State or Province:** Enter the complete name of the state or province where the facility is physically located.
- **Facility Zip/Postal Code:** Enter the postal code or the zip code where the facility is physically located.

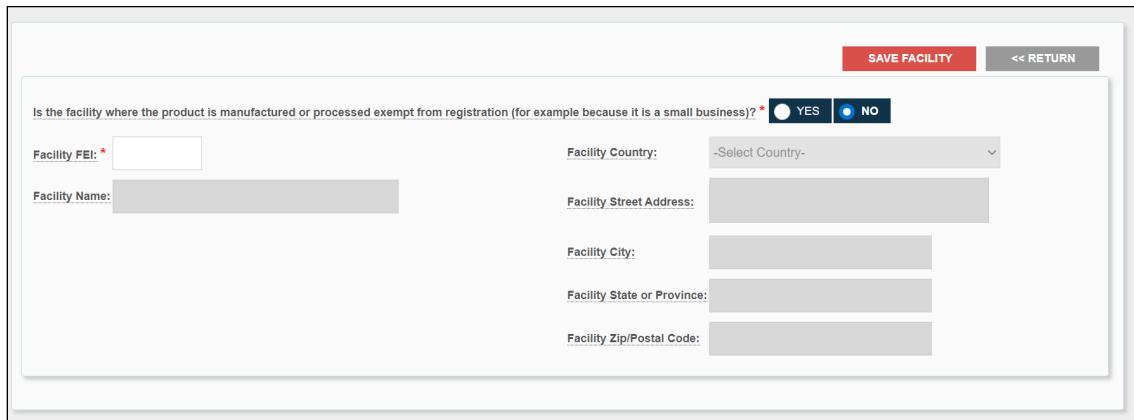
e. **PLEASE NOTE:** For more information visit: [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)

20. If selected **YES** to the question, “*Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?*” all data fields are optional. As shown below:



The screenshot shows a web-based form for facility registration. At the top right are two buttons: 'SAVE FACILITY' in red and '<< RETURN' in grey. Below these buttons is a question: 'Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)? *'. There are two radio buttons: 'YES' (selected) and 'NO'. The form contains several input fields: 'Facility FEI:' (text box), 'Facility Name:' (text box), 'Facility Country:' (dropdown menu with placeholder '-Select Country-'), 'Facility Street Address:' (text box), 'Facility City:' (text box), 'Facility State or Province:' (text box), and 'Facility Zip/Postal Code:' (text box). The 'Facility Name:' field is currently empty and greyed out.

21. If selected **NO** to the question, “*Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?*” the FEI is mandatory, and the name/address is greyed. As shown below:



This screenshot shows the same facility registration form as above, but with different field behaviors. The 'Facility FEI:' field is now highlighted with a red border and a red asterisk, indicating it is mandatory. The 'Facility Name:' field is also greyed out and appears to be disabled. The other fields ('Facility Country:', 'Facility Street Address:', 'Facility City:', 'Facility State or Province:', 'Facility Zip/Postal Code:') are still present but appear to be standard text input fields.

22. Once complete, clicking 'SAVE FACILITY' and the FACILITY will be saved on the previous page under the **LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED** tab in the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section with a saved banner on the top of the page, as shown below:

Cosmetic Product Facility Saved.

All Submissions > Cosmetic Product Listing > Cosmetic Products > Product(s), Ingredient(s), and Facility(ies) >

COSMETIC PRODUCTS

Cosmetic Product Listing Number:

Product Name (As listed on label): *

Product Webpage Link:

Fragrance or Flavor: *

Professional Use Only: *

PRODUCT CATEGORY CODE(S)

INGREDIENTS

LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

ADD FACILITY

EDIT	IS THIS FACILITY SMALL BUSINESS?	FACILITY FEI	FACILITY NAME	FACILITY ADDRESS
	No	3457234		

1 - 1

PRODUCT IMAGES

23. If any edit needs to be made in the **LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED**, after coming back to the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)**, select the icon under the **EDIT** tab, as shown below:

EDIT



LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

ADD FACILITY

EDIT	IS THIS FACILITY SMALL BUSINESS?	FACILITY FEI	FACILITY NAME	FACILITY ADDRESS
	No	3457234		

a. Multiple **FACILITY(IES)** can be added by selecting the **ADD FACILITY** on the top right, as shown above.

24. The **PRODUCT IMAGES** section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section, a red asterisk (*) indicates a required field throughout the submission process:

a. (optional) Upload an image of the label, any sides of the label whether it front back or sides by selecting or drag and drop the image, as shown below. The image must be in .jpg format.

PRODUCT IMAGES
Upload image(s) of the label, any sides of the label whether it front, back or sides.

Drag and Drop
Image of Product Label (Attach images of the front and back product labels by selecting the icon.)

UPLOAD **CANCEL**

b. **PLEASE NOTE:** The image must be uploaded in .JPEG format. The max image size allowed is 1MB. Please make sure that the image is a true jpg without special characters. They must be valid jpg file and the name should consist of letters (a-z, A-Z) and/or numbers (0-9). Special characters and symbols are not allowed.

c. The image will display under the **PRODUCT IMAGES** section under **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)**, as shown below:

IMAGE	IMAGE PREVIEW	DELETE
product_listing_demo_1.jpg		

1 - 1

25. Select **SAVE PRODUCT** after completing all the required sections of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)**, as shown below:

SAVE PRODUCT

COSMETIC PRODUCTS

Cosmetic Product Listing Number:

Product Name (As listed on label):*

Product Webpage Link:

Fragrance or Flavor:

Professional Use Only:

PRODUCT CATEGORY CODE(S)

INGREDIENTS

LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

PRODUCT IMAGES

26. AFTER selecting **SAVE PRODUCT**, an overall product detail will be displayed under **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)**, as shown below:

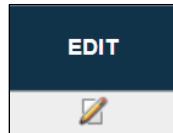
Product(s), Ingredient(s), and Facility(ies)					
ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)					
EDIT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	FRAGRANCE OR FLAVOR	IS THIS PRODUCT FOR PROFESSIONAL USE ONLY?	CLONE
		shampoo	Fragrance & Flavor	N/A	

row(s) 1 - 1 of 1

- Multiple **PRODUCT** can be added by selecting the **ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** on the top right, as shown above.

ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)

- If any edit needs to be made, select the icon under the **EDIT** tab, as shown below:



EDIT



27. ANY similar PRODUCT with common ingredient(S) can be CLONED by selecting the **CLONE** icon, as shown below:

The screenshot shows a 'Clone' product listing. The product name is 'shampoo', the fragrance or flavor is 'Fragrance & Flavor', and the status is 'N/A'. There is a 'Clone' button in the top right corner of the table header.

28. In the **CONFIRMATION STATEMENT** section, fill in the following blank fields.

The 'CONFIRMATION STATEMENT' section includes a checkbox labeled 'I Agree' which is checked, and fields for 'Date' and 'Name of Submitter'.

29. Click 'AGREE' after reading and understanding the confirmation statement:



30. If you would like to list additional contact information for an authorized agent, go to the '**Additional Contact Information for Authorized Agent**' section and fill in the following blanks:

The section contains four input fields: 'Additional Contact Name', 'Email', 'Phone Number (Include Country/Area Code)', and 'Phone Extension'.

a. **PLEASE NOTE:** ALL the above elements are optional.

- **Additional Contact Name:** (optional field) Enter an additional contact information for individuals associated with the listing. For more information visit: *Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)*.
- **Email:** (optional field) Provide the additional contact person's email address.
- **Phone Number (Include Country/Area Code):** (optional field) Enter the additional contact person's phone number including the country code

and the area code. The format for Phone number should be <Country Code>-<Area Code>-<Subscriber Number>.

- **Phone Extension:** (optional field) Enter additional contact person's phone extension, if any.

31. After filling in all the required information, return to the top of the SPL submission page, select **SAVE AND VALIDATE** to identify any errors OR select **SUBMIT SPL** for the form to be submitted to FDA.

SUBMIT SPL	SAVE AS DRAFT	SAVE AND VALIDATE	DELETE	<< RETURN
------------	---------------	-------------------	--------	-----------

- SUBMIT SPL:** Submit SPL will send the submission to FDA for additional validation and processing.
- SAVE AS DRAFT:** Save Draft button allows you to save your work, preserving your progress without submitting it to the FDA.
 - **PLEASE NOTE:** Click 'SAVE AS DRAFT' from any screen during the process of registering the cosmetic product facility. The system saves all the information you inputted and will bring you back to the homepage. The status column will be in 'DRAFT'.

STATUS
DRAFT

- Validate SPL:** You can check your SPL for an initial validation before submitting to FDA. This option does not automatically submit your SPL to FDA, even if it passes the initial validation, but scans for certain errors prior to the actual submission.
- DELETE:** This will remove the submission from your account.
- RETURN:** will guide the user to Cosmetics Product Listing Submissions home page

32. Click 'RETURN' at any time to return to the Cosmetic Product listing home page.

4.4.3.1 Save and Validate

1. Click 'SAVE AND VALIDATE' if you want to check for errors with your SPL. To submit your SPL to FDA,
 - a. **PLEASE NOTE:** This option is only for an initial validation of your SPL before submitting to FDA. It does not automatically submit your SPL to FDA, even if it

passes the initial validation, but scans for certain errors prior to the actual submission. To submit your data to the FDA, select “Submit SPL”.

2. The status of your SPL will be in ‘VALIDATION IN PROGRESS’. A yellow message will appear across your screen stating, “Additional in-depth validation by the FDA is in progress. Check back on the status after a few minutes by refreshing the page or logging back into the system.”

Additional in-depth validation by the FDA is in progress. Check back on the status after a few minutes by refreshing the page or logging back into the system.

3. Once the system has completed validation, the status ‘VALIDATION IN PROGRESS’ will change to ‘READY FOR SUBMISSION’.

Click here to view submissions that have completed validation.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION
READY FOR SUBMISSION	0c066ca6-f8da-b44d-e063-6a94af0ab7ab	0c066ca6-f8db-b44d-e063-6a94af0ab7ab		1

4. Click ‘READY FOR SUBMISSION’, the homepage will change to reflect the following:

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Registration of Cosmetic Product Facility submission form. A red asterisk (*) indicates a required field.

For assistance with validation errors and general questions regarding electronic registration and listing of cosmetic product facilities and products, contact cosmeticcsd@fda.hhs.gov

Note: This submission has passed the initial validation but has not been actually submitted to FDA. Click on "Submit SPL" to submit.

- a. The system will generate a message stating that, ‘*This submission has passed the INITIAL VALIDATION but has NOT been ACTUALLY SUBMITTED TO FDA. Click ON "SUBMIT SPL" to SUBMIT.*’

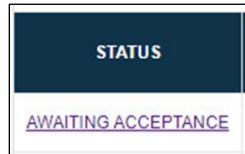
4.4.3.2 Submit SPL to FDA

1. Click ‘SUBMIT SPL’ if you are ready to submit your SPL to FDA.

- a. A green message will appear across your screen stating, “Your submission has been sent to FDA for additional validation and processing. Check the status of your submission after a few minutes by refreshing the page or logging back into the system. You will also receive an email from FDA when the processing is complete.”

Your submission has been sent to FDA for additional validation and processing. Check the status of your submission after a few minutes by refreshing the page or logging back into the system. You will also receive an email from FDA when the processing is complete.

- b. The status field should read ‘AWAITING ACCEPTANCE’.



4.4.3.3 Submission Accepted

1. The status column will change to '**SUBMISSION ACCEPTED**' after the submission has been successfully completed and **ACCEPTED BY FDA**. A '**SUBMISSION ID**' will be generated automatically when an SPL is submitted to FDA.

Please Note: A '**SUBMISSION ID**' does not always mean that the submission was in fact accepted by FDA. The '**Submission ID**' will also appear with '**Awaiting Acceptance**' and '**Submission Failure**'.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION
SUBMISSION ACCEPTED	0c066ca6-f8da-b44d-e063-6a94af0ab7ab	0c066ca6-f8db-b44d-e063-6a94af0ab7ab	cm1397680542.5304619872@direct	1

2. Click on '**SUBMISSION ACCEPTED**' to **VIEW SPL** and **DOWNLOAD SPL**.
 - a. To clone and create a new version of your successfully submitted SPL, click '**CREATE A NEW VERSION**'



- **PLEASE NOTE:** After selecting, your SPL will be successfully cloned and the ROOT ID, VERSION NUMBER, and EFFECTIVE DATE will change. All other fields will retain the same information from the initial successfully submitted SPL.

Set ID: *	0c066ca6-f8da-b44d-e063-6a94af0ab7ab	Generate New	Version Number: *	<input type="text" value="2"/>
Root ID: *	0c06eb2a-30c9-7866-e063-6b94af0af38e	Generate New	Effective Date: *	<input type="text" value="12-08-2023"/> Calendar

- b. To view your SPL, click '**VIEW SPL**'



- c. To download your SPL for your records, click '**DOWNLOAD SPL**'



d. When your submission has been validated by the FDA. You will receive an email to your account email address when the submission status changes. A '**SUBMISSION ACCEPTED**' status will appear in the status column of your SPL submission if it has been successfully submitted to the FDA. At this point, the process is finished and there is no further action needed unless you need to make any changes to your registration.

4.4.3.4 Submission Failed

1. If the status column changes to '**SUBMISSION FAILED**', your submission has not passed the FDA's requirements and has been rejected.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION
SUBMISSION FAILED	0c066ca6-f8da-b44d-e063-6a94af0ab7ab	0c06eb2a-30c9-7866-e063-6b94af0af38e	cm6301528479.1247385960@direct	2

a. You must open your submission at this stage to review error messages and update your submission to correct them. click on (GO TO ERROR) and the system will direct right to the error.

2 ERRORS HAVE OCCURRED

- Error in Cosmetic Product : shampoo (Go to error)
- After reviewing these errors and still want to submit your data, click on Submit SPL...

ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)

EDIT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	FRAGRANCE OR FLAVOR	IS THIS PRODUCT FOR PROFESSIONAL USE ONLY?	CLONE
		shampoo	Fragrance & Flavor	N/A	

Row(s) 1 - 1 of 1

b. Submit again and your submission will once again be '**AWAITING ACCEPTANCE**'.

2. If the status column changes to '**SUBMISSION ACCEPTED**', refer to section 4.2.3.3 for additional information.

4.4.3.5 Validation Failure

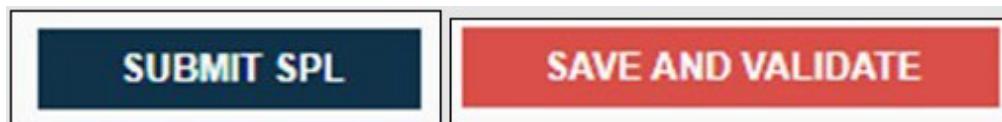
1. After clicking '**SAVE AND VALIDATE**', the product listing of cosmetic product listing home page will have the following details as shown below. The status column will be in '**VALIDATION IN PROGRESS**'. However, if the system finds any errors the status will change to '**VALIDATION FAILURE**'.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION
VALIDATION FAILURE	0c066ca6-f8da-b44d-e063-6a94af0ab7ab	0c066ca6-f8db-b44d-e063-6a94af0ab7ab		1

2. Click '**VALIDATION FAILURE**', the system will provide a list of errors that need to be fixed before submitting the SPL:



a. After reviewing and fixing the errors, you can select either '**SUBMIT SPL**' to resubmit, or '**SAVE AND VALIDATE**' to check for additional errors.



4.4.4 Abbreviated Renewal Listing

This document type should be selected for the renewal of any cosmetic product listing, as required under section 607(c)(3), for which there has been no change since the responsible person submitted the previous listing.

1. Under Document Type, select 'COSMETIC – ABBREVIATED RENEWAL'.

DOCUMENT TYPE DETAILS

Document Type: *	COSMETIC - ABBREVIATED RENEWAL
Set ID: *	--Select One-- COSMETIC PRODUCT LISTING COSMETIC - UPDATE COSMETIC - ABBREVIATED RENEWAL 0c028e8a-46d4-6672-e063-6a94af0a11c2
Root ID: *	Generate New

a. **PLEASE NOTE:** The following message will appear, "By selecting this document type, you are certifying that no changes have been made to your Cosmetic Product Listing since the previous submission was submitted. Any changes made to the submission will be lost and the submission details will be reverted to the previous submission" Select, '**OK**' to proceed.

direct.preprod.fda.gov says

By selecting this document type, you are certifying that no changes have been made to your Cosmetic Product Listing since the previous submission was submitted. Any changes made to the submission will be lost and the submission details will be reverted to the previous submission.

OK

Cancel

2. After selecting 'OK', the fields for Product, Ingredient and Facility Listing of the Cosmetic Product, Confirmation Statement, and Additional Contact Information for Authorized Agent will be grayed out and can no longer undergo changes.
3. Refer to the steps in Sections 4.4.3.1 – 4.4.3.5 for Submit to FDA instructions.

4.4.5 Cosmetic – Update

This document type should be selected if the responsible person has any updates to such listing annually (CHANGES TO LISTING or DISCONTINUATION OF LISTING) (section 607(c)(5) of the FD&C Act). This includes an update that the product was discontinued.

1. Under Document Type, select 'COSMETIC – UPDATE.'

DOCUMENT TYPE DETAILS

Document Type: *	COSMETIC PRODUCT LISTING
Set ID: *	--Select One-- COSMETIC PRODUCT LISTING COSMETIC - UPDATE COSMETIC - ABBREVIATED RENEWAL Uc028e8a-46d4-b672-e0b3-6a94af0a11c2
Root ID: *	Generate New Generate New

2. Update any necessary information to your SPL submission. Please refer to sections 4.4.2 – 4.4.3 to make additional updates to the SPL submission.

- a. **PLEASE NOTE:** The following cannot be updated:
 - Product Name
 - Ingredients (including fragrance, color, and flavor)
 - Product Categories
 - Responsible Person
3. If you need to update one of the above fields, then you will need to submit an INITIAL-Cosmetic Product Listing. Then, you will need to discontinue the products from the previous submission (see 4.4.5.1 Discontinue).
4. Refer to the steps from Sections 4.4.3.1 – 4.4.3.5 for Submit to FDA instructions.

4.4.5.1 Discontinue

The discontinuation of cosmetic product listing feature provides responsible persons the option to discontinue cosmetic products previously listed in Cosmetics Direct that are no longer on the market. Please note that discontinuing a product differs from deleting a product. When a product is discontinued, it remains in the SPL file and can be relisted. Conversely, once a product is deleted, it is permanently removed from the SPL file and cannot be retrieved for relisting.

There are three ways to discontinue a product from your SPL submission:

1. Open an existing submission that has been previously accepted.
2. Click 'CREATE NEW VERSION'

CREATE NEW VERSION

3. Under Document Type, select 'COSMETIC – UPDATE.'

DOCUMENT TYPE DETAILS

Document Type: *	COSMETIC PRODUCT LISTING	Generate New
Set ID: *	--Select One--	Generate New
Root ID: *	COSMETIC PRODUCT LISTING COSMETIC - UPDATE COSMETIC - ABBREVIATED RENEWAL UcU28e8a-46d4-6672-e063-6a94af0a11c2	

Option 1 – Edit/Update Product

- Locate the EDIT/UPDATE PRODUCT column under the PRODUCT(S), INGREDIENT(S), AND FACILITY(IES) section.

PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)				
ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)				
row(s) 1 - 2 of 2				
EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	3-776340-572892	Productname A	LISTED	
	3-420734-348199	Productname B	LISTED	

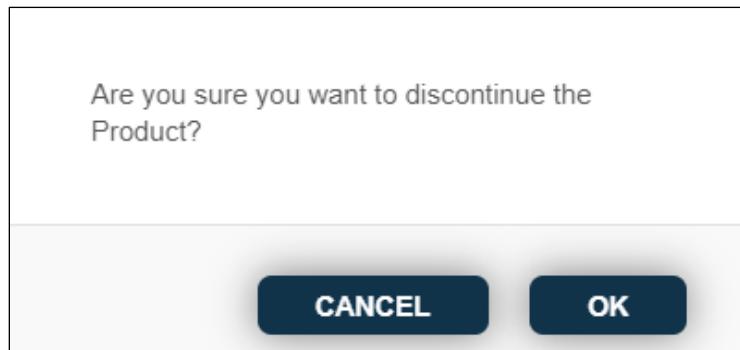
- Click on the pencil icon of the product you would wish to discontinue.



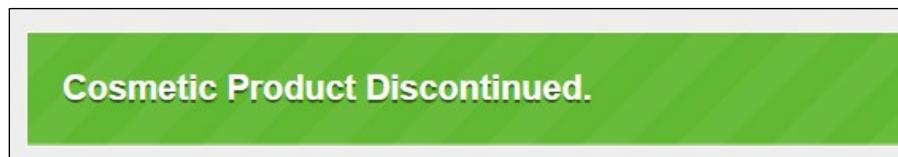
- Select 'DISCONTINUE PRODUCT' to discontinue the product.



- PLEASE NOTE:** The following message will appear, "Are you sure you want to discontinue the Product?" Select, 'OK' to proceed.



- After selecting 'OK', a green message will appear across your screen stating, "Cosmetic Product Discontinued." The discontinued product will be shaded red, and the Product Marketing Status will list the product as DISCONTINUED.



PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)				ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)
EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	row(s) 1 - 2 of 2
	53-776340-572892	Productname A	LISTED	
	53-420734-348199	Productname B	DISCONTINUED	

e. Using the pencil icon, you can re-enter into the selected DISCONTINUED product to view that the product is marked as discontinued. A yellow message will appear next to the Cosmetic Product Listing Number stating, “Product marked as discontinued!”

COSMETIC PRODUCTS		RELIST PRODUCT	DELETE	<< RETURN
Cosmetic Product Listing Number:	53-420734-348199	Product marked as discontinued!		
Product Name (As listed on label): *	Productname B			
Product Webpage Link:				
Fragrance or Flavor: *	Flavor			
Professional Use Only :	-- Select --			
PRODUCT CATEGORY CODE(S)				
PRODUCT CATEGORIES				
• (01) Baby products - (A) Baby shampoos 1 - 1				
INGREDIENTS				
Note that any update regarding Fragrance and/or Flavor made through the ingredient upload tool, will automatically update the above "Fragrance or Flavor" selection field in the previous section.				
INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)			
	FLAVOR			
row(s) 1 - 1 of 1				
LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED				
IS THIS FACILITY SMALL BUSINESS?	FACILITY FEI	FACILITY NAME	FACILITY ADDRESS	
Yes		EXEMPT FACILITY	1 - 1	
PRODUCT IMAGES				
Upload image(s) of the label, any sides of the label whether it front, back or sides.				

- **PLEASE NOTE:** Once a product is discontinued, no additional edits can be made on the page unless the product is RELISTED. Please see section 4.4.5.2 Relist for additional instructions.

Option 2 – Product Marketing Status

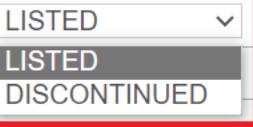
f. Locate the PRODUCT MARKETING STATUS column under the PRODUCT(S), INGREDIENT(S), AND FACILITY(IES) section.

PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)				ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)
EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	53-776340-572892	Productname A	LISTED	
	53-420734-348199	Productname B	LISTED	

g. Identify the listed products you wish to discontinue. In the PRODUCT STATUS column, click the drop-down menu and select 'DISCONTINUED'.

PRODUCT MARKETING STATUS

CHANGE STATUS FOR ALL PRODUCTS ▾

 LISTED
LISTED
DISCONTINUED

h. If you wish to discontinue all the LISTED products, select 'DISCONTINUE ALL PRODUCTS'

PRODUCT MARKETING STATUS

CHANGE STATUS FOR ALL PRODUCTS ▾

CHANGE STATUS FOR ALL PRODUCTS

LIST ALL PRODUCTS

DISCONTINUE ALL PRODUCTS

i. After selecting, the Product Marketing Status for all the listed cosmetic products will change to DISCONTINUED.

EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	53-776340-572892	Productname A	DISCONTINUED	
	53-420734-348199	Productname B	DISCONTINUED	

j. Click 'SAVE AS DRAFT' or 'SAVE AND VALIDATE' located at the top right of this page to save your selection(s). This will change your products to 'DISCONTINUED'. To submit your data to the FDA, select 'SUBMIT SPL'.

SUBMIT SPL

Option 3 – Delete

k. Locate the EDIT/UPDATE PRODUCT column under the PRODUCT(S), INGREDIENT(S), AND FACILITY(IES) section.

PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)				
ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)				
row(s) 1 - 2 of 2				
EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	3-776340-572892	Productname A	LISTED	
	3-420734-348199	Productname B	LISTED	

l. Click on the pencil icon of the product you would wish to discontinue.



m. Select 'DELETE', to delete the product from the SPL file.



- **PLEASE NOTE:** The following message will appear, "Are you sure you want to delete the Product?" This will remove the product from the SPL file permanently. Once the product is deleted, it cannot be relisted. If the deleted product needs to be relisted, a new INITIAL-SPL submission is required. Select 'OK' to proceed.



n. After selecting 'OK', the product will be removed from your SPL submission. A green message will appear across your screen stating, "Cosmetic Product Deleted."



o. Under PRODUCT(S), INGREDIENT(S), AND FACILITY(IES), the cosmetic product selected for deletion will no longer be visible.

PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)				
ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)				
row(s) 1 - 1 of 1				
EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	53-776340-572892	Productname A	LISTED ▼	

row(s) 1 - 1 of 1

- Refer to the steps from Sections 4.4.3.1 – 4.4.3.5 for Submit to FDA instructions.

4.4.5.2 Relist

The relist feature provides responsible persons the option to relist cosmetic products that were previously discontinued in Cosmetics Direct.

There are two ways to relist a product from your SPL submission:

- Open an existing submission that has been previously accepted.
- Click 'CREATE NEW VERSION'

CREATE NEW VERSION

- Under Document Type, select 'COSMETIC – UPDATE.'

DOCUMENT TYPE DETAILS

Document Type: *	COSMETIC PRODUCT LISTING ▼
Set ID: *	--Select One-- COSMETIC PRODUCT LISTING Generate New
Root ID: *	COSMETIC - UPDATE COSMETIC - ABBREVIATED RENEWAL Generate New

Option 1 – Edit/Update Product

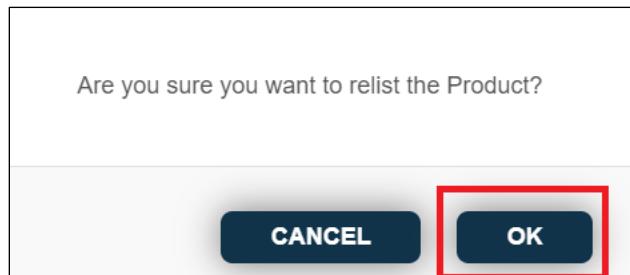
- Locate the EDIT/UPDATE PRODUCT column under the PRODUCT(S), INGREDIENT(S), AND FACILITY(IES) section. Click on the pencil icon of the product you would wish to relist.

PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)				
row(s) 1 - 1 of 1				
EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	53-776340-572892	Productname A	CHANGE STATUS FOR ALL PRODUCTS ▾ DISCONTINUED ▾	

b. Click on 'RELIST PRODUCT.'

COSMETIC PRODUCTS		RELIST PRODUCT	DELETE	<< RETURN
Cosmetic Product Listing Number:	53-776340-572892	Product marked as discontinued!		
Product Name (As listed on label): *	Productname A			
Product Webpage Link:				
Fragrance or Flavor: *	Flavor			
Professional Use Only :	-- Select --			

c. To relist the product, click 'OK' when prompted.



d. After clicking 'OK', you will be taken back to the Cosmetic Product Listing page and a green message will appear across your screen stating, "Cosmetic Product Relisted."



e. Under PRODUCT(S), INGREDIENT(S), AND FACILITY(IES), the product will now show as 'LISTED.'

PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)				
row(s) 1 - 1 of 1				
EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	53-776340-572892	Productname A	CHANGE STATUS FOR ALL PRODUCTS ▾ LISTED ▾	

Option 2 – Product Marketing Status

f. Locate the PRODUCT MARKETING STATUS column under the PRODUCT(S), INGREDIENT(S), AND FACILITY(IES) section.

EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	53-776340-572892	Productname A	DISCONTINUED ▾	
	53-420734-348199	Productname B	DISCONTINUED ▾	

g. Identify the discontinued product you wish to relist. In the PRODUCT STATUS column, click the drop-down menu and select 'LISTED.'

EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	53-776340-572892	Productname A	DISCONTINUED ▾	
	53-420734-348199	Productname B	LISTED DISCONTINUED	

h. If you wish to relist all discontinued products, click the drop-down menu and locate 'LIST ALL PRODUCTS.'

EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	53-776340-572892	Productname A	CHANGE STATUS FOR ALL PRODUCTS ▾	
	53-420734-348199	Productname B	CHANGE STATUS FOR ALL PRODUCTS LIST ALL PRODUCTS DISCONTINUE ALL PRODUCTS	

4. Refer to the steps from Sections 4.4.3.1 – 4.4.3.5 for Submit to FDA instructions.

4.5 Filters

4.5.1 Cosmetic Facility Registration

On the Cosmetic Facility Registration page, there is a default header:

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT TYPE	LAST MODIFIED USER	LAST MODIFIED DATE	
--------	--------	---------	---------------	---------	---------------	--------------	---------------	---------------	--------------------	--------------------	--

- Status: The current status of your submissions. For further explanation of the different status types, see Section 3.2: Submission Statuses.
- Set ID: A 'Globally Unique Identifier' (GUID) that remains the same for each submission 'set,' which is a group of submission versions. When you submit a different version of a submission, the set ID stays the same through each new version.

3. **Root ID:** A GUID that is generated uniquely for every single SPL submission that is submitted to the FDA. When you create a new submission or submit a new version of a previous submission, the root ID will change every time (unlike the set ID).
4. **Submission ID:** Unique identifier generated per submission. Also known as the 'Core ID.'
5. **Version:** A number greater than zero that provides a sequence to the versions of the document. A '1' in this column indicates that it is the first submission. Subsequent versions will increment upwards.
6. **Facility Name:** The complete name of the existing facility.
7. **Facility FEI:** A unique identifier assigned by the FDA to identify firms associated with FDA-regulated products.
8. **Facility DUNS:** The existing 9-digit facility DUNS number.
9. **Document Type:** The submission type. For example, 'Cosmetic Facility Registration' or 'Cosmetic Facility Registration Amendment.'
10. **Last Modified User:** The username of the person who last made changes to a submission.
11. **Last Modified Date:** The most recent date that changes were made to a submission.

4.5.2 Cosmetic Product Listing

On the Cosmetic Product Listing page, there is a default header:

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	RESPONSIBLE PERSON NAME	DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE	
--------	--------	---------	---------------	---------	---------------	-------------------------	---------	--------------------	--------------------	---------------------------------------------------------------------------------------

1. **Status:** The current status of your submissions. For further explanation of the different status types, see Section 3.2: Submission Statuses.
2. **Set ID:** A 'Globally Unique Identifier' (GUID) that remains the same for each submission 'set,' which is a group of submission versions. When you submit a different version of a submission, the set ID stays the same through each new version.
3. **Root ID:** A GUID that is generated uniquely for every single SPL submission that is submitted to the FDA. When you create a new submission or submit a new version of a previous submission, the root ID will change every time (unlike the set ID).
4. **Submission ID:** Unique identifier generated per submission. Also known as the 'Core ID.'

5. **Version:** A number greater than zero that provides a sequence to the versions of the document. A '1' in this column indicates that it is the first submission. Subsequent versions will increment upwards.
6. **Document Type:** The submission type. For example, 'Cosmetic Facility Registration' or 'Cosmetic Facility Registration Amendment.'
7. **Responsible Person Name:** The manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product.
8. **Details:** Provides the user with more information pertaining to the cosmetic product listing. When the 'bell symbol' is present, it is notifying the user that a listing number has been assigned to the submission.
9. **Last Modified User:** The username of the person who last made changes to a submission.
10. **Last Modified Date:** The most recent date that changes were made to a submission.

4.5.2.1 Filtering on Column Header

You can click on any of the above headers directly to filter out submissions:

1. Clicking the 'Status' header will display a dropdown of all status types tied to your submissions:

STATUS	SET ID	F
↑=	↓=	Filter...
DRAFT	cd3 ice3 b951 cc2 dcf- b951	
SUBMISSION ACCEPTED	cd2 971 b951	
SUBMISSION FAILED	b951	
VALIDATION FAILURE	cd3 9b5 a951 cc3	

2. Select an option—Draft, for example—and all your submissions currently in that status will be displayed:

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	🔒
DRAFT				5	COSMETIC PRODUCT LISTING		02-JUL-2024 08:03:16	
DRAFT				7	COSMETIC - UPDATE		01-JUL-2024 11:20:52	
DRAFT				5	COSMETIC PRODUCT LISTING		27-JUN-2024 14:26:59	
DRAFT				1	COSMETIC PRODUCT LISTING		27-JUN-2024 14:18:19	
DRAFT				1	COSMETIC PRODUCT LISTING		17-JUN-2024 13:26:14	
DRAFT				1	COSMETIC FACILITY REGISTRATION		17-JUN-2024 12:50:55	
DRAFT				4	COSMETIC PRODUCT LISTING		14-JUN-2024 09:12:37	
DRAFT				3	COSMETIC FACILITY REGISTRATION - AMENDMENT		12-JUN-2024 13:31:07	

3. You can also use the dropdown buttons to further sort your data:

Icon	Description
↑=	Sort ascending
↓=	Sort descending
☒	Hide column
☰	Clearly separate each submission

On the left, a screenshot of a table interface shows the 'DOCUMENT TYPE' column header highlighted with a red box. Below the table are four buttons: ↑=, ↓=, ☒, and ☰. To the right of the table is a 'Filter...' input field and a 'for' dropdown menu.

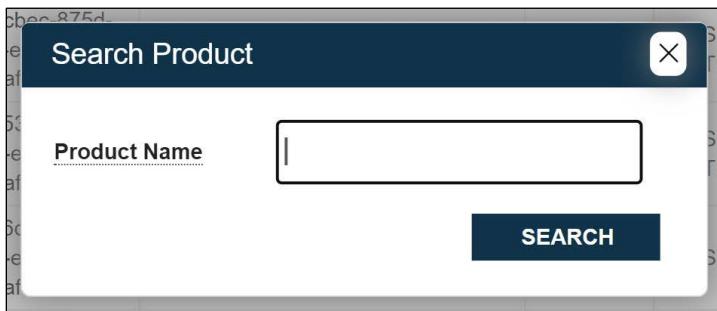
4.5.2.2 Search Product

A product can be searched by name:

1. Click 'SEARCH PRODUCT' box next to 'CREATE NEW/UPLOAD FILE':

SEARCH PRODUCT	CREATE NEW / UPLOAD FILE				
DOCUMENT TYPE	RESPONSIBLE PERSON NAME	DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE	🔒

2. Enter the name of the product and click 'SEARCH'.



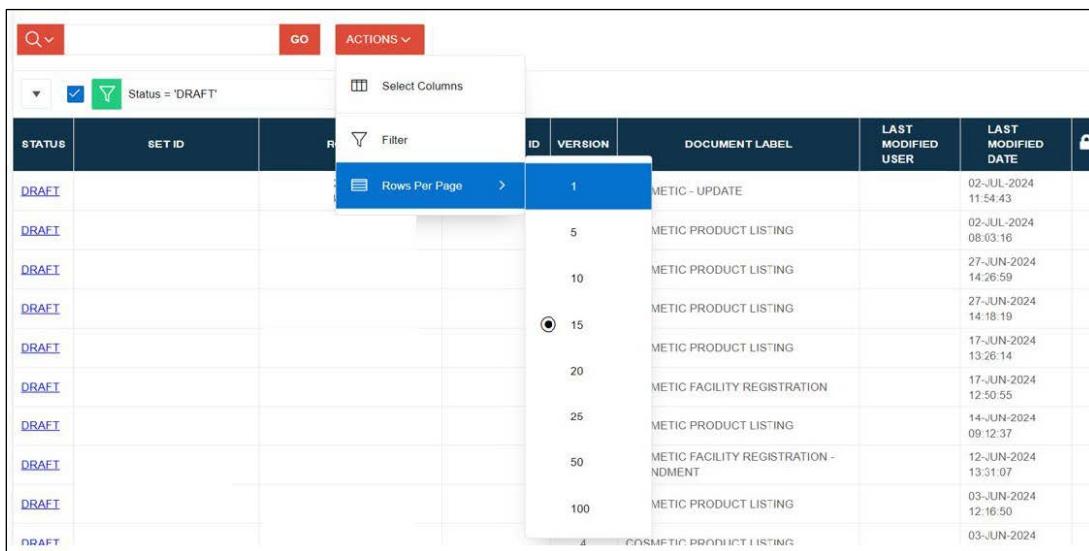
A screenshot of a 'Search Product' dialog box. It has a dark blue header with the text 'Search Product' and a white 'X' button. The main area contains a 'Product Name' label and a text input field. At the bottom is a dark blue 'SEARCH' button.

3. The page will update immediately with your filter.

4.5.2.3 Rows Per Page

To adjust the number of submissions visible per page:

1. Click the 'Actions' button and select 'Rows Per Page':



A screenshot of a table interface showing a 'Rows Per Page' dropdown menu. The menu is open, displaying options: 1, 5, 10, 15 (selected), 20, 25, 50, 100, and 4. The table itself shows a list of submissions with columns for STATUS, SET ID, ID, VERSION, DOCUMENT LABEL, LAST MODIFIED USER, and LAST MODIFIED DATE. The 'STATUS' column shows 'DRAFT' for all rows.

2. You can choose to have 1-100 submissions viewable per page. The page will update immediately after your selection is made.

5 DRUG REGISTRATION AND LISTING

5.1 Drug Establishment Registration SPL

A drug **Establishment Registration** SPL submission is used to maintain the registration of all establishments involved in the manufacture or processing of drugs sold in the United States. If you have a CDER Direct or Combined account, you are required to update your establishment registration annually between October 1st and December 31st. For Cosmetics Direct accounts, cosmetic facility registrations must be renewed biennially.

The Establishment Registration SPL submission template can be used for the following purposes:

- [Establishment Registration](#): For initial registration or updating establishment information.
- [Establishment De-Registration](#): To cancel registration when the establishment no longer engages in FDA-regulated activities but remains operational.
- [Out of Business](#): To inform the FDA that the establishment has ceased all operations.
- [No Change Notification](#): Informing the FDA that no changes have occurred since the previous submission was made.

5.1.1 Registering a New Drug Establishment

To use the Establishment Registration SPL:

1. Log in to FDA Direct.
2. Select '**Establishment Registration**' under the *Establishment Registration & Drug Listing* section:

3. Click '**Create New/Upload File**':

ESTABLISHMENT REGISTRATION

For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic establishment registration and drug listing, contact eDRLS@fda.hhs.gov.

- Under section 510 of the Act, and 21 CFR 207, with some limited exceptions, firms that manufacture, prepare, propagate, compound, or process drugs in the United States or that are offered for import into the U.S. must be registered with the FDA, see 21 U.S.C. 360(b), (c), (d), and (i).
- Firms that are solely Private Label Distributors (PLDs) who are not involved in the manufacturing process, as outlined above, should not register as a drug establishment via Establishment Registration.
- After receiving a successful submission, indicated by "Submission Accepted," the establishment's information will appear on the [Drug Establishment Current Registration Site \(DECRS\)](#) within 1-2 business days.
- Establishment registrations submitted during the October 1 to December 31 period are considered registered until the end of following calendar year. Any registration submission received outside of this timeframe does not extend the registration expiration date beyond the current calendar year.

Q GO ACTIONS SEARCH ESTABLISHMENT CREATE NEW / UPLOAD FILE

4. You will be given two options:

CREATE NEW ESTABLISHMENT REGISTRATION

Create New Establishment Registration using a blank form
 Import an existing Establishment Registration 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

- a. To upload a file from your computer directly, follow the steps outlined in Section 3: Submission Information. Then skip to Step 12 below to continue editing.
5. To create an SPL submission using a blank template, select the '**Create New Establishment Registration using a blank form**' option.
6. Click '**Continue**' and a blank template will display:

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 Establishment Registration submission form. Red asterisk indicate required fields.

HEADER DETAILS

Document Type: *	--Select One--		
Set ID: *	05b62798-ecb5-6144-e063-fb95b40a8212	Generate New	Version Number: *
Root ID: *	05b62798-ecb7-6144-e063-fb95b40a8212	Generate New	Effective Date: * 09-19-2023 Edit

REGISTRANT DETAILS

Registrant Name: *			
Registrant DUNS: *			

REGISTRANT CONTACT DETAILS

Contact Name: *	Country: *		
Contact Email: *	Street Address: *		
Contact Phone: *	City: *		
Phone Extension:	State/Province:		
Postal Code:			

ESTABLISHMENTS

None ADD ESTABLISHMENT

7. Selecting the 'Save As Draft' button on the top right will save your work without submitting it. The 'Return' button will send you back to the main Establishment Registration page without saving your changes.
8. Select 'Establishment Registration' from the *Document Type* dropdown:

9. Fill in all blank fields in the *Registrant Details* section:

10. To add multiple establishments, click the 'Add Establishment' button at the bottom of the page:

11. You will be shown a separate form. Fill in all the necessary fields:

All Submissions | Establishment Registration | SPL Submission | Establishment | **Establishment**

ESTABLISHMENT DETAILS

Establishment Name: *

Establishment DUNS: *

Establishment FEI:

ESTABLISHMENT ADDRESS

Country: * -Select Country-

Street Address: *

City: *

State/Province:

Postal Code:

ESTABLISHMENT CONTACT DETAILS

Same as Registrant Contact Details and Address

Contact Name: *

Contact Email: *

Contact Phone: * Format

Phone Extension:

ESTABLISHMENT CONTACT ADDRESS

Country: * -Select Country-

Street Address: *

City: *

State/Province:

Postal Code:

U.S. AGENT

Agent Name: *

Agent DUNS: *

Agent Email: *

Agent Phone: * Format

Phone Extension:

Note: Enter the one or more drug manufacturing and processing operations performed at the establishment.

BUSINESS OPERATION(S)

12. At the bottom of the page, click the 'Add Business Operation' button. A dialog box will display:

Business Operation/Qualifier

Business Operations:

Qualifier

CANCEL **SAVE** **SAVE AND ADD**

13. Select your business operations from the dropdown. Check all qualifier boxes that apply:

Business Operation/Qualifier

Business Operations: MANUFACTURE

Qualifier

CONTRACT MANUFACTURING FOR HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER A MONOGRAPH
 MANUFACTURES ANIMAL OVER-THE-COUNTER DRUG PRODUCTS
 MANUFACTURES ANIMAL OVER-THE-COUNTER TYPE A MEDICATED ARTICLE DRUG PRODUCTS
 MANUFACTURES ANIMAL PRESCRIPTION DRUG PRODUCTS
 MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS
 MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS NEITHER PRODUCED UNDER AN APPROVED DRUG APPLICATION NOR UNDER A MONOGRAPH
 MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER A MONOGRAPH
 MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER AN APPROVED DRUG APPLICATION
 MANUFACTURES HUMAN PRESCRIPTION DRUG PRODUCTS
 MANUFACTURES NON-GENERICs
 MANUFACTURES VETERINARY FEED DIRECTIVE TYPE A MEDICATED ARTICLE DRUG PRODUCTS
 TRANSFILLS MEDICAL GAS

CANCEL **SAVE** **SAVE AND ADD**

***Some qualifiers may become greyed out depending on your selections:**

Business Operation/Qualifier

Business Operations: HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY

Qualifier

INTENT TO COMPOUND 506E (DRUG SHORTAGE) DRUGS
 NO INTENT TO COMPOUND 506E (DRUG SHORTAGE) DRUGS
 COMPOUNDING FROM BULK INGREDIENT
 NOT COMPOUNDING FROM BULK INGREDIENT
 COMPOUNDING STERILE PRODUCTS
 NOT COMPOUNDING STERILE PRODUCTS

CANCEL **SAVE** **SAVE AND ADD**

14. To add more business operations, click '**Save And Add**' at the bottom. To finish with your selections and close the dialog box, click '**Save**.' Your selections will display at the bottom of the page:

Note: Enter the one or more drug manufacturing and processing operations performed at the establishment.

BUSINESS OPERATION(S)			ADD BUSINESS OPERATION
EDIT	DELETE	BUSINESS OPERATION	QUALIFIER
		MANUFACTURE	<ul style="list-style-type: none"> CONTRACT MANUFACTURING FOR HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER A MONOGRAPH MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER A MONOGRAPH
		LABEL	<ul style="list-style-type: none"> CONTRACT MANUFACTURING FOR HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER A MONOGRAPH MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS NEITHER PRODUCED UNDER AN APPROVED DRUG APPLICATION NOR UNDER A MONOGRAPH

1 - 2

15. Return to the top of the page and select '**Save Establishment**' when finished. You will be returned to the main entry page, with the newly added establishment(s) listed at the bottom. Click the pencil icon to make edits to the establishment:

ESTABLISHMENTS

ESTABLISHMENT DUNS			ESTABLISHMENT FEI	ESTABLISHMENT NAME	ADD ESTABLISHMENT
	222222222	-	-	CNI124	row(s) 1 - 1 of 1

16. Return to the top of the page where you can do the following:

- 'Save As Draft'** – Save your entry and return to the main Establishment Registration page. No submission will be made.
- 'Save And Validate'** - Save your entry + validate. This will check your submission for errors prior to submitting to the FDA. Validation may take some time. If you are ready to submit your SPL, you may skip this step entirely.
- 'Submit SPL'** - Submit your Establishment Registration to the FDA. You will then be returned to the Establishment Registration main page where you can view your pending submission(s) status:

ESTABLISHMENT REGISTRATION

For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic establishment registration and drug listing, contact eDRS@fda.hhs.gov

- Under section 510 of the Act, and 21 CFR 207, with some limited exceptions, firms that manufacture, prepare, propagate, compound, or process drugs in the United States or that are offered for import into the U.S. must be registered with the FDA, see 21 U.S.C. 360(b), (c), (d), and (i).
- Firms that are solely Private Label Distributors (PLDs) who are not involved in the manufacturing process, as outlined above, should not register as a drug establishment via Establishment Registration.
- After receiving a successful submission, indicated by "Submission Accepted," the establishment's information will appear on the [Drug Establishment Current Registration Site](#) (DECRS) within 1-2 business days.
- Establishment registrations submitted during the October 1 to December 31 period are considered registered until the end of following calendar year. Any registration submission received outside of this timeframe does not extend the registration expiration date beyond the current calendar year.

SEARCH	GO	ACTIONS	SEARCH ESTABLISHMENT	CREATE NEW / UPLOAD FILE				
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME	DOCUMENT LABEL	DETAILS
AWAITING ACCEPTANCE	05b82798-ecb8-6144-e063-fb95b40a8212	05b82798-ecb7-6144-e063-fb95b40a8212		1	11111111	CNI123	ESTABLISHMENT REGISTRATION	

- d. **'Delete'** – Delete your draft entry completely.
- 17. Click **'Return'** at any time to return to the main Establishment Registration page.
- 18. The *Status* field should read **'Submission Accepted'** when your submission has been validated and accepted by the FDA. You will receive an email to your account email address when the submission status changes.
- 19. Once your submission has been accepted, you will be able to download a copy of the submission as a zip file. Go to the main Establishment Registration page and click the latest **'Submission Accepted'** text link:



- 20. Click **'Download SPL'** on the top left of the page to download the zip file. You can also select **'View SPL'** for a quick look at your submission.

All Submissions Establishment Registration SPL Submission

VIEW SPL **DOWNLOAD SPL**

Note: Click on the Data Element Name for each field below to display instructions and

HEADER DETAILS

Document Type: * ESTABLISHMENT REGISTRATION

- 21. If you already have multiple submissions, you can search for a specific establishment:

 - a. Click **'Search Establishment'** on the Establishment Registration main page:

received outside of this timeframe does not extend the registration expiration date beyond the current calendar year.

Q GO ACTIONS SEARCH ESTABLISHMENT CREATE NEW / UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME	DOCUMENT LABEL	DETAILS
05682798...	05682798...							

b. Enter one or both of the fields in the ensuing popup box. Partial entries (ex: 'sys' instead of 'systems') are permitted:

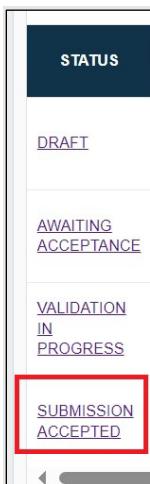
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME
DRAFT						

c. Click 'Search' and your results will populate.
d. See Section 9.2: Searching and Filtering for additional help with filters and searching multiple establishments.

5.1.2 De-Registering a Drug Establishment

There are two ways to de-register your drug establishment with the FDA:

1. Go to the *Establishment Registration* page.
2. Find the most recent submission of the establishment you want to de-register with the '*Submission Accepted*' status and select the link:



- Select 'Create New Version' at the top right of the page:

The screenshot shows a navigation bar with 'All Submissions', 'Establishment Registration', and 'SPL Submission'. Below the navigation are 'VIEW SPL' and 'DOWNLOAD SPL' buttons. On the right side, there is a 'CREATE NEW VERSION' button highlighted with a red box, and a '<< RETURN' link.

- Click the *Document Type* dropdown under the *Header Details* section, then select either option depending on your reasons:

- Establishment De-Registration
- Out Of Business Notification

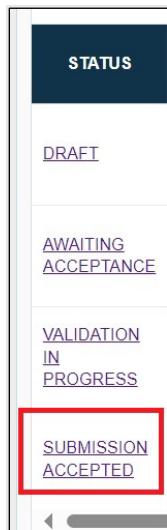
The screenshot shows the 'Header Details' section. It includes fields for 'Document Type' (dropdown), 'Set ID' (text input), 'Root ID' (text input), 'Version Number' (text input with value '1'), and 'Effective Date' (text input with value '09-20-2023'). The 'Document Type' dropdown is expanded, showing options: 'ESTABLISHMENT REGISTRATION', 'ESTABLISHMENT DE-REGISTRATION', 'NO CHANGE NOTIFICATION', and 'OUT OF BUSINESS NOTIFICATION'. Red arrows point from the text labels to the 'Generate New' buttons next to the 'ESTABLISHMENT REGISTRATION' and 'OUT OF BUSINESS NOTIFICATION' options.

- Click 'Submit SPL' at the top right of the page and you will be taken to the *Establishment Registration* page. An email will be sent to your account email address to confirm your establishment de-registration/out of business status.
- Click 'Create New/Upload File' on the *Establishment Registration* page.
 - Select 'Import an Existing Establishment Registration SPL' and click 'Continue.'
 - See Steps (b-c) in the previous section.

5.1.3 No Changes to Establishment Registration

If you have no changes to report for the current registration period, you may submit a **No Change Notification**:

- Go to the *Establishment Registration* page.
- Follow Steps 2-2(a) in the section above if you have submitted using FDA Direct previously.
 - Select 'No Change Notification' from the *Document Type* dropdown.
 - Click 'Submit SPL.'
 - You will receive an email to your account email address with the confirmed No Change renewal status update.
- Follow Step 3 in the previous section above if you are uploading a submission file from your computer and have not used FDA Direct previously.



a. Select '**Create New Version**' at the top right of the page:

b. Click the *Document Type* dropdown under the *Header Details* section, then select either option depending on your reasons:

- **Establishment De-Registration**
- **Out Of Business Notification**

c. Click '**Submit SPL**' at the top right of the page and you will be taken to the *Establishment Registration* page. An email will be sent to your account email address to confirm your establishment de-registration/out of business status.

4. Click '**Create New/Upload File**' on the *Establishment Registration* page.

- Select '**Import an Existing Establishment Registration SPL**' and click '**Continue.**'
- See Steps 3(b)-3(c) in the previous section.

5.2 Drug NDC Labeler Code Request

A drug **NDC Labeler Code Request** SPL submission will allow you to list drugs (prescription or OTC) that are manufactured or distributed in the United States. Use this only when you are ready to launch your drug products for commercial registration in the U.S. The same labeler code may be used for multiple sites if they fall under one company (parent, subsidiary, and/or affiliate).

The NDC Labeler Code Request SPL submission template can be used for the following purposes:

- Registration - Requesting a new NDC Labeler Code, or confirming or updating labeler code details.
- Inactivation – Suspend use of an existing NDC Labeler Code.

To submit an NDC Labeler Code Request SPL, do the following:

1. Log in to FDA Direct.
2. Select '**NDC Labeler Code Request**' under the *Establishment Registration & Drug Listing* section:

3. Click 'Create New/Upload File':

4. You will be given two options:

CREATE NEW NDC LABELER CODE REQUEST

Create a new NDC Labeler Code Request using a blank form
 Import an existing NDC Labeler Code Request 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**

- a. To upload a file from your computer directly, follow the steps outlined in Section 3: Submission Information. Then skip to Step 11 below and continue the instructions.
5. To create an SPL submission using a blank template, select the '**Create a new NDC Labeler Code Request using a blank form**' option.
6. Click '**Continue**' and a blank template will display:

All Submissions NDC Labeler Code Request **SPL Submission**

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 Labeler Code Request submission form. Red asterisk indicate required fields.

HEADER DETAILS

Document Type: *	--Select One--	
Set ID: *	05e17063-ba6d-5322-e063-fa95b40a09d8	Generate New
Root ID: *	05e17063-ba6e-5322-e063-fa95b40a09d8	Generate New
Version Number: *	1	
Effective Date: *	09-21-2023	<input type="button" value="Format"/>

LABELER DETAILS

Labeler Name: *	Labeler Code:
Labeler DUNS: *	

LABELER CONTACT DETAILS

Contact Name: *	Country: *
Contact Email: *	Street Address: *
Contact Phone: *	City: *
Phone Extension:	State/Province:
	Postal Code:

LABELER CONTACT ADDRESS

Contact Name: *	Country: *
Contact Email: *	Street Address: *
Contact Phone: *	City: *
Phone Extension:	State/Province:
	Postal Code:

ADDITIONAL LABELER DETAILS (Optional - Including the following information will expedite the processing of your request)

LABELER ADDRESS

Same as Labeler Contact Address	U.S. AGENT
Country: *	Agent Name:
Street Address: *	Agent DUNS:
City: *	Agent Email:
State/Province:	Agent Phone:
Postal Code:	Phone Extension:

BUSINESS OPERATION(S)

ADD BUSINESS OPERATION

7. Selecting the '**Save Draft**' button at any time will save your work without submitting it. The '**Return**' button will send you back to the main NDC Labeler Code Request page without saving your changes.
8. Select '**NDC Labeler Code Request**' from the *Document Type* dropdown:

HEADER DETAILS

Document Type: * --Select One--

Set ID: * NDC LABELER CODE REQUEST

Root ID: * 05e17063-ba6e-5322-e063-fa95b40a09d8

Version Number: * 1

Effective Date: * 09-21-2023

9. Fill in all blank fields in the *Labeler Details* section. If you are requesting a labeler code, leave the "Labeler Code" field blank:

LABELER DETAILS

Labeler Name: *

Labeler DUNS: *

LABELER CONTACT DETAILS

Contact Name: *

Contact Email: *

Contact Phone: * Format

Phone Extension:

LABELER CONTACT ADDRESS

Country: * -Select Country-

Street Address: *

City: *

State/Province:

Postal Code:

10. Information provided in the *Additional Labeler Details* section is optional, but including this information will expedite the processing of your NDC Labeler Code request:

ADDITIONAL LABELER DETAILS (Optional - Including the following information will expedite the processing of your request)

LABELER ADDRESS

Same as Labeler Contact Address

Country: * --Select Country--

Street Address: *

City: *

State/Province:

Postal Code:

U.S. AGENT

Agent Name:

Agent DUNS:

Agent Email:

Agent Phone: Format

Phone Extension:

11. At the bottom of the page, click the '**Add Business Operation**' button. A dialog box will display:

Business Operation/Qualifier

Business Operations:

Qualifier

CANCEL **SAVE** **SAVE AND ADD**

12. Select your business operations from the dropdown. Check all qualifier boxes that apply:

Business Operation/Qualifier

Business Operations: API/FDF ANALYTICAL TESTING

Qualifier

COMPOUNDING FROM BULK INGREDIENT
 COMPOUNDING STERILE PRODUCTS
 DISTRIBUTES HUMAN OVER-THE-COUNTER DRUG PRODUCTS
 DISTRIBUTES HUMAN PRESCRIPTION DRUG PRODUCTS
 INTENT TO COMPOUND 506E (DRUG SHORTAGE) DRUGS
 MANUFACTURES ANIMAL OVER-THE-COUNTER DRUG PRODUCTS
 MANUFACTURES ANIMAL OVER-THE-COUNTER TYPE A MEDICATED ARTICLE DRUG PRODUCTS
 MANUFACTURES ANIMAL PRESCRIPTION DRUG PRODUCTS
 MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS
 NEITHER PRODUCED UNDER AN APPROVED DRUG APPLICATION NOR UNDER A MONOGRAPH
 MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER A MONOGRAPH
 MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER AN APPROVED DRUG APPLICATION
 MANUFACTURES HUMAN PRESCRIPTION DRUG PRODUCTS
 MANUFACTURES NON-GENERICs
 MANUFACTURES VETERINARY FEED DIRECTIVE TYPE A MEDICATED ARTICLE DRUG PRODUCTS
 NO INTENT TO COMPOUND 506E (DRUG SHORTAGE) DRUGS
 NOT COMPOUNDING FROM BULK INGREDIENT
 NOT COMPOUNDING STERILE PRODUCTS
 TRANSFILLS MEDICAL GAS

CANCEL **SAVE** **SAVE AND ADD**

***Some qualifiers may become greyed out depending on your selections (shown above)**

13. To add more business operations, click '**Save And Add**' at the bottom. To finish with your selections and close the dialog box, click '**Save**.' Your selections will display at the bottom of the page:

Note: Enter the one or more drug manufacturing and processing operations performed at the establishment.

BUSINESS OPERATION(S)			ADD BUSINESS OPERATION
EDIT	DELETE	BUSINESS OPERATION	QUALIFIER
		MANUFACTURE	<ul style="list-style-type: none"> CONTRACT MANUFACTURING FOR HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER A MONOGRAPH MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER A MONOGRAPH
		LABEL	<ul style="list-style-type: none"> CONTRACT MANUFACTURING FOR HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER A MONOGRAPH MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS NEITHER PRODUCED UNDER AN APPROVED DRUG APPLICATION NOR UNDER A MONOGRAPH

1 - 2

14. Click the pencil icon to make edits to any of the Business Operations or click the X to delete the specified operation.

15. Return to the top of the page where you can do the following:

- '**Save As Draft**' – Save your entry and return to the main NDC Labeler Code Request page. No submission will be made.
- '**Save And Validate**' - Save your entry + validate. This will check your submission for errors prior to submitting to the FDA. Validation may take some time. If you are ready to submit your SPL, you may skip this step entirely.
- '**Submit SPL**' - Submit your NDC Labeler Code Request to the FDA. You will then be returned to the NDC Labeler Code Request main page where you can view your pending submission(s) status:

All Submissions > NDC Labeler Code Request >

ESTABLISHMENT REGISTRATION & DRUG LISTING		NDC LABELER CODE REQUEST						
Establishment Registration	NDC Labeler Code Request	For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov For general questions regarding electronic establishment registration and drug listing, contact eORLS@fda.hhs.gov <ul style="list-style-type: none"> The purpose of requesting a labeler code is to list drugs (prescription or OTC) that are manufactured or distributed in the US. Firms should apply for a labeler code once they are read to launch drugs for commercial distribution in the U.S. §207.33 (c)(1) provides information on who must obtain an NDC labeler code and how the code is assigned and updated. The processing time for initial Labeler Code Requests can take up to 21 days. After processing, the contact email provided in the Labeler Code Request will receive an email notification. Please note that the same Labeler Code (LC) can be used for multiple sites if they are under one company (parent, subsidiary, and/or affiliate). The labeler is usually the company that owns the brand, and the company most likely associated with the LC. If the company has multiple sites, each site must have its own DUNS and FEI number, but may operate under the same LC. To clarify, DUNS and FEI are site-specific and labeler codes are company-specific. 						
OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING		Q ACTIONS						
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME	LAST MODIFIED USER
AWAITING ACCEPTANCE	05e17063-ba8d-5322-e063-fa95b40a09d8	05e17063-ba8d-5322-e063-fa95b40a09d8		1	NDC LABELER CODE REQUEST	123123123	123chn	Zee Dee

- '**Delete**' – Delete your draft entry completely.

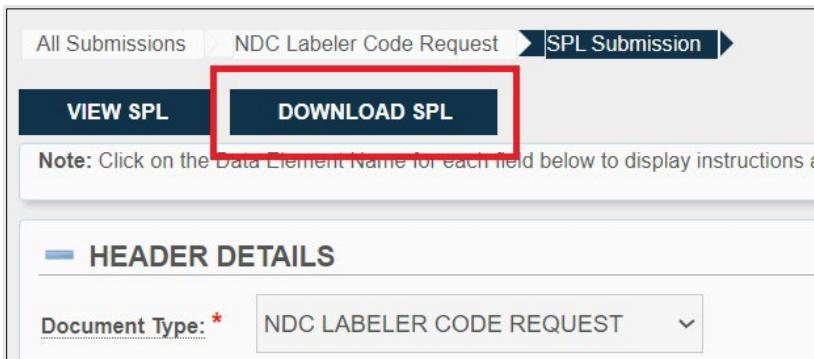
16. The *Status* field on the NDC Labeler Code Request main page should read 'Submission Accepted' when your submission has been validated and accepted by the FDA.

17. You will receive an email to your FDA Direct account email address when your request has been processed. This can take up to 21 days.

18. Once your submission has been accepted, you will be able to download a copy of the submission as a zip file. Go to the main NDC Labeler Code Request page and click the latest 'Submission Accepted' text link:



19. Click 'Download SPL' on the top left of the page to download the zip file. You can also select 'View SPL' for a quick look at your submission.



5.3 Drug NDC Reservation

A drug **NDC Reservation** SPL submission reserves an NDC for a future drug listing with the FDA without requiring all data elements to be provided. It is NOT a drug listing submission. This submission template should only be used if you intend to begin commercial distribution within 2 years, as an NDC can only be reserved for up to 2 years. This submission is not required prior to a drug product listing submission. If your product is ready to be listed, please use the Drug Listing submission as outlined in Section 5.4. Once commercial distribution begins, the NDC Reservation SPL submission must be updated and converted to a Drug Product Listing SPL.

To reserve an NDC, do the following:

1. Log in to FDA Direct.
2. Select '**NDC Reservation**' under *Establishment Registration & Drug Listing*:

3. Click 'Create New/Upload File' on the NDC Reservation main page:

4. You will be given two options:

a. To upload a file from your computer directly, follow the steps outlined in Section 3: Submission Information. Then skip to Step 9 below to continue the instructions.

5. To create a new reservation using a blank template, select the '**Create a new NDC Reservation using a blank**' option.

6. Use the dropdown to select your *Reservation Product Type*:

CREATE NEW NDC RESERVATION

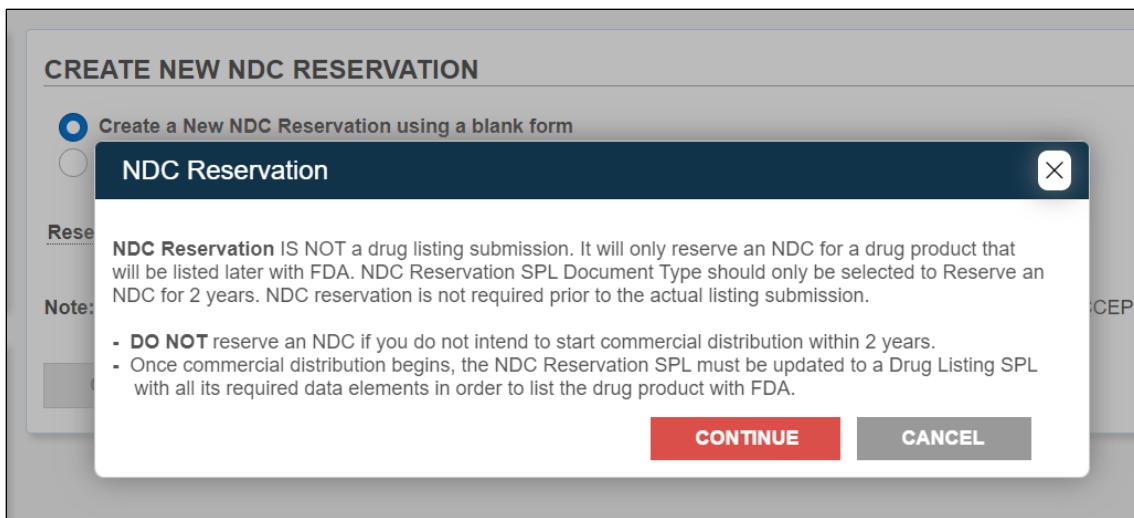
Create a New NDC Reservation using a blank form
 Import an existing NDC Reservation

Reservation Product Type: *

Note: To update an existing submission, click

-- Select Document Type --
 BULK INGREDIENT
 CELLULAR THERAPY
 DRUG FOR FURTHER PROCESSING
 HUMAN OTC DRUG LABEL
 HUMAN PRESCRIPTION DRUG LABEL
 NON-STANDARDIZED ALLERGENIC LABEL
 PLASMA DERIVATIVE
 STANDARDIZED ALLERGENIC
 VACCINE LABEL

7. An informational dialog box will appear:



IMPORTANT: An NDC Reservation IS NOT a drug listing submission. It will only reserve an NDC for a drug product that will be listed later with FDA. The NDC Reservation SPL Document Type should only be selected to reserve an NDC for 2 years. An NDC reservation is not required prior to the actual listing submission. If your product is ready to be listed, please use the Drug Listing submission as outlined in Section 5.4.

- DO NOT reserve an NDC if you do not intend to start commercial distribution within 2 years.
- Once commercial distribution begins, the NDC Reservation SPL must be updated to a Drug Listing SPL with all its required data elements in order to list the drug product with FDA.

8. Click 'Continue' to display the NDC Reservation blank template:

All Submissions NDC Reservation Products

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 Products submission form. Red asterisk indicate required fields.

Note: This form is only to Reserve a Product NDC. The Product NDC can be reserved for up to 2 years from the time of submission. After successfully reserving a NDC, it can be converted to an active listing.

HEADER DETAILS

Document Type: * HUMAN PRESCRIPTION DRUG LABEL **NDC RESERVATION** Version Number: * 1

Set ID: * 1c8269ec-394d-d229-e063-fa95b40a9a94 [Generate New](#) Effective Date: * 07-05-2024

Root ID: * 1c8269ec-394e-d229-e063-fa95b40a9a94 [Generate New](#)

Title

LABELER DETAILS

Labeler Name: * Labeler DUNS: *

REGISTRANT DETAILS

Registrant Name: Registrant DUNS:
 Confidential

PRODUCTS **ADD PRODUCT**

SEARCH	GO	ACTIONS
None.		

ESTABLISHMENTS **ADD ESTABLISHMENT**

None

- Fill out the *Labeler Details* section.
- The *Registrant Details* section is optional. Clicking the '**Confidential**' check box in this section will keep this submission from being visible to the public:

REGISTRANT DETAILS

Registrant Name:

Confidential

- To add products, click the '**Add Product**' button at the bottom of the template:

12. A blank template will display. Enter all fields applicable. If you are unsure about what to enter for any of the fields, click the underlined text beside the blank fields for more information.

13. Fill out the requested information in the *Product Data Elements* section.

a. To add a 'Route of Administration,' select the dropdown and choose from the list:

PRODUCT DATA ELEMENTS

Product NDC: *	AURICULAR (OTIC) BUCCAL CONJUNCTIVAL CUTANEOUS DENTAL ELECTRO-OSMOSIS ENDOCERVICAL ENDOSINUSIAL ENDOTRACHEAL ENTERAL EPIDURAL EXTRA-AMNIOTIC EXTRACORPOREAL HEMODIALYSIS INFILTRATION INTERSTITIAL INTRA-ABDOMINAL INTRA-AMNIOTIC INTRA-ARTERIAL
Proprietary Name:	
Suffix:	
Non Proprietary Name: *	
DEA Schedule:	
Dosage Form: *	
Source NDC:	
Route of Administration:	<input type="button" value="ADD"/>

ROUTE OF ADMINISTRATION

1 - 1

b. Click the 'Add' button and your selection will appear in the Route of Administration box.

Route of Administration:	<input type="button" value="ADD"/>
ROUTE OF ADMINISTRATION	
HEMODIALYSIS	<input type="button" value="X"/>
1 - 1	

c. To remove a selection, simply click the 'X' beside a route of administration:

Route of Administration:	<input type="button" value="ADD"/>
ROUTE OF ADMINISTRATION	
HEMODIALYSIS	<input type="button" value="X"/>
INTRA-ARTERIAL	<input type="button" value="X"/>
1 - 2	

14. Enter information into the *Marketing Details* section.

15. To 'Add An Ingredient,' click the button under the *Ingredients* section:

INGREDIENTS

Note: * At least one active ingredient is required.
None

ADD INGREDIENT

a. You will be taken to a separate page where you can enter information about a single ingredient:

All Submissions NDC Reservation Products Product Details **Ingredient Details**

SAVE INGREDIENT **<< RETURN**

Note: The denominator strength and UOM for all Ingredients within a product should be the same. Should you need to change the values, all the ingredients added thus far should be deleted and added with the new values.

INGREDIENT DETAILS

Type: * -- Select One --

Ingredient UNII - Name: *

Numerator Strength: * Unit Of Measure: * -- Select One --

Denominator Strength: * Unit of Measure: * -- Select One --

b. Select the dropdown for 'Type':

INGREDIENT DETAILS

Type: * -- Select One --

Ingredient UNII - Name: *

Numerator Strength: * Unit Of Measure: * -- Select One --

Denominator Strength: * Unit of Measure: * -- Select One --

c. Selecting either of the first two Active Ingredient options 'Ingredient is Basis of Strength' or 'Moiety is Basis of Strength' will display the 'Active Moiety' field and a checkbox:

INGREDIENT DETAILS

Type: * Active Ingredient, Ingredient is Basis of Strength

Ingredient UNII - Name: *

Active Moiety: *

Moiety same as Ingredient

Numerator Strength: * Unit Of Measure: * -- Select One --

Denominator Strength: * Unit of Measure: * -- Select One --

ADD ACTIVE MOIETY

d. Enter an Ingredient UNII, or simply begin typing the ingredient name into the empty field:

INGREDIENT DETAILS

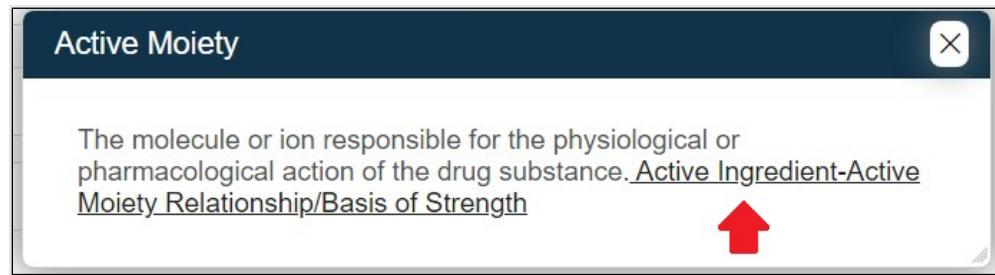
Type: *	Active Ingredient, Ingredient is Basis of Strength
Ingredient UNII - Name: *	ketocon
Active Moiety: *	(P7P4A1FD7Z) N-DEACETYL KETOCONAZOLE
	(3INP7D7X13) KETOCONAZOLE, TRANS-
Numerator Strength: *	(R9400W927I) KETOCONAZOLE
Denominator Strength: *	(2DJ8R0NT7K) LEVOKETOCONAZOLE
ADD ACTIVE MOIETY	
	(A5BAG8KDK5) KETOCONAZOLE-HYDROXY
	(2EWW9YYR6A) KETOCONAZOLE, (2R,4R)-

e. If the ingredient and moiety are the same, simply click the checkbox labeled 'Moiety Same As Ingredient' to automatically copy the ingredient to the active moiety field.

f. If you are unsure of the active moiety in your ingredient, you can click the underlined 'Active Moiety' helptext link.

A box will display with a download link entitled 'Active Ingredient-Active Moiety Relationship/Basis of Strength.' This will download a zip file to your computer that contains a spreadsheet with a full active ingredient list and corresponding active moieties:

Active Moiety: *	<input type="checkbox"/> Moiety same as Ingred
-------------------------	------------------------------------------------



A	B	C	D	E	F	G	
1	AI UNII	Active Ingredient	AM UNII	Active Moiety	Basis of Strength	RD UNII	Referenced Drug
6930	690G0D6V8H	KETAMINE	690G0D6V8H	KETAMINE	Active Ingredient		
6931	018YLU0083	KETAMINE HYDROCHLORIDE	690G0D6V8H	KETAMINE	Active Moiety		
6932	5F91OR6H84	KETAMINE HYDROCHLORIDE, R-	690G0D6V8H	KETAMINE			
6933	97F9DE4CT4	KETANSERIN	97F9DE4CT4	KETANSERIN			
6934	6454980K7H	KETANSERIN TARTRATE	97F9DE4CT4	KETANSERIN			
6935	61041G518S	KETAZOCINE	61041G518S	KETAZOCINE	Active Ingredient		
6936	92A214MD7Y	KETAZOLAM	92A214MD7Y	KETAZOLAM	Active Ingredient		
6937	E00MDP8254	KETHOXAL	E00MDP8254	KETHOXAL	Active Ingredient		
6938	U5C4H63K5U	KETIPRAMINE	U5C4H63K5U	KETIPRAMINE	Active Ingredient		
6939	POS1L14CF	KETOBEMIDONE	PC51L14CF	KETOBEMIDONE	Active Ingredient		
6940	97F9DE4CT4	KETOBEMIDONE HYDROCHLORIDE	PC51L14CF	KETOBEMIDONE			
6941	WA1RT8G9XK	KETOCAINE	WA1RT8G9XK	KETOCAINE	Active Ingredient		
6942	UQG7PXR4V	KETOCAINOL	UQG7PXR4V	KETOCAINOL	Active Ingredient		
6943	92400W237I	KETOCANZOLE	92400W237I	KETOCANZOLE	Active Ingredient		
6944	00Y40CC304K	KETOPROFEN	90Y40C304K	KETOPROFEN	Active Ingredient		
6945	5W1D00E3D4C	KETOPROFEN LYSINE	90Y40C304K	KETOPROFEN			
6946	SR10M3K57	KETOPROFEN SODIUM	90Y40C304K	KETOPROFEN			
6947	Z20ZXE70XL	KETORFANOL	8Z0ZXE70XL	KETORFANOL	Active Ingredient		
6948	Y215105V0L	KETOROLAC	Y215105V0L	KETOROLAC	Active Ingredient		
6949	4EV5946BHQ	KETOROLAC TROMETHAMINE	Y215105V0L	KETOROLAC	Active Ingredient		
6950	4EV5946BHQ	KETOROLAC TROMETHAMINE	Y215105V0L	KETOROLAC	Active Moiety		
6951	X49220T18G	KETOTIFEN	X49220T18G	KETOTIFEN	Active Ingredient		
6952	HB0503W0R0	KETOTIFEN FUMARATE	X49220T18G	KETOTIFEN	Active Moiety		
6953	504RN634MM	KETOTREXATE	504RN634MM	KETOTREXATE	Active Ingredient		
6954	FV4Y0J02CX	KEYHOLE LIMPET HEMOCYANIN	FV4Y0J02CX	KEYHOLE LIMPET HEMOCYANIN	Active Ingredient		
6955	5G117T0TJZ	KHELLIN	5G117T0TJZ	KHELLIN	Active Ingredient		

g. If you selected the third 'Type' option 'Reference Ingredient is Basis of Strength', a Reference Ingredient field will display below the Active Moiety field:

INGREDIENT DETAILS

Type: *	Active Ingredient, Reference Ingredient is Basis of Strength
Ingredient UNII - Name: *	
Active Moiety: *	<input type="checkbox"/> Moiety same as Ingredient
Reference Ingredient: *	

h. If you selected the 'Inactive Ingredient' option for 'Type,' a checkbox labeled 'Confidential' will appear below the Ingredient UNII field:

INGREDIENT DETAILS

Type: *	Inactive Ingredient
Ingredient UNII - Name: *	
<input type="checkbox"/> Confidential	

i. Enter your 'Numerator/Denominator Strength' and 'Unit of Measure' (not available if you selected 'Inactive Ingredient'):

Numerator Strength: *	<input type="text"/>	Unit Of Measure: *	-- Select One -- ▾
Denominator Strength: *	<input type="text"/>	Unit of Measure: *	-- Select One -- ▾

j. For all ingredient types (except 'Inactive Ingredient'), you will have the option to click the button '**Add Active Moiety**' to add additional active moieties:

Denominator Strength: *	<input type="text"/>
ADD ACTIVE MOIETY	

k. To add more ingredients, redo Step 15 above.

l. When finished, click '**Save Ingredient**' at the top right of the page. This will return you to the Add Product page.

m. You can edit an ingredient on the Product Details page by clicking the pencil icon:

INGREDIENTS	
<p>Note: * At least one active ingredient is required.</p>	
	SUBSTANCE NAME 2,5-DIMETHYLPYRROL-3-YL-2-FURYLKETONE

16. If your product is a **solid oral dosage form only**, add a product image (JPG format):

PRODUCT IMAGE (FOR SOLID ORAL DOSAGE FORMS ONLY)		UPLOAD IMAGE
Important: Do not enter package images and other labeling. These should be uploaded under the Content of Labeling tab. Select a File: <input type="file"/> <input type="button" value="Choose File"/>		

17. Add your product's Characteristics (color, flavor, score, shape, imprint, size) here:

CHARACTERISTICS	ADD CHARACTERISTIC
None	

a. You will be sent to a separate *Characteristics* page:

CHARACTERISTICS

Characteristic: * -- Select One --

Value: * -- Select One --

b. First, select the appropriate '**Characteristic**' from the dropdown. Then select the '**Value**' of that characteristic:

CHARACTERISTICS

Characteristic: * Color

Value: * -- Select One --

Additional Description:

-- Select One --

Black
Blue
Brown
Gray
Green
Orange

c. You can enter more specific details for a selected characteristic in the '**Additional Description**' field, which can include shades of colors ("ivory" white) or shape variations (triangle with "rounded edges"):

CHARACTERISTICS

Characteristic: * Color

Value: * White

Additional Description: Ivory

- d. Click '**Save Characteristic**' on the top right of the page when finished. You will be returned to the Product Details page.
- e. Only one characteristic can be entered at a time, so repeat the above steps to add additional characteristics.
- f. To edit a characteristic, click the pencil icon beside the selected characteristic on the Product Details page (toward the bottom of the page):

CHARACTERISTICS				ADD CHARACTERISTIC
	CHARACTERISTIC	VALUE	ADDITIONAL DESCRIPTION	
	SPLCOLOR	BLACK	STEEL	

row(s) 1 - 1 of 1

18. To add a Package:

- a. Click '**Add Package**' at the bottom of the product details page:

PACKAGING

None

ADD PACKAGE

- b. Enter all applicable data for the inner package:

All Submissions NDC Reservation Products Product Details **Packaging**

SAVE PACKAGE **DONE** **<< RETURN**

PACKAGING

ONLY LEVEL

Check for Deletion 

Is this a sample package ?

Package NDC:

Package Type: *

Quantity: *

Unit of Measure: *

Combination Product Type:

ADD OUTER PACKAGE **DELETE** **▲ TO TOP**

- c. Click the '**Add Outer Package**' button at the bottom of this page to enter outer package details (you can click this multiple times):

PACKAGING

INNERMOST LEVEL

Check for Deletion

Package NDC:

Package Type: *

Quantity: *

Unit of Measure: *

Combination Product Type:

OUTERMOST LEVEL

Check for Deletion

Is this a sample package ?

Package NDC:

Package Type: *

Quantity: *

Unit of Measure: *

Unit of Measure: *

Combination Product Type:

d. To delete an outer package, click the 'Check for Deletion' checkbox and then select the 'Delete' button:

OUTERMOST LEVEL

Check for Deletion

Is this a sample package ?

Package NDC:

Package Type: *

Quantity: *

Unit of Measure: *

Unit of Measure: *

Combination Product Type:

Are you sure you want to delete?

CANCEL **OK**

ADD OUTER PACKAGE **DELETE**

e. When finished, click 'Save Package' at the top of the page to save your changes and return to the product details page.

f. To edit a package, click the pencil icon beside the package (on the previous Product Details page):

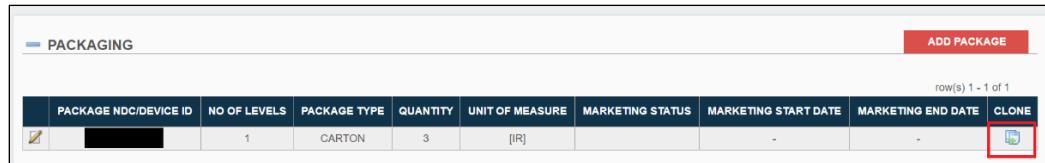
PACKAGING

ADD PACKAGE

ROW(S) 1 - 1 of 1

PACKAGE NDC/DEVICE ID	NO OF LEVELS	PACKAGE TYPE	QUANTITY	UNIT OF MEASURE	MARKETING STATUS	MARKETING START DATE	MARKETING END DATE	CLONE
 [REDACTED]	1	CARTON	3	[IR]		-	-	

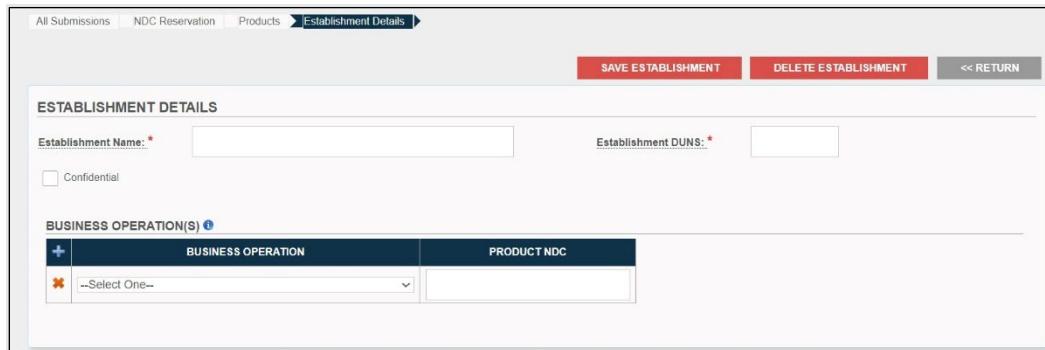
g. To make an exact duplicate of a package you previously created, click the 'Clone' icon:



PACKAGING									ADD PACKAGE
PACKAGE NDC/DEVICE ID	NO OF LEVELS	PACKAGE TYPE	QUANTITY	UNIT OF MEASURE	MARKETING STATUS	MARKETING START DATE	MARKETING END DATE	CLONE	
[REDACTED]	1	CARTON	3	[IR]		-	-		

19. Repeat Steps 11-18 to add more products.

20. Navigate to the *Establishments* section at the bottom of the page. To enter an establishment, click the 'Add Establishment' button. You will be sent to a separate page:



All Submissions NDC Reservation Products **Establishment Details**

ESTABLISHMENT DETAILS

Establishment Name: *

Establishment DUNS: *

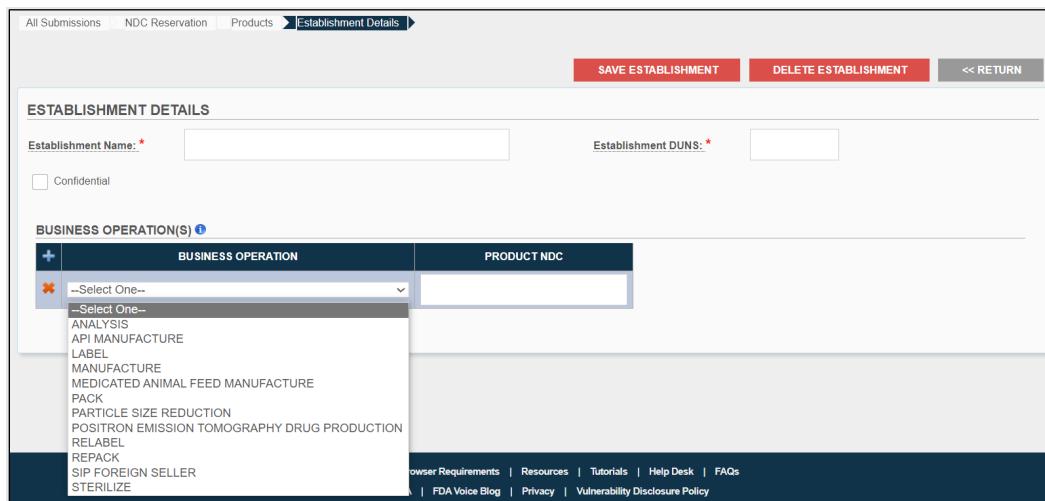
Confidential

BUSINESS OPERATION(S) ?

BUSINESS OPERATION	PRODUCT NDC
 --Select One--	

a. Enter your Establishment Name and DUNS.

b. Select your business operation(s) from the dropdown and input the product NDC for each operation:



All Submissions NDC Reservation Products **Establishment Details**

ESTABLISHMENT DETAILS

Establishment Name: *

Establishment DUNS: *

Confidential

BUSINESS OPERATION(S) ?

BUSINESS OPERATION	PRODUCT NDC
 --Select One--	
 --Select One--	
ANALYSIS	
API MANUFACTURE	
LABEL	
MANUFACTURE	
MEDICATED ANIMAL FEED MANUFACTURE	
PACK	
PARTICLE SIZE REDUCTION	
POSITRON EMISSION TOMOGRAPHY DRUG PRODUCTION	
RELABEL	
REPACK	
SIP FOREIGN SELLER	
STERILIZE	

c. You can click the + button to add multiple rows, if needed:



BUSINESS OPERATION(S) <small>i</small>		
+	BUSINESS OPERATION	PRODUCT NDC
	--Select One--	
	--Select One--	
	--Select One--	

d. Click '**Save Establishment**' button to save your work and return to the previous page. Click '**Delete Establishment**' to delete your establishment addition(s) and return to the previous page. The '**Return**' button will send you back to the previous page without saving the establishment changes.

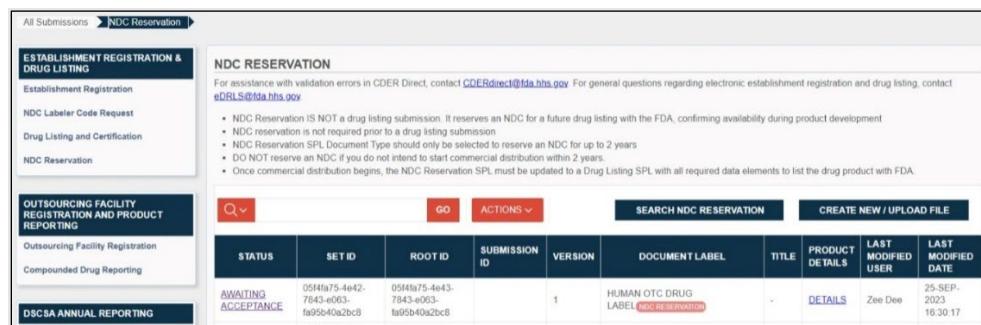
21. All added establishment details will display under the *Establishments* section:



ESTABLISHMENTS				ADD ESTABLISHMENT
	ESTABLISHMENT DUNS	ESTABLISHMENT NAME	CONFIDENTIAL	row(s) 1 - 1 of 1
	1111111111	CNI124	N	

22. When all fields have been entered to your satisfaction, you can do the following:

- 'Save As Draft'** – Save your entry and return to the main NDC Reservation page. No submission will be made.
- 'Save And Validate'** - Save your entry + validate. This will check your submission for errors prior to submitting to the FDA. Validation may take some time. If you are ready to submit your SPL, you may skip this step entirely.
- 'Submit SPL'** - Submit your NDC Reservation SPL submission to the FDA. You will then be returned to the NDC Reservation main page where you can view your pending submission(s) status:



All Submissions

ESTABLISHMENT REGISTRATION & DRUG LISTING

- Establishment Registration
- NDC Labeler Code Request
- Drug Listing and Certification
- NDC Reservation

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING

- Outsourcing Facility Registration
- Compounded Drug Reporting

DSCSA ANNUAL REPORTING

NDC RESERVATION

For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic establishment registration and drug listing, contact eCRLS@fda.hhs.gov

- NDC Reservation IS NOT a drug listing submission. It reserves an NDC for a future drug listing with the FDA, confirming availability during product development
- NDC reservation is not required prior to a drug listing submission
- NDC Reservation SPL Document Type should only be selected to reserve an NDC for up to 2 years
- DO NOT reserve an NDC if you do not intend to start commercial distribution within 2 years
- Once commercial distribution begins, the NDC Reservation SPL must be updated to a Drug Listing SPL with all required data elements to list the drug product with FDA

ACTIONS

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
AWAITING ACCEPTANCE	0544fa75-4e42-7643-e063-fa95b40a2bc8	0544fa75-4e43-7943-e063-fa95b40a2bc8		1	HUMAN OTC DRUG LABEL NDC RESERVATION	-	DETAILS	Zee Dee	25-SEP-2023 16:30:17

- 'Delete'** – Delete your entry draft completely.

23. Click '**Return**' at any time to return to the main NDC Reservation page.
24. The **Status** field should read '**Submission Accepted**' when your submission has been validated and accepted by the FDA. You will receive an email to your account email address when the submission status changes.
25. Once your submission has been accepted, you will be able to download a copy of the submission as a zip file. Go to the main NDC Reservation page and click the latest '**Submission Accepted**' text link:

STATUS	
1	
SUBMISSION	d
ACCEPTED	8
	9

26. Click '**Download SPL**' on the top left of the page to download the zip file. You can also select '**View SPL**' for a quick look at your submission.

VIEW SPL
DOWNLOAD SPL

Note: Click on the Data Element Name for each field below to display instructions and

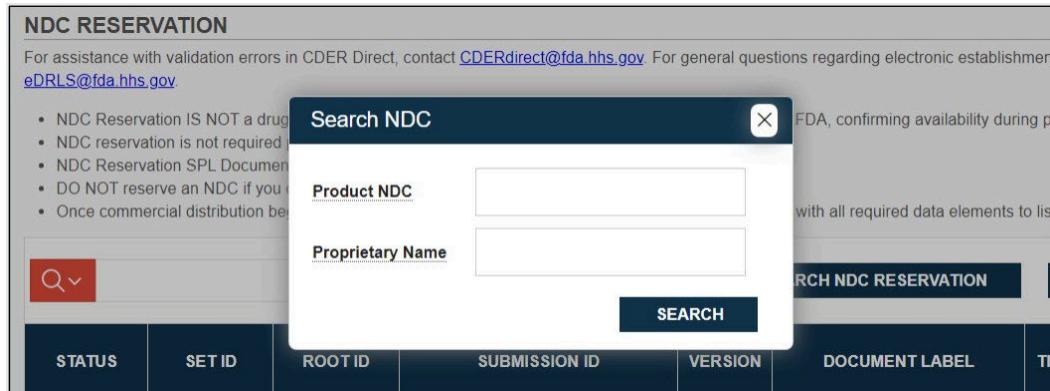
27. If you have multiple NDC reservations, you can search for a specific reservation:

- a. Click '**Search Establishment**' on the NDC Reservation main page:

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING
Outsourcing Facility Registration
SEARCH NDC RESERVATION
CREATE NEW / UPLOAD FILE

STATUS	SET ID	BODY ID	SUBMISSION	VERSION	DOCUMENT LABEL	TITLE	PRODUCT	LAST MODIFIED	LAST MODIFIED
--------	--------	---------	------------	---------	----------------	-------	---------	---------------	---------------

- b. Enter one or both of the fields in the ensuing popup box. Partial entries (ex: 'sys' instead of 'systems') are permitted:



- c. Click 'Search' and your results will populate.
- d. See Section 9.2: Searching and Filtering for additional help with filters and searching multiple reservations.

5.4 Drug Product Listing and Certification

A **Drug Product Listing and Certification** SPL submission will allow you to list and certify your drug products. This includes the following types of drugs:

- Bulk Ingredient
- Cellular Therapy
- Drug For Further Processing
- Human OTC Drug Label
- Human Prescription Drug Label
- Non-Standardized Allergenic
- Plasma Derivative
- Standardized Allergenic
- Vaccine Label

To list a drug product with the FDA:

1. Log in to FDA Direct.
2. Select '**Drug Listing and Certification**' under *Establishment Registration & Drug Listing*:

3. Click 'Create New/Upload File' on the Drug Listing and Certification main page:

4. You will be given two options:

- a. To upload a file from your computer directly, follow the steps outlined in Section 3: Submission Information. Then skip to Step 8 below and continue the instructions.
5. To create a new drug listing SPL submission using a blank template, select the 'Create a new Drug Listing and Certification using a blank form' option.
6. Use the dropdown to select your SPL Document Type:

7. For most document types, skip to [Step 10](#).

8. For the ‘**Blanket No Changes Certification of Product Listing**’ document type only, complete the following:

- Select ‘**Blanket No Changes Certification of Product Listing**’ from the *Document Type* dropdown, then press ‘**Continue**’.
- A blank template will display:

The screenshot shows the 'Blanket No Changes Certification of Product Listing' submission form. The 'HEADER DETAILS' section is filled with the following data:

- Document Type: BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING
- Set ID: 06e56d9d-c4e6-9310-e063-fa95b40a37b8
- Root ID: 06e56d9d-c4e7-9310-e063-fa95b40a37b8
- Version Number: 1
- Effective Date: 10-04-2023

The 'AUTHORIZED AGENT DETAILS' section contains fields for:

- Organization DUNS: (empty)
- Organization Name: (empty)
- Phone Number: (empty)
- Name: (empty)
- Email: (empty)
- Phone Extension: (empty)

The 'LABELERS' section includes a 'REFRESH ESTABLISHMENTS' button.

The 'ESTABLISHMENTS' section includes a search bar, a 'SHOW PRODUCTS' button, and an 'ADD ESTABLISHMENT' button.

- All fields in the *Header Details* section will be automatically generated.
- To name yourself as the Authorized Agent, select the ‘**Same as CDER Direct account details**’ checkbox, and the fields will populate automatically:

e. To add a Labeler, click the '**Add Labeler**' button then enter a valid labeler code:

f. Click '**Refresh Establishments**' to update the following section with establishment data based on your labeler code entries.

g. If an establishment has been marked as confidential, their data must be added via the '**Add Establishment**' button:

"If the establishment was submitted using this CDER Direct account, the confidential establishment will be included."

h. To search on an establishment, enter a partial or full search term. This can be the establishment DUNS, the establishment name, establishment's physical address, or contact details. You can also search under a specific column instead of all of them (default):

- i. For more advanced search and filtering options, see Section 9.2: Searching and Filtering.
- j. Click the 'Show Products' button under the *Establishments* section:

Establishments

SHOW PRODUCTS

ADD ESTABLISHMENT

* Establishments whose drug listing files are certified for.

* The list below only contains those establishments associated with the labeler that have not been indicated to be of confidential relationship. To add establishments that may have been

- k. You can add a product via the 'Add Prod NDC' button if your product does not display at the bottom of the *Products* page:

All Submissions Drug Listing and Certification Products Certification Products

PRODUCTS

SAVE / UPDATE ADD PROD NDC RETURN

Note: By selecting a product ndc certifies the product across all root id's. If you don't find your Product NDC in the list, you can add it using the "Add Prod NDC"

Note: Blanket No Changes Certification of Product Listings can only be submitted between October 1st and December 31st.

Filter products by Establishments: Show All

STATUS:

- Certified: This product listing has already been certified. Certification date expires on December 31 of the next calendar year.
- Uncertified: This product listing has not been certified for the next calendar year and is available for certification.
- Pending Compliance Case: An open listing compliance case exists on this product and the listing data cannot be certified until the case is closed.
- Completed: Product is discontinued. The listing data is not available for certification.
- Current: The listing data for this product is current because it was either submitted or revised in the current calendar year. No certification is needed.
- Validation Errors: The current version of the previously submitted drug/biological product listing file for this NDC or ISBT product item code does not conform to current validation procedures.
- Inactivated: The listing data for this product has been inactivated by FDA and cannot be certified.
- Expired: The listing data is expired because it was not certified. To change the status to a current listing, submit a new version of the existing listing data.

Q v GO Rows: 15 ACTIONS

ADD PRODUCT NDC

PRODUCT NDC:

ADD

- l. Your product will then display below the search bar. Click the 'Save/Update' button at the top of the page to be returned to the previous *Products Certification* page.
- m. Skip to [Step 25](#) when you are ready to submit.

9. For all other document types (*not* the Blanket No-Change type): select your document type, press 'Continue' and a blank template will display:

The screenshot shows the 'Products' section of the FDA DIRECT submission form. It includes fields for Document Type (HUMAN OTC DRUG LABEL), Set ID, Root ID, Title, Labeler Name, Labeler DUNS, Registrant Name, Registrant DUNS, and a Confidential checkbox. The 'Establishments' and 'Products' sections are also visible, each with an 'Add' button. The 'Products' section shows a table with columns for ROOT ID, SET ID, and VERSION NUMBER.

10. Fill out all applicable fields.
11. To keep this submission from being visible to the public, click the '**Confidential**' check box under *Registrant Details*.
12. To enter an establishment, click the '**Add Establishment**' button under the *Establishments* section. You will be sent to a separate page:

The screenshot shows the 'Establishment Details' page. It includes fields for Establishment Name, Establishment DUNS, and a Confidential checkbox. Below these are sections for 'BUSINESS OPERATION(S)' and 'PRODUCT NDC'. The 'BUSINESS OPERATION(S)' section contains a table with columns for BUSINESS OPERATION and PRODUCT NDC, and a dropdown menu for selecting operations.

- a. Enter your Establishment Name and DUNS.
- b. Select your business operation(s) from the dropdown and input the product NDC for each operation:

ESTABLISHMENT DETAILS

Establishment Name: * [Establishment Name Help](#)

Confidential

BUSINESS OPERATION(S) i

	BUSINESS OPERATION	PRODUCT NDC
	--Select One--	
	--Select One--	
	ANALYSIS	
	API MANUFACTURE	
	LABEL	
	MANUFACTURE	
	MEDICATED ANIMAL FEED MANUFACTURE	
	PACK	
	PARTICLE SIZE REDUCTION	
	POSITRON EMISSION TOMOGRAPHY DRUG PRODUCTION	
	RELABEL	
	REPACK	
	SIP FOREIGN SELLER	
	STERILIZE	

[Browser Requirements](#) | [Resources](#) | [Tutorials](#) | [Help](#) | [FDA Voice Blog](#) | [Privacy](#) | [Vulnerability Disclosure](#)

c. You can click the + button to add multiple rows, if needed:

BUSINESS OPERATION(S) i

	BUSINESS OPERATION	PRODUCT NDC
	--Select One--	
	--Select One--	
	--Select One--	

d. Click **'Save Establishment'** button to save your work and return to the previous page.

e. Click **'Delete Establishment'** to delete your establishment addition(s) and return to the previous page.

f. The **'Return'** button will send you back to the previous page without saving the establishment changes.

13. All added establishment details will display under the *Establishments* section:

ESTABLISHMENTS			
ADD ESTABLISHMENT			
row(s) 1 - 1 of 1			
ESTABLISHMENT DUNS	ESTABLISHMENT NAME	CONFIDENTIAL	
111111111	CNI124	N	

14. To add products, click the 'Add Product' button:

PRODUCTS		
Q. v	GO	ACTIONS ▾
None.		
ADD PRODUCT		

15. A blank template will display. Enter all fields applicable. If you are unsure about what to enter for any of the fields, click the underlined text beside the blank fields for more information.

All Submissions		Drug Listing and Certification	Products	Product Details
SAVE PRODUCT				
<< RETURN				
PRODUCT DATA ELEMENTS				
Product NDC: *	<input type="text"/>			
Proprietary Name: *	<input type="text"/>			
Suffix:	<input type="text"/>			
Non Proprietary Name: *	<input type="text"/>			
DEA Schedule:	<input type="text"/>			
Dosage Form: *	<input type="text"/>			
Source NDC:	<input type="text"/>			
Route of Administration: *	<input type="text"/>			
ADD				
ROUTE OF ADMINISTRATION				
1 - 1				
MARKETING DETAILS				
Marketing Status: *	<input type="text"/>			
Marketing Start Date: *	<input type="text"/>			
Marketing Category: *	<input type="text"/>			
Application Number/ Monograph ID:	<input type="text"/>			
INGREDIENTS				
ADD INGREDIENT				
None				
PRODUCT IMAGE (FOR SOLID ORAL DOSAGE FORMS ONLY)				
UPLOAD IMAGE				
<small>Important: Do not enter package images and other labeling. These should be uploaded under the Content of Labeling tab.</small>				
<input type="text"/> <input type="button" value="Choose File"/>				
CHARACTERISTICS				
ADD CHARACTERISTIC				
None				
PACKAGING				
ADD PACKAGE				
None				

16. Fill out the requested information in the *Product Data Elements* section.

- To add a '**Route of Administration**', select the dropdown and choose from the list:

PRODUCT DATA ELEMENTS

Product NDC: * AURICULAR (OTIC)
BUCCAL
CONJUNCTIVAL
CUTANEOUS
DENTAL
ELECTRO-OSMOSIS
ENDOCERVICAL
ENDOSINUSIAL
ENDOTRACHEAL
ENTERAL
EPIDURAL
EXTRA-AMNIOTIC
EXTRACORPOREAL
HEMODIALYSIS
INFILTRATION
INTERSTITIAL
INTRA-ABDOMINAL
INTRA-AMNIOTIC
INTRA-ARTERIAL

Proprietary Name: *

Suffix:

Non Proprietary Name: *

DEA Schedule:

Dosage Form: *

Source NDC:

Route of Administration: * **ADD**

ROUTE OF ADMINISTRATION

1 - 1

- Click the '**Add**' button and your selection will appear in the Route of Administration box.

ROUTE OF ADMINISTRATION

HEMODIALYSIS **X**

1 - 1

- To remove a selection, simply click the 'X' beside a route of administration:

ROUTE OF ADMINISTRATION

HEMODIALYSIS **X**

INTRA-ARTERIAL **X**

1 - 2

17. Enter information into the *Marketing Details* section.

18. To 'Add An Ingredient,' click the button under the *Ingredients* section:

INGREDIENTS

Note: * At least one active ingredient is required.
None

ADD INGREDIENT

a. You will be taken to a separate page where you can enter information about a single ingredient:

SAVE INGREDIENT << RETURN

Note: The denominator strength and UOM for all Ingredients within a product should be the same. Should you need to change the values, all the ingredients added thus far should be deleted and added with the new values.

INGREDIENT DETAILS

Type: * -- Select One --

Ingredient UNII - Name: *

Numerator Strength: * Unit Of Measure: * -- Select One --

Denominator Strength: * Unit of Measure: * -- Select One --

b. Select the dropdown for 'Type':

INGREDIENT DETAILS

Type: * -- Select One --

Ingredient UNII - Name: *

Numerator Strength: * Unit Of Measure: * -- Select One --

Denominator Strength: * Unit of Measure: * -- Select One --

- Select One --
Active Ingredient, Ingredient is Basis of Strength
Active Ingredient, Moiety is Basis of Strength
Active Ingredient, Reference Ingredient is Basis of Strength
Inactive Ingredient

c. Selecting either of the first two Active Ingredient options 'Ingredient is Basis of Strength' or 'Moiety is Basis of Strength' will display the 'Active Moiety' field and a checkbox:

INGREDIENT DETAILS

Type: *	Active Ingredient, Ingredient is Basis of Strength
Ingredient UNII - Name: *	<input type="text"/>
Active Moiety: *	<input type="text"/>
<input type="checkbox"/> Moiety same as Ingredient	
Numerator Strength: *	<input type="text"/>
Denominator Strength: *	<input type="text"/>
Unit Of Measure: * -- Select One --	
Unit of Measure: * -- Select One --	
<input type="button" value="ADD ACTIVE MOIETY"/>	

d. Enter an Ingredient UNII, or simply begin typing the ingredient name into the empty field:

INGREDIENT DETAILS

Type: *	Active Ingredient, Ingredient is Basis of Strength
Ingredient UNII - Name: *	<input type="text" value="ketocon"/>
Active Moiety: *	<p>(P7P4A1FD7Z) N-DEACETYLKETOCONAZOLE</p> <p>(3INP7D7X13) KETOCONAZOLE, TRANS-</p> <p>(R9400W927I) KETOCONAZOLE</p> <p>(2DJ8R0NT7K) LEVOKETOCONAZOLE</p> <p>(A5BAG8KDK5) KETOCONAZOLE-HYDROXY</p> <p>(2EWW9YYR6A) KETOCONAZOLE, (2R,4R)-</p>
<input type="button" value="ADD ACTIVE MOIETY"/>	

e. If the ingredient and moiety are the same, simply click the checkbox labeled 'Moiety Same As Ingredient' to automatically copy the ingredient to the active moiety field.

f. If you are unsure of the active moiety in your ingredient, you can click the underlined 'Active Moiety' helptext link.

A box will display with a download link entitled 'Active Ingredient-Active Moiety Relationship/Basis of Strength.' This will download a zip file to your computer that contains a spreadsheet with a full active ingredient list and corresponding active moieties:

Active Moiety: *

Moiety same as Ingredient

Active Moiety

The molecule or ion responsible for the physiological or pharmacological action of the drug substance. Active Ingredient-Active Moiety Relationship/Basis of Strength

A	B	C	D	E	F	G
AI UNII	Active Ingredient	AM UNII	Active Moiety	Basis of Strength	RD UNII	Referenced Drug
1	6930 690G0D6V8H	KETAMINE	690G0D6V8H	KETAMINE		
6931	C18YU0183	KETAMINE HYDROCHLORIDE	690G0D6V8H	KETAMINE		
6932	F5910R6H84	KETAMINE HYDROCHLORIDE, R-	690G0D6V8H	KETAMINE		
6933	97F9DEACT4	KETANSERIN	97F9DEACT4	KETANSERIN		
6934	645498QK7H	KETANSERIN TARTRATE	97F9DEACT4	KETANSERIN		
6935	81041G518S	KETAZOCINE	61041G518S	KETAZOCINE		
6936	92A214MD7Y	KETAZOLAM	92A214MD7Y	KETAZOLAM		
6937	E00MDP8254	KETHOXAL	E00MDP8254	KETHOXAL		
6938	U5C4H63K5U	KETIPRAMINE	U5C4H63K5U	KETIPRAMINE		
6939	POS1L514CF	KETOBEMIDONE	PQS1L514CF	KETOBEMIDONE		
6940	U9J6LT80J	KETOBEMIDONE HYDROCHLORIDE	PQS1L514CF	KETOBEMIDONE		
6941	WA1R789G9X	KETOCAINE	WA1R789G9X	KETOCAINE		
6942	UQG78PXR4W	KETOCAINOL	UQG78PXR4W	KETOCAINOL		
6943	R9400W927I	KETOCONAZOLE	R9400W927I	KETOCONAZOLE		
6944	90Y4QC304K	KETOPROFEN	90Y4QC304K	KETOPROFEN		
6945	5WD00E3D4C	KETOPROFEN LYSINE	90Y4QC304K	KETOPROFEN		
6946	5R10M33K57	KETOPROFEN SODIUM	90Y4QC304K	KETOPROFEN		
6947	BZ02XE70XL	KETORFANOL	BZ02XE70XL	KETORFANOL		
6948	Y215105V0L	KETOROLAC	Y215105V0L	KETOROLAC		
6949	4EV5946BQ	KETOROLAC TROMETHAMINE	Y215105V0L	KETOROLAC		
6950	4EV5946BQ	KETOROLAC TROMETHAMINE	Y215105V0L	KETOROLAC		
6951	X49220T18G	KETOTIFEN	X49220T18G	KETOTIFEN		
6952	HB0503W0R0	KETOTIFEN FUMARATE	X49220T18G	KETOTIFEN		
6953	504RN634MM	KETOTREXATE	504RN634MM	KETOTREXATE		
6954	FV4Y0J02CX	KEYHOLE LIMPET HEMOCYANIN	FV4Y0J02CX	KEYHOLE LIMPET HEMOCYANIN		
6955	5G117T0TJZ	KHELLIN	5G117T0TJZ	KHELLIN		

g. If you selected the third 'Type' option 'Reference Ingredient is Basis of Strength', a Reference Ingredient field will display below the Active Moiety field:

INGREDIENT DETAILS

Type: *	Active Ingredient, Reference Ingredient is Basis of Strength
Ingredient UNII - Name: *	<input type="text"/>
Active Moiety: *	<input type="text"/>
<input type="checkbox"/> Moiety same as Ingredient	
Reference Ingredient: *	<input type="text"/>

h. If you selected the 'Inactive Ingredient' option for 'Type,' a checkbox labeled 'Confidential' will appear below the Ingredient UNII field:

INGREDIENT DETAILS

Type: *	Inactive Ingredient
Ingredient UNII - Name: *	<input type="text"/>
<input type="checkbox"/> Confidential	

i. Enter your 'Numerator/Denominator Strength' and 'Unit of Measure' (not available if you selected 'Inactive Ingredient'):

Numerator Strength: *	<input type="text"/>	Unit Of Measure: *	-- Select One --
Denominator Strength: *	<input type="text"/>	Unit of Measure: *	-- Select One --

j. For all ingredient types (except 'Inactive Ingredient'), you will have the option to click the button '**Add Active Moiety**' to add additional active moieties:

Denominator Strength: *	<input type="text"/>
<input type="button" value="ADD ACTIVE MOIETY"/>	

k. To add more ingredients, redo Step 18 above.

l. When finished, click '**Save Ingredient**' at the top right of the page. This will return you to the Product Details page.

m. You can edit an ingredient on the Product Details page by clicking the pencil icon:

INGREDIENTS

SUBSTANCE NAME	
	STRONTIUM SULFATE
	SUCROSE

19. If your product is a **solid oral dosage form only**, add a product image (JPG format):

PRODUCT IMAGE (FOR SOLID ORAL DOSAGE FORMS ONLY)

Important: Do not enter package images and other labeling. These should be uploaded under the Content of Labeling tab.

Select a File: Choose File

20. Add your product's Characteristics (color, flavor, score, shape, imprint, size) here:

CHARACTERISTICS

None

a. You will be sent to a separate *Characteristics* page:

CHARACTERISTICS

Characteristic: *

Value: *

b. First, select the appropriate 'Characteristic' from the dropdown. Then select the 'Value' of that characteristic:

CHARACTERISTICS

Characteristic: *

Value: *

Additional Description:

-- Select One --
Black
Blue
Brown
Gray
Green
Orange

c. You can enter more specific details for a selected characteristic in the 'Additional Description' field, which can include shades of colors ("ivory" white) or shape variations (triangle with "rounded edges"):

CHARACTERISTICS

Characteristic: *	Color
Value: *	White
Additional Description:	Ivory

- d. Click '**Save Characteristic**' on the top right of the page when finished. You will be returned to the Product Details page.
- e. Only one characteristic can be entered at a time, so repeat the above steps to add additional characteristics.
- f. To edit a characteristic, click the pencil icon beside the selected characteristic on the Product Details page (toward the bottom of the page):

CHARACTERISTICS

row(s) 1 - 1 of 1

	CHARACTERISTIC	VALUE	ADDITIONAL DESCRIPTION	ADD CHARACTERISTIC
	SPLCOLOR	BLACK	STEEL	

21. To add a Package:

- a. Click '**Add Package**' at the bottom of the product details page:

PACKAGING

None

ADD PACKAGE

- b. Enter all applicable data for the inner package:

PACKAGING

ONLY LEVEL

Check for Deletion

Is this a sample package?

Package NDC:

Package Type: *

Quantity: *

Unit of Measure: *

Combination Product Type:

Marketing Status:

Marketing Start Date:

Marketing End Date:

ADD OUTER PACKAGE **DELETE** **▲ TO TOP**

c. Click the '**Add Outer Package**' button at the bottom of this page to enter outer package details (you can click this multiple times):

PACKAGING

INNERMOST LEVEL

Check for Deletion

Is this a sample package?

Package NDC:

Package Type: *

Quantity: *

Unit of Measure: *

Combination Product Type:

Marketing Status:

Marketing Start Date:

Marketing End Date:

OUTERMOST LEVEL

Check for Deletion

Is this a sample package?

Package NDC:

Package Type: *

Quantity: *

Unit of Measure: *

Combination Product Type:

Marketing Status:

Marketing Start Date:

Marketing End Date:

ADD OUTER PACKAGE **DELETE** **▲ TO TOP**

d. To delete an outer package, click the '**Check for Deletion**' checkbox and then select the '**Delete**' button:

- e. When finished, click '**Save Package**' at the top of the page to save your changes and return to the product details page.
- f. To edit a package, click the pencil icon beside the package (on the previous Product Details page):

row(s) 1 - 4 of 4									
	PACKAGE NDC/DEVICE ID	NO OF LEVELS	PACKAGE TYPE	QUANTITY	UNIT OF MEASURE	MARKETING STATUS	MARKETING START DATE	MARKETING END DATE	CLONE
	[REDACTED]	1	VIAL, GLASS	80	1	ACTIVE	09-28-2023	-	
	[REDACTED]	1	VIAL, GLASS	200	1	ACTIVE	09-28-2023	-	

- g. To make an exact duplicate of a package you previously created, click the '**Clone**' icon:

row(s) 1 - 4 of 4									
	PACKAGE NDC/DEVICE ID	NO OF LEVELS	PACKAGE TYPE	QUANTITY	UNIT OF MEASURE	MARKETING STATUS	MARKETING START DATE	MARKETING END DATE	CLONE
	[REDACTED]	1	VIAL, GLASS	80	1	ACTIVE	09-28-2023	-	
	[REDACTED]	1	VIAL, GLASS	200	1	ACTIVE	09-28-2023	-	

22. Repeat Steps 16-21 to add more products.
23. Once you are back on the product details page, enter the Content of Labeling information:

- a. Click the '**Content of Labeling**' button at the top:

- b. A blank template will display. Fill in all applicable fields:

CREATE / EDIT SECTION

Section Type: * - Select Section Type -

Effective Date: *

Parent Section: Sequence: * 1

Title:

Content:
[Rich Text Editor]

SAVE SECTION << RETURN

c. Clicking the 'Section Type' dropdown will display a list of packaging sections, which will act as headings for your label. For each section/heading that applies to your label, add the appropriate label graphic and text (as explained later).

CREATE / EDIT SECTION

Section Type: * - Select Section Type -

Effective Date: * - Select Section Type -

Parent Section:

Title:

Content:
[List of Section Types]

ABUSE SECTION
ACCESSORIES
ADVERSE REACTIONS SECTION
ALARMS
ANIMAL PHARMACOLOGY & OR TOXICOLOGY SECTION
ASSEMBLY OR INSTALLATION INSTRUCTIONS
BOXED WARNING SECTION
CALIBRATION INSTRUCTIONS
CARCINOGENESIS & MUTAGENESIS & IMPAIRMENT OF FERTILITY SECTION
CLEANING, DISINFECTING, AND STERILIZATION INSTRUCTIONS
CLINICAL PHARMACOLOGY SECTION
CLINICAL STUDIES SECTION
CLINICAL TRIALS EXPERIENCE SECTION
COMPATIBLE ACCESSORIES
COMPONENTS
CONTRAINdicATIONS SECTION
CONTROLLED SUBSTANCE SECTION
DEPENDENCE SECTION
DESCRIPTION SECTION

d. 'Effective Date' is the date this labeling change/submission will occur.

Effective Date: *

e. The 'Sequence' field allows you to organize your label sections (headings) so that they display in the appropriate order. Here is an example list of three sections that were created in Content of Labeling:

The screenshot shows the 'Content of Labeling' section of the FDA DIRECT interface. It displays three sections: 'ADVERSE REACTIONS SECTION', 'WARNINGS AND PRECAUTIONS SECTION', and 'HOW SUPPLIED SECTION'. Each section has an 'EDIT' button to its right. The sections are listed vertically, with the first one being the 'Adverse Reactions Section'.

The first label section above ('Adverse Reactions Section') was created first and is automatically assigned the number '1':

The screenshot shows the 'CREATE / EDIT SECTION' form. It includes fields for 'Section Type' (set to 'ADVERSE REACTIONS SECTION'), 'Effective Date' (set to '08-01-2024'), and 'Sequence' (set to '1'). The 'Sequence' field is highlighted with a red box.

Each section is automatically assigned the next number in numerical order (2, 3, 4, etc). If you need to reorganize any existing or new sections so that they display in a different order, simply change the number in the '**Sequence**' field of a desired section.

In the example below, the 'Adverse Reactions Section' previously at the top was moved to the bottom by simply entering '3' into that section's '**Sequence**' field then clicking '**Apply**':

The top screenshot shows the 'CREATE / EDIT SECTION' form with the 'Sequence' field set to '3'. The bottom screenshot shows the 'Content of Labeling' interface with the 'ADVERSE REACTIONS SECTION' moved to the bottom of the list, indicated by a red arrow pointing to it.

- Choose a title for your section. If you don't enter anything, whatever you selected from the '**Section Type**' dropdown will become the title.

Title:	
--------	--

- g. Some Section Types will have a '**Highlight Text**' box. This box only displays for certain section types. Enter information there, if applicable.
- h. The '**Content**' box is intended for text and graphics that pertain to the '**Section Type**.' If you chose 'Adverse Reactions' as a section type, you must enter images and/or text that are appropriate for that section of your labeling.

Content:	
----------	------------------------------------------------------------------------------------

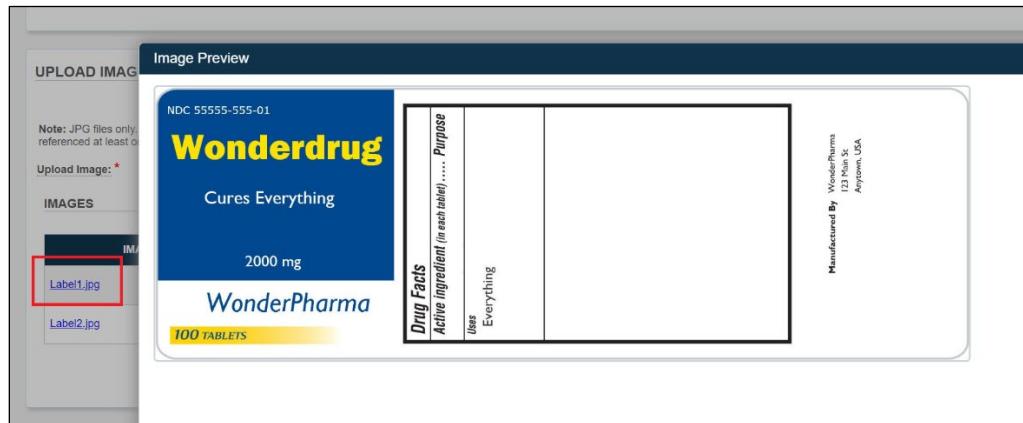
- i. To upload a product label image, click '**Choose File**' to select an image from your computer. The extension/ending of the file MUST be a **.jpg no larger than 1MB**.

UPLOAD IMAGES	
<small>Note: JPG files only. Any image used above in the Content of Labeling must first be uploaded and displayed in the list of images below. Furthermore, any image uploaded and appearing on the list below must be referenced at least once in a section of the Content of Labeling.</small>	
<small>Upload Image: *</small> <input type="file"/>	<input type="button" value="Choose File"/>
<input type="button" value="UPLOAD"/>	
IMAGES	
<small>None</small>	

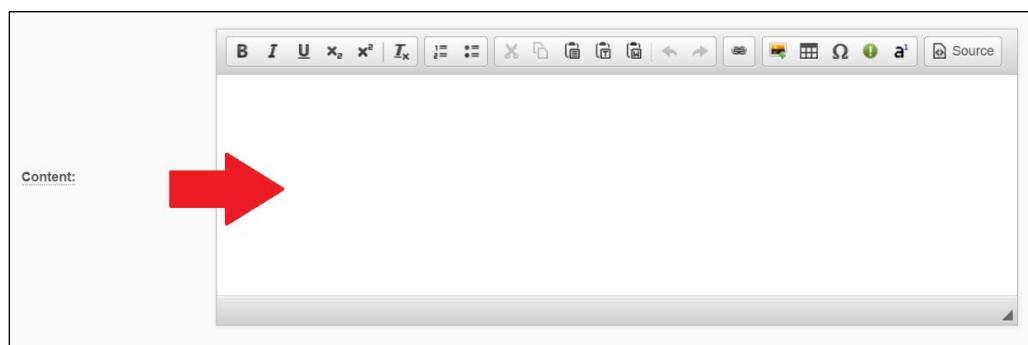
- j. When you have selected a JPG image from your computer, click the '**Upload**' button. Only one image can be uploaded at a time.
- k. Your image(s) will display in the *Images* section:

UPLOAD IMAGES													
<small>Note: JPG files only. Any image used above in the Content of Labeling must first be uploaded and displayed in the list of images below. Furthermore, any image uploaded and appearing on the list below must be referenced at least once in a section of the Content of Labeling.</small>													
<small>Upload Image: *</small> <input type="file"/>	<input type="button" value="Choose File"/>												
<input type="button" value="UPLOAD"/>													
IMAGES													
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="background-color: black; color: white; text-align: left; padding: 2px;">IMAGE NAME</th> <th style="background-color: black; color: white; text-align: center; padding: 2px;">IMAGE</th> <th style="background-color: black; color: white; text-align: center; padding: 2px;">DELETE IMAGE</th> <th style="background-color: black; color: white; text-align: center; padding: 2px;">REFERENCED</th> </tr> </thead> <tbody> <tr> <td style="padding: 2px;">Label1.jpg</td> <td style="text-align: center; padding: 2px;">  </td> <td style="text-align: center; padding: 2px;"> <input type="button" value="X"/> </td> <td style="text-align: center; padding: 2px;">No</td> </tr> <tr> <td style="padding: 2px;">Label2.jpg</td> <td style="text-align: center; padding: 2px;">  </td> <td style="text-align: center; padding: 2px;"> <input type="button" value="X"/> </td> <td style="text-align: center; padding: 2px;">No</td> </tr> </tbody> </table>		IMAGE NAME	IMAGE	DELETE IMAGE	REFERENCED	Label1.jpg		<input type="button" value="X"/>	No	Label2.jpg		<input type="button" value="X"/>	No
IMAGE NAME	IMAGE	DELETE IMAGE	REFERENCED										
Label1.jpg		<input type="button" value="X"/>	No										
Label2.jpg		<input type="button" value="X"/>	No										

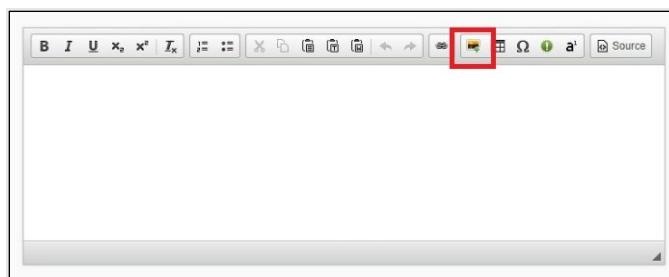
- I. Click the red X beside an image to delete the image. Doing this will cause images to disappear or not display properly if they have been used ("referenced") in a section.
- m. Click the name of the image to display a closeup preview:



- n. You must now "reference" your image(s) before you can submit your SPL. To reference an image, go back up to the *Create/Edit* section and click anywhere inside the '**Content**' box:



- o. Select the 'insert an image' icon  from the options bar (hover over any of the icons for a short text description):

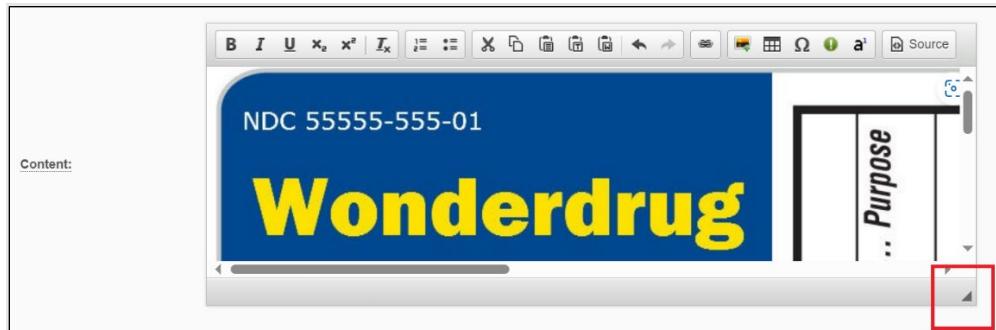


p. A popup box will display. Your previously uploaded image(s) will now be available to select from the dropdown:



q. Next, add some Image Text. This is alt text (description text for an image that is not visible anywhere but can be picked up and read by screen reading technology).

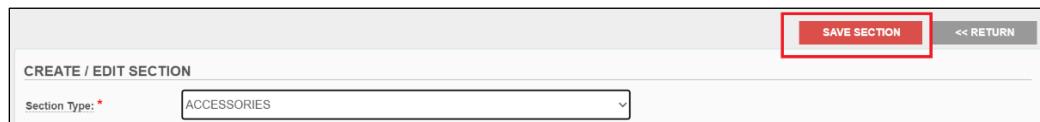
r. Click 'OK.' Your image will now display within the Content box. Click and drag the corner arrow to view more of the image:



IMPORTANT: You only need to upload an image file **once!** File images are “stored” in the *Images* section upon upload. You can use this “storage” area to upload files here once, then use those same files across multiple Content of Labeling entries.

If you delete an image from the *Images* section, it will be automatically removed from each ‘Content’ section in every Content of Labeling entry that references it!

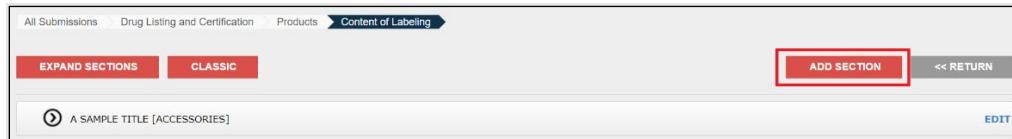
s. When you are finished, click the ‘Save Section’ button at the top right of the page to save your new section:



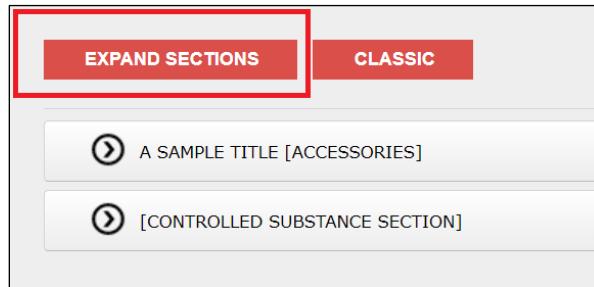
- t. You will be returned to the main Content of Labeling list page. Clicking 'Edit' will allow you to modify an existing section:



- u. To add another section to this list, click the 'Add Section' button:



- v. If you have at least one section created, clicking the 'Expand Sections' button (top left) will automatically display the full contents of all of your sections listed:





- w. Click 'Collapse Sections' (top left) to close all entries.
- x. You also have the option to switch between 'Classic' and 'Enhanced' (top left button) mode, which simply changes the look of the lists.
- y. See Section 9.1 for additional help with the Content of Labeling section.
- z. When you are finished with Content of Labeling, click the 'Return' button at the top right of the page. You will be sent back to the product details page.

24. **IMPORTANT:** This is an **optional section** and should **NOT** be used unless you are familiar with FDA core documents, as this will allow you to append or replace core documents.

RELATED DOCUMENTS			
Type Code:	--Select One--		
	ROOT ID	SET ID	VERSION NUMBER

25. Repeat [Steps 15-22](#) to add more products.

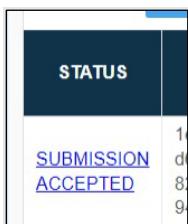
26. When all fields have been entered to your satisfaction, you can do the following:

- ‘Save As Draft’ – Save your entry and return to the main Drug Listing and Certification page. No submission will be made.
- ‘Save And Validate’ - Save your entry + validate. This will check your submission for errors prior to submitting to the FDA. Validation may take some time. If you are ready to submit your SPL, you may skip this step entirely.
- ‘Submit SPL’ - Submit your Drug Listing and Certification SPL submission to the FDA. You will then be returned to the Drug Listing and Certification main page where you can view your pending submission(s) status:

STATUS	SET ID	ROOF ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
AWAITING ACCEPTANCE	0624743-c4de-4237-e033-9a5940a644ec	0624743-c4de-4237-e033-9a5940a644ec	1		HUMAN OTC DRUG LABEL			Zee Dee	03-CCT-2021-13:49:51

- ‘Delete’ – Delete your entry draft completely.

- Click ‘Return’ at any time to return to the main Drug Listing and Certification page.
- The *Status* field should now read ‘Submission Accepted,’ indicating that your submission has been validated and accepted by the FDA. You will receive an email to your account email address when the submission status changes.
- Once your submission has been accepted, you will be able to download a copy of the submission as a zip file. Go to the main Drug Listing and Certification page and click the latest ‘Submission Accepted’ text link:



- Click ‘Download SPL’ on the top left of the page to download the zip file. You can also select ‘View SPL’ for a quick look at your submission.

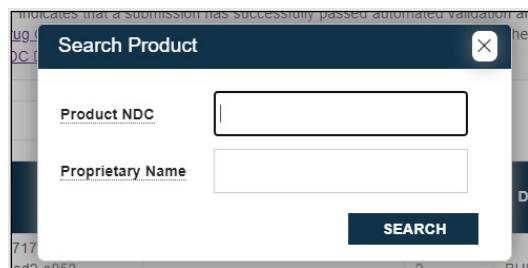


31. If you already have multiple Drug Listing and Certification submissions, you can search for a specific submission:

a. Click 'Search Product' on the Drug Listing and Certification main page:



b. Enter one or both of the fields in the ensuing popup box. Partial entries (ex: 'sys' instead of 'systems') are permitted:



c. Click 'Search' and your results will populate.
d. See Section 9.2: Searching and Filtering for additional help with filters and searching multiple products.

6 OUTSOURCING FACILITY REGISTRATION AND COMPOUNDED PRODUCT REPORTING

6.1 Outsourcing Facility Registration

The Outsourcing Facility Registration SPL submission template can be used for the following purposes:

- [Establishment Registration](#): Registering a facility for the first time.
- [Establishment De-Registration](#): Dissolving a facility's registration.
- [Out of Business](#): De-registering a facility due to going out of business.
- [No Change Notification](#): Informing the FDA that no changes have occurred since the previous facility registration submission was made.

For more information on outsourcing facilities and compounded products, visit the FDA's [Information for Outsourcing Facilities](#) website.

6.1.1 Registering A New Outsourcing Facility

The '**Outsourcing Facility Registration**' SPL submission is used by outsourcing facilities who compound human drugs. A facility is considered an "outsourcing facility" (according to [Section 503B of the FD&C Act](#)) if the facility:

- is engaged in the compounding of sterile drugs (and may also compound non-sterile drugs);
- has elected to register as an outsourcing facility;
- complies with all of the requirements of section 503B;
- is not required to be a licensed pharmacy, but compounding must be by or under the direct supervision of a licensed pharmacist; and
- may or may not obtain prescriptions for identified individual patients.

To submit an '**Outsourcing Facility Registration**' SPL, do the following:

1. Log in to FDA Direct.
2. Select '**Outsourcing Facility Registration**' under the *Outsourcing Facility Registration and Product Reporting* section:

3. Click 'Create New/Upload File':

4. You will be given two options:

- a. To upload a file from your computer directly, follow the steps outlined in Section 3: Submission Information. Then skip to Step 9 below and continue the instructions.
5. To create a new outsourcing facility registration using a blank template, select the '**Create New Outsourcing Facility Registration using a blank form**' option.
6. Click '**Continue**' and a blank template will display:

7. Selecting the 'Save As Draft' button on the top right will save your work without submitting it. The 'Return' button will send you back to the main Outsourcing Facility Registration page without saving your changes.
8. Select 'Establishment Registration' from the Document Type dropdown:

9. Fill in all blank fields in the *Registrant Details* section:

10. To add multiple establishments, click the 'Add Establishment' button at the bottom of the page:

ESTABLISHMENTS

None

ADD ESTABLISHMENT

11. You will be shown a separate form. Fill in all the necessary fields:

All Submissions Outsourcing Facility Registration SPL Submission Establishment ►

ESTABLISHMENT DETAILS

Establishment Name: *

Establishment DUNS: *

Establishment FEI:

ESTABLISHMENT ADDRESS

Country: * -Select Country-

Street Address: *

City: *

State/Province:

Postal Code:

ESTABLISHMENT CONTACT DETAILS

Same as Registrant Contact Details and Address

Contact Name: *

Contact Email: *

Contact Phone: * Format

Phone Extension:

ESTABLISHMENT CONTACT ADDRESS

Country: * -Select Country-

Street Address: *

City: *

State/Province:

Postal Code:

U.S. AGENT

Agent Name: *

Agent DUNS: *

Agent Email: *

Agent Phone: * Format

Phone Extension:

Note: Enter the one or more drug manufacturing and processing operations performed at the establishment.

IMPORTERS

BUSINESS OPERATION(S)

12. At the bottom of the page, click the 'Add Importer' button. A popup box will display:

Importer

Importer Name: *

Importer DUNS: *

Importer Email: *

Importer Phone: *

Phone Extension:

CANCEL SAVE SAVE AND ADD

13. Enter importer details then either click '**Save And Add**' to keep the window open and add another importer, or select '**Save**' to close the window and finish your entry. Your information will display under the *Importers* section:

Note: Enter the one or more drug manufacturing and processing operations performed at the establishment						
Importers						
EDIT	DELETE	NAME	DUNS	EMAIL	PHONE	EXTENSION
		Importer123	11111111	imp123@mail.com	123-456-7890	
1 - 1						

14. Click the '**Add Business Operation**' button. A dialog box will display:

Business Operation/Qualifier

Business Operations:

Qualifier

CANCEL **SAVE** **SAVE AND ADD**

15. Select your business operation from the dropdown:

Business Operation/Qualifier

Business Operations:

Qualifier

CANCEL

ANALYSIS
API MANUFACTURE
HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY
LABEL
MANUFACTURE
MEDICATED ANIMAL FEED MANUFACTURE
OUTSOURCING ANIMAL DRUG COMPOUNDING
PACK
PARTICLE SIZE REDUCTION
POSITRON EMISSION TOMOGRAPHY DRUG PRODUCTION
RELABEL
REPACK
SIP FOREIGN SELLER
STERILIZE
TRANSFILL

16. Check all qualifier boxes that apply to your selected business operation:

Business Operation/Qualifier

Business Operations:

Qualifier

CANCEL **SAVE** **SAVE AND ADD**

CONTRACT MANUFACTURING FOR HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER A MONOGRAPH
 MANUFACTURES ANIMAL OVER-THE-COUNTER DRUG PRODUCTS
 MANUFACTURES ANIMAL OVER-THE-COUNTER TYPE A MEDICATED ARTICLE DRUG PRODUCTS
 MANUFACTURES ANIMAL PRESCRIPTION DRUG PRODUCTS
 MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS
 MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS NEITHER PRODUCED UNDER AN APPROVED DRUG APPLICATION NOR UNDER A MONOGRAPH
 MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER A MONOGRAPH
 MANUFACTURES HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER AN APPROVED DRUG APPLICATION
 MANUFACTURES HUMAN PRESCRIPTION DRUG PRODUCTS
 MANUFACTURES NON-GENERICs
 MANUFACTURES VETERINARY FEED DIRECTIVE TYPE A MEDICATED ARTICLE DRUG PRODUCTS
 TRANSFILLS MEDICAL GAS

***Some qualifiers may become greyed out depending on your selections:**

Business Operation/Qualifier

Business Operations: HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY

Qualifier

- INTENT TO COMPOUND 506E (DRUG SHORTAGE) DRUGS
- NO INTENT TO COMPOUND 506E (DRUG SHORTAGE) DRUGS
- COMPOUNDING FROM BULK INGREDIENT
- NOT COMPOUNDING FROM BULK INGREDIENT
- COMPOUNDING STERILE PRODUCTS
- NOT COMPOUNDING STERILE PRODUCTS

CANCEL **SAVE** **SAVE AND ADD**

17. To add more business operations, click '**Save And Add**' at the bottom. To finish with your selections and close the window, click '**Save**.' Your selections will display at the bottom of the page:

BUSINESS OPERATION(S)		ADD BUSINESS OPERATION	
EDIT	DELETE	BUSINESS OPERATION	QUALIFIER
		HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY	<ul style="list-style-type: none"> • INTENT TO COMPOUND 506E (DRUG SHORTAGE) DRUGS • COMPOUNDING FROM BULK INGREDIENT
		MANUFACTURE	<ul style="list-style-type: none"> • CONTRACT MANUFACTURING FOR HUMAN OVER-THE-COUNTER DRUG PRODUCTS PRODUCED UNDER A MONOGRAPH • MANUFACTURES ANIMAL PRESCRIPTION DRUG PRODUCTS

18. Return to the top of the page and select '**Save Establishment**' when finished. You will be returned to the initial template entry page, with the newly added establishment(s) listed at the bottom. Click the pencil icon to make edits to the establishment:

ESTABLISHMENTS				ADD ESTABLISHMENT
ESTABLISHMENT DUNS	ESTABLISHMENT FEI	ESTABLISHMENT NAME	row(s) 1 - 1 of 1	
222222222	-	Estab123		

19. Return to the top of the page where you can do the following:

- '**Save As Draft**' – Save your entry and return to the main Outsourcing Facility Registration page. No submission will be made.
- '**Save And Validate**' - Save your entry + validate. This will check your submission for errors prior to submitting to the FDA. Validation may take some time. If you are ready to submit your SPL, you may skip this step entirely.
- '**Submit SPL**' - Submit your Outsourcing Facility Registration submission to the FDA. You will then be returned to the Outsourcing Facility Registration main page where you can view your pending submission(s) status:

d. ‘Delete’ – Delete your draft entry completely.

20. Click ‘Return’ at any time to return to the main Outsourcing Facility Registration page.

21. The *Status* field should read ‘Submission Accepted’ when your submission has been validated and accepted by the FDA. You will receive an email to your account email address when the submission status changes.

22. Once your submission has been accepted, you will be able to download a copy of the submission as a zip file. Go to the main Outsourcing Facility Registration page and click the latest ‘Submission Accepted’ text link:



23. Click ‘Download SPL’ on the top left of the page to download the zip file. You can also select ‘View SPL’ for a quick look at your submission.

24. If you already have multiple submissions, you can search for a specific establishment:

- Click ‘Search Establishment’ on the Outsourcing Facility Registration main page:

SEARCH		GO	ACTIONS	SEARCH ESTABLISHMENT		CREATE NEW / UPLOAD FILE		
ROOTID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME	DOCUMENT LABEL	DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE

b. Enter one or both of the fields in the ensuing popup box. Partial entries (ex: 'sys' instead of 'systems') are permitted:

Search Establishment

Establishment DUNS	X
Establishment Name	
<input type="button" value="SEARCH"/>	

c. Click 'Search' and your results will populate.
d. See Section 9.2: Searching and Filtering for additional help with filters and searching multiple establishments.

6.1.2 De-Registering An Outsourcing Facility

There are two ways to de-register an outsourcing facility with the FDA:

1. Go to the *Outsourcing Facility Registration* page.
2. Find the most recent submission with the '*Submission Accepted*' status and select the link:



- a. Select '**Create New Version**' at the top right of the page:

A screenshot of a web page titled 'SPL Submission'. At the top, there are buttons for 'VIEW SPL' and 'DOWNLOAD SPL'. On the right, there are buttons for 'CREATE NEW VERSION' (which is highlighted with a red box) and '<< RETURN'. The main content area is labeled 'HEADER DETAILS' and contains fields for 'Document Type', 'Set ID', 'Root ID', 'Version Number', and 'Effective Date'.

- b. Click the *Document Type* dropdown under the *Header Details* section, then select an option depending on your reasons:

- **Establishment De-Registration**

OR

- **Out Of Business Notification**

A screenshot of the 'Header Details' section of the SPL Submission page. The 'Document Type' dropdown is open, showing options: 'ESTABLISHMENT REGISTRATION', 'ESTABLISHMENT DE-REGISTRATION', 'NO CHANGE NOTIFICATION', and 'OUT OF BUSINESS NOTIFICATION'. Red arrows point to the 'ESTABLISHMENT DE-REGISTRATION' and 'OUT OF BUSINESS NOTIFICATION' options. Other fields in the section include 'Set ID', 'Root ID', 'Version Number' (1), and 'Effective Date' (09-20-2023).

- c. Click '**Submit SPL**' at the top right of the page and you will be taken to the *Outsourcing Facility Registration* page. An email will be sent to your account email address to confirm the facility de-registration/out of business status.

3. Click '**Create New/Upload File**' on the *Outsourcing Facility Registration* page.
 - a. Select '**Import an Existing Establishment Registration SPL**' and click '**Continue**'.
 - b. See [Step 2\(b\)-2\(c\)](#) in the previous section.

6.1.3 No Change To Outsourcing Facility Registration

If you have no changes to report for the current registration period, you may submit a **No Change Notification**:

1. Go to the *Outsourcing Facility Registration* page.
2. Follow [Steps 2-2\(a\)](#) in the section above if you have submitted using FDA Direct previously.
 - a. Select '**No Change Notification**' from the *Document Type* dropdown.
 - b. Click '**Submit SPL**'.
 - c. You will receive an email to your account email address with the confirmed No Change renewal status update.
3. Follow [Steps 3\(a\)-3\(b\)](#) in the section above if you are uploading an SPL submission file from your computer and have not used FDA Direct previously.

6.2 Compounded Drug Reporting

The '**Compounded Drug Reporting**' SPL submission is used to identify all sterile and non-sterile drugs compounded at an outsourcing facility during the previous six-month period:

- Drug product reports submitted between June 1 and June 30 of each year must report drug products produced from December 1 through May 31.
- Drug product reports submitted between December 1 and December 30 of each year must report drug products produced from June 1 through November 30.

For further information, visit the FDA's [Human Drug Compounding Registration and Product Reporting Procedures](#) website.

To submit a '**Compounded Drug Reporting**' SPL, do the following:

2. Log in to FDA Direct.
3. Select '**Compounded Drug Reporting**' under *Outsourcing Facility Registration And Product Reporting*:

4. Click '**Create New/Upload File**' on the Compounded Drug Reporting main page:

5. You will be given two options:

- a. To upload a file from your computer directly, follow the steps outlined in Section 3: Submission Information. Then skip to Step 9 below and continue the instructions.
6. To create a new compounded drug submission using a blank template, select the 'Create a new Compounded Drug Reporting using a blank form' option.
7. A blank template will display:

8. Enter your 'Reporting Period' in the *Header Details* section:

- a. Selecting 'Initial Reporting Period' will prompt you to enter a Start Date and End Date:

9. If this is not for an initial reporting period, select the appropriate date range from the dropdown.
10. Go to the *Establishments* section of the page.
11. Enter an establishment by clicking the '**Add Establishment**' button. You will be sent to a separate page:

- a. Enter your Establishment Name and DUNS.
- b. The 'Human Drug Compounding Outsourcing Facility' business operation is automatically selected.
- c. Click the '**Save Establishment**' button to save your work and return to the previous page.
- d. Click '**Delete Establishment**' to delete your establishment addition(s) and return to the previous page.
- e. The '**Return**' button will send you back to the previous page without saving the establishment changes.
12. If you added an establishment, you will be returned to the previous page where you can view the establishment. You can click the pencil icon at any time to edit the establishment details:

ESTABLISHMENTS				ADD ESTABLISHMENT
row(s) 1 - 1 of 1				
	ESTABLISHMENT DUNS	ESTABLISHMENT NAME	CONFIDENTIAL	
	4444444444	CNI MGMT COMPANY	N	

13. Use the dropdown in the next section, *Products*, to determine whether or not you will enter products:

PRODUCTS		ADD PRODUCT
Do you have any products to report: * No Yes No		

14. If you selected 'Yes' from the dropdown above, click the '**Add Product**' button:

PRODUCTS

Do you have any products to report? * Yes

Q GO ACTIONS

None.

ADD PRODUCT

15. A blank template will display. Enter all fields applicable. If you are unsure about what to enter for any of the fields, click the underlined text beside the blank fields for more information.

PRODUCT DATA ELEMENTS

Product NDC:

Proprietary Name: *

Suffix:

Non Proprietary Name: *

DEA Schedule:

Dosage Form: *

Route of Administration: * ADD

ROUTE OF ADMINISTRATION
1 + 1

MARKETING DETAILS

Marketing Category: *

INGREDIENTS

ADD INGREDIENT

CHARACTERISTICS

ADD CHARACTERISTIC

PACKAGING

ADD PACKAGE

a. Select the dosage under the 'Dosage Form' dropdown. If you select 'Kit', you have the option to add a part via separate form:

PARTS

None

ADD PART

The screenshot shows the 'Product Details' section of the FDA DIRECT system. At the top, there are navigation links: 'All Submissions', 'Compounded Drug Reporting', 'Products', and 'Product Details'. On the right, there are 'SAVE PART' and '<< RETURN' buttons.

PRODUCT DATA ELEMENTS

- Part Quantity:
- Part Denominator:
- Part Unit of Measure: -- Select One --
- Product NDC:
- Proprietary Name:
- Suffix:
- Non Proprietary Name:
- DEA Schedule: -- Select DEA Schedule --
- Dosage Form: -Select Dosage Form-
- Route of Administration:

ROUTE OF ADMINISTRATION
1 - 1

MARKETING DETAILS

- Marketing Category: -Select Marketing Category-

INGREDIENTS

- None

CHARACTERISTICS

- None

PACKAGING

- None

b. To add a '**Route of Administration**,' select the dropdown and choose from the list:

PRODUCT DATA ELEMENTS

Product NDC:

Proprietary Name: *

Suffix:

Non Proprietary Name: *

DEA Schedule:

Dosage Form: *

Route of Administration: *

ROUTE OF ADMINISTRATION

1 - 1

c. Click the 'Add' button and your selection will appear in the Route of Administration box.

Route of Administration:

ROUTE OF ADMINISTRATION

HEMODIALYSIS X

1 - 1

d. To remove a selection, simply click the 'X' beside a route of administration:

Route of Administration:

ROUTE OF ADMINISTRATION

HEMODIALYSIS X

INTRA-ARTERIAL X

1 - 2

16. Enter the marketing category in the *Marketing Details* section:

MARKETING DETAILS

Marketing Category: * -Select Marketing Category-
 -Select Marketing Category-
 OUTSOURCING FACILITY COMPOUNDED HUMAN DRUG PRODUCT (EXEMPT FROM APPROVAL REQUIREMENTS)
 OUTSOURCING FACILITY COMPOUNDED HUMAN DRUG PRODUCT (NOT MARKETED - NOT DISTRIBUTED)

a. If you select 'Not Marketed – Not Distributed,' you will receive a notice:

MARKETING DETAILS

Marketing Category: * OUTSOURCING FACILITY COMPOUNDED HUMAN DRUG PRODUCT (NOT MARKETED - NOT DISTRIBUTED)
 FDA does not intend to publish information about a drug submitted under this marketing category. For more information see Section IV.D. Confidentiality of Reporting Information in our Guidance for Industry at <https://www.fda.gov/media/90173/download>.

17. Next click 'Add Ingredient' in the *Ingredients* section:

INGREDIENTS

None ADD INGREDIENT

a. You will be taken to a separate page where you can enter information about a single ingredient:

INGREDIENT DETAILS

Note: The denominator strength and UOM for all Ingredients within a product should be the same. Should you need to change the values, all the ingredients added thus far should be deleted and added with the new values.

SAVE INGREDIENT << RETURN

Type: * -- Select One --
 Ingredient UNII - Name: *
 Numerator Strength: * Unit Of Measure: * -- Select One --
 Denominator Strength: * Unit of Measure: * -- Select One --

b. Select the dropdown for 'Type':

INGREDIENT DETAILS

Type: * -- Select One --
 -- Select One --
 Active Ingredient, Ingredient is Basis of Strength
 Active Ingredient, Moiety is Basis of Strength
 Active Ingredient, Reference Ingredient is Basis of Strength
 Inactive Ingredient
 Ingredient - Dietary Supplement
 Ingredient UNII - Name: *
 Numerator Strength: * Unit of Measure: * -- Select One --
 Denominator Strength: *

e. Selecting either of the first two Active Ingredient options 'Ingredient is Basis of Strength' or 'Moiety is Basis of Strength' will display the 'Active Moiety' field and a checkbox, along with a section to add source NDCs:

INGREDIENT DETAILS

Type: *	Active Ingredient, Ingredient is Basis of Strength										
Ingredient UNII - Name: *	<input type="text"/>										
Active Moiety: *	<input type="text"/>										
<input type="checkbox"/> Moiety same as Ingredient											
Numerator Strength: *	<input type="text"/>	Unit Of Measure: * -- Select One --									
Denominator Strength: *	<input type="text"/>	Unit of Measure: * -- Select One --									
ADD ACTIVE MOIETY											
Note: Please enter the NDC Product Code (ex. 12345-678) for the bulk or finished drug from which the active ingredient for the compounded drug was obtained.											
<table border="1" style="width: 100%;"> <thead> <tr> <th style="width: 10px;"></th> <th style="width: 100px;">SOURCE NDC</th> <th style="width: 100px;">DOCUMENT TYPE</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">+</td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> <tr> <td style="text-align: center;">✖</td> <td><input type="text"/></td> <td><input type="text"/></td> </tr> </tbody> </table>				SOURCE NDC	DOCUMENT TYPE	+	<input type="text"/>	<input type="text"/>	✖	<input type="text"/>	<input type="text"/>
	SOURCE NDC	DOCUMENT TYPE									
+	<input type="text"/>	<input type="text"/>									
✖	<input type="text"/>	<input type="text"/>									

f. Enter an Ingredient UNII, or simply begin typing the ingredient name into the empty field:

INGREDIENT DETAILS

Type: *	Active Ingredient, Ingredient is Basis of Strength	
Ingredient UNII - Name: *	<input type="text"/> ketocor	
Active Moiety: *	(P7P4A1FD7Z) N-DEACETYL KETOCONAZOLE (3INP7D7XI3) KETOCONAZOLE, TRANS-	
Numerator Strength: *	(R9400W927I) KETOCONAZOLE	
Denominator Strength: *	(2DJ8R0NT7K) LEVOKETOCONAZOLE	

g. If the ingredient and moiety are the same, simply click the checkbox labeled 'Moiety Same As Ingredient' to automatically copy the ingredient to the active moiety field.

h. If you are unsure of the active moiety in your ingredient, you can click the underlined 'Active Moiety' helptext link. A box will display with a download link entitled 'Active Ingredient-Active Moiety Relationship/Basis of Strength.' This will download a zip file to your computer that contains a spreadsheet with a full active ingredient list and corresponding active moieties:

Active Moiety: *	
<input type="checkbox"/> Moiety same as Ingredient	

Active Moiety

The molecule or ion responsible for the physiological or pharmacological action of the drug substance. Active Ingredient-Active Moiety Relationship/Basis of Strength

A	B	C	D	E	F	G
AI UNII	Active Ingredient	AM UNII	Active Moiety	Basis of Strength	RD UNII	Referenced Drug
1 690G0D6V8H	KETAMINE	690G0D6V8H	KETAMINE	Active Ingredient		
6931 C18YU0183	KETAMINE HYDROCHLORIDE	690G0D6V8H	KETAMINE	Active Moiety		
6932 5F910RH684	KETAMINE HYDROCHLORIDE, R-	690G0D6V8H	KETAMINE			
6933 97F9DEACT4	KETANSERIN	97F9DEACT4	KETANSERIN	Active Ingredient		
6934 645498QK7H	KETANSERIN TARTRATE	97F9DEACT4	KETANSERIN			
6935 610416518S	KETAZOCINE	610416518S	KETAZOCINE	Active Ingredient		
6936 92A214MD7Y	KETAZOLAM	92A214MD7Y	KETAZOLAM	Active Ingredient		
6937 E00MDP8254	KETHOXAL	E00MDP8254	KETHOXAL	Active Ingredient		
6938 U5C4H63K5U	KETIPRAMINE	U5C4H63K5U	KETIPRAMINE	Active Ingredient		
6939 P0S1L514CF	KETOBEMIDONE	P0S1L514CF	KETOBEMIDONE	Active Ingredient		
6940 U9J6LT80J	KETOBEMIDONE HYDROCHLORIDE	P0S1L514CF	KETOBEMIDONE			
6941 WA1R789G9X	KETOCAINE	WA1R789G9X	KETOCAINE	Active Ingredient		
6942 UQG78PXR4W	KETOCAINOL	UQG78PXR4W	KETOCAINOL	Active Ingredient		
6943 R9400W927I	KETOCONAZOLE	R9400W927I	KETOCONAZOLE	Active Ingredient		
6944 90Y4QC304K	KETOPROFEN	90Y4QC304K	KETOPROFEN	Active Ingredient		
6945 5WD00E3D4C	KETOPROFEN LYSINE	90Y4QC304K	KETOPROFEN			
6946 5R10M39K57	KETOPROFEN SODIUM	90Y4QC304K	KETOPROFEN			
6947 8Z02X7E70XL	KETORFANOL	8Z02X7E70XL	KETORFANOL	Active Ingredient		
6948 Y215105V0L	KETOROLAC	Y215105V0L	KETOROLAC	Active Ingredient		
6949 4EV5946BQ	KETOROLAC TROMETHAMINE	Y215105V0L	KETOROLAC	Active Ingredient		
6950 4EV5946BQ	KETOROLAC TROMETHAMINE	Y215105V0L	KETOROLAC	Active Moiety		
6951 X49220T18G	KETOTIFEN	X49220T18G	KETOTIFEN	Active Ingredient		
6952 HD503WOR0	KETOTIFEN FUMARATE	X49220T18G	KETOTIFEN	Active Moiety		
6953 504RN634MM	KETOTREXATE	504RN634MM	KETOTREXATE	Active Ingredient		
6954 FV4Y0J02CX	KEYHOLE LIMPET HEMOCYANIN	FV4Y0J02CX	KEYHOLE LIMPET HEMOCYANIN	Active Ingredient		
6955 5G117T0TJZ	KHELLIN	5G117T0TJZ	KHELLIN	Active Ingredient		

- Click the 'Add Active Moiety' button to add another moiety. Click the button again to remove that moiety.

Denominator Strength: *	Denominator Strength: *
ADD ACTIVE MOIETY	REMOVE ACTIVE MOIETY

- Add the source NDC Product Code at the bottom of the page. You can click the '+' button to add more source NDCs, or the 'X' button to remove them:

Note: Please enter the NDC Product Code (ex. 12345-678) for the bulk or finished drug from which the active ingredient for the compounded drug was obtained.		
+	SOURCE NDC	DOCUMENT TYPE
*		

- If you selected the third 'Type' option 'Reference Ingredient is Basis of Strength', a Reference Ingredient field will display below the Active Moiety field:

INGREDIENT DETAILS

Type: *	Active Ingredient, Reference Ingredient is Basis of Strength
Ingredient UNII - Name: *	
Active Moiety: *	<input type="checkbox"/> Moiety same as Ingredient
Reference Ingredient: *	

I. If you selected the 'Inactive Ingredient' option for 'Type,' the 'Numerator/Denominator Strength' fields will not be required:

INGREDIENT DETAILS

Type: *	Inactive Ingredient		
Ingredient UNII - Name: *			
Numerator Strength:		Unit Of Measure:	-- Select One --
Denominator Strength:		Unit of Measure:	-- Select One --

m. If you selected the 'Dietary Supplement' option for 'Type,' the *Source NDC Manufacturer Details* section will display:

INGREDIENT DETAILS

Type: *	Ingredient - Dietary Supplement		
Ingredient UNII - Name: *			
Numerator Strength:		Unit Of Measure:	-- Select One --
Denominator Strength:		Unit of Measure:	-- Select One --
SOURCE NDC MANUFACTURER DETAILS			
No Source NDC Information	<input type="checkbox"/>		
Source NDC: *			
No Manufacture Information for this Source NDC	<input type="checkbox"/>		
Manufacturer DUNS: *			
Manufacturer Name: *			

- n. When finished with your ingredient entry, click '**Save Ingredient**' at the top right of the page. This will return you to the Product Details page.
- o. To add more ingredients, re-do Step 17. You can edit an ingredient on the Product Details page by clicking the pencil icon:

INGREDIENTS						ADD INGREDIENT
	SUBSTANCE NAME	UNII / NDC	STRENGTH	TYPE	SOURCE NDC	row(s) 1 - 2 of 2
<input checked="" type="checkbox"/>	2-HYDROXY-5-METHYLACETOPHENONE	11661U1ZEN	1 g	ACTIB	-	
<input checked="" type="checkbox"/>	2,5-DIMETHYL-1-NITROSOPIRROLIDINE, CIS-	62Z1C3UUHS	100 [IU]	IACT	-	

18. Next, click '**Add Characteristic**' to enter color/flavor/score/shape/imprint/size details:

CHARACTERISTICS

None

ADD CHARACTERISTIC

- a. You will be sent to a separate *Characteristics* page:

CHARACTERISTICS

Characteristic: *

Value: *

- b. First, select the appropriate '**Characteristic**' from the dropdown. Then select the '**Value**' of that characteristic:

CHARACTERISTICS

Characteristic: *

Value: *

Additional Description:

-- Select One --

Black

Blue

Brown

Gray

Green

Orange

- c. You can enter more specific details for a selected characteristic in the 'Additional Description' field, which can include shades of colors ("ivory" white) or shape variations (triangle with "rounded edges"):

CHARACTERISTICS

Characteristic: * Color

Value: * White

Additional Description: Ivory

- d. Click 'Save Characteristic' on the top right of the page when finished. You will be returned to the Product Details page.
- e. Only one characteristic can be entered at a time, so repeat Step 18 to add additional characteristics.
- f. To edit a characteristic, click the pencil icon beside the selected characteristic on the Product Details page:

CHARACTERISTICS				ADD CHARACTERISTIC
	CHARACTERISTIC	VALUE	ADDITIONAL DESCRIPTION	
	SPLCOLOR	WHITE	IVORY	
	SPLSHAPE	BULLET	-	
	SPLOPAC	SPLOPAC		

row(s) 1 - 4 of 4

19. To add a Package:

- a. Click 'Add Package' at the bottom of the product details page:

PACKAGING

None

ADD PACKAGE

- b. Enter all applicable data for the package:

PACKAGING

ONLY LEVEL

Check for Deletion

Package NDC:

Package Type: *

Quantity: *

Unit of Measure: *

Number of Units Produced: *

ADD OUTER PACKAGE DELETE ▲ TO TOP

c. If there are multiple layers of packaging, click the 'Add Outer Package' button at the bottom of the page (you can click this button multiple times):

PACKAGING

INNERMOST LEVEL

Check for Deletion

Package NDC:

Package Type: *

Quantity: *

Unit of Measure: *

Number of Units Produced: *

OUTERMOST LEVEL

Check for Deletion

Package NDC:

Package Type: *

Quantity: *

Unit of Measure: *

Number of Units Produced: *

ADD OUTER PACKAGE DELETE ▲ TO TOP

d. To delete an outer package, click the 'Check For Deletion' checkbox and then select the 'Delete' button. A popup box will ask for confirmation to delete:

OUTERMOST LEVEL

Check for Deletion

Package NDC:

Package Type: *

Quantity:

Unit of Measure: *

Number of Units Produced: *

ADD OUTER PACKAGE

- e. When finished, click 'Save Package' at the top of the page to return to the Product Details page.
- f. To edit a package, click the pencil icon beside the package (on the previous Product Details page):

PACKAGING							ADD PACKAGE
row(s) 1 - 1 of 1							
	PACKAGE NDC/DEVICE ID	NO OF LEVELS	PACKAGE TYPE	QUANTITY	UNIT OF MEASURE	NUMBER OF UNITS PRODUCED	CLONE
	-	1	BOTTLE, PLASTIC	90	mg	1000	

- g. To make an exact duplicate of a package you previously created, click the 'Clone' icon:

PACKAGING							ADD PACKAGE
row(s) 1 - 1 of 1							
	PACKAGE NDC/DEVICE ID	NO OF LEVELS	PACKAGE TYPE	QUANTITY	UNIT OF MEASURE	NUMBER OF UNITS PRODUCED	CLONE
	-	1	BOTTLE, PLASTIC	90	mg	1000	
	-	1	BOTTLE, PLASTIC	90	mg	0	

IMPORTANT: When cloning, don't forget to add the 'Number of Units Produced'! The number **does not** carry over to the new package:

PACKAGING							ADD PACKAGE
row(s) 1 - 2 of 2							
	PACKAGE NDC/DEVICE ID	NO OF LEVELS	PACKAGE TYPE	QUANTITY	UNIT OF MEASURE	NUMBER OF UNITS PRODUCED	CLONE
	-	1	BOTTLE, PLASTIC	90	mg	1000	
	-	1	BOTTLE, PLASTIC	90	mg	0	

20. Repeat Steps 13-19 to add more products.
21. Click 'Save Product' at the top right of the Product Details page. This will return you to the Products page, where you can edit a product:
 - a. Click the pencil icon beside a product to go to its Product Details page and make edits:

SELECT	PRODUCT NDC	PROPRIETARY NAME	dosage form	INCLUDED IN SPL	INGREDIENTS	CLONE PRODUCT
<input checked="" type="checkbox"/>	-	Conazol	CAPSULE, LIQUID FILLED	YES	SHOW INGREDIENTS	
<input checked="" type="checkbox"/>	-	Conazol	CAPSULE, LIQUID FILLED	NO	SHOW INGREDIENTS	

b. You can also edit the number of units produced for all of your products by clicking the 'Update Volume' button:

PRODUCT NDC	PACKAGE NDC	PROPRIETARY NAME	NON PROPRIETARY NAME	SOURCE NDC	PACKAGE TYPE	PACKAGE LEVELS	NUMBER OF UNITS PRODUCED
-	-	Conazole	Ketoconazole	-	CAN	2	100 UPDATE

22. Back on the Products page, enter the Content of Labeling information:

a. Click the 'Content of Labeling' button at the top:

b. Click 'Add Section':

c. A blank template will display. Fill in all applicable fields:

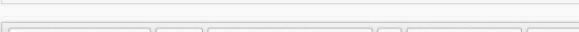
CREATE / EDIT SECTION

Section Type: *

Effective Date: * 

Parent Section:  **Sequence:** *

Title:

Content: 

d. Clicking the '**Section Type**' dropdown will display a list of packaging sections, which will act as headings for your label. For each section/heading that applies to your label, add the appropriate label graphic and text (as explained later).

CREATE / EDIT SECTION

Section Type: *	- Select Section Type -
Effective Date: *	- Select Section Type -
Parent Section:	ABUSE SECTION ACCESSORIES ADVERSE REACTIONS SECTION ALARMS ANIMAL PHARMACOLOGY & OR TOXICOLOGY SECTION ASSEMBLY OR INSTALLATION INSTRUCTIONS BOXED WARNING SECTION CALIBRATION INSTRUCTIONS CARCINOGENESIS & MUTAGENESIS & IMPAIRMENT OF FERTILITY SECTION CLEANING, DISINFECTING, AND STERILIZATION INSTRUCTIONS CLINICAL PHARMACOLOGY SECTION CLINICAL STUDIES SECTION CLINICAL TRIALS EXPERIENCE SECTION COMPATIBLE ACCESSORIES COMPONENTS CONTRAINdications SECTION CONTROLLED SUBSTANCE SECTION DEPENDENCE SECTION DESCRIPTION SECTION
Title:	
Content:	

e. **'Effective Date'** is the date this labeling change/submission will occur.

Effective Date: 

f. The **‘Sequence’** field allows you to organize your label sections (headings) so that they display in the appropriate order. Here is an example list of three sections that were created in Content of Labeling:

The screenshot shows the 'Content of Labeling' section of the FDA DIRECT interface. It displays three sections: 'ADVERSE REACTIONS SECTION', 'WARNINGS AND PRECAUTIONS SECTION', and 'HOW SUPPLIED SECTION'. Each section has an 'EDIT' button to its right. The sections are listed vertically, with the first one being the 'Adverse Reactions Section'.

The first label section above ('Adverse Reactions Section') was created first and is automatically assigned the number '1':

The screenshot shows the 'CREATE / EDIT SECTION' dialog box. It includes fields for 'Section Type' (set to 'ADVERSE REACTIONS SECTION'), 'Effective Date' (set to '08-01-2024'), 'Parent Section' (empty), and 'Sequence' (set to '1'). The 'Sequence' field is highlighted with a red box.

Each section is automatically assigned the next number in numerical order (2, 3, 4, etc). If you need to reorganize any existing or new sections so that they display in a different order, simply change the number in the 'Sequence' field of a desired section.

In the example below, the 'Adverse Reactions Section' previously at the top was moved to the bottom by simply entering '3' into that section's 'Sequence' field then clicking 'Apply':

The screenshot shows the 'CREATE / EDIT SECTION' dialog box again, with the 'Sequence' field set to '3'. Below the dialog, a list of sections is shown in a different order: 'WARNINGS AND PRECAUTIONS SECTION', 'HOW SUPPLIED SECTION', and 'ADVERSE REACTIONS SECTION'. A red arrow points to the 'ADVERSE REACTIONS SECTION' entry in the list.

- Choose a title for your section. If you don't enter anything, whatever you selected from the 'Section Type' dropdown will become the title.

Title:	
--------	--

- h. The '**Highlighted Text**' box only displays for certain section types. Enter information there, if applicable.
- i. The '**Content**' box is intended for text and graphics that pertain to the '**Section Type**.' If you chose 'Adverse Reactions' as a section type, you must enter images and/or text that are appropriate for that section of your labeling.

Content:	
----------	------------------------------------------------------------------------------------

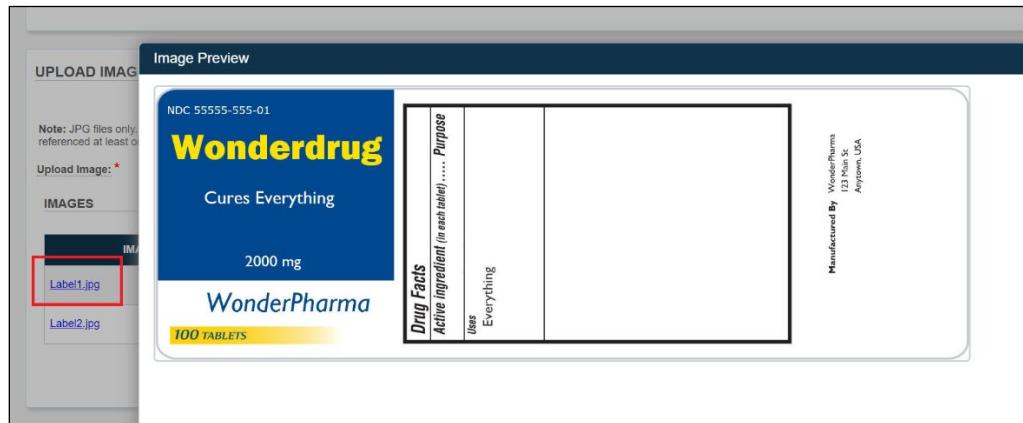
- j. To upload a product label image, click '**Choose File**' to select an image from your computer. The extension/ending of the file **MUST** be a **.jpg no larger than 1MB**.

UPLOAD IMAGES	
<small>Note: JPG files only. Any image used above in the Content of Labeling must first be uploaded and displayed in the list of images below. Furthermore, any image uploaded and appearing on the list below must be referenced at least once in a section of the Content of Labeling.</small>	
Upload Image: * <input type="file"/>	<input type="button" value="Choose File"/>
IMAGES	
<small>None</small>	

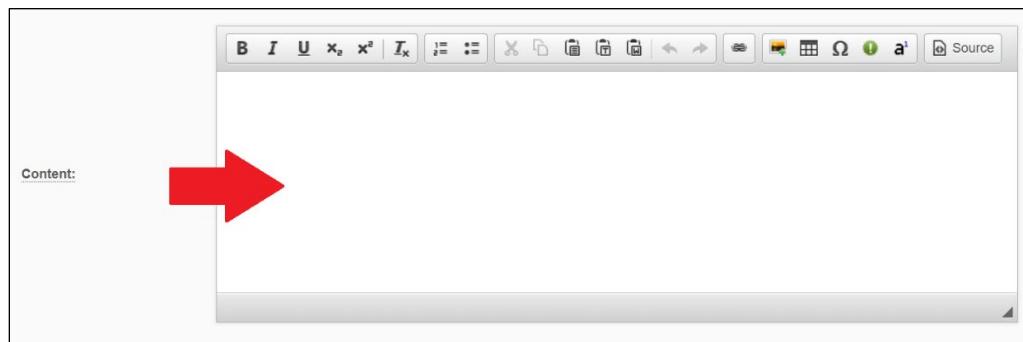
- k. When you have selected a JPG image from your computer, click the '**Upload**' button. Only one image can be uploaded at a time.
- l. Your image(s) will display in the *Images* section:

UPLOAD IMAGES													
<small>Note: JPG files only. Any image used above in the Content of Labeling must first be uploaded and displayed in the list of images below. Furthermore, any image uploaded and appearing on the list below must be referenced at least once in a section of the Content of Labeling.</small>													
Upload Image: * <input type="file"/>	<input type="button" value="Choose File"/>												
IMAGES													
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="background-color: #002060; color: white; text-align: left; padding: 2px;">IMAGE NAME</th> <th style="background-color: #002060; color: white; text-align: center; padding: 2px;">IMAGE</th> <th style="background-color: #002060; color: white; text-align: center; padding: 2px;">DELETE IMAGE</th> <th style="background-color: #002060; color: white; text-align: center; padding: 2px;">REFERENCED</th> </tr> </thead> <tbody> <tr> <td style="text-align: left; padding: 2px;">Label1.jpg</td> <td style="text-align: center; padding: 2px;">  </td> <td style="text-align: center; padding: 2px;"> <input type="button" value="X"/> </td> <td style="text-align: center; padding: 2px;">No</td> </tr> <tr> <td style="text-align: left; padding: 2px;">Label2.jpg</td> <td style="text-align: center; padding: 2px;">  </td> <td style="text-align: center; padding: 2px;"> <input type="button" value="X"/> </td> <td style="text-align: center; padding: 2px;">No</td> </tr> </tbody> </table>		IMAGE NAME	IMAGE	DELETE IMAGE	REFERENCED	Label1.jpg		<input type="button" value="X"/>	No	Label2.jpg		<input type="button" value="X"/>	No
IMAGE NAME	IMAGE	DELETE IMAGE	REFERENCED										
Label1.jpg		<input type="button" value="X"/>	No										
Label2.jpg		<input type="button" value="X"/>	No										

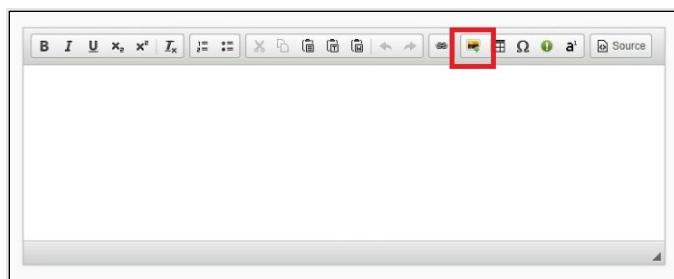
- m. Click the red X beside an image to delete the image. Doing this will cause images to disappear or not display properly if they have been used ("referenced") in a section.
- n. Click the name of the image to display a closeup preview:



- o. Click You must now "reference" your image(s) before you can submit your SPL. To reference an image, go back up to the *Create/Edit* section and click anywhere inside the '**Content**' box:



- p. Select the 'insert an image' icon  from the options bar (hover over any of the icons for a short text description):

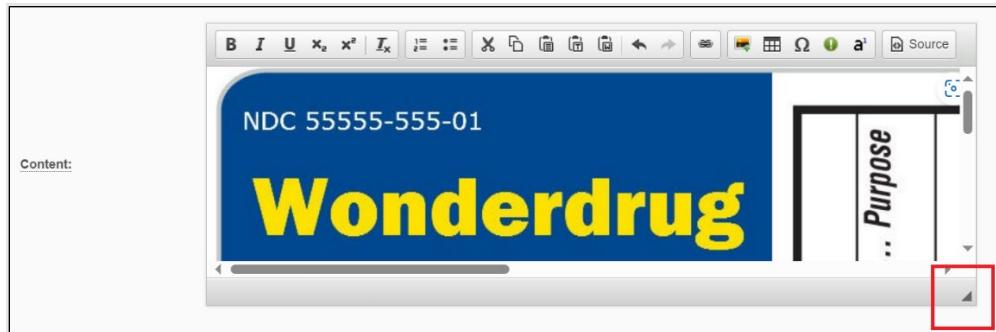


q.

- r. A popup box will display. Your previously uploaded image(s) will now be available to select from the dropdown:



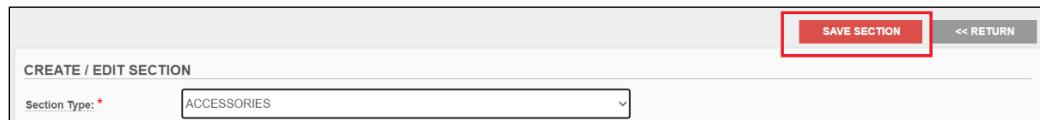
- s. Next, add some Image Text. This is alt text (description text for an image that is not visible anywhere but can be picked up and read by screen reading technology).
- t. Click 'OK.' Your image will now display within the Content box. Click and drag the corner arrow to view more of the image:



IMPORTANT: You only need to upload an image file **once!** File images are “stored” in the *Images* section upon upload. You can use this “storage” area to upload files here once, then use those same files across multiple Content of Labeling entries.

If you delete an image from the *Images* section, it will be automatically removed from each ‘Content’ section in every Content of Labeling entry that references it!

- u. When you are finished, click the ‘Save Section’ button at the top right of the page to save your new section:



- v. You will be returned to the main Content of Labeling list page. Clicking ‘Edit’ will allow you to modify an existing section:

The screenshot shows a web-based application for managing product labeling. At the top, there are navigation links: 'All Submissions', 'Drug Listing and Certification', 'Products', and 'Content of Labeling'. Below these are two buttons: 'EXPAND SECTIONS' and 'CLASSIC'. On the right side, there are 'ADD SECTION', '<< RETURN', and 'EDIT' buttons. The main content area contains a list item with a circular icon and the text 'A SAMPLE TITLE [ACCESSORIES]'. The 'EDIT' button is highlighted with a red box.

w. To add another section to this list, click the 'Add Section' button:

This screenshot is similar to the previous one, but the 'ADD SECTION' button is highlighted with a red box. The rest of the interface and content are identical.

x. If you have at least one section created, clicking the 'Expand Sections' button (top left) will automatically display the full contents of all of your sections listed:

This screenshot shows the 'EXPAND SECTIONS' button highlighted with a red box. Below it, two sections are listed: 'A SAMPLE TITLE [ACCESSORIES]' and '[CONTROLLED SUBSTANCE SECTION]'. The 'CLASSIC' button is also visible.

This screenshot shows the expanded state of the content. The top section, 'A SAMPLE TITLE [ACCESSORIES]', is displayed with its content: 'NDC 55555-555-01', 'Wonderdrug', 'Cures Everything', '2000 mg', 'WonderPharma', and '100 TABLETS'. The bottom section, '[CONTROLLED SUBSTANCE SECTION]', is also expanded, showing a table with columns for 'Drug Facts', 'Active ingredient (in each tablet) Purpose', and 'Uses'. The 'Uses' column contains the text 'Everything'.

- y. Click '**Collapse Sections**' (top left) to close all entries.
- z. You also have the option to switch between '**Classic**' and '**Enhanced**' (top left button) mode, which simply changes the look of the lists.
 - aa. See Section 9.1 for additional help with the Content of Labeling section.
 - bb. When you are finished with Content of Labeling, click the '**Return**' button at the top right of the page. You will be sent back to the product details page.

23. When all fields have been entered to your satisfaction, you can do the following:

- a. '**Save As Draft**' – Save your entry and return to the main Compounded Drug Reporting page. No submission will be made.
- b. '**Save And Validate**' - Save your entry + validate. This will check your submission for errors prior to submitting to the FDA. Validation may take some time. If you are ready to submit your SPL, you may skip this step entirely,
- c. '**Submit SPL**' - Submit your Compounded Drug Reporting SPL submission to the FDA. You will then be returned to the Compounded Drug Reporting main page where you can view your pending submission(s) status:

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE
AWAITING ACCEPTANCE	0767dad8-b637-0717-e003-fb95d40a4e41	0767dad8-b638-0717-e003-fb95d40a4e41		1	HUMAN COMPOUNDED DRUG LABEL	Zee Dee	11-OCT-2023 14:21:59

- d. '**Delete**' – Delete your entry draft completely.

24. Click '**Return**' at any time to return to the main Compounded Product Reporting page.

25. The *Status* field will read '*Submission Accepted*' when your submission has been validated and accepted by the FDA. You will receive an email to your account email address whenever the submission status changes.

26. Once your submission has been accepted, you will be able to download a copy of the submission as a zip file. Go to the main Compounded Drug Reporting page and click the latest '*Submission Accepted*' text link:



27. Click 'Download SPL' on the top left of the page to download the zip file. You can also select 'View SPL' for a quick look at your submission.

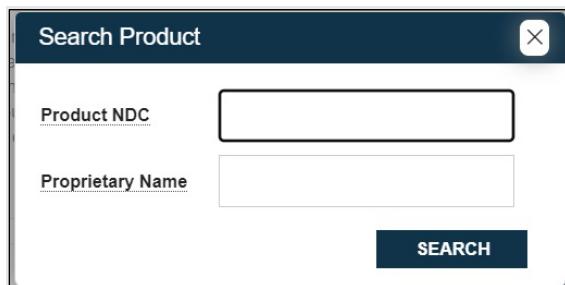


28. If you already have multiple Compounded Product Reporting submissions, you can search for a specific submission:

a. Click 'Search Product' on the Compounded Product Reporting main page:



b. Enter one or both of the fields in the ensuing popup box. Partial entries (ex: 'sys' instead of 'systems') are permitted:



c. Click 'Search' and your results will populate.
d. See Section 9.2: Searching and Filtering for additional help with filters and searching multiple products.

7 WHOLESALE DRUG DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER REPORTS

A Wholesale Drug Distributor And Third Party Logistics Provider Reports (WDD/3PL) SPL submission can be used for wholesale distributors and third-party logistics providers that distribute prescription drugs covered by the Drug Supply Chain Security Act (DSCSA).

The **WDD/3PL** SPL submission template can be used for the following purposes:

- Facility Reporting: Reporting facility information.
- Withdrawal of Facility Reporting: Removing previously reported facility information.
- Out of Business: De-registering due to going out of business.

To submit a WDD/3PL SPL, do the following:

1. Log in to FDA Direct.
2. Select '**Wholesale Drug Distributor And Third Party Logistics Provider Reports**' under the *DSCSA Annual Reporting* section:

3. Click 'Create New/Upload File':

All Submissions WDD/SPL

ESTABLISHMENT REGISTRATION & DRUG LISTING

- Establishment Registration
- NDC Labeler Code Request
- Drug Listing and Certification
- NDC Reservation

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING

- Outsourcing Facility Registration
- Compounded Drug Reporting

DSCSA ANNUAL REPORTING

- Wholesale Drug Distributor and Third-Party Logistics Provider Reports
- WDD/3PL Facilities
- WDD/3PL Licenses

WHOLESALE DRUG DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER REPORTS

For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic establishment registration and drug listing, contact eDRS@fda.hhs.gov.

- The Drug Supply Chain Security Act (DSCSA) contains licensure and annual reporting requirements for wholesale distributors and third-party logistics providers that distribute prescription drugs covered by the DSCSA.

CREATE NEW / UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	REPORTER DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE	LOCK
DRAFT	06bcd3a-82be-6e9f-e063-fa95b40ac226	06bcd3a-82bf-6e9f-e063-fa95b40ac226		1	WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT	DETAILS	Zee Dee	10-02-2023 16:35:59	

1 - 1

4. You will be given two options:

CREATE NEW WHOLESALE DRUG DISTRIBUTION & THIRD PARTY LOGISTICS

Create a new Wholesale Drug Distribution & Third Party Logistics using a blank form

Import an existing Wholesale Drug Distribution & Third Party Logistics 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**

- a. To upload a file from your computer directly, follow the steps outlined in Section 3: Submission Information. Then skip to Step 7 below and continue the instructions.
5. To create a new WDD/3PL submission using a blank template, select the '**Create a new Wholesale Drug Distribution and Third Party Logistics using a blank form**' option.
6. Click '**Continue**' and a blank template will display:

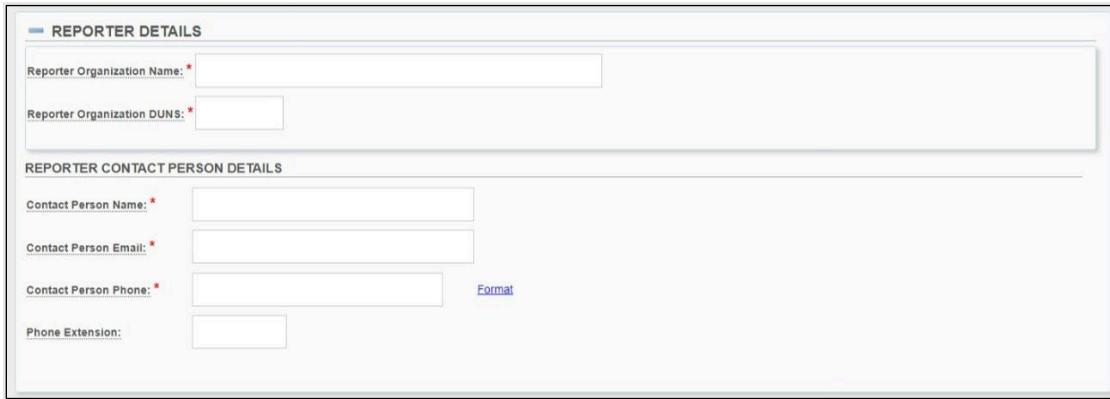
7. Selecting the '**Save Draft**' button at any time will save your work without submitting it. The '**Return**' button will send you back to the main WDD/3PL Provider Reports page without saving your changes.
8. In the *Header Details* section, select one of the options from the dropdown:

9. To enter a **Withdrawal** or an **Out Of Business** submission, select the option that applies from the dropdown.
 - a. Enter your submission Root ID and/or Set ID.

IMPORTANT: This step can be skipped **only if you uploaded your submission during Step 4**, as the correct IDs will automatically populate those fields.

 - b. Click '**Save As Draft**' at the top. You will be returned to main WDD/3PL page.
 - c. Click '**Submit SPL**' when you are ready to send you submission to the FDA.

10. To enter a '**Wholesale Drug Distributors and Third-Party Logistics Facility Report**' submission, select the option from the dropdown.
11. Fill in all blank fields in the *Reporter Details* section. The reporter is the company that owns or operates the wholesale distributor or 3PL and is reporting the facility(s) information.



REPORTER DETAILS

Reporter Organization Name: *

Reporter Organization DUNS: *

REPORTER CONTACT PERSON DETAILS

Contact Person Name: *

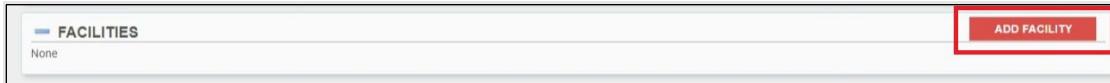
Contact Person Email: *

Contact Person Phone: *

Format

Phone Extension:

12. At the bottom of the page, click the '**Add Facility**' button. A blank template will display on a new page:



FACILITIES

None

ADD FACILITY

The screenshot shows the 'Facility' submission page. At the top, there are navigation links: 'All Submissions', 'WDD/3PL', 'SPL Submission', and 'Facility'. On the right, there are 'SAVE FACILITY' and '<< RETURN' buttons. The main form area is divided into sections:

- FACILITY DETAILS**: Fields for 'Facility Name (Legal Name)' and 'Facility DUNS'.
- FACILITY ADDRESS**: Fields for 'Country' (set to 'United States'), 'Street Address', 'Street Address Confidential' (checkbox), 'City', 'State' (dropdown), and 'Zip Code'.
- DOING BUSINESS AS (DBAs)**: A section with a 'None' option and an 'ADD DBA' button.
- FACILITY CONTACT DETAILS**: Fields for 'Contact Name', 'Contact Email', 'Contact Phone' (with a 'Format' dropdown), and 'Phone Extension'.
- BUSINESS OPERATION(s) OF FACILITY**: A section with checkboxes for 'WDD OPERATION' and '3PL OPERATION'.

13. Complete the *Facility Details* and *Facility Address* fields. Click the 'Street Address Confidential' check box if you want to keep the street name private:

This is a zoomed-in view of the 'Facility Address' section. It includes fields for 'Country' (set to 'United States'), 'Street Address', 'Street Address Confidential' (checkbox), 'City', 'State' (dropdown), and 'Zip Code'.

14. To enter DBA (Doing Business As) information click the 'Add DBA' button and a popup box will display:

This is a screenshot of a 'Doing Business As (DBAs)' dialog box. It contains a single option 'None' and an 'ADD DBA' button.

- Enter your '**DBA Name**' and select the appropriate business operation from the dropdown.
- To add multiple DBAs without closing the popup, click the '**Save And Add**' button for each new DBA entry.
- When you are finished adding DBAs, click '**Save**' and you will be returned to the facility page. Your saved DBAs will display under the *Doing Business As* section:

DOING BUSINESS AS (DBAs)				ADD DBA
EDIT	DELETE	DBA NAME	BUSINESS OPERATION OF DBA	ROW(S) 1 - 3 of 3
		Yes123	WDD	
		No123	3PL	
		YesAndNo123	BOTH (WDD/3PL)	

- Click the pencil icon to make edits to any of the DBAs or click the X to delete the specified DBA.

15. Under *Facility Contact Details*, you have the option to select '**Same As Reporter Contact**' to copy over contact information from the initial page (*Reporter Contact Person Details*).

16. To add business operations, select one or both of the check boxes:

17. Click '**Add License**' and you will be taken to a separate page where you will enter licensing information for the specified business operation (WDD or 3PL):

LICENSE INFORMATION

License Type: WHOLESALE DRUG DISTRIBUTOR

Controlled-substance license or permit:

License Number: *

Issuer: * -Select State-

Expiration Date: *

State/Territory

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

None

LICENSE INFORMATION

License Type: THIRD-PARTY LOGISTICS PROVIDER

Controlled-substance license or permit:

License Number: *

Issuer: * -Select State-

Expiration Date: *

State/Territory

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

None

18. If you select the '**Controlled-substance license or permit**' check box, you must enter at least one disciplinary action via the '**Add Disciplinary Action**' button. This will send you to a new page:

ACTION DETAILS

Action Type: * - Select Action -

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 filename should have an extension of ".pdf".

Document: Choose File

ADD DOCUMENT

a. Fill out the *Action Details* section then upload any relevant document with a '**.pdf**' file extension. Upload a PDF file from your computer by clicking '**Choose File**' then clicking the '**Add Document**' button:

RELEVANT DOCUMENTS

Note: Upload relevant documents related to disciplinary action in pdf form only. Browse for document then click **Add Document** button. The filename should have an extension of ".pdf"

Document: **Choose File**

ADD DOCUMENT

- b. Repeat the above step to add additional documents.
- c. Once you add a document, it will display at the bottom of this page:

RELEVANT DOCUMENTS

Note: Upload relevant documents related to disciplinary action in pdf form only. Browse for document then click **Add Document** button. The filename should have an extension of ".pdf"

Document: **Choose File**

row(s) 1 - 1 of 1

DOCUMENT NAME	DATE ADDED	DELETE
sample1.pdf	10-05-2023	

ADD DOCUMENT

- d. Clicking the **X** will delete the uploaded file.
- e. When finished, click '**Save Action**' at the top to save your entry and return to the license page. If you do not want to save your changes, simply click the grey '**Return**' button instead.
- f. You will be sent back to the licensing page.

19. Click '**Save License**' when you are finished making changes. If you do not want to save your entry, click '**Return**'.

20. You will be sent back to the facility page and your licenses will display at the bottom. Click the pencil icon beside each entry to edit a license.

21. If you selected both of the business operations boxes under *Business Operation(s) of Facility*, you have the option to switch between licenses.

a. To do this, you must first select the checkbox next to the desired license:

WDD LICENSES			
Enter wholesale distributor licenses. Only enter DEA registration or state controlled-substance license if there is a significant disciplinary action.			
	EDIT	LICENSE NUMBER	LICENSE STATE
<input type="checkbox"/>		100000	ALABAMA
3PL LICENSES			
Enter 3PL licenses. Only enter DEA registration or state controlled-substance license if there is a significant disciplinary action.			
	EDIT	LICENSE NUMBER	LICENSE STATE
<input type="checkbox"/>		123	ARIZONA

b. Then click 'Switch To 3PL/WDD License':

row(s) 1 - 1 of 1			
LICENSE STATE	EXPIRATION DATE	CONTROLLED SUBSTANCE	DISCIPLINARY ACTION
	12-31-2023	Yes	Yes
row(s) 1 - 1 of 1			
LICENSE STATE	EXPIRATION DATE	CONTROLLED SUBSTANCE	DISCIPLINARY ACTION
	10-27-2023	No	No

c. Your license will now be moved under the selected license business operation and removed from the previous one:

22. When you are finished editing the facility page, scroll to the top and click '**Save**' to save and return to the initial form page, or '**Return**' to exit the facility page without saving.

23. Your facilities will display at the bottom of the page, and can be edited by clicking the pencil icon beside each facility entry.

24. When you are fully finished, go to the top of the WDD/3PL submission page where you can do the following:

- '**Save As Draft**' – Save your entry and return to the main WDD/3PL Provider Reports page. No submission will be made.
- '**Save And Validate**' - Save your entry + validate. This will check your submission for errors prior to submitting to the FDA. Validation may take some time. If you are ready to submit your SPL, you may skip this step entirely.
- '**Submit SPL**' - Submit your WDD/3PL submission to the FDA. You will then be returned to the WDD/3PL Provider Reports page where you can view your pending submission(s) status:

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	REPORTER DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE	LOCK
AWAITING ACCEPTANCE	05fb250a-b23c-92ab-e063-b99b40a9a24	06fb250a-b23d-92ab-e063-b99b40a9a24	cd38790164522394681507@direct	1	WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT	DETAILS	Zee Dee	10-05-2023 18:07:11	-

d. **'Delete'** – Delete your draft entry completely.

25. The *Status* field on the WDD/3PL Provider Reports main page should read 'Submission Accepted' when your submission has been validated and accepted by the FDA. You will receive an email to your account email address when the submission status changes.

26. Once your submission has been accepted, you will be able to download a copy as a zip file. Go to the main WDD/3PL Provider Reports page and click the latest 'Submission Accepted' text link:



27. Click '**Download SPL**' on the top left of the page to download the zip file. You can also select '**View SPL**' for a quick look at your submission.

VIEW SPL **DOWNLOAD SPL**

Note: Click on the Data Element Name for each field below (if applicable)

HEADER DETAILS

Document Type: * WHOLESALE DRUG DISTRIBUTOR

7.1 WDD/3PL Facilities

This section lists all the facilities you have entered in your submissions. Only facilities entered from submissions with the ‘Submission Accepted’ status will populate in this section:

SELECT	DUNS	NAME	STREET	CITY	STATE	ZIP	COUNTRY	STATUS	SPL SET ID
		CNI Facility	123 Way Rd	Pago Pago	-	96799	ASM	Reported	05fb25ba-b23c-92ab-e063-fb05b40a8a24

To view any of your listed facilities:

1. Click the pencil icon under the *Select* column (above). You will be redirected to the submission associated with that facility. Click the pencil icon beside the facility:

All Submissions WDD/3PL **SPL Submission**

VIEW SPL **DOWNLOAD SPL** **CREATE NEW VERSION** **<< RETURN**

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 DETAILS

Document Type: * WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT

Set ID: * 06fb25ba-b23c-92ab-e063-fb95b40a8a24 Version Number: * 1

Root ID: * 06fb25ba-b23d-92ab-e063-fb95b40a8a24 Effective Date: * 10-05-2023

REPORTER DETAILS

Reporter Organization Name: * Zee LLC

Reporter Organization DUNS: * 100000000

REPORTER CONTACT PERSON DETAILS

Contact Person Name: * Tuli Lei

Contact Person Email: * lelato@global.org

Contact Person Phone: * 2-222-222-2222

Phone Extension:

FACILITIES

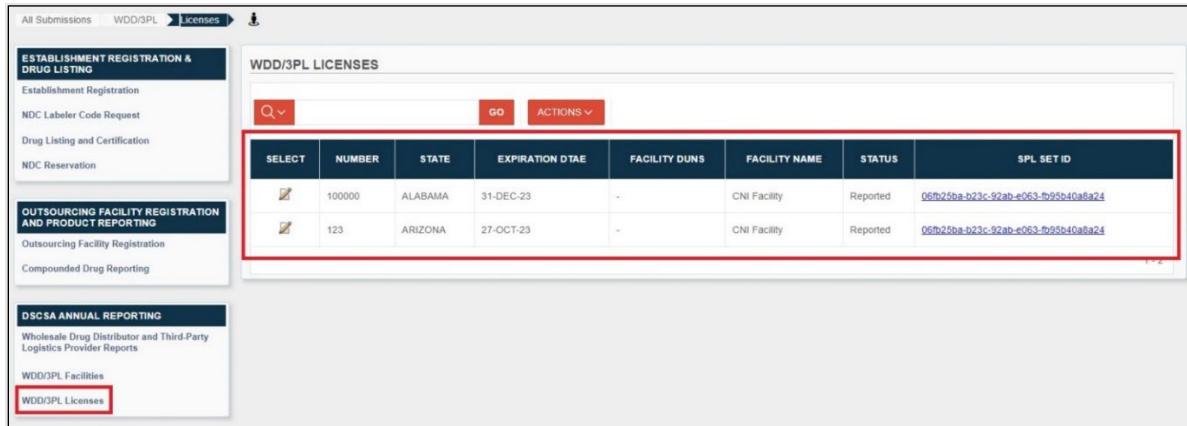
EDIT	FACILITY DUNS	FACILITY NAME	FACILITY CITY	FACILITY STATE
		CNI Facility	Pago Pago	-

row(s) 1 - 1 of 1

2. When finished viewing facility information, click the grey 'Return' button at the top right of each page to return to a previous page.

7.2 WDD/3PL Licenses

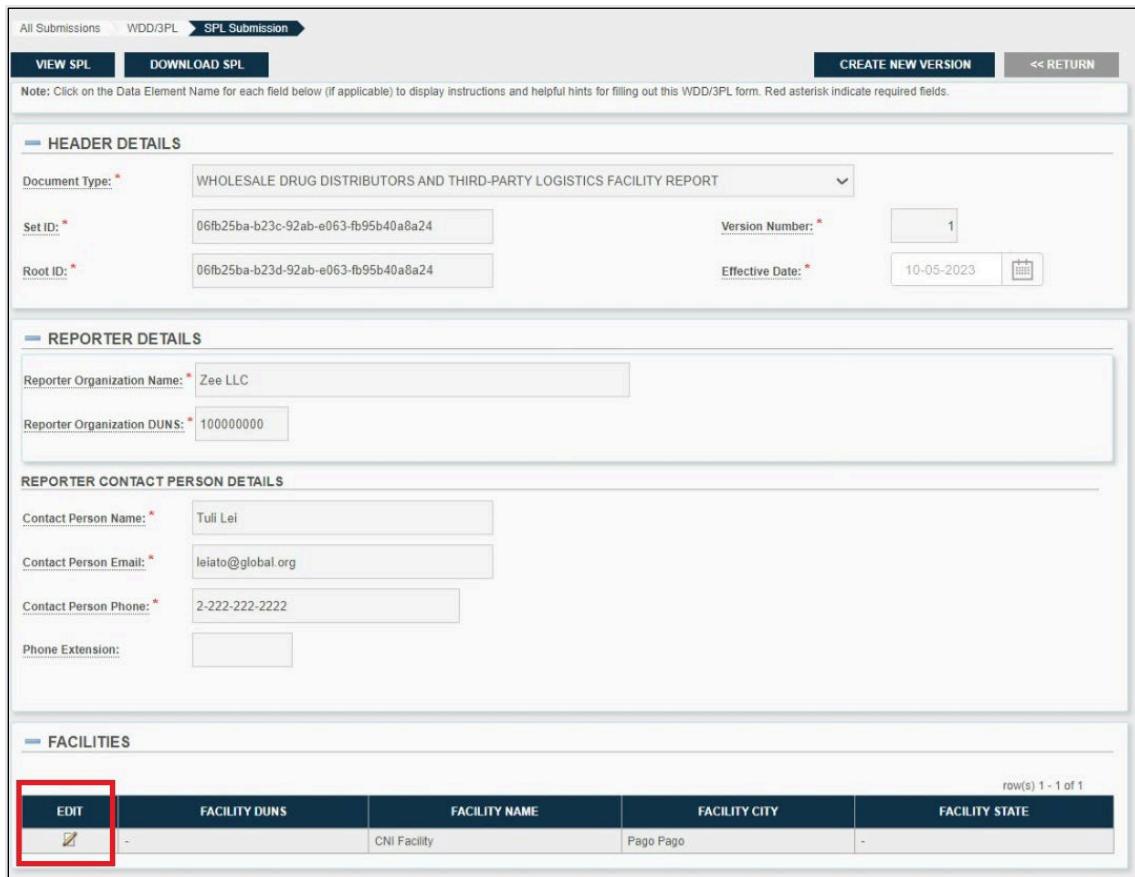
This section lists all the licenses you have entered in your submissions. Only licenses entered from submissions with the 'Submission Accepted' status will populate in this section:



SELECT	NUMBER	STATE	EXPIRATION DATE	FACILITY DUNS	FACILITY NAME	STATUS	SPL SET ID
	100000	ALABAMA	31-DEC-23	-	CNI Facility	Reported	06fb25ba-b23c-92ab-e063-fb95b40a8a24
	123	ARIZONA	27-OCT-23	-	CNI Facility	Reported	06fb25ba-b23c-92ab-e063-fb95b40a8a24

To view any of your listed licenses:

3. Click the pencil icon under the *Select* column (above). You will be redirected to the submission associated with that license. Click the pencil icon beside the facility associated with the license:



The screenshot shows the FDA Direct SPL Submission interface. At the top, there are buttons for 'VIEW SPL', 'DOWNLOAD SPL', 'CREATE NEW VERSION', and '<< RETURN'. Below this, a note says: '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.' The interface is divided into sections: 'HEADER DETAILS', 'REPORTER DETAILS', 'REPORTER CONTACT PERSON DETAILS', and 'FACILITIES'. The 'FACILITIES' section contains a table with columns: EDIT, FACILITY DUNS, FACILITY NAME, FACILITY CITY, and FACILITY STATE. The 'EDIT' column for the first row is highlighted with a red box. The table data is as follows:

EDIT	FACILITY DUNS	FACILITY NAME	FACILITY CITY	FACILITY STATE
	-	CNI Facility	Pago Pago	-

4. Select the pencil icon for the desired license, under *Edit*:

All Submissions > WDD/3PL > SPL Submission > Facility

FACILITY DETAILS

Facility Name (Legal Name):* CNI Facility

Facility DUNS:

Facility DUNS Not Available:

FACILITY ADDRESS

Country: * American Samoa

Street Address: * 123 Way Rd

Street Address Confidential:

City: * Pago Pago

State: * -Select State-

Zip Code: * 96799

DOING BUSINESS AS (DBAs)

None

FACILITY CONTACT DETAILS

Contact Name: * Tuli Lei

Contact Email: * lelato@global.org

Contact Phone: * 2-222-222-2222

Phone Extension:

BUSINESS OPERATION(s) OF FACILITY *

WDD OPERATION 3PL OPERATION

WDD LICENSES

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

EDIT	LICENSE NUMBER	LICENSE STATE	EXPIRATION DATE	CONTROLLED SUBSTANCE	DISCIPLINARY ACTION
	18	ARIZONA	10-27-2023	No	No

row(s) 1 - 1 of 1

3PL LICENSES

Enter 3PL licenses.
Only enter DEA registration or state controlled-substance license if there is a significant disciplinary action.

EDIT	LICENSE NUMBER	LICENSE STATE	EXPIRATION DATE	CONTROLLED SUBSTANCE	DISCIPLINARY ACTION
	00000	ALABAMA	12-31-2023	Yes	Yes

row(s) 1 - 1 of 1

- When finished viewing license information, click the grey 'Return' button at the top right of each page to return to a previous page.

8 GENERIC FACILITY GDUFA SELF-IDENTIFICATION

8.1 Generic Facility GDUFA Self-Identification

A **Generic Facility GDUFA Self-Identification** SPL submission is intended for human generic drug facilities to provide identification information to the FDA.

You are required to self-identify if you represent a generic industry facility/site/organization that is:

- Manufacturing, or intends to manufacture, human generic drug APIs or FDFs, or both.
- A site/organization that packages the FDF of a human generic drug into the primary container/closure system and label the primary container/closure system. (Site/organization)
- A site identified in a generic drug submission and pursuant to a contract with the applicant remove the drug from a primary container/closure system and subdivide the contents into a different primary container/closure system. (Site)
- A bioequivalence (BE)/bioavailability (BA) site identified in a generic drug submission and conducts clinical BE/BA testing, bioanalytical testing of samples collected from clinical BE/BA testing, and/or in vitro BE testing.
- A site that is identified in a generic drug submission and performs testing of one or more attributes or characteristics of the FDF or the API pursuant to a contract with the applicant to satisfy a current good manufacturing practice (CGMP) testing requirement (excludes sites that are testing for research purposes only).
- For more information, see the [FDA's Self-Identification FAQ](#) website.

To submit a Generic Facility GDUFA Self-Identification SPL, do the following:

1. Log in to FDA Direct.
2. Select '**Generic Facility GDUFA Self-Identification**' under the *Generic Drug Self-Identification* section:

All Submissions > GDUFA Self-Identification

ESTABLISHMENT REGISTRATION & DRUG LISTING
Establishment Registration
NDC Labeler Code Request
Drug Listing and Certification
NDC Reservation

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING
Outsourcing Facility Registration
Compounded Drug Reporting

DSCSA ANNUAL REPORTING
Wholesale Drug Distributor and Third-Party Logistics Provider Reports

GENERIC DRUG SELF-IDENTIFICATION
Generic Facility GDUFA Self-Identification

GDUFA FACILITY SELF-IDENTIFICATION
For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic establishment registration and drug listing, contact eDRLS@fda.hhs.gov

None

CREATE NEW / UPLOAD FILE

3. Click 'Create New/Upload File':

GDUFA FACILITY SELF-IDENTIFICATION
For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic establishment registration and drug listing, contact eDRLS@fda.hhs.gov

None

CREATE NEW / UPLOAD FILE

4. You will be given two options:

CREATE NEW GDUFA FACILITY SELF-IDENTIFICATION

Create New Generic Facility GDUFA Self-Identification using a blank form
 Import an existing Generic Facility GDUFA Self-Identification 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

- a. To upload a file from your computer directly, follow the steps outlined in Section 3: Submission Information. Then skip to Step 7 below and continue the instructions.
5. To create a new GDUFA submission using a blank template, select the '**Create New Generic Facility GDUFA Self-Identification using a blank form**' option.
6. Click '**Continue**' and a blank template will display:

All Submissions | GDUFA Self-Identification | SPL Submission ►

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

Set ID: * 06ec7198-eb54-2c4e-e063-fb95b40a13e8 [Generate New](#) Version Number: * 1

Root ID: * 06ec7198-eb55-2c4e-e063-fb95b40a13e8 [Generate New](#) Effective Date: * 10-04-2023 [Calendar](#)

REGISTRANT DETAILS

Registrant Name: *

Registrant DUNS: *

REGISTRANT CONTACT DETAILS

Contact Name: *

Contact Email: *

Contact Phone: * Format

Phone Extension:

Contact Fax:

REGISTRANT CONTACT ADDRESS

Country: * -Select Country-

Street Address: *

City: *

State/Province:

Postal Code:

FACILITIES

None [ADD FACILITY](#)

7. Selecting the 'Save Draft' button at any time will save your work without submitting it. The 'Return' button will send you back to the main Generic Facility GDUFA Self-Identification page without saving your changes.
8. Fill in the blank fields in the *Registrant Details* section:

REGISTRANT DETAILS

Registrant Name: *

Registrant DUNS: *

REGISTRANT CONTACT DETAILS

Contact Name: *

Contact Email: *

Contact Phone: * Format

Phone Extension:

Contact Fax:

REGISTRANT CONTACT ADDRESS

Country: * -Select Country-

Street Address: *

City: *

State/Province:

Postal Code:

9. Information provided in the *Additional Labeler Details* section is optional, but including this information will expedite your NDC Labeler Code request:
10. Click the '**Add Facility**' button at the bottom of the page, under *Facilities*:

The screenshot shows a user interface for managing facilities. At the top, there is a header with the text 'FACILITIES' and 'None' below it. To the right of this is a red rectangular button with the white text 'ADD FACILITY'.

11. You will be shown a separate form. Enter all applicable facility information:

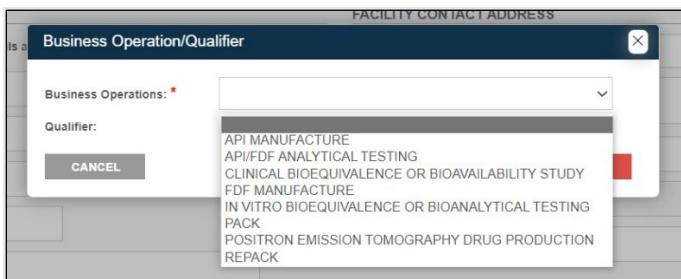
The screenshot shows a detailed facility submission form. At the top, there are navigation links: 'All Submissions', 'GDUFA Self-Identification', 'SPL Submission', and 'Facility' (which is highlighted with a blue arrow). To the right of these are 'SAVE FACILITY' and '<< RETURN' buttons. The form is divided into several sections:

- FACILITY DETAILS:** Fields for 'Facility Name' (with a red asterisk), 'Facility DUNS' (with a red asterisk), and 'Facility FEI' (with a red asterisk).
- FACILITY ADDRESS:** Fields for 'Country' (with a red asterisk), 'Street Address' (with a red asterisk), 'City' (with a red asterisk), 'State/Province', and 'Postal Code'.
- FACILITY CONTACT DETAILS:** A checkbox for 'Same as Registrant Contact Details and Address'. Below it are fields for 'Contact Name' (with a red asterisk), 'Contact Email' (with a red asterisk), 'Contact Phone' (with a red asterisk), 'Phone Extension', and 'Contact Fax'.
- FACILITY CONTACT ADDRESS:** Fields for 'Country' (with a red asterisk), 'Street Address' (with a red asterisk), 'City' (with a red asterisk), 'State/Province', and 'Postal Code'.
- BUSINESS OPERATION(S):** A note: 'Enter the one or more drug manufacturing and processing operations performed at the facility.' To the right is a red 'ADD BUSINESS OPERATION' button.

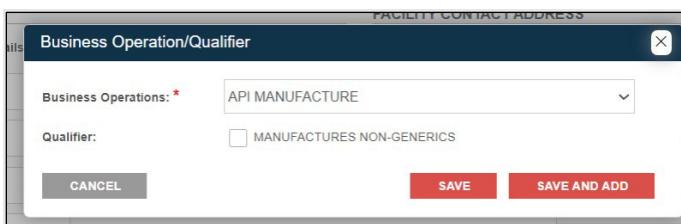
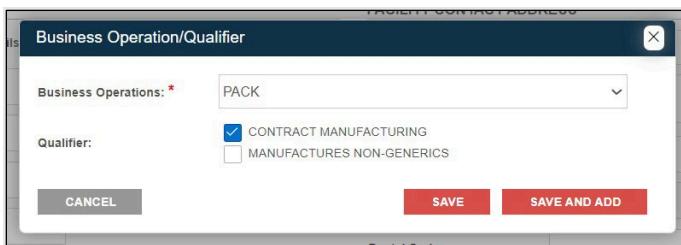
12. Click the '**Add Business Operation**' button at the bottom of this page:

The screenshot shows a section for adding business operations. It includes a note: 'Enter the one or more drug manufacturing and processing operations performed at the facility.' To the right is a red 'ADD BUSINESS OPERATION' button.

13. A popup box will display. Select the facility's business operation from the '**Business Operations**' dropdown:



14. Depending on your selection, different business qualifiers will display. Click the check box beside any listed qualifier to select it as business operation qualifier(s):



15. To keep adding more business operations without closing the popup box, click '**Save And Add**.' To finish with your selections and close the popup box, click '**Save**.' Your selections will display at the bottom of the page:

BUSINESS OPERATION(S)				ADD BUSINESS OPERATION
Note: Enter the one or more drug manufacturing and processing operations performed at the facility.				
EDIT	DELETE	BUSINESS OPERATION	QUALIFIER	
		API MANUFACTURE	<ul style="list-style-type: none"> MANUFACTURES NON-GENERIC CONTRACT MANUFACTURING MANUFACTURES NON-GENERIC 	
		PACK		

16. Click the pencil icon to make edits to any of the business operations or click the X to delete the specified operation.

17. At the top of the facility page, you can either delete your entry ('**Delete Facility**' button) or add it as a facility ('**Save Facility**'):



18. You will then be sent back to the initial template. Redo [Steps 10-17](#) to add more facilities.
19. Return to the top of the page where you can do the following:
 - a. **'Save As Draft'** – Save your entry and return to the main Generic Facility GDUFA Self-Identification page. No submission will be made.
 - b. **'Save And Validate'** - Save your entry + validate. This will check your submission for errors prior to submitting to the FDA. Validation may take some time. If you are ready to submit your SPL, you may skip this step entirely.
 - c. **'Submit SPL'** - Submit your Generic Facility GDUFA Self-Identification SPL submission to the FDA. You will then be returned to the Generic Facility GDUFA Self-Identification main page where you can view your pending submission(s) status:

GDUFA Self Identification							
ENT REGISTRATION & REPORTING		GDUFA FACILITY SELF-IDENTIFICATION					
Registration		For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov . For general questions regarding electronic establishment registration and drug listing, contact eDRLS@fda.hhs.gov					
SEARCH	CREATE NEW / UPLOAD FILE	Q	GO	ACTIONS			
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE
AWAITING ACCEPTANCE	06ec7198-eb54-2c4e-e063-fb95b40a13e8	06ec7198-eb55-2c4e-e063-fb95b40a13e8		1	GENERIC DRUG FACILITY IDENTIFICATION SUBMISSION	Zee Dee	05-OCT-2023 13:10:43

- d. **'Delete'** – Delete your draft entry completely.
20. The *Status* field on the Generic Facility GDUFA Self-Identification main page should read **'Submission Accepted'** when your submission has been validated and accepted by the FDA.
21. You will receive an email to your account email address when your submission status has changed. Refresh the main page periodically or log in at a later time.
22. Once your submission has been accepted, you will be able to download a copy of the SPL submission as a zip file. Go to the main Generic Facility GDUFA Self-Identification page and click the latest **'Submission Accepted'** text link:

STATUS
1
2
3
4
5
6
7
8
9
SUBMISSION ACCEPTED

23. Click 'Download SPL' on the top left of the page to download the zip file. You can also select 'View SPL' for a quick look at your submission.



9 USEFUL INFO

9.1 Content of Labeling

This section contains helpful reference when using the Content of Labeling section of FDA Direct.

9.1.1 Text Editing Tools

Several text editing tools available in the text field section:



A description of each of these tools is below:

Icon	Description
B	Bold
<i>I</i>	Italicize
<u>U</u>	Underline
x_2	Create smaller text/superscript
x^2	Create smaller text/subscript
<u>I_x</u>	Remove formatting
$1 \frac{1}{2}$	Insert a numbered list
$\bullet \frac{1}{2}$	Insert a bulleted list
	Cut/remove

Icon	Description
	Paste as plain text
	Paste from Microsoft Word
	Undo the last change
	Reapply the last change
	Insert a link/cross-reference to another section
	Add an uploaded image from the Images table
	Insert a table
Ω	Insert a special character
	Identify as a Recent Change

Icon	Description
	Copy
	Paste

Icon	Description
a^1	Add a footnote
	Switch to source code

9.1.2 Adding and Deleting Footnotes

Footnote numbers appear sequentially for sections or subsections, beginning with the number "1". FDA Direct automatically numbers all the footnotes sequentially for the entire label.

To add a footnote:

From the Content of Labeling screen, click 'Edit' on the label you want to make changes to:



Insert your cursor at the appropriate point in the text and click the 'footnote' icon:

CREATE / EDIT SECTION

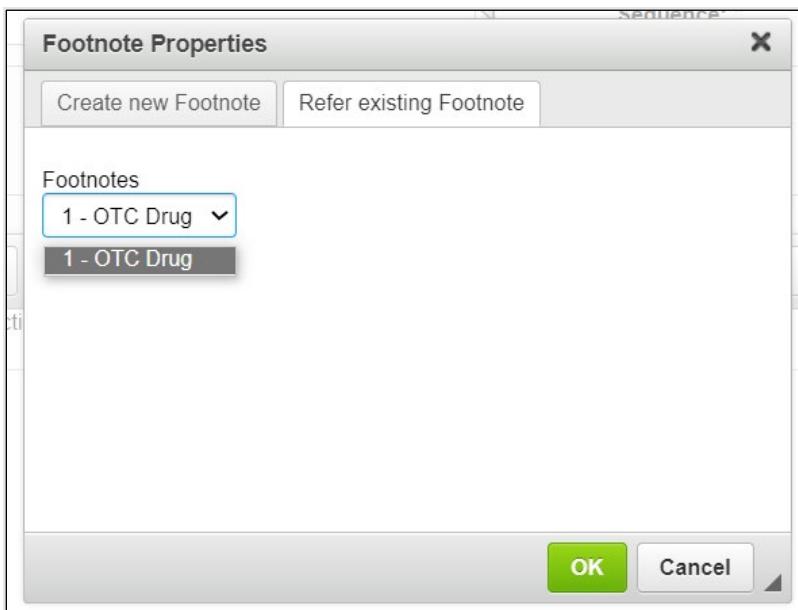
Section Type: *	OTC - ACTIVE INGREDIENT SECTION
Effective Date: *	09-28-2023 <input type="button" value="Calendar"/>
Parent Section:	<input type="text"/> <input type="button" value="Edit"/>
Title:	<input type="text"/> <input type="button" value="Edit"/>
Content:	<div style="border: 1px solid #ccc; padding: 5px;"> <p>This is the Active Ingredient Section.</p> <div style="border: 1px solid #ccc; padding: 2px; margin-top: 5px;"> a¹ <input type="button" value="Source"/> </div> </div>

A popup window will display. Enter text for your footnote:

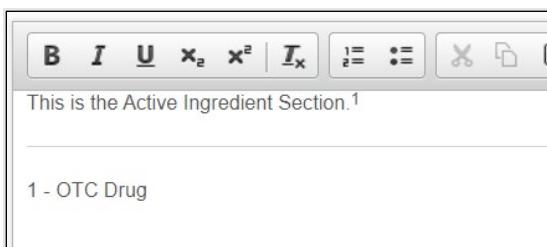
Footnote Properties

<input type="button" value="Create new Footnote"/>	<input type="button" value="Refer existing Footnote"/>
Footnote Text	
<div style="border: 1px solid #ccc; height: 100px; margin-top: 5px;"></div>	
<input type="button" value="OK"/> <input type="button" value="Cancel"/>	

Refer an existing footnote:

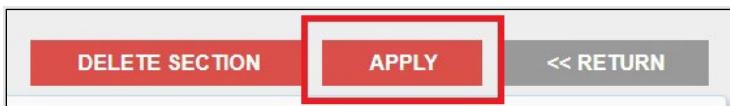


Your footnote will display in the text field:



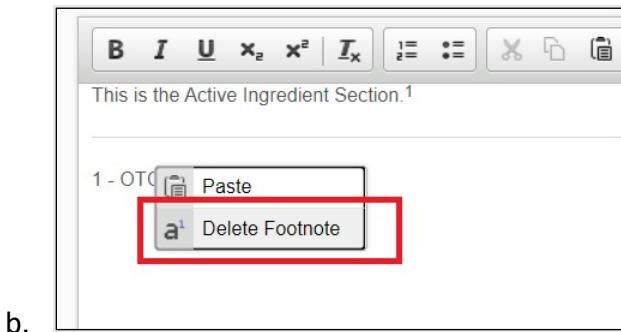
All section footnotes will appear sequentially at the bottom of the text box.

Click '**Apply**' (top right of the page) to save your changes:



To delete a footnote:

- a. Place your cursor anywhere within the footnote listed at the bottom of the page, and right-click. Select '**Delete Footnote**'.



9.1.3 Links & Cross References

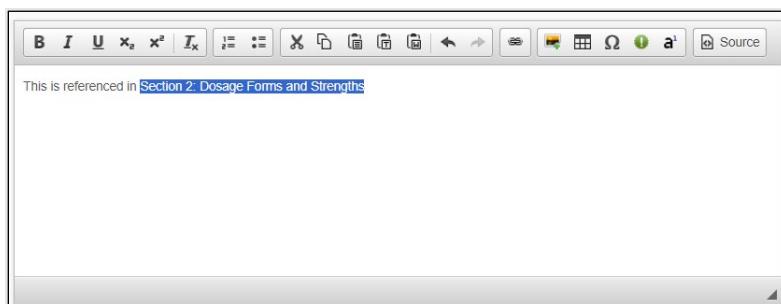
You can create 'links' or 'cross references' which are linked pieces of text that, when clicked, will send you to a different section within a Content of Labeling label.

To create a link/cross reference:

Click 'Edit' on a particular Content of Labeling section:



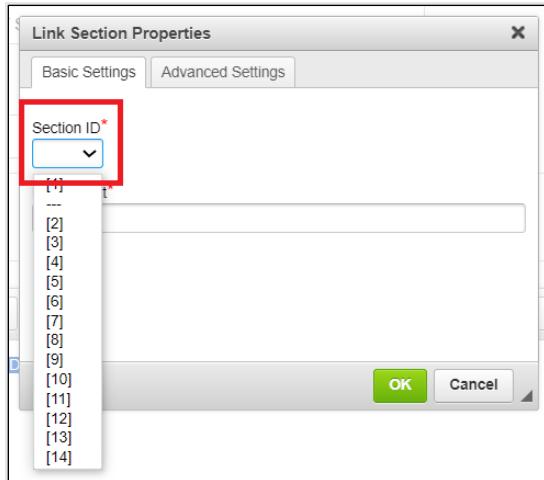
Select/highlight the text you want to make linkable:



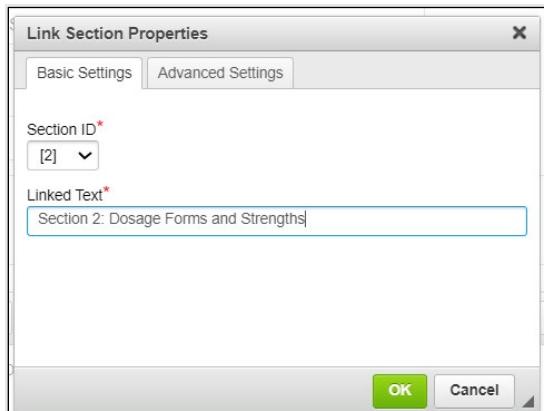
Click the 'link' icon:



A popup box will display. Click '**Section ID**' for a dropdown list of all your section numbers:



Choose a section number. Then use the '*Linked Text*' field to enter or paste your display text:



Press the '**OK**' button to save your changes.

The linked text will be underlined in blue. Click '**Apply**' to save your changes:

You will be returned to your list of labels where your new link will be available:

To delete a link/cross-reference:

1. Click 'Edit' on the section with the link.
2. Click anywhere inside the link text with your cursor:

3. Click the 'link' icon to unlink and revert to standard black text:



9.1.4 Sections and Subsections

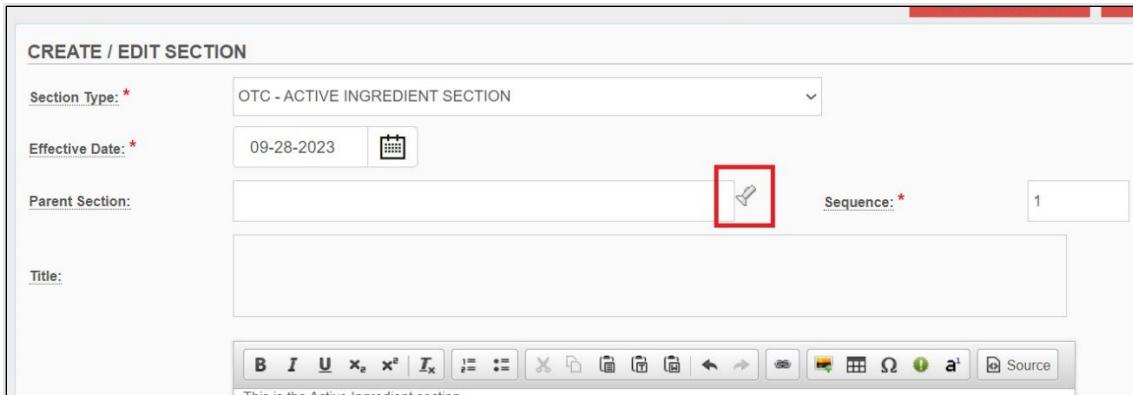
You can create subsections, and alter the positions of both sections and subsections in a product label.

To create a subsection:

1. On the Content of Labeling list page, click 'Edit' next to the section you want to become a subsection:



2. Select the 'flashlight' icon next to the 'Parent Section' field:



3. The Sections Hierarchy—an ordered list of all your label sections—will display in a new window:

SECTIONS HIERARCHY	
[1]	[OTC - ACTIVE INGREDIENT SECTION]
[2]	[DOSAGE FORMS & STRENGTHS SECTION]
[3]	[OTC - ACTIVE INGREDIENT SECTION]
[4]	[OTC - PURPOSE SECTION]

4. Click on the desired section. This section will become the parent section.
5. The window will close automatically and your selection will show up in the 'Parent Section' field. Click 'Apply' on the top right of the page:

CREATE / EDIT SECTION

Section Type: * OTC - ACTIVE INGREDIENT SECTION

Effective Date: * 09-28-2023

Parent Section: [OTC - ACTIVE INGREDIENT SECTION]

Sequence: * 1

DELETE SECTION **APPLY** << RETURN

6. You will be returned to the list page. Click the 'plus' icon on the parent section to view its new subsection:

EXPAND SECTIONS CLASSIC

(+) [OTC - ACTIVE INGREDIENT SECTION]

(-) [OTC - ACTIVE INGREDIENT SECTION]

(-) [OTC - ACTIVE INGREDIENT SECTION]

EXPAND SECTIONS CLASSIC

(-) [OTC - ACTIVE INGREDIENT SECTION]

(-) [OTC - ACTIVE INGREDIENT SECTION]

7. To reorder sections, simply click anywhere on a section then drag and drop it in the new location:

9.2 Searching and Filtering

How to use the search, filter, and sorting features of FDA Direct.

9.2.1 Search

To do a general search on your submissions:

1. Navigate your account main page by clicking the 'All Submissions' button or by clicking the FDA logo above the button:

- This page will list **all** submissions you have made since the creation of your account. Click on one of the submission types in the left menu to narrow down your search to a particular submission (ex: 'NDC Labeler Code Request')

2. Click the search area and type in your search term(s). You can type partial or full words, multiple words, and numbers/special characters.

The screenshot shows the 'All Submissions' page. On the left, there are two vertical navigation menus: 'ESTABLISHMENT REGISTRATION & DRUG LISTING' and 'OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING'. The main area is titled 'ALL SUBMISSIONS' with a sub-instruction: 'For assistance with validation errors contact the appropriate Help Desk: [cderdirect@fda.hhs.gov](#) (CDER Direct) or [cosmeticsdirect@fda.hhs.gov](#) (Cosmetics Direct). For general questions regarding electronic establishment registration and drug listing, contact [eDRLS@fda.hhs.gov](#). For questions regarding electronic registration and listing of cosmetic product facilities, contact [eRLC@fda.hhs.gov](#)'.

Below the instructions is a search bar with a dropdown menu, a text input field containing 'submission accepted', a 'GO' button, and an 'ACTIONS' button. Below the search bar is a table with columns: STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, DOCUMENT LABEL, LAST MODIFIED USER, LAST MODIFIED DATE, and a lock icon.

- **IMPORTANT:** This search bar does *not* search information within a submission. Only information displayed below the column headers is searchable.

3. Click 'Go' and your search term will be listed with the results populated below the column headers:

The screenshot shows the 'All Submissions' page with a search bar containing 'Row text contains "submission accepted"'. Below the search bar is a table with the same columns as the previous screenshot: STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, DOCUMENT LABEL, LAST MODIFIED USER, LAST MODIFIED DATE, and a lock icon. The table contains three rows of data, each representing a submission accepted.

4. You can search multiple terms at once to find your submission(s):

The screenshot shows the 'All Submissions' page with a search bar containing '!' and three search terms: '@direct', 'nov', and 'out of business'. Below the search bar is a table with the same columns as the previous screenshots. The table contains one row of data, representing a submission accepted with status 'SUBMISSION ACCEPTED'.

5. Uncheck the box beside search terms you do not want to use. Your search results will be updated immediately:

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE
SUBMISSION ACCEPTED	06fb25ba-b23c-92ab-e063-f95b40a8a24	09830409-54e0-dc80-e063-f95b40a7ed2	cd8976245130.6753108942@direct	4	OUT OF BUSINESS NOTIFICATION	Zee Dee	06-NOV-2023 15:59:53
SUBMISSION ACCEPTED	06fb25ba-b23c-92ab-e063-f95b40a8a24	098202ac-86d2-b6e0-e063-f95b40aaftb8	cd385461927.1478623950@direct	3	WITHDRAWAL OF WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT	Zee Dee	06-NOV-2023 15:07:52

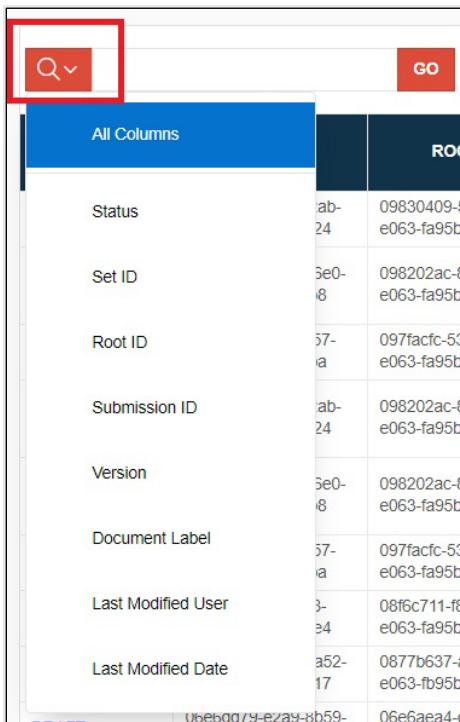
6. Click the 'x' beside a term to remove it completely:

Row text contains '@direct'
Row text contains 'out of business'

7. If you have multiple search terms taking up space, you can click the arrow to collapse them:

Q 4 @direct, nov, out of business, submission accepted

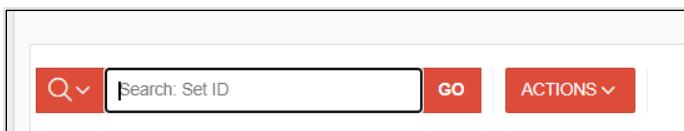
8. You can also search via a specific column header only. This is useful if you need to search by a set ID or root ID. Click the magnifying glass beside the search bar and list of the columns will display:



The screenshot shows a search interface with a red box highlighting the search dropdown menu. The table below lists various search results with columns for Status, Set ID, Root ID, Submission ID, Version, Document Label, Last Modified User, and Last Modified Date. The first row is highlighted in blue.

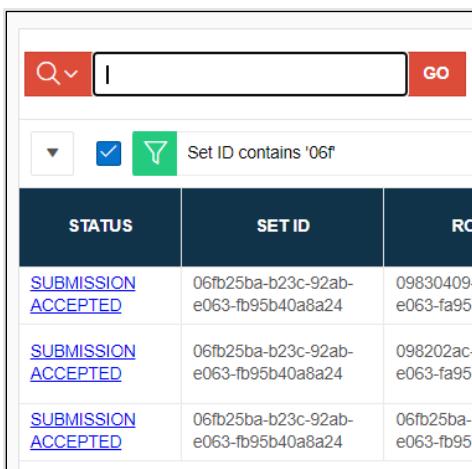
All Columns		Root ID
Status	ab-24	09830409-e063-fa95b
Set ID	5e0-8	098202ac-3e063-fa95b
Root ID	57-a	097facfc-53e063-fa95b
Submission ID	ab-24	098202ac-3e063-fa95b
Version	5e0-8	098202ac-3e063-fa95b
Document Label	57-a	097facfc-53e063-fa95b
Last Modified User	3-34	08f6c711-f8e063-fa95b
Last Modified Date	a52-17	0877b637-e063-fb95b
ubeb00/9-e2ay-kh59-		06e6aea4-1

9. Select one of the dropdown options. Your selection will now be reflected in the search bar:



The screenshot shows a search interface with a red box highlighting the search dropdown menu. The search bar contains the text 'Search: Set ID'.

10. Enter your search term and press 'Go.' Only the selected column header will be searched on:



The screenshot shows a search interface with a red box highlighting the search dropdown menu. The search bar contains the text 'I'. Below the search bar, a filter dropdown shows 'Set ID contains '06''. The table below lists search results with columns for STATUS, SET ID, and Root ID. The first row is highlighted in blue.

STATUS	SET ID	Root ID
SUBMISSION ACCEPTED	06fb25ba-b23c-92ab-e063-fb95b40a8a24	09830409-e063-fa95b
SUBMISSION ACCEPTED	06fb25ba-b23c-92ab-e063-fb95b40a8a24	098202ac-3e063-fa95b
SUBMISSION ACCEPTED	06fb25ba-b23c-92ab-e063-fb95b40a8a24	06fb25ba-1e063-fb95b

11. Search filters are cleared when you log out of FDA Direct.

9.2.2 Filters

Whenever you log in to FDA Direct, there is always a default column view:

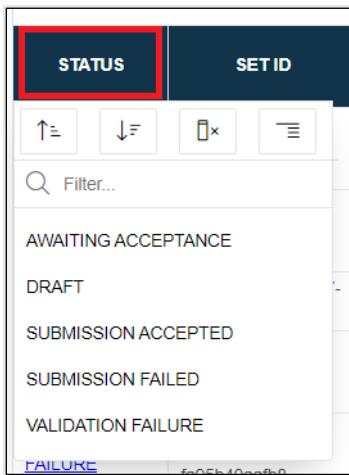
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	LOCK
--------	--------	---------	---------------	---------	----------------	--------------------	--------------------	------

1. Status: The current status of your submissions. For further explanation of the different status types, see Section 3.2: Submission Statuses.
2. Set ID: A 'Globally Unique Identifier' (GUID) that remains the same for each submission 'set,' which is a group of submission versions. When you submit a different version of a submission, the set ID stays the same through each new version.
3. Root ID: Root ID: A GUID that is generated uniquely for every single submission. When you create a new submission, the root ID is always different (unlike the set ID).
4. Submission ID: Unique identifier generated per submission. Also known as the 'Core ID.'
5. Version: A number greater than zero that provides a sequence to the versions of the document. A '1' in this column indicates that it is the first submission. Subsequent versions will increment upwards.
6. Document Label: The submission type. For example, 'Out of Business Notification' or 'Human OTC Drug Label.'
7. Last Modified User: The username of the person who last made changes to a submission.
8. Last Modified Date: The most recent date that changes were made to a submission.

9.2.2.1 Filtering on Column Header

You can click on any of the above headers directly to filter out submissions:

1. Clicking the '**Status**' header will display a dropdown of all status types tied to your submissions:

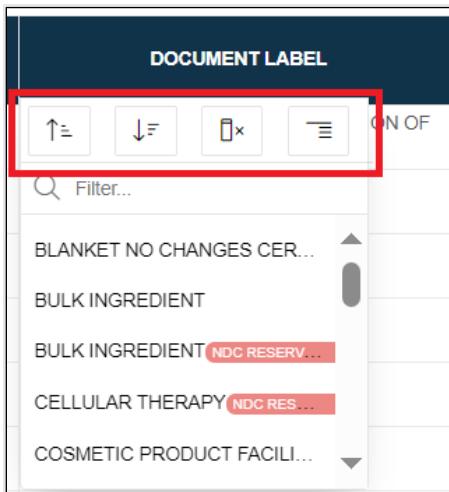


2. Select an option—Draft, for example—and all your submissions currently in that status will be displayed:

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	HEADER ID	🔒
DRAFT	097facfc-53b2-2e57-e063-fa95b40a0fba	097facfc-53b3-2e57-e063-fa95b40a0fba		1	COSMETIC PRODUCT FACILITY REGISTRATION	Zee Dee	06-NOV-2023 14:19:10	146783	
DRAFT	08fc7c11-f8f4-19d8-e063-fa95b40a3ee4	08fc7c11-f8f5-f9d8-e063-fa95b40a3ee4		1	ESTABLISHMENT REGISTRATION	Zee Dee	30-OCT-2023 17:32:46	146737	
DRAFT	0877b637-a4a9-8a52-e063-fb95b40a6617	0877b637-a4a9-8a52-e063-fb95b40a6617		1	BULK INGREDIENT <small>NDC RESERVATION</small>	Zee Dee	24-OCT-2023 13:42:20	146715	
DRAFT	0666d670-e2a9-b599-e063-fb95b40a65458	0666aee4-d70-943f-e063-fa95b40ae089		2	HUMAN OTC DRUG LABEL	Zee Dee	13-OCT-2023 10:13:48	146587	
DRAFT	ef952f04-b99e-4de7-ab02-c7175e5b-8d1a-7ed2-e053			2	BULK INGREDIENT	Zee Dee	12-OCT-2023	104150	

Options in the dropdown are pulled only from your data, so available options may differ from the example.

3. You can also use the dropdown buttons to further sort your data:

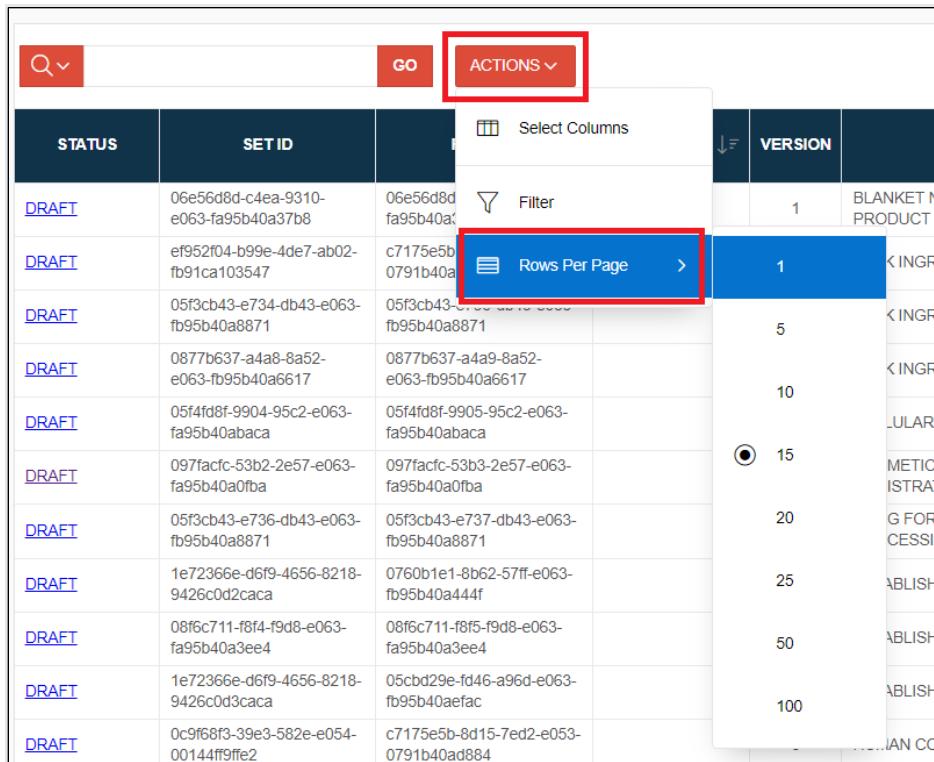


Icon	Description
↑	Sort ascending
↓	Sort descending
☒	Hide column
☰	Clearly separate each submission

9.2.3 Rows Per Page

To adjust the amount of submissions visible per page:

1. Click the 'Actions' button and select 'Rows Per Page':



The screenshot shows a table of submissions with columns for STATUS, SET ID, and VERSION. The 'Actions' button is highlighted with a red box. A dropdown menu is open, showing 'Rows Per Page' with a red box around it. The menu lists options: 1, 5, 10, 15 (selected), 20, 25, 50, 100, and -.

STATUS	SET ID	VERSION
DRAFT	06e56d8d-c4ea-9310-e063-fa95b40a37b8	06e56d8d-fa95b40a37b8
DRAFT	ef952f04-b99e-4de7-ab02-fb91ca103547	c7175e5b-0791b40a
DRAFT	05f3cb43-e734-db43-e063-fb95b40a8871	05f3cb43-c. 50 00 00 0000-fb95b40a8871
DRAFT	0877b637-a4a8-8a52-e063-fb95b40a6617	0877b637-a4a9-8a52-e063-fb95b40a6617
DRAFT	05f4fd8f-9904-95c2-e063-fa95b40abaca	05f4fd8f-9905-95c2-e063-fa95b40abaca
DRAFT	097facfc-53b2-2e57-e063-fa95b40a0fba	097facfc-53b3-2e57-e063-fa95b40a0fba
DRAFT	05f3cb43-e736-db43-e063-fb95b40a8871	05f3cb43-e737-db43-e063-fb95b40a8871
DRAFT	1e72366e-d6f9-4656-8218-9426c0d2caca	0760b1e1-8b62-57ff-e063-fb95b40a444f
DRAFT	08f6c711-f8f4-f9d8-e063-fa95b40a3ee4	08f6c711-f8f5-f9d8-e063-fa95b40a3ee4
DRAFT	1e72366e-d6f9-4656-8218-9426c0d3caca	05cbd29e-fd46-a96d-e063-fb95b40aefac
DRAFT	0c9f68f3-39e3-582e-e054-00144ff9ffe2	c7175e5b-8d15-7ed2-e053-0791b40ad884

2. You can choose to have 1-100 submissions viewable per page. The page will update immediately after your selection is made.
3. This view resets after you log out. You will need to redo Steps 1-2 when you log back in.