



U.S. Food and Drug Administration



USER'S GUIDE
to Cosmetics Direct
(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/distribute both drugs and cosmetics. For help with changing your account type, visit the [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, USCSA 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 (OCAC) 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 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. At any time, and for any lawful Government purpose, the Government may monitor, record, and audit your system use and/or internet, search and select 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 \(SPL\) 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](#) and click **Create New Account**.

LOGIN

Username:

Password:

[Forgot your password?](#)

[I accept the Terms of Service](#)

LOGIN

OR

CREATE NEW ACCOUNT

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

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

ORGANIZATION TYPE

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

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

- **CDER Direct** – Select this option to register human drug or biological products. You will have access to all drug-related submission forms including *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 both cosmetic and drug products. This account should be used by companies that manufacture/distribute both drugs and cosmetics. A complete list of all forms will be shown upon selecting this option.

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

ORGANIZATION TYPE

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

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

ORGANIZATION INFORMATION

Name: *

DUNS: *

ORGANIZATION ADDRESS

Country: *

Street Address: *

City: *

State: *

Postal Code: *

CONTACT INFORMATION

First Name: *

Middle Name:

Last Name: *

Job Title:

Contact Email: *

CONTACT PHONE

Country Code: *

Phone Number: *

Phone Extension:

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

- 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.

<p><input checked="" type="checkbox"/> ESTABLISHMENT REGISTRATION AND DRUG LISTING</p> <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 <p><input checked="" type="checkbox"/> COSMETIC REGISTRATION AND LISTING</p> <ul style="list-style-type: none"> • REGISTRATION OF COSMETIC PRODUCT FACILITY • COSMETIC PRODUCT LISTING 	<p><input checked="" type="checkbox"/> DRUG REPORTING BY OUTSOURCING FACILITY</p> <ul style="list-style-type: none"> • OUTSOURCING FACILITY REGISTRATION • COMPOUNDED DRUG REPORTING <p><input checked="" type="checkbox"/> DSOSA ANNUAL REPORTING</p> <ul style="list-style-type: none"> • WHOLESALE DRUG DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER REPORTS <p><input checked="" type="checkbox"/> GENERIC DRUG SELF-IDENTIFICATION</p> <ul style="list-style-type: none"> • GENERIC FACILITY GDUFA SELF-IDENTIFICATION
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- 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.

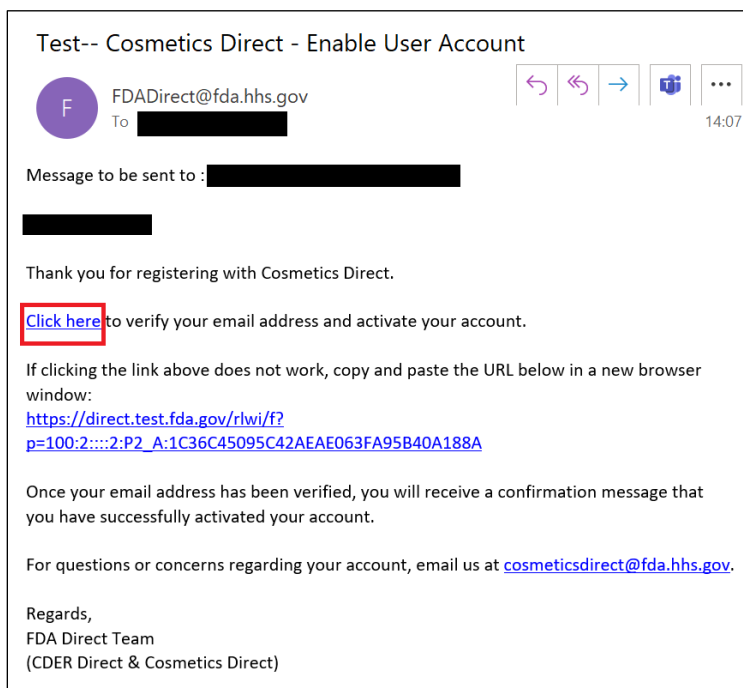
If you still have not received your activation email after 5-10 minutes, you can contact the Help Desk at:

- 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:

FDA **FDA Direct.**
CDER Direct & Cosmetics Direct

ACTIVATE ACCOUNT

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

Username: *

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

Password: *

Confirm Password: *

SUBMIT **CANCEL**

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

- Capital letter
- Lowercase letter
- Number
- Special character

A green checkmark will indicate that your username is acceptable:

ACTIVATE ACCOUNT

Username must be at least 8 characters and no more than 32 characters. It can consist of

Username: * ✓

9. Click **'Submit'** when all fields have been filled.

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:

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

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

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]

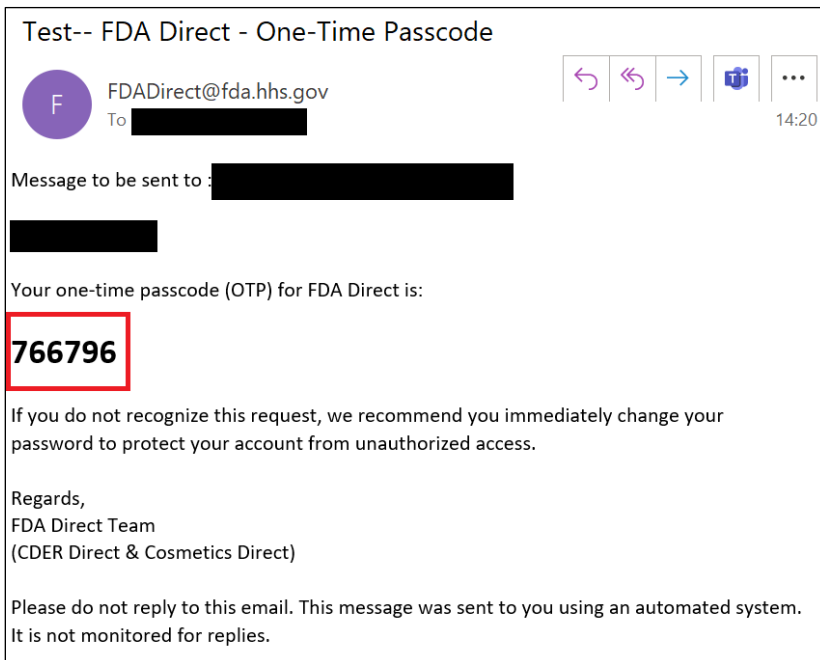
Contact Email: [redacted]@fda.hhs.gov Select the Pencil Icon ONLY if you need to change the email address associated with this username.

One-Time Passcode (OTP): [input field]

SUBMIT **CANCEL**

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

- 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.



- Enter the passcode from your email into the OTP field:

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): [input field]

SUBMIT **CANCEL**

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

PAPERWORK REDUCTION ACT NOTICE
 MB Control No. 0910-0599
 Expiration Date: December 31, 2026

Public reporting burden for this collection of information is estimated to average between 15 to 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Department of Health and Human Services
 Food and Drug Administration
 Office of Chief Information Officer
 Paperwork Reduction Act (PRA) Staff
PRAsstaff@fda.hhs.gov

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.

PLEASE NOTE: The system will automatically time out if there is no activity for 30 minutes.

OK

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

The screenshot shows the FDA Direct account dashboard. The top navigation bar includes the FDA logo and 'FDA Direct' and 'Cosmetics Direct' text. Below the navigation bar, there is a sidebar with menu items: 'All Submissions', 'COSMETIC REGISTRATION AND LISTING' (with sub-items 'Registration of Cosmetic Product Facility' and 'Cosmetic Product Listing'), and 'ESTABLISHMENT REGISTRATION & DRUG LISTING' (with sub-item 'Establishment Registration'). The main content area is titled 'ALL SUBMISSIONS' and contains a search bar with a magnifying glass icon, a search button, and an 'ACTIONS' dropdown menu. Below the search bar, the text 'None' is displayed, indicating no submissions are currently listed. A footer note provides contact information for assistance with validation errors.

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 large white warning banner is centered over the page. 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 the network or to a computer on this network.

This system is provided for Government authorized use only.

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

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

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

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

Buttons for 'CLOSE' and 'I AGREE' are visible at the bottom of the banner. The background shows the login form with fields for 'Username:' and 'Password:', a 'LOGIN' button, and a 'CREATE NEW ACCOUNT' button. A footer contains navigation links like 'FDA Home', 'Browser Requirements', 'Resources', 'Tutorials', 'Help Desk', and 'FAQs'.

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

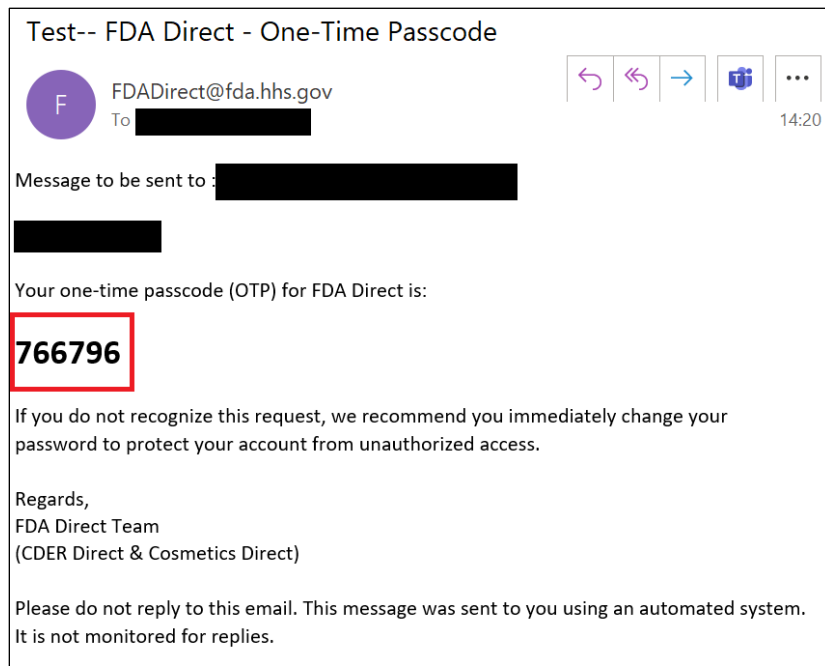
The screenshot shows the 'VERIFICATION CODE' page. It contains the following text:

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.

Fields for 'Username:' and 'One-Time Passcode (OTP):' are present. There is a checkbox for 'Remember this Device for 8 hours'. At the bottom are 'SUBMIT' and 'CANCEL' buttons.

- 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 number from your email into the OTP field, then check the box *'Remember this device for 8 hours'*:

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 homepage.
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'*:



FDA **FDA Direct**
CDER Direct & Cosmetics Direct

LOGIN

Username:

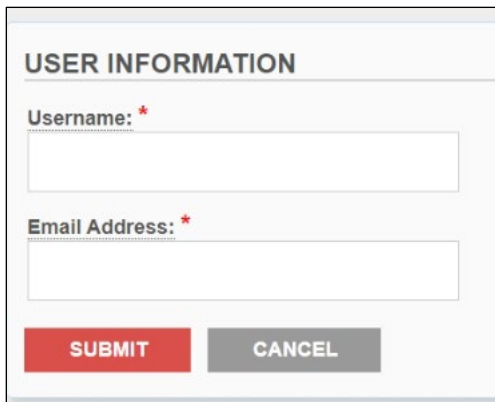
Password:

[Forgot your password?](#)

[I accept the Terms of Service](#)

LOGIN

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



USER INFORMATION

Username: *

Email Address: *

SUBMIT **CANCEL**

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

LOGIN

Username:

Password:

[Forgot your password?](#)

[I accept the Terms of Service](#)

LOGIN

OR

CREATE NEW ACCOUNT

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

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

User Information **Recover Account** Reset Password

RECOVER ACCOUNT

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

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

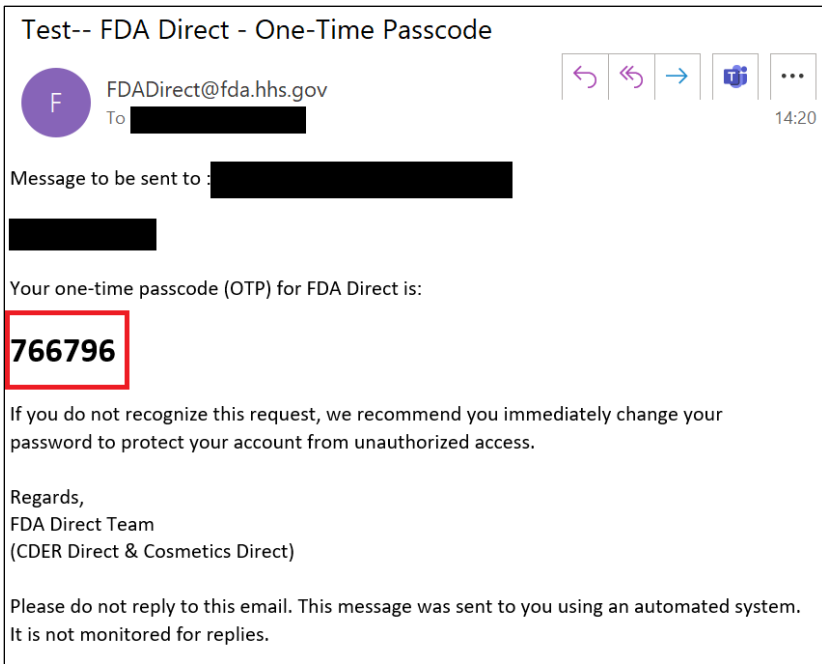
Username: *

Email Address: *

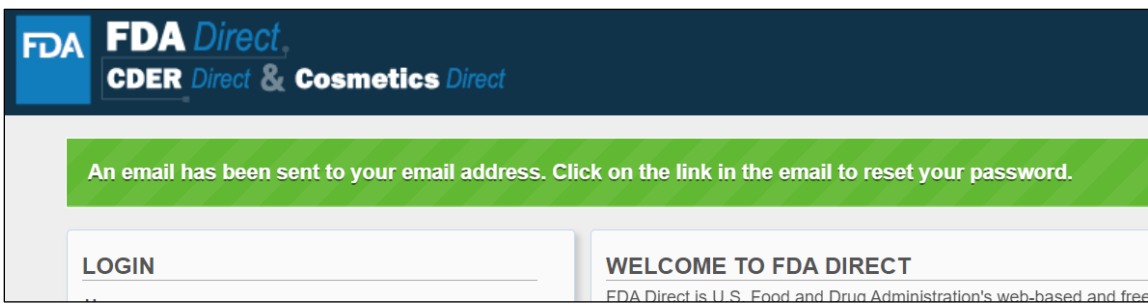
One-Time Passcode (OTP):

SUBMIT **CANCEL**

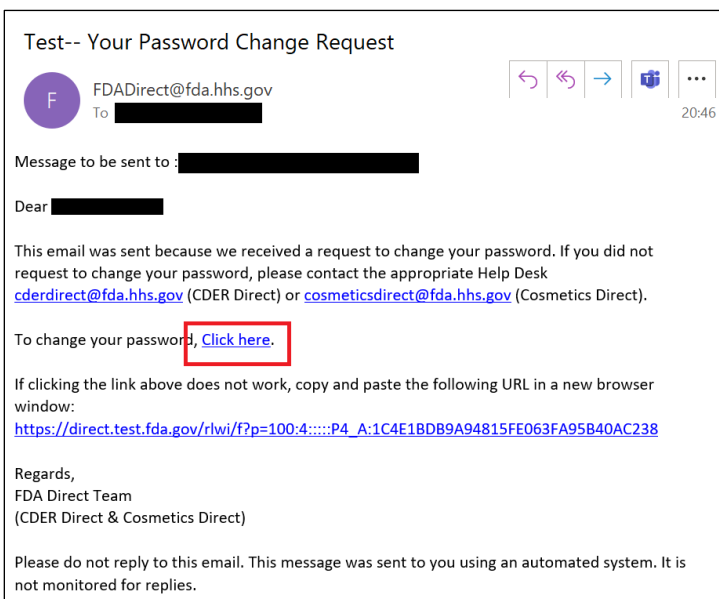
4. Check your email address for the OTP. If you have not received an email after several minutes, you can click the '**Request New Passcode**' link (shown above) to send another code.



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':

User Information Recover Account **Reset Password**

CHANGE PASSWORD

Username: *
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.

New Password: *

Confirm Password: *

SAVE

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:

Password:

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...
 submissions, or a single account that includes both CDER Direct subr...

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

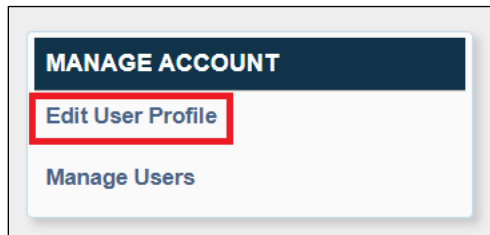
Your account main page will display each time you log in to FDA Direct:

The screenshot displays the FDA Direct Cosmetics Direct user interface. On the left, a vertical navigation menu is organized into several sections: 'COSMETIC REGISTRATION AND LISTING' (with sub-items: Registration of Cosmetic Product Facility, Cosmetic Product Listing), 'ESTABLISHMENT REGISTRATION & DRUG LISTING' (with sub-items: Establishment Registration, NDC Labeler Code Request, Drug Listing and Certification, NDC Reservation), 'OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING' (with sub-items: Outsourcing Facility Registration, Compounded Drug Reporting), 'DSCSA ANNUAL REPORTING' (with sub-item: Wholesale Drug Distributor and Third-Party Logistics Provider Reports), 'GENERIC DRUG SELF-IDENTIFICATION' (with sub-item: Generic Facility GDUFA Self-Identification), 'SELF HELP' (with sub-items: Structured Product Labeling Resources, UNII Search, Request UNII, DUNS Search, FEI Search Portal, Registration and Listing of Cosmetic Product Facilities and Products Industry Guidance), and 'MANAGE ACCOUNT' (with sub-items: Edit User Profile, Manage Users). The main content area is titled 'ALL SUBMISSIONS' and contains 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, indicating no submissions are currently listed.

- 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 [Step 4 of 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.

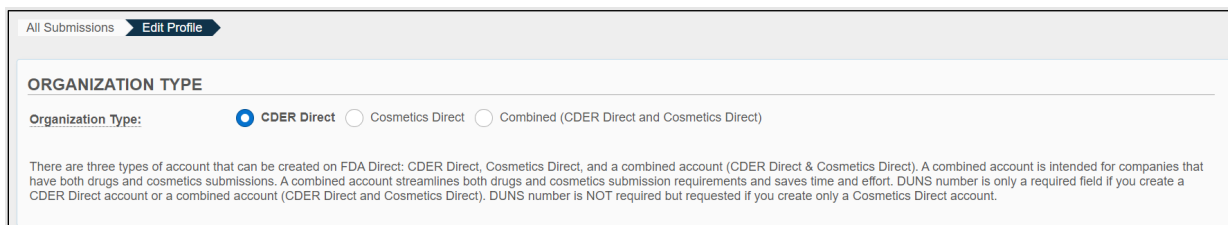
2.4.1 Edit Profile

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 for more information.**

Select the desired account type:

A screenshot of a web page titled 'Edit Profile'. At the top left, there are two tabs: 'All Submissions' and 'Edit Profile', with 'Edit Profile' being the active tab. Below the tabs, there is a section titled 'ORGANIZATION TYPE'. Under this section, there is a label 'Organization Type:' followed by three radio buttons: 'CDER Direct' (which is selected), 'Cosmetics Direct', and 'Combined (CDER Direct and Cosmetics Direct)'. Below the radio buttons, there is a small block of text explaining the three types of accounts and the requirements for a DUNS number.

***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: *

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

COSMETIC REGISTRATION AND LISTING

- REGISTRATION OF COSMETIC PRODUCT FACILITY
- COSMETIC PRODUCT LISTING

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING

- OUTSOURCING FACILITY REGISTRATION
- COMPOUNDED DRUG REPORTING

DSCSA ANNUAL REPORTING

- WHOLESALE DRUG DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER REPORTS

GENERIC DRUG SELF-IDENTIFICATION

- GENERIC FACILITY GDUFA SELF-IDENTIFICATION

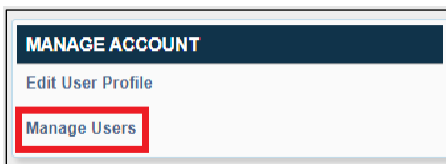
Click **'Submit'** to finalize all changes made, or **'Cancel'** to abandon your changes.

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 *Manage Account* section:

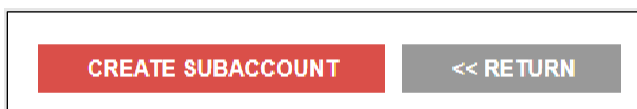


If you have already created subaccounts, they will display in a list. Otherwise, the page will be empty:



2.5.1 Creating A Subaccount:

1. Click the 'Create Subaccount' button



2. Enter all required fields for the subaccount user:

 A screenshot of the 'CONTACT INFORMATION' form for creating a subaccount user. The form is titled 'CONTACT INFORMATION' and has a breadcrumb trail: 'All Submissions > Manage Users > Create / Edit User'. The form contains several fields:

- 'First Name: *' with an empty text input field.
- 'Middle Name:' with an empty text input field.
- 'Last Name: *' with an empty text input field.
- 'User Role: *' with a dropdown menu currently set to 'USER'.
- 'Job Title:' with an empty text input field.
- 'Contact Email: *' with an empty text input field.
- 'Country Code: *' with a dropdown menu currently set to '-Select Country Phone Code-'.
- 'Phone Number: *' with an empty text input field.
- 'Extension:' with an empty text input field.

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: ▼

4. Select which forms the subaccount will have access to. This view will differ based on your organizational account type, which is modifiable in the Section 2.4.1: Edit Profile section. 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
---	---

COSMETICS DIRECT ACCESS

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

COSMETIC REGISTRATION AND LISTING

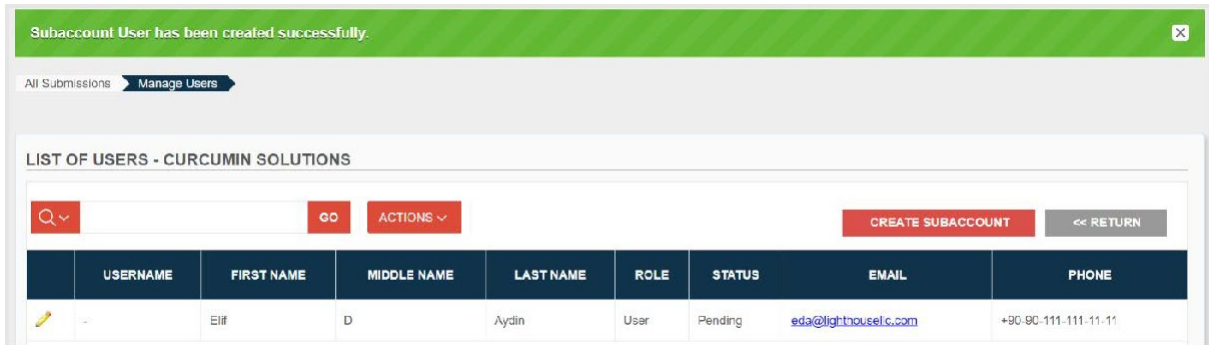
- REGISTRATION OF COSMETIC PRODUCT FACILITY
- COSMETIC PRODUCT LISTING

FDA DIRECT (CDER DIRECT AND COSMETICS DIRECT)


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

<input checked="" type="checkbox"/> ESTABLISHMENT REGISTRATION AND DRUG LISTING <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 checked="" type="checkbox"/> COSMETIC REGISTRATION AND LISTING <ul style="list-style-type: none"> • REGISTRATION OF COSMETIC PRODUCT FACILITY • COSMETIC PRODUCT LISTING 	<input checked="" type="checkbox"/> OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING <ul style="list-style-type: none"> • OUTSOURCING FACILITY REGISTRATION • COMPOUNDED DRUG REPORTING <input checked="" type="checkbox"/> DSCSA ANNUAL REPORTING <ul style="list-style-type: none"> • WHOLESALE DRUG DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER REPORTS <input checked="" type="checkbox"/> GENERIC DRUG SELF-IDENTIFICATION <ul style="list-style-type: none"> • GENERIC FACILITY GDUFA SELF-IDENTIFICATION
---	--

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




The screenshot displays a web interface with a green confirmation banner at the top: "Subaccount User has been created successfully." Below this, there are navigation links for "All Submissions" and "Manage Users". The main content area is titled "LIST OF USERS - CURCUMIN SOLUTIONS" and features a search bar with a "GO" button and an "ACTIONS" dropdown menu. To the right of the search bar are buttons for "CREATE SUBACCOUNT" and "<< RETURN". Below these elements is a table with the following data:

	USERNAME	FIRST NAME	MIDDLE NAME	LAST NAME	ROLE	STATUS	EMAIL	PHONE
	-	Elif	D	Aydin	User	Pending	eda@lighthouses.com	+90.90.111-111-11-11

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

2.5.2 Managing A Subaccount

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

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

You may edit the following information on this page:

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

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

CONTACT INFORMATION

First Name: *	<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"/>

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:

- a. 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 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

- b. 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.

- c. 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 SPL file into FDA Direct:

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

The screenshot shows the 'All Submissions' page with a sidebar menu on the left. The menu items are: ESTABLISHMENT REGISTRATION & DRUG LISTING, OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING, DSCSA ANNUAL REPORTING, GENERIC DRUG SELF-IDENTIFICATION, and COSMETIC REGISTRATION AND LISTING. The main content area displays a table of submissions with columns for STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, DOCUMENT LABEL, LAST MODIFIED USER, and LAST MODIFIED DATE.

b. Click 'Create New/Upload File':

The screenshot shows the 'ESTABLISHMENT REGISTRATION' page. The 'CREATE NEW / UPLOAD FILE' button is highlighted with a red box. The page includes a search bar, a table of submissions, and a list of instructions for registration.

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

The screenshot shows the 'CREATE NEW ESTABLISHMENT REGISTRATION' form. The 'Import an existing Establishment Registration S-L' radio button is selected and highlighted with a red box. The 'CONTINUE' button is also visible.

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

The screenshot shows the 'UPLOAD ESTABLISHMENT REGISTRATION FILE' area. The 'Establishment Registration File' upload area is highlighted with a red box. The area includes a note about uploading a zip file and 'UPLOAD' and 'CANCEL' buttons.

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

UPLOAD ESTABLISHMENT REGISTRATION FILE

Establishment Registration File

c7175e5b-8d18-7ed2-e053-0791b40ad884.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

- 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 acceptance/rejection by the FDA. Displays right after an SPL has been submitted. No changes can be made after the SPL is sent, but the submission is viewable.
- **Validation In Progress**: A submission that is being screened and pre-validated for potential errors prior to being sent to the FDA. This status will display after clicking 'Save And Validate,' and will typically last only a few minutes before changing to 'Validation Failure' or 'Ready For Submission.'
- **Ready For Submission**: A submission that has passed the initial screening and pre-validation check and is ready to be sent to the FDA. If you receive this status after clicking 'Save And Validate,' you must open your submission and click 'Submit' to complete the process.
- **Submission Accepted** – A submission that has been accepted by the FDA.
 - ***For NDC labeler code requests only:*** If you did not enter the optional labeler details in an initial NDC Labeler Code Request submission, you will receive an email from the FDA to supply the data.
- **Submission Failed** – A submission that has not been accepted by the FDA's automated validations and has been rejected. You must open your submission to review error messages and update the data to correct them. Submit again and your submission will once again be in 'Awaiting Acceptance' Status.
- **Submission Override** – If you are unable to resolve a failed submission because you are correcting a previous error, the data may need to be manually loaded. A manual override


request can be forwarded to the following email addresses:

- spl@fda.hhs.gov for non-GDUFA related documents
- CDERefacility@fda.hhs.gov for GDUFA documents

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

3.3 Submission Header Information

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

— HEADER DETAILS			
<u>Document Type:</u> *	<input type="text" value="HUMAN OTC DRUG LABEL"/>	<u>Version Number:</u> *	<input type="text" value="1"/>
<u>Set ID:</u> *	<input type="text" value="0ac4630f-6fa2-a749-e063-fa95b40a3a84"/> Generate New	<u>Effective Date:</u> *	<input type="text" value="11-22-2023"/> 
<u>Root ID:</u> *	<input type="text" value="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 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).
3. Version Number: A number greater than zero that provides a sequence to the versions of the document. Any number can be inputted here, and the next version will automatically continue upward from that number (ex: 23, 24, 25, etc).
4. Effective Date: The date this form is created.

3.4 Submission Help

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

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

PRODUCT DATA ELEMENTS

NDC Product Code: * **Proprietary Name: ***

Non Proprietary Name: * **Suffix:**

DEA Schedule: -- Select DEA Schedule -- v

Dosage Form: * -Select Dosage Form- v

PRODUCT DATA ELEMENTS

NDC Product Code: *

Non Proprietary Name: *

Dosage Form: * -Select Dosa

NDC Product Code [X]

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

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

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

Tutorials will show you how to complete specific actions like creating an account or submitting a drug product listing. They are less detailed than this User Guide, and in slideshow format.

Recommended for users familiar with FDA Direct who may want a quick refresher.

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

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

LOGIN

Username:

Password:

[Forgot your password?](#)

I accept the Terms of Service

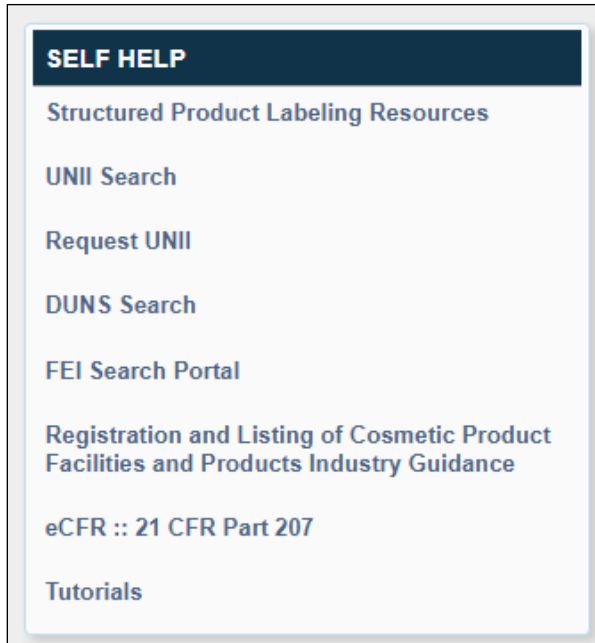
LOGIN

OR

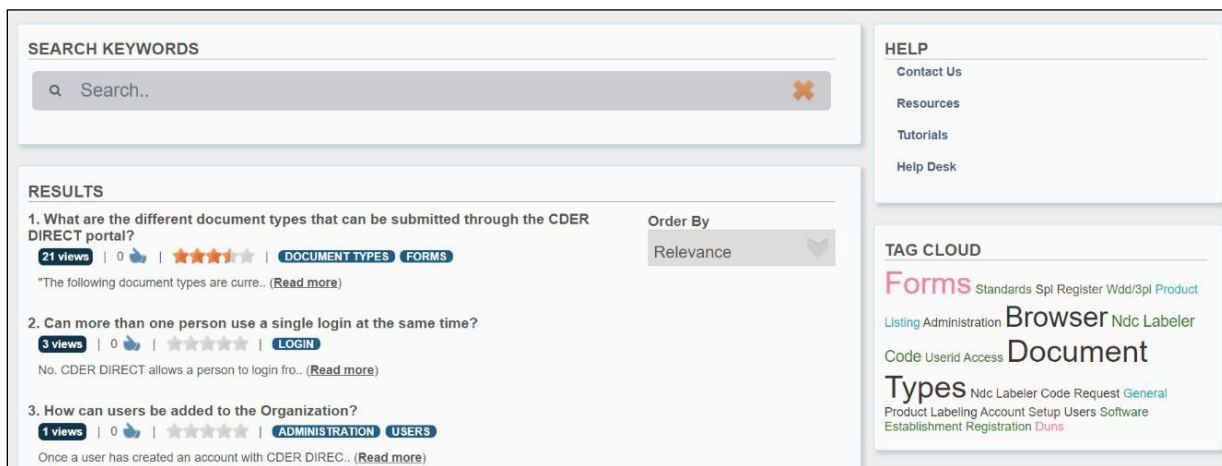
CREATE NEW ACCOUNT

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

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



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



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

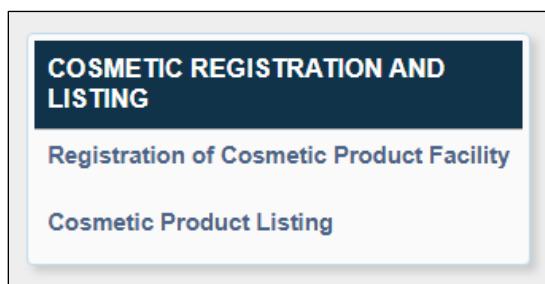
4.1 Cosmetic Registration and Product Listing SPL

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. [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 about cosmetic product manufacturers/processors and cosmetic products on the market.



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

4.2 Document Types

4.2.1 Registration of Cosmetic Facility

- **Cosmetic Facility Registration (INITIAL):** Every person that, on December 29, 2022, owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States must register each facility no later than December 29, 2023 (section 607(a)(1)(A) of the FD&C Act).

Every person that owns or operates a facility that first engages, after December 29, 2022, in manufacturing or processing of a cosmetic product for distribution in the United States, must register such facility within 60 days of first engaging in such activity or by February 27, 2024, whichever is later (section 607(a)(1)(B) of the FD&C Act).

- **PLEASE NOTE:** Cosmetic Facility Registration (Initial) is preselected when entering the SPL application.
- **Additional note:** On November 8, 2023, FDA issued a guidance for industry titled “Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product

Listing.” This guidance explains that FDA does not intend to enforce the requirements under section 607 of the FD&C Act related to cosmetic product facility registration until July 1, 2024.

- **Cosmetic Facility Registration (ABBREVIATED REGISTRATION RENEWAL):** FDA is providing for an abbreviated renewal of registrations when there have not been any updates to the registration since the most recent facility registration submission, as required under section 607(a)(4) of the FD&C Act.
- **Cosmetic Facility Registration (AMENDMENT):** Every person who is required to register must update their registration within 60 days of any changes to the information required for registration (section 607(a)(4) of the FD&C Act) (an “amended” registration). This includes any changes that result in cancellation of the registration.
- **Cosmetic Facility Registration (BIENNIAL REGISTRATION RENEWAL):** Every person who is required to register a facility must renew such registration biennially (i.e., every two years) (section 607(a)(2) of the FD&C Act).
- **Cosmetic Facility Registration (CANCELLATION):** Every person who is required to register must update their registration within 60 days of any changes to the information required for registration (section 607(a)(4) of the FD&C Act). This includes any changes that result in cancellation of the registration.

4.2.2 Cosmetic Product Listing

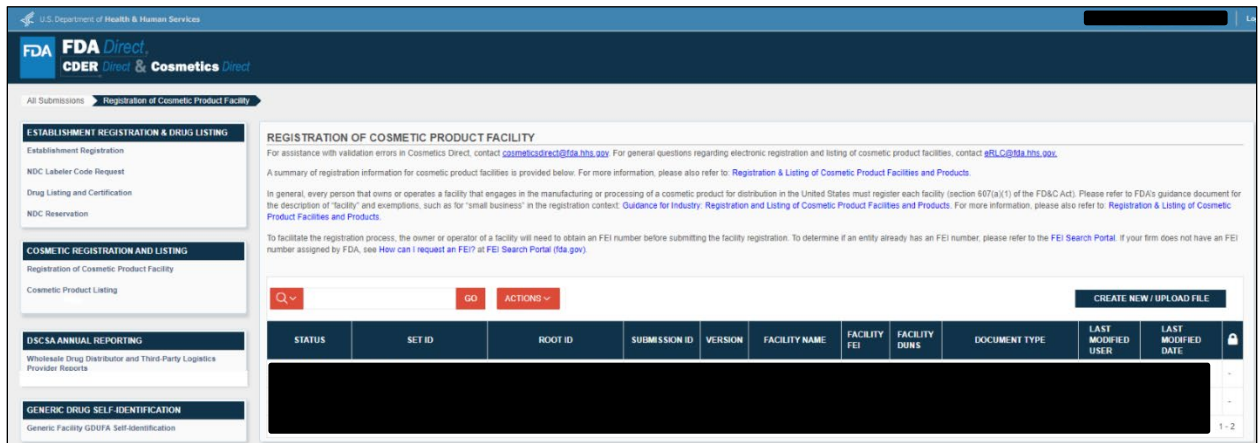
- **COSMETIC-(INITIAL):** The responsible person of a cosmetic product that is marketed on December 29, 2022, must submit a cosmetic product listing, or ensure such submission is made, not later than December 29, 2023, or for a cosmetic product that is first marketed after December 29, 2022, within 120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

- **COSMETIC-UPDATE (CHANGES TO LISTING or DISCONTINUATION OF LISTING) (annual):**

The responsible person must provide any updates to such listing annually (CHANGES TO LISTING or DISCONTINUATION OF LISTING) (section 607(c)(5) of the FD&C Act). This includes an update that the product was discontinued.

4.3 Registering a New Cosmetic Product Facility

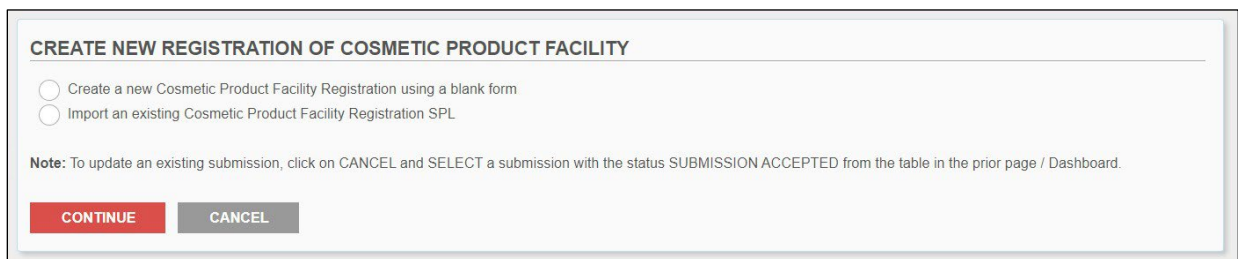
1. Log in to FDA Direct
2. Select **'Registration of Cosmetic Product Facility'** under *Cosmetic Registration and Listing* section:



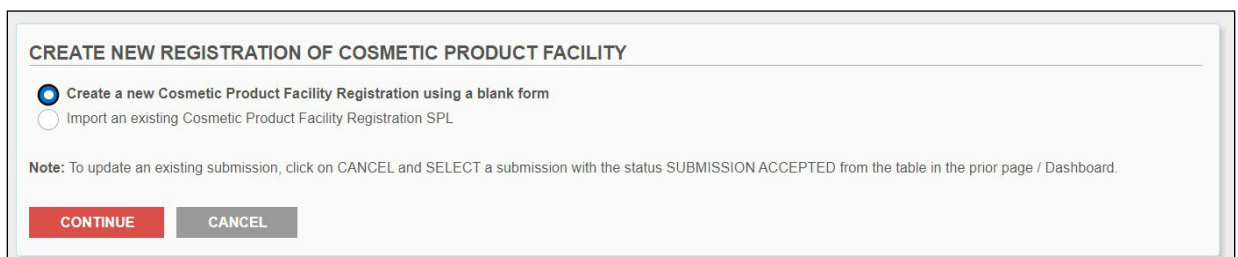
3. Click **'Create New/Upload File'**:



You will be given two options:



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



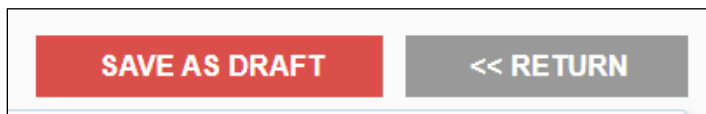
5. A blank template will display with required fields marked with a red (*) and optional fields:

The screenshot shows the 'SPL Submission' form. At the top, there are navigation links: 'All Submissions', 'Registration of Cosmetic Product Facility', and 'SPL Submission'. On the right, there are two buttons: 'SAVE AS DRAFT' (red) and '<< RETURN' (grey). Below the navigation is a note: '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'.

The form is divided into two main sections:

- DOCUMENT TYPE DETAILS:**
 - Document Type:** * COSMETIC FACILITY REGISTRATION (dropdown menu)
 - Set ID:** * 10e45b7f-e2b0-e571-e063-6a94af0a439c (text field with 'Generate New' link)
 - Version Number:** * 1 (text field)
 - Root ID:** * 10e45b7f-e2b1-e571-e063-6a94af0a439c (text field with 'Generate New' link)
 - Effective Date:** * 02-08-2024 (text field with calendar icon)
- REGISTRATION DETAILS:**
 - Is this a facility registration for a small business (optional registration)?:** Yes No
 - Facility Name:** * (text field)
 - Facility Country:** * -Select Country- (dropdown menu)
 - Facility FEI Number:** * (text field)
 - Facility Street Address:** * (text field)
 - Facility D&B D-U-N-S Number:** (text field)
 - Facility City:** * (text field)
 - Parent Company Name (if applicable):** (text field)
 - Facility State or Province:** (text field)
 - Facility Zip/Postal Code:** (text field)

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:

This screenshot shows the 'DOCUMENT TYPE DETAILS' section of the form, which is pre-populated with the following values:

- Document Type:** * COSMETIC FACILITY REGISTRATION (dropdown menu)
- Set ID:** * 10e45b7f-e2b0-e571-e063-6a94af0a439c (text field with 'Generate New' link)
- Version Number:** * 1 (text field)
- Root ID:** * 10e45b7f-e2b1-e571-e063-6a94af0a439c (text field with 'Generate New' link)
- Effective Date:** * 02-08-2024 (text field with calendar icon)

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

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

- b. **Root ID***: **This field is auto generated by the system.** The Root ID uniquely identifies a specific SPL file. Each new version of an SPL file has a new id root. The id root is a Globally Unique Identifier (GUID). A GUID is a string of numbers and lower-case letters generated using a specifically defined mathematical algorithm to ensure a very low probability of identical GUID used in the same system. An example is: 9aa9d2e6-6982-48e5-831d-dbe7c04a14ed.
- c. **Version Number***: The Version Number gives sequential order to the different versions of an SPL submission. The version number is a whole number greater than zero, such as 6, 7, or 8. The version number is increased with each change to the SPL submission. Enter a number greater than zero (0) in the Version Number field.
- d. **Effective Date***: The date the submission is created, users can modify it. However, the system will only use the actual registration date submitted to FDA. It also provides a date reference to the SPL version. Select the date by clicking on the calendar icon. Once an SPL has been submitted, this date cannot be edited by users.
8. Fill in all the blank fields in the Registrant Details and Facility Contact Details section:

REGISTRATION DETAILS

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

Facility Name: *	Facility Country: *
Facility FEI Number: *	Facility Street Address: *
Facility D&B D-U-N-S Number:	Facility City: *
Parent Company Name (if applicable):	Facility State or Province:
	Facility Zip/Postal Code:

- 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

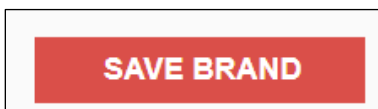
- (01) Baby products
 - (A) Baby shampoos
 - (B) Lotions, oils, powders, and creams
 - (C) Baby wipes
 - (D) Other baby products
- (02) Bath preparations
 - (A) Bath oils, tablets, and salts
 - (B) Bubble baths
 - (C) Bath capsules
 - (D) Other bath preparations
- (03) Eye makeup preparations (other 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.

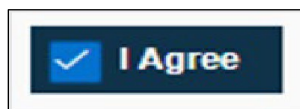
WARNING: A willfully false statement is a criminal offense, [U.S. Code, Title 18, Section 1001](#).

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:

Email:

Phone Number (Include Country/Area Code):

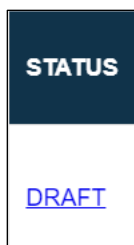
Phone Extension:

- 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:



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



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

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

4.3.1 Save and Validate

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

The screenshot shows the FDA Direct Cosmetics Direct interface. At the top, there is a blue header with the FDA logo and 'FDA Direct Cosmetics Direct'. Below the header, a yellow banner contains the message: "Additional in-depth validation by the FDA is in progress. Check back on the status after a few minutes by refreshing the page or logging back into the system." The main content area is titled "REGISTRATION OF COSMETIC PRODUCT FACILITY" and includes a search bar, a "GO" button, and an "ACTIONS" dropdown menu. A table below displays the registration details:

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-f8db-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'**.

The screenshot shows a green banner with the text: "Click here to view submissions that have completed validation." Below this, a table displays the updated registration details:

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-f8db-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:

All Submissions > Registration of Cosmetic Product Facility > SPL Submission

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 cosmeticdirect@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.

DOCUMENT TYPE DETAILS

Document Type: * COSMETIC FACILITY REGISTRATION

Set ID: * 0c066ca6-fbda-b44d-e063-6a94af1ab7ab

Version Number: * 1

Root ID: * 0c066ca6-fbda-b44d-e063-6a94af1ab7ab

Effective Date: * 12-08-2023

+ REGISTRATION DETAILS

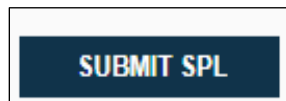
+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

- 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

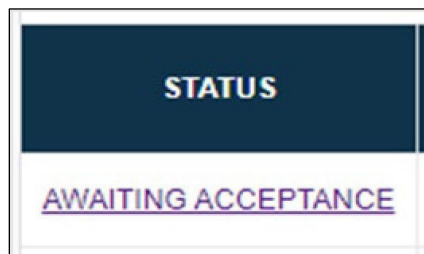
5. Click **'SUBMIT SPL'** if you are ready to submit your SPL to FDA.



- 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

6. 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 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 .								
Q		GO	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

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

CREATE 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.

DOCUMENT TYPE DETAILS

Document Type: * COSMETIC FACILITY REGISTRATION

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

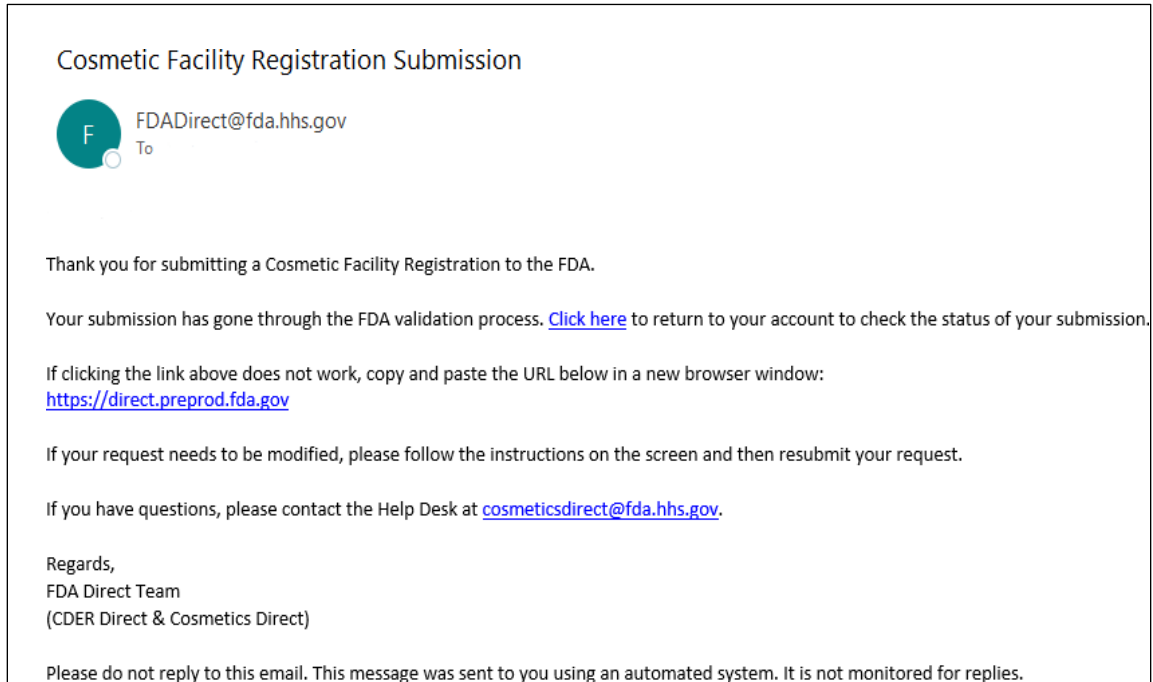
- To view your SPL, click **'VIEW SPL'**

VIEW SPL

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

DOWNLOAD SPL

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



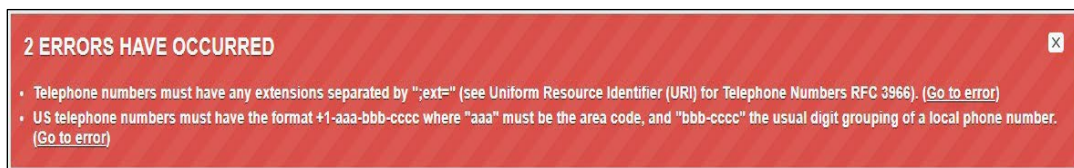
- e. A **'SUBMISSION ACCEPTED'** status will appear in the status column of your SPL submission if it has been successfully submitted to the FDA. At this point, the process is finished and there is no further action needed unless you need to make any changes to your registration.

4.3.4 Submission Failed

- 8. 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-e063-6b94af0af39e	cm6301528479.1247385960@direct	2	COSMETIC FACILITY REGISTRATION

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



- b. Submit again and your submission will once again be **'AWAITING ACCEPTANCE.'**
- 9. If the status column changes to **'SUBMISSION ACCEPTED'**, refer to section 4.3.3 Submission Accepted for additional information.

4.3.5 Validation Failure

- 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**.

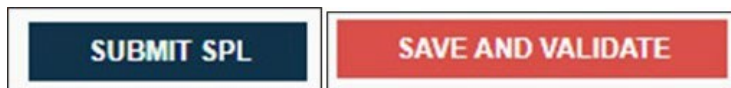
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT TYPE
VALIDATION FAILURE	0c066ca6-f8da-b44d-e063-6a94af0ab7ab	0c066ca6-f8db-b44d-e063-6a94af0ab7ab		1	FACILITY NAME	1234567890	-	COSMETIC FACILITY REGISTRATION

- 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. [\(Go to error\)](#)

- 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)

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

DOCUMENT TYPE DETAILS

Document Type: * ▼
 COSMETIC FACILITY REGISTRATION

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

Root ID: *

- Repeat the steps in Section 4.3.
- 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**'.

The screenshot shows a form titled "DOCUMENT TYPE DETAILS". It has three fields: "Document Type:", "Set ID:", and "Root ID:". The "Document Type:" field is a dropdown menu that is currently open, showing a list of options. The selected option is "COSMETIC FACILITY REGISTRATION - CANCELLATION". The other options in the list are: "--Select One--", "COSMETIC FACILITY REGISTRATION", "COSMETIC FACILITY REGISTRATION - ABBREVIATED RENEWAL", "COSMETIC FACILITY REGISTRATION - AMENDMENT", "COSMETIC FACILITY REGISTRATION - BIENNIAL RENEWAL", and "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**':

The screenshot shows a warning message dialog box with the following text: "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." Below the text are two buttons: "OK" (highlighted in blue) and "Cancel".

3. 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.
4. 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 – BIENNIALREGISTRATION RENEWAL**'.

The screenshot shows a form titled "DOCUMENT TYPE DETAILS". It has three fields: "Document Type:", "Set ID:", and "Root ID:". The "Document Type:" field is a dropdown menu that is currently open, showing a list of options. The selected option is "COSMETIC FACILITY REGISTRATION - BIENNIAL RENEWAL". The other options in the list are: "--Select One--", "COSMETIC FACILITY REGISTRATION", "COSMETIC FACILITY REGISTRATION - ABBREVIATED RENEWAL", "COSMETIC FACILITY REGISTRATION - AMENDMENT", "COSMETIC FACILITY REGISTRATION - BIENNIAL RENEWAL", and "COSMETIC FACILITY REGISTRATION - CANCELLATION".

2. Repeat the steps in Section 4.3
3. Refer to the steps in Section 4.3.2 for Submit to FDA instructions.

4.3.9 Abbreviated Renewal 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: * COSMETIC FACILITY REGISTRATION - BIENNIAL RENEWAL

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

Root ID: *

- 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

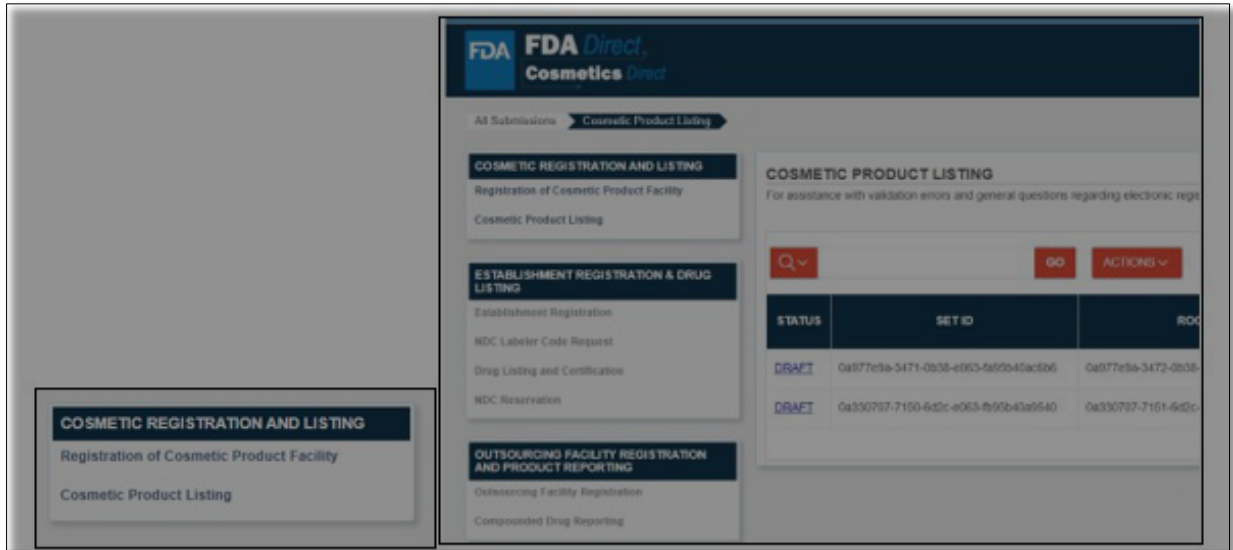
2. After selecting '**OK**', the fields for Registration Details, Confirmation Statement, and Additional Contact Information for Authorized Agent will be grayed out and can no longer undergo changes.
3. Click '**SUBMIT SPL**' to submit your request to FDA.

SUBMIT SPL

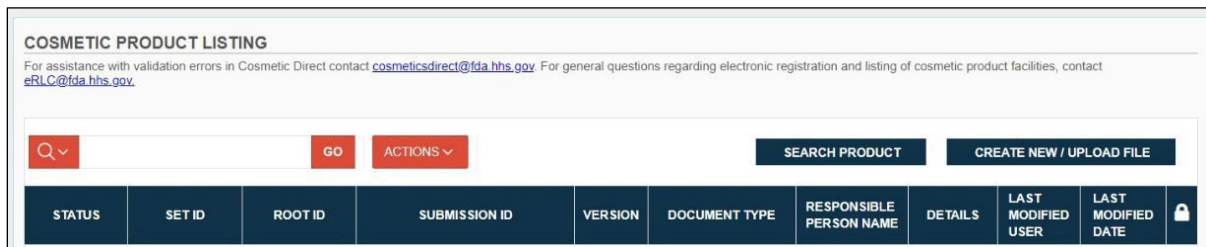
4.4 Cosmetics Product Listing

4.4.1 New Cosmetics Product Listing

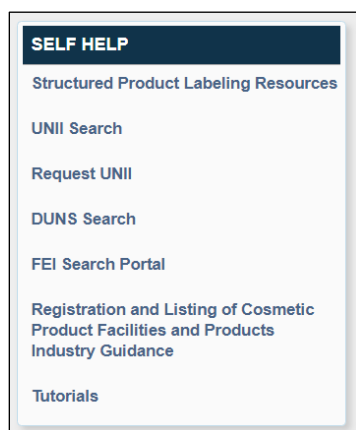
1. Log in to FDA Direct.
2. Select '**Cosmetic Product Listing**' under *Cosmetic Registration and Listing* section, on the left side of the FDA Direct menu.



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**.

SEARCH PRODUCT

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.

CREATE NEW / UPLOAD FILE

4.4.2 Create a New Cosmetic Product Listing

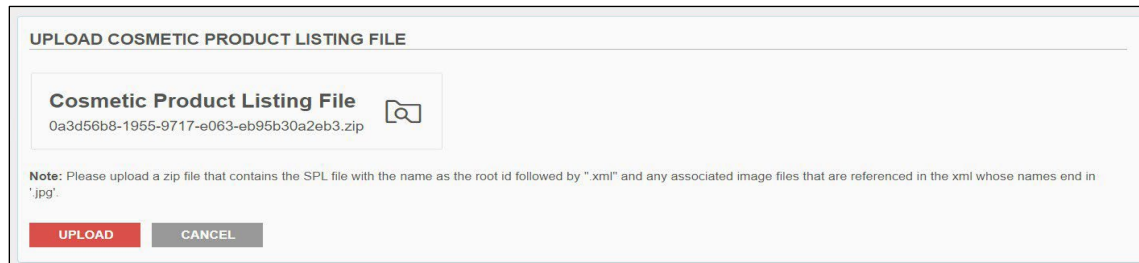
1. Click '**Create New/Upload File**':

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 (UNII)s
 - **PLEASE NOTE:** For more information and to search for UNIIs please refer to the webpage at: <https://precision.fda.gov/uniisearch>. For UNII requests contact: FDA-SRS@fda.hhs.gov.
 - Additional contact information for individuals associated with the listing.
- c. If you are **uploading/importing an existing Cosmetic Product Listing SPL** file containing multiple product listings, make sure that the file is in the correct SPL format. This file may contain both the XML file and image (jpg) files, for bulk submission. Once the file has been uploaded, a user can SAVE AND VALIDATE to run a system validation check or SUBMIT SPL.



UPLOAD COSMETIC PRODUCT LISTING FILE

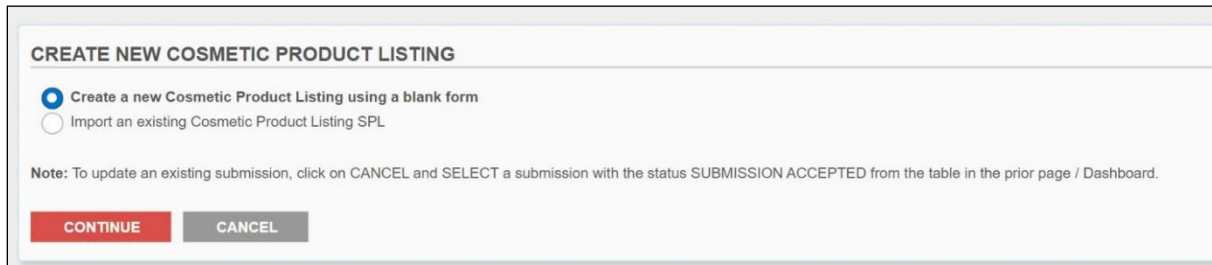
Cosmetic Product Listing File 

0a3d56b8-1955-9717-e063-eb95b30a2eb3.zip

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

UPLOAD **CANCEL**

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



CREATE NEW COSMETIC PRODUCT LISTING

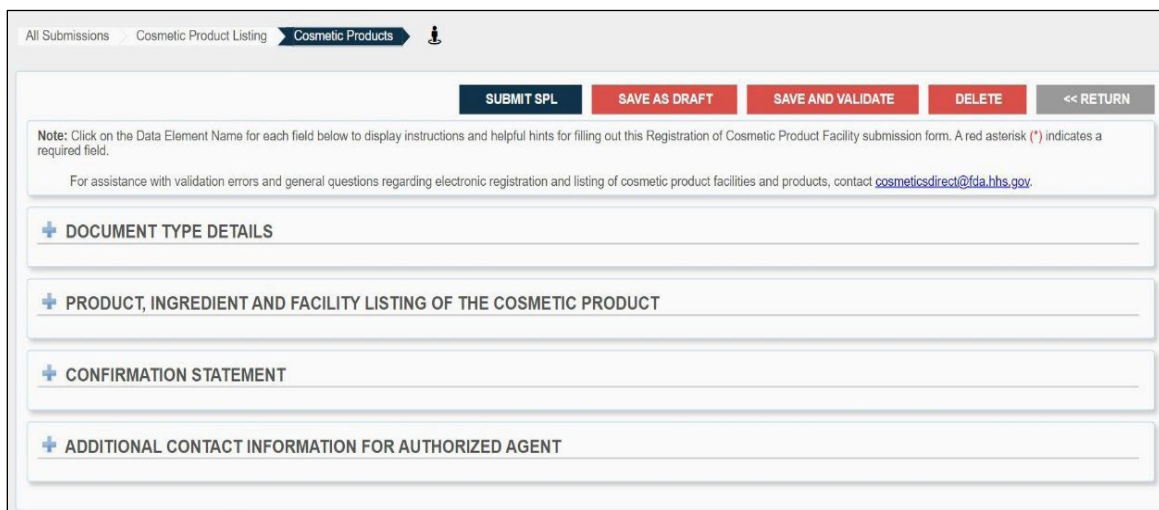
Create a new Cosmetic Product Listing using a blank form


Import an existing Cosmetic Product Listing SPL

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

CONTINUE **CANCEL**

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



All Submissions > Cosmetic Product Listing > Cosmetic Products 

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 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**

+ **PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT**



+ **CONFIRMATION STATEMENT**

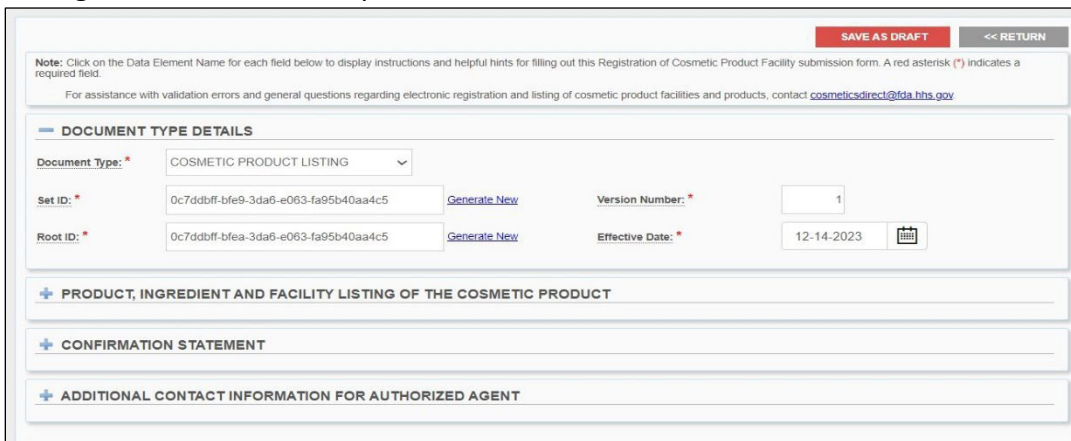
+ **ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT**

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.

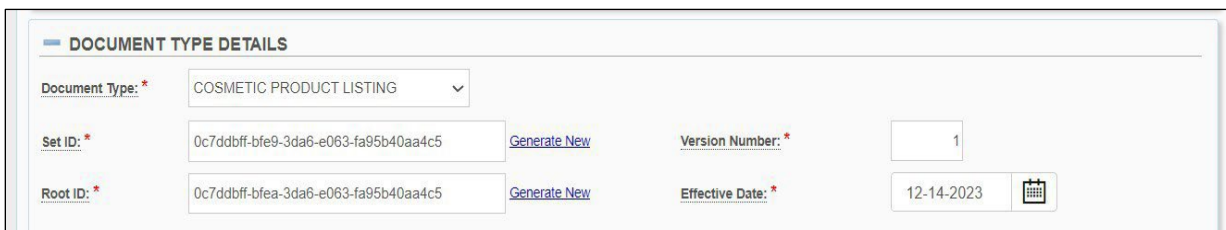
7. A tour guide  is available to walk a user through the submission icon as shown below.

SUBMIT SPL	SAVE AS DRAFT	SAVE AND VALIDATE	DELETE	<< RETURN
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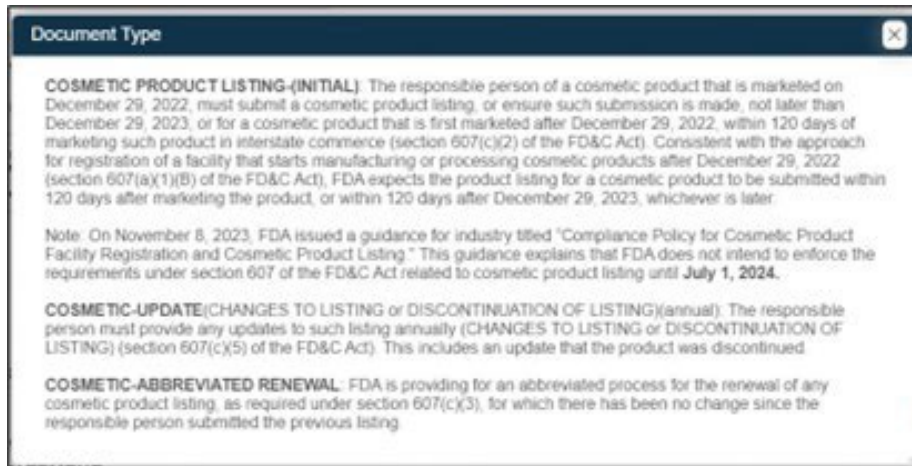
- SUBMIT SPL:** Submit SPL will send the submission to FDA for additional validation and processing.
 - SAVE AS DRAFT:** Save Draft button allows you to save your work, preserving your progress without submitting it to the FDA.
 - SAVE AND VALIDATE:** You can check your SPL for an initial validation 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.
 - DELETE:** This will remove the submission from your account.
 - RETURN:** 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:  



- 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:



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



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

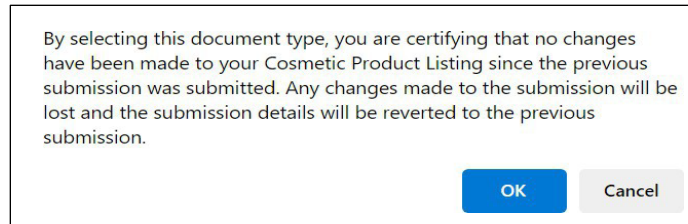


- a. **DOCUMENT TYPES INFORMATION*:**

- **COSMETIC PRODUCT LISTING -(INITIAL):** The responsible person of a cosmetic product that is marketed on December 29, 2022, must submit a cosmetic product listing, or ensure such submission is made, not later than December 29, 2023, or for a cosmetic product that is first marketed after December 29, 2022, within 120 days of marketing such product in interstate commerce (section 607(c)(2) of the FD&C Act). Consistent with the approach for registration of a facility that starts manufacturing or processing cosmetic products after December 29, 2022 (section 607(a)(1)(B) of the FD&C Act), FDA expects the product listing for a cosmetic product to be submitted within 120 days after marketing the product, or within 120 days after December 29, 2023, whichever is later.
 - **PLEASE NOTE:** On November 8, 2023, FDA issued a guidance for industry titled “Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing.” This guidance explains that FDA does not

intend to enforce the requirements under section 607 of the FD&C Act related to cosmetic product listing until **July 1, 2024**.

- **PLEASE NOTE:** Cosmetic Product Listing (Initial) is preselected when entering the SPL application form.
- **COSMETIC-ABBREVIATED RENEWAL:** FDA is providing for an abbreviated process for the renewal of any cosmetic product listing, as required under section 607(c)(3), for which there has been no change since the responsible person submitted the previous listing.
 - **PLEASE NOTE:** When making this selection an ALERT box will appear, *“By selecting this document type, you are certifying that no changes have been made to your product listing since the previous listing was submitted”*.



- **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: *	<input type="text" value="0ae8f51f-68ca-38ff-e063-fa95b40ac758"/> Generate New	Version Number: *	<input type="text" value="1"/>
Root ID: *	<input type="text" value="0ae8f51f-68cb-38ff-e063-fa95b40ac758"/> Generate New	Effective Date: *	<input type="text" value="11-24-2023"/>

- a. **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.
- b. The other four elements under section one: Document Type Details

- Set ID
- Root ID
- Version Number
- Effective Date

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

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

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

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

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

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

PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT

Is this a product listing for a small business (optional product listing)?: 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:

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.
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.

- o 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:

MANUFACTURER PACKER 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:	<input type="text"/>
---	----------------------

- 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:





- PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)	<input type="button" value="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.

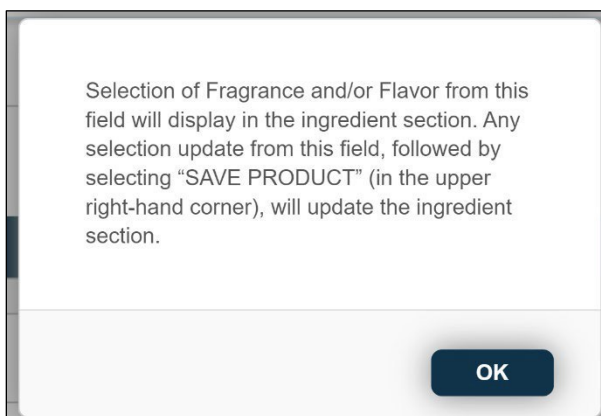
4.4.3 Product(s), Ingredient(s), and Facility(ies)

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:

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

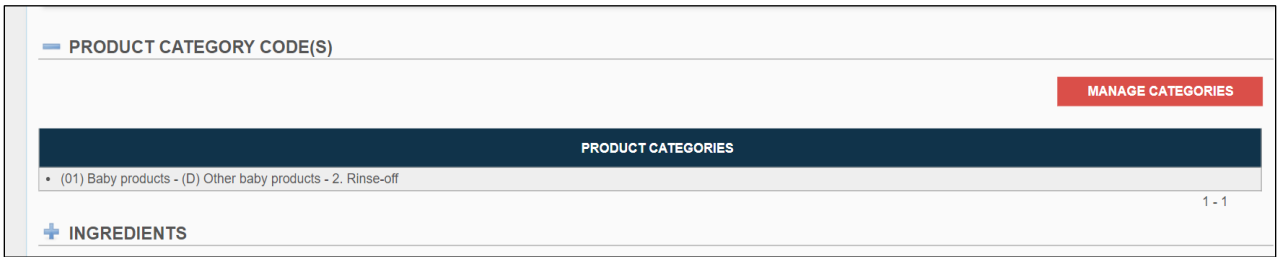
- 1. Leave-on
- 2. Rinse-off

- (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.

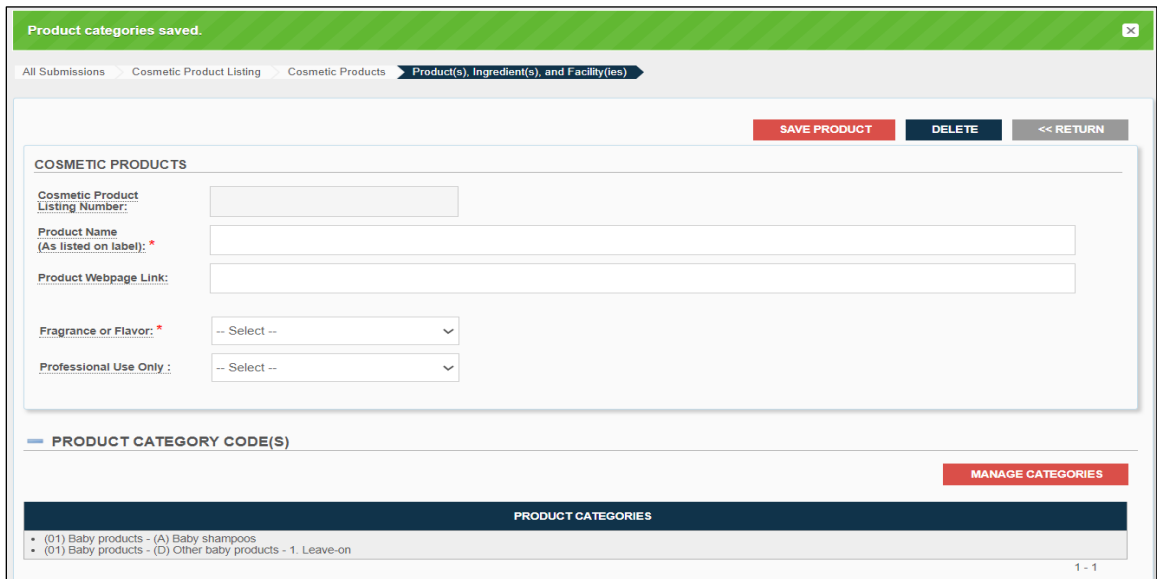
- Once completed Click '**SAVE CATEGORIES**', located at the top right of the page:



- 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:



- 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.



- 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.



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:

- 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: *

Professional Use Only :

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: * 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.

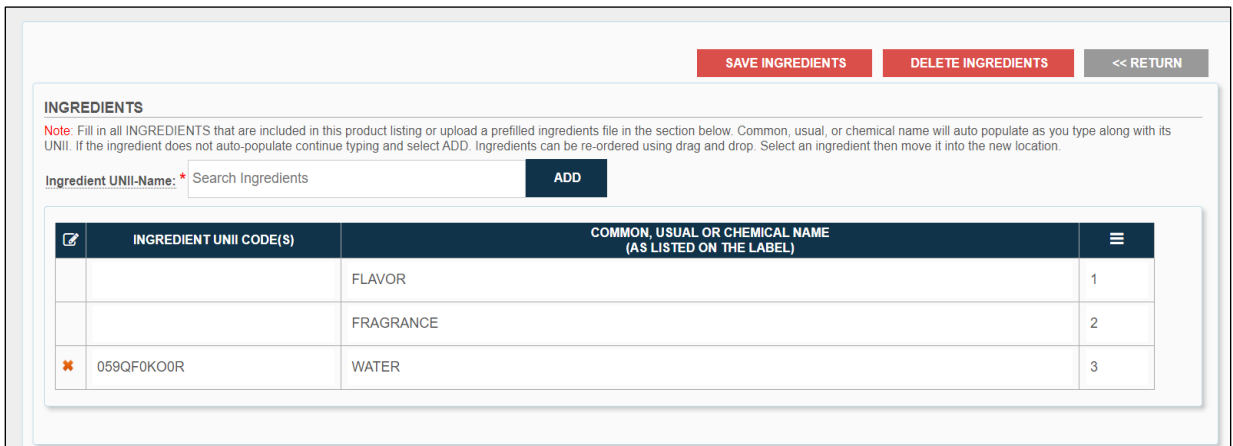
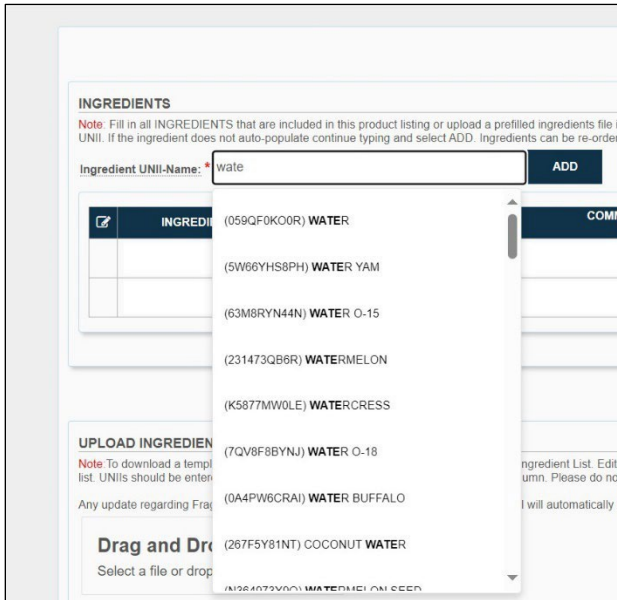
UPLOAD
CANCEL

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**.

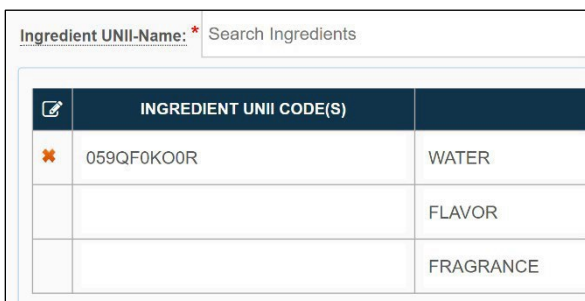
a. **PLEASE NOTE:**

- 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.

As an example, shown below:



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



- 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: * ADD

<input type="checkbox"/>	INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)	
		FLAVOR	1
*	059QF0KO0R	WATER	3
		FRAGRANCE	2

Ingredient UNII-Name: * ADD

<input type="checkbox"/>	INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)	
*	059QF0KO0R	WATER	1
		FLAVOR	2
		FRAGRANCE	3

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

DOWNLOAD CURRENT INGREDIENT LIST

SAVE INGREDIENTS
DELETE INGREDIENTS
<< RETURN

INGREDIENTS

Note: Fill in all INGREDIENTS that are included in this product listing or upload a prefiled 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

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 prefiled 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:

UPLOAD
CANCEL

[DOWNLOAD CURRENT INGREDIENT LIST](#)

UPLOAD INGREDIENT FILE

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

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

Drag and Drop

Select a file or drop one here.

UPLOAD
CANCEL

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

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

SAVE INGREDIENTS
DELETE INGREDIENTS
<< RETURN

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

SAVE INGREDIENTS
DELETE INGREDIENTS
<< RETURN

INGREDIENTS

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

Ingredient UNIL-Name: ADD

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

DOWNLOAD CURRENT INGREDIENT LIST

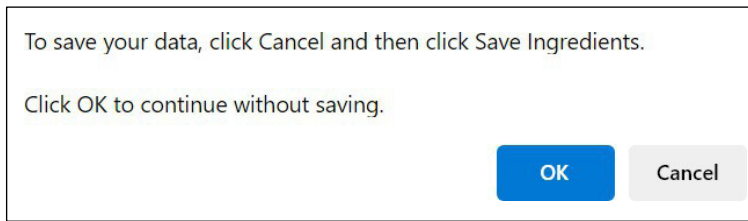
UPLOAD INGREDIENT FILE

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. UNILs should be entered in the first column and ingredient names in the second column. Please do not enter CAS numbers instead of UNILs. CAS numbers will not be recognized by the system.

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

Drag and Drop

Select a file or drop one here.



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

Product Ingredients Saved.
✕

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

SAVE PRODUCT
DELETE
<< RETURN

COSMETIC PRODUCTS

Cosmetic Product Listing Number:

Product Name (As listed on label):*

Product Webpage Link:

Fragrance or Flavor:* Fragrance & Flavor ▾

Professional Use Only: -- Select -- ▾

+ PRODUCT CATEGORY CODE(S)

- INGREDIENTS

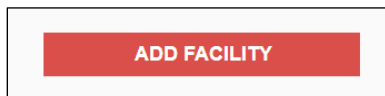
Note that any update regarding Fragrance and/or Flavor made through the ingredient upload tool, will automatically update the above "Fragrance or Flavor" selection field in the previous section.

MANAGE INGREDIENTS

INGREDIENT UNII 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.



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

- Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?*: Indicate by selecting one of the options, whether the facility where the product is manufactured or processed is exempt from registration (for example because it is a small business).
- SMALL BUSINESSES.** — Under section 612(b) of the FD&C Act, regardless of their average gross annual sales, businesses that engage in the manufacturing or processing of the following are not exempt from the registration and listing requirements:
 - Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual;
 - Cosmetic products that are injected;
 - Cosmetic products that are intended for internal use; or
 - Cosmetic products that are intended to alter appearance for more than 24 hours under conditions of use that are customary or usual and removal by the consumer is not part of such conditions of use that are customary or usual.

- c. **Facility FEI:** Enter the existing 7 to 10-digit facility FEI number. The FEI number is a unique identifier assigned by the FDA to identify firms associated with FDA-regulated products. To facilitate the registration process, the owner or operator of a facility will need to obtain an FEI number before submitting the facility registration.
- d. **PLEASE NOTE:** To determine if an entity already has an FEI number, please refer to the [FEI Search Portal](#). If your firm does not have an FEI number assigned by FDA, see [How can I request an FEI?](#) at [FEI Search Portal](#)
- **Facility Name:** Enter the complete name of the existing facility.
 - **Facility country:** Select facility's country name where the facility is physically located.
 - **Facility Street Address:** Enter the complete information of the street where the facility is physically located.
 - **Facility City:** Enter the complete name of the city where the facility is physically located.
 - **Facility State or Province:** Enter the complete name of the state or province where the facility is physically located.
 - **Facility Zip/Postal Code:** Enter the postal code or the zip code where the facility is physically located.
- e. **PLEASE NOTE:** For more information visit: [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)
20. If selected **YES** to the question, ***“Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?”*** all data fields are optional. As shown below:

The screenshot shows a web form with the following elements:

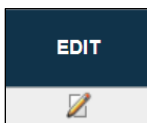
- Buttons: **SAVE FACILITY** (red) and **<< RETURN** (grey).
- Question: **Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?** with **YES** (selected) and **NO** radio buttons.
- Fields:
 - Facility FEI: [Text input]
 - Facility Name: [Text input]
 - Facility Country: [-Select Country-] (dropdown)
 - Facility Street Address: [Text input]
 - Facility City: [Text input]
 - Facility State or Province: [Text input]
 - Facility Zip/Postal Code: [Text input]

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:

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:

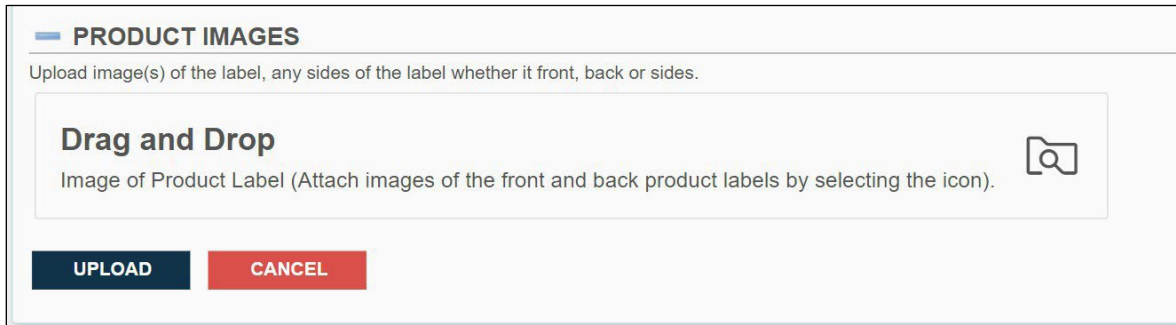
EDIT	IS THIS FACILITY SMALL BUSINESS?	FACILITY FEI	FACILITY NAME	FACILITY ADDRESS
	No	3457234		

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



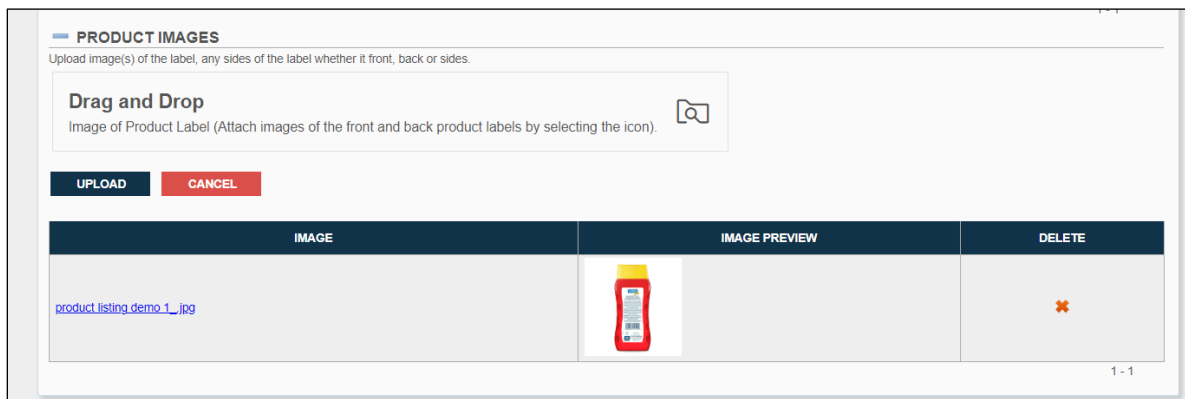
EDIT	IS THIS FACILITY SMALL BUSINESS?	FACILITY FEI	FACILITY NAME	FACILITY ADDRESS
	No	3457234		

- a. Multiple **FACILITY(IES)** can be added by selecting the **ADD FACILITY** on the top right, as shown above.
24. The **PRODUCT IMAGES** section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section, a red asterisk (*) indicates a required field throughout the submission process:
- a. (optional) Upload an image of the label, any sides of the label whether it front back or sides by selecting or drag and drop the image, as shown below. The image must be in a .jpg.



PLEASE NOTE: It is important that the image uploaded is to be 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.** Additionally, if you are uploading more than one image, ensure that the naming convention for each image is different/unique.

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



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



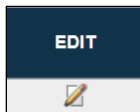
26. AFTER selecting SAVE PRODUCT, an overall product detail will be displayed under **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)**, as shown below:

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	

- 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:

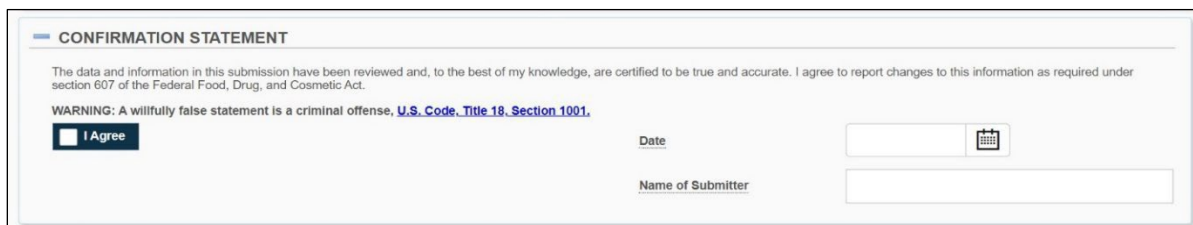


27. ANY similar PRODUCT with common ingredient(S) can be CLONED by selecting the CLONE icon, as shown below:



The image shows a 'CLONE' button with a document icon below it. Below the button is a table titled 'PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)'. The table has columns for 'EDIT', 'COSMETIC PRODUCT LISTING NUMBER', 'PRODUCT NAME (AS LISTED ON LABEL)', 'FRAGRANCE OR FLAVOR', 'IS THIS PRODUCT FOR PROFESSIONAL USE ONLY?', and 'CLONE'. A row is visible with 'stampo' in the product name column and 'Fragrance & Flavor' in the fragrance column. A 'CLONE' icon is in the last column of that row. A red button 'ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)' is at the top right of the table area.

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



The image shows the 'CONFIRMATION STATEMENT' section. It contains a paragraph of text, a warning about false statements, and a checkbox labeled 'I Agree'. There are also input fields for 'Date' and 'Name of Submitter'.

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



The image shows a button with a checkmark icon and the text '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:



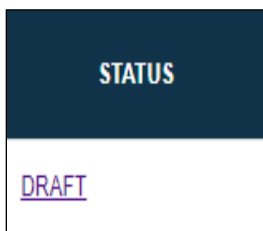
The image shows the 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT' section. It contains four input fields: 'Additional Contact Name', 'Email', 'Phone Number (Include Country/Area Code)', and 'Phone Extension'.

- a. **PLEASE NOTE:** ALL the above elements are optional.
- **Additional Contact Name:** (optional field) Enter an additional contact information for individuals associated with the listing. For more information visit: *Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)*.
 - **Email:** (optional field) Provide the additional contact person's email address.
 - **Phone Number** (Include Country/Area Code): (optional field) Enter the additional contact person's phone number including the country code and the area code. The format for Phone number should be <Country Code>-<Area Code>-<Subscriber Number>.
 - **Phone Extension:** (optional field) Enter additional contact person's phone extension, if any.

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



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



- c. 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.
 - d. DELETE: This will remove the submission from your account.
 - e. 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

12. Click '**SAVE AND VALIDATE**' if you want to check for errors with your SPL. To submit your SPL to FDA,
 - a. **PLEASE NOTE:** This option is only for an initial validation of your SPL before submitting to FDA. It does not automatically submit your SPL to FDA, even if it passes the initial validation, but scans for certain errors prior to the actual submission. To submit your data to the FDA, select "Submit SPL".
13. 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.

14. 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	0c096ca6-f90a-b44d-e063-6a94af0ab7ab	0c096ca6-f90a-b44d-e063-6a94af0ab7ab		1

15. 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.

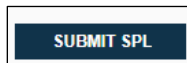
For assistance with validation errors and general questions regarding electronic registration and listing of cosmetic product facilities and products, contact casmeticscdsc@fda.hhs.gov

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

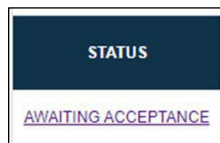
16. Click '**SUBMIT SPL**' if you are ready to submit your SPL to FDA.



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

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

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



4.4.3.3 Submission Accepted

17. The status column will change to '**SUBMISSION ACCEPTED**' after the submissions 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

18. Click on '**SUBMISSION ACCEPTED**' to **VIEW SPL** and **DOWNLOAD SPL**.

- a. To clone and create a new version of your successfully submitted SPL, click '**CREATE A NEW VERSION**'

CREATE NEW VERSION

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

Set ID: *	0c066ca6-f8da-b44d-e063-6a94af0ab7ab	Generate New	Version Number: *	<input type="text" value="2"/>
Root ID: *	0c06eb2a-30c9-7866-e063-6b94af0af38e	Generate New	Effective Date: *	12-06-2023

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

VIEW SPL

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

DOWNLOAD SPL

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

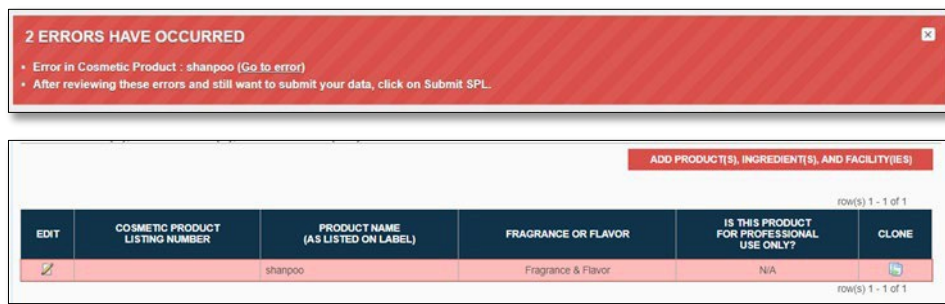
4.4.3.4 Submission Failed

19. 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.



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

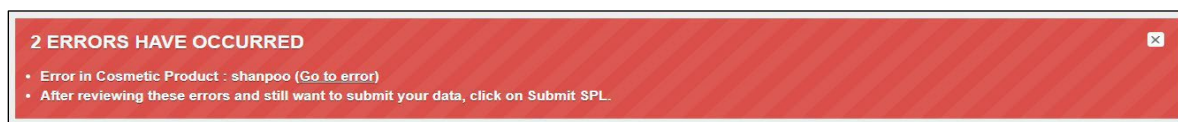
20. If the status column changes to **'SUBMISSION ACCEPTED'**, refer to section 4.2.3.3 for additional information.

4.4.3.5 Validation Failure

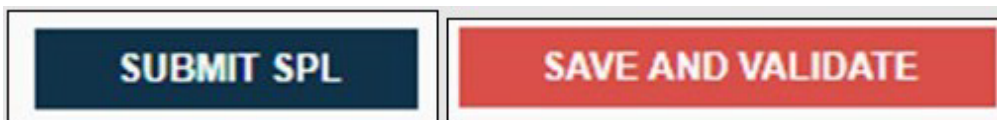
21. After clicking **'SAVE AND VALIDATE'**, the product listing of cosmetic product listing home page will have the following details as shown below. The status column will be in **VALIDATION IN PROGRESS**. However, if the system finds any errors the status will change to **VALIDATION FAILURE**.

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

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



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



4.4.4 Abbreviated Renewal Listing

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

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

DOCUMENT TYPE DETAILS

Document Type: * COSMETIC - ABBREVIATED RENEWAL ▾

Set ID: * --Select One--
COSMETIC PRODUCT LISTING
COSMETIC - UPDATE
COSMETIC - ABBREVIATED RENEWAL
1a099c50-0b02-0490-e003-0094a10aa31c

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

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

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.

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

4.4.5 Cosmetic – Update

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

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

The screenshot shows a form titled "DOCUMENT TYPE DETAILS". It contains three required fields: "Document Type:", "Set ID:", and "Root ID:". The "Document Type:" dropdown menu is open, showing the following options: "--Select One--", "COSMETIC PRODUCT LISTING", "COSMETIC - UPDATE" (which is highlighted), and "COSMETIC - ABBREVIATED RENEWAL". To the right of the "Set ID:" and "Root ID:" fields, there are two "Generate New" buttons.

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

a. **PLEASE NOTE:** The following cannot be updated:

1. Product Name
2. Ingredients (including fragrance, color, and flavor)
3. Product Categories
4. Responsible Person

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).

3. 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 - UPDATE ▼

Set ID: * --Select One-- [Generate New](#)

Root ID: * COSMETIC PRODUCT LISTING [Generate New](#)

COSMETIC - UPDATE

COSMETIC - ABBREVIATED RENEWAL

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)				
EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	XX-XXXXXX-XXXXXX	PRODUCT NAME	LISTED ▼	
	XX-XXXXXX-XXXXXX	PRODUCT NAME	LISTED ▼	

row(s) 1 - 2 of 2

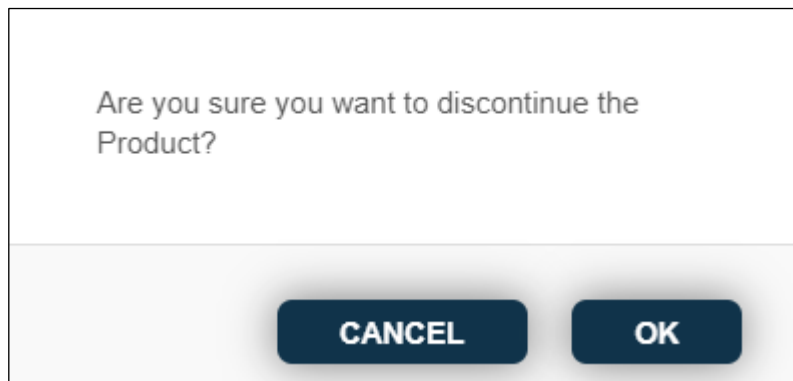
- b. Click on the pencil icon of the product you would wish to discontinue.



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



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



- 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)					
EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	row(s) 1 - 2 of 2	
			CHANGE STATUS FOR ALL PRODUCTS		
	XX-XXXXXX-XXXXXX	PRODUCT NAME	DISCONTINUED	row(s) 1 - 2 of 2	

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!"

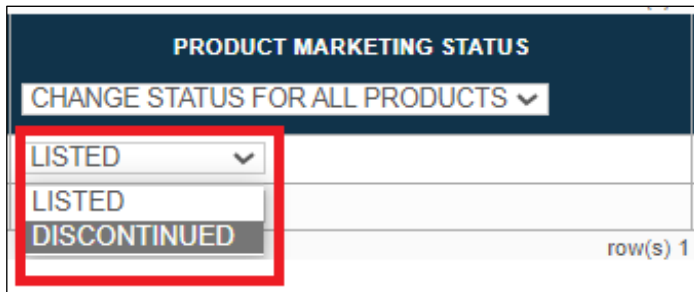
PLEASE NOTE: Once a product is discontinued, no additional edits can be made on the page unless the product is RELISTED. Please see section 4.4.5.2 Relist for additional instructions.

Option 2 – Product Marketing Status

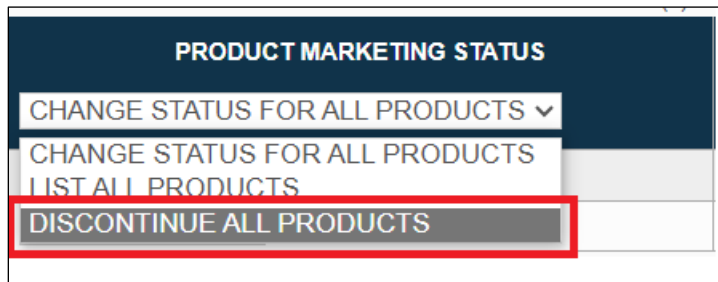
- e. Locate the PRODUCT MARKETING STATUS column under the PRODUCT(S), INGREDIENT(S), AND FACILITY(IES) section.

EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	XX-XXXXXX-XXXXXX	PRODUCT NAME	LISTED	
	XX-XXXXXX-XXXXXX	PRODUCT NAME	LISTED	

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



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

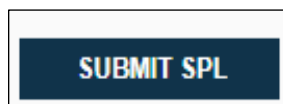


- g. After selecting, the Product Marketing Status for all the listed cosmetic products will change to DISCONTINUED.

EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	XX-XXXXXX-XXXXXX	PRODUCT NAME	DISCONTINUE ALL PRODUCTS	
	XX-XXXXXX-XXXXXX	PRODCUT NAME	DISCONTINUED	
			DISCONTINUED	

row(s) 1 - 2 of 2

- h. 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'.



Option 3 – Delete

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

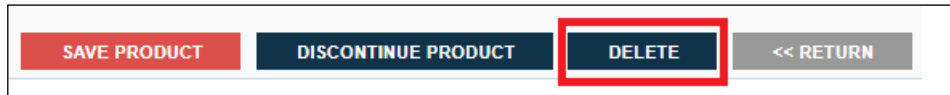
PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)				
ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)				
EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	XX-XXXXXX-XXXXXX	PRODUCT NAME	CHANGE STATUS FOR ALL PRODUCTS	
	XX-XXXXXX-XXXXXX	PRODUCT NAME	LISTED	
			LISTED	

row(s) 1 - 2 of 2

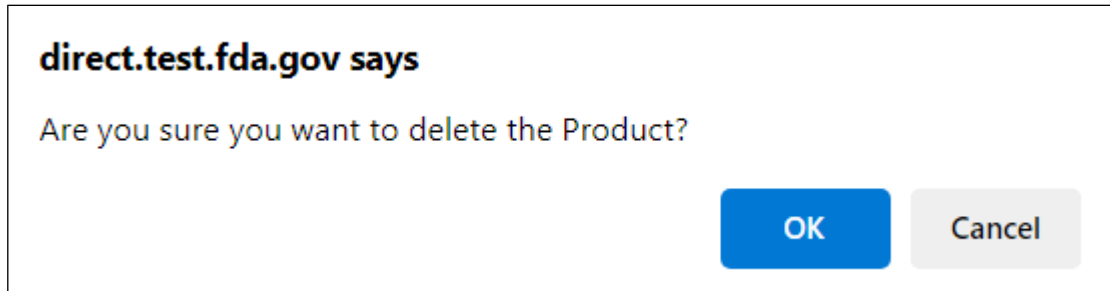
- j. Click on the pencil icon of the product you would wish to discontinue.



- k. Select "**DELETE**", to delete the product from the SPL file.



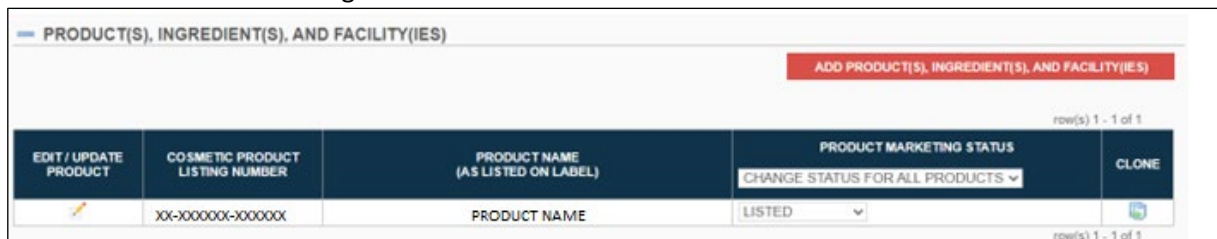
- i. **PLEASE NOTE:** The following message will appear, "Are you sure you want to delete the Product?" This will remove the product from the SPL file permanently, Once the product is deleted, it cannot be relisted. If the deleted product needs to be relisted, a new INITIAL-SPL submission is required.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



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



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



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.**'

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.

- b) Click on 'RELIST PRODUCT'.

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

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

Cosmetic Product Relisted. X

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
	XX-XXXXXX-XXXXXX	PRODUCT NAME	CHANGE STATUS FOR ALL PRODUCTS ▾ LISTED ▾	
row(s) 1 - 1 of 1				

Option 2 – Product Marketing Status

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

row(s) 1 - 2 of 2			
EDIT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS
	XX-XXXXXX-XXXXXX	PRODUCT ONE	DISCONTINUED
	XX-XXXXXX-XXXXXX	PRODUCT TWO	DISCONTINUED
row(s) 1 - 2 of 2			

- f) 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
	XX-XXXXXX-XXXXXX	PRODUCT ONE	DISCONTINUE ALL PRODUCTS ▾ DISCONTINUED ▾
	XX-XXXXXX-XXXXXX	PRODUCT TWO	LISTED ▾ LISTED DISCONTINUED

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

row(s) 1 - 2 of 2				
EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	XX-XXXXXX-XXXXXX	PRODUCT ONE	CHANGE STATUS FOR ALL PRODUCTS ▾ CHANGE STATUS FOR ALL PRODUCTS LIST ALL PRODUCTS DISCONTINUE ALL PRODUCTS	
	XX-XXXXXX-XXXXXX	PRODUCT TWO		
row(s) 1 - 2 of 2				

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

5.5 Filters

5.5.1 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
--------	--------	---------	---------------	---------	---------------	--------------	---------------	---------------	--------------------

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.

5.5.2 Cosmetic Product Listing

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

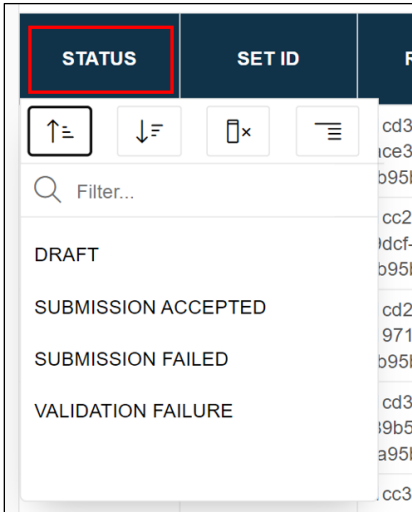
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	RESPONSIBLE PERSON NAME	DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE	
--------	--------	---------	---------------	---------	---------------	-------------------------	---------	--------------------	--------------------	---

1. Status: The current status of your submissions. For further explanation of the different status types, see Section 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 Update' or 'Product Listing.'
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.

5.5.2.1 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:



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	

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

The screenshot shows a table with columns: 'ION', 'DOCUMENT TYPE', and 'RESPONSIBLE PERSON NAME'. A dropdown menu is open for 'DOCUMENT TYPE', showing options: 'COSMETIC - UPDATE' and 'COSMETIC PRODUCT LISTING'. To the right is a legend table:

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

5.5.2.2 Search Product

A product can be searched by name:

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

The screenshot shows a dark blue header with two buttons: 'SEARCH PRODUCT' (highlighted with a red box) and 'CREATE NEW / UPLOAD FILE'. Below the buttons is a table with columns: 'TYPE', 'RESPONSIBLE PERSON NAME', 'DETAILS', 'LAST MODIFIED USER', 'LAST MODIFIED DATE', and a lock icon. The 'LAST MODIFIED DATE' column shows '03-JUL-'.

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

The screenshot shows a modal window titled 'Search Product' with a close button (X). It contains a text input field labeled 'Product Name' and a 'SEARCH' button.

3. The page will update immediately with your filter.

5.5.2.3 Rows Per Page

To adjust the number of submissions visible per page:

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

STATUS	SET ID	ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE
DRAFT			1	METIC - UPDATE		02-JUL-2024 11:54:43
DRAFT			5	METIC PRODUCT LISTING		02-JUL-2024 08:03:16
DRAFT			10	METIC PRODUCT LISTING		27-JUN-2024 14:26:59
DRAFT			15	METIC PRODUCT LISTING		27-JUN-2024 14:18:19
DRAFT			20	METIC PRODUCT LISTING		17-JUN-2024 13:26:14
DRAFT			25	METIC FACILITY REGISTRATION		17-JUN-2024 12:50:55
DRAFT			50	METIC PRODUCT LISTING		14-JUN-2024 09:12:37
DRAFT			100	METIC FACILITY REGISTRATION - NDMENT		12-JUN-2024 13:31:07
DRAFT				METIC PRODUCT LISTING		03-JUN-2024 12:16:50
DRAFT				COSMETIC PRODUCT LISTING		03-JUN-2024

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