

U.S. Food and Drug Administration



USER'S GUIDE

to FDA Direct

July 2024

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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/>

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](#)

WELCOME TO FDA DIRECT

FDA Direct is U.S. Food and Drug Administration's web-based and free structured product labeling (SPL) authoring tool. Previously CDER Direct, FDA Direct now includes CDER Direct and Cosmetics Direct. Users can create separate accounts, depending on drugs or cosmetics submissions, or a single account that includes both CDER Direct submissions as well as Cosmetics Direct submissions.

CDER Direct

CDER Direct allows users to easily create and submit data directly to the FDA. This system will provide information to FDA/CDER about drug manufacturers and private label distributors, outsourcing facilities, wholesale drug distributors and third-party logistics, and generic drug facilities, along with their drugs in U.S. commercial distribution. CDER Direct has several sections which allows submission of the following data to the FDA: Establishment Registration and Drug Listing, including NDC Labeler Code Requests and NDC Reservations, Outsourcing Facility and Product Reporting, DSCSA Annual Reporting, and Generic Drug Self-Identification.

Cosmetics Direct

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. [Click here](#) to learn more about 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/Office of Cosmetics and Colors (OCC) about cosmetic product manufacturers/processors 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 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/>.

WARNING: 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 all devices/storage media attached to this system. This system is provided to 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. At any time, and for any lawful Government purpose, the Government may monitor, record, and audit your system use and/or intercept, search and seize any communication or data transmitted or stored on this system. Therefore, you have no reasonable expectation of privacy. Any communication or data transmitted or stored on this system may be disclosed or used for any lawful Government purpose.

FDA Home | Browser Requirements | Resources | Tutorials | CDER Direct Help Desk | Cosmetic Direct Help Desk | FAQs
Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy

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](#)

- 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.

- 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.**

- 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

☒ **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 GDUFA SELF-IDENTIFICATION

☒ **COSMETIC REGISTRATION AND LISTING**

- REGISTRATION OF COSMETIC PRODUCT FACILITY
- COSMETIC PRODUCT LISTING

- 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.

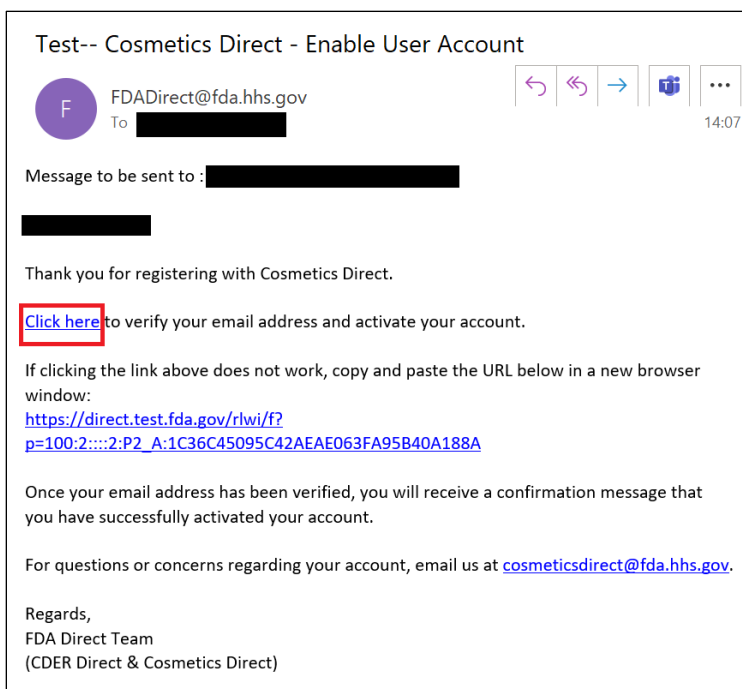
If you still have not received your activation email after 5-10 minutes, you can contact the Help Desk at:

- 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:

Username 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:

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:

FDA Direct
CDER Direct & Cosmetics Direct

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

LOGIN

Username:
[Redacted]

Password:
[Redacted]

[Forgot your password?](#)

☐ I accept the Terms of Service

LOGIN

OR

CREATE NEW ACCOUNT

WELCOME TO FDA DIRECT

FDA Direct is U.S. Food and Drug Administration's web-based and free system for submitting drug and cosmetic data to the FDA. FDA Direct now includes CDER Direct and Cosmetics Direct. Users can create separate accounts for each type of submission, or a single account that includes both CDER Direct submissions and Cosmetics Direct submissions.

CDER Direct

CDER Direct allows users to easily create and submit data directly to the FDA for drug submissions. CDER Direct is used by drug manufacturers and private label distributors, outsourcing facilities, wholesalers, and their drugs in U.S. commercial distribution. CDER Direct has several features, including: Establishment Registration and Drug Listing, including NDC Labeler Product Reporting, DSCSA Annual Reporting, and Generic Drug Self-Identification.

Cosmetics Direct

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (MoCRA). Among other things, MoCRA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishing requirements for cosmetic product registration and listing. Section 607(a) of the FD&C Act requires every person that owns or operates a facility that manufactures, processes, packs, or distributes a cosmetic product for distribution in the United States to register each facility and list each cosmetic product. The responsible person must submit to FDA a cosmetic product registration and listing. Certain cosmetic products, including over-the-counter drugs, are exempt from the registration and listing requirements. [Click here for more information.](#)

This free tool allows you to create and submit the following types of data: Drug Data, Cosmetic Product Listing. This system will provide information to FDA/Office of Regulatory Affairs, manufacturers/processors and cosmetic products on the market.

Note: Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by the ADA Amendments Act of 2008 (42 U.S.C. 12182) requires that this system be accessible to individuals with disabilities.

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

FDA Direct
CDER Direct & Cosmetics Direct

LOGIN

Username:
[Redacted]

Password:
[Redacted]

[Forgot your password?](#)

☒ I accept the Terms of Service

LOGIN

OR

CREATE NEW ACCOUNT

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

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.

i 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 transiting 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 transiting or stored on this system. Any communication or data transiting 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**

- 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:

FDA Direct
CDER Direct & Cosmetics Direct

VERIFY EMAIL ADDRESS

FDA Direct will begin using Multi Factor Authentication (MFA) in corresponding login attempts for added account security.

Please enter the One Time Passcode (OTP) sent to [redacted]@fda.hhs.gov. The OTP will be 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]

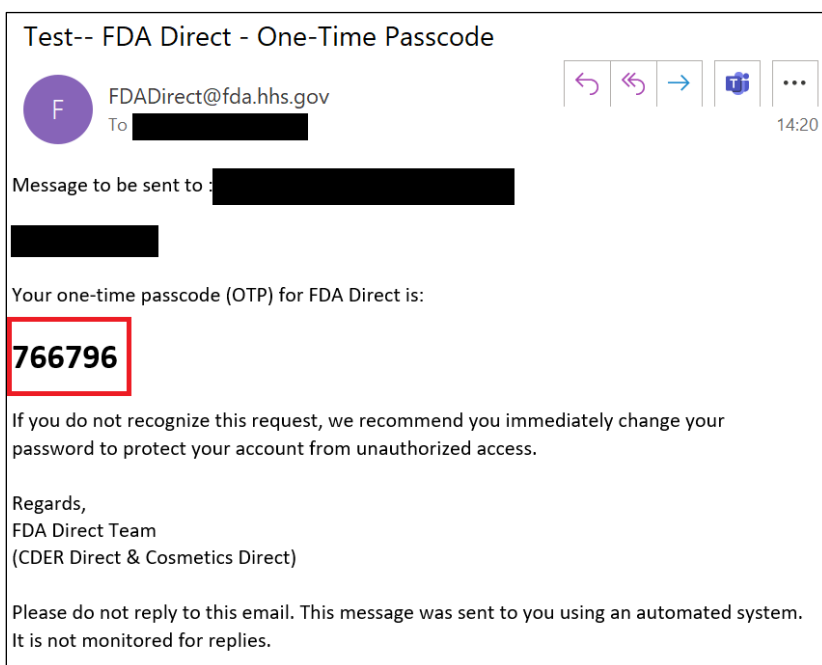
Contact Email: [redacted]@fda.hhs.gov Select the Pencil Icon ONLY if you need to change the email address associated with this username.

One-Time Passcode (OTP): [redacted]

SUBMIT **CANCEL**

***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.



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

The screenshot shows a login form with two main input fields. The first field is labeled 'Contact Email:' and contains a redacted email address followed by '@fda.hhs.gov'. To the right of this field is a small icon of a red pencil and the text 'Select the P'. The second field is labeled 'One-Time Passcode (OTP):' and is empty. Below these fields are two buttons: a dark blue 'SUBMIT' button and a red 'CANCEL' button.

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

The screenshot shows a dark blue dialog box titled 'PAPERWORK REDUCTION ACT NOTICE'. Below the title, it displays 'MB Control No. 0910-0599' and 'Expiration Date: December 31, 2026'. The main body of text explains the public reporting burden for this collection of information, estimated to average between 15 to 60 minutes per response. It includes contact information for the Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, Paperwork Reduction Act (PRA) Staff, with the email PRStaff@fda.hhs.gov. A note states that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. A 'PLEASE NOTE' section states: 'The system will automatically time out if there is no activity for 30 minutes.' At the bottom right, there is a white 'OK' button.

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.

The screenshot shows the FDA Direct Cosmetics Direct dashboard. The header includes the FDA logo and 'FDA Direct Cosmetics Direct'. Below the header, there is a navigation bar with 'All Submissions' selected. On the left, there are two main sections: 'COSMETIC REGISTRATION AND LISTING' with links for 'Registration of Cosmetic Product Facility' and 'Cosmetic Product Listing', and 'ESTABLISHMENT REGISTRATION & DRUG LISTING' with a link for 'Establishment Registration'. The main content area is titled 'ALL SUBMISSIONS' and includes a search bar with a magnifying glass icon, a 'GO' button, and an 'ACTIONS' dropdown menu. Below the search bar, the text 'None' is displayed.

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**'.

The screenshot shows the FDA Direct login interface. A central warning banner is displayed over the login form. The banner contains the following text:

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 transiting 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 transiting or stored on this system. Any communication or data transiting 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.

At the bottom of the banner are two buttons: **CLOSE** and **I AGREE**.

The background login form includes fields for Username and Password, a 'Forgot your password?' link, an 'Accept the Terms of Service' checkbox, and 'LOGIN' and 'CREATE NEW ACCOUNT' buttons. Quick links for Resources, Tutorials, FAQs, Direct Help Desk, and Cosmetic Direct Desk are visible at the bottom.

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:

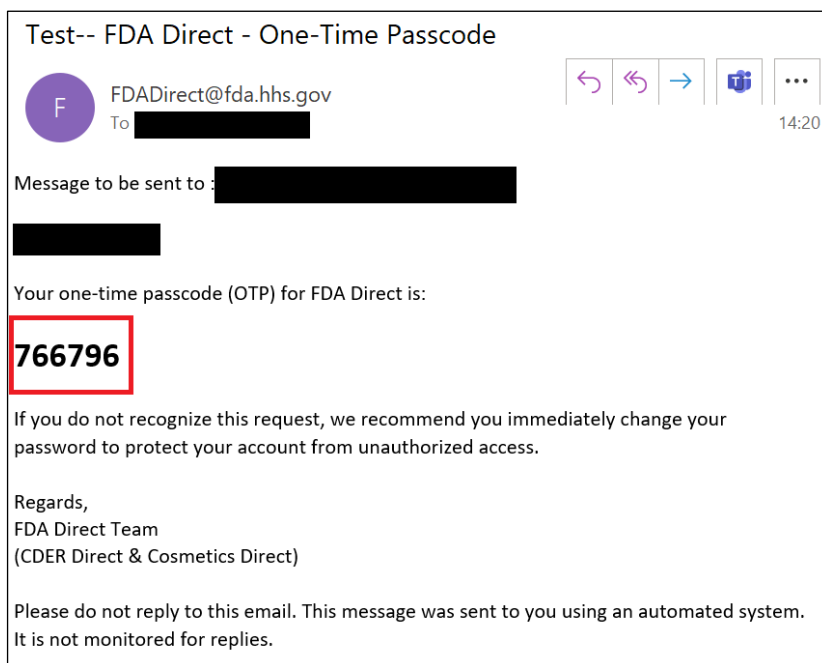
The screenshot shows the 'VERIFICATION CODE' page. It contains the following information:

A one-time passcode (OTP) has been sent to [redacted]@fda.hhs.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.

Below the note are input fields for Username and One-Time Passcode (OTP). There is also a checkbox for 'Remember this Device for 8 hours'. At the bottom are **SUBMIT** and **CANCEL** buttons.

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*':

One-Time Passcode (OTP):

☐ Remember this Device for 8 hours

SUBMIT **CANCEL**

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.

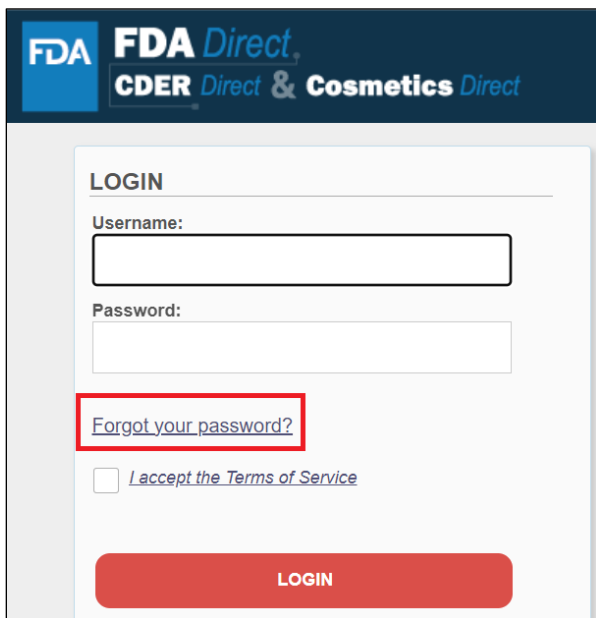
6. Click '**Submit.**' You will then be taken to your account main page.
7. If you have a Cosmetics account or a Combined account, a Paperwork Reduction Act (PRA) banner will display. Click '**OK**' to continue.

You are now logged in to your account.

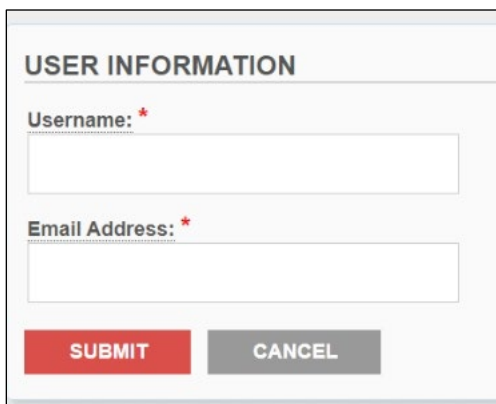
2.3.1 Forgot Password

If you forgot your password, do the following:

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



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



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](#)

- 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.

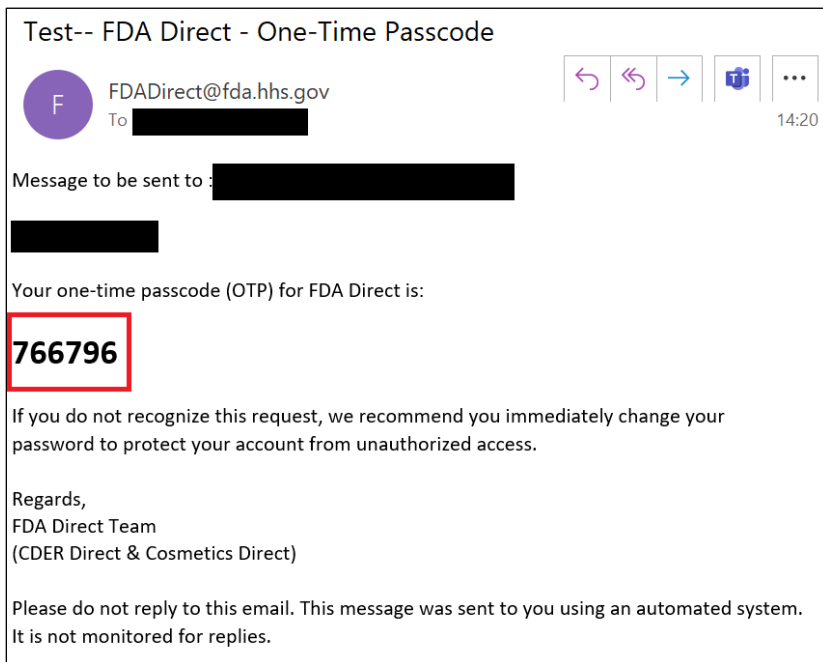
Username: * [redacted]

Email Address: * [redacted]

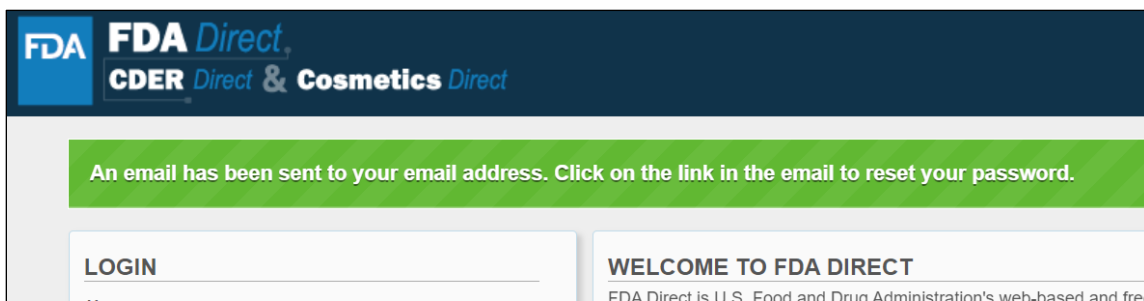
One-Time Passcode (OTP):

SUBMIT **CANCEL**

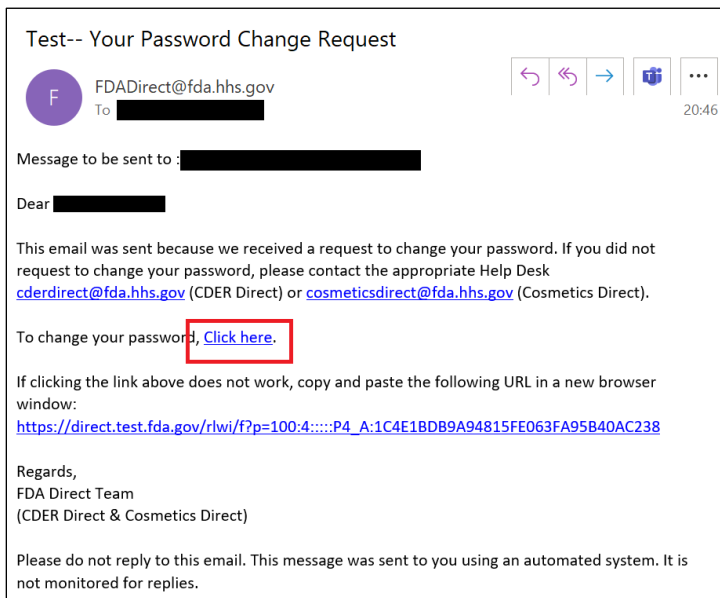
- Check your email address for the OTP. If you have not received an email after several minutes, you can click the '**Request New Passcode**' link (shown above) to send another code.



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



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



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

CHANGE PASSWORD

Username: * [Redacted]

New Password: * [Text Box]

Confirm Password: * [Text Box]

SAVE

Password must be at least 15 characters and no more than 32 characters. It must include a capital letter, a lowercase letter, a number, and a special character.

8. Another confirmation will display:

FDA Direct
CDER Direct & Cosmetics Direct

The password has been successfully changed. Please log in with your Username and Password.

LOGIN

Username: [Text Box]

Password: [Text Box]

WELCOME TO FDA DIRECT


FDA Direct is U.S. Food and Drug Administration's web-based and free FDA Direct now includes CDER Direct and Cosmetics Direct. Users can submit submissions, or a single account that includes both CDER Direct sub...

CDER Direct

CDER Direct allows users to easily create and submit data directly to manufacturers and private label distributors, outsourcing facilities, wh...


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  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:



One-Time Passcode (OTP):

☐ 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:

All Submissions

COSMETIC REGISTRATION AND LISTING
Registration of Cosmetic Product Facility
Cosmetic Product Listing

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

SELF HELP
Structured Product Labeling Resources
UNII Search
Request UNII
DUNS Search
FEI Search Portal
Registration and Listing of Cosmetic Product Facilities and Products Industry Guidance
Tutorials

MANAGE ACCOUNT
Edit User Profile
Manage Users

ALL SUBMISSIONS
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.

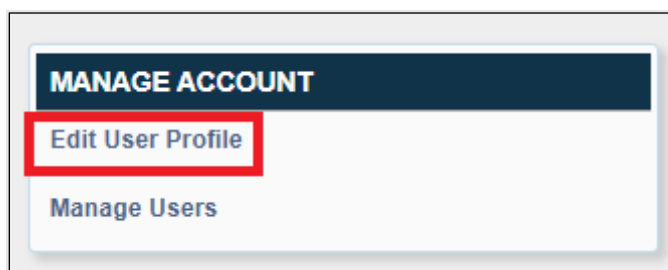
Q **GO** **ACTIONS** ▾

None

- 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:

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 but requested if you create only a Cosmetics Direct account.

****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 but requested if you create only a Cosmetics Direct account.

CONTACT INFORMATION

First Name: *

Middle Name:

Last Name: *

Job Title:

Contact Email: *

CONTACT PHONE

Country Code: *

Phone Number: *

Extension:

CHANGE PASSWORD

Username: *

Password: * [Change Password](#)

ORGANIZATION INFORMATION

Name: *

DUNS: *

ORGANIZATION ADDRESS

Country: *

Street Address: *

City: *

State: *

Postal Code: *

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

☒ **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

☒ **COSMETIC REGISTRATION AND LISTING**

- REGISTRATION OF COSMETIC PRODUCT FACILITY
- COSMETIC PRODUCT LISTING

SUBMIT
CANCEL

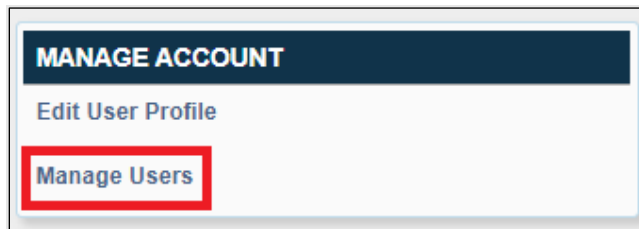
Click **'Submit'** to finalize all changes made, or **'Cancel'** to abandon your changes.

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:

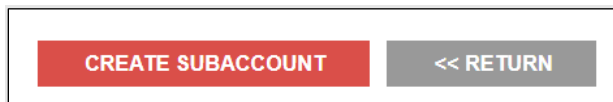


If you have already created subaccounts, they will display in a list. Otherwise, the page will be empty:



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: *	<input type="text"/>	User Role: *	USER ▾	Country Code: *	-Select Country Phone Code- ▾
Middle Name:	<input type="text"/>	Job Title:	<input type="text"/>	Phone Number: *	<input type="text"/>
Last Name: *	<input type="text"/>	Contact Email: *	<input type="text"/>	Extension:	<input type="text"/>

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

User Role: *

Username:

Job Title:

USER ▾

USER
ADMIN

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.

☒ **COSMETIC REGISTRATION AND LISTING**

- 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.

☒ **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

☒ **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 GDOFA SELF-IDENTIFICATION

☒ **COSMETIC REGISTRATION AND LISTING**

- REGISTRATION OF COSMETIC PRODUCT FACILITY
- COSMETIC PRODUCT LISTING

SUBMIT **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

Q **GO** **ACTIONS** **CREATE SUBACCOUNT** **<< RETURN**

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

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@lighthouseilc.com	+90-90-111-111-11

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: * USER Country Code: * -Select Country Phone 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:

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.

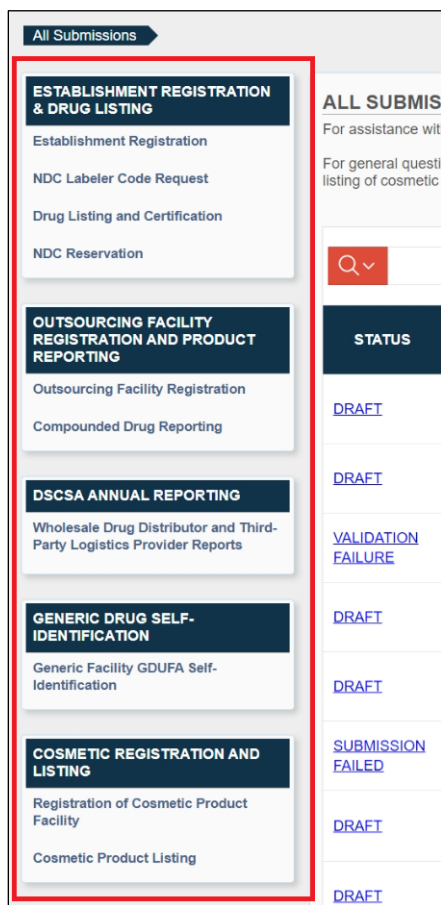
- Make any necessary changes, then return to the top and click **'Submit.'**

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:

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



- b. Click 'Create New/Upload File':

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

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

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

- 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
 - CDERFacility@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			
<u>Document Type:</u> *	HUMAN OTC DRUG LABEL	<u>Version Number:</u> *	1
<u>Set ID:</u> *	0ac4630f-6fa2-a749-e063-fa95b40a3a84	Generate New	<u>Effective Date:</u> * 11-22-2023 
<u>Root ID:</u> *	0ac4630f-6fa3-a749-e063-fa95b40a3a84	Generate New	

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			
<u>NDC Product Code:</u> *		<u>Proprietary Name:</u> *	
<u>Non Proprietary Name:</u> *		<u>Suffix:</u>	
		<u>DEA Schedule:</u>	-- Select DEA Schedule -- ▾
<u>Dosage Form:</u> *	-Select Dosage Form- ▾		

The screenshot shows a form titled "PRODUCT DATA ELEMENTS" with three input fields: "NDC Product Code: *", "Non Proprietary Name: *", and "Dosage Form: *". A tooltip titled "NDC Product Code" is open, providing a detailed explanation of the NDC (National Drug Code) and its structure. The tooltip text states: "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 provided are "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.

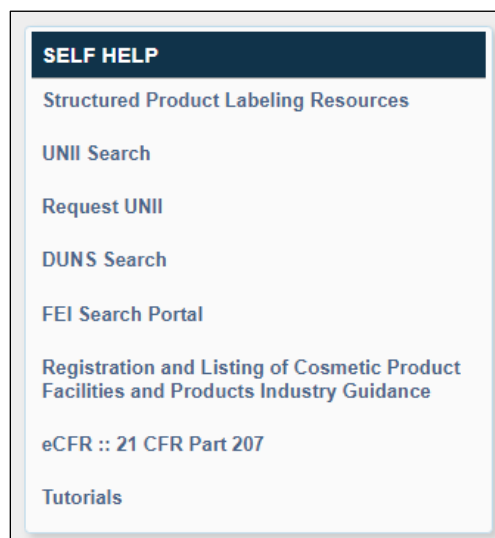
Tutorials will show you how to complete specific actions like creating an account or submitting a drug product listing. They are less detailed than this User Guide, and in slideshow format. Recommended for users familiar with FDA Direct who may want a quick refresher.

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

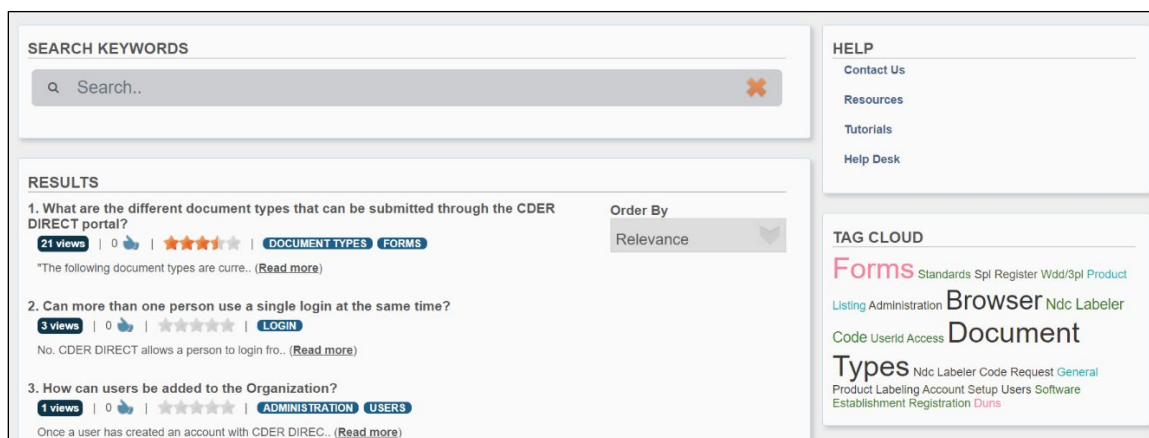
- a. In the *Quick Links* section below the login area on the [FDA Direct homepage](#):

The screenshot shows the FDA Direct login page. At the top is the header "FDA Direct CDER Direct & Cosmetics Direct". Below this is a "LOGIN" section with fields for "Username:" and "Password:". There is a link for "Forgot your password?" and a checkbox for "I accept the Terms of Service". A red button labeled "LOGIN" is below the password field. Below the login button is the word "OR". Below "OR" is a dark blue button labeled "CREATE NEW ACCOUNT". A red arrow points from the "CREATE NEW ACCOUNT" button down to a "Quick Links" section. The "Quick Links" section is enclosed in a red box and contains the following 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).



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).

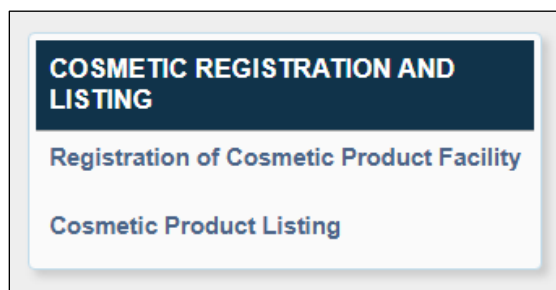
4 COSMETIC REGISTRATION AND LISTING

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:

The screenshot shows the FDA Direct Cosmetics Direct interface. On the left is a navigation menu with options like 'All Submissions', 'Registration of Cosmetic Product Facility', 'Cosmetic Registration and Listing', and 'Cosmetic Product Listing'. The main content area is titled 'REGISTRATION OF COSMETIC PRODUCT FACILITY' and includes a search bar, a 'GO' button, an 'ACTION' dropdown, and a 'CREATE NEW / UPLOAD FILE' button.

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

A close-up of the 'CREATE NEW / UPLOAD FILE' button, which is a dark blue rectangle with white text.

You will be given two options:

The screenshot shows a form titled 'CREATE NEW REGISTRATION OF COSMETIC PRODUCT FACILITY'. It contains two radio button options: 'Create a new Cosmetic Product Facility Registration using a blank form' (which is selected) and 'Import an existing Cosmetic Product Facility Registration SPL'. Below the options 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.

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

This screenshot is identical to the previous one, showing the 'CREATE NEW REGISTRATION OF COSMETIC PRODUCT FACILITY' form with the 'Create a new Cosmetic Product Facility Registration using a blank form' option selected.

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

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.

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

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:

- 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.

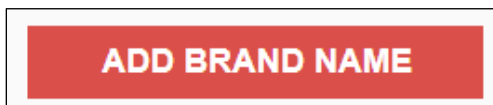
9. Fill in all the blank fields in the U.S. Agent Contact Information section (for foreign facilities):

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



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

- 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:



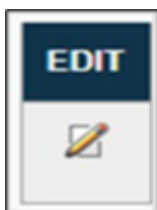
15. The platform will return to the SPL Submission page with the verification banner 'Product brand saved.'



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) - (e) Rinses (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)

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:

- Date: (Optional field) Enter today's date, two-digit month, two-digit day, and four-digit year.
- 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](#).

☐ I Agree

Date



Name of Submitter

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:

Phone Number
(Include Country/Area Code):

Email:

Phone Extension:

- 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
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- 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'**.

STATUS
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."

U.S. Department of Health & Human Services

FDA Direct
Cosmetics Direct

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.

All Submissions **Registration of Cosmetic Product Facility**

COSMETIC REGISTRATION AND LISTING
Registration of Cosmetic Product Facility
Cosmetic Product Listing

ESTABLISHMENT REGISTRATION & DRUG LISTING
Establishment Registration
NDC Labeler Code Request
Drug Listing and Certification
NDC Reservation

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.

Q GO ACTIONS

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

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.](#)

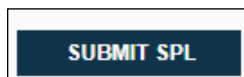
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT TYPE
READY FOR SUBMISSION	0c066ca6-f8da-b44d-e063-6a94af0ab7ab	0c066ca6-f8da-b44d-e063-6a94af0ab7ab		1	FACILITY NAME	1234567890	-	COSMETIC FACILITY REGISTRATION

- 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:

- 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.'

4.3.2 Submit SPL to FDA

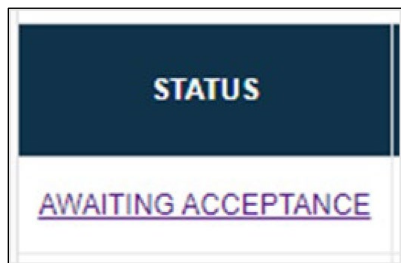
1. Click 'SUBMIT SPL' if you are ready to submit your SPL to FDA.



- 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."



- b. 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								
<input type="text"/> <input type="button" value="GO"/> <input type="button" value="ACTIONS"/>								
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

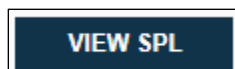
2. Click on **'SUBMISSION ACCEPTED'** to **VIEW SPL** and **DOWNLOAD SPL**.
 - a. To clone and create a new version of your successfully submitted SPL, click **'CREATE A NEW VERSION'**



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	Generate New	Version Number:
Root ID:	0c06eb2a-30c9-7866-e063-6b94af0af38e	Generate New	Effective Date:
			2
			12-08-2023

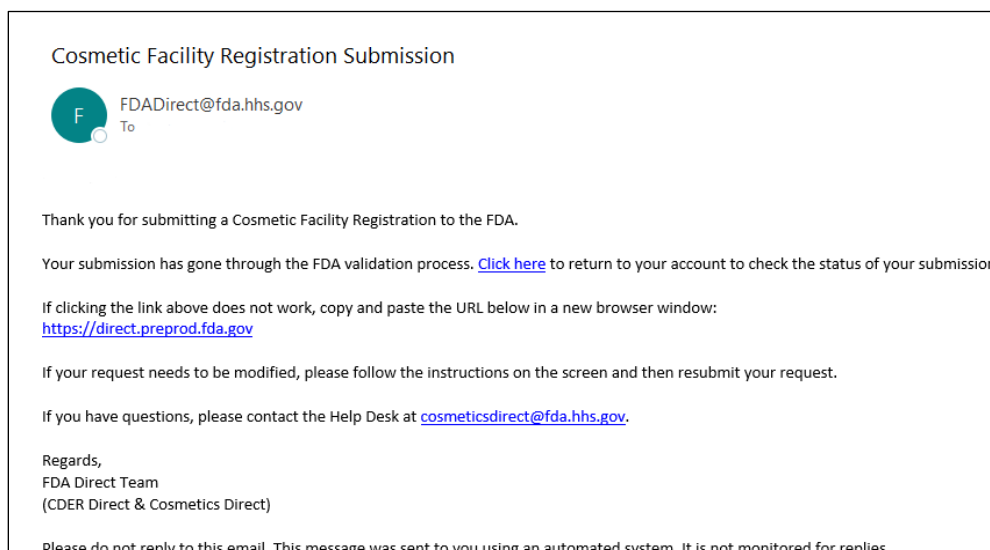
- b. To view your SPL, click '**VIEW SPL**'



- 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.



- 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-f8da-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.

2 ERRORS HAVE OCCURRED ✕

- Telephone numbers must have any extensions separated by ".ext=" (see Uniform Resource Identifier (URI) for Telephone Numbers RFC 3966). [\(Go to error\)](#)
- US telephone numbers must have the format +1-aaa-bbb-cccc where "aaa" must be the area code, and "bbb-cccc" the usual digit grouping of a local phone number. [\(Go to error\)](#)

- 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**.

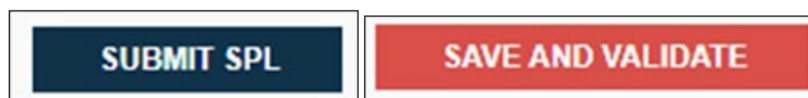
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT TYPE
VALIDATION FAILURE	0c066ca6-f8da-b44d-e063-6a94af0ab7ab	0c066ca6-f8db-b44d-e063-6a94af0ab7ab		1	FACILITY NAME	1234567890	-	COSMETIC FACILITY REGISTRATION

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

2 ERRORS HAVE OCCURRED ✕

- Enter a valid Facility Phone Number. The phone number format should be <CountryCode>-<AreaCode>-<SubscriberNumber> [\(Go to error\)](#)
- Facility Zip/Postal Code should be 5 digits with optionally a dash followed by 4 digits. [\(Go to error\)](#)

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

Set ID: *
.....

Root ID: *
.....

COSMETIC FACILITY REGISTRATION

--Select One--

COSMETIC FACILITY REGISTRATION

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: *
.....

Set ID: *
.....

Root ID: *
.....

COSMETIC FACILITY REGISTRATION - CANCELLATION

--Select One--

COSMETIC FACILITY REGISTRATION

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.



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: *
.....

Set ID: *
.....

Root ID: *
.....

COSMETIC FACILITY REGISTRATION - CANCELLATION ▼

--Select One--

COSMETIC FACILITY REGISTRATION

COSMETIC FACILITY REGISTRATION - ABBREVIATED RENEWAL

COSMETIC FACILITY REGISTRATION - AMENDMENT

COSMETIC FACILITY REGISTRATION - BIENNIAL RENEWAL

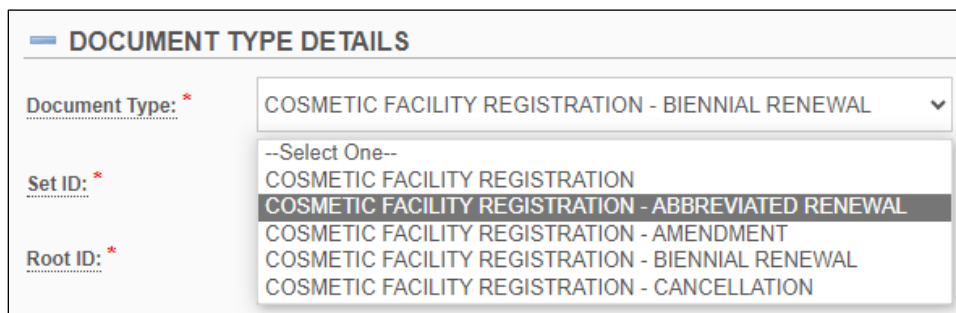
COSMETIC FACILITY REGISTRATION - CANCELLATION

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

4.3.9 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.

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



DOCUMENT TYPE DETAILS

Document Type: *
.....

Set ID: *
.....

Root ID: *
.....

COSMETIC FACILITY REGISTRATION - BIENNIAL RENEWAL

--Select One--

COSMETIC FACILITY REGISTRATION

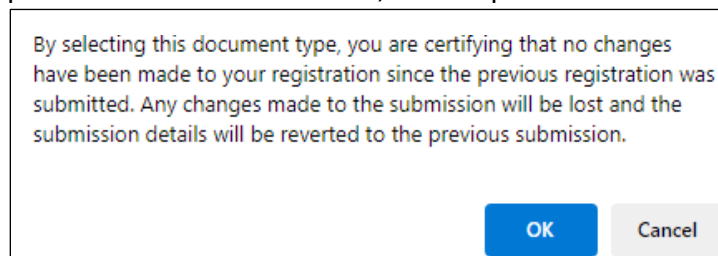
COSMETIC FACILITY REGISTRATION - ABBREVIATED RENEWAL

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, 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

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 request to FDA.

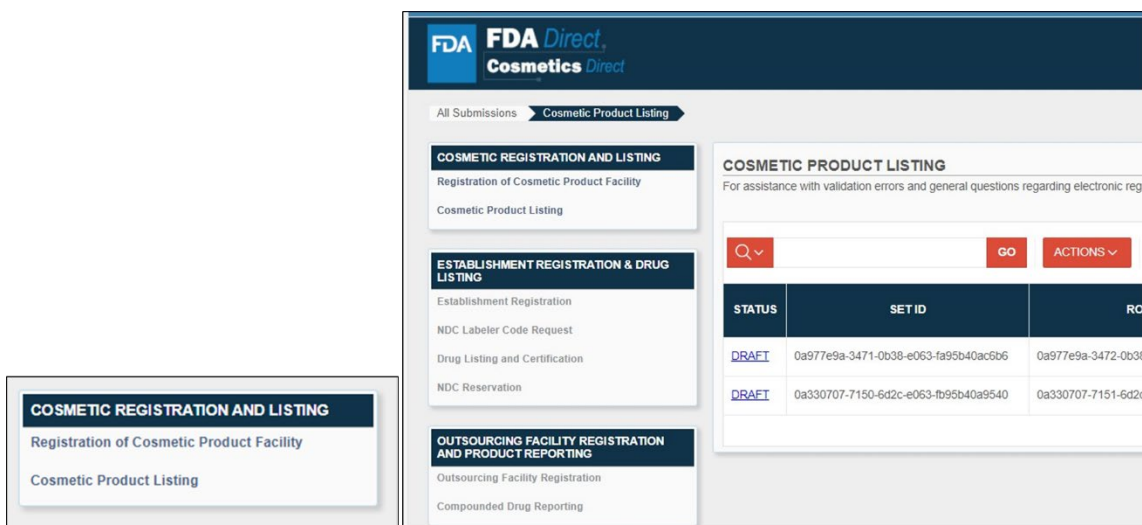


SUBMIT SPL

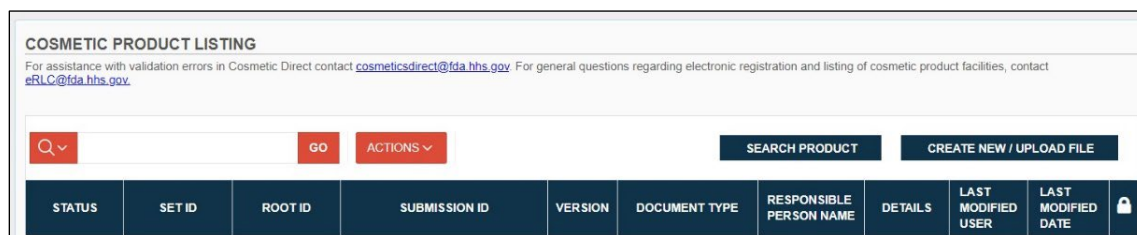
4.4 Cosmetics Product Listing

4.4.1 New Cosmetics Product Listing

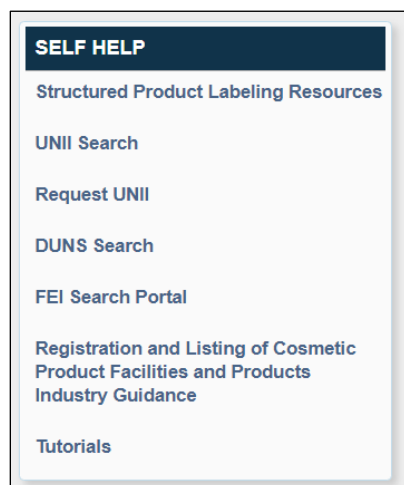
1. Log in to FDA Direct.
2. Select '**Cosmetic Product Listing**' under *Cosmetic Registration and Listing* section, on the left side of the FDA Direct menu.



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.



- 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**.



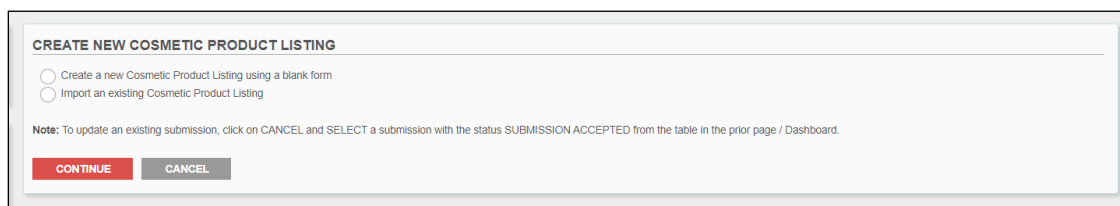
PLEASE NOTE: For assistance with validation errors in Cosmetic Direct contact cosmeticsdirect@fda.hhs.gov. For general questions regarding electronic registration and listing of cosmetic product facilities, contact eRLC@fda.hhs.gov.

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.

2. 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.

- a. 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 (UNIIIs)
 - **PLEASE NOTE:** For more information and to search for UNIIIs 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:

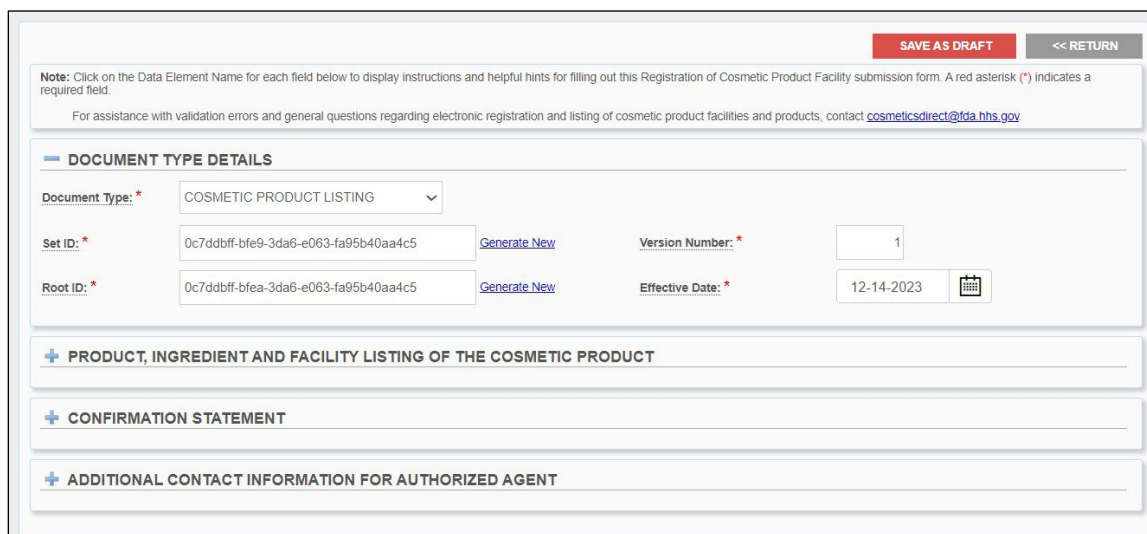
6. Enter the required information as indicated by red asterisk (*) throughout the submission process.
 - a. **PLEASE NOTE:** For assistance with validation errors in Cosmetic Direct contact CosmeticsDirect@fda.hhs.gov. For general questions regarding electronic registration and listing of cosmetic product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



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 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


DOCUMENT TYPE DETAILS

Document Type: * COSMETIC PRODUCT LISTING

Set ID: * 0c7ddbff-bfe9-3da6-e063-fa95b40aa4c5 [Generate New](#)

Version Number: * 1

Root ID: * 0c7ddbff-bfe9-3da6-e063-fa95b40aa4c5 [Generate New](#)

Effective Date: * 12-14-2023 

+ 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: * 0c7ddbff-bfe9-3da6-e063-fa95b40aa4c5 [Generate New](#)

Version Number: * 1

Root ID: * 0c7ddbff-bfe9-3da6-e063-fa95b40aa4c5 [Generate New](#)

Effective Date: * 12-14-2023 

- 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.

Document Type

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.

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**.

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.

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.

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

DOCUMENT TYPE DETAILS

Document Type: *
COSMETIC PRODUCT LISTING

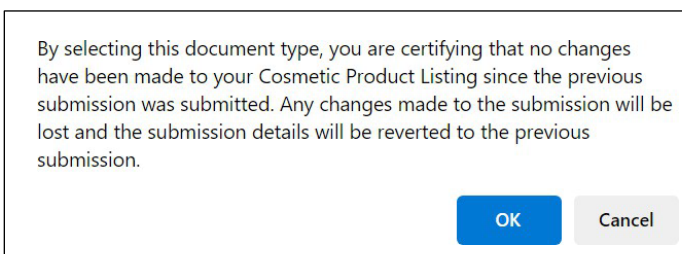
Set ID: *
--Select One--
COSMETIC PRODUCT LISTING
COSMETIC - UPDATE
COSMETIC - ABBREVIATED RENEWAL
0C7d0b11-d1ea-3da0-e063-1a95b40aa4c0

Root ID: *

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”*.



- **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 

- 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
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- **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
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- **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 type="checkbox"/> No	
Responsible Person (as listed on label):	Type of Business: <input 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 PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)	
Add all required information by selecting 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)?: ☐ Yes ☐ No

Responsible Person (as listed on label):

Type of Business: ☐ MANUFACTURER ☐ PACKER ☐ DISTRIBUTOR

Responsible Person Name (as listed on label): *

Parent Company Name (if applicable):

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

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:

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

+ INGREDIENTS

+ LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

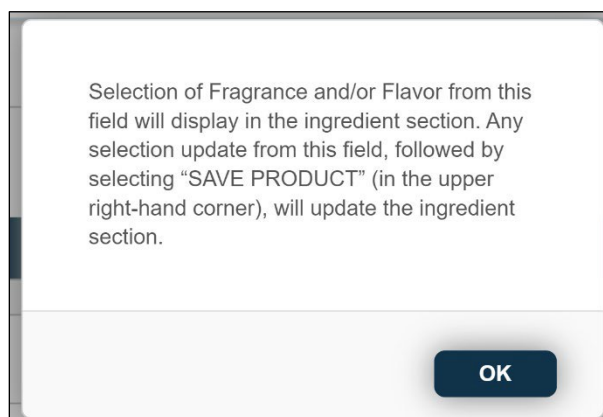
+ PRODUCT IMAGES

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.

- a. 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 ACCPETED 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:



- 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:



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

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

SAVE CATEGORIES **<< RETURN**

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/guidance-for-industry)

- + (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

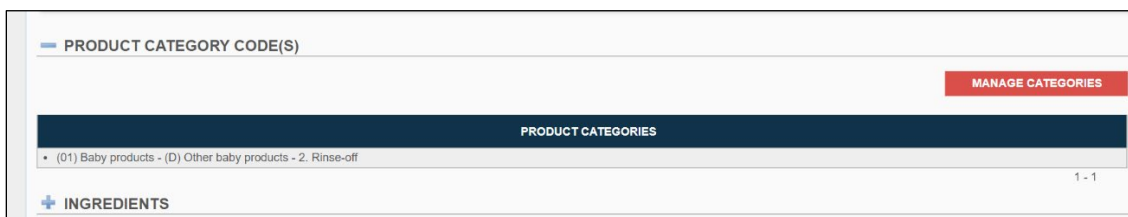
- ☐ 1. Leave-on
- ☐ 2. Rinse-off

- (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>

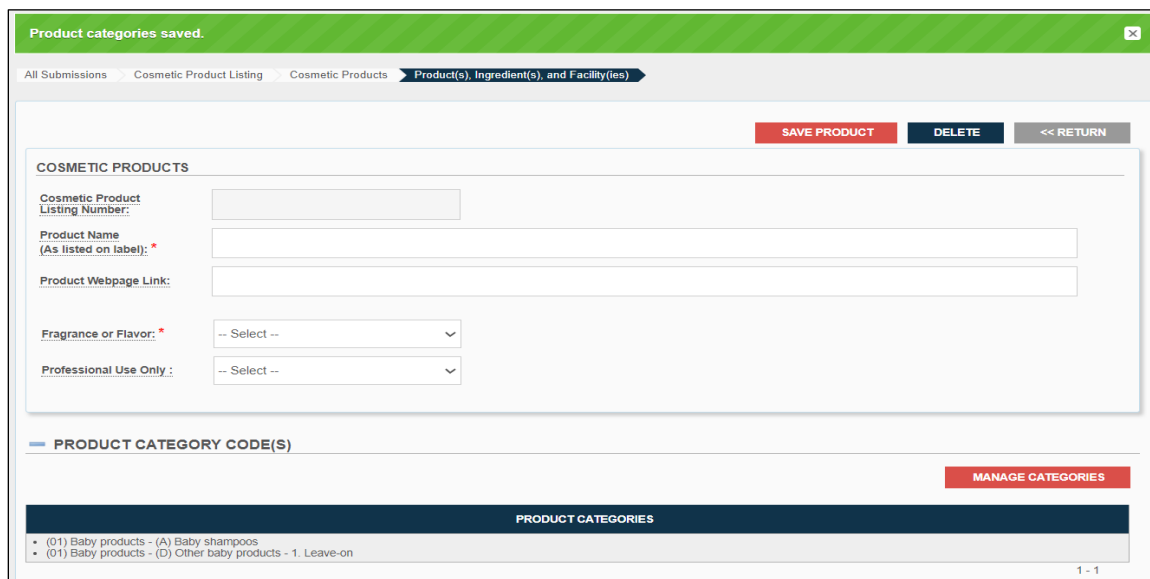
- c. **PLEASE NOTE:** Any combination can be selected, EXCEPT leave-on and rinse-off (one or the other may be selected). However, if sub-product category has been selected, then a sub-sub product category must be selected.
5. Once completed Click '**SAVE CATEGORIES**', located at the top right of the page:



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:



- 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.



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(es)**

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)

— 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(es) **Cosmetic Ingredients**

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-Name: * ADD

✍	INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)	≡
✖			1

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:

Product Name (As listed on label): *

Product Webpage Link:

Fragrance or Flavor: *

Fragrance & Flavor

Professional Use Only :

-- Select --

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 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-Name: *

Search Ingredients

ADD

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

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

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 prefilled 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**

(059QF0K00R) WATER
(5W66YHS8PH) WATER YAM
(63M8RYN44N) WATER O-15
(231473QB6R) WATERMELON
(K5877MW0LE) WATERCRESS
(7QV8F8BYNJ) WATER O-18
(0A4PW6CRAI) WATER BUFFALO
(267FSY81NT) COCONUT WATER
(195AAT2V0N) WATERMELON CIDER

UPLOAD INGREDIENTS

Note: To download a template ingredients list, UNII should be entered in the field below. Any update regarding Fragrance will automatically update the ingredient list.

Drag and Drop

Select a file or drop ingredients here

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-Name: **ADD**

	INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)	
		FLAVOR	1
		FRAGRANCE	2
	059QF0K00R	WATER	3

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)	
059QF0K00R	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:

Product Name (As listed on label): *

Product Webpage Link:

Fragrance or Flavor: *

Professional Use Only:

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)	
059QF0K00R	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)	
059QF0K00R	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-Name: ADD

<input checked="" type="checkbox"/>	INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)	
		FLAVOR	1
		FRAGRANCE	2
✖	059QF0K00R	WATER	3

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

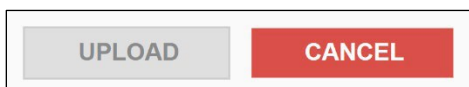
	INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME
1		
2	059QF0K00R	WATER
3		FLAVOR
4		FRAGRANCE
5		
6		
7		

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

- a. **PLEASE NOTE:** DO NOT enter CAS numbers instead of UNII's. 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:



A screenshot of the "UPLOAD INGREDIENT FILE" section. At the top right is a red button labeled "DOWNLOAD CURRENT INGREDIENT LIST". Below the title, there is a note: "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. UNIs should be entered in the first column and ingredient names in the second column. Please do not enter CAS numbers instead of UNIs. CAS numbers will not be recognized by the system." Below the note is a sub-note: "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." In the center, there is a "Drag and Drop" area with a folder icon and the text "Select a file or drop one here." At the bottom are two buttons: a grey "UPLOAD" button and a red "CANCEL" button.

- 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:



A screenshot of the "INGREDIENTS" section. At the top, there is a breadcrumb trail: "All Submissions > Cosmetic Product Listing > Cosmetic Products > Product(s), Ingredient(s), and Facility(ies) > Cosmetic Ingredients". Below the breadcrumb trail are three buttons: "SAVE INGREDIENTS", "DELETE INGREDIENTS", and "<< RETURN". The "INGREDIENTS" section has a note: "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." Below the note is a search bar labeled "Ingredient UNII-Name: * Search Ingredients" with an "ADD" button. Below the search bar is a table with three columns: "INGREDIENT UNII CODE(S)", "COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)", and a column with numbers 1, 2, and 3. The table contains three rows: "FLAVOR" (1), "FRAGRANCE" (2), and "059QF0K00R" (3). Below the table is a red button labeled "DOWNLOAD CURRENT INGREDIENT LIST". At the bottom, there is an "UPLOAD INGREDIENT FILE" section with a note: "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. UNIs should be entered in the first column and ingredient names in the second column. Please do not enter CAS numbers instead of UNIs. CAS numbers will not be recognized by the system." Below the note is a sub-note: "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." In the center, there is a "Drag and Drop" area with a folder icon and the text "Select a file or drop one here." At the bottom are two buttons: a grey "UPLOAD" button and a red "CANCEL" button.

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): * shampoo

Product Webpage Link:

Fragrance or Flavor: * Fragrance & Flavor

Professional Use Only : -- Select --

+ 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 UNIT CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)
	FLAVOR
	FRAGRANCE
059QF0K00R	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

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:* -- Select --

Professional Use Only : -- Select --

+ PRODUCT CATEGORY CODE(S)

+ INGREDIENTS

- LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

SAVE PRODUCT DELETE << RETURN

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:

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

Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?* ☒ YES ☐ NO

Facility FEI:

Facility Name:

Facility Country: -Select Country-

Facility Street Address:

Facility City:

Facility State or Province:

Facility Zip/Postal Code:

SAVE FACILITY << RETURN

- a. 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).
- b. **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 form for facility registration. At the top right are two buttons: 'SAVE FACILITY' (red) and '<< RETURN' (grey). Below them is a question: 'Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?' with radio buttons for 'YES' (selected) and 'NO'. The form contains several input fields: 'Facility FEI' (text), 'Facility Country' (dropdown menu showing '-Select Country-'), 'Facility Name' (text), 'Facility Street Address' (text), 'Facility City' (text), 'Facility State or Province' (text), and 'Facility Zip/Postal Code' (text). All fields are active and have a light blue border.

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:

The screenshot shows the same web form as in the previous image, but with 'NO' selected for the exemption question. The 'Facility FEI' field now has a red asterisk, indicating it is mandatory. The 'Facility Name', 'Facility Street Address', 'Facility City', 'Facility State or Province', and 'Facility Zip/Postal Code' fields are now greyed out, indicating they are optional. The 'Facility Country' dropdown remains active. The 'SAVE FACILITY' and '<< RETURN' buttons are still present at the top right.

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)**

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)

+ INGREDIENTS

- LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

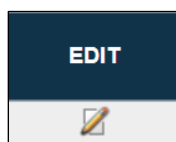
ADD FACILITY

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:



- 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

- 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:

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

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

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: * -- Select --

Professional Use Only: -- Select --

+ PRODUCT CATEGORY CODE(S)

+ INGREDIENTS

+ LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

+ PRODUCT IMAGES

SAVE PRODUCT DELETE << RETURN

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)

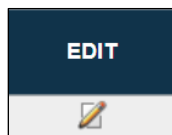
EDIT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	FRAGRANCE OR FLAVOR	IS THIS PRODUCT FOR PROFESSIONAL USE ONLY?	CLONE
		shampoo	Fragrance & Flavor	N/A	

row(s) 1 - 1 of 1

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



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



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

CLONE

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

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

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 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](#).

☒ I Agree

Date

Name of Submitter

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

I Agree

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:

ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

Additional Contact Name:

Email:

Phone Number (Include Country/Area Code):

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
<u>DRAFT</u>

- 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

- Click '**SAVE AND VALIDATE**' if you want to check for errors with your SPL. To submit your SPL to FDA,
 - 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:

EDIT SUBMIT SPL << RETURN

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.

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.

SUBMIT SPL

- 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**'.

STATUS
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: *	2
Root ID: *	0c06eb2a-30c9-7866-e063-6b94af0af38e	Generate New	Effective Date: *	12-08-2023

- 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**.

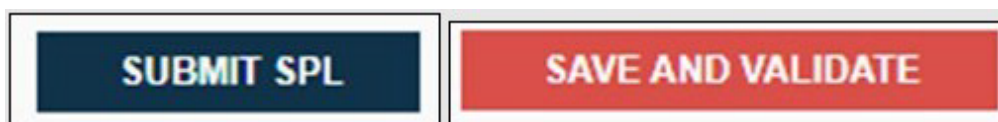
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION
VALIDATION FAILURE	0c066ca6-f8da-b44d-e063-6a94af0ab7ab	0c066ca6-f8db-b44d-e063-6a94af0ab7ab		1

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

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.

- 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.

- 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: * 0c028e8a-46d4-6672-e063-6a94af0a11c2

[Generate New](#)

[Generate New](#)

- 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

- 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.
- 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.

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

DOCUMENT TYPE DETAILS

Document Type: *

COSMETIC PRODUCT LISTING

--Select One--
COSMETIC PRODUCT LISTING
COSMETIC - UPDATE
COSMETIC - ABBREVIATED RENEWAL
0c028e8a-46d4-6672-e063-6a94af0a11c2

Set ID: *

Generate New

Root ID: *

Generate New

- 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'**



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

DOCUMENT TYPE DETAILS

Document Type: *

COSMETIC PRODUCT LISTING

--Select One--
COSMETIC PRODUCT LISTING
COSMETIC - UPDATE
COSMETIC - ABBREVIATED RENEWAL
0c028e8a-46d4-6672-e063-6a94af0a11c2

Set ID: *





Generate New

Root ID: *

Generate New

Option 1 – Edit/Update Product

- a. 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	

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



- c. Select 'DISCONTINUE PRODUCT' to discontinue the product.



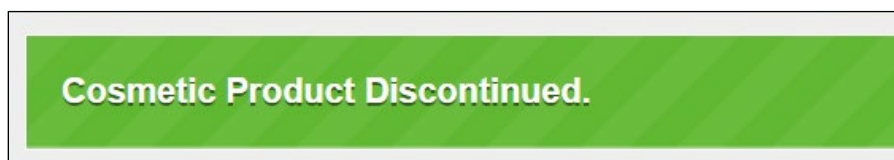
- **PLEASE NOTE:** The following message will appear, "Are you sure you want to discontinue the Product?" Select, 'OK' to proceed.

Are you sure you want to discontinue the Product?

CANCEL

OK

- d. 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)				
row(s) 1 - 2 of 2				
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	DISCONTINUED ▾	
row(s) 1 - 2 of 2				

- 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!"

RELIST PRODUCTDELETE<< RETURN

COSMETIC PRODUCTS

Cosmetic Product Listing Number:53-420734-348199Product 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	CHANGE STATUS FOR ALL PRODUCTS ▾	
	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	DISCONTINUE ALL PRODUCTS ▾	
	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 CHANGE STATUS FOR ALL PRODUCTS ▾	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.

SAVE PRODUCT	DISCONTINUE PRODUCT	DELETE	<< RETURN
--------------	---------------------	--------	-----------

- **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.

direct.preprod.fda.gov says

Are you sure you want to delete the Product?



OK

Cancel

- 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	CHANGE STATUS FOR ALL PRODUCTS LISTED	
row(s) 1 - 1 of 1				

4. 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:

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



3. 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

0c028e8a-46d4-6672-e063-6a94af0a11c2

Root ID: *

Generate New

Generate New

Option 1 – Edit/Update Product

- a. 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)				
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	CHANGE STATUS FOR ALL PRODUCTS ▾ DISCONTINUED ▾	

- b. Click on 'RELIST PRODUCT.'

RELIST PRODUCT

DELETE

<< RETURN

COSMETIC PRODUCTS

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.

Are you sure you want to relist the Product?

CANCEL

OK

- 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."

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)				
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	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
			CHANGE STATUS FOR ALL PRODUCTS ▾	
	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
			CHANGE STATUS FOR ALL PRODUCTS ▾	
	53-776340-572892	Productname A	DISCONTINUED ▾	
	53-420734-348199	Productname B	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
			CHANGE STATUS FOR ALL PRODUCTS ▾	
	53-776340-572892	Productname A	DISCONTINUED ▾	
	53-420734-348199	Productname B	DISCONTINUED ▾	

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	
--------	--------	---------	---------------	---------	---------------	-----------------	------------------	---------------	--------------------------	--------------------------	--

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. 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	
--------	--------	---------	---------------	---------	---------------	-------------------------	---------	--------------------	--------------------	---

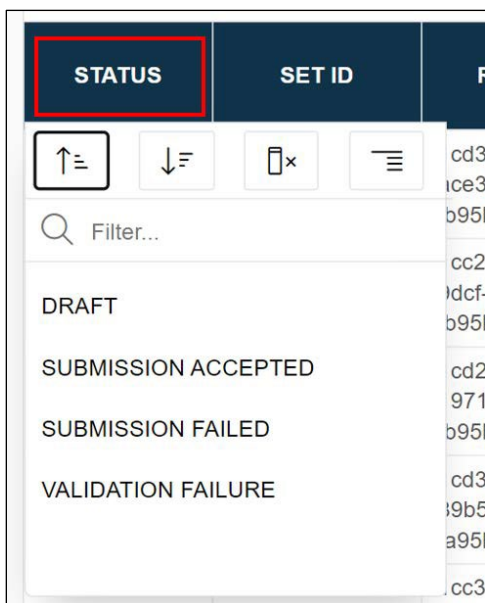
1. Status: The current status of your submissions. For further explanation of the different status types, see Section 3.2: Submission Statuses.
2. Set ID: A 'Globally Unique Identifier' (GUID) that remains the same for each submission 'set,' which is a group of submission versions. When you submit a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



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:

ION

DOCUMENT TYPE

RESPONSIBLE PERSON NAME

↑=

↓=

✕

≡

Filter...

COSMETIC - UPDATE

COSMETIC PRODUCT LISTING

COSMETIC

PRODUCT LISTING

Icon	Description
<div>↑=</div>	Sort ascending
<div>↓=</div>	Sort descending
<div>✕</div>	Hide column
<div>≡</div>	Clearly separate each submission

4.5.2.2 Search Product

A product can be searched by name:

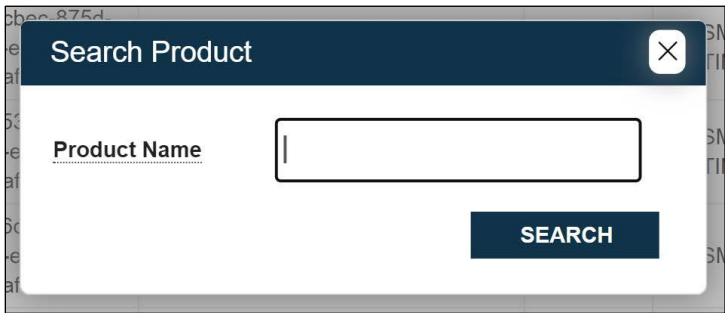
1. Click 'SEARCH PRODUCT' box next to 'CREATE NEW/UPLOAD FILE':

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'.



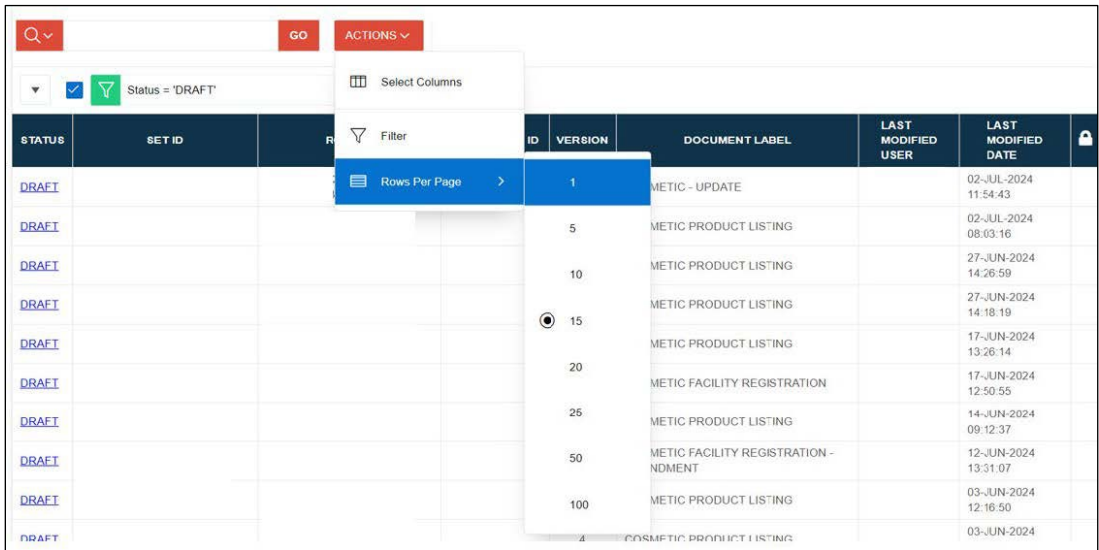
A modal window titled "Search Product" with a close button (X) in the top right corner. Inside the modal, there is a label "Product Name" followed by a text input field. Below the input field is a dark blue button with the text "SEARCH" in white capital letters.

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':



The screenshot shows a web application interface. At the top, there is a search bar with a magnifying glass icon and a red "GO" button. To the right is a red "ACTIONS" button with a dropdown arrow. Below the search bar, there is a filter section with a green checkmark icon and the text "Status = 'DRAFT'". A dropdown menu is open from the "ACTIONS" button, showing options: "Select Columns", "Filter", and "Rows Per Page". The "Rows Per Page" option is selected, and a sub-menu is displayed showing a list of numbers: 1, 5, 10, 15, 20, 25, 50, and 100. The number 15 is currently selected. In the background, a table is visible with columns: STATUS, SET ID, ID, VERSION, DOCUMENT LABEL, LAST MODIFIED USER, and LAST MODIFIED DATE. The table contains several rows of data, with the first row having a "DRAFT" status and a "METIC - UPDATE" document label.

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.

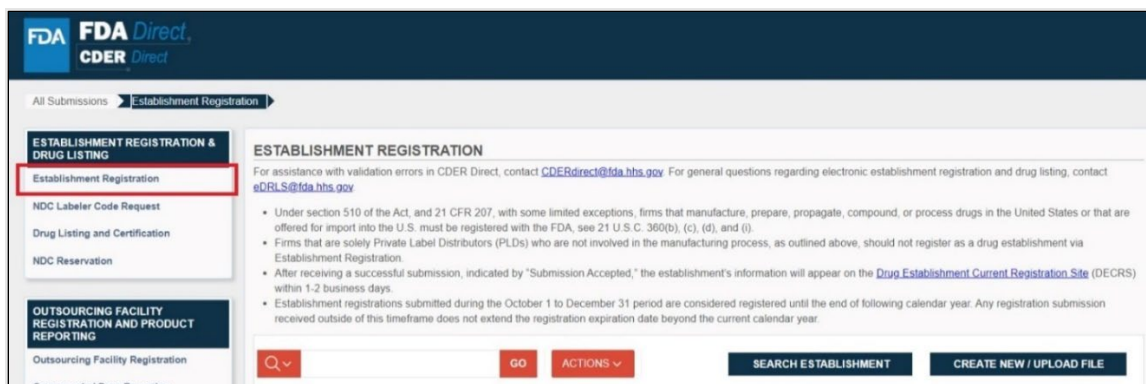
The Establishment Registration SPL submission template can be used for the following purposes:

- [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.

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.

- 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:

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: *

Set ID: * [Generate New](#) Version Number: *

Root ID: * [Generate New](#) Effective Date: *

REGISTRANT DETAILS

Registrant Name: *

Registrant DUNS: *

REGISTRANT CONTACT DETAILS

Contact Name: *

Contact Email: * [Format](#)

Contact Phone: *

Phone Extension:

REGISTRANT CONTACT ADDRESS

Country: *

Street Address: *

City: *

State/Province:

Postal Code:

ESTABLISHMENTS

None

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:

HEADER DETAILS

Document Type: * --Select One--
 Set ID: * --Select One--
 Root ID: *

ESTABLISHMENT REGISTRATION
 ESTABLISHMENT DE-REGISTRATION
 NO CHANGE NOTIFICATION
 OUT OF BUSINESS NOTIFICATION

Generate New
 Generate New

Version Number: * 1
 Effective Date: * 09-19-2023

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

REGISTRANT DETAILS

Registrant Name: *
 Registrant DUNS: *

REGISTRANT CONTACT DETAILS

Contact Name: *
 Contact Email: *
 Contact Phone: *
 Phone Extension:

REGISTRANT CONTACT ADDRESS

Country: * --Select Country--
 Street Address: *
 City: *
 State/Province:
 Postal Code:

Format

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:

The screenshot shows the 'Establishment' registration form. At the top, there are navigation tabs: 'All Submissions', 'Establishment Registration', 'SPL Submission', and 'Establishment'. Below the tabs are two buttons: 'SAVE ESTABLISHMENT' and '<< RETURN'. The form is organized into four main sections:

- ESTABLISHMENT DETAILS:** Includes fields for 'Establishment Name:', 'Establishment DUNS:', and 'Establishment FEI:'.
- ESTABLISHMENT ADDRESS:** Includes fields for 'Country:', 'Street Address:', 'City:', 'State/Province:', and 'Postal Code:'.
- ESTABLISHMENT CONTACT DETAILS:** Includes a checkbox 'Same as Registrant Contact Details and Address', and fields for 'Contact Name:', 'Contact Email:', 'Contact Phone:', and 'Phone Extension:'. There is a 'Format' link next to the 'Contact Phone:' field.
- U.S. AGENT:** Includes fields for 'Agent Name:', 'Agent DUNS:', 'Agent Email:', 'Agent Phone:', and 'Phone Extension:'. There is a 'Format' link next to the 'Agent Phone:' field.

At the bottom of the form, there is a note: 'Note: Enter the one or more drug manufacturing and processing operations performed at the establishment.' Below the note is a section labeled 'BUSINESS OPERATION(S)' with a red button 'ADD BUSINESS OPERATION'.

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

The screenshot shows the 'Business Operation/Qualifier' dialog box. It has a dark blue header with the title 'Business Operation/Qualifier' and a close button (X). The main content area includes:

- A dropdown menu labeled 'Business Operations:'.
- A section labeled 'Qualifier' with several checkboxes (not all are visible).
- At the bottom, there are three buttons: 'CANCEL', 'SAVE', and '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-GENERIC
☐ 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 ADD ESTABLISHMENT

row(s) 1 - 1 of 1

	ESTABLISHMENT DUNS	ESTABLISHMENT FEI	ESTABLISHMENT NAME
	222222222	-	CNI124

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

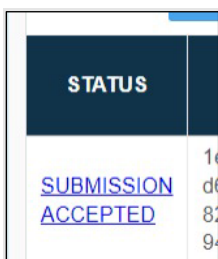
For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic establishment registration and drug listing, contact eDRLS@fda.hhs.gov.

- 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

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	111111111	CNI123	ESTABLISHMENT REGISTRATION	DETAILS

- 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.



21. If you already have multiple submissions, you can search for a specific establishment:
 - a. Click **'Search Establishment'** on the Establishment Registration main page:



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

The screenshot shows a 'Search Establishment' modal window. It contains two text input fields labeled 'Establishment DUNS' and 'Establishment Name', followed by a blue 'SEARCH' button. The background is a blurred view of the 'Establishment Registration' page, which includes a table with the following headers: STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, REGISTRANT DUNS, and REGISTRANT NAME.

- 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:

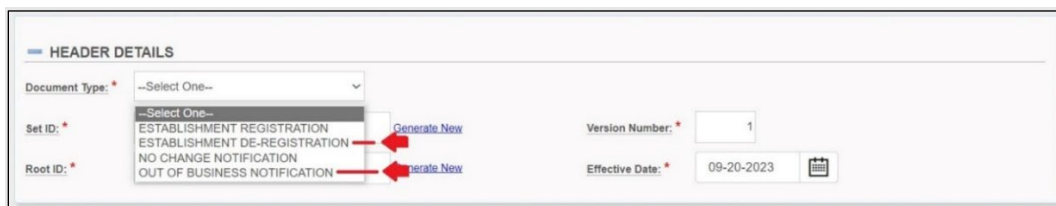
The screenshot shows a vertical sidebar menu titled 'STATUS'. It contains four links: 'DRAFT', 'AWAITING ACCEPTANCE', 'VALIDATION IN PROGRESS', and 'SUBMISSION ACCEPTED'. The 'SUBMISSION ACCEPTED' link is highlighted with a red rectangular box.

- 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**

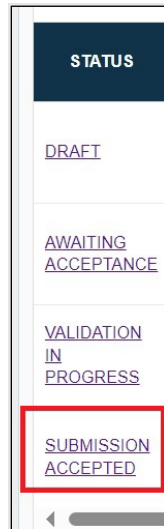


- c. Click '**Submit SPL**' at the top right of the page and you will be taken to the *Establishment Registration* page. An email will be sent to your account email address to confirm your establishment de-registration/out of business status.
3. Click '**Create New/Upload File**' on the *Establishment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

1. Go to the *Establishment 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 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.
 - a. Select '**Import an Existing Establishment Registration SPL**' and click '**Continue.**'
 - b. 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:

The screenshot shows the FDA Direct web application. On the left sidebar, under the 'ESTABLISHMENT REGISTRATION & DRUG LISTING' section, the 'NDC Labeler Code Request' link is highlighted with a red rectangular box. The main content area is titled 'NDC LABELER CODE REQUEST' and contains instructions and a list of bullet points. At the bottom of the main content area, there is a search bar with a magnifying glass icon, a 'GO' button, an 'ACTIONS' button with a dropdown arrow, and a 'CREATE NEW / UPLOAD FILE' button which is also highlighted with a red rectangular box.

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

This screenshot is a closer view of the 'NDC LABELER CODE REQUEST' page. It shows the same content as the previous screenshot, but the 'CREATE NEW / UPLOAD FILE' button at the bottom right is highlighted with a red rectangular box. The search bar, 'GO' button, and 'ACTIONS' button are also visible.

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](#)

Version Number: * 1

Root ID: * 05e17063-ba6e-5322-e063-fa95b40a09d8 [Generate New](#)

Effective Date: * 09-21-2023

LABELER DETAILS

Labeler Name: *

Labeler Code:

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:

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:

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: * --Select One--
 Root ID: * 05e17063-ba6e-5322-e063-fa95b40a09d8
 Version Number: * 1
 Effective Date: * 09-21-2023

Document Type Options:
 NDC LABELER CODE REQUEST
 NDC LABELER CODE INACTIVATION

[Generate New](#) [Generate New](#)

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

[Format](#)

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)

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

[Format](#)

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

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

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 eDRLS@fda.hhs.gov.

- 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 ready 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.

Q GO ACTIONS CREATE NEW / UPLOAD FILE

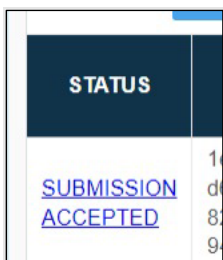
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LABELER DUNS	LABELER NAME	LAST MODIFIED USER
AWAITING ACCEPTANCE	05e17063-ba6d-5322-e063-fa95b40a09d8	05e17063-ba6e-5322-e063-fa95b40a09d8		1	NDC LABELER CODE REQUEST	123123123	123cni	Zee Dee

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

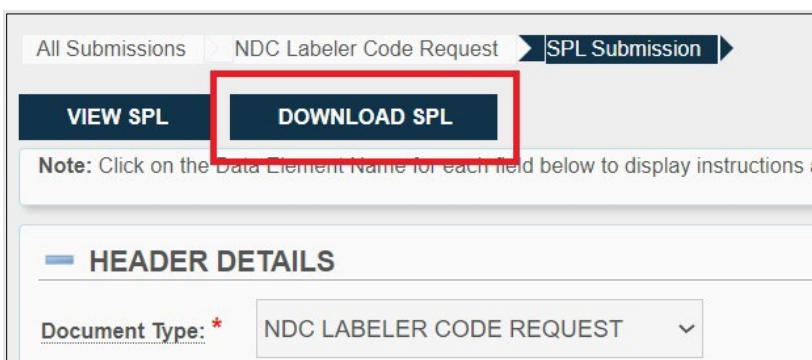
16. The *Status* field on the NDC Labeler Code Request main page should read 'Submission Accepted' when your submission has been validated and accepted by the FDA.

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: * -- Select Document Type --

Note: To update an existing submission, click [button] SUBMISSION ACCEPTED from the table in the prior page / Dashboard.

CONTINUE CANCEL

-- 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:

CREATE NEW NDC RESERVATION

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

Reservation Product Type: * -- Select Document Type --

Note: To update an existing submission, click [button] SUBMISSION ACCEPTED from the table in the prior page / Dashboard.

CONTINUE CANCEL

NDC Reservation

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. NDC Reservation SPL Document Type should only be selected to Reserve an NDC for 2 years. NDC reservation is not required prior to the actual listing submission.

- **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.

CONTINUE CANCEL

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**

GO **ACTIONS**

None.

ESTABLISHMENTS **ADD ESTABLISHMENT**

None

9. Fill out the *Labeler Details* section.

10. 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

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

PRODUCTS

ADD PRODUCT

Q

GO ACTIONS

None

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.

All Submissions NDC Reservation Products **Product Details**

SAVE PRODUCT << RETURN

Note: NDC Reservation for Kits is currently not available, this feature is anticipated to be available soon.

PRODUCT DATA ELEMENTS

Product NDC: *

Proprietary Name:

Suffix:

Non Proprietary Name: *

DEA Schedule: -- Select DEA Schedule --

Dosage Form: * -Select Dosage Form-

Source NDC:

Route of Administration: ADD

ROUTE OF ADMINISTRATION

1 x 1

MARKETING DETAILS

Marketing Status: * --Select One--

Reserved Until Date: *

Marketing Category: -Select Marketing Category-

Application Number/
Monograph ID:

INGREDIENTS

ADD INGREDIENT

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

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: Choose File

CHARACTERISTICS

ADD CHARACTERISTIC

None

PACKAGING

ADD PACKAGE

None

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:

The screenshot shows the 'PRODUCT DATA ELEMENTS' form. On the left, there are input fields for 'Product NDC: *', 'Proprietary Name:', 'Suffix:', 'Non Proprietary Name: *', 'DEA Schedule:', 'Dosage Form: *', 'Source NDC:', and 'Route of Administration:'. The 'Route of Administration:' field has a dropdown arrow. A dropdown menu is open, displaying a list of route options: AURICULAR (OTIC), BUCCAL, CONJUNCTIVAL, CUTANEOUS, DENTAL, ELECTRO-OSMOSIS, ENDOCERVICAL, ENDOSINUSIAL, ENDOTRACHEAL, ENTERAL, EPIDURAL, EXTRA-AMNIOTIC, EXTRACORPOREAL, HEMODIALYSIS, INFILTRATION, INTERSTITIAL, INTRA-ABDOMINAL, INTRA-AMNIOTIC, and INTRA-ARTERIAL. To the right of the dropdown is a red 'ADD' button. Below the dropdown is a dark blue button labeled 'ROUTE OF ADMINISTRATION'. At the bottom right, it says '1 - 1'.

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

This screenshot shows the 'Route of Administration' section. The 'Route of Administration:' dropdown is empty. The red 'ADD' button is visible. Below it, a dark blue button labeled 'ROUTE OF ADMINISTRATION' is shown. Underneath this button, a list contains 'HEMODIALYSIS' with a red 'X' icon to its right. At the bottom right, it says '1 - 1'.

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

This screenshot shows the 'Route of Administration' section with two items in the list: 'HEMODIALYSIS' and 'INTRA-ARTERIAL'. Both have red 'X' icons to their right. A red box highlights the 'X' icon next to 'INTRA-ARTERIAL'. At the bottom right, it says '1 - 2'.

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

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

INGREDIENTS

ADD INGREDIENT

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

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

All SubmissionsNDC ReservationProductsProduct DetailsIngredient 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 --

-- 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: *

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:

The screenshot shows the 'INGREDIENT DETAILS' form. The 'Type' field is set to 'Active Ingredient, Ingredient is Basis of Strength'. The 'Ingredient UNII - Name' field contains 'ketocor'. The 'Active Moiety' field is open, showing a list of suggestions: (P7P4A1FD7Z) N-DEACETYLKETOCONAZOLE, (3INP7D7XI3) KETOCONAZOLE, TRANS-, (R9400W927I) KETOCONAZOLE, (2DJ8R0NT7K) LEVOKETOCONAZOLE, (A5BAG8KDK5) KETOCONAZOLE-HYDROXY, and (2EWW9YYR6A) KETOCONAZOLE, (2R,4R)-. There is a red button labeled 'ADD ACTIVE MOIETY' and a link for '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:

The screenshot shows the 'Active Moiety' field with a red box highlighting the label 'Active Moiety: *'. To the right of the field is a checkbox labeled '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

1	A	B	C	D	E	F	G
	AI UNII	Active Ingredient	AM UNII	Active Moiety	Basis of Strength	RD UNII	Referenced Drug
6930	690G0D6V8H	KETAMINE	690G0D6V8H	KETAMINE	Active Ingredient		
6931	018YUC0I83	KETAMINE HYDROCHLORIDE	690G0D6V8H	KETAMINE	Active Moiety		
6932	5F91OR6H84	KETAMINE HYDROCHLORIDE, R-	690G0D6V8H	KETAMINE			
6933	97F9DE4CT4	KETANSERIN	97F9DE4CT4	KETANSERIN	Active Ingredient		
6934	645498QK7H	KETANSERIN TARTRATE	97F9DE4CT4	KETANSERIN			
6935	6IO4IG518S	KETAZOCINE	6IO4IG518S	KETAZOCINE	Active Ingredient		
6936	92A214MD7Y	KETAZOLAM	92A214MD7Y	KETAZOLAM	Active Ingredient		
6937	E00MDP82S4	KETHOXAL	E00MDP82S4	KETHOXAL	Active Ingredient		
6938	USC4H83KSU	KETIPRAMINE	USC4H83KSU	KETIPRAMINE	Active Ingredient		
6939	POS1L514CF	KETOBEMIDONE	POS1L514CF	KETOBEMIDONE	Active Ingredient		
6940	U9U6LTV80K	KETOBEMIDONE HYDROCHLORIDE	POS1L514CF	KETOBEMIDONE			
6941	WA1RT89G9X	KETOCAINE	WA1RT89G9X	KETOCAINE	Active Ingredient		
6942	UQG78PX4W	KETOCAINOL	UQG78PX4W	KETOCAINOL	Active Ingredient		
6943	R9400W927I	KETOCONAZOLE	R9400W927I	KETOCONAZOLE	Active Ingredient		
6944	90Y4QC304K	KETOPROFEN	90Y4QC304K	KETOPROFEN	Active Ingredient		
6945	5VD00E3D4C	KETOPROFEN LYSINE	90Y4QC304K	KETOPROFEN			
6946	5R10M39K57	KETOPROFEN SODIUM	90Y4QC304K	KETOPROFEN			
6947	820ZXE70XL	KETORFANOL	820ZXE70XL	KETORFANOL	Active Ingredient		
6948	YZI5105V0L	KETOROLAC	YZI5105V0L	KETOROLAC	Active Ingredient		
6949	4EVE5948BQ	KETOROLAC TROMETHAMINE	YZI5105V0L	KETOROLAC	Active Ingredient		
6950	4EVE5948BQ	KETOROLAC TROMETHAMINE	YZI5105V0L	KETOROLAC	Active Moiety		
6951	X49220T18G	KETOTIFEN	X49220T18G	KETOTIFEN	Active Ingredient		
6952	H8D503WORO	KETOTIFEN FUMARATE	X49220T18G	KETOTIFEN	Active Moiety		
6953	504RN634MM	KETOTREXATE	504RN634MM	KETOTREXATE	Active Ingredient		
6954	FV4YQJ02CX	KEYHOLE LIMPET HEMOCYANIN	FV4YQJ02CX	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 Strei

Ingredient UNII - Name: *

Active Moiety: *

☐ 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: *

☐ 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: *

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>			
	<table border="1"> <thead> <tr> <th>SUBSTANCE NAME</th> </tr> </thead> <tbody> <tr> <td>2,5-DIMETHYLPYRROL-3-YL-2-FURYLKETONE</td> </tr> </tbody> </table>	SUBSTANCE NAME	2,5-DIMETHYLPYRROL-3-YL-2-FURYLKETONE
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: Choose File

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

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

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

- 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"):

- 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: * - Select Value -









Quantity: *

Unit of Measure: * - Select Value -

Combination Product Type: - Select Value -


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 	<input type="checkbox"/>
Package NDC:	<input type="text"/>
Package Type: *	- Select Value - 
Quantity: *	<input type="text"/>
Unit of Measure: *	- Select Value - 
Combination Product Type:	- Select Value - 
OUTERMOST LEVEL	
Check for Deletion 	<input type="checkbox"/>
Is this a sample package ?	<input type="checkbox"/>
Package NDC:	<input type="text"/>
Package Type: *	- Select Value - 
Quantity: *	<input type="text"/>
Unit of Measure: *	1 
Combination Product Type:	- Select Value - 

- 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: *

Combination Product Type:

☒

☐

- Select Value -

- Select Value -

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):

<div> <div>PACKAGING</div> <div>ADD PACKAGE</div> </div>									
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								
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	[R]		-	-	

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

SAVE ESTABLISHMENT | DELETE ESTABLISHMENT | << RETURN

ESTABLISHMENT DETAILS

Establishment Name: * Establishment DUNS: *

☐ Confidential

BUSINESS OPERATION(S) ⓘ

BUSINESS OPERATION	PRODUCT NDC
✖ --Select One--	<input type="text"/>

- 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

SAVE ESTABLISHMENT | DELETE ESTABLISHMENT | << RETURN

ESTABLISHMENT DETAILS

Establishment Name: * Establishment DUNS: *

☐ Confidential

BUSINESS OPERATION(S) ⓘ

BUSINESS OPERATION	PRODUCT NDC
✖ --Select One--	<input type="text"/>

ANALYSIS
API MANUFACTURE
LABEL
MANUFACTURE
MEDICATED ANIMAL FEED MANUFACTURE
PACK
PARTICLE SIZE REDUCTION
POSITRON EMISSION TOMOGRAPHY DRUG PRODUCTION
RELABEL
REPACK
SIP FOREIGN SELLER
STERILIZE

Owner Requirements | Resources | Tutorials | Help Desk | FAQs
FDA Voice Blog | Privacy | Vulnerability Disclosure Policy

- c. You can click the + button to add multiple rows, if needed:

BUSINESS OPERATION(S) ⓘ

	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

row(s) 1 - 1 of 1

	ESTABLISHMENT DUNS	ESTABLISHMENT NAME	CONFIDENTIAL
	111111111	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 **NDC Reservation**

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 edrls@fda.hhs.gov.

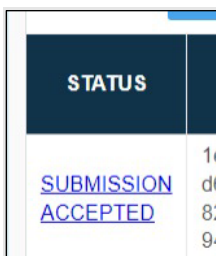
- NDC Reservation IS NOT a drug listing submission. It reserves an NDC for a future drug listing with the FDA, confirming availability during product development.
- NDC reservation is not required prior to a drug listing submission.
- NDC Reservation SPL Document Type should only be selected to reserve 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.

GO ACTIONS SEARCH NDC RESERVATION CREATE NEW / UPLOAD FILE

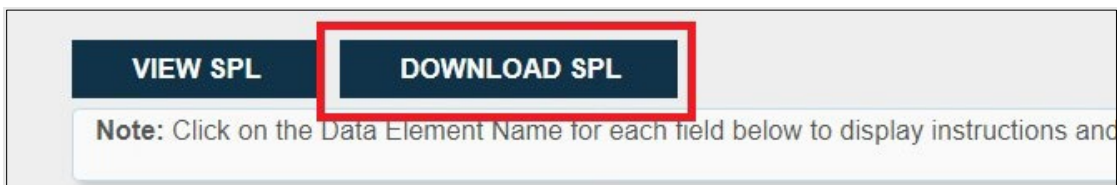
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
AWAITING ACCEPTANCE	0594b75-4e42-7943-e063-fa95b40a2bc8	0594b75-4e43-7943-e063-fa95b40a2bc8		1	HUMAN OTC DRUG LABEL		DETAILS	Zee Dee	25-SEP-2023 16:30:17

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

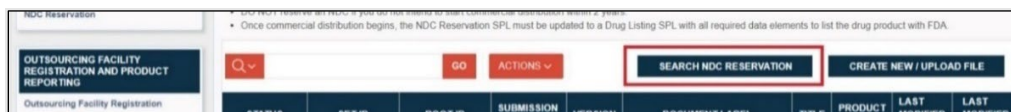
23. Click **'Return'** at any time to return to the main NDC Reservation page.
24. The *Status* field should read **'Submission Accepted'** when your submission has been validated and accepted by the FDA. You will receive an email to your account email address when the submission status changes.
25. 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:



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.



27. If you have multiple NDC reservations, you can search for a specific reservation:
 - a. Click **'Search Establishment'** on the NDC Reservation main page:



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

NDC RESERVATION

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

- NDC Reservation IS NOT a drug
- NDC reservation is not required
- NDC Reservation SPL Document
- DO NOT reserve an NDC if you
- Once commercial distribution begins

Search NDC

Product NDC

Proprietary Name

SEARCH

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	TI
--------	--------	---------	---------------	---------	----------------	----

- Click **'Search'** and your results will populate.
- 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:

- Log in to FDA Direct.
- Select **'Drug Listing and Certification'** under *Establishment Registration & Drug Listing*:

- Click 'Create New/Upload File' on the Drug Listing and Certification main page:

- You will be given two options:

- 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.
- 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.
 - Use the dropdown to select your *SPL Document Type*:

- For most document types, skip to [Step 10](#).

8. For the 'Blanket No Changes Certification of Product Listing' document type only, complete the following:
 - a. Select 'Blanket No Changes Certification of Product Listing' from the *Document Type* dropdown, then press 'Continue.'
 - b. A blank template will display:

All Submissions Drug Listing and Certification Products Certification

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 Certification submission form. Red asterisk indicate required fields.

* Please note that the Blanket No Changes Certification of Product Listing is intended to certify Drug Listing files only. The Blanket No Changes Certification does not affect Establishment Registration files and cannot be used for establishment registration or to annually renew an establishment registration.

* To submit an annual Establishment Registration, use the document type Establishment Registration or No Change Notification.

Note: Blanket No Changes Certification of Product Listings can only be submitted between October 1st and December 31st.

HEADER DETAILS

Document Type: * BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING

Set ID: * 06e56d8d-c4e6-9310-e063-fa95b40a37b8 [Generate New](#) Version Number: * 1

Root ID: * 06e56d8d-c4e7-9310-e063-fa95b40a37b8 [Generate New](#) Effective Date: * 10-04-2023

AUTHORIZED AGENT DETAILS

☐ Same as CDER Direct account details.

Organization DUNS: * Name: *

Organization Name: * Email: *

Phone Number: * [Format](#) Phone Extension:

SEARCH

LABELERS

Note: Labelers whose drug listing files are certified for.

* Click on the "Refresh Establishments" button to update the establishment list based on the labeler selection.

* Use check box in the report header for "Select All" functionality.

REFRESH ESTABLISHMENTS

ESTABLISHMENTS

Note: 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 previously indicated as confidential, please use the Add Establishment button. If the establishment was submitted using this CDER Direct account, the confidential establishment will be included.

* Use check box in the report header for "Select All" functionality.

SHOW PRODUCTS ADD ESTABLISHMENT

Q GO Rows 15 ACTIONS

- c. All fields in the *Header Details* section will be automatically generated.
- d. To name yourself as the Authorized Agent, select the 'Same as CDER Direct account details' checkbox, and the fields will populate automatically:

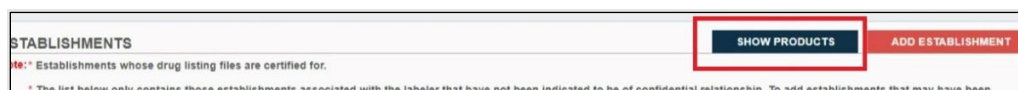
- e. To add a Labeler, click the **'Add Labeler'** button then enter a valid labeler code:

- 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:

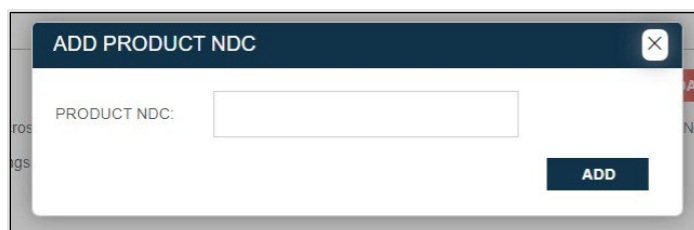
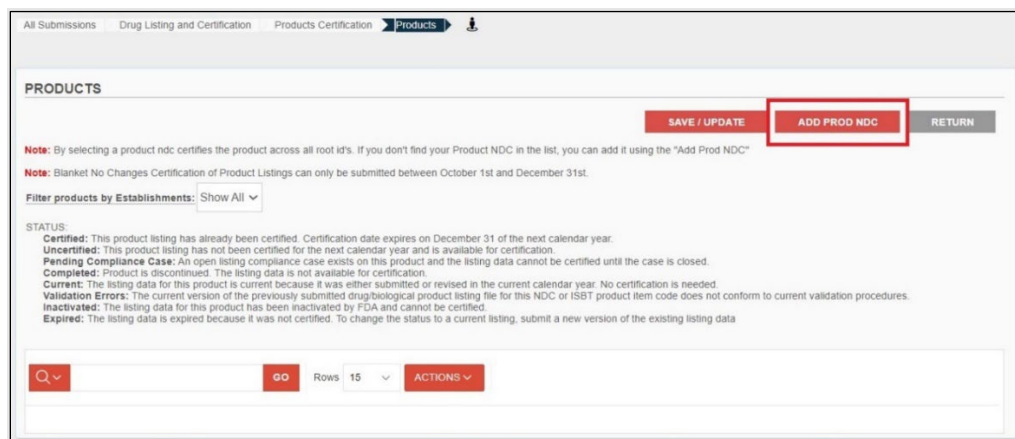
"If the establishment was submitted using this CDER Direct account, the confidential establishment will be included."

- 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:



- 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:



- 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:

10. Fill out all applicable fields.
11. To keep this submission from being made 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:

- 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 ID:

☐ Confidential

BUSINESS OPERATION(S) ⓘ

	BUSINESS OPERATION	PRODUCT NDC
+	--Select One--	<input type="text"/>
✕	--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](#) | [FDA Voice Blog](#) | [Privacy](#) | [Vulnerability Disc](#)

- c. You can click the + button to add multiple rows, if needed:

BUSINESS OPERATION(S) ⓘ

	BUSINESS OPERATION	PRODUCT NDC
+	--Select One--	<input type="text"/>
✕	--Select One--	<input type="text"/>
✕	--Select One--	<input type="text"/>
✕	--Select One--	<input type="text"/>

- 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
ADD PRODUCT

Q GO ACTIONS

None

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: *

Proprietary Name: *

Suffix:

Non Proprietary Name: *

DEA Schedule: -- Select DEA Schedule --

Dosage Form: * --Select Dosage Form--

Source NDC:

Route of Administration: *

ROUTE OF ADMINISTRATION 1 x 1

MARKETING DETAILS

Marketing Status: * --Select One--

Marketing Start Date: *

Marketing Category: * --Select Marketing Category--

Application Number/ Monograph ID:

INGREDIENTS

None

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

CHARACTERISTICS

None

PACKAGING

None

16. 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:

The screenshot shows the 'PRODUCT DATA ELEMENTS' form. On the left, there are input fields for 'Product NDC:', 'Proprietary Name:', 'Suffix:', 'Non Proprietary Name:', 'DEA Schedule:', 'Dosage Form:', 'Source NDC:', and 'Route of Administration:'. The 'Route of Administration:' field is currently empty. To its right, a dropdown menu is open, displaying a list of route options: AURICULAR (OTIC), BUCCAL, CONJUNCTIVAL, CUTANEOUS, DENTAL, ELECTRO-OSMOSIS, ENDOCERVICAL, ENDOSINUSIAL, ENDOTRACHEAL, ENTERAL, EPIDURAL, EXTRA-AMNIOTIC, EXTRACORPOREAL, HEMODIALYSIS, INFILTRATION, INTERSTITIAL, INTRA-ABDOMINAL, INTRA-AMNIOTIC, and INTRA-ARTERIAL. Below the dropdown is a red 'ADD' button. At the bottom of the form, there is a dark blue bar labeled 'ROUTE OF ADMINISTRATION' and a pagination indicator '1 - 1'.

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

This screenshot shows the 'Route of Administration' section after clicking the 'ADD' button. The dropdown menu is now closed, and 'HEMODIALYSIS' has been added to the 'ROUTE OF ADMINISTRATION' list. A red 'X' icon is visible next to 'HEMODIALYSIS' in the list. The pagination indicator at the bottom right shows '1 - 1'.

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

This screenshot shows the 'Route of Administration' section with two items in the list: 'HEMODIALYSIS' and 'INTRA-ARTERIAL'. Both items have a red 'X' icon next to them, indicating they can be removed. The 'INTRA-ARTERIAL' item's removal icon is highlighted with a red box. The pagination indicator at the bottom right shows '1 - 2'.

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

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

The screenshot shows a header bar for the 'INGREDIENTS' section. On the right side of the bar is a red button labeled 'ADD INGREDIENT'. Below the header bar, a note states: 'Note: * At least one active ingredient is required. None'.

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

The screenshot shows the 'INGREDIENT DETAILS' form. At the top right are two buttons: 'SAVE INGREDIENT' (red) and '<< RETURN' (grey). A note at the top reads: '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.' The form fields include: 'Type: *' with a dropdown menu (currently showing '-- Select One --'), 'Ingredient UNII - Name: *' with a text input field, 'Numerator Strength: *' with a text input field, 'Unit Of Measure: *' with a dropdown menu (currently showing '-- Select One --'), 'Denominator Strength: *' with a text input field, and another 'Unit of Measure: *' dropdown menu (currently showing '-- Select One --').

- b. Select the dropdown for 'Type':

This screenshot shows the 'INGREDIENT DETAILS' form with the 'Type: *' dropdown menu open. The dropdown list contains the following options: '-- Select One --', 'Active Ingredient, Ingredient is Basis of Strength', 'Active Ingredient, Moiety is Basis of Strength', 'Active Ingredient, Reference Ingredient is Basis of Strength', and 'Inactive Ingredient'. The other form fields remain the same as in the previous screenshot.

- 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:

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

- 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
X

The molecule or ion responsible for the physiological or pharmacological action of the drug substance. Active Ingredient-Active Moiety Relationship/Basis of Strength

1	A	B	C	D	E	F	G
	AI UNII	Active Ingredient	AM UNII	Active Moiety	Basis of Strength	RD UNII	Referenced Drug
6930	690G0D6V8H	KETAMINE	690G0D6V8H	KETAMINE	Active Ingredient		
6931	O18YU00I83	KETAMINE HYDROCHLORIDE	690G0D6V8H	KETAMINE	Active Moiety		
6932	5F91OR6H84	KETAMINE HYDROCHLORIDE, R-	690G0D6V8H	KETAMINE			
6933	97F9DE4CT4	KETANSERIN	97F9DE4CT4	KETANSERIN	Active Ingredient		
6934	645496CK7H	KETANSERIN TARTRATE	97F9DE4CT4	KETANSERIN			
6935	6I04IG5185	KETAZOCINE	8I04IG5185	KETAZOCINE	Active Ingredient		
6936	92A214MD7Y	KETAZOLAM	92A214MD7Y	KETAZOLAM	Active Ingredient		
6937	E00MDP82S4	KETHOXAL	E00MDP82S4	KETHOXAL	Active Ingredient		
6938	U5C4H63K5U	KETIPRAMINE	U5C4H63K5U	KETIPRAMINE	Active Ingredient		
6939	PQS1L514CF	KETOBEMIDONE	PQS1L514CF	KETOBEMIDONE	Active Ingredient		
6940	U9U6LTV80K	KETOBEMIDONE HYDROCHLORIDE	PQS1L514CF	KETOBEMIDONE			
6941	WA1RT89G9X	KETOCALINE	WA1RT89G9X	KETOCALINE	Active Ingredient		
6942	UOG78PXR4W	KETOCALINOL	UOG78PXR4W	KETOCALINOL	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	820ZXE70XL	KETORFANOL	820ZXE70XL	KETORFANOL	Active Ingredient		
6948	Y2I5105V0L	KETOROLAC	Y2I5105V0L	KETOROLAC	Active Ingredient		
6949	4EVE5946BQ	KETOROLAC TROMETHAMINE	Y2I5105V0L	KETOROLAC	Active Ingredient		
6950	4EVE5946BQ	KETOROLAC TROMETHAMINE	Y2I5105V0L	KETOROLAC	Active Moiety		
6951	X49220T18G	KETOTIFEN	X49220T18G	KETOTIFEN	Active Ingredient		
6952	HB503WORO	KETOTIFEN FUMARATE	X49220T18G	KETOTIFEN	Active Moiety		
6953	504RN634MM	KETOTREXATE	504RN634MM	KETOTREXATE	Active Ingredient		
6954	FV4YQJ02CX	KEYHOLE LIMPET HEMOCYANIN	FV4YQJ02CX	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 Strei ▾

Ingredient UNII - Name: *

Active Moiety: *

☐ 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: *

☐ Confidential

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

Numerator Strength: *

Unit Of Measure: *

-- Select One --

Denominator Strength: *

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: *

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	7
	SUCROSE	0

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)

UPLOAD IMAGE

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

ADD CHARACTERISTIC

None

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

CHARACTERISTICS

Characteristic: *

-- Select One -- v

Value: *

-- Select One -- v

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

CHARACTERISTICS

Characteristic: *

Color v

Value: *

-- Select One -- v

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

row(s) 1 - 1 of 1

	CHARACTERISTIC	VALUE	ADDITIONAL DESCRIPTION
	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:

- Select Value -

Quantity:

Unit of Measure:

- Select Value -

Combination Product Type:

- Select Value -

Marketing Status:

- Select Value -

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

Package NDC:

Package Type:

- Select Value -

Quantity:

Unit of Measure:

- Select Value -

Combination Product Type:

- Select Value -

Marketing Status:

- Select Value -

Marketing Start Date:

Marketing End Date:

OUTERMOST LEVEL

Check for Deletion

Is this a sample package ?

Package NDC:

Package Type:

- Select Value -

Quantity:

Unit of Measure:

1

Combination Product Type:

- Select Value -

Marketing Status:

- Select Value -

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:

The screenshot shows the 'OUTERMOST LEVEL' form. A red box highlights the 'Check for Deletion' checkbox, which is checked. Another red box highlights the 'DELETE' button at the bottom right. A modal dialog box is open in the center, asking 'Are you sure you want to delete?' with 'CANCEL' and 'OK' buttons.

- 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):

The screenshot shows the 'PACKAGING' section with a table of 4 rows. A red box highlights the pencil icon in the first row, indicating the edit action.

	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:

The screenshot shows the 'PACKAGING' section with a table of 4 rows. A red box highlights the 'CLONE' button in the first row, indicating the clone action.

	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:

The screenshot shows the 'CONTENT OF LABELING' button highlighted with a red box. Other buttons like 'SUBMIT SPL', 'SAVE AS DRAFT', 'SAVE AND VALIDATE', 'DELETE', and '<< RETURN' are also visible.

- 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:

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: *

Parent Section:

Title:

Content:

- Select Section Type -
 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: * 08-01-2024

- 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:

This screenshot shows the 'Content of Labeling' interface. At the top, there are tabs for 'All Submissions', 'Drug Listing and Certification', 'Products', and 'Content of Labeling'. Below the tabs are buttons for 'EXPAND SECTIONS', 'CLASSIC', 'ADD SECTION', and '<< RETURN'. The main area displays a list of sections: '[ADVERSE REACTIONS SECTION]', '[WARNINGS AND PRECAUTIONS SECTION]', and '[HOW SUPPLIED SECTION]'. Each section has an 'EDIT' link to its right.

The first label section above ('Adverse Reactions Section') was created first and is automatically assigned the number '1':

This screenshot shows the 'CREATE / EDIT SECTION' form. The 'Section Type' dropdown is set to 'ADVERSE REACTIONS SECTION'. The 'Effective Date' is '08-01-2024'. The 'Sequence' field is highlighted with a red box and contains the number '1'. There is also a 'Parent Section' field and a 'Sequence' field with a red asterisk.

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**':

This screenshot shows the 'CREATE / EDIT SECTION' form. The 'Section Type' dropdown is set to 'ADVERSE REACTIONS SECTION'. The 'Effective Date' is '08-01-2024'. The 'Sequence' field is highlighted with a red box and contains the number '3'. The 'APPLY' button is also highlighted with a red box.

This screenshot shows the 'Content of Labeling' interface after the change. The sections are now listed in the order: '[WARNINGS AND PRECAUTIONS SECTION]', '[HOW SUPPLIED SECTION]', and '[ADVERSE REACTIONS SECTION]'. A red arrow points to the '[ADVERSE REACTIONS SECTION]'.

- f. 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:

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Source

- 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

UPLOAD

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.

Upload Image: *

Choose File

IMAGES

None

- 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





UPLOAD

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.

Upload Image: *

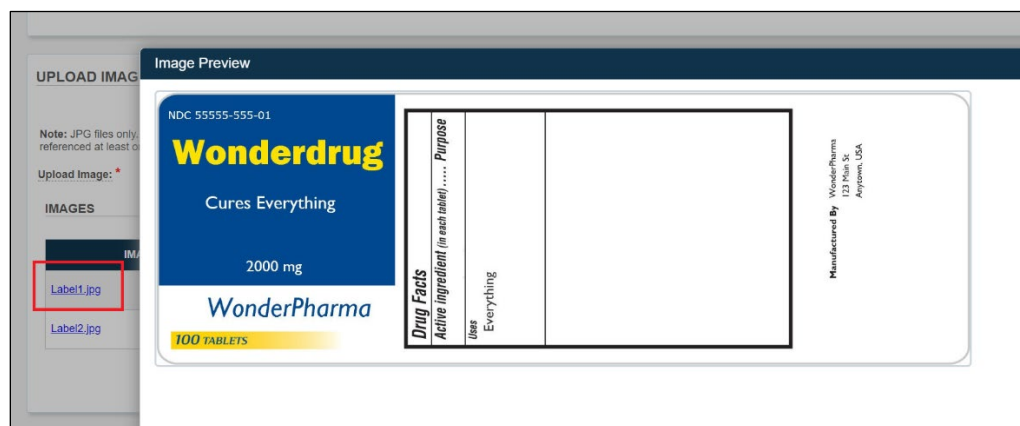
Choose File

IMAGES

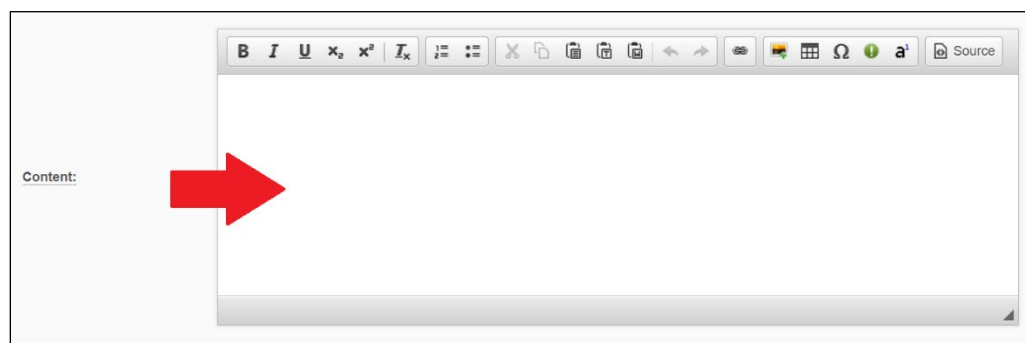
IMAGE NAME	IMAGE	DELETE IMAGE	REFERENCED
Label1.jpg			No
Label2.jpg			No


154

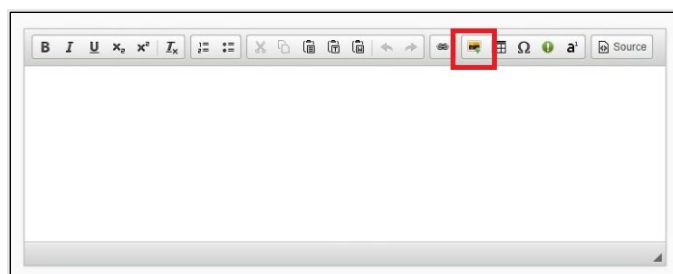
- l. Click the red **X** beside an image to delete the image. Doing this will cause images to disappear or not display properly if they have been used (“referenced”) in a section.
- m. Click the name of the image to display a closeup preview:



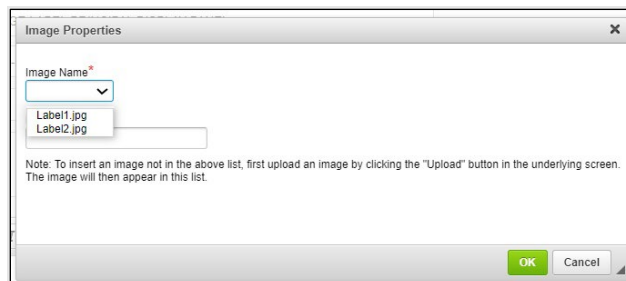
- n. You must now “reference” your image(s) before you can submit your SPL. To reference an image, go back up to the *Create/Edit* section and click anywhere inside the ‘**Content**’ box:



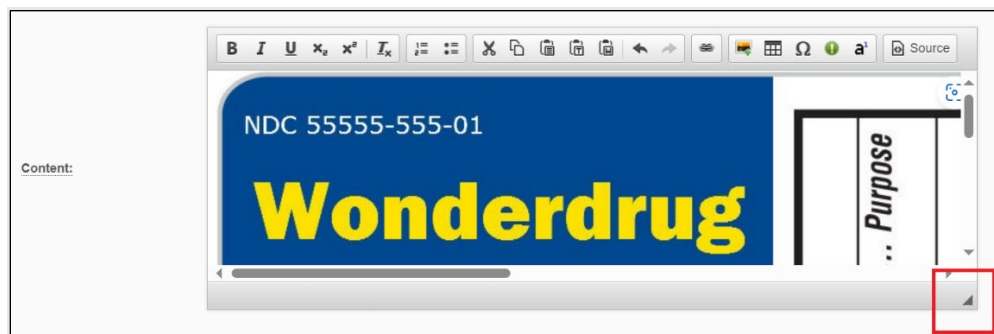
- o. Select the ‘insert an image’ icon  from the options bar (hover over any of the icons for a short text description):



- p. A popup box will display. Your previously uploaded image(s) will now be available to select from the dropdown:



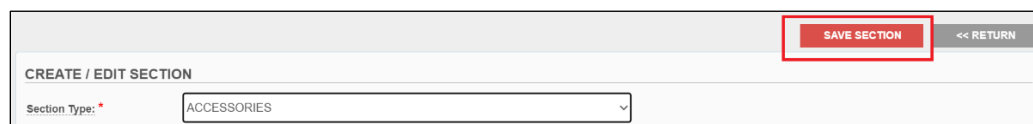
- q. Next, add some Image Text. This is alt text (description text for an image that is not visible anywhere but can be picked up and read by screen reading technology).
- r. Click '**OK.**' Your image will now display within the Content box. Click and drag the corner arrow to view more of the image:



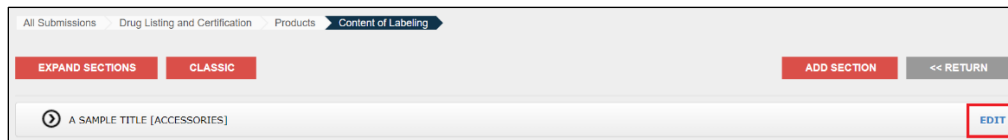
IMPORTANT: You only need to upload an image file *once*! File images are “stored” in the *Images* section upon upload. You can use this “storage” area to upload files here once, then use those same files across multiple Content of Labeling entries.

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!

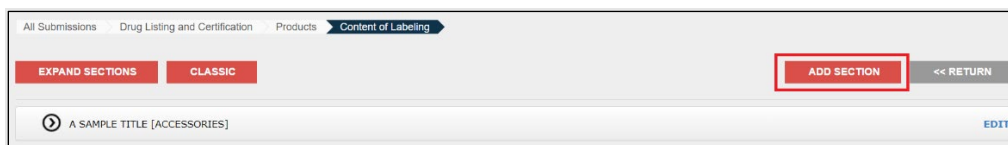
- s. When you are finished, click the '**Save Section**' button at the top right of the page to save your new section:



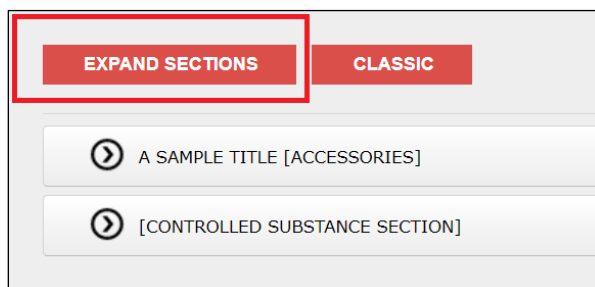
- t. You will be returned to the main Content of Labeling list page. Clicking '**Edit**' will allow you to modify an existing section:



- 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:



The screenshot displays the 'Content of Labeling' section in the FDA Direct system. It features two examples of drug labels for 'Wonderdrug' (NDC 55555-555-01). The top example is a black and white label, and the bottom example is a blue and yellow label. Both labels include the text 'Cures Everything', '2000 mg', 'WonderPharma', and '100 TABLETS'. To the right of each label is a table with three columns: 'Drug Facts', 'Active ingredient (in each tablet)..... Purpose', and 'Uses'. The 'Drug Facts' column contains the text 'Everything', and the 'Uses' column contains the text 'Everything'.

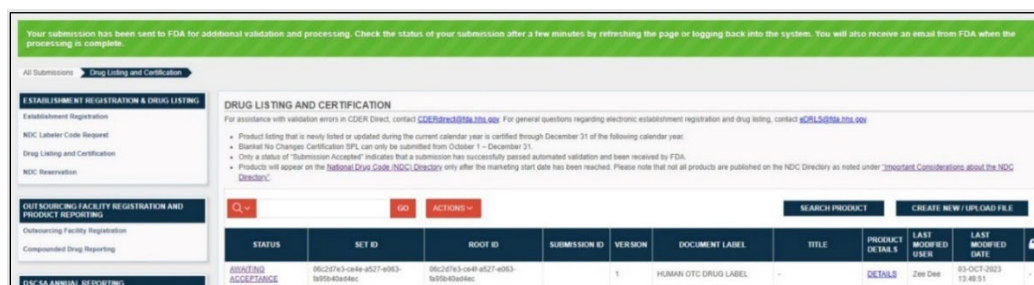
- w. Click 'Collapse Sections' (top left) to close all entries.
 - x. You also have the option to switch between 'Classic' and 'Enhanced' (top left button) mode, which simply changes the look of the lists.
 - y. See Section 9.1 for additional help with the Content of Labeling section.
 - z. When you 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.

The screenshot displays the 'RELATED DOCUMENTS' section. It features a dropdown menu for 'Type Code' with the text '--Select One--'. Below the dropdown is a table with three columns: 'ROOT ID', 'SET ID', and 'VERSION NUMBER'. The table has a header row with a plus sign icon and a body row with an orange 'x' icon.

	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:

- a. **'Save As Draft'** – Save your entry and return to the main Drug Listing and Certification 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 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:

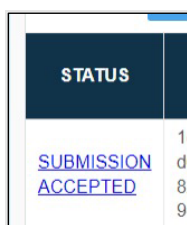


- d. **'Delete'** – Delete your entry draft completely.

27. Click **'Return'** at any time to return to the main Drug Listing and Certification page.

28. 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.

29. 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:

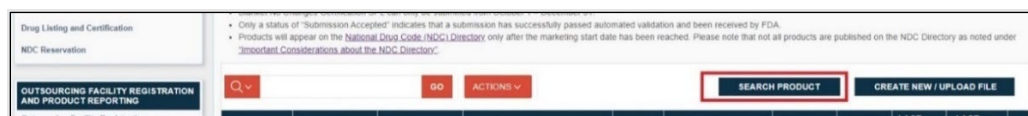


30. Click **'Download SPL'** on the top left of the page to download the zip file. You can also select **'View SPL'** for a quick look at your submission.

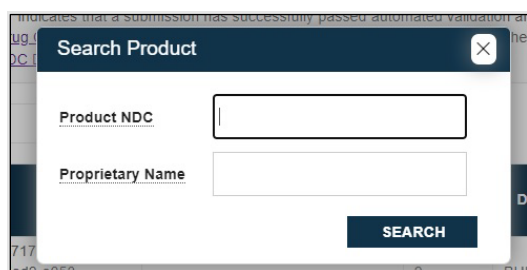


31. If you already have multiple Drug Listing and Certification submissions, you can search for a specific submission:

- 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**

SAVE ESTABLISHMENT << RETURN

ESTABLISHMENT DETAILS

Establishment Name: *
Establishment DUNS: *
Establishment FEI:

ESTABLISHMENT ADDRESS

Country: *
Street Address: *
City: *
State/Province:
Postal Code:

ESTABLISHMENT CONTACT DETAILS

☐ Same as Registrant Contact Details and Address

Contact Name: *
Contact Email: *
Contact Phone: *
Phone Extension:

ESTABLISHMENT CONTACT ADDRESS

Country: *
Street Address: *
City: *
State/Province:
Postal Code:

U.S. AGENT

Agent Name: *
Agent DUNS: *
Agent Email: *
Agent Phone: *
Phone Extension:

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

IMPORTERS
BUSINESS OPERATION(S)

ADD IMPORTER
ADD BUSINESS OPERATION

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

ADD IMPORTER

EDIT	DELETE	NAME	DUNS	EMAIL	PHONE	EXTENSION
		Importer123	111111111	imp123@email.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

NAME DUNS PHONE

porter123 111111111

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: MANUFACTURE

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-GENERIC
☐ MANUFACTURES VETERINARY FEED DIRECTIVE TYPE A MEDICATED ARTICLE DRUG PRODUCTS
☐ TRANSFILLS MEDICAL GAS

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

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
				row(s) 1 - 1 of 1
	ESTABLISHMENT DUNS	ESTABLISHMENT FEI	ESTABLISHMENT NAME	
	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:

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

The screenshot shows the top navigation bar of the FDA DIRECT interface. It includes a search bar with a magnifying glass icon, a 'GO' button, and an 'ACTIONS' dropdown menu. A red box highlights the 'SEARCH ESTABLISHMENT' button. To the right is a 'CREATE NEW / UPLOAD FILE' button. Below the navigation bar is a table with the following headers: ROOT ID, SUBMISSION ID, VERSION, REGISTRANT DUNS, REGISTRANT NAME, DOCUMENT LABEL, DETAILS, LAST MODIFIED USER, and 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:

The screenshot shows a 'Search Establishment' popup box. It has a title bar with a close button. Inside, there are two input fields: 'Establishment DUNS' and 'Establishment Name'. Below these fields is a 'SEARCH' button.

- 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:

The screenshot shows a vertical sidebar menu with the title 'STATUS'. It contains four links: 'DRAFT', 'AWAITING ACCEPTANCE', 'VALIDATION IN PROGRESS', and 'SUBMISSION ACCEPTED'. The 'SUBMISSION ACCEPTED' link is highlighted with a red box.

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



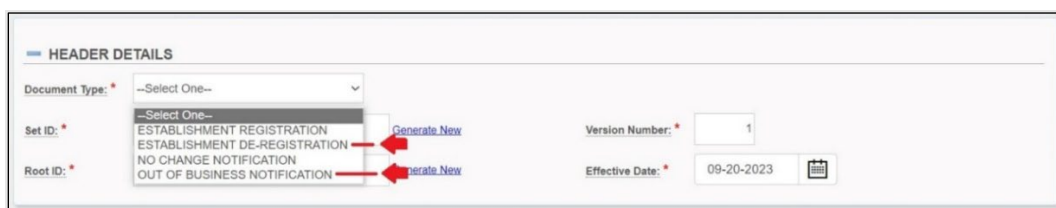
The screenshot shows a navigation bar with three tabs: 'All Submissions', 'Outsourcing Facility Registration', and 'SPL Submission'. Below the tabs are three buttons: 'VIEW SPL', 'DOWNLOAD SPL', and 'CREATE NEW VERSION' (which is highlighted with a red box). To the right of these buttons is a '<< RETURN' button.

- 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**



The screenshot shows the 'HEADER DETAILS' section. The 'Document Type' dropdown menu is open, showing four options: 'ESTABLISHMENT REGISTRATION', 'ESTABLISHMENT DE-REGISTRATION', 'NO CHANGE NOTIFICATION', and 'OUT OF BUSINESS NOTIFICATION'. Red arrows point from the last two options to 'Generate New' links. The 'Set ID' and 'Root ID' fields are empty. The 'Version Number' is set to 1. The 'Effective Date' is 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:

The screenshot shows the 'Compounded Drug Reporting' form. At the top, there are tabs for 'All Submissions', 'Compounded Drug Reporting', and 'Products'. Below the tabs, there are buttons for 'SAVE AS DRAFT' and '<< RETURN'. A note states: '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.' The 'HEADER DETAILS' section is expanded, showing fields for Document Type (HUMAN COMPOUNDED DRUG LABEL), Version Number (1), Set ID (0767dad8-b637-0717-e063-fb95b40a4e41), Effective Date (10-10-2023), Root ID (0767dad8-b638-0717-e063-fb95b40a4e41), and Reporting Period (Select a Reporting Period). There are also sections for Labeler Details, Establishments, and Products.

8. Enter your **'Reporting Period'** in the *Header Details* section:

The screenshot shows the 'HEADER DETAILS' section of the form. The 'Reporting Period' dropdown menu is open, showing options: 'Initial Reporting Period', '2022-2 (06/01/2022 - 11/30/2022)', '2023-1 (12/01/2022 - 05/31/2023)', and '2023-2 (06/01/2023 - 11/30/2023)'. The other fields in the section are the same as in the previous screenshot.

- a. Selecting **'Initial Reporting Period'** will prompt you to enter a Start Date and End Date:

The screenshot shows the 'HEADER DETAILS' section of the form. The 'Reporting Period' dropdown menu is set to 'Initial Reporting Period'. The 'Start Date' and 'End Date' fields are highlighted with red boxes, indicating they are required fields.

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:

	ESTABLISHMENT DUNS	ESTABLISHMENT NAME	CONFIDENTIAL
	44444444	CNI MGMT COMPANY	N

13. Use the dropdown in the next section, *Products*, to determine whether or not you will enter products:

14. If you selected 'Yes' from the dropdown above, click the '**Add Product**' button:

PRODUCTS

ADD PRODUCT

Do you have any products to report: *

Yes

Q

GO

ACTIONS

None

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.

SAVE PRODUCT

<< RETURN

PRODUCT DATA ELEMENTS

Product NDC:

Proprietary Name: *

Suffix:

Non Proprietary Name: *

DEA Schedule:

-- Select DEA Schedule --

Dosage Form: *

-Select Dosage Form-

Route of Administration: *

ADD

ROUTE OF ADMINISTRATION

1 - 1

MARKETING DETAILS

Marketing Category: *

-Select Marketing Category-

INGREDIENTS

ADD INGREDIENT

None

CHARACTERISTICS

ADD CHARACTERISTIC

None

PACKAGING

ADD PACKAGE

None

- 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

ADD PART

None

All Submissions
Compounded Drug Reporting
Products
Product Details

SAVE PART
<< RETURN

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: *
ADD

ROUTE OF ADMINISTRATION

1 - 1

Marketing Category: *
--Select Marketing Category--

None

None

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: *
 GRANULE, FOR SUSPENSION, EXTENDED RELEASE
 GUM, CHEWING
 IMPLANT
 INHALANT
 INJECTABLE FOAM
 INJECTABLE, LIPOSOMAL
 INJECTION
 INJECTION, EMULSION
 INJECTION, LIPID COMPLEX
 INJECTION, POWDER, FOR SOLUTION
 INJECTION, POWDER, FOR SUSPENSION
 INJECTION, POWDER, FOR SUSPENSION, EXTENDED RELEASE
 INJECTION, POWDER, LYOPHILIZED, FOR LIPOSOMAL SUSPENSION
 INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION
 INJECTION, POWDER, LYOPHILIZED, FOR SUSPENSION
 INJECTION, POWDER, LYOPHILIZED, FOR SUSPENSION, EXTENDED RELEASE
 INJECTION, SOLUTION
 INJECTION, SOLUTION, CONCENTRATE
 INJECTION, SUSPENSION
 INJECTION, SUSPENSION, EXTENDED RELEASE

Route of Administration: * _____ **ADD**

ROUTE OF ADMINISTRATION

1 - 1

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

Route of Administration: _____ **ADD**

ROUTE OF ADMINISTRATION

HEMODIALYSIS **X**

1 - 1

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

Route of Administration: _____ **ADD**

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 MARKETING - 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 MARKETING - 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 ADD INGREDIENT

None

- 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 --

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
Ingredient - Dietary Supplement

- 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: *

Active Moiety: *

☐ Moiety same as Ingredient

Numerator Strength: *

Unit Of Measure: *

-- Select One --

Denominator Strength: *

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.

+	SOURCE NDC	DOCUMENT TYPE
✗		

- 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: *

ketocon

Active Moiety: *

(P7P4A1FD7Z) N-DEACETYL**KETOCONAZOLE**
(3INP7D7X13) **KETOCONAZOLE**, TRANS-
(R9400W927I) **KETOCONAZOLE**
(2DJ8R0NT7K) LEVO**KETOCONAZOLE**

Numerator Strength: *

Denominator Strength: *

- 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: *

☐ 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

1	AI UNII	Active Ingredient	AM UNII	Active Moiety	Basis of Strength	RD UNII	Referenced Drug
6930	690GD6V8H	KETAMINE	690GD6V8H	KETAMINE	Active Ingredient		
6931	O18YU00I83	KETAMINE HYDROCHLORIDE	690GD6V8H	KETAMINE	Active Moiety		
6932	5F91OR6H84	KETAMINE HYDROCHLORIDE, R-	690GD6V8H	KETAMINE			
6933	97F9DE4CT4	KETANSERIN	97F9DE4CT4	KETANSERIN	Active Ingredient		
6934	645496CK7H	KETANSERIN TARTRATE	97F9DE4CT4	KETANSERIN			
6935	6I04IG5185	KETAZOCINE	8I04IG5185	KETAZOCINE	Active Ingredient		
6936	92A214MD7Y	KETAZOLAM	92A214MD7Y	KETAZOLAM	Active Ingredient		
6937	E00MDP82S4	KETHOXAL	E00MDP82S4	KETHOXAL	Active Ingredient		
6938	U5C4H63K5U	KETIPRAMINE	U5C4H63K5U	KETIPRAMINE	Active Ingredient		
6939	PQS1L514CF	KETOBEMIDONE	PQS1L514CF	KETOBEMIDONE	Active Ingredient		
6940	U9U6LTV80K	KETOBEMIDONE HYDROCHLORIDE	PQS1L514CF	KETOBEMIDONE			
6941	WA1RT89G9X	KETOCABINE	WA1RT89G9X	KETOCABINE	Active Ingredient		
6942	UOG78PXR4W	KETOCABINOL	UOG78PXR4W	KETOCABINOL	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	820ZXE70XL	KETORFANOL	820ZXE70XL	KETORFANOL	Active Ingredient		
6948	YZ15105V0L	KETOROLAC	YZ15105V0L	KETOROLAC	Active Ingredient		
6949	4EVE5946BQ	KETOROLAC TROMETHAMINE	YZ15105V0L	KETOROLAC	Active Ingredient		
6950	4EVE5946BQ	KETOROLAC TROMETHAMINE	YZ15105V0L	KETOROLAC	Active Moiety		
6951	X49220T18G	KETOTIFEN	X49220T18G	KETOTIFEN	Active Ingredient		
6952	HBDS03WORO	KETOTIFEN FUMARATE	X49220T18G	KETOTIFEN	Active Moiety		
6953	504RN634MM	KETOTREXATE	504RN634MM	KETOTREXATE	Active Ingredient		
6954	FV4YQJ02CX	KEYHOLE LIMPET HEMOCYANIN	FV4YQJ02CX	KEYHOLE LIMPET HEMOCYANIN	Active Ingredient		
6955	5G117T0TJZ	KHELLIN	5G117T0TJZ	KHELLIN	Active Ingredient		

- i. Click the 'Add Active Moiety' button to add another moiety. Click the button again to remove that moiety.

Denominator Strength: *

ADD ACTIVE MOIETY

Denominator Strength: *

REMOVE ACTIVE MOIETY

- j. 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
+		
X		

- k. 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 Strei

Ingredient UNII - Name: *

Active Moiety: *

☐ Moiety same as Ingredient

Reference Ingredient: *

- l. 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

☐

Source NDC: *



No Manufacture Information for this Source NDC

☐

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
						row(s) 1 - 2 of 2
	SUBSTANCE NAME	UNII / NDC	STRENGTH	TYPE	SOURCE NDC	
	2-HYDROXY-5-METHYLACETOPHENONE	11661U1ZEN	1 g	ACTIB	-	
	2,5-DIMETHYL-1-NITROSPYRROLIDINE, CIS-	62Z1C3UUHS	100 [IU]	IACT	-	

18. Next, click **'Add Characteristic'** to enter color/flavor/score/shape/imprint/size details:

CHARACTERISTICS
ADD CHARACTERISTIC

None

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

CHARACTERISTICS

Characteristic: * -- Select One -- v

Value: * -- Select One -- v

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

CHARACTERISTICS

Characteristic: * Color v

Value: * -- Select One -- v

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"):

The screenshot shows a form titled "CHARACTERISTICS". It contains three fields: "Characteristic:" with a dropdown menu set to "Color", "Value:" with a dropdown menu set to "White", and "Additional Description:" with a text input field containing the word "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:

The screenshot shows a table titled "CHARACTERISTICS" with a red "ADD CHARACTERISTIC" button in the top right corner. The table has four columns: "CHARACTERISTIC", "VALUE", and "ADDITIONAL DESCRIPTION". The first row shows "SPLCOLOR" with a value of "WHITE" and an additional description of "IVORY". The second row shows "SPLSHAPE" with a value of "BULLET" and an additional description of "-". A pencil icon is highlighted in the first row, indicating it can be edited.

	CHARACTERISTIC	VALUE	ADDITIONAL DESCRIPTION
	SPLCOLOR	WHITE	IVORY
	SPLSHAPE	BULLET	-

19. To add a Package:

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

The screenshot shows a form titled "PACKAGING". It contains a single option "None" and a red "ADD PACKAGE" button in the top right corner.

- b. Enter all applicable data for the package:

The screenshot shows the 'PACKAGING' section of the FDA DIRECT interface. At the top, there are navigation tabs: 'All Submissions', 'Compounded Drug Reporting', 'Products', 'Product Details', and 'Packaging' (which is active). Below the tabs are three buttons: 'SAVE PACKAGE', 'DONE', and '<< RETURN'. The main form area is titled 'PACKAGING' and contains a section labeled 'ONLY LEVEL'. This section includes a 'Check for Deletion' checkbox (which is unchecked), a 'Package NDC' text input field, a 'Package Type' dropdown menu (showing '- Select Value -'), a 'Quantity' text input field, a 'Unit of Measure' dropdown menu (showing '- Select Value -'), and a 'Number of Units Produced' text input field. At the bottom right of the form, there are three buttons: 'ADD OUTER PACKAGE', 'DELETE', and '▲ 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):

The screenshot shows the 'PACKAGING' section of the FDA DIRECT interface, displaying two levels of packaging. The top section is labeled 'INNERMOST LEVEL' and contains the same fields as the previous screenshot: 'Check for Deletion' (unchecked), 'Package NDC', 'Package Type' (dropdown), 'Quantity', 'Unit of Measure' (dropdown), and 'Number of Units Produced'. Below this is a section labeled 'OUTERMOST LEVEL', which also contains the same fields. In the 'OUTERMOST LEVEL' section, the 'Unit of Measure' dropdown is set to '1' and the 'Number of Units Produced' text input field contains the value '0'. At the bottom right of the form, the 'ADD OUTER PACKAGE' button is highlighted with a red rectangle, and a red arrow points to it from the left. The 'DELETE' button is also visible next to it.

- 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:

The screenshot shows the 'OUTERMOST LEVEL' form. A red box highlights the 'Check for Deletion' checkbox, which is checked. A confirmation dialog box is displayed in the center, asking 'Are you sure you want to delete?' with 'CANCEL' and 'OK' buttons. At the bottom right, another red box highlights the 'DELETE' button. The form fields include: Package NDC (empty), Package Type (dropdown with '- Select Value -'), Quantity (empty), Unit of Measure (dropdown with '1'), and Number of Units Produced (empty).

- 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):

The screenshot shows the 'PACKAGING' table. A red box highlights the pencil icon in the first row. The table has columns: PACKAGE NDC/DEVICE ID, NO OF LEVELS, PACKAGE TYPE, QUANTITY, UNIT OF MEASURE, NUMBER OF UNITS PRODUCED, and CLONE. The first row contains: -, 1, BOTTLE, PLASTIC, 90, mg, 1000.

- g. To make an exact duplicate of a package you previously created, click the '**Clone**' icon:

The screenshot shows the 'PACKAGING' table. A red box highlights the 'CLONE' button in the first row. The table has columns: PACKAGE NDC/DEVICE ID, NO OF LEVELS, PACKAGE TYPE, QUANTITY, UNIT OF MEASURE, NUMBER OF UNITS PRODUCED, and CLONE. The first row contains: -, 1, BOTTLE, PLASTIC, 90, mg, 1000.

IMPORTANT: When cloning, don't forget to add the 'Number of Units Produced'! The number **does not** carry over to the new package:

The screenshot shows the 'PACKAGING' table with two rows. A red box highlights the 'NUMBER OF UNITS PRODUCED' column. The first row contains: -, 1, BOTTLE, PLASTIC, 90, mg, 1000. The second row contains: -, 1, BOTTLE, PLASTIC, 90, mg, 0. A red arrow points to the '0' in the second row.

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:

PRODUCTS

Do you have any products to report: * Yes ▾

Q ▾ GO ACTIONS ▾

1 - 2 of 2

SELECT	PRODUCT NDC	PROPRIETARY NAME	DOSAGE FORM	INCLUDED IN SPL	INGREDIENTS	CLONE PRODUCT
	-	Conazol	CAPSULE, LIQUID FILLED	YES	SHOW INGREDIENTS	
	-	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:

PRODUCTS

Do you have any products to report: * Yes ▾

UPDATE VOLUME ADD PRODUCT

Update Package Volumes

Note: Only packages with number of units produced greater than 0 will be included in the submission.

SAVE

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

1 - 1

22. Back on the Products page, enter the Content of Labeling information:

- a. Click the **'Content of Labeling'** button at the top:

All Submissions Compounded Drug Reporting Products

CONTENT OF LABELING SUBMIT SPL SAVE AS DRAFT SAVE AND VALIDATE DELETE << 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.

- b. Click **'Add Section'**:

All Submissions Compounded Drug Reporting Products Content of Labeling

ADD SECTION << RETURN

- c. A blank template will display. Fill in all applicable fields:

- 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).

- e. '**Effective Date**' is the date this labeling change/submission will occur.

- 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 first label section above ('Adverse Reactions Section') was created first and is automatically assigned the number '1':

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':

- g. 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:

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Source

- 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

UPLOAD

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.

Upload Image: *

Choose File

IMAGES

None

- 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



UPLOAD

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.

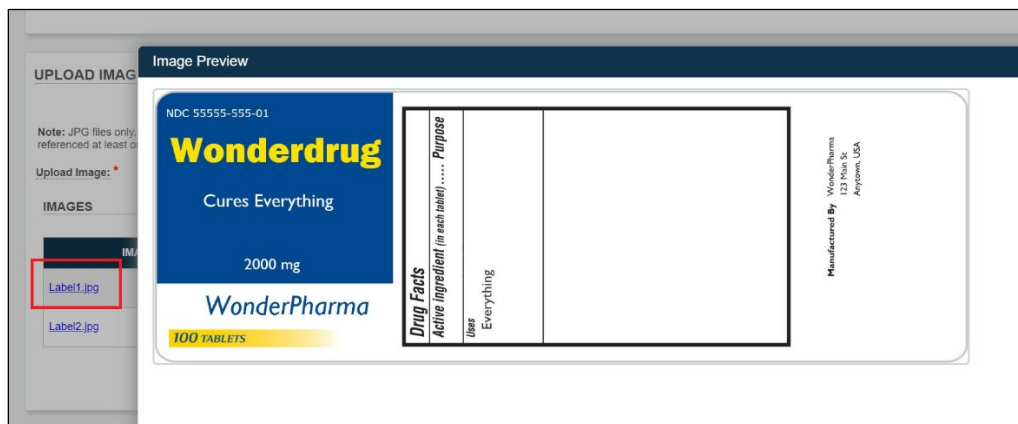
Upload Image: *

Choose File

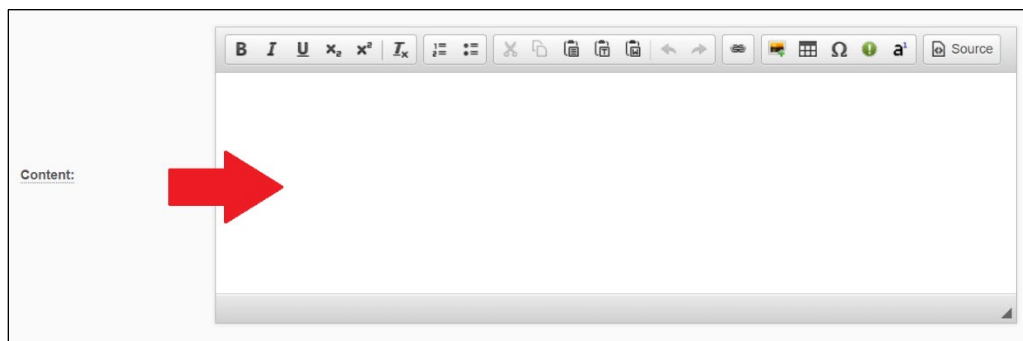
IMAGES


IMAGE NAME	IMAGE	DELETE IMAGE	REFERENCED
Label1.jpg		✖	No
Label2.jpg		✖	No

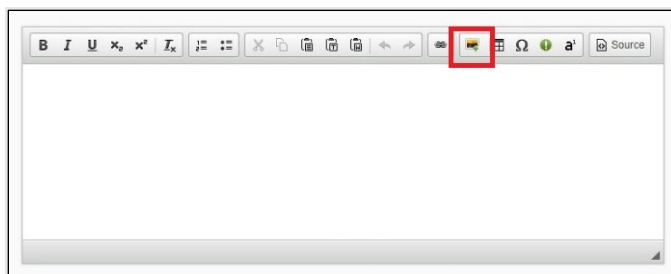
- m. Click the red **X** beside an image to delete the image. Doing this will cause images to disappear or not display properly if they have been used (“referenced”) in a section.
- n. Click the name of the image to display a closeup preview:



- 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:

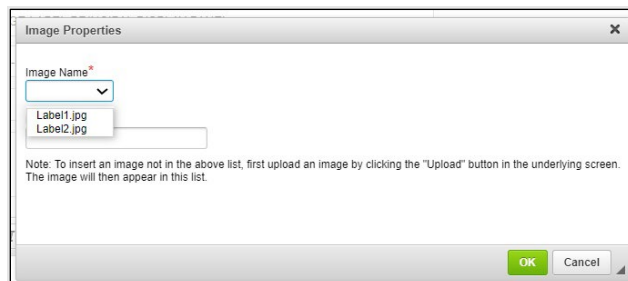


- p. Select the ‘insert an image’ icon  from the options bar (hover over any of the icons for a short text description):

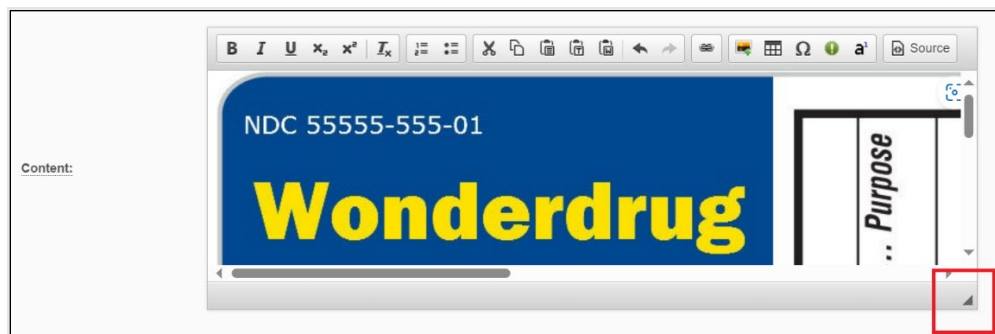


- q.

- r. A popup box will display. Your previously uploaded image(s) will now be available to select from the dropdown:



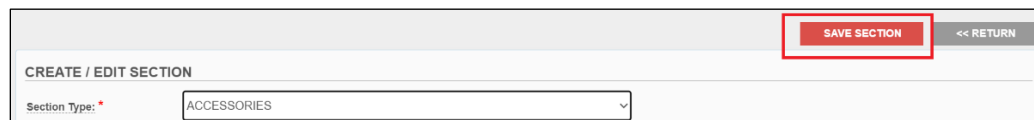
- s. Next, add some Image Text. This is alt text (description text for an image that is not visible anywhere but can be picked up and read by screen reading technology).
- t. Click 'OK.' Your image will now display within the Content box. Click and drag the corner arrow to view more of the image:



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:

This screenshot shows the 'Content of Labeling' page. At the top, there are navigation tabs: '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 two buttons: 'ADD SECTION' and '<< RETURN'. At the bottom, there is a list of sections, with the first one being 'A SAMPLE TITLE [ACCESSORIES]'. The 'EDIT' button next to this section 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 now highlighted with a red box. The 'EDIT' button is no longer highlighted.

- 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 'Content of Labeling' page with the 'EXPAND SECTIONS' button highlighted with a red box. Below the buttons, there is a list of sections: 'A SAMPLE TITLE [ACCESSORIES]' and '[CONTROLLED SUBSTANCE SECTION]'. Each section has a circular arrow icon to its left.

This screenshot shows the 'Content of Labeling' page with the 'EXPAND SECTIONS' button highlighted with a red box. Below the buttons, there is a list of sections: 'A SAMPLE TITLE [ACCESSORIES]' and '[CONTROLLED SUBSTANCE SECTION]'. Each section has a circular arrow icon to its left. The first section, 'A SAMPLE TITLE [ACCESSORIES]', is expanded and shows a sample drug label for 'Wonderdrug'. The second section, '[CONTROLLED SUBSTANCE SECTION]', is also expanded and shows a sample drug label for 'Wonderdrug'. The labels include the NDC number, drug name, strength, manufacturer, and a table for 'Drug Facts'.

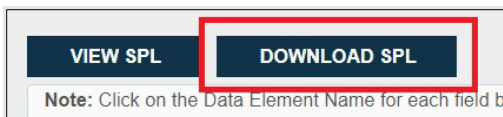
- y. Click **'Collapse Sections'** (top left) to close all entries.
 - z. You also have the option to switch between **'Classic'** and **'Enhanced'** (top left button) mode, which simply changes the look of the lists.
 - aa. See Section 9.1 for additional help with the Content of Labeling section.
 - 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-a063-b055b40a4e41	0767dad8-b638-0717-a063-b055b40a4e41	1	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.

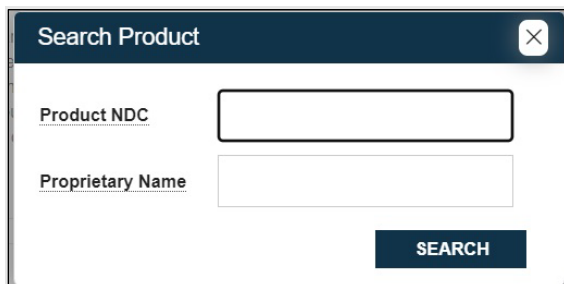


28. If you already have multiple Compounded Product Reporting submissions, you can search for a specific submission:

- 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:

The screenshot shows the FDA Direct interface. On the left sidebar, under the 'DSCSA ANNUAL REPORTING' section, 'Wholesale Drug Distributor And Third Party Logistics Provider Reports' is highlighted with a red box. The main content area is titled 'WHOLESALE DRUG DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER REPORTS'. It includes a search bar with a magnifying glass icon, a 'GO' button, and an 'ACTIONS' dropdown menu. Below this is a table with columns: STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, DOCUMENT LABEL, REPORTER DETAILS, LAST MODIFIED USER, and LAST MODIFIED DATE. The table contains one row with the status 'DRAFT', a SET ID of '0b6dc3a-82be-5e9f-e053-fa95940ac226', a ROOT ID of '0b6dc3a-82be-5e9f-e053-fa95940ac226', a SUBMISSION ID of '1', a VERSION of '1', a DOCUMENT LABEL of 'WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT', a REPORTER DETAILS of 'DETAILS', a LAST MODIFIED USER of 'Zee Dee', and a LAST MODIFIED DATE of '10-02-2023 16:35:59'. A 'CREATE NEW / UPLOAD FILE' button is located at the top right of the table area.

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

The screenshot shows the FDA Direct dashboard with the 'WHOLESALE DRUG DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER REPORTS' section. The left sidebar contains navigation links for 'ESTABLISHMENT REGISTRATION & DRUG LISTING', 'OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING', and 'DSCSA ANNUAL REPORTING'. The main content area includes a search bar, a 'GO' button, and an 'ACTIONS' dropdown. A table lists existing submissions with columns for STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, DOCUMENT LABEL, REPORTER DETAILS, LAST MODIFIED USER, and LAST MODIFIED DATE. A red box highlights the 'CREATE NEW / UPLOAD FILE' button in the top right corner.

4. You will be given two options:

The screenshot shows the 'CREATE NEW WHOLESALE DRUG DISTRIBUTION & THIRD PARTY LOGISTICS' form. It contains two radio button options: 'Create a new Wholesale Drug Distribution & Third Party Logistics using a blank form' and 'Import an existing Wholesale Drug Distribution & Third Party Logistics SPL'. A note states: '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, there are 'CONTINUE' and 'CANCEL' buttons. The 'CONTINUE' button is highlighted with a red box.

- 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:

The screenshot shows the 'SPL Submission' form in the FDA Direct system. At the top, there are navigation links for 'All Submissions', 'WDD/3PL', and 'SPL Submission'. On the right, there are buttons for 'SAVE AS DRAFT' and '<< RETURN'. A note states: '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 'HEADER DETAILS' section contains the following fields:

- Document Type:** A dropdown menu currently showing 'WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT'.
- Set ID:** A text field containing '06fb25ba-b23c-92ab-e063-fb95b40a8a24' with a 'Generate New' link.
- Version Number:** A text field containing '1'.
- Root ID:** A text field containing '06fb25ba-b23d-92ab-e063-fb95b40a8a24' with a 'Generate New' link.
- Effective Date:** A date field containing '10-05-2023' with a calendar icon.

Below the header details is the 'REPORTER DETAILS' section, which includes fields for 'Reporter Organization Name' and 'Reporter Organization DUNS'. Below that is the 'REPORTER CONTACT PERSON DETAILS' section, which includes fields for 'Contact Person Name', 'Contact Person Email', 'Contact Person Phone', and 'Phone Extension'. A 'Format' link is next to the phone number field.

At the bottom of the form is the 'FACILITIES' section, which currently shows 'None' and an 'ADD FACILITY' button.

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:

This screenshot shows the 'HEADER DETAILS' section of the form with the 'Document Type' dropdown menu open. The dropdown list contains the following options:

- Select One--
- WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT
- WITHDRAWAL OF WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT
- OUT OF BUSINESS NOTIFICATION

The other fields in the 'HEADER DETAILS' section remain the same as in the previous screenshot: Set ID is '06fb25ba-b23c-92ab-e063-fb95b40a8a24', Version Number is '1', Root ID is '06fb25ba-b23d-92ab-e063-fb95b40a8a24', and Effective Date is '11-06-2023'.

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' tab in the FDA DIRECT system. The form is divided into several sections:

- FACILITY DETAILS:** Includes fields for Facility Name (Legal Name), Facility DUNS, and Facility DUNS Not Available (checkbox).
- FACILITY ADDRESS:** Includes fields for Country (dropdown), Street Address, Street Address Confidential (checkbox), City, State (dropdown), and Zip Code.
- DOING BUSINESS AS (DBAs):** Includes a text field and an 'ADD DBA' button.
- FACILITY CONTACT DETAILS:** Includes fields for Contact Name, Contact Email, Contact Phone, and Phone Extension. There is a 'Format' link next to the Contact Phone field.
- BUSINESS OPERATION(S) OF FACILITY:** Includes checkboxes for WDD OPERATION and 3PL OPERATION.

Navigation buttons at the top right include 'SAVE FACILITY' and '<< RETURN'. A 'SAME AS REPORTER CONTACT' button is also present in the Facility Contact Details section.

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 close-up screenshot focuses on the 'FACILITY ADDRESS' section. The 'Street Address Confidential' checkbox is highlighted with a red rectangle, indicating where the user should click to keep the street name private.

14. To enter DBA (Doing Business As) information click the '**Add DBA**' button and a popup box will display:

This close-up screenshot focuses on the 'DOING BUSINESS AS (DBAs)' section. The 'ADD DBA' button is highlighted with a red rectangle, indicating where the user should click to add new DBA information.

- a. Enter your **'DBA Name'** and select the appropriate business operation from the dropdown.
- b. To add multiple DBAs without closing the popup, click the **'Save And Add'** button for each new DBA entry.
- c. 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
				ROW(S) 1 - 3 of 3
EDIT	DELETE	DBA NAME	BUSINESS OPERATION OF DBA	
		Yes123	WDD	
		No123	3PL	
		YesAndNo123	BOTH (WDD/3PL)	

- d. 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):

The image displays two screenshots of the 'License' form in the FDA Direct system. Both screenshots show the 'License' tab selected in the navigation bar. The top screenshot shows the 'License Type' as 'WHOLESALE DRUG DISTRIBUTOR'. The bottom screenshot shows the 'License Type' as 'THIRD-PARTY LOGISTICS PROVIDER'. Both screenshots show the following fields: 'License Number' (required), 'Expiration Date' (required with a calendar icon), 'Issuer' (required with a dropdown menu), and 'State/Territory'. A note states: 'To Add a new disciplinary action or to Update an existing disciplinary action that is resolved click the ADD DISCIPLINARY ACTION button.' Below the note is a section titled 'DISCIPLINARY ACTION DETAILS' with a 'None' entry and an 'ADD DISCIPLINARY ACTION' button. The 'SAVE LICENSE' and '<< RETURN' buttons are visible in the top right corner of both screenshots.

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:

The image shows the 'Disciplinary Action' form in the FDA Direct system. The 'Disciplinary Action' tab is selected in the navigation bar. The form is divided into two main sections: 'ACTION DETAILS' and 'RELEVANT DOCUMENTS'. The 'ACTION DETAILS' section includes 'Action Type' (required, dropdown menu) and 'Issuing Date' (required, calendar icon). The 'RELEVANT DOCUMENTS' section includes a 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"'. Below the note is a 'Document' field with a 'Choose File' button. An 'ADD DOCUMENT' button is located to the right of the 'RELEVANT DOCUMENTS' section. The 'SAVE ACTION' and '<< RETURN' buttons are visible in the top right corner.

- 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 ADD DOCUMENT

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

- 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 ADD DOCUMENT

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

DOCUMENT NAME	DATE ADDED	DELETE
sample1.pdf	10-05-2023	

row(s) 1 - 1 of 1

- 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.

<input type="checkbox"/>	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.

<input type="checkbox"/>	EDIT	LICENSE NUMBER	LICENSE STATE
<input type="checkbox"/>		123	ARIZONA

- b. Then click 'Switch To 3PL/WDD License':

ADD WDD LICENSE

SWITCH TO 3PL LICENSE

ction.

row(s) 1 - 1 of 1

LICENSE STATE	EXPIRATION DATE	CONTROLLED SUBSTANCE	DISCIPLINARY ACTION
	12-31-2023	Yes	Yes

ADD 3PL LICENSE

SWITCH TO WDD LICENSE

ction.

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:

BUSINESS OPERATION(S) OF FACILITY *

☒ WDD OPERATION ☒ 3PL OPERATION

WDD LICENSES ADD WDD LICENSE SWITCH TO 3PL LICENSE

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

3PL LICENSES ADD 3PL LICENSE SWITCH TO WDD LICENSE

Enter 3PL licenses.
Only enter DEA registration or state controlled-substance license if there is a significant disciplinary action.

row(s) 1 - 2 of 2

	EDIT	LICENSE NUMBER	LICENSE STATE	EXPIRATION DATE	CONTROLLED SUBSTANCE	DISCIPLINARY ACTION
<input type="checkbox"/>		100000	ALABAMA	12-31-2023	Yes	Yes
<input type="checkbox"/>		123	ARIZONA	10-27-2023	No	No

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.

WDD/3PL FACILITIES

GO ACTIONS

SELECT	DUNS	NAME	STREET	CITY	STATE	ZIP	COUNTRY	STATUS	SPL SET ID
	-	CNI Facility	123 Way Rd	Pago Pago	-	96799	ASM	Reported	06fb25ba-b23c-92ab-e063-fb95b40a8a24

1 - 1

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:

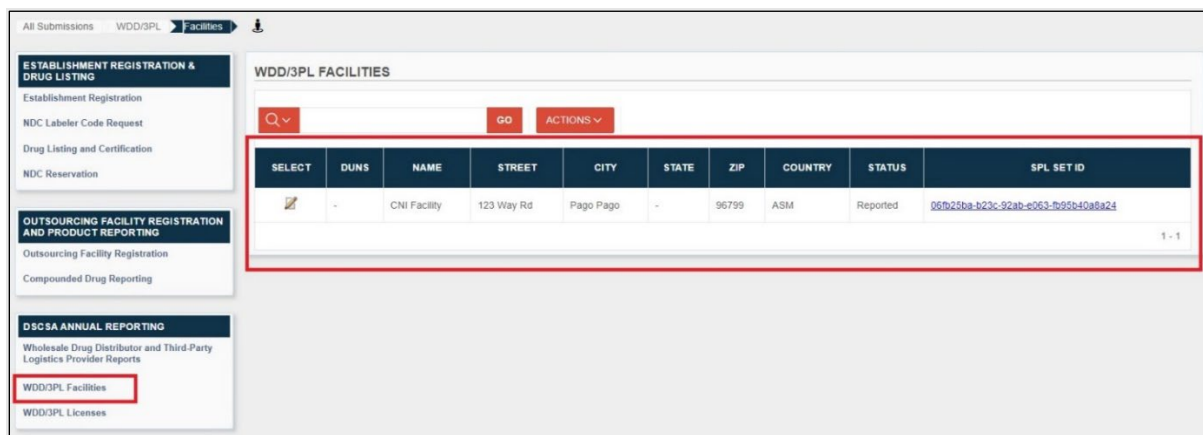
d. **'Delete'** – Delete your draft entry completely.

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.

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:



The screenshot shows the 'WDD/3PL Facilities' section of the FDA DIRECT interface. The sidebar on the left contains several categories: 'ESTABLISHMENT REGISTRATION & DRUG LISTING', 'OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING', and 'DSCSA ANNUAL REPORTING'. Under 'ESTABLISHMENT REGISTRATION & DRUG LISTING', there are links for 'Establishment Registration', 'NDC Labeler Code Request', 'Drug Listing and Certification', and 'NDC Reservation'. Under 'OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING', there are links for 'Outsourcing Facility Registration' and 'Compounded Drug Reporting'. Under 'DSCSA ANNUAL REPORTING', there are links for 'Wholesale Drug Distributor and Third-Party Logistics Provider Reports', 'WDD/3PL Facilities' (highlighted with a red box), and 'WDD/3PL Licenses'. The main content area is titled 'WDD/3PL FACILITIES' and contains a search bar with a 'GO' button and an 'ACTIONS' dropdown. Below the search bar is a table with the following columns: SELECT, DUNS, NAME, STREET, CITY, STATE, ZIP, COUNTRY, STATUS, and SPL SET ID. The table contains one row of data for a facility named 'CNI Facility' located at '123 Way Rd', 'Pago Pago', '96799', 'ASM', with a status of 'Reported' and an SPL SET ID of '057c25ba-b23c-92ab-e063-fb05b40a8a24'. A red box highlights the 'SELECT' column header and the pencil icon in the first row. The page number '1 - 1' is visible at the bottom right of the table.

SELECT	DUNS	NAME	STREET	CITY	STATE	ZIP	COUNTRY	STATUS	SPL SET ID
	-	CNI Facility	123 Way Rd	Pago Pago	-	96799	ASM	Reported	057c25ba-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: * leiato@global.org

Contact Person Phone: * 2-222-222-2222

Phone Extension: *

FACILITIES

row(s) 1 - 1 of 1

EDIT	FACILITY DUNS	FACILITY NAME	FACILITY CITY	FACILITY STATE
		CNI Facility	Pago Pago	-

- 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:

WDD/3PL LICENSES

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-b95b40a8a24
	123	ARIZONA	27-OCT-23	-	CNI Facility	Reported	06fb25ba-b23c-92ab-e063-b95b40a8a24

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:

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: * leiato@global.org

Contact Person Phone: * 2-222-222-2222

Phone Extension:

FACILITIES

row(s) 1 - 1 of 1

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**

[<< RETURN](#)

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:* leiato@global.org

Contact Phone:* 2-222-2222

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.


row(s) 1 - 1 of 1

EDIT	LICENSE NUMBER	LICENSE STATE	EXPIRATION DATE	CONTROLLED SUBSTANCE	DISCIPLINARY ACTION
	13	ARIZONA	10-27-2023	No	No

3PL LICENSES

Enter 3PL licenses.
Only enter DEA registration or state controlled-substance license if there is a significant disciplinary action.

row(s) 1 - 1 of 1

EDIT	LICENSE NUMBER	LICENSE STATE	EXPIRATION DATE	CONTROLLED SUBSTANCE	DISCIPLINARY ACTION
	00000	ALABAMA	12-31-2023	Yes	Yes

- 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:

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 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

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 **ADD FACILITY**

None

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 header bar with the text "FACILITIES" and a sub-header "None". On the right side of the bar is a red button labeled "ADD FACILITY".

11. You will be shown a separate form. Enter all applicable facility information:

The screenshot shows a form titled "Facility" with a navigation bar at the top containing "All Submissions", "GDUFA Self-Identification", "SPL Submission", and "Facility" (which is highlighted). The form is divided into four main sections:

- FACILITY DETAILS:** Includes fields for Facility Name, Facility DUNS, and Facility FEI.
- FACILITY ADDRESS:** Includes fields for Country (a dropdown menu), Street Address, City, State/Province, and Postal Code.
- FACILITY CONTACT DETAILS:** Includes a checkbox for "Same as Registrant Contact Details and Address", and fields for Contact Name, Contact Email, Contact Phone, Phone Extension, and Contact Fax. There is a "Format" link next to the Contact Phone field.
- FACILITY CONTACT ADDRESS:** Includes fields for Country (a dropdown menu), Street Address, City, State/Province, and Postal Code.

 At the bottom of the form, there is a section for "BUSINESS OPERATION(S)" with a note: "Note: Enter the one or more drug manufacturing and processing operations performed at the facility." and a red button labeled "ADD BUSINESS OPERATION".

12. Click the '**Add Business Operation**' button at the bottom of this page:

The screenshot shows a header bar with the text "BUSINESS OPERATION(S)" and a sub-header "Note: Enter the one or more drug manufacturing and processing operations performed at the facility." On the right side of the bar is a red button labeled "ADD BUSINESS OPERATION".

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	• MANUFACTURES NON-GENERIC	
		PACK	• CONTRACT MANUFACTURING • MANUFACTURES NON-GENERIC	

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:

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	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
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
I_x	Remove formatting
1 2	Insert a numbered list
■	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
a¹	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:



The screenshot shows the 'Content of Labeling' interface. At the top, there are buttons for 'EXPAND SECTIONS', 'CLASSIC', 'ADD SECTION', and '<< RETURN'. Below these are three sections, each with a circular icon and a label: '[OTC - ACTIVE INGREDIENT SECTION]', '[DOSAGE FORMS & STRENGTHS SECTION]', and '[OTC - ACTIVE INGREDIENT SECTION]'. To the right of each section label is an 'EDIT' button. The 'EDIT' button for the first '[OTC - ACTIVE INGREDIENT SECTION]' is highlighted with a red rectangular box.

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

Parent Section: Sequence: * 1

Title:

Content:

This is the Active Ingredient Section.

Footnote: a¹

A popup window will display. Enter text for your footnote:

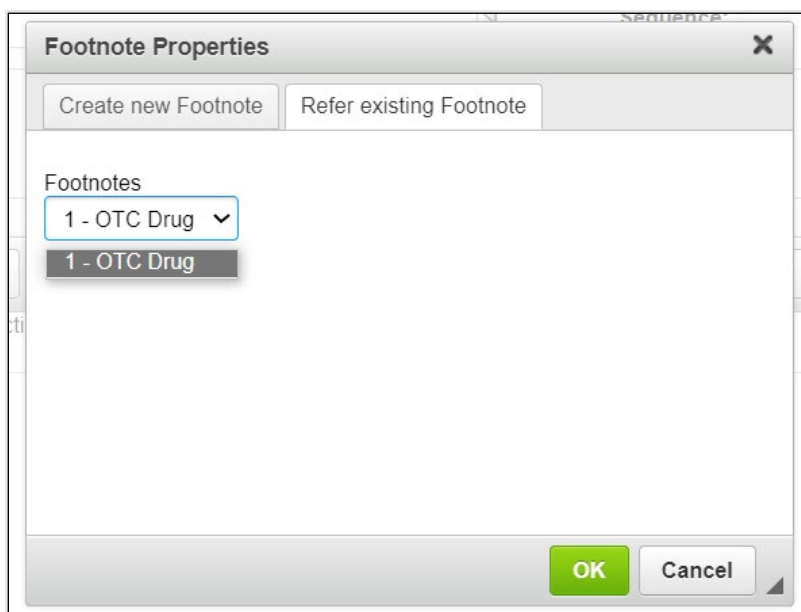
Footnote Properties

Create new Footnote Refer existing Footnote

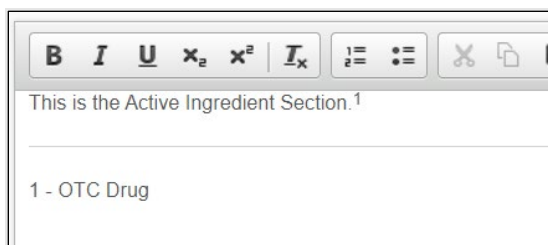
Footnote Text

OK Cancel

Refer an existing footnote:

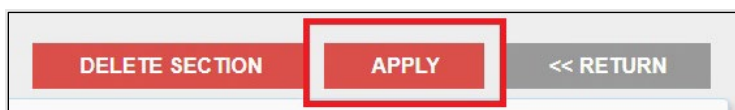


Your footnote will display in the text field:



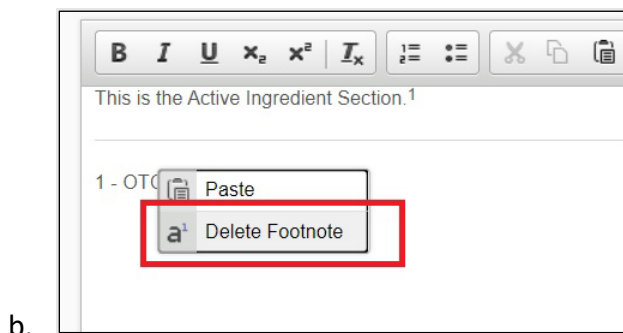
All section footnotes will appear sequentially at the bottom of the text box.

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

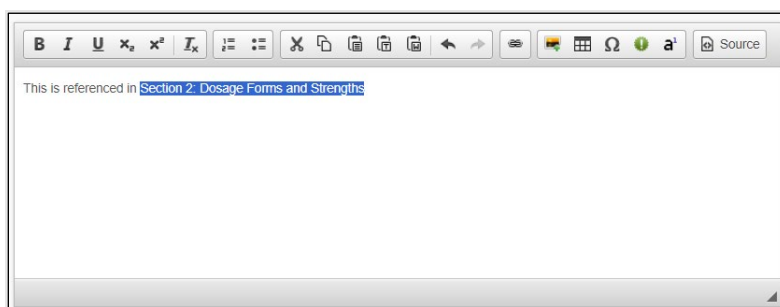
You can create 'links' or 'cross references' which are linked pieces of text that, when clicked, will send you to a different section within a Content of Labeling label.

To create a link/cross reference:

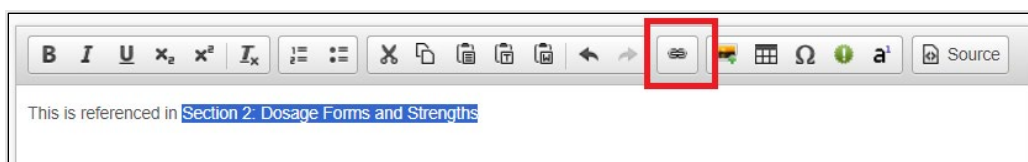
Click 'Edit' on a particular Content of Labeling section:



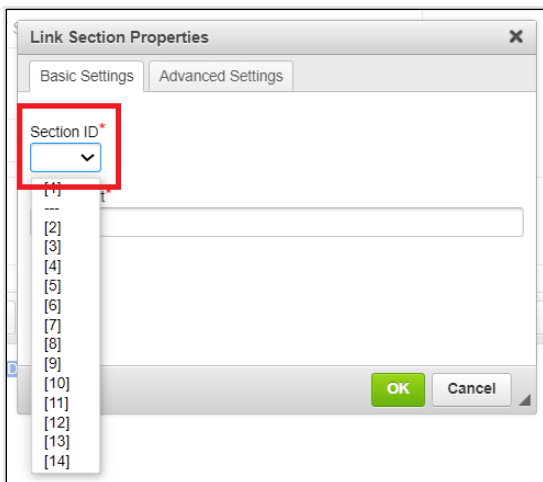
Select/highlight the text you want to make linkable:



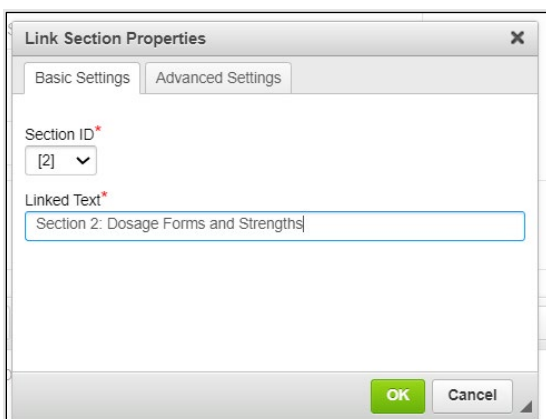
Click the 'link' icon:



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:

DELETE SECTION APPLY

EDIT SECTION

OTC - ACTIVE INGREDIENT SECTION

09-28-2023

Sequence: 1

This is referenced in [Section 2: Dosage Forms and Strengths](#)

You will be returned to your list of labels where your new link will be available:

All Submissions Drug Listing and Certification Products Content of Labeling

EXPAND SECTIONS CLASSIC

[+/-] [OTC - ACTIVE INGREDIENT SECTION]

This is referenced in [Section 2: Dosage Forms and Strengths](#)

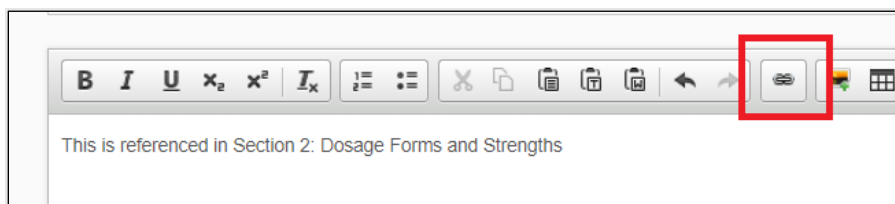
To delete a link/cross-reference:

1. Click 'Edit' on the section with the link.
2. Click anywhere inside the link text with your cursor:

B I U x₂ x² I_x [List Icons] [Link Icon]

This is referenced in [Section 2: Dosage Forms and Strengths](#)

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:

CREATE / EDIT SECTION

Section Type: * OTC - ACTIVE INGREDIENT SECTION

Effective Date: * 09-28-2023

Parent Section:  Sequence: * 1

Title:

This is the Active Ingredient section

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]

- Click on the desired section. This section will become the parent section.
- 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

- 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]

- 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.

ALL SUBMISSIONS

For assistance with validation errors contact the appropriate Help Desk: cdirect@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.

Search:

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

- **IMPORTANT:** This search bar does *not* search information within a submission. Only information displayed below the column headers is searchable.

- Click 'Go' and your search term will be listed with the results populated below the column headers:

ALL SUBMISSIONS

For assistance with validation errors contact the appropriate Help Desk: cdirect@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.

Search:

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE
SUBMISSION ACCEPTED	06fb25ba-b23c-92ab-e063-fb95b40a8a24	09830409-54e0-dc80-e063-fa95b40a7ed2	cd8976245130.6753108942@direct	4	OUT OF BUSINESS NOTIFICATION	Zee Dee	06-NOV-2023 15:59:53
SUBMISSION ACCEPTED	06fb25ba-b23c-92ab-e063-fb95b40a8a24	098202ac-66d2-b6e0-e063-fa95b40aafb8	cd385461927.1478623950@direct	3	WITHDRAWAL OF WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT	Zee Dee	06-NOV-2023 15:07:52
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	Zee Dee	05-OCT-2023 16:13:53

- You can search multiple terms at once to find your submission(s):

ALL SUBMISSIONS

For assistance with validation errors contact the appropriate Help Desk: cdirect@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.

Search:

☒ Row text contains '@direct'
 ☒ Row text contains 'nov'
 ☒ Row text contains 'out of business'
 ☒ Row text contains 'submission accepted'

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE
SUBMISSION ACCEPTED	06fb25ba-b23c-92ab-e063-fb95b40a8a24	09830409-54e0-dc80-e063-fa95b40a7ed2	cd8976245130.6753108942@direct	4	OUT OF BUSINESS NOTIFICATION	Zee Dee	06-NOV-2023 15:59:53

1 - 1

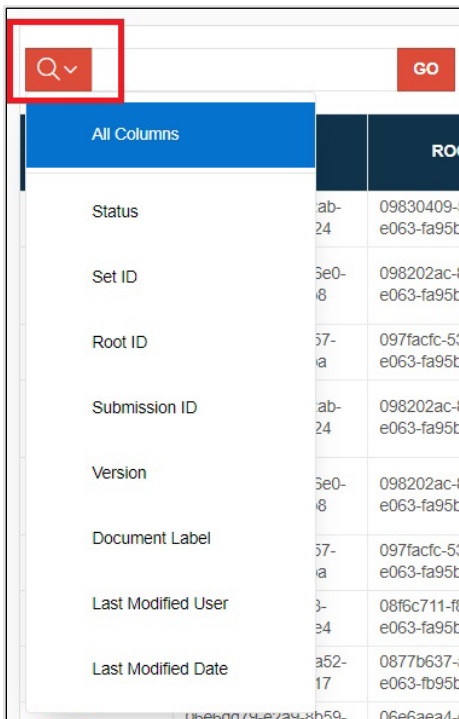
- Uncheck the box beside search terms you do not want to use. Your search results will be updated immediately:

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
SUBMISSION ACCEPTED	06fb25ba-b23c-92ab-e063-fb95b40a8a24	09830409-54e0-dc50-e063-fa95b40a7ed2	cd8976245130.6753108942@direct	4	OUT OF BUSINESS NOTIFICATION	Zee Dee	06-NOV-2023 15:59:53	
SUBMISSION ACCEPTED	06fb25ba-b23c-92ab-e063-fb95b40a8a24	098202ac-86d2-b5e0-e063-fa95b40aafb8	cd385461927.1478623950@direct	3	WITHDRAWAL OF WHOLESALE DRUG DISTRIBUTORS AND THIRD-PARTY LOGISTICS FACILITY REPORT	Zee Dee	06-NOV-2023 15:07:52	

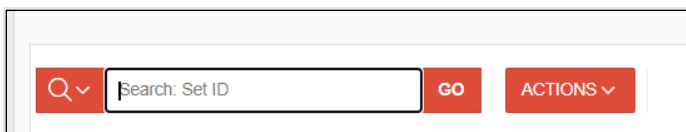
6. Click the 'x' beside a term to remove it completely:

7. If you have multiple search terms taking up space, you can click the arrow to collapse them:

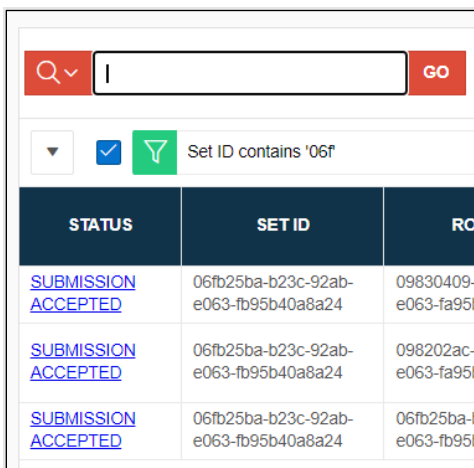
8. You can also search via a specific column header only. This is useful if you need to search by a set ID or root ID. Click the magnifying glass beside the search bar and list of the columns will display:



9. Select one of the dropdown options. Your selection will now be reflected in the search bar:



10. Enter your search term and press 'Go.' Only the selected column header will be searched on:



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:

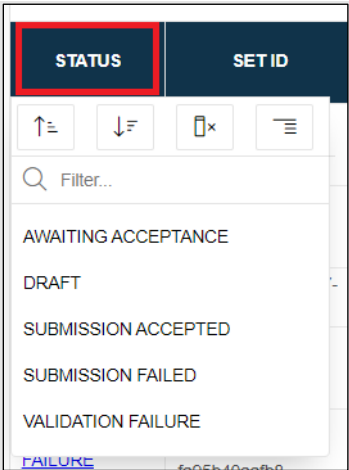
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
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1. Status: The current status of your submissions. For further explanation of the different status types, see Section 3.2: Submission Statuses.
2. Set 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:

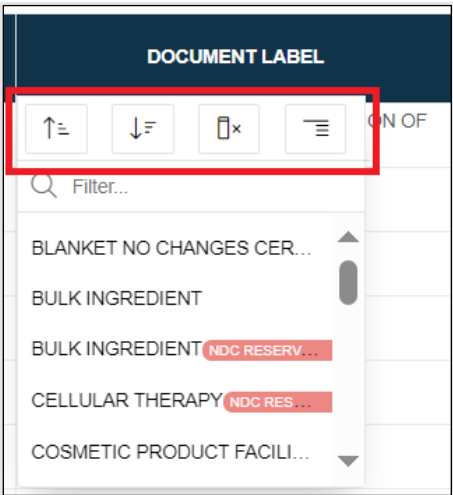


2. Select an option—Draft, for example—and all your submissions currently in that status will be displayed:

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	08f5c711-fb74-f9d8-e063-fa95b40a3ee4	08f5c711-fb75-f9d8-e063-fa95b40a3ee4		1	ESTABLISHMENT REGISTRATION	Zee Dee	30-OCT-2023 17:32:46	146737	
DRAFT	0877b637-a4a8-8a52-e063-fb95b40a6617	0877b637-a4a9-8a52-e063-fb95b40a6617		1	BULK INGREDIENT NDC RESERVATION	Zee Dee	24-OCT-2023 13:42:20	146715	
DRAFT	06e6dd79-e2a9-8b59-e063-fb95b40a5458	06e6ae4-d7f0-943f-e063-fa95b40ae069		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 10:41:50	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:

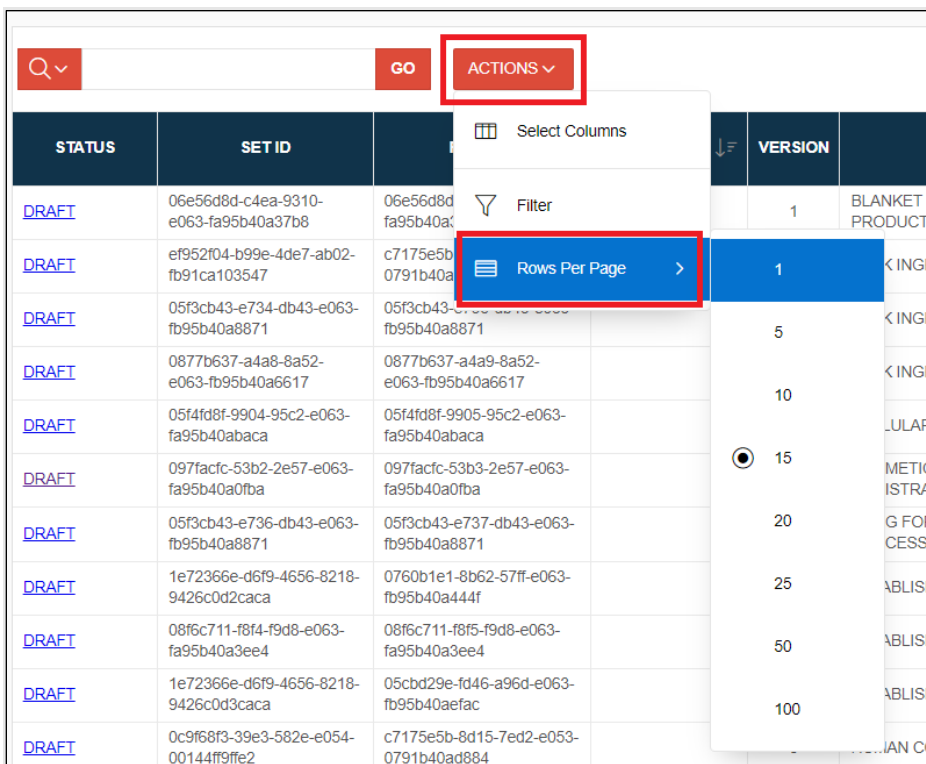


Icon	Description
	Sort ascending
	Sort descending
	Hide column
	Clearly separate each submission

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 with columns: STATUS, SET ID, and VERSION. The 'ACTIONS' button is highlighted with a red box. A dropdown menu is open, showing options: Select Columns, Filter, and Rows Per Page. The 'Rows Per Page' option is highlighted with a red box. The 'Rows Per Page' dropdown menu is also open, showing options: 1, 5, 10, 15, 20, 25, 50, and 100. The '15' option is selected.

STATUS	SET ID	VERSION
DRAFT	06e56d8d-c4ea-9310-e063-fa95b40a37b8	1
DRAFT	ef952f04-b99e-4de7-ab02-fb91ca103547	1
DRAFT	05f3cb43-e734-db43-e063-fb95b40a8871	5
DRAFT	0877b637-a4a8-8a52-e063-fb95b40a6617	10
DRAFT	05f4fd8f-9904-95c2-e063-fa95b40abaca	15
DRAFT	097facfc-53b2-2e57-e063-fa95b40a0fba	20
DRAFT	05f3cb43-e736-db43-e063-fb95b40a8871	25
DRAFT	1e72366e-d6f9-4656-8218-9426c0d2caca	50
DRAFT	08f6c711-f8f4-f9d8-e063-fa95b40a3ee4	100
DRAFT	1e72366e-d6f9-4656-8218-9426c0d3caca	
DRAFT	0c9f68f3-39e3-582e-e054-00144ff9ffe2	

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.