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:

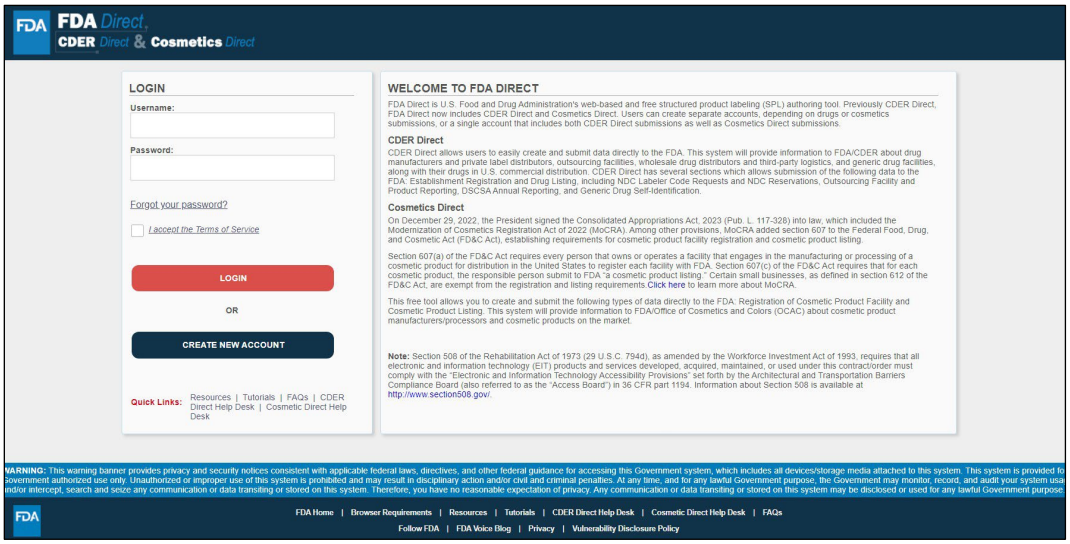
- *Registration of Cosmetic Product Facility*
- *Cosmetic Product Listing*

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/



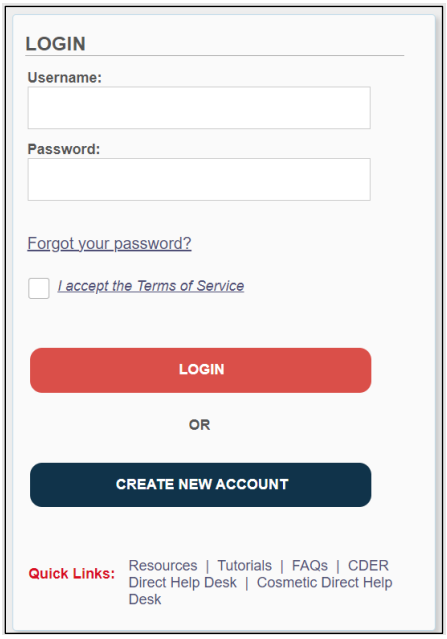
At the bottom of the Login area, there are ***Quick Links*** that can provide you with further assistance on various topics:

- **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.

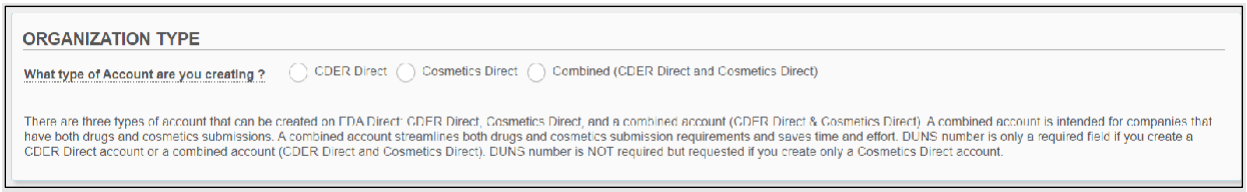
2.2 Account Creation

Follow these steps to create a new account:

1. Navigate to the FDA Direct main page and click **Create New Account**.

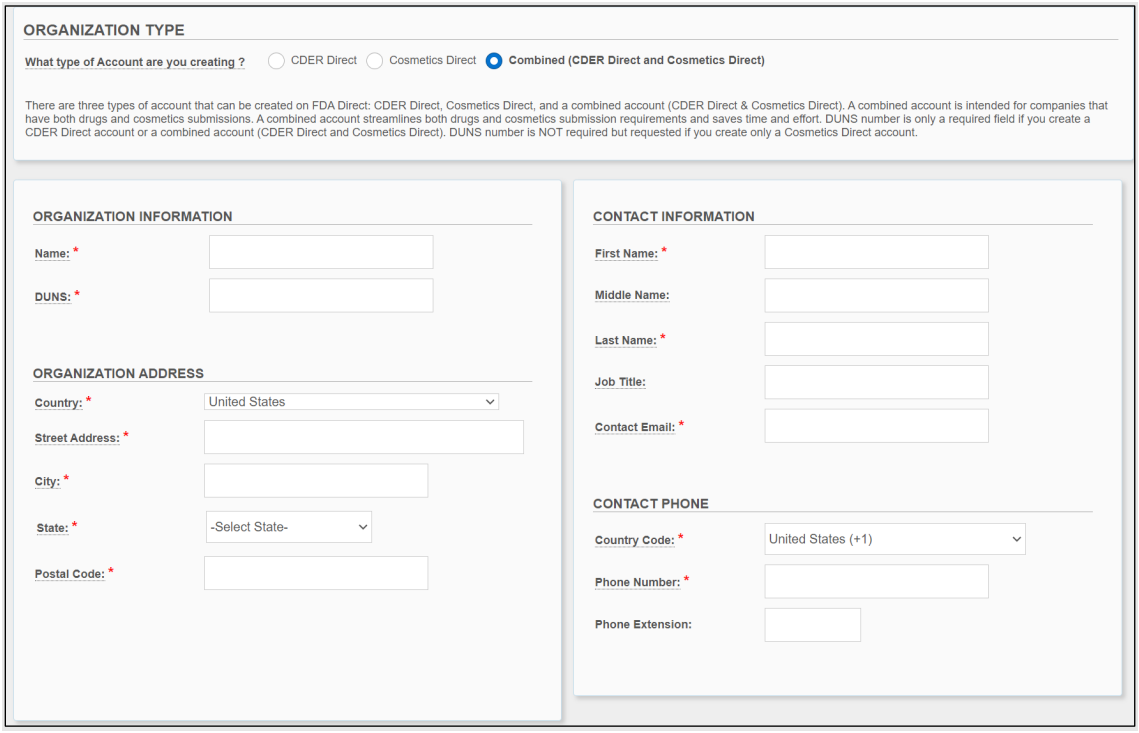


2. Select your desired account type. This can be changed after account creation:



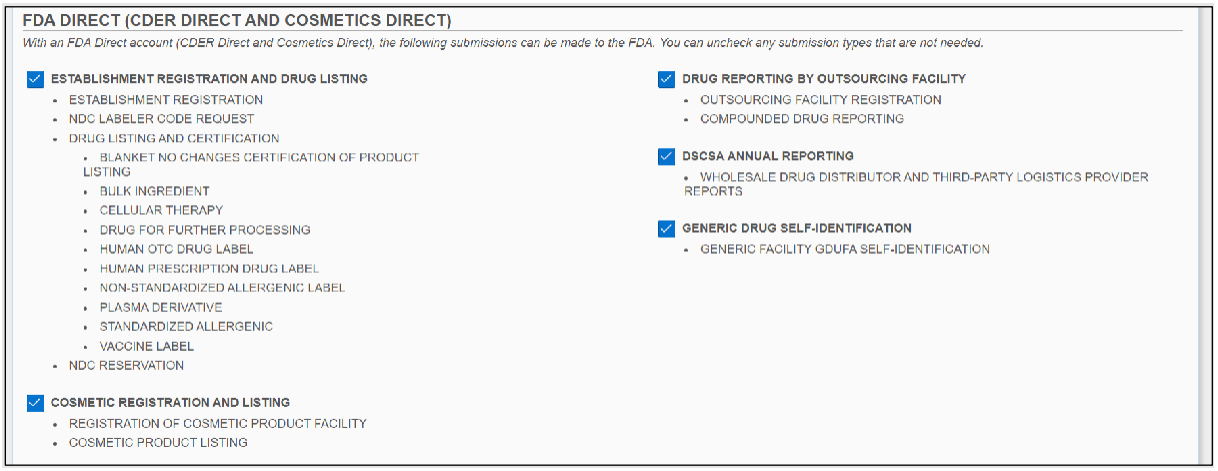
- **CDER Direct –** Select this option to register human drug or biological products. You will have access to all drug-related submission forms including *Establishment Registration and Drug Listing*, *Outsourcing Facility Registration and Product Reporting*, *DSCSA Annual Reporting,* and *Generic Drug 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:

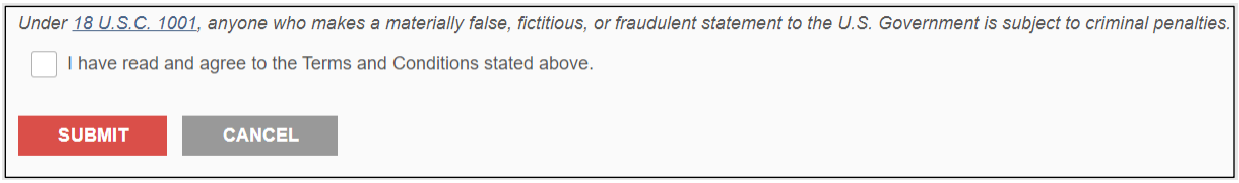


***The** DUNS field is optional in Cosmetics Direct account creation only.

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



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



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.

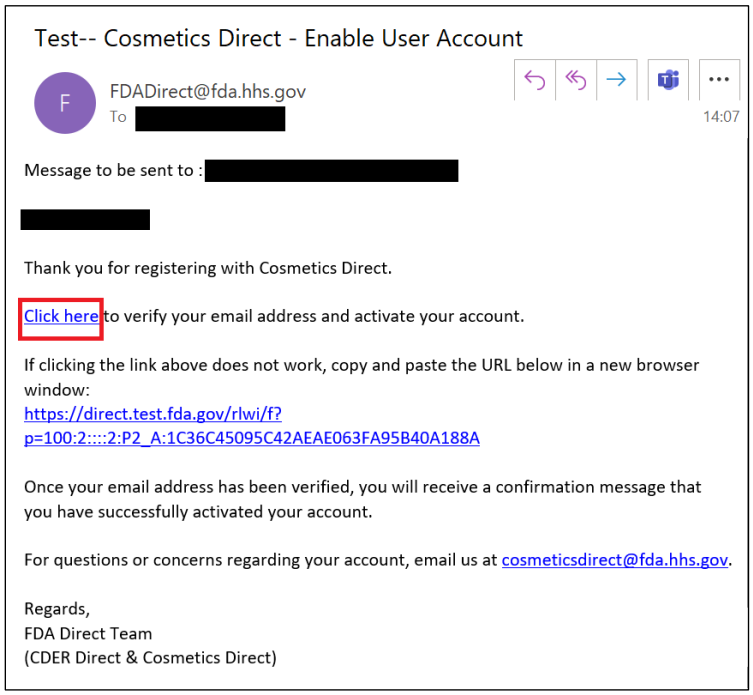
   If you still have not received your activation email after 5-10 minutes, you can contact the Help Desk at:

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

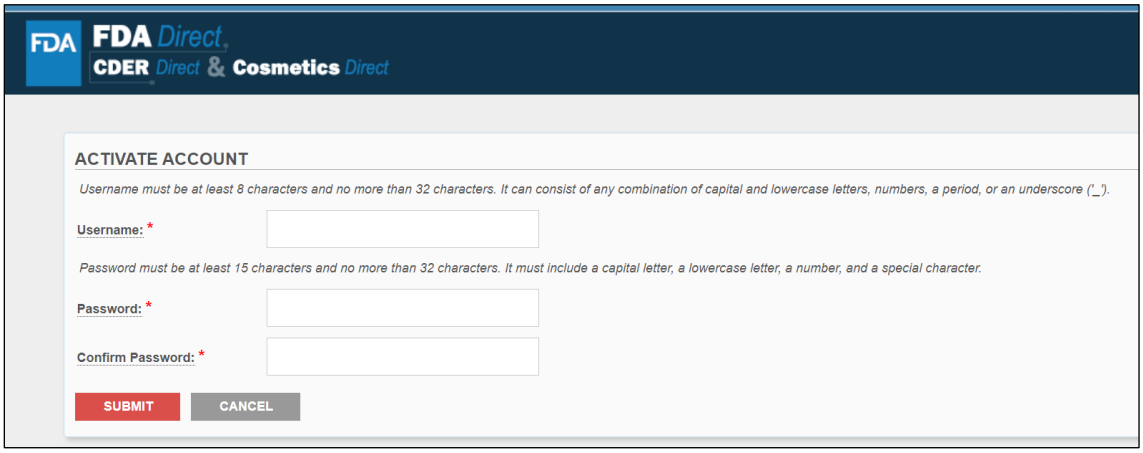
     OR

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

7. Click the link in the activation email:



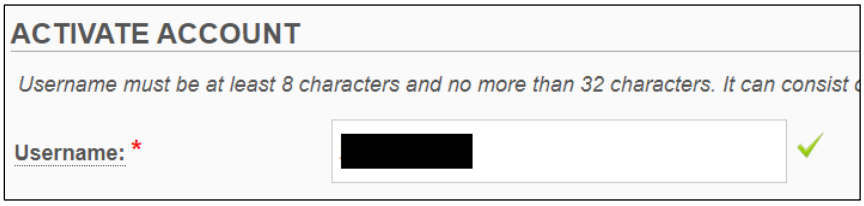
8. The link will open the FDA Direct website in your browser. Enter your desired Username and Password:



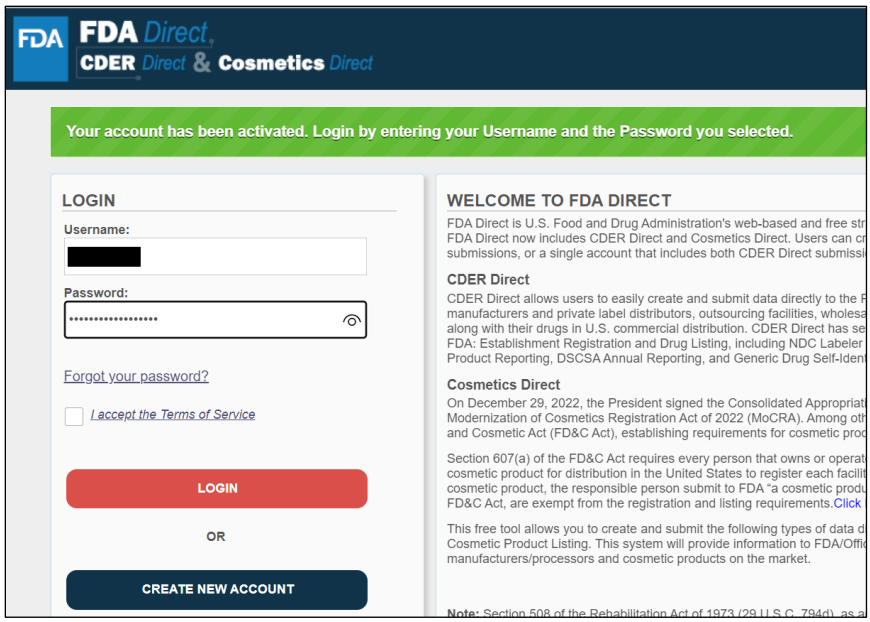
Usernames must be within 8-32 characters in length. Passwords must be between 15-32 characters long, and include at least **one** of the following:

- Capital letter
- Lowercase letter
- Number
- Special character

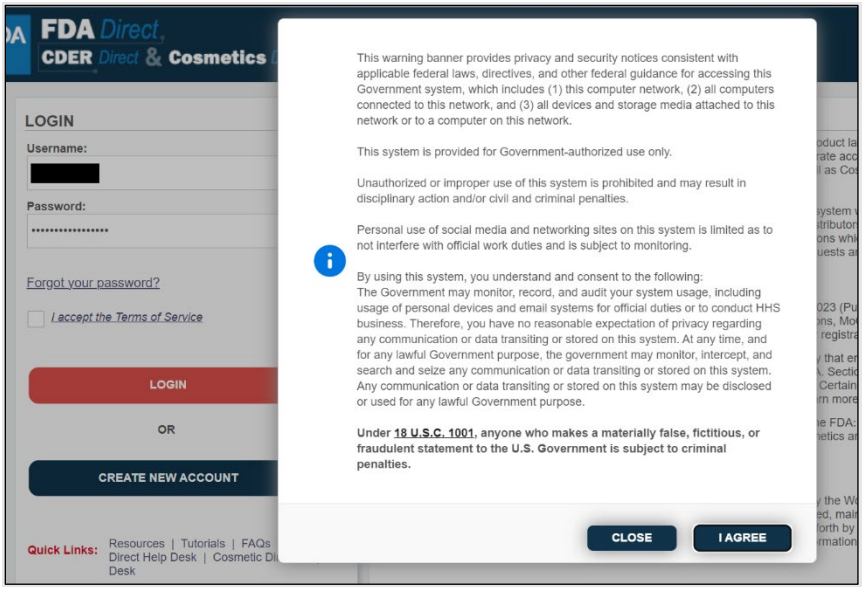
A green checkmark will indicate that your username is acceptable:



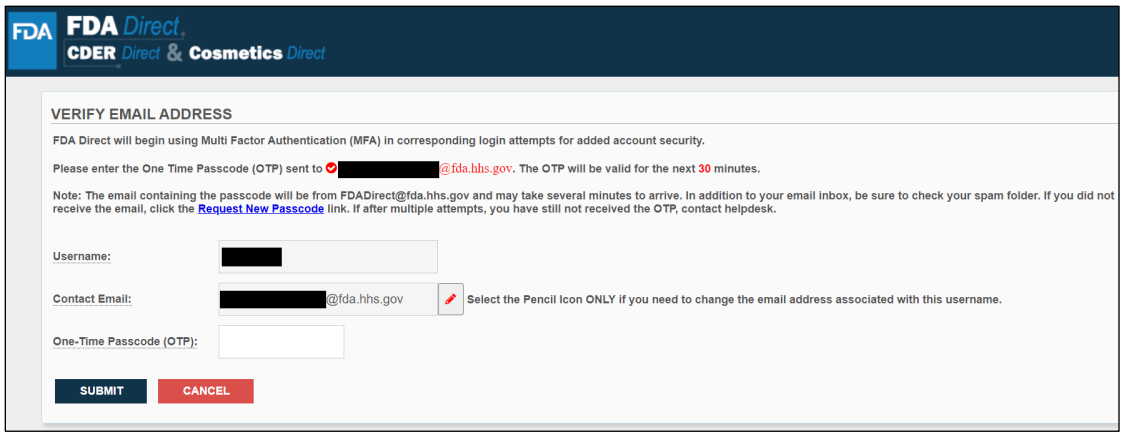
9. Click '**Submit**' when all fields have been filled.
10. You will be redirected to the FDA Direct login page. A green banner at the top of the page will confirm your account activation. Enter your new username and password:



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

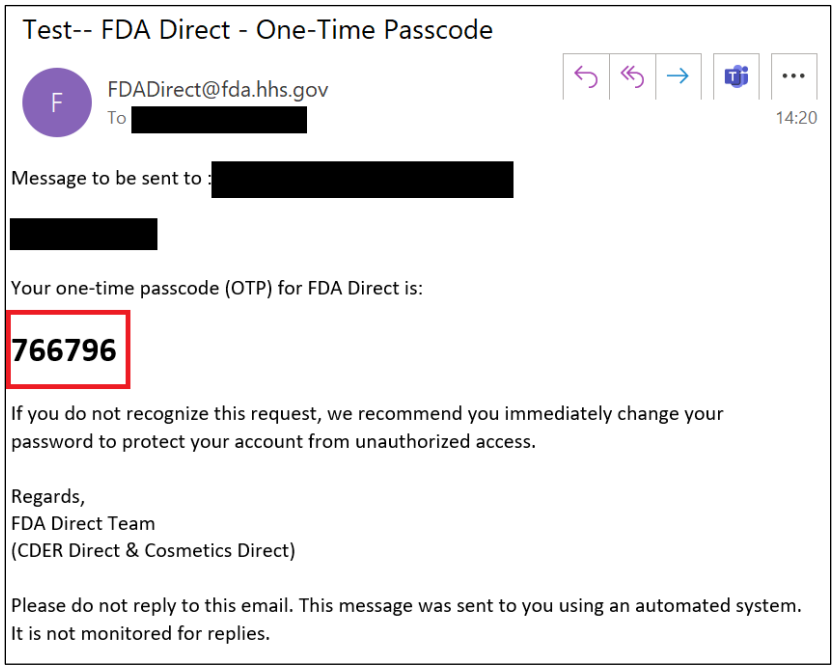


12. The FDA uses **MFA (Multi-Factor Authentication)** for security verification. The 'Verify Email Address' screen below will only display once, immediately after your initial login to your new account:

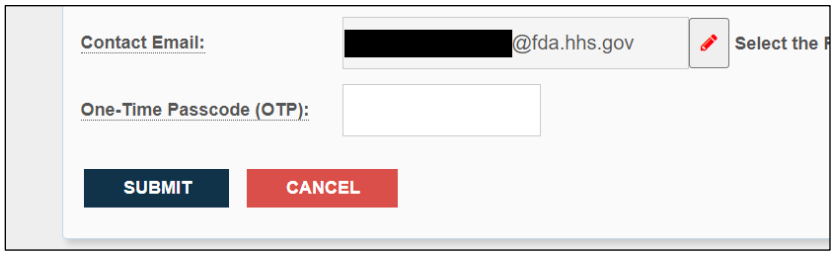


*** Click the pencil icon beside your email address to update your email address, or change it later in the Manage Account settings (see Section 2.4)**

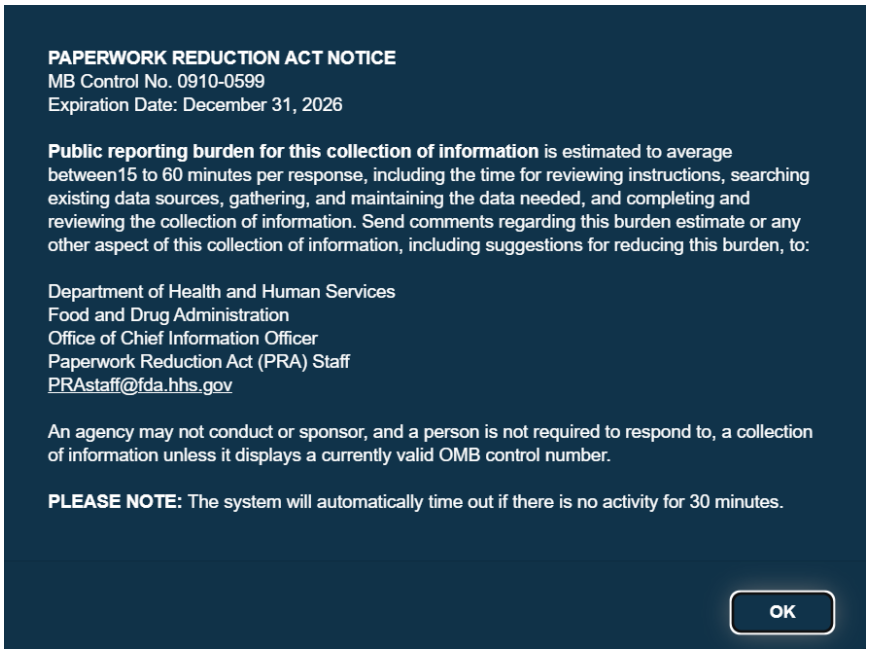
13. To retrieve your One-Time Passcode (OTP), check your email. If you still have not received a passcode after several minutes, click the '**Request New Passcode**' link (shown above) to send another code, then check your email again.



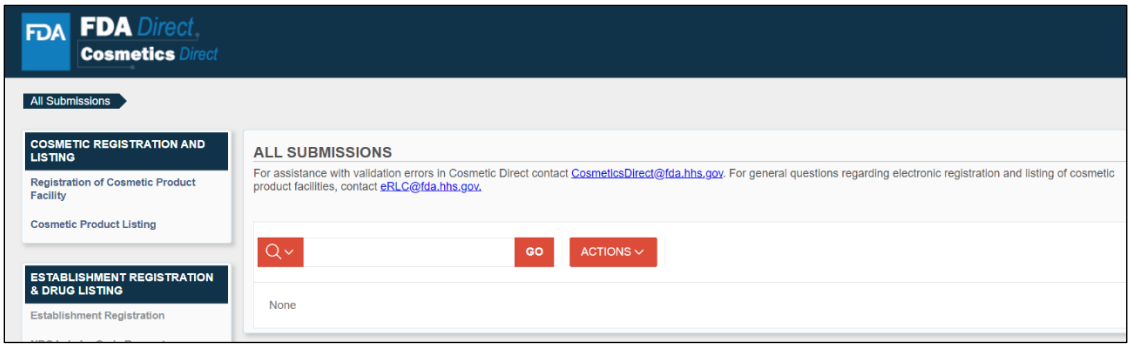
14. Enter the passcode from your email into the OTP field:



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



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

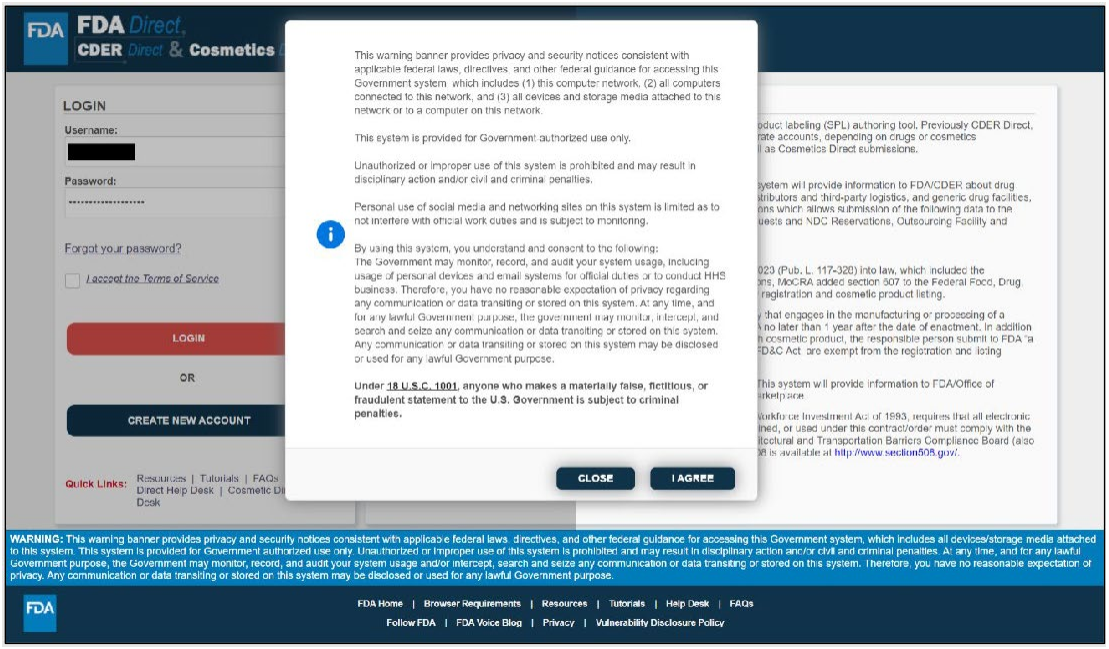


2.3 Account Login

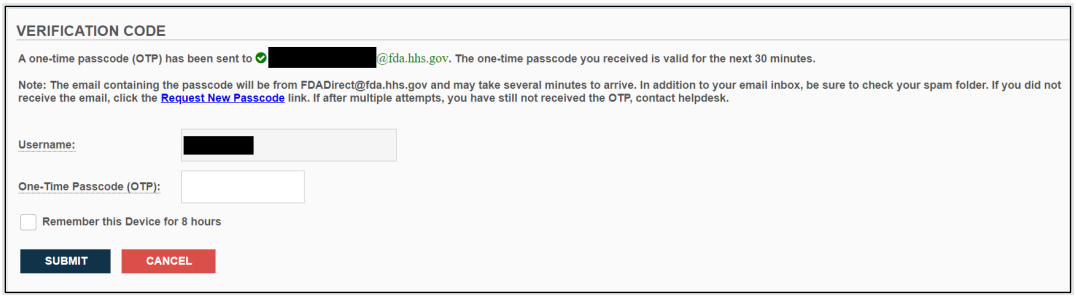
Once you have completed account activation in the steps above, you can return at any time to the FDA Direct homepage (https://direct.fda.gov).

To log in to FDA Direct and access your account:

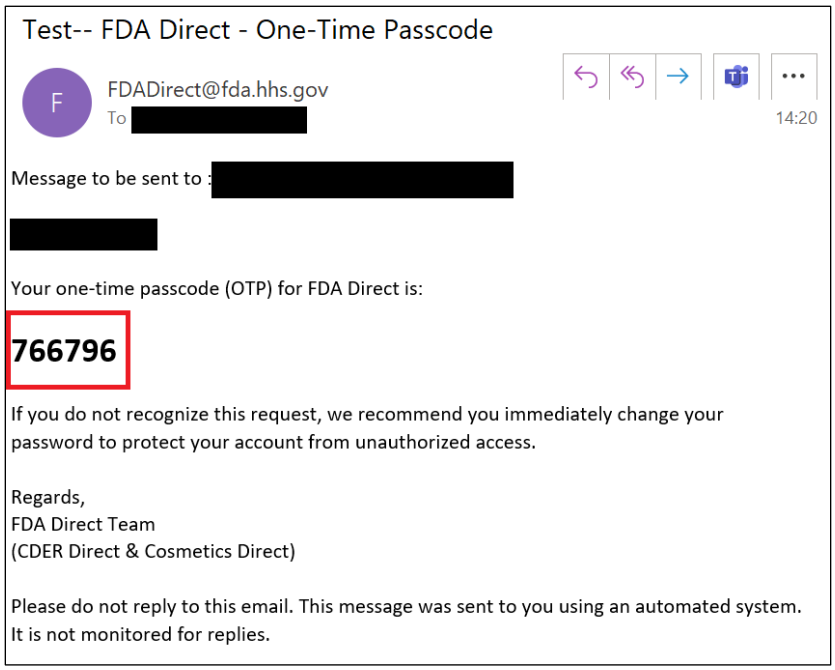
1. Enter your username and password.
2. Check the '*I accept the Terms of Service*' box and a warning banner will display. Then click '**I Agree**'.



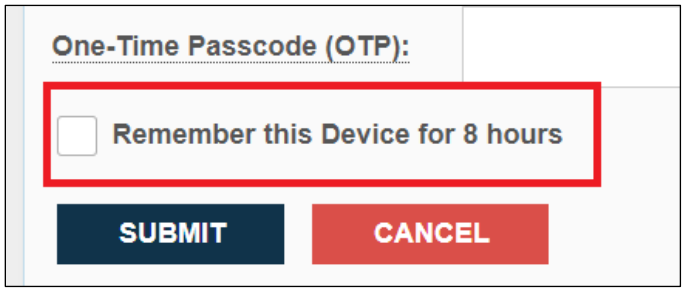
3. Click the 'Login' button. If this is your **first time logging in for <u>the day</u>**, you will be redirected to the 'Verification Code' page:



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



5. Enter the 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.

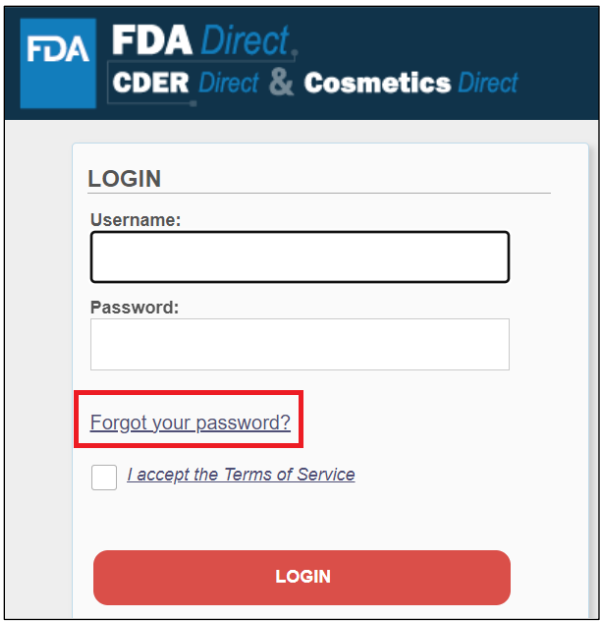
6. Click '**Submit**.' You will then be taken to your account homepage.
7. If you have a Cosmetics account or a Combined account, a Paperwork Reduction Act (PRA) banner will display. Click '**OK**' to continue.

   You are now logged in to your account.

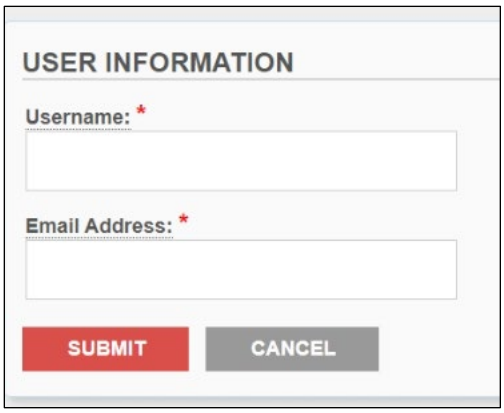
2.3.1 Forgot Password

If you forgot your password, do the following:

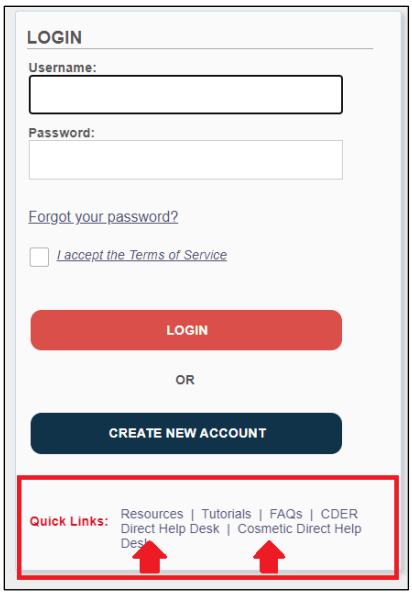
1. Go to the FDA Direct homepage (http://direct.fda.gov/) and click '*Forgot Password*':



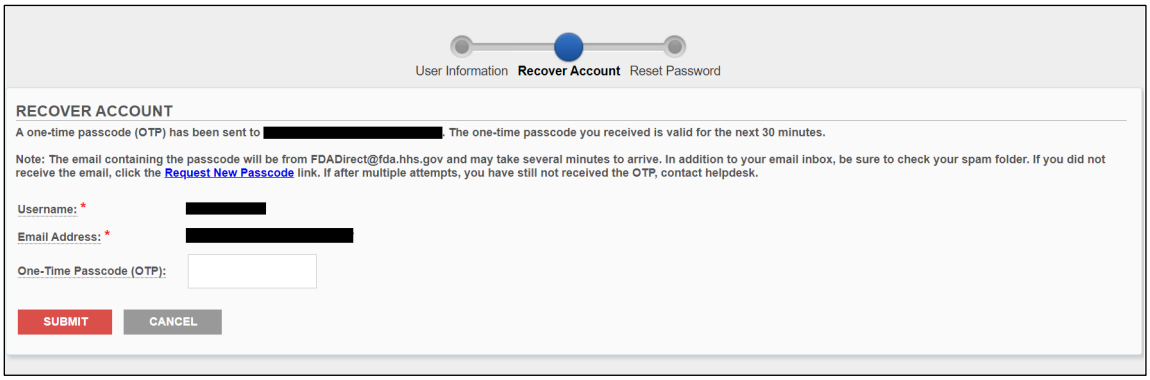
2. Enter your username and your email address in the next page:



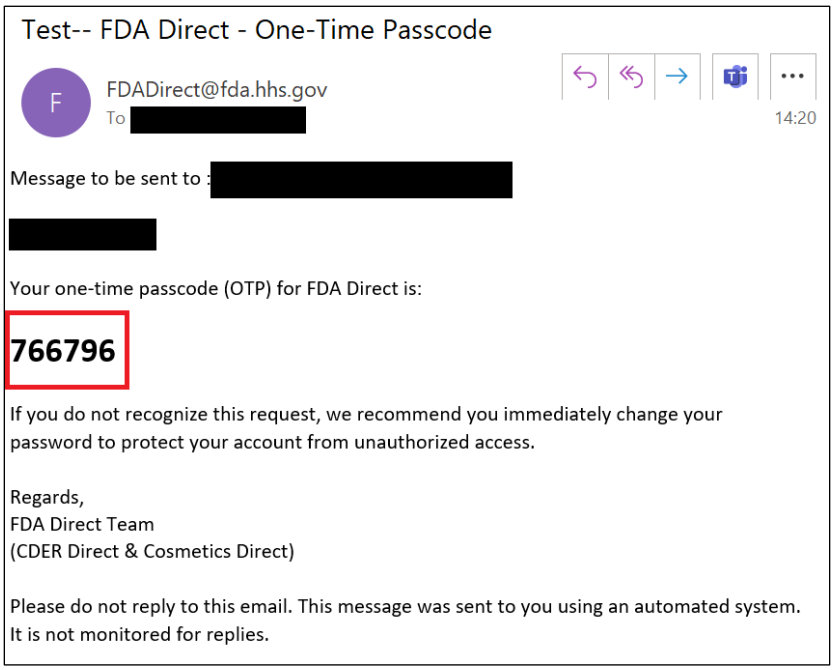
IMPORTANT: If you do not remember one or both of these details, you must contact the Help Desk by returning to the FDA homepage and clicking one of the Help Desk links in the ***Quick Links*** section:



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:



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


Test-- FDA Direct - One-Time Passcode

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

Message to be sent to : [redacted]

[redacted]

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

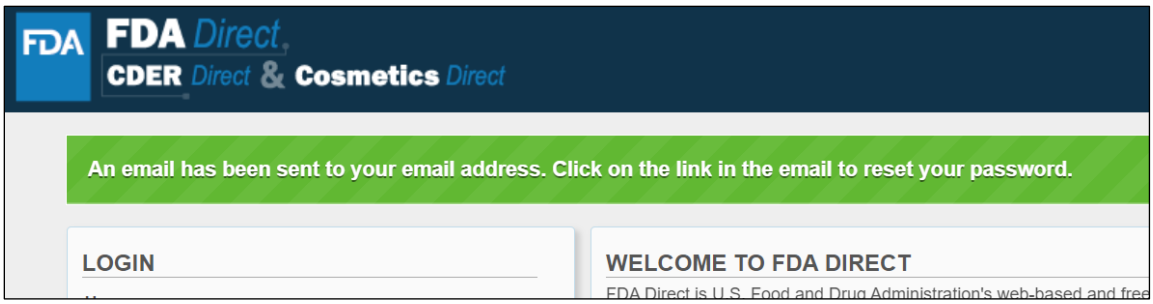
766796

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

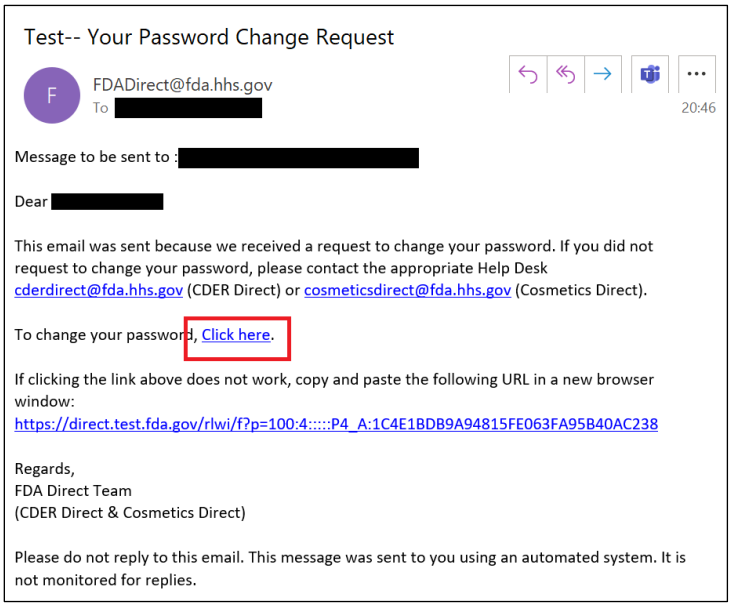
Regards,
FDA Direct Team
(CDER Direct & Cosmetics Direct)

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

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



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


Test-- Your Password Change Request

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

Message to be sent to : [redacted]

Dear [redacted]

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

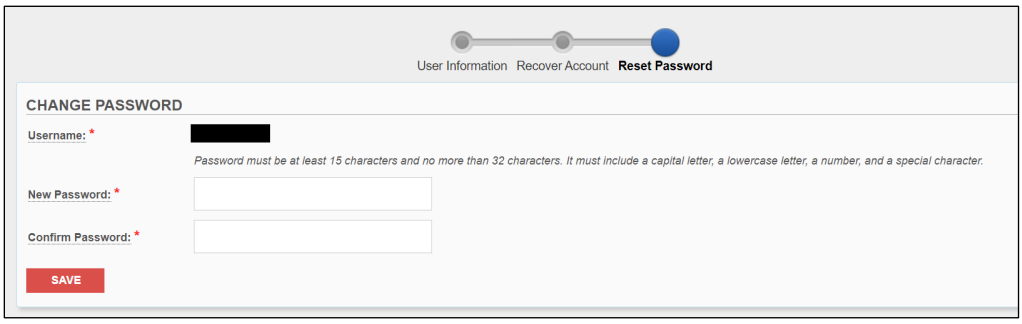
To change your password, Click here.

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

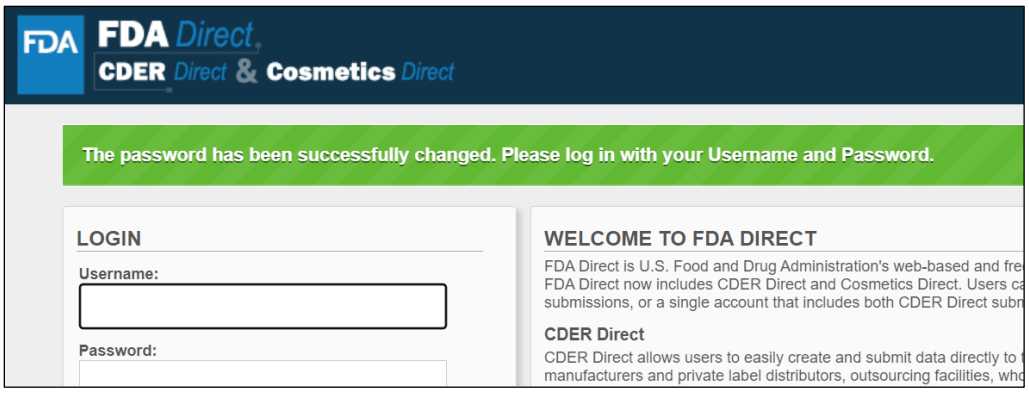
Regards,
FDA Direct Team
(CDER Direct & Cosmetics Direct)

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

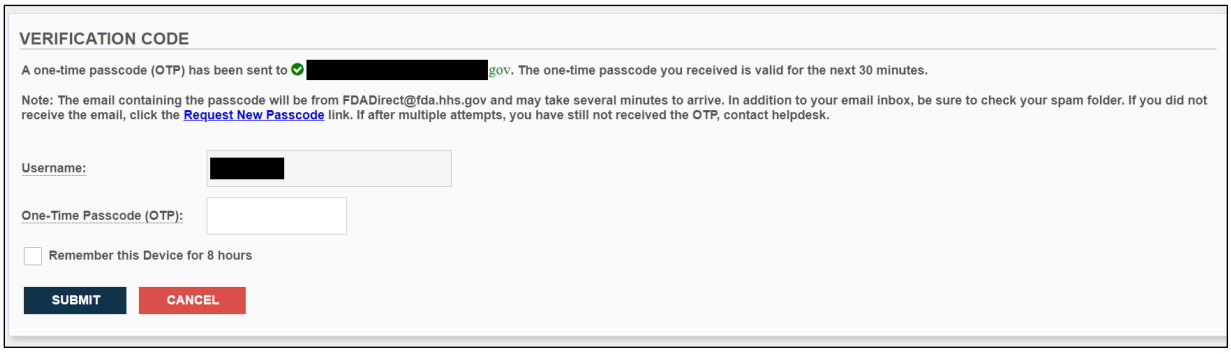
7. Enter a new password in the 'Reset/Change Password' then click '**Save**':



8. Another confirmation will display:



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

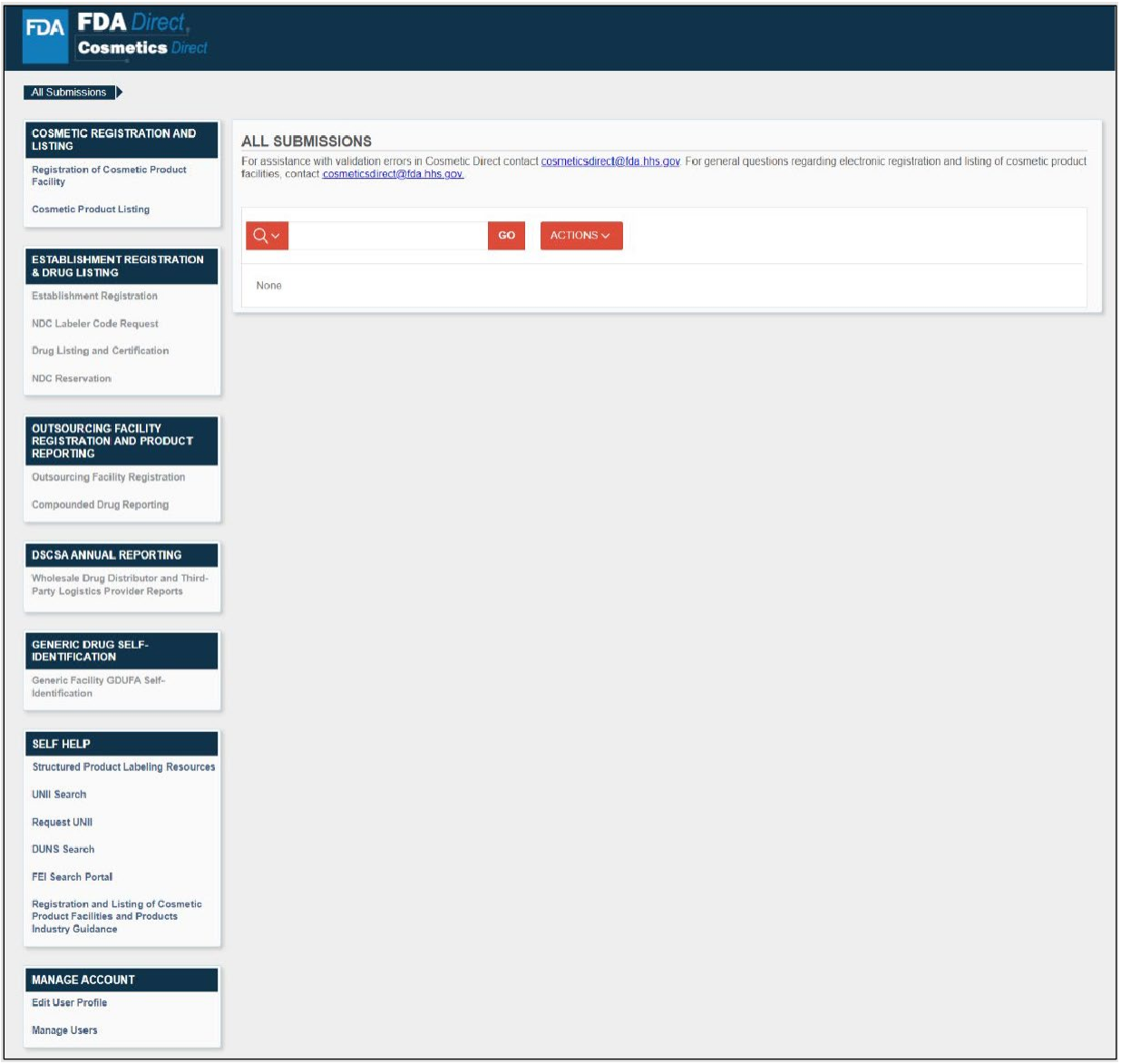


10. Check your email one last time for a One-Time Passcode. Enter the passcode from that email, check the '*Remember This Device For 8 Hours*' box, and finally click '**Submit**.'

    You will now have access to your account.

2.4 Account Management

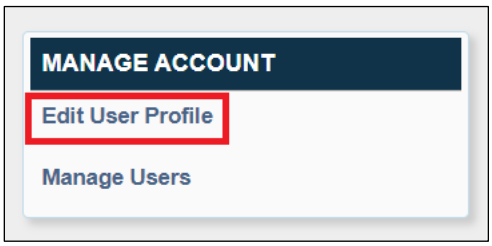
Your account main page will display each time you log in to FDA Direct:



- The left menu displays all available submission forms in FDA Direct. Access to certain forms is limited based on both your account type (Cosmetic/CDER/Combined) and any de-selections made in 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.

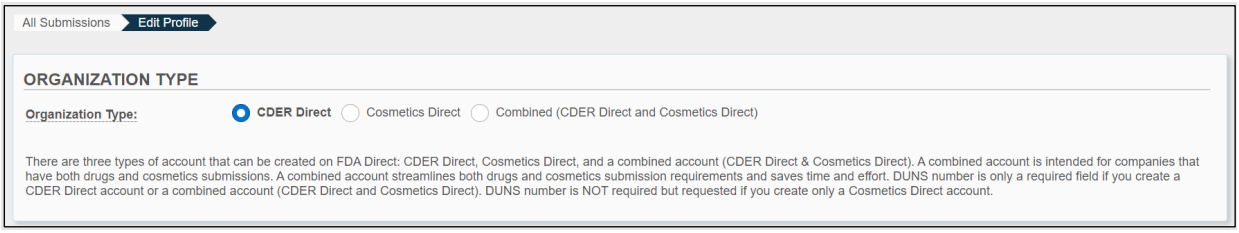
2.4.1 Edit Profile

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.**

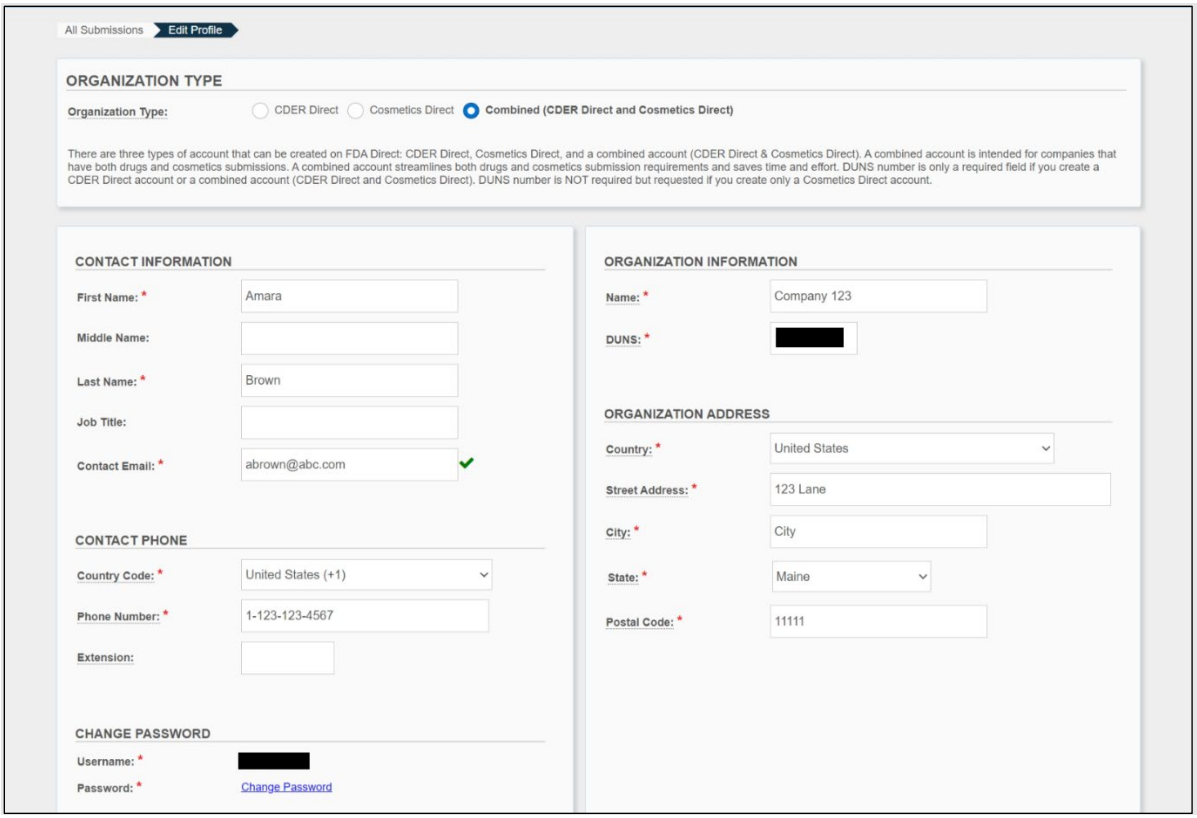
Select the desired account type:



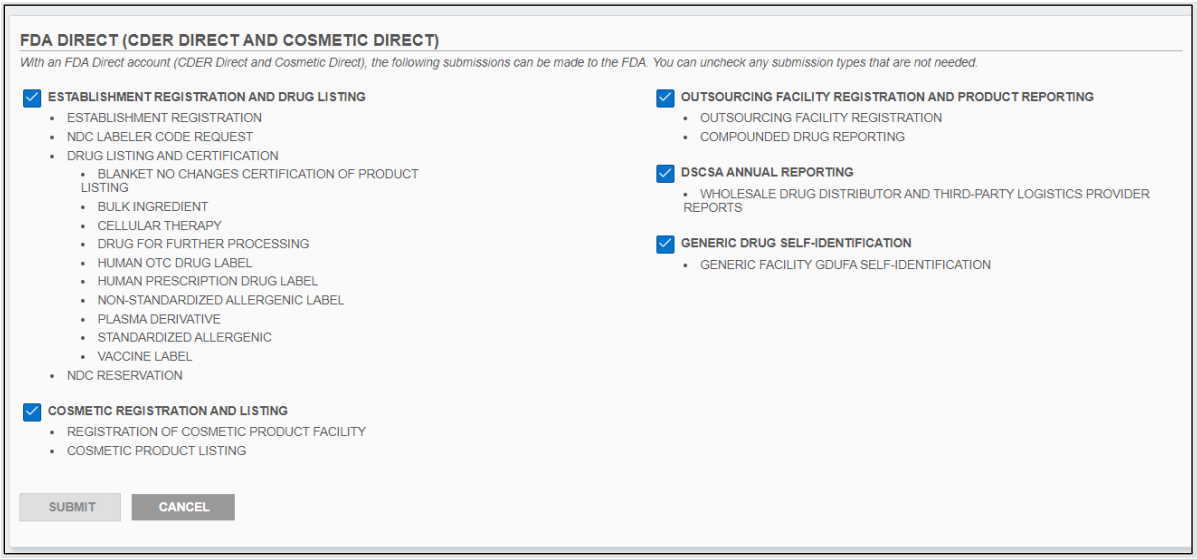
*****If you are converting from a Cosmetics Direct account to a CDER Direct or Combined account, you must enter a valid DUNS number to successfully switch accounts.

You can modify the following in the next section:

- Contact Information
- Organization Information
- Account Password



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



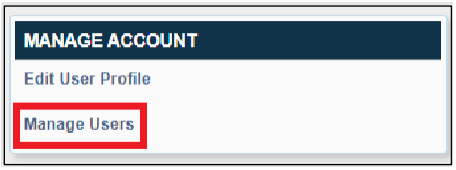
Click '**Submit**' to finalize all changes made, or '**Cancel**' to abandon your changes.

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.

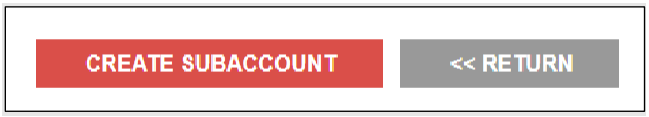
Log in to FDA Direct. Scroll to the bottom of your account main page and select '**Manage Users**' under the *Manage Account* section:



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

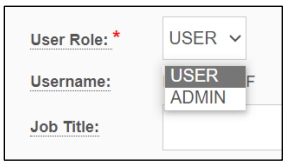
2.5.1 Creating A Subaccount:

1. Click the '**Create Subaccount**' button

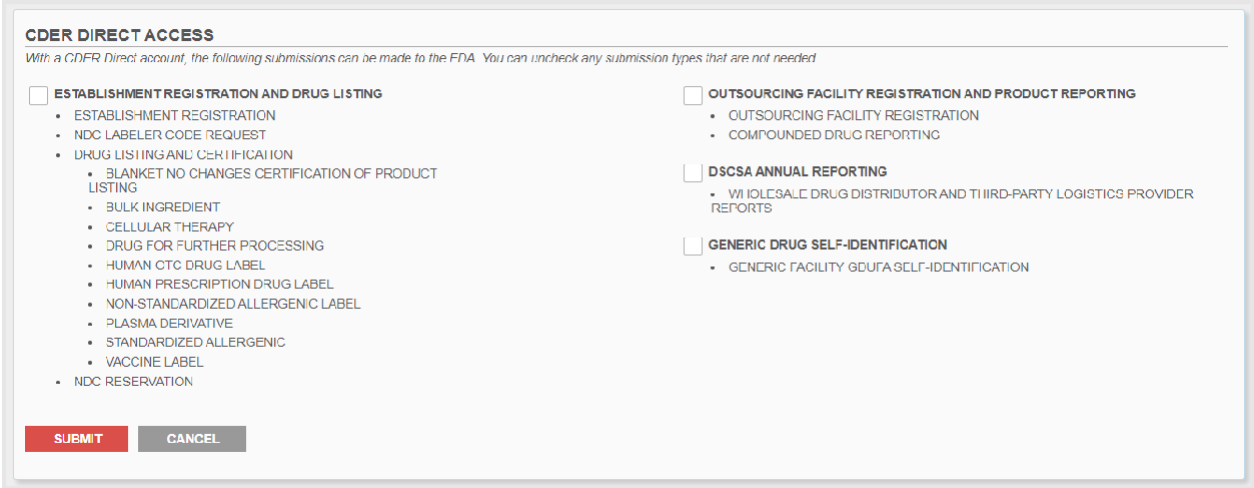


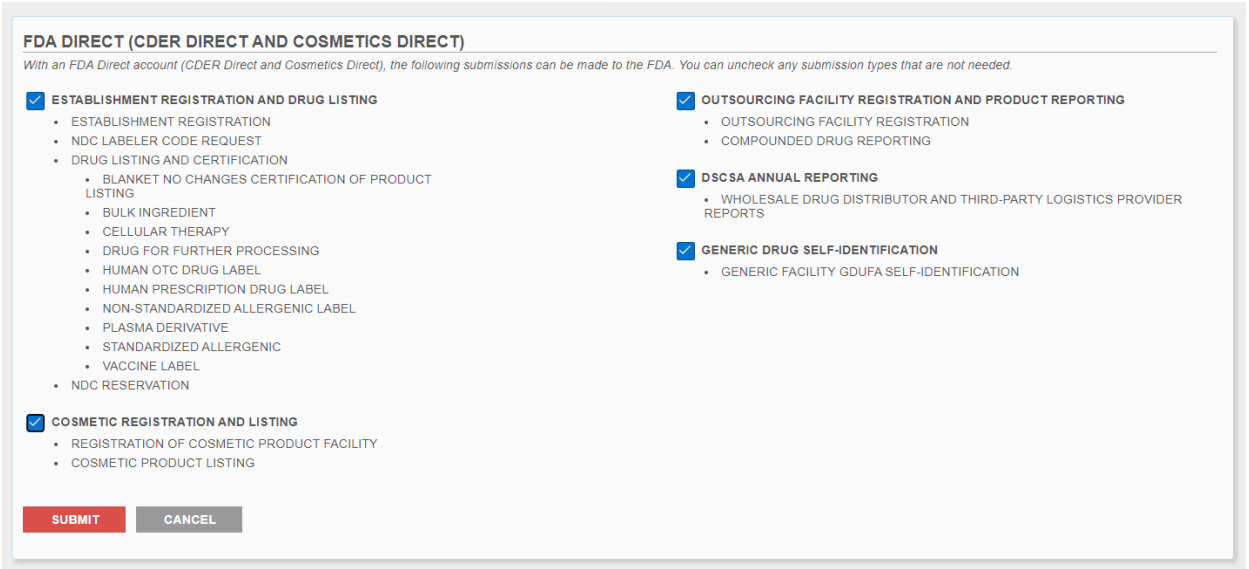
2. Enter all required fields for the subaccount user:

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

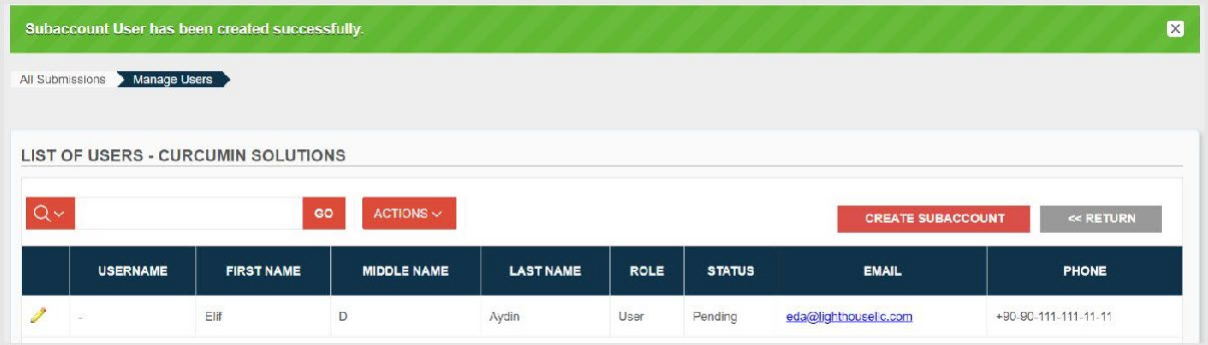


4. Select which forms the subaccount will have access to. This view will differ based on your organizational account type, which is modifiable in the Section 2.4.1: Edit Profile section. Click the form checkboxes then click 'Submit.'





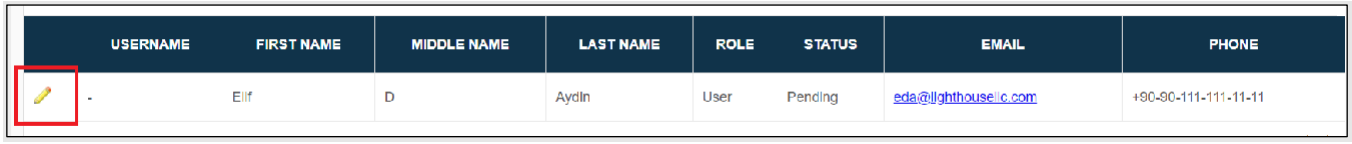
5. Subaccount creation confirmation will display at the top of the page, and the new user will be listed immediately:



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

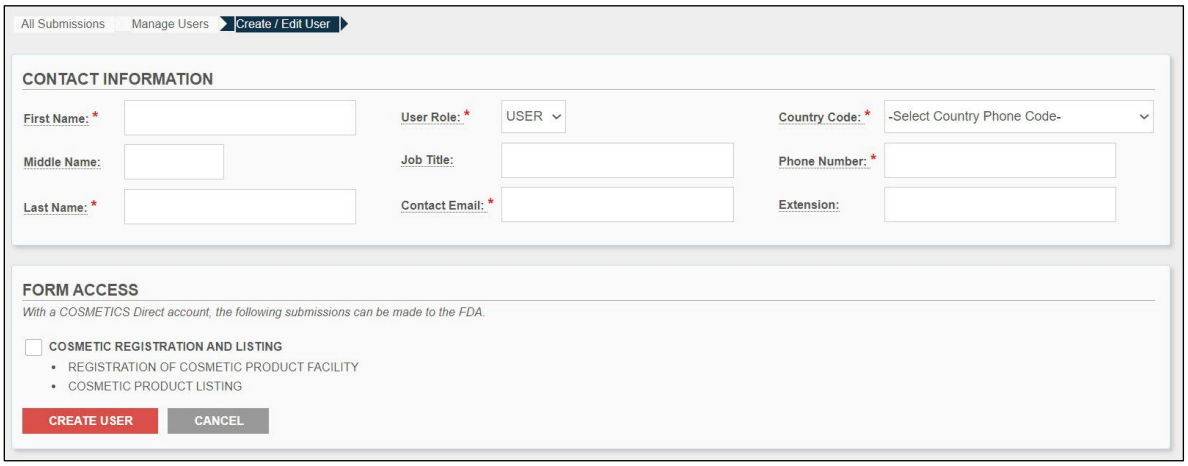
2.5.2 Managing A Subaccount

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



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.



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.

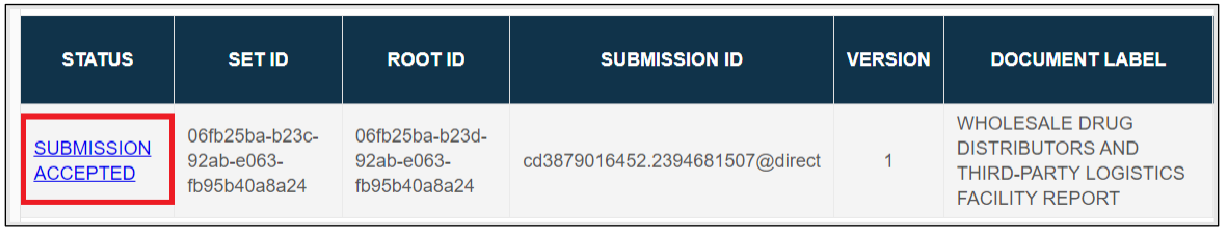
   Recommended if you have never submitted an establishment registration, product listing, etc. FDA Direct has several blank templates available for different types of submissions. See Sections 4 – 8 for walkthroughs based on specific submission types.

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:

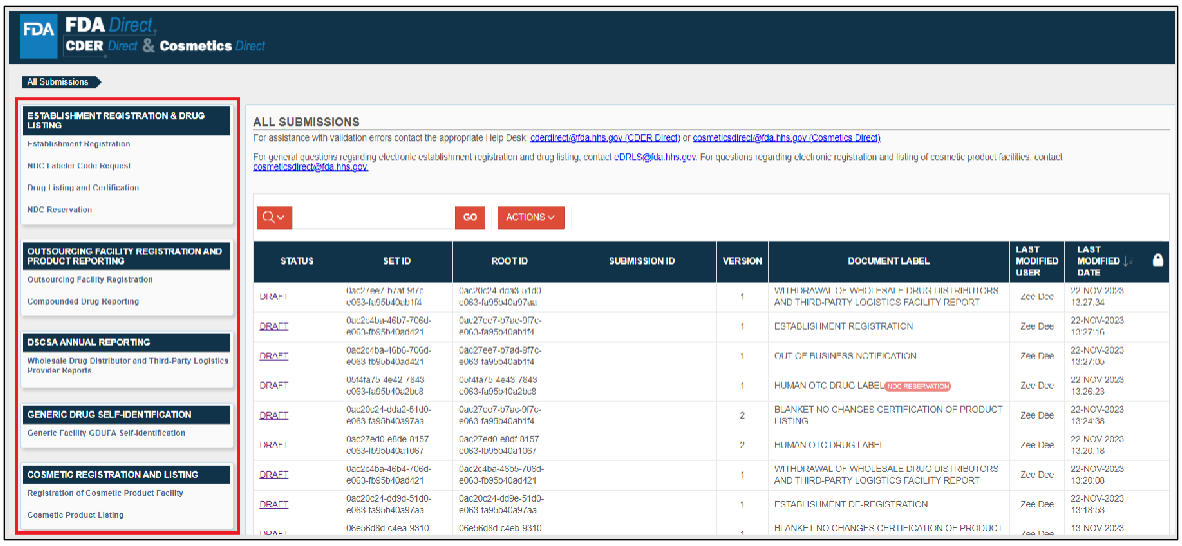
   c. Make any necessary changes, then return to the top and click '**Submit**.'

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.

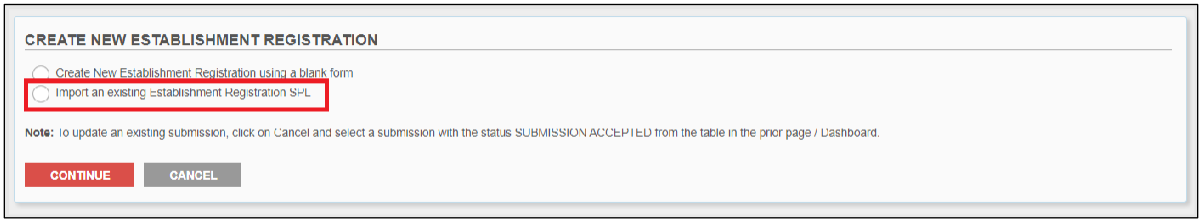
   To upload a completed SPL file into FDA Direct:

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



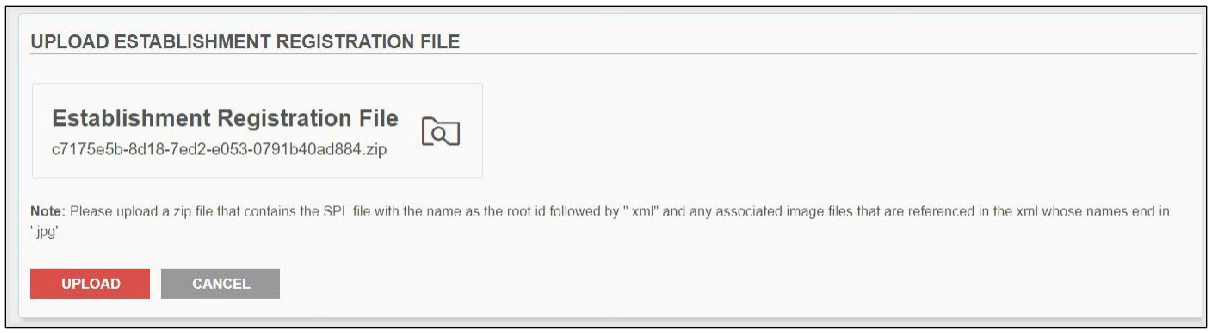
b. Click '**Create New/Upload File**':

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



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

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



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

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

3.2 Submission Statuses

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

- **Draft –** An in-progress submission that has been started but has not been sent to the FDA.
- **Awaiting Acceptance** - A submission that is sent but is pending 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

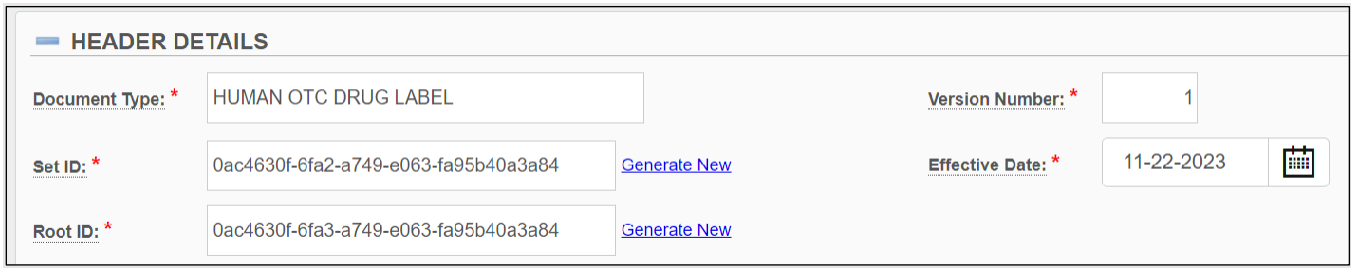
request can be forwarded to the following email addresses:

- 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:

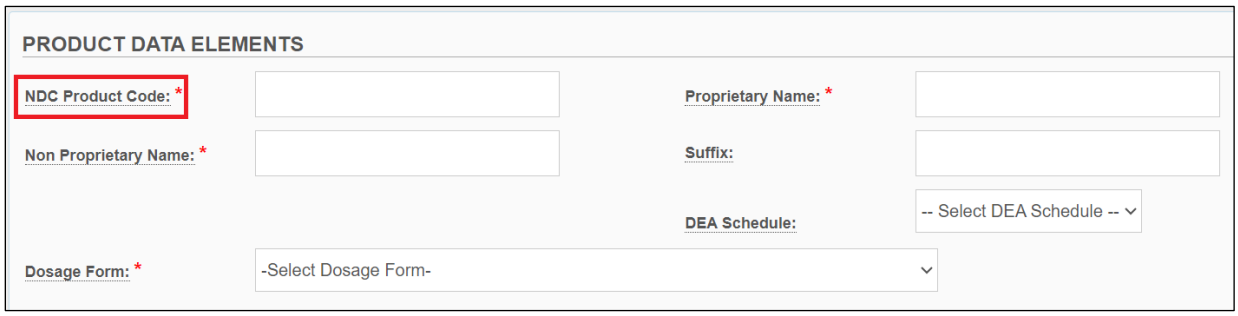


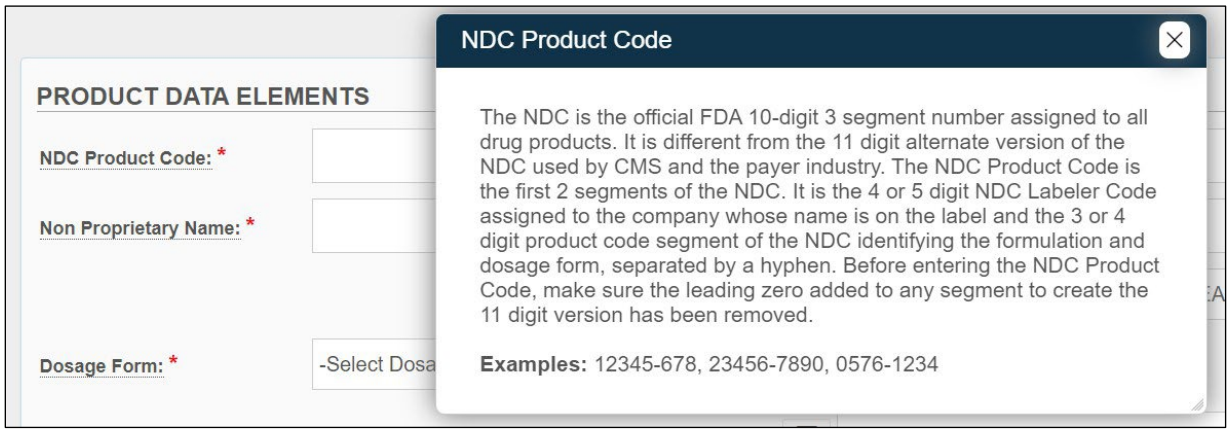
1. Set ID: A 'Globally Unique Identifier' (GUID) that remains the same for each submission 'set,' which is a group of submission versions. When you submit a different version of a submission, the set ID stays the same through each new version.
2. Root ID: A GUID that is generated uniquely for every single 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:





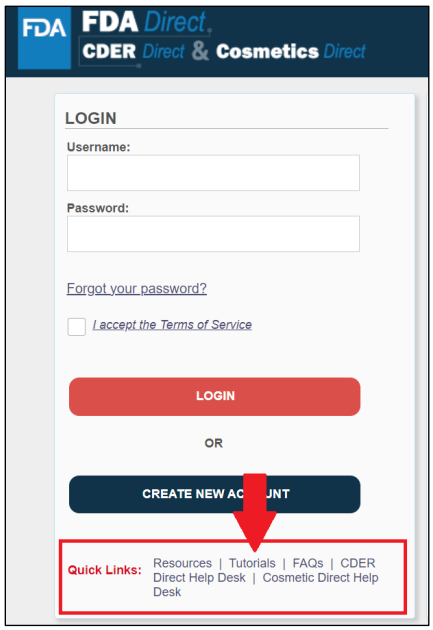
2. Tutorials/User Guide: This User Guide provides complete and detailed information on all aspects of FDA Direct. It is recommended for first-time users of FDA Direct.

   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.

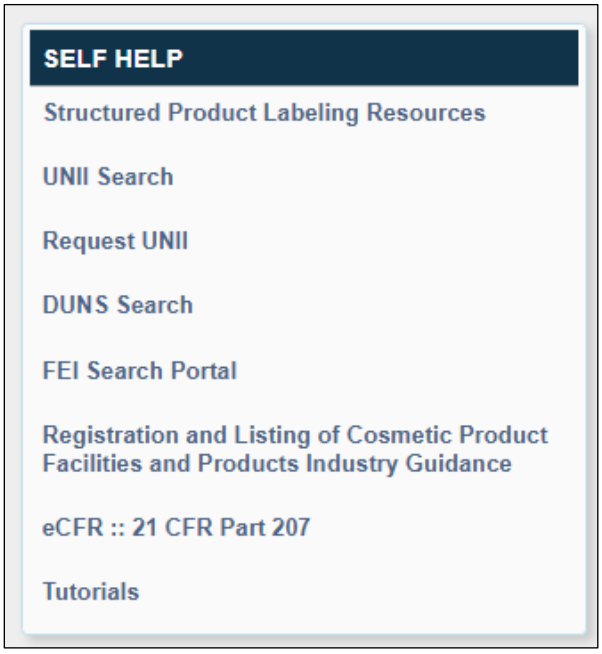
   Recommended for users familiar with FDA Direct who may want a quick refresher.

   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:



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

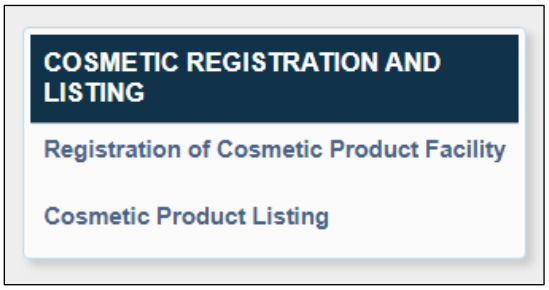
4.1 Cosmetic Registration and Product Listing SPL

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

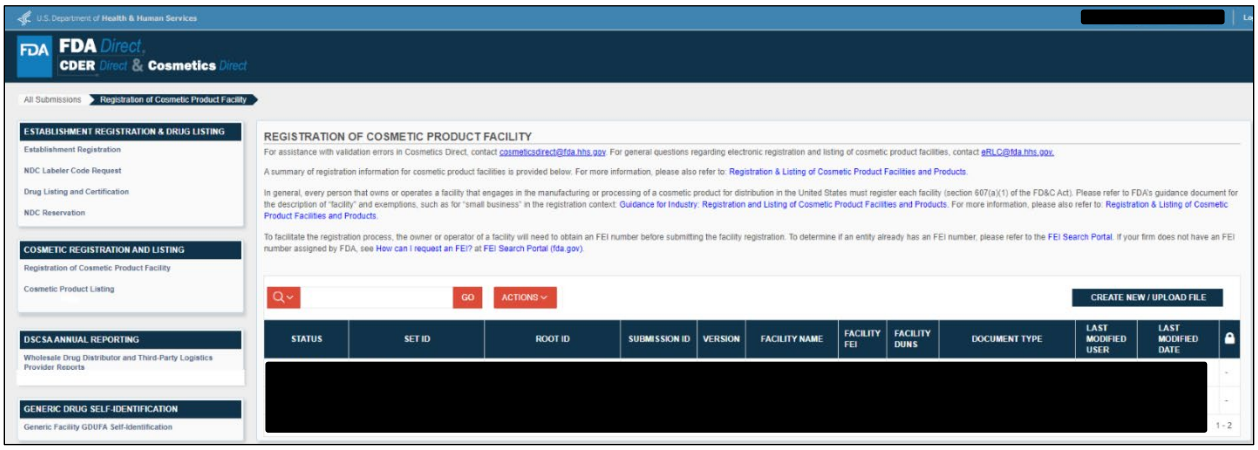
- **COSMETIC**-(**INITIAL**): The responsible person of a cosmetic product that is marketed on December 29, 2022, must submit a cosmetic product listing, or ensure such submission is made, not later than December 29, 2023, or for a cosmetic product that is first marketed after December 29, 2022, within 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.

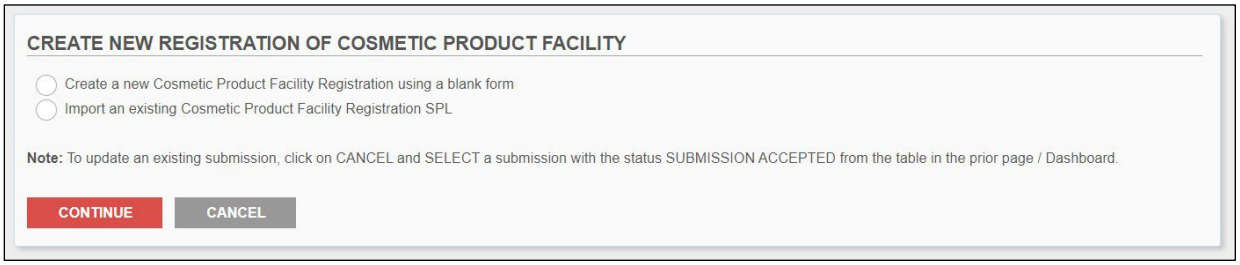
4.3 Registering a New Cosmetic Product Facility

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

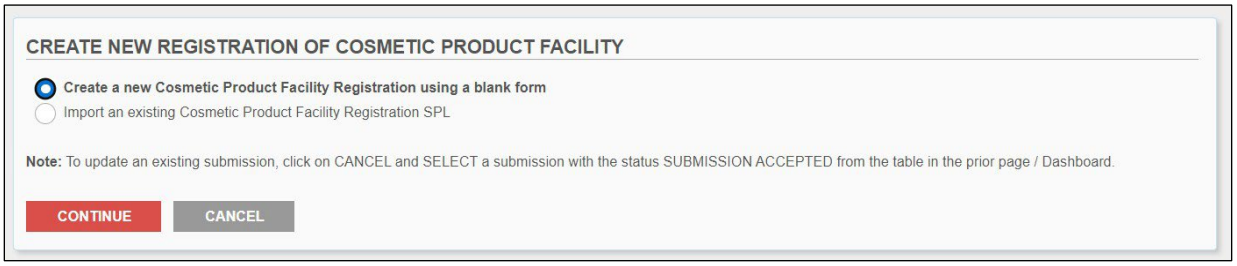


3. Click '**Create New/Upload File**':

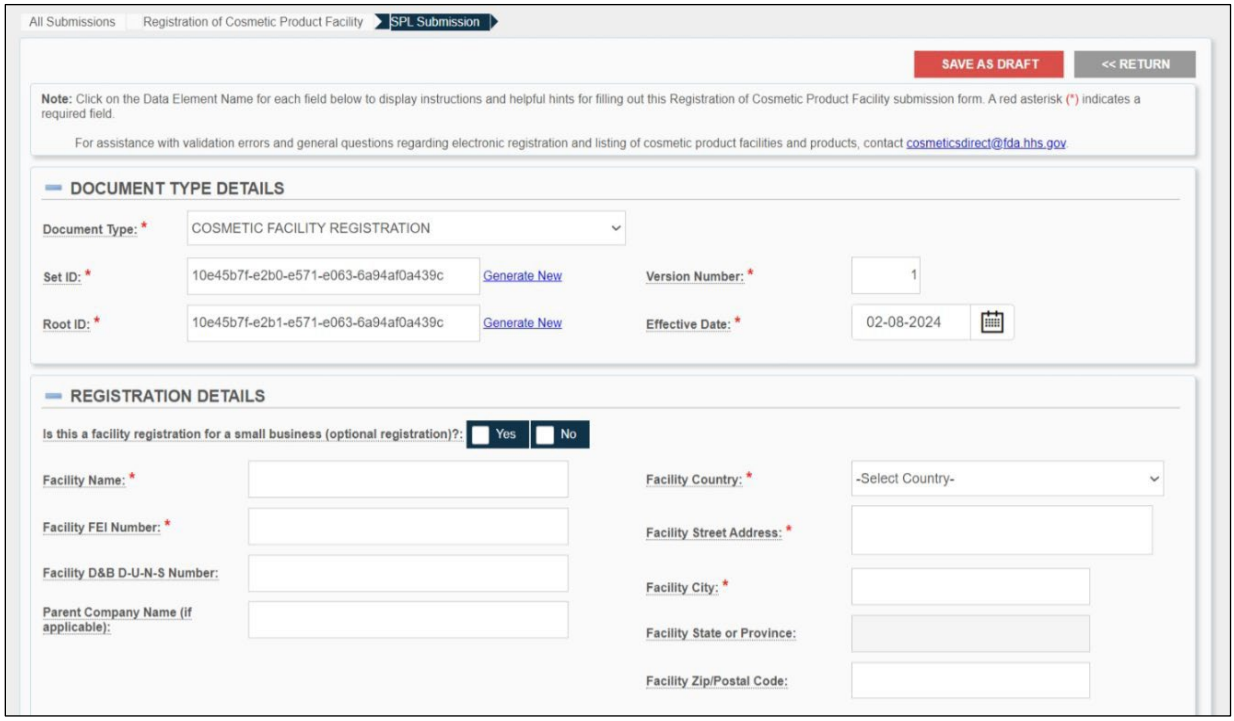
You will be given two options:



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

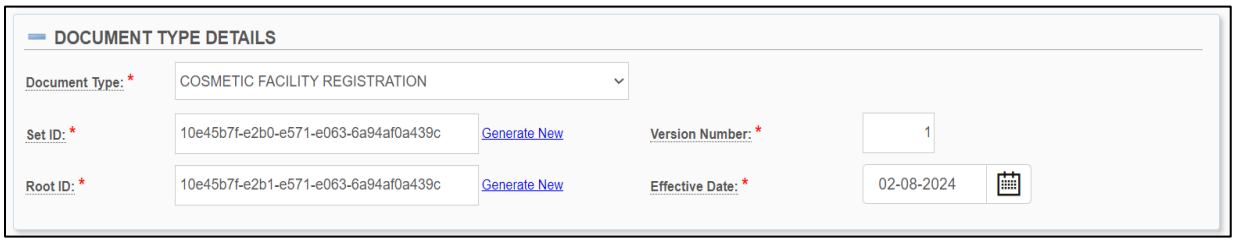


5. A blank template will display with required fields marked with a red (*) and optional fields:



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

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



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

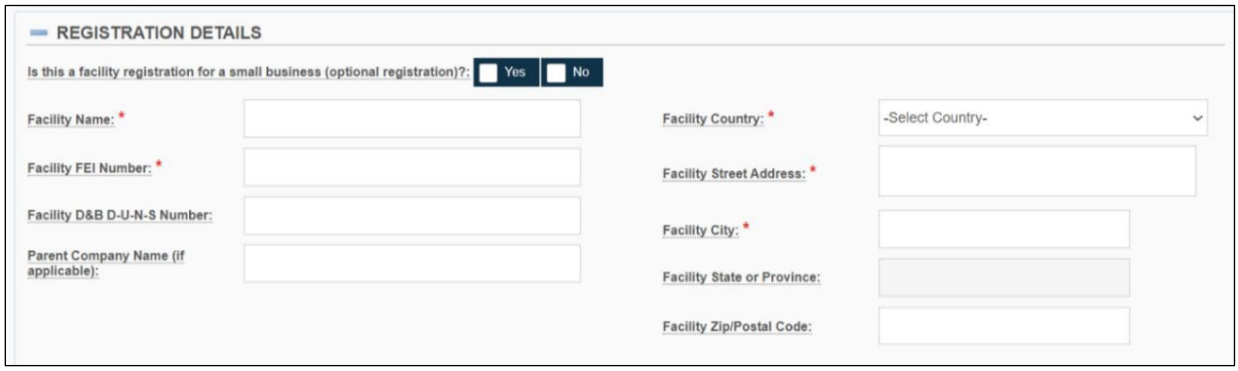
a. Set ID*: **This field is auto generated by the system.** The Set ID uniquely identifies a group of versions of an SPL submission. When an SPL submission changes, a new Root ID is assigned to the new SPL submission, but the Set ID in the original SPL submission also is used. The Set ID is a Globally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

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

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

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

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



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

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

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

c. Facility FEI Number*: Enter the existing 7 to 10-digit facility FEI number. The FEI number is a unique identifier assigned by the FDA to identify firms associated with

FDA-regulated products. To facilitate the registration process, the owner or operator of a facility will need to obtain an FEI number before submitting the facility registration.

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

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

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

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

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

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

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

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

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

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

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

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

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.

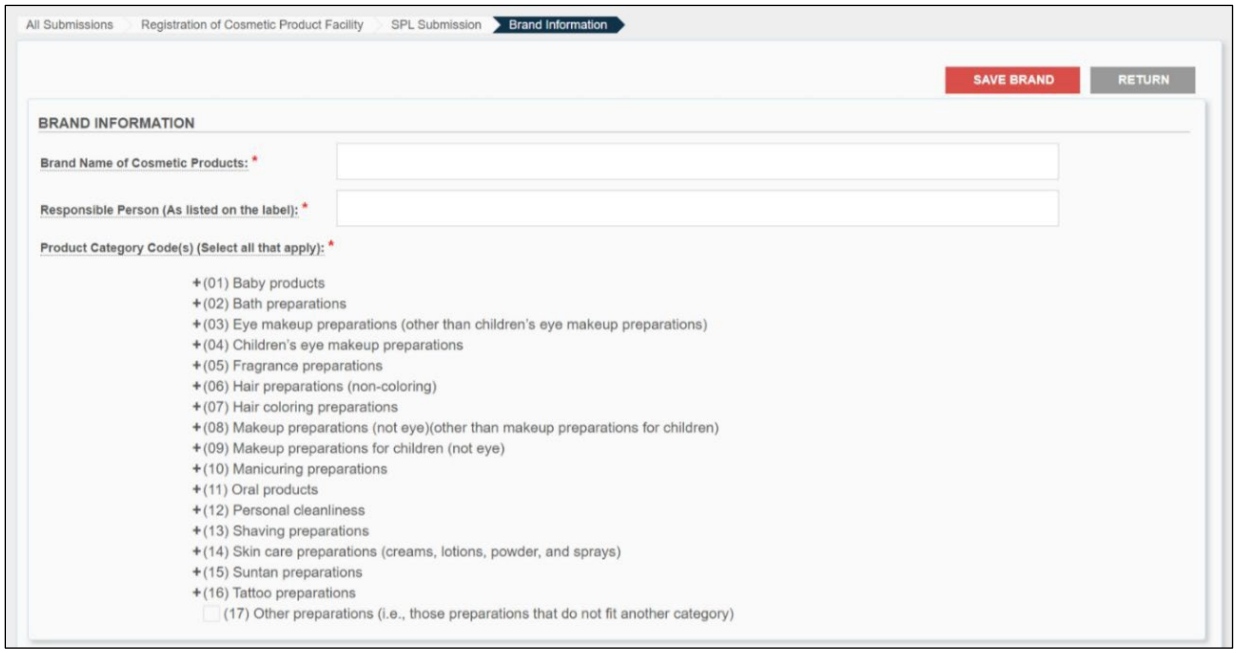
c. U.S. Agent Phone Number (Include Country/Area Code) *: For foreign facilities, enter the U.S. agent telephone number including the country code and the area code. The format for Phone number should be <Area Code>-<Subscriber Number>. For example, in the U.S. the phone number would be 1-999-9999999 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.



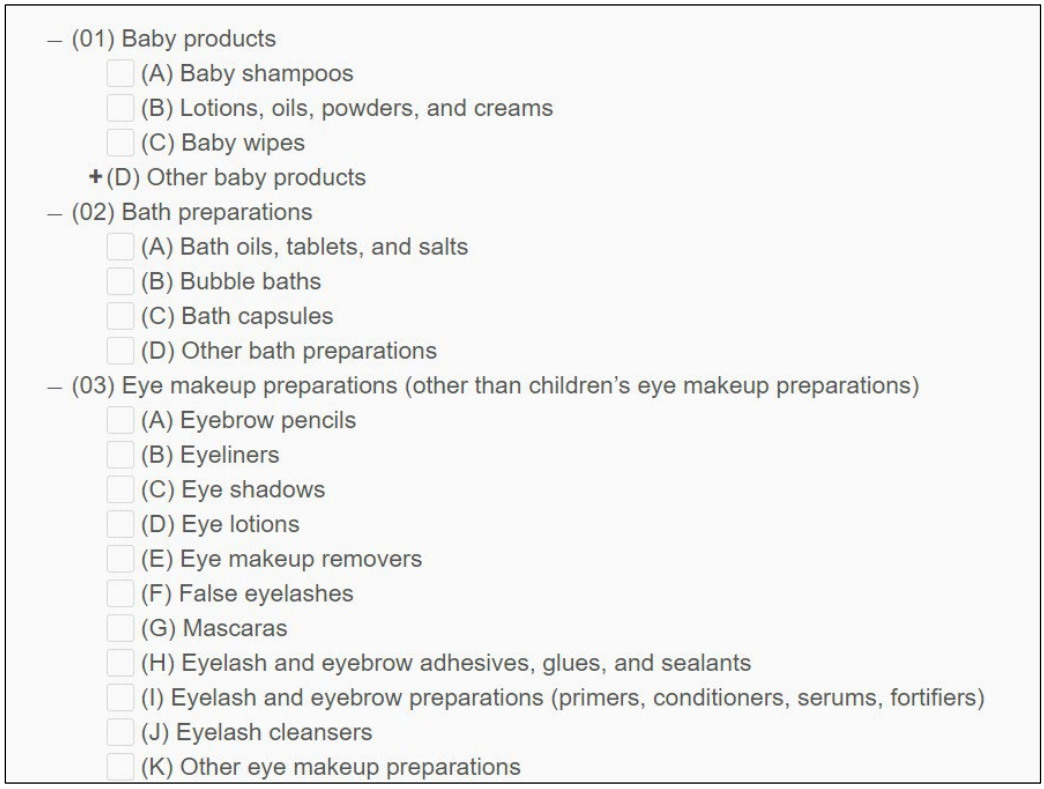
a. Brand Name of Cosmetic Product*: Enter brand names under which cosmetic products manufactured or processed in the facility are sold.

b. Responsible Person (As listed on the label) *: Enter the responsible person name as it appears on the label.

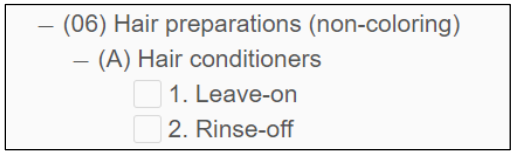
c. Product Category Code(s) (Select all that apply) *: Select the product category or

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



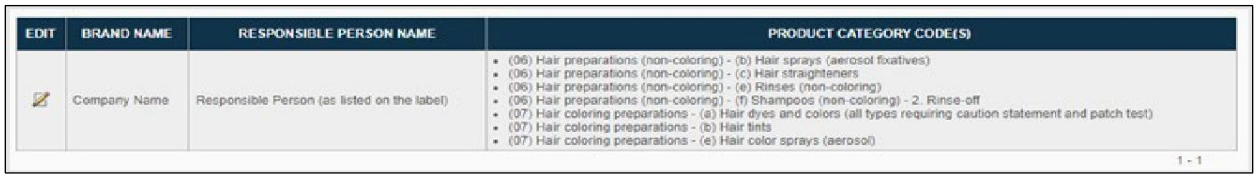
    b. (A) - (K) are Sub Product Categories. If that sub product category has a Sub-Subcategory, (+) can be selected to display the Sub-Subcategories (select if one or both apply; if none, leave unselected):
        - Leave-on
        - Rinse-off



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

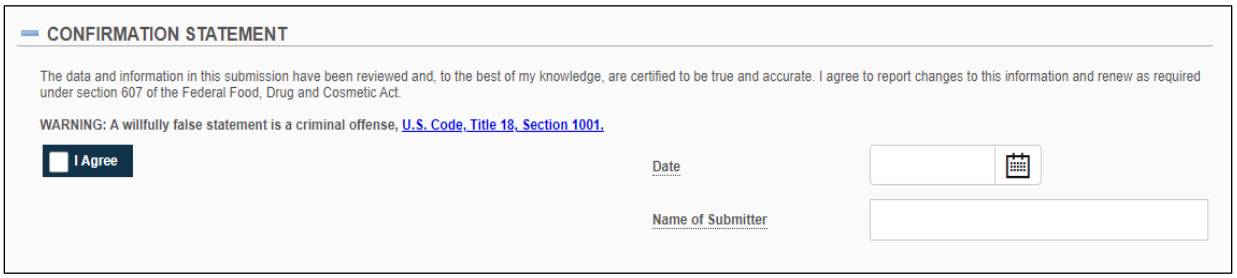
15. The platform will return to the SPL Submission page with the verification banner 'Product brand saved.'

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



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

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



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:

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.

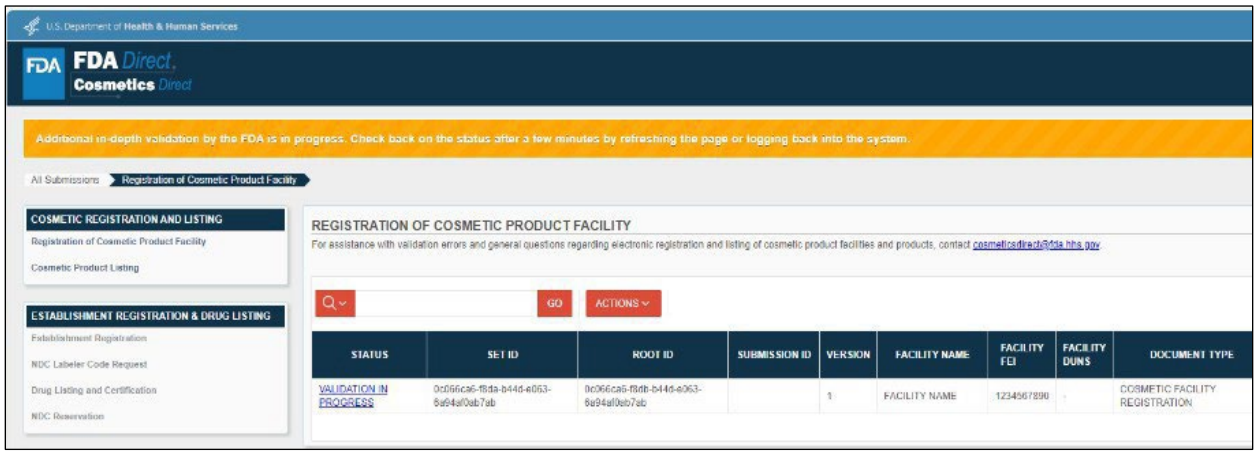
b. '**DELETE**'

- Delete will remove the submission from your account.

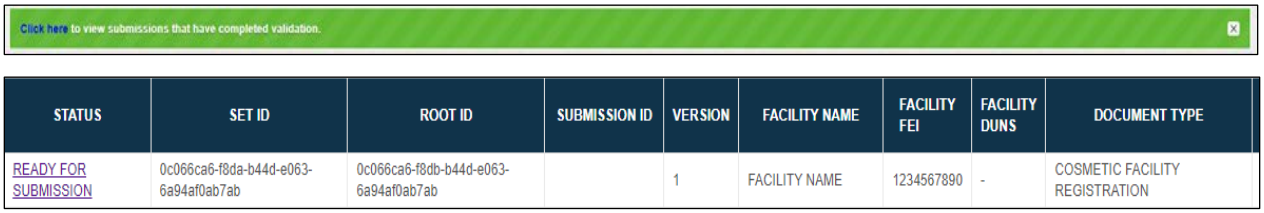
21. Click '**RETURN**' at any time to return to the Registration of Cosmetic Product Facility main page.

4.3.1 Save and Validate

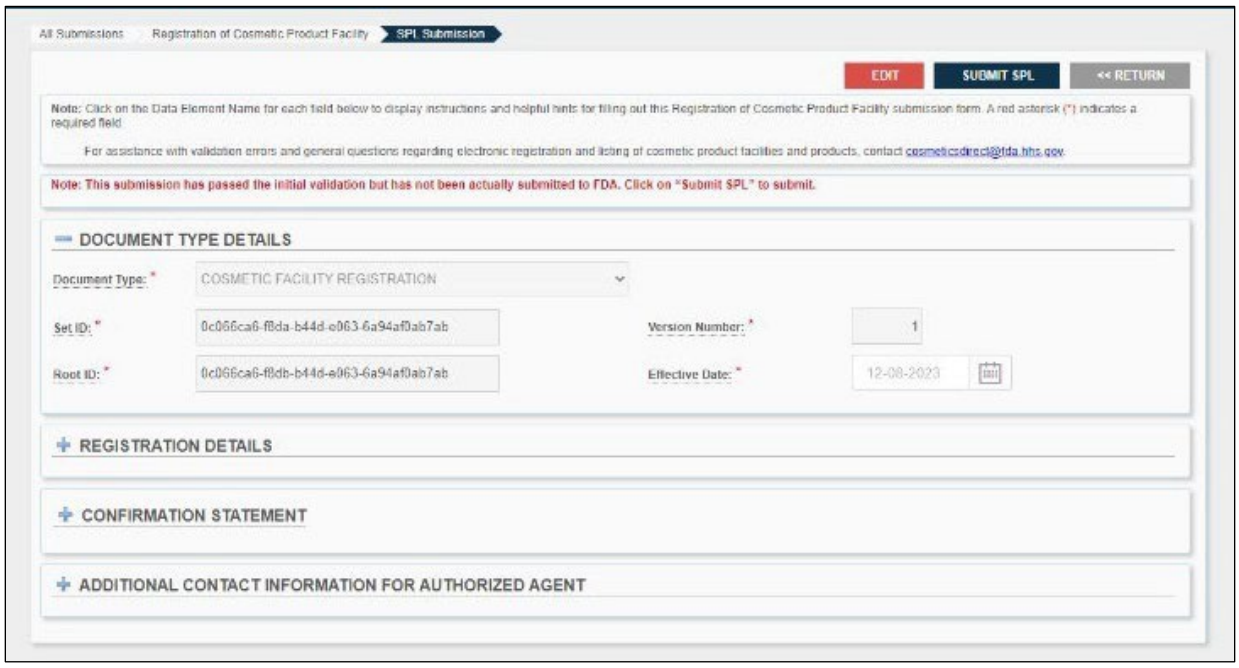
1. Click '**SAVE AND VALIDATE**' if you want to check for errors within your SPL. To submit your SPL to FDA, skip to section 4.3.2 Submit to FDA.
    a. **PLEASE NOTE:** This option is only for an initial validation of your SPL before submitting to FDA. It does not automatically submit your SPL to FDA, 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."



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



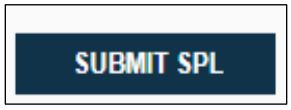
    a. If the system finds any errors, the status field will change to '**VALIDATION FAILURE**', see section 4.3.5 Validation Failure for additional details.
4. Click '**READY FOR SUBMISSION**', the homepage will change to reflect the following:



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

4.3.2 Submit SPL to FDA

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



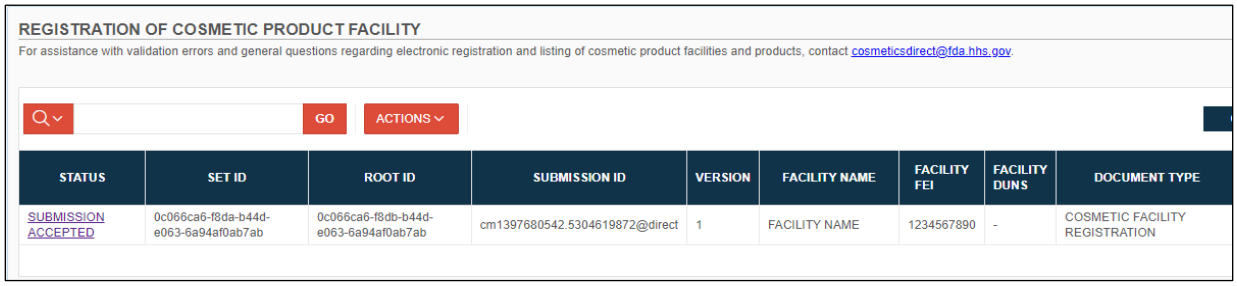
a. A green message will appear across your screen stating, "Your submission has been sent to FDA for additional validation and processing. Check the status of your submission after a few minutes by refreshing the page or logging back into the system. You will also receive an email from FDA when the processing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

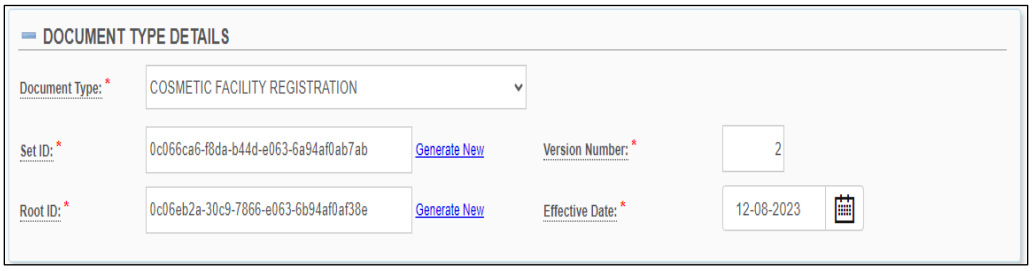
   Please Note: A '**SUBMISSION ID**' does not always mean that the submission was in fact accepted by FDA. The **'Submission ID'** will also appear with "**Awaiting Acceptance'** and **'Submission Failure**



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

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

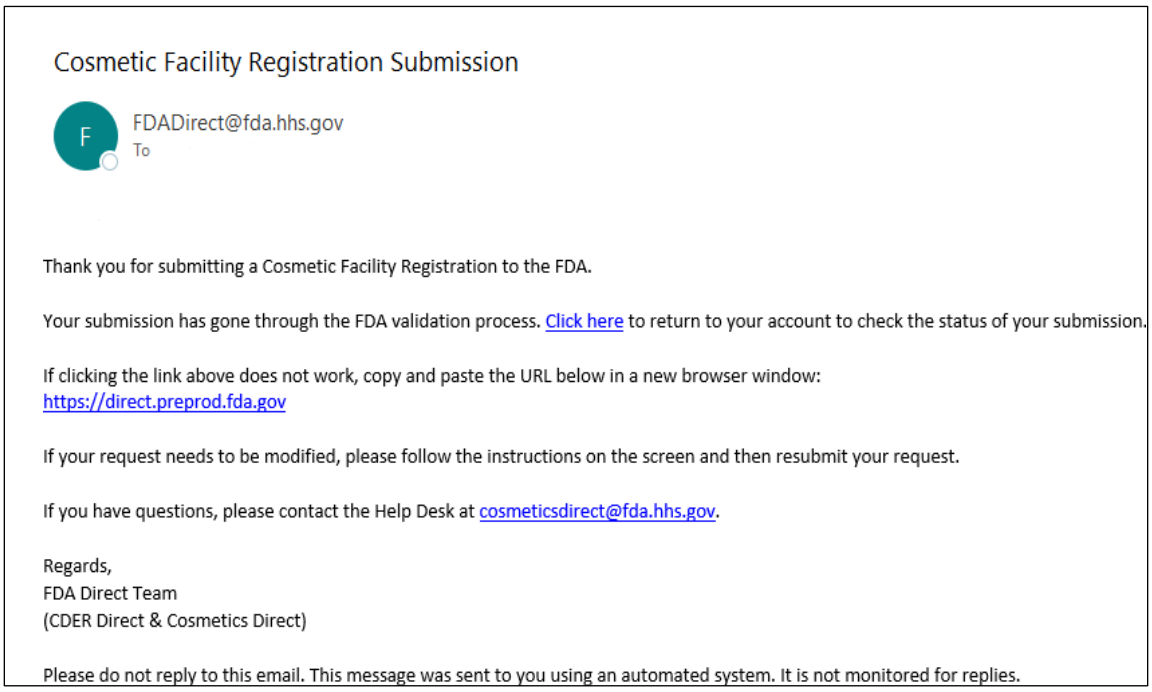
      1. **PLEASE NOTE:** After selecting, your SPL will be successfully cloned and the ROOT ID, VERSION NUMBER, and EFFECTIVE DATE will change. All other fields will retain the same information from the initial successfully submitted SPL.



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

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

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



Cosmetic Facility Registration Submission

F FDADirect@fda.hhs.gov
To

Thank you for submitting a Cosmetic Facility Registration to the FDA.

Your submission has gone through the FDA validation process. Click here to return to your account to check the status of your submission.

If clicking the link above does not work, copy and paste the URL below in a new browser window:
https://direct.preprod.fda.gov

If your request needs to be modified, please follow the instructions on the screen and then resubmit your request.

If you have questions, please contact the Help Desk at cosmeticsdirect@fda.hhs.gov.

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

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

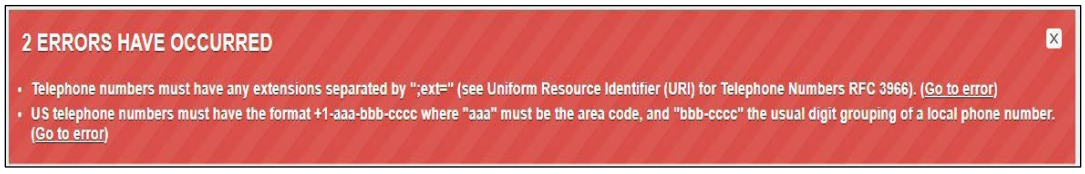
e. A '**SUBMISSION ACCEPTED**' status will appear in the status column of your SPL submission if it has been successfully submitted to the FDA. At this point, the process is finished and there is no further action needed unless you need to make any changes to your registration.

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-e063-6b94af0af38e	cm6301528479.1247385960@direct	2	COSMETIC FACILITY REGISTRATION

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



2 ERRORS HAVE OCCURRED

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

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

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

10. 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

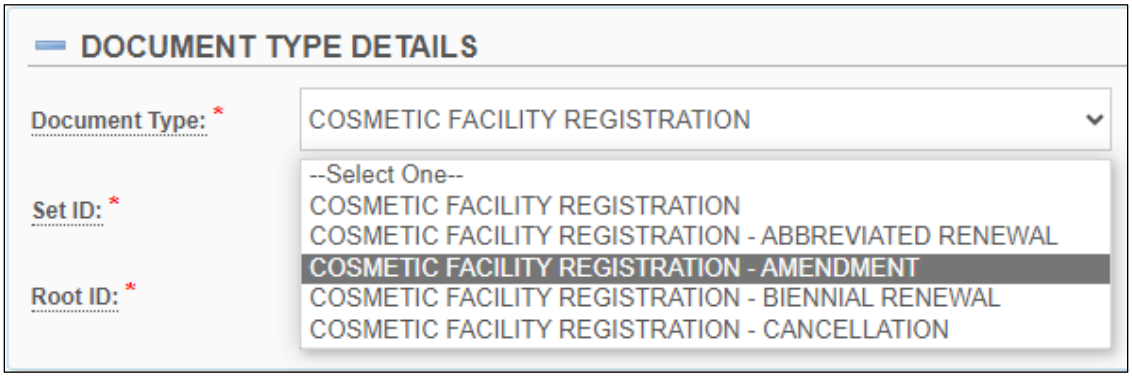
11. Click '**VALIDATION FAILURE**', the system will provide a list of errors that need to be fixed before submitting the SPL:

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

4.3.6 Amending Cosmetic Product Facility Registration

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

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

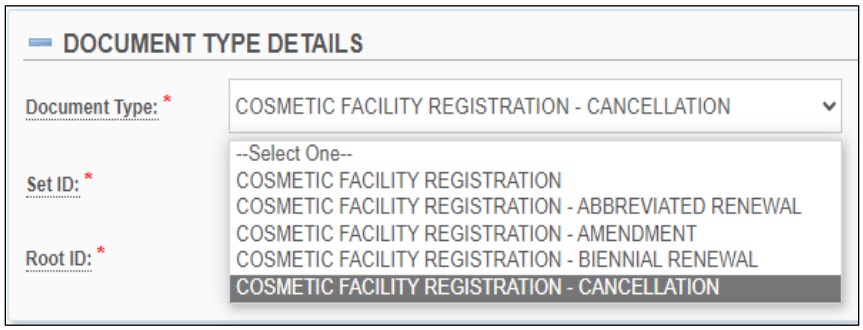


2. Repeat the steps in Section 4.3.
3. Refer to the steps in Section 4.3.2 for Submit to FDA instructions.

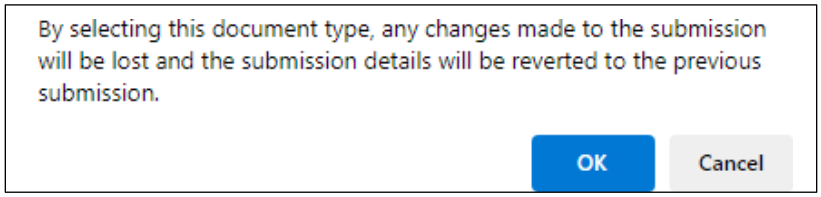
4.3.7 Amending Cosmetic Product Facility Cancellation

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**'.



   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**':



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).

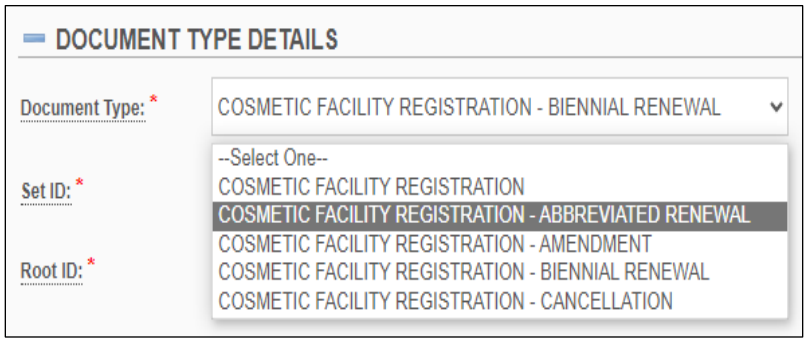
1. Under Document Type, select '**COSMETIC PRODUCT FACILITY REGISTRATION – BIENNIALREGISTRATION RENEWAL**'.

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

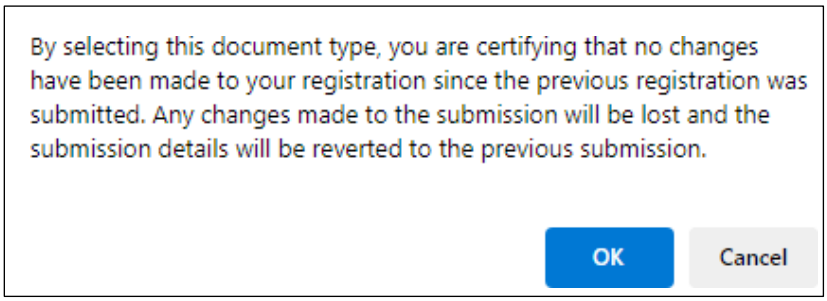
4.3.9 Abbreviated Renewal Cosmetic Product Facility Registration

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**'.



   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.

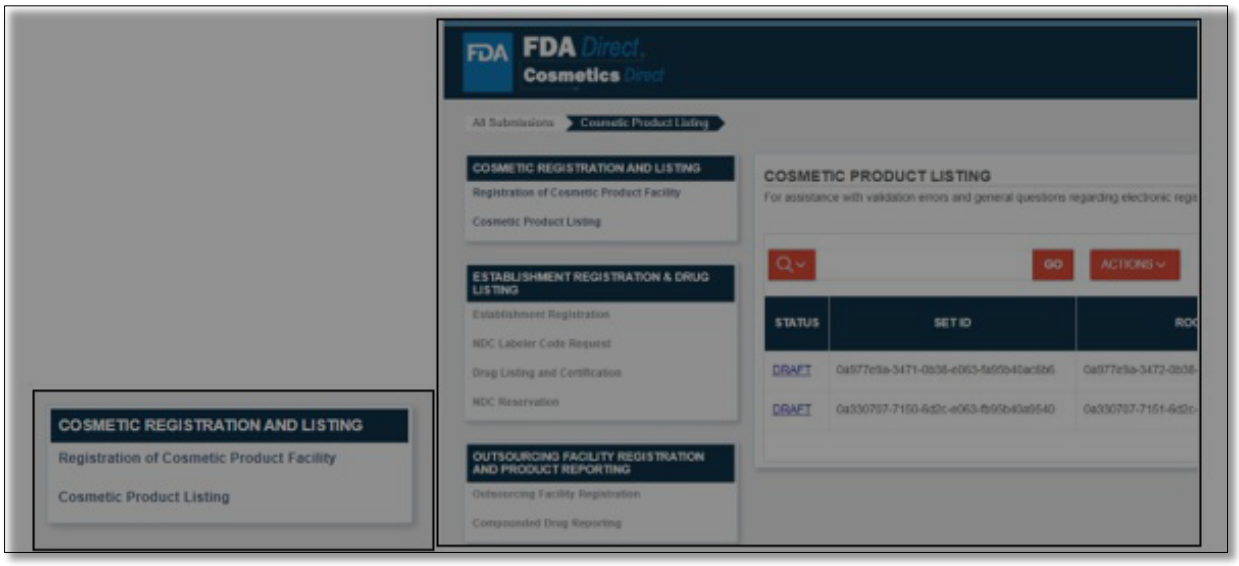


2. After selecting '**OK**', the fields for Registration Details, Confirmation Statement, and Additional Contact Information for Authorized Agent will be grayed out and can no longer undergo changes.
3. Click '**SUBMIT SPL**' to submit your request to FDA.

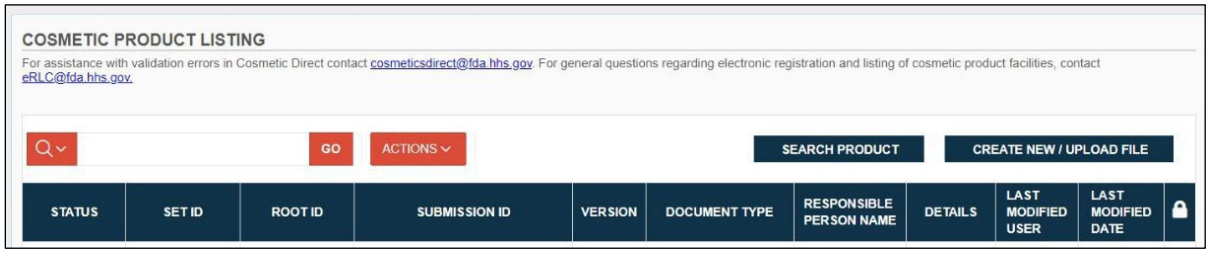
4.4 Cosmetics Product Listing

4.4.1 New Cosmetics Product Listing

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

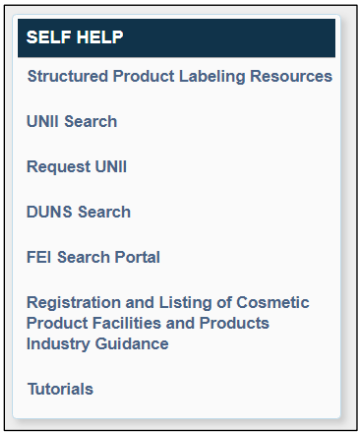


3. Navigate to the Cosmetic Product Listing Home Page AFTER selecting '**Cosmetic Product Listing**' under *Cosmetic Registration and Listing* section, on the left side of the FDA Direct menu. This will navigate the user to the **Cosmetic Product Listing Home Page**. The **Cosmetic Product Listing Home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



a. Submission status: The status of each submission made to FDA. The status types are draft, validation in process, validation failure, ready for submission, and submission accepted.

b. **Self-Help** box is also available at the bottom of the left side underneath all the submission boxes.



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

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

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

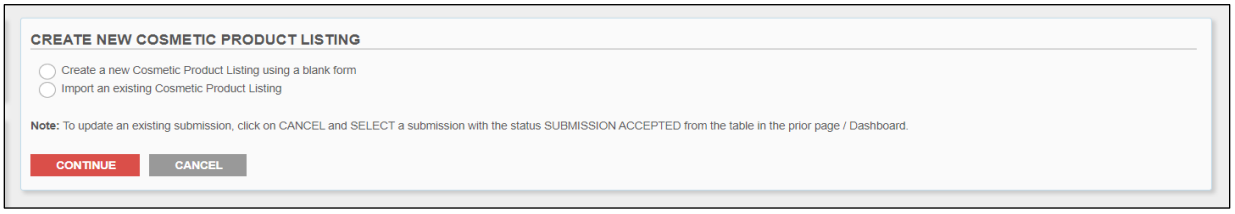
d. A product can be searched by select the **SEARCH PRODUCT** box next to **CREATE NEW/UPLOAD FILE**.

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

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

4.4.2 Create a New Cosmetic Product Listing

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



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:

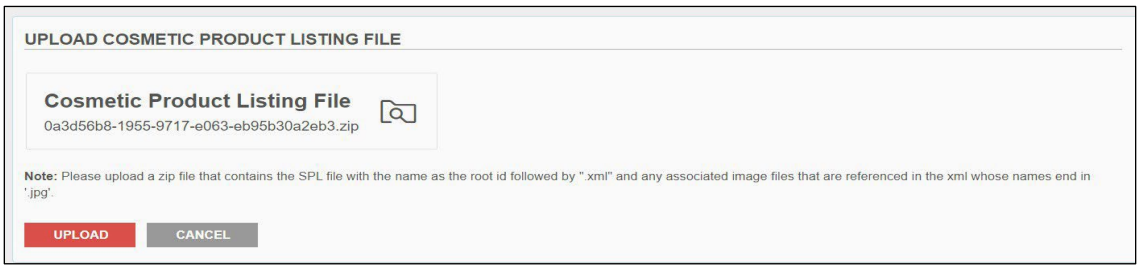
    - **PLEASE NOTE:** The responsible person will need to obtain the relevant facility registration number(s) for each facility where its cosmetic products are manufactured or processed, because the facility registration number(s) is required for the product listing submission. If the facility is exempt 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).

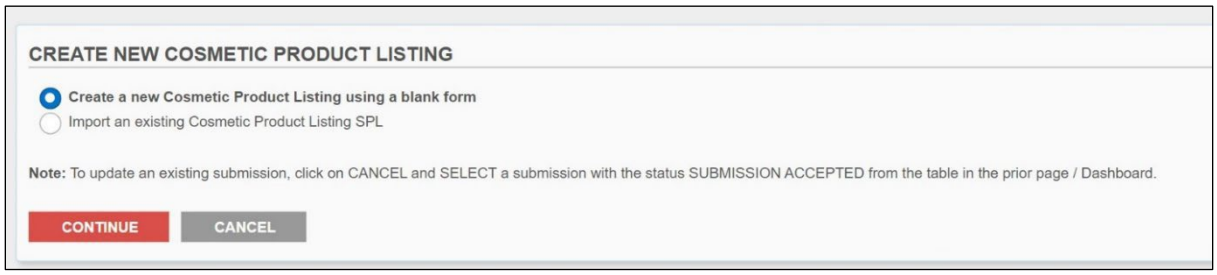
b. Additional information can be provided, such as:

- 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 (UNIIs)
    - **PLEASE NOTE:** For more information and to search for UNIIs please refer to the webpage at: https://precision.fda.gov/uniisearch. For UNII requests contact: FDA-SRS@fda.hhs.gov.
- Additional contact information for individuals associated with the listing.

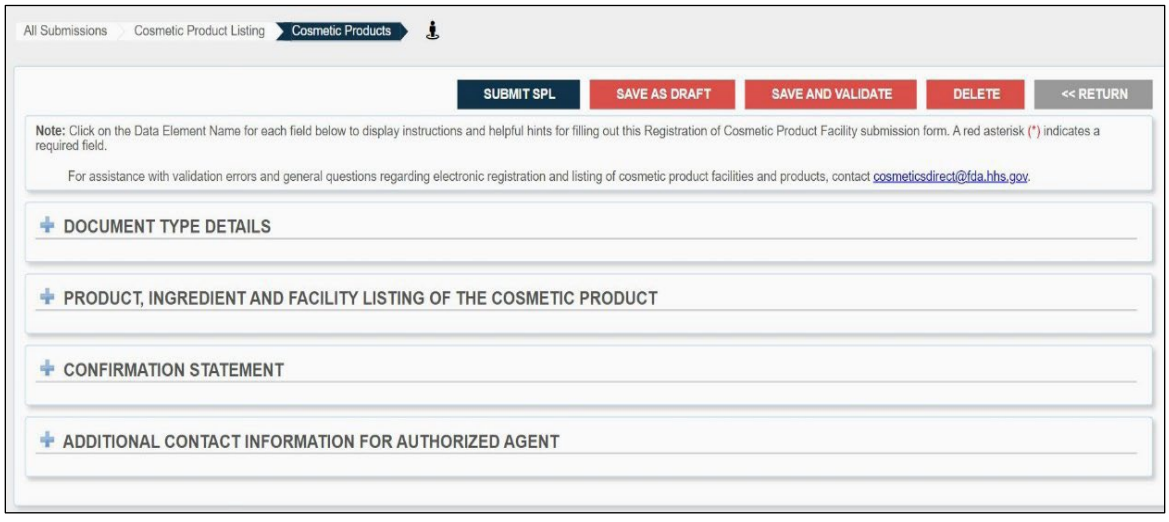
c. If you are **uploading/importing an existing Cosmetic Product Listing SPL** file containing multiple product listings, make sure that the file is in the correct SPL format. This file may contain both the XML file and image (jpg) files, for bulk submission. Once the file has been uploaded, a user can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



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



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



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

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

   a. **SUBMIT SPL**: Submit SPL will send the submission to FDA for additional validation and processing.

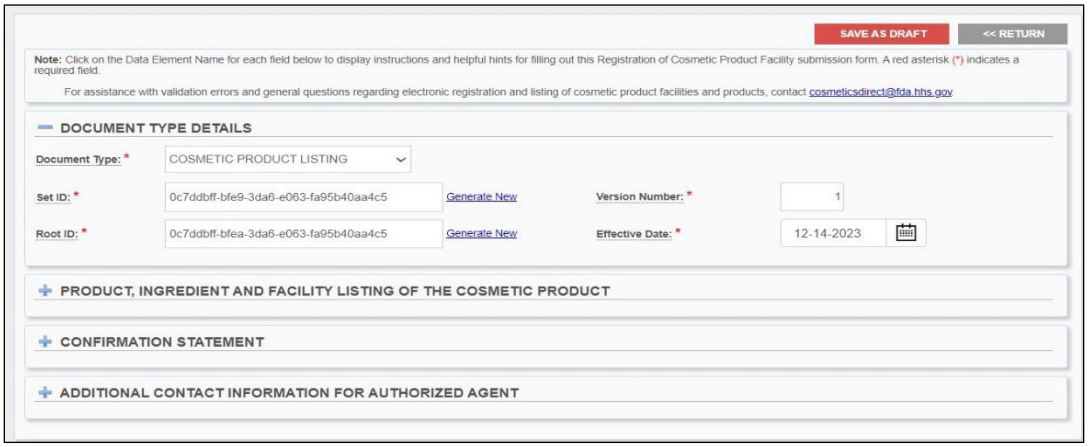
   b. **SAVE AS DRAFT:** Save Draft button allows you to save your work, preserving your progress without submitting it to the FDA.

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

   d. **DELETE**: This will remove the submission from your account.

   e. **RETURN**: will guide the user to Cosmetics Product Listing Submissions home page without saving your changes

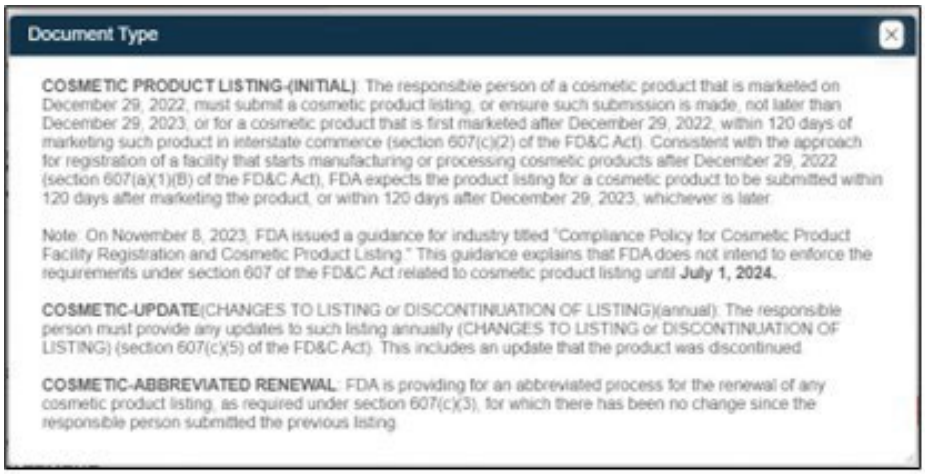
8. Select the **' +'** to open or '-' to close the **DOCUMENT TYPES** section of the **COSMETIC PRODUCT LISTING** to focus one section at a time, a red asterisk (*) indicates a required field throughout the submission process: 



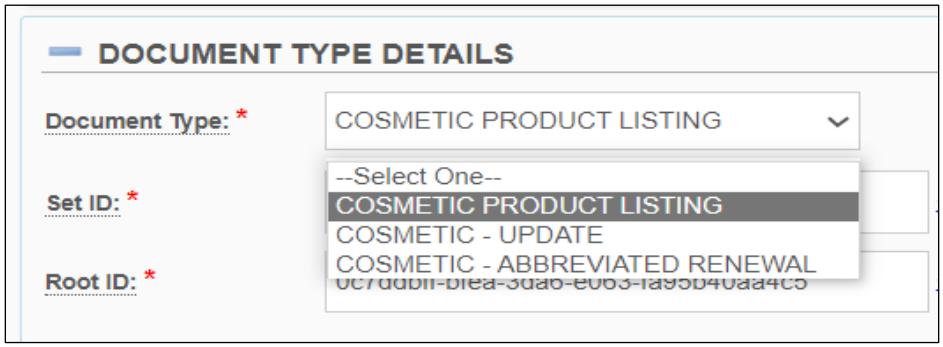
   a. **PLEASE NOTE:** The **DOCUMENT TYPE** of the **DOCUMENT TYPE DETAILS** section is preselected to COSMETIC PRODUCT LISTING, which is the (**INITIAL**) submission. The **Set ID, Root ID, Version Number, and Effective Date** fields will always auto- populate for the **INITIAL SUBMISSION**:

9. Select "**DOCUMENT TYPE DETAILS**," a red asterisk (*) indicates a required field throughout the submission process:

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:



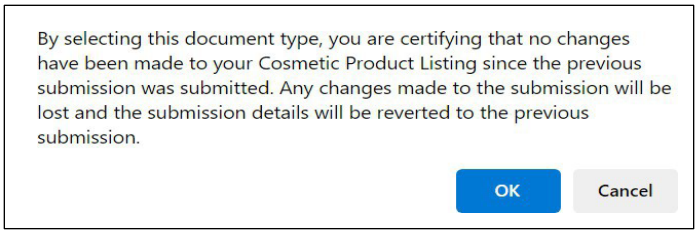
a. DOCUMENT TYPES INFORMATION*:

- **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.

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:

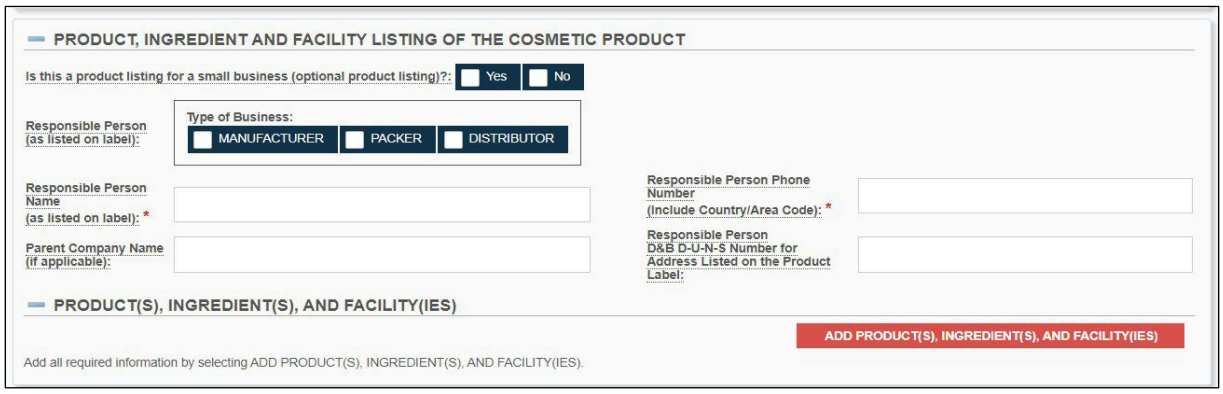
- **SET ID***: The Set ID uniquely identifies a group of versions of an SPL submission. When an SPL submission changes, a new Root ID is assigned to the new SPL submission, but the Set ID in the original SPL submission also is used. The Set ID is a Globally Unique Identifier (GUID). A GUID is a string 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.

- **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.

- **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.

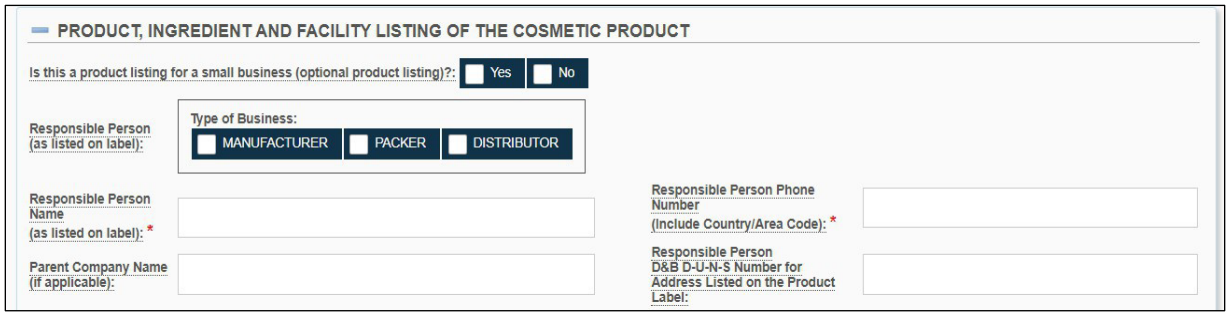
- **EFFECTIVE DATE***: The date the submission is created, users can modify it. However, the system will only use the actual registration date submitted to FDA. It also provides a date reference to the SPL version. Select the date by clicking on the calendar icon. Once an SPL has been submitted, this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

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:



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:



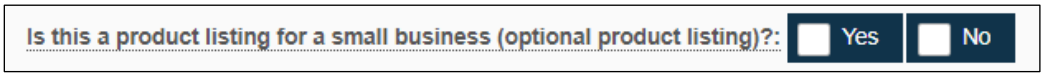
14. **The elements toward the LEFT side of the webpage** section of the **PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT** section, a red asterisk (*) indicates a required field throughout the submission process:

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

- Section 612 of the FD&C Act provides exemptions to certain small businesses from the requirements of section 607 (Registration and Product Listing). However, such exemptions from the requirements of section 607 of the FD&C Act do not apply to any responsible person or facility engaged in the manufacturing or processing of any of the following products listed in section 612(b) of the FD&C Act:
    - Cosmetic products that regularly come into contact with mucus membrane of the eye under conditions of use that are customary or usual.
    - Cosmetic products that are injected.
    - Cosmetic products that are intended for internal use.

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

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



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).

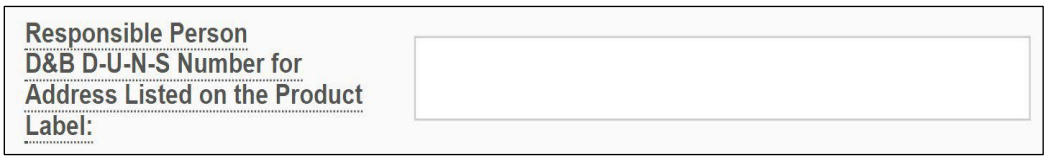
c. Responsible Person Name (as Listed on the label) *: Enter the responsible person name as it appears on the label.

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

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:

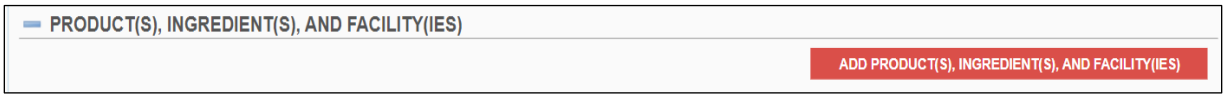
a. Responsible Person Phone Number (Include Country /Area Code) *: Enter the responsible person's phone number including the area or the country code. The format for Phone number should be <Country Code>-<Area Code>-<Subscriber Number >For example, in the U.S. the phone number would be 1-999-9999999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

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



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)

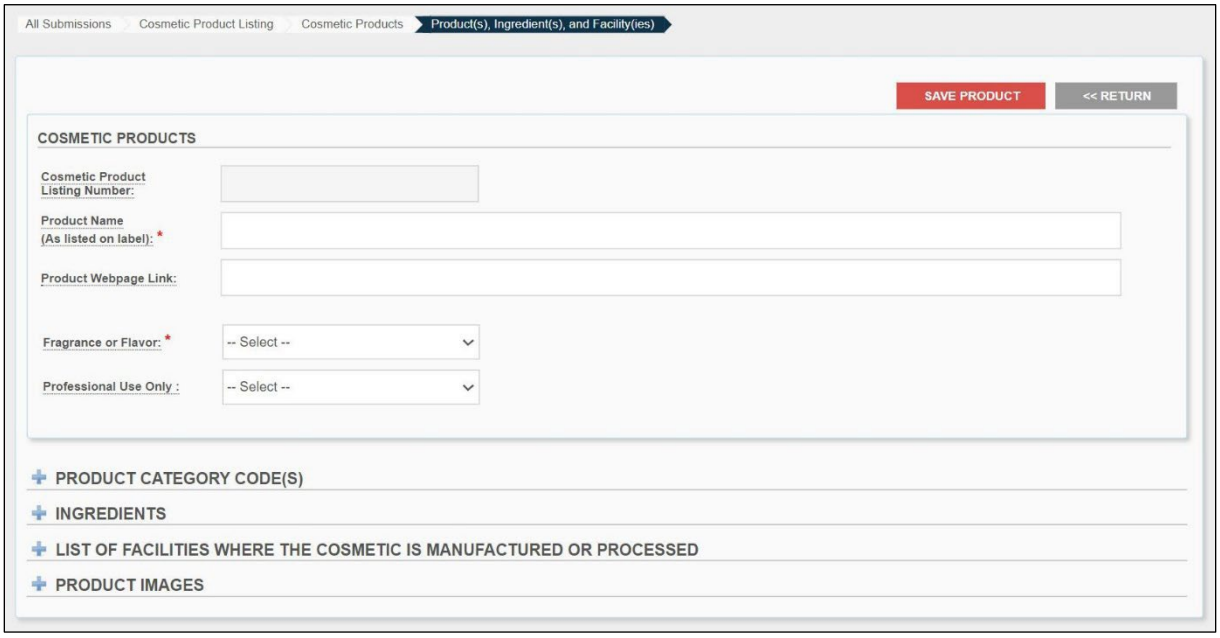
16. To add **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** to your SPL template, click the '**ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)'** button in the **PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT** section as shown below, a red asterisk (*) indicates a required field throughout the submission process:



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.

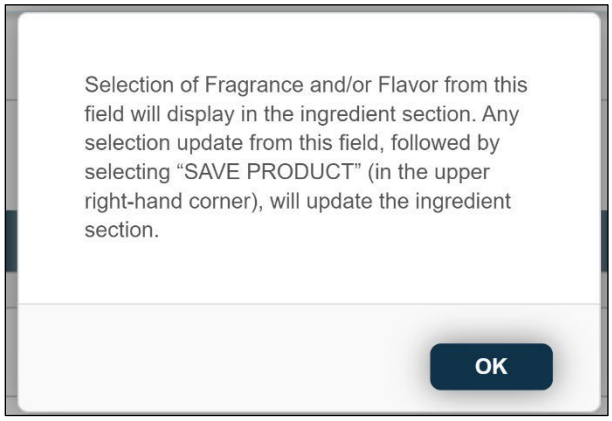
   a. Product Listing Number*: This 14-digit number will be generated by the system for each cosmetic product submission after acceptance. **PLEASE NOTE: THE PRODUCT LISTING NUMBER WILL BE GENERATED AFTER A SUBMISSION HAS BEEN ACCPETED BY FDA.**

   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.

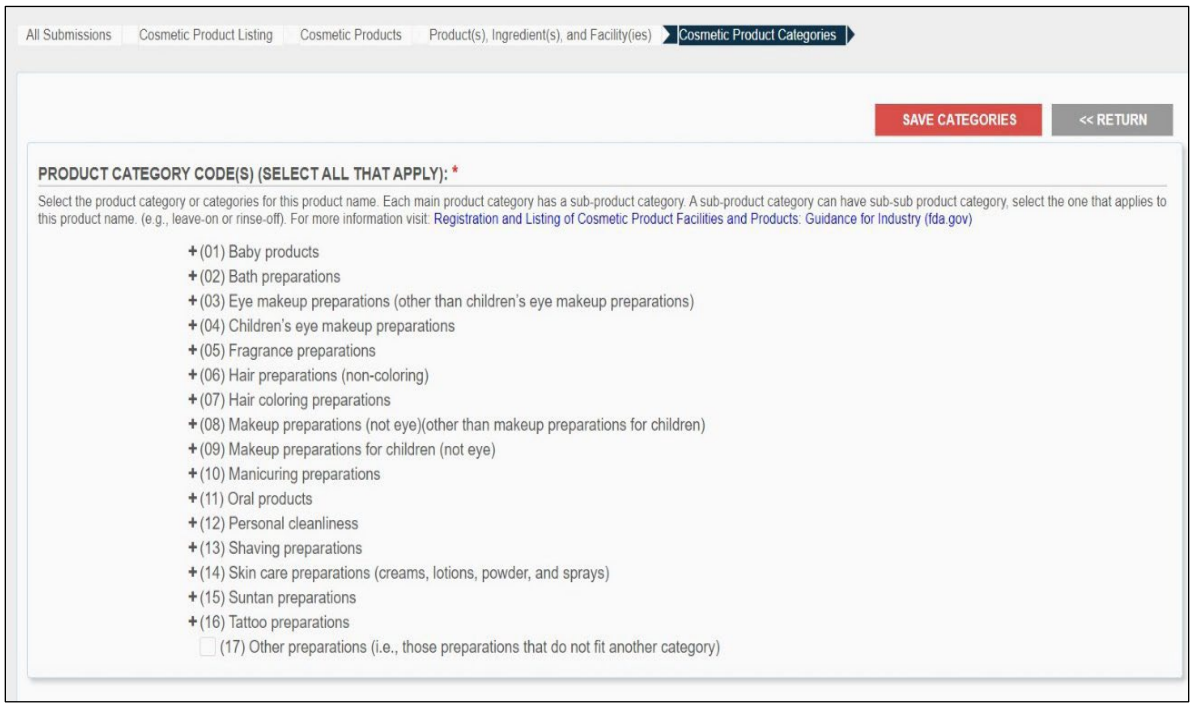
      - **PLEASE NOTE:** An INFORMATION BANNER will pop-up when FRAGRANCE OR FLAVOR SELECTION is made, as shown below:



   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.



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:

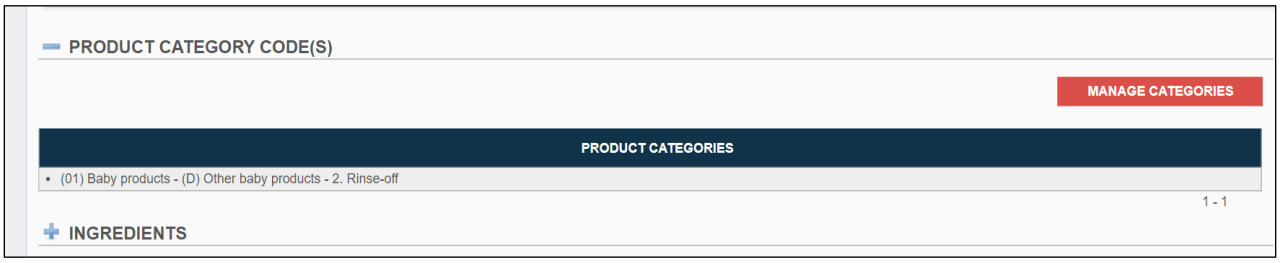
- (01) is considered a main product category (e.g. any section that begins with (#) are main product category).
- (A) to (D) are considered sub- product categories (e.g., any section that begins with (capital letter) are a sub-product category).
- 1. and 2. are considered a sub-sub product (e.g., any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

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

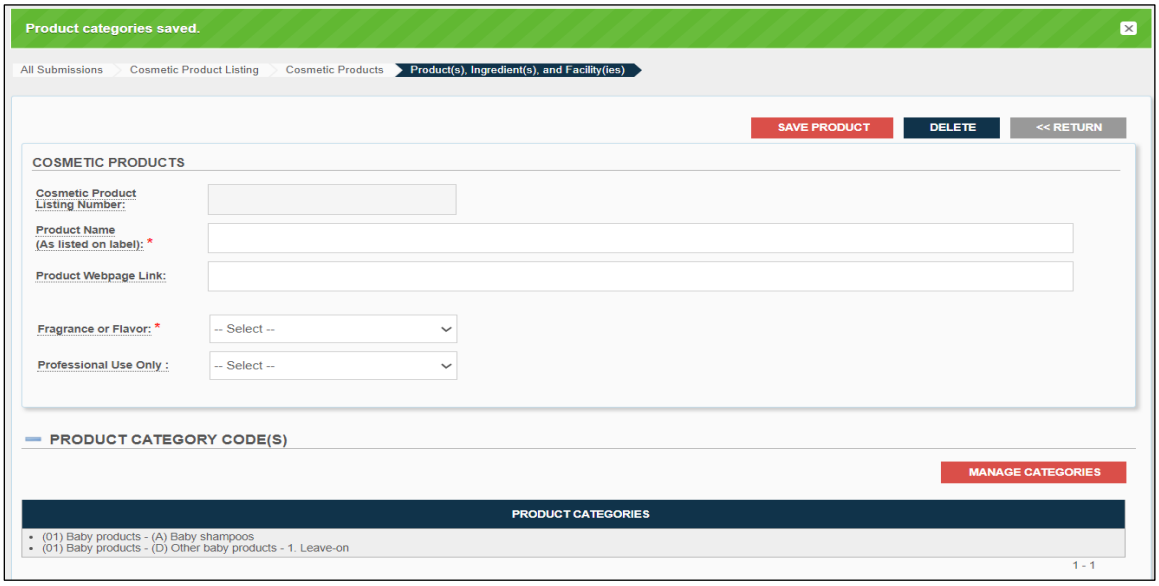
c. **PLEASE NOTE:** Any combination can be selected, EXCEPT leave-on and rinse-off (one or the other may be selected). However, if sub- product category has been selected, then a sub-sub product category must be selected.

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

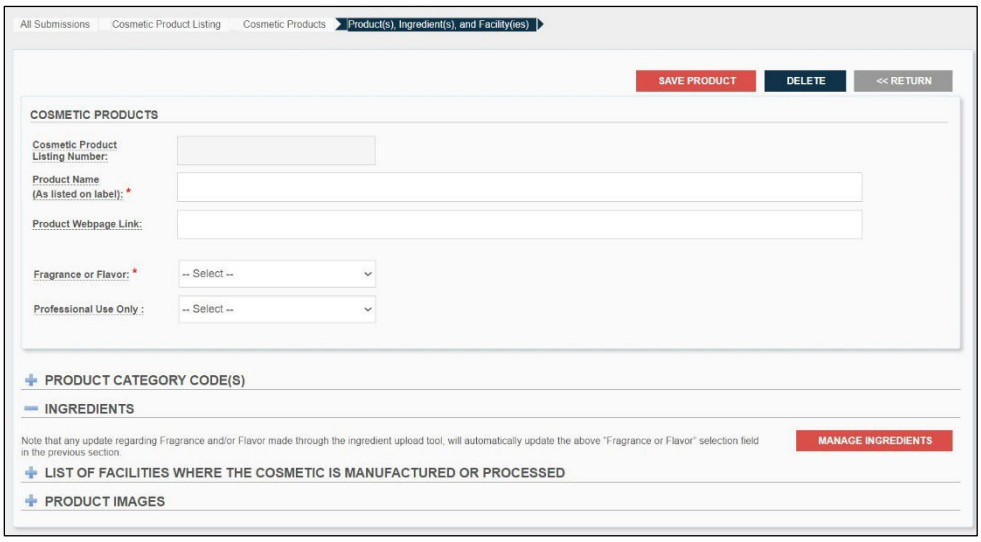
6. After clicking '**SAVE CATEGORIES**' all the selection that was made on the previous page will be stated under the PRODUCT CATEGORY CODE(S) tab in the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section with a saved banner on the top of the page, as shown below:



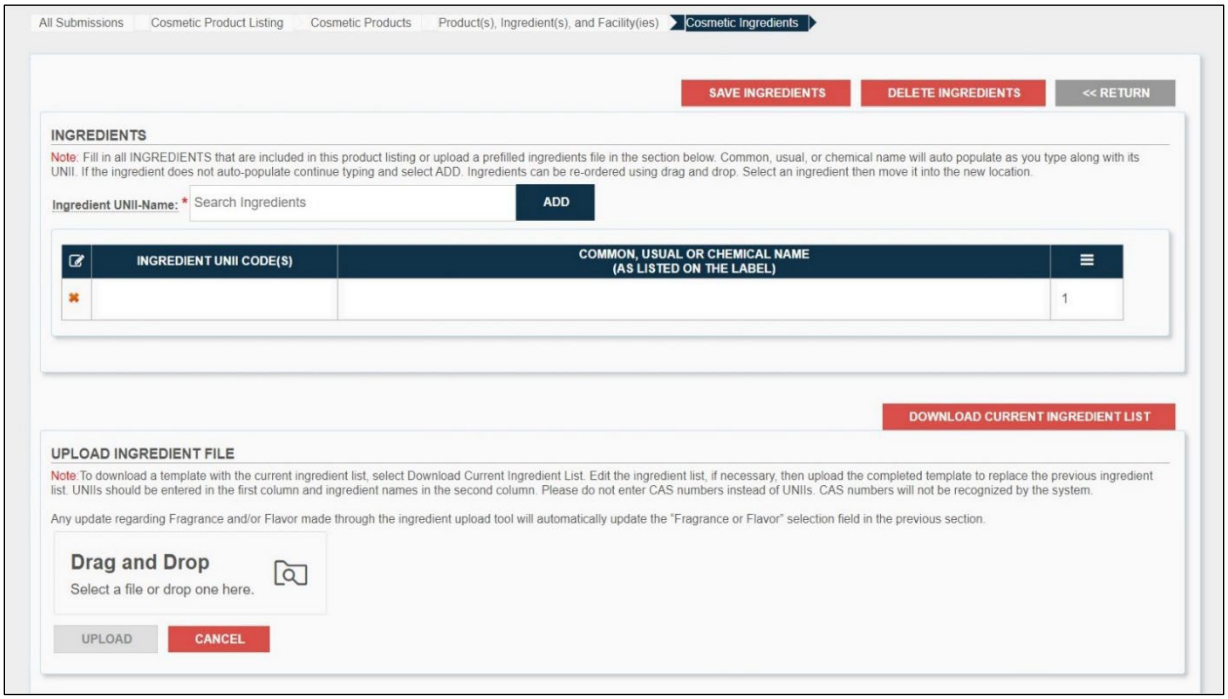
   a. At this point, the option to '**DELETE**' this product tab on the upper right hand will appear along with **'SAVE PRODUCT'** and **'RETURN'** as shown below.



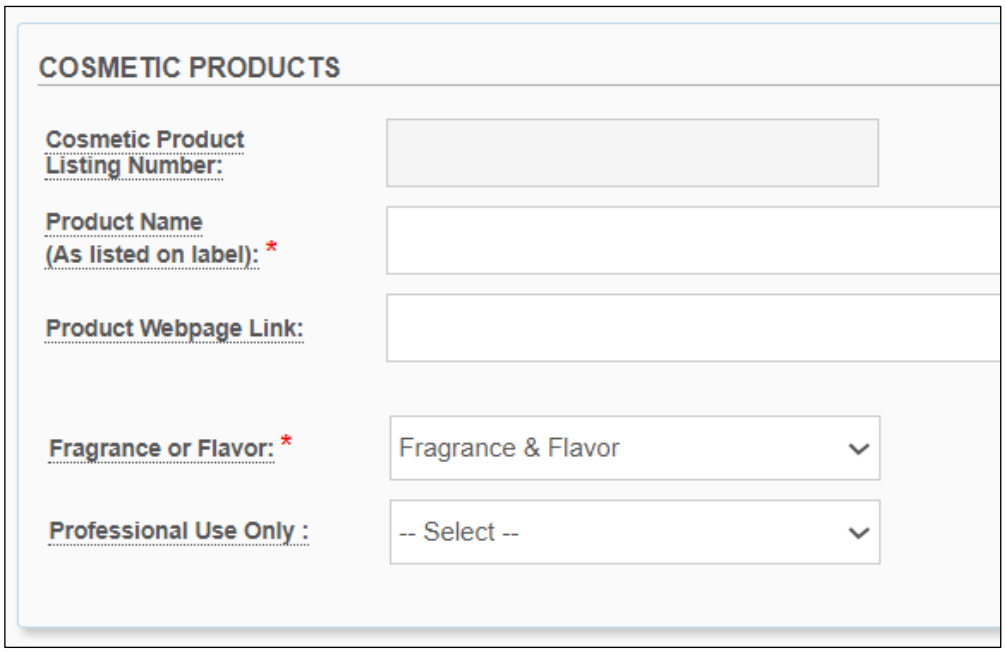
7. To add **PRODUCT INGREDIENTS** section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section, click the '**MANAGE INGREDIENTS**' button in ***INGREDIENTS*** section, as shown below. A red asterisk (*) indicates a required field throughout the submission process.

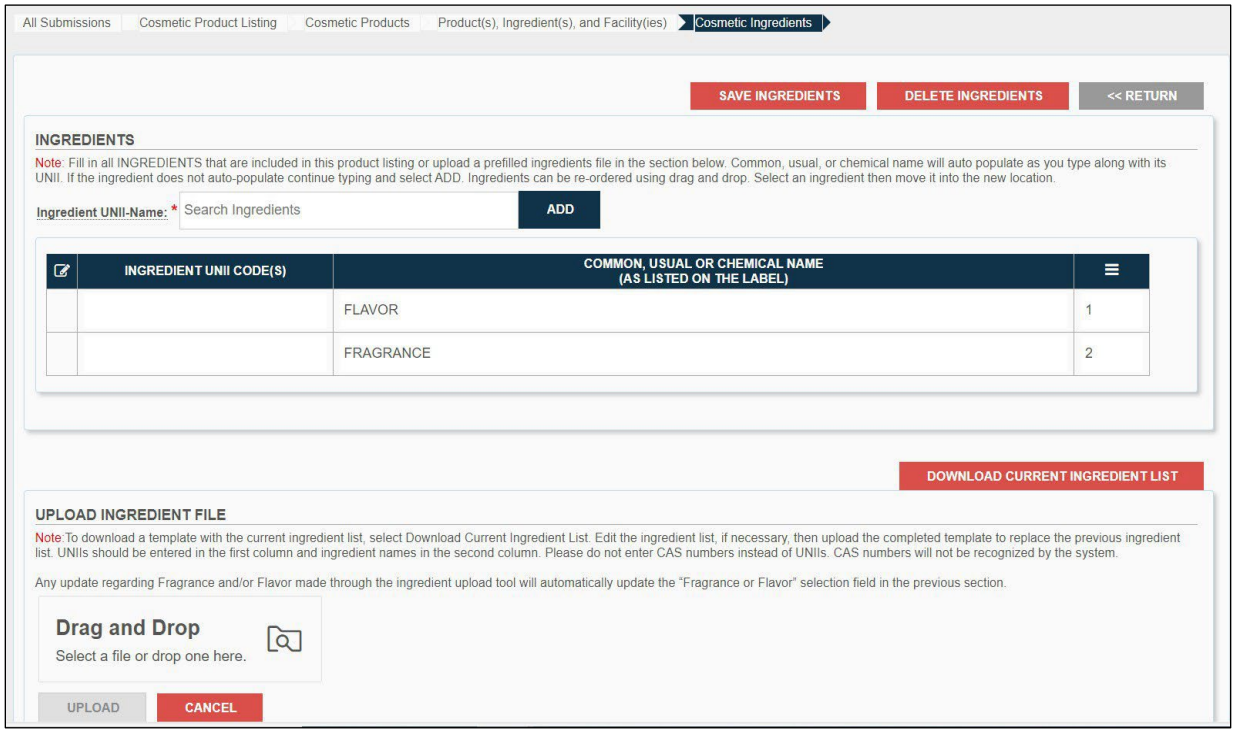


8. A blank template titled *COSMETIC INGREDIENTS* will display. Ingredients can be searched, added or uploaded, in the **INGREDIENTS** section., A red asterisk (*) indicates a required field throughout the submission process:



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:



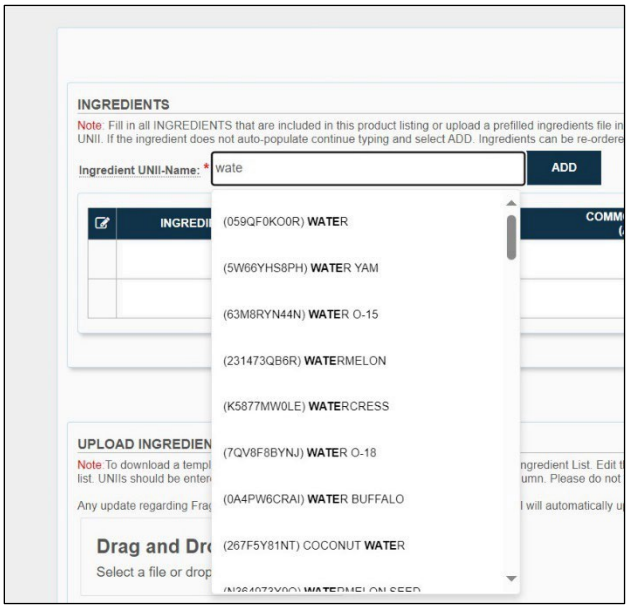


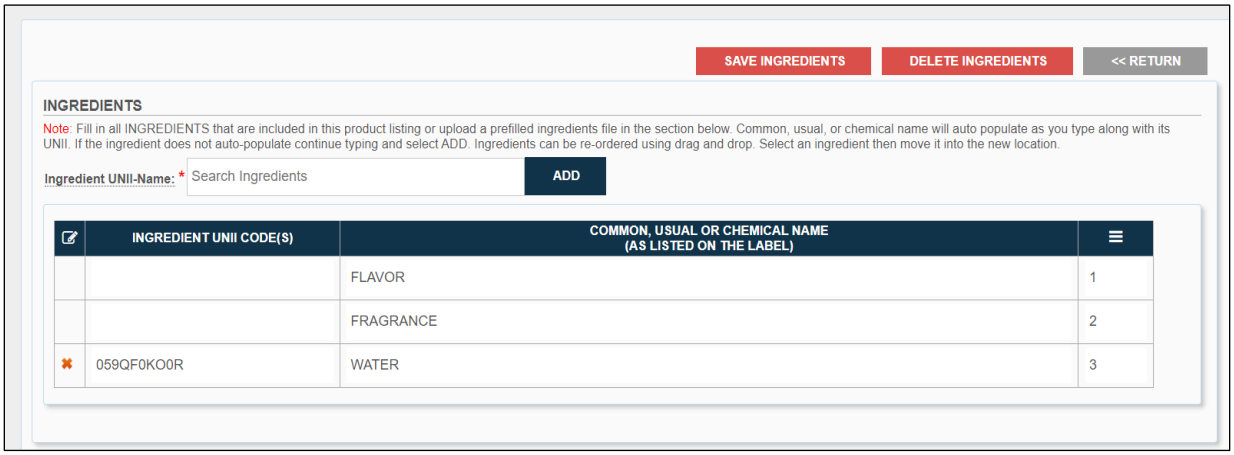
9. Fill in all the ingredients that are included in this product (as listed on label). Common, usual, or chemical name will auto-populate as you type along with its UNII. If an ingredient does not auto- populate, continue typing and select **ADD**.

    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.

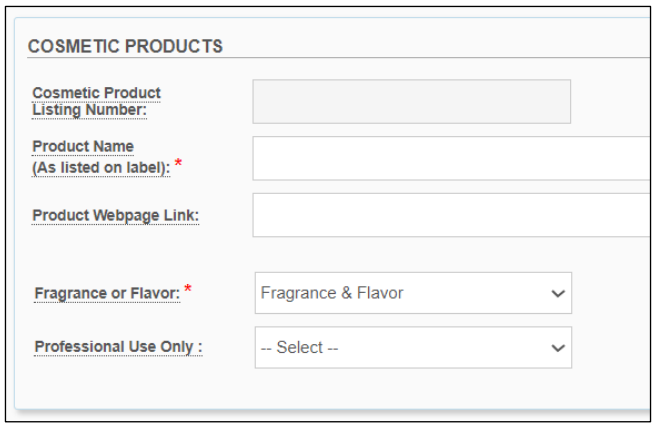
As an example, shown below:



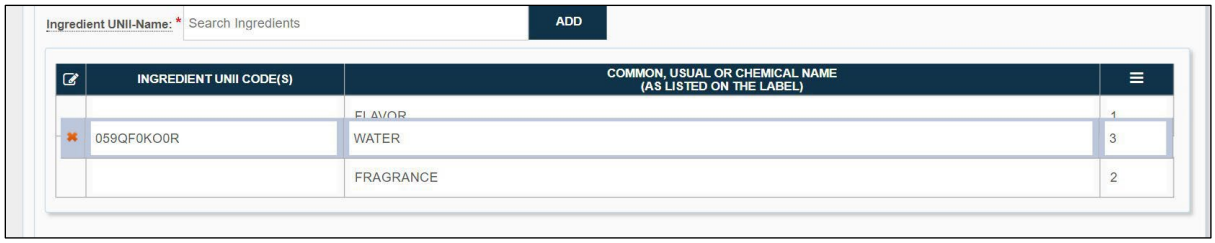


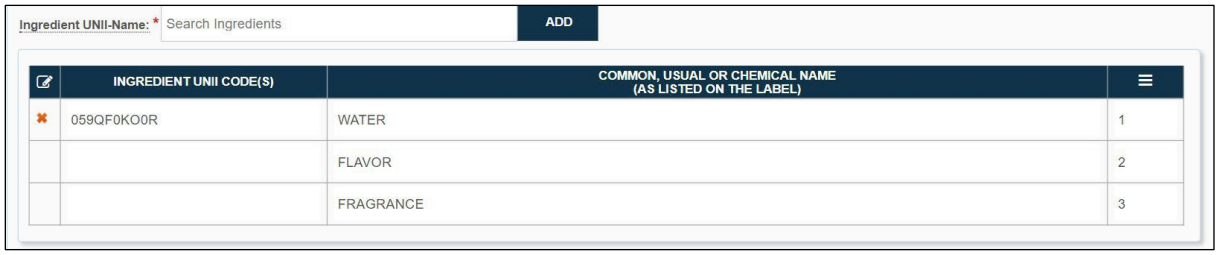
10. An ingredient can be deleted by selecting the **X** on the left-most column. As an example, shown below:

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.

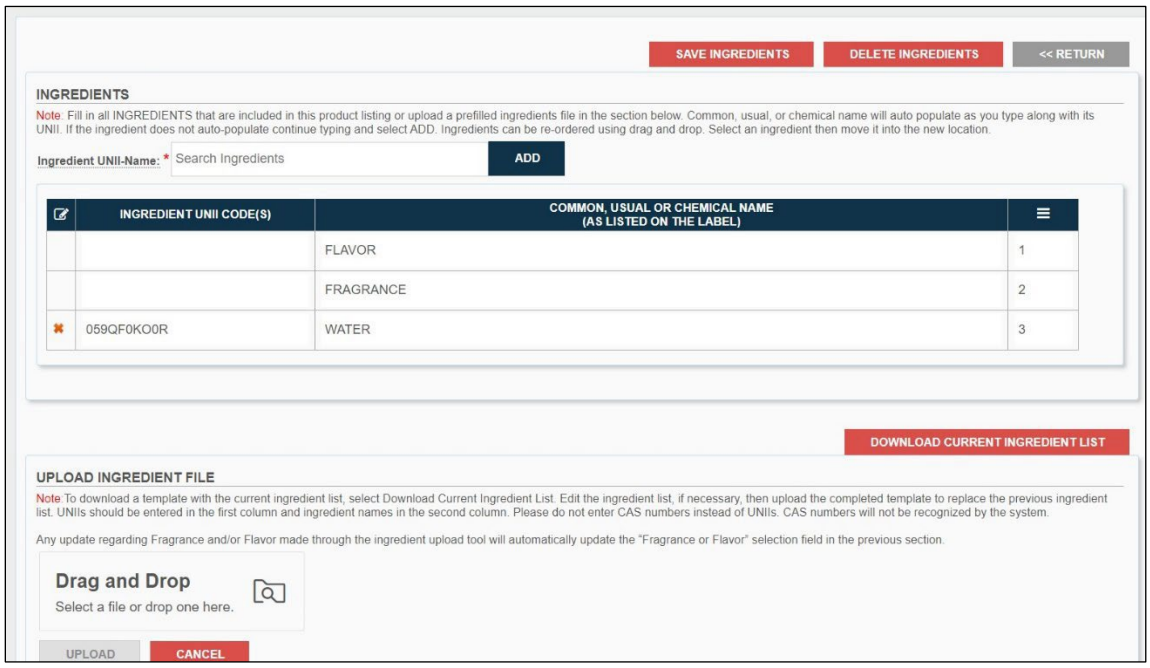


11. **Ingredients** can be **re-ordered** using the **drag and drop feature**. Select an ingredient then move it into the new location as shown below:

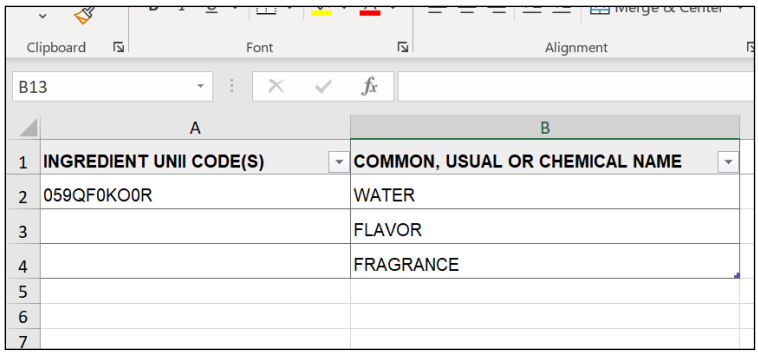




12. To download current ingredient list with its UNII CODE(S) from the **INGREDIENTS** section, click the '**DOWNLOAD CURRENT INGREDIENT LIST**', as shown below:



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

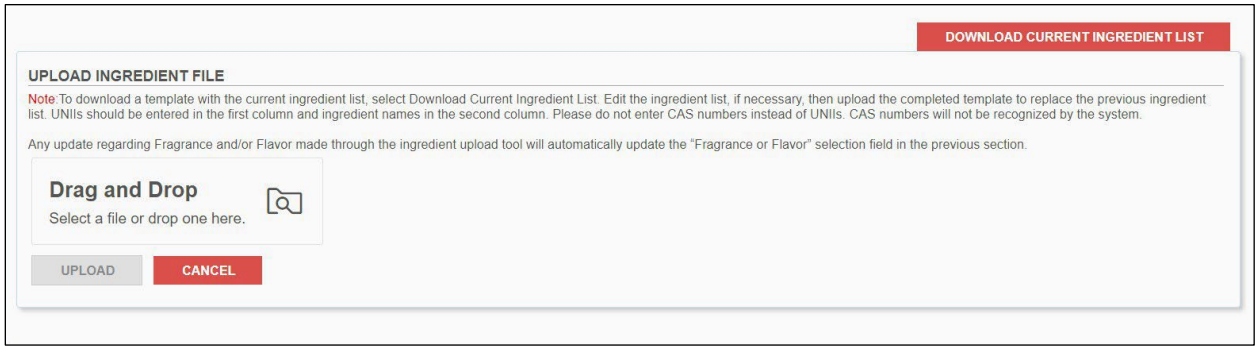


13. Edit the ingredient list, if necessary, then upload the completed template to replace the previous ingredient list. UNIIs should be entered in the first column and ingredient names in the second column.

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

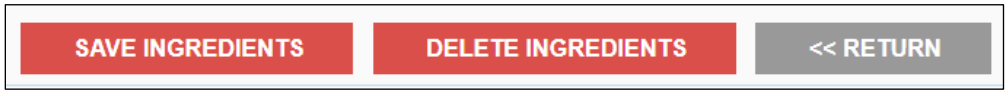
14. SAVE it on to the computer.

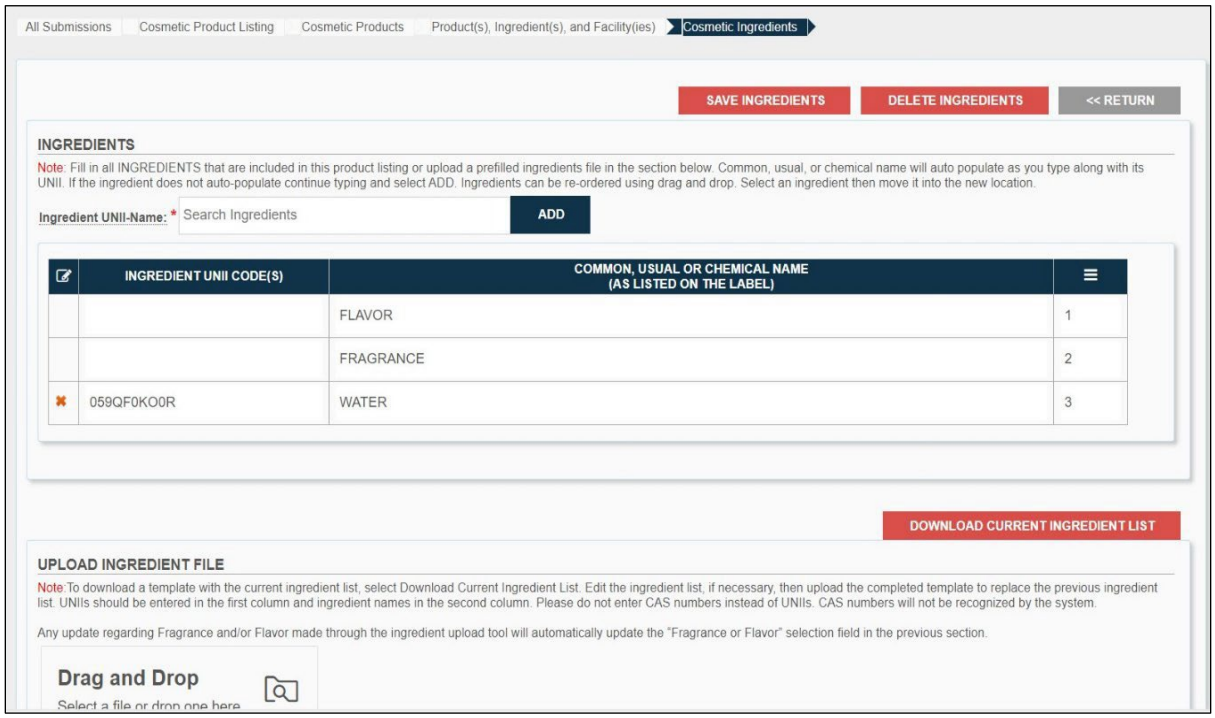
15. Upload the completed template to replace the previous ingredient list**,** by selecting the UPLOAD button underneath the DRAG AND DROP in the UPLOAD INGREDIENT FILE section. As shown below:

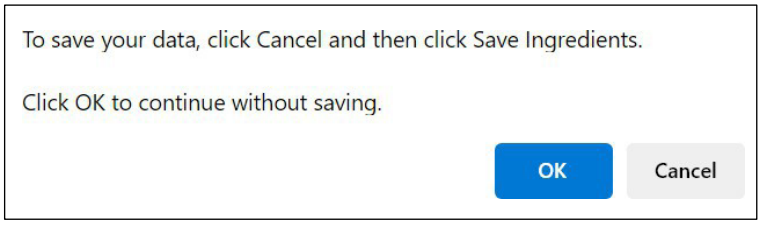


a. **PLEASE NOTE:** Any update regarding Fragrance and/or Flavor made through the ingredient upload tool, will automatically update the above "Fragrance or Flavor" selection field in the previous section.

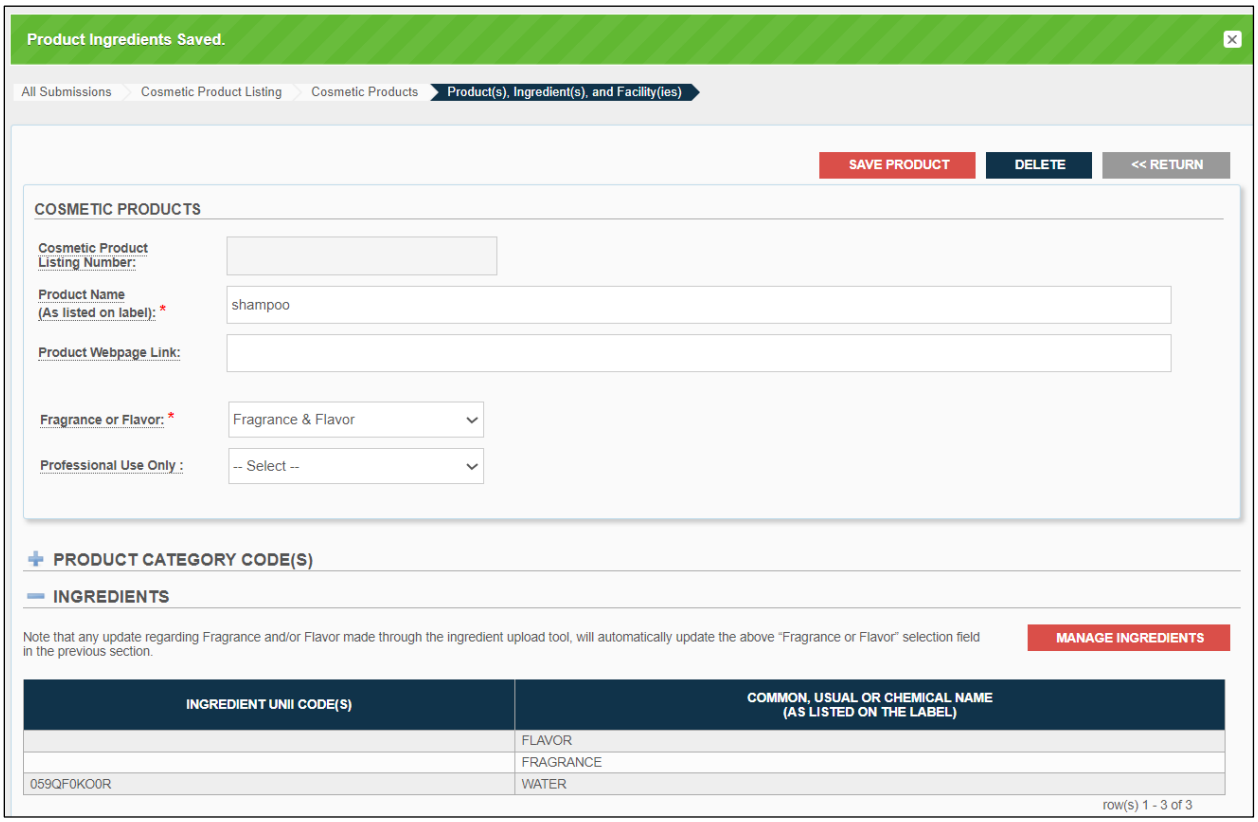
16. Once all the **INGREDIENT(S)** are listed, select **SAVE INGREDIENTS.** If the user chooses to delete the ingredient's list, select **DELETE INGREDIENT**. By selecting RETURN, a warning banner will appear. As an example, shown below:



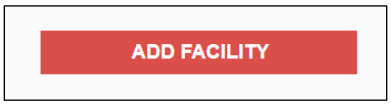


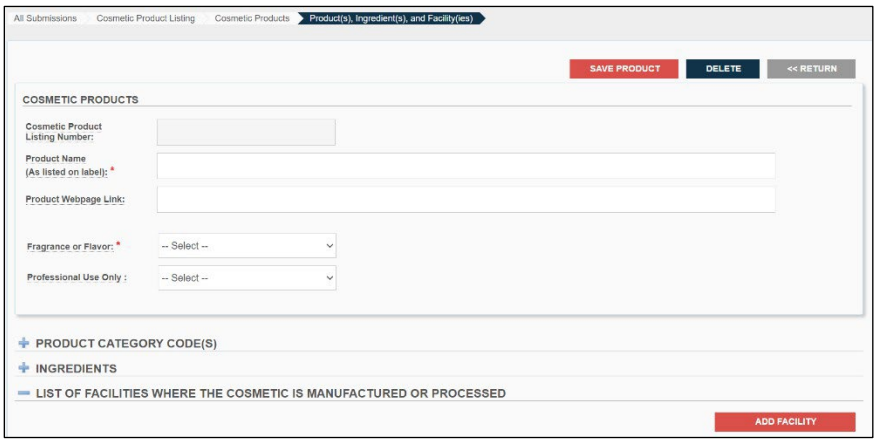


17. After clicking '**SAVE INGREDIENTS**' all the INGREDIENTS that were listed on the previous page will be listed under the ingredients tab in the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section with a saved banner on the top of the page, as shown below:

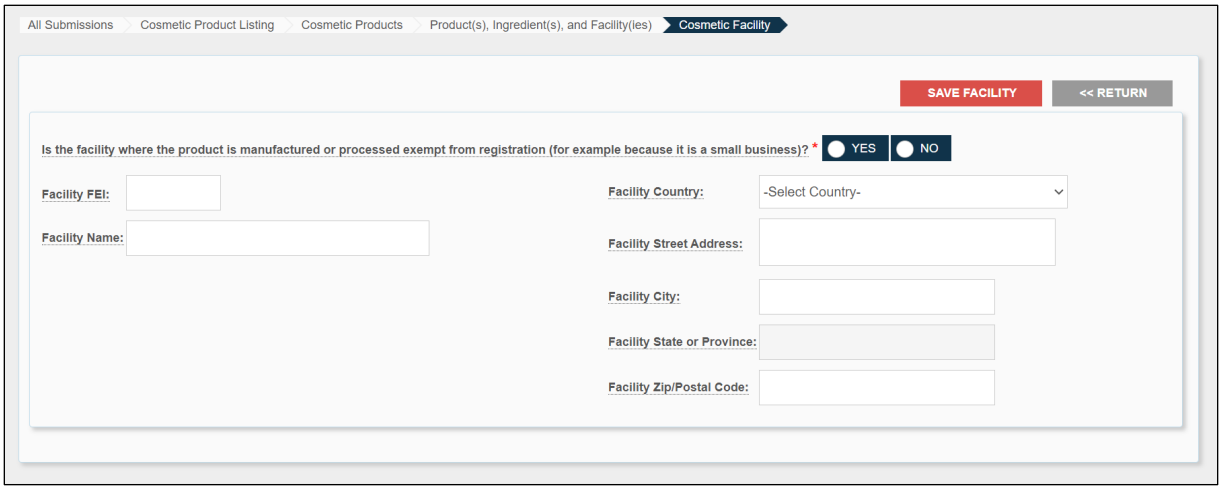


18. To add the LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED, section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section, click the '**ADD FACILITY**' button in ***LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED*** section, as shown below. A red asterisk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



a. Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?*: Indicate by selecting one of the options, whether the facility where the product is manufactured or processed is exempt from registration (for example because it is a small business).

b. SMALL BUSINESSES. — Under section 612(b) of the FD&C Act, regardless of their average gross annual sales, businesses that engage in the manufacturing or processing of the following are not exempt from the registration and listing requirements:

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

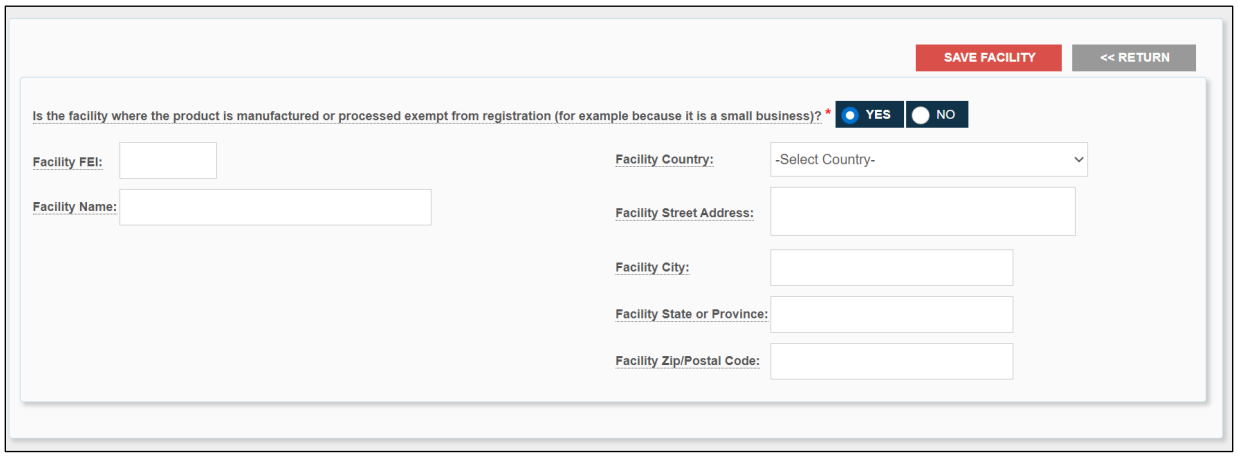
c. Facility FEI: Enter the existing 7 to 10-digit facility FEI number. The FEI number is a unique identifier assigned by the FDA to identify firms associated with FDA-regulated products. To facilitate the registration process, the owner or operator of a facility will need to obtain an FEI number before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

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

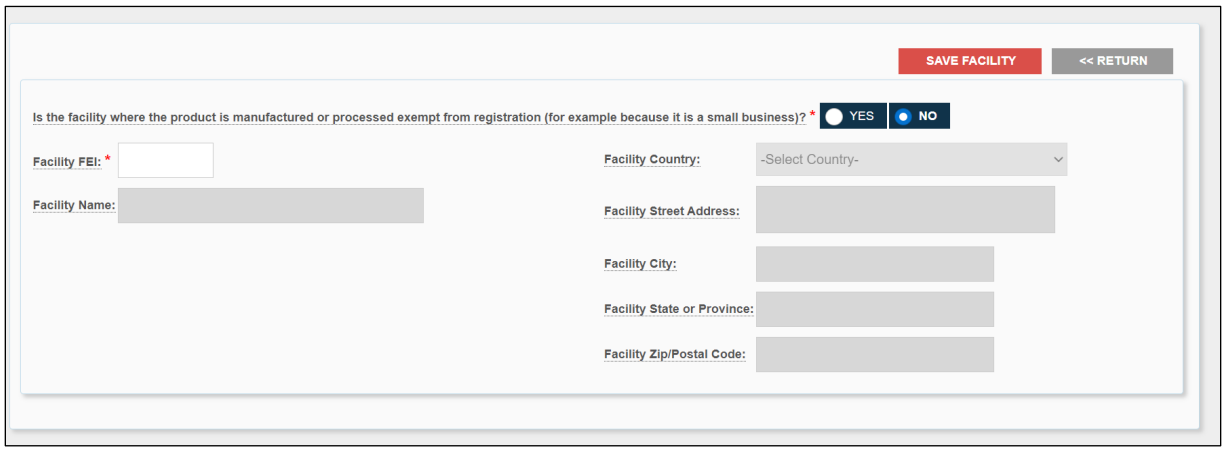
- Facility Name: Enter the complete name of the existing facility.
- Facility country: Select facility's country name where the facility is physically located.
- Facility Street Address: Enter the complete information of the street where the facility is physically located.
- Facility City: Enter the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

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

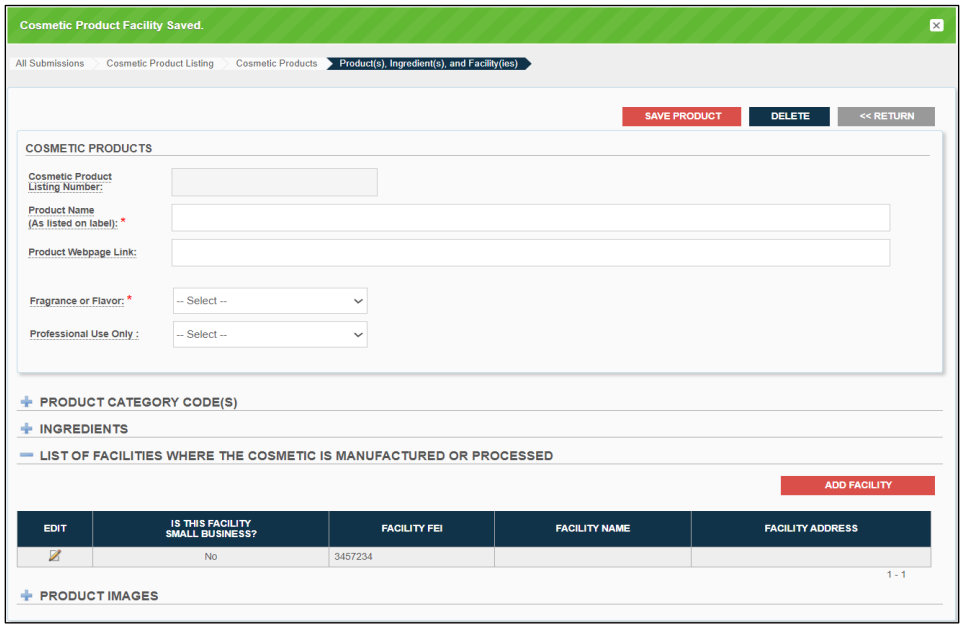
20. If selected **YES** to the question, "***Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?"*** all data fields are optional. As shown below:



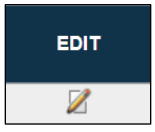
21. If selected **NO** to the question, "***Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?"*** the FEI is mandatory, and the name/address is greyed. As shown below:

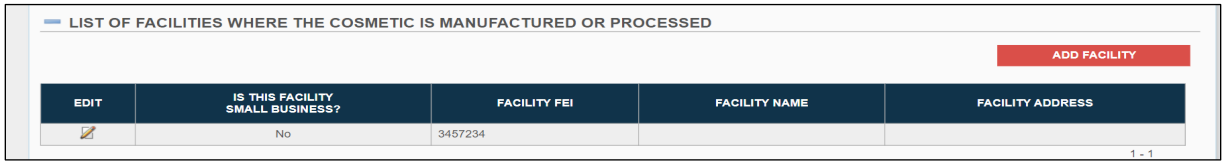


22. Once complete, clicking '**SAVE FACILITY**' and the FACILITY will be saved on the previous page under the **LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED** tab in the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section with a saved banner on the top of the page, as shown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



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:

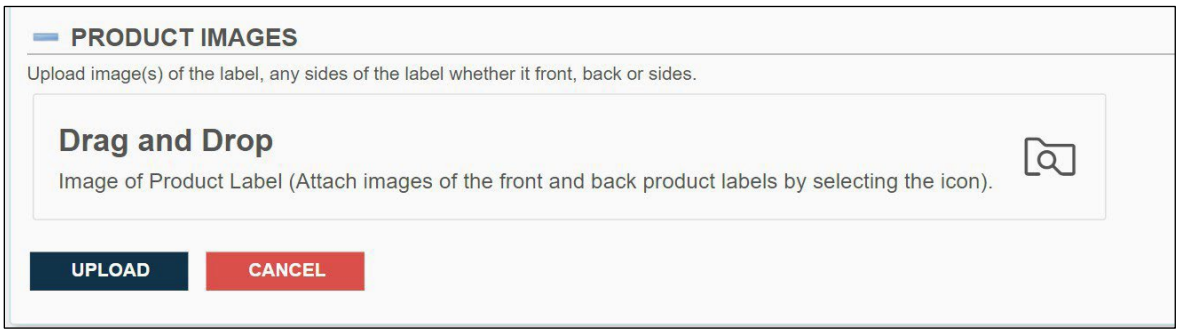




a. Multiple **FACILITY(IES)** can be added by selecting the **ADD FACILITY** on the top right, as shown above.

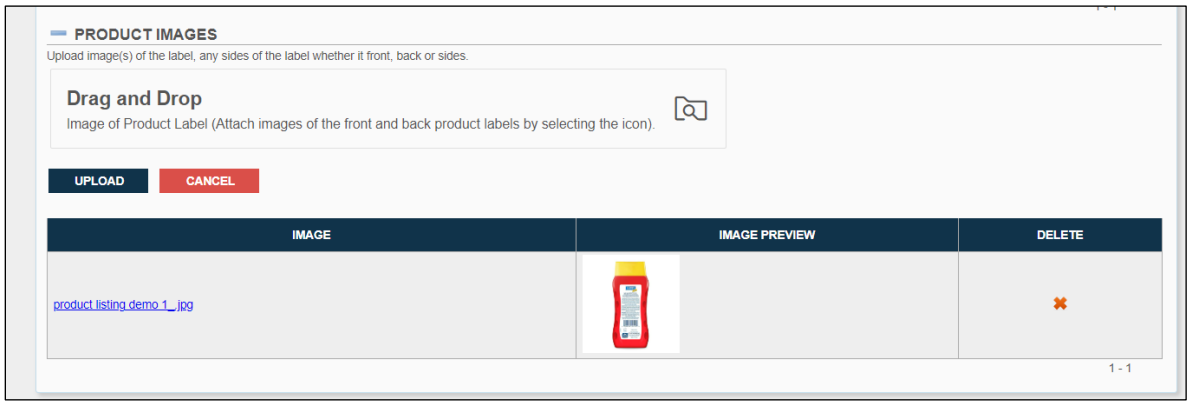
24. The **PRODUCT IMAGES** section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section, a red asterisk (*) indicates a required field throughout the submission process:

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.

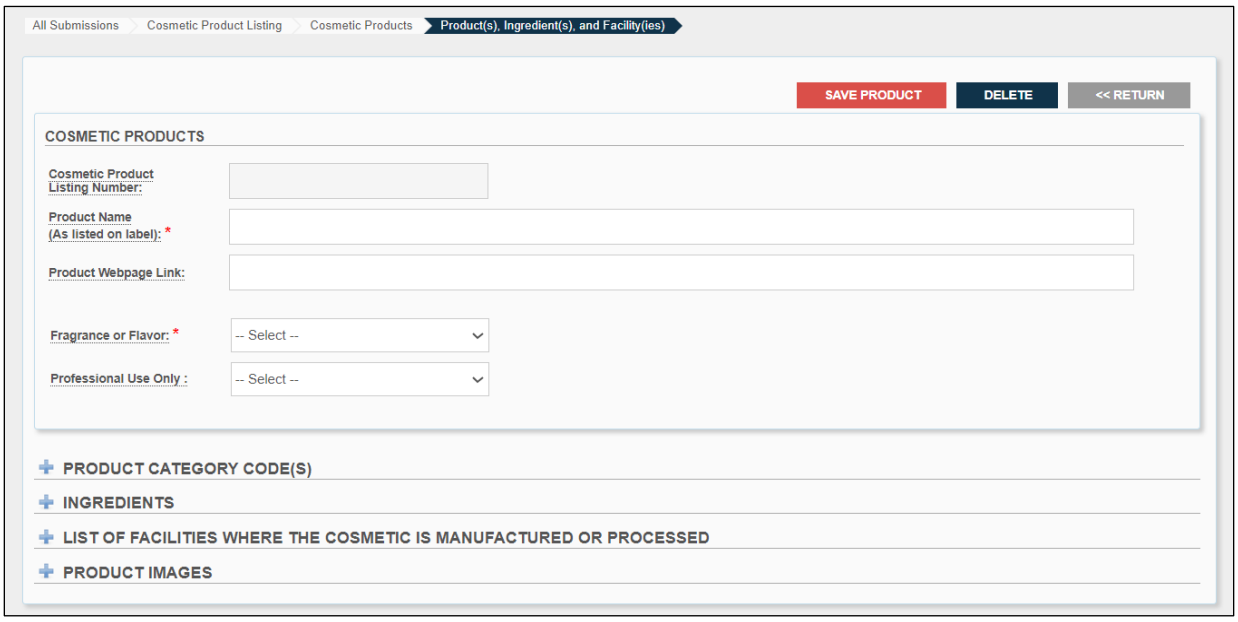


PLEASE NOTE: It is important that the image uploaded is to be in .JPEG format. The max image size allowed is 1MB. **Please make sure that the image is a true jpg without special characters. They must be valid jpg file and the name should consist of letters (a-z, A-Z) and/or numbers (0-9). Special characters 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.

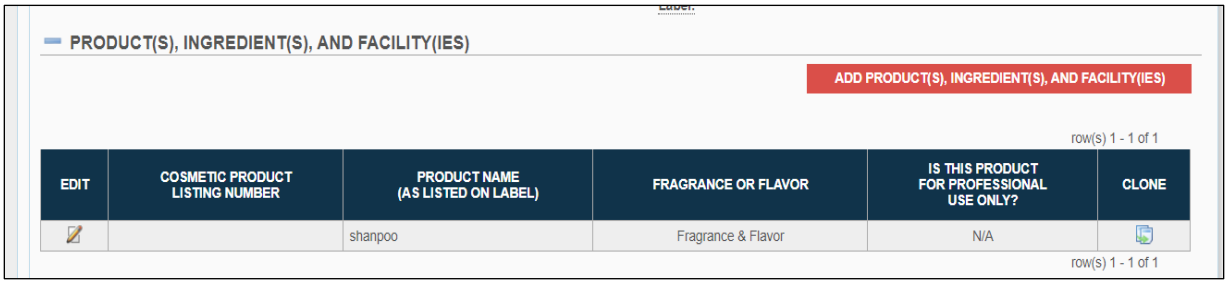
b. The image will display under the **PRODUCT IMAGES** section under **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES),** as shown below:



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:

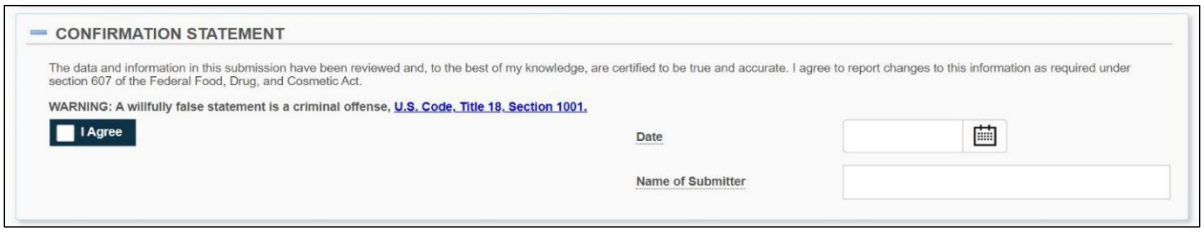


a. Multiple **PRODUCT** can be added by selecting the **ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)**on the top right, as shown above.

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:

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



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

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

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

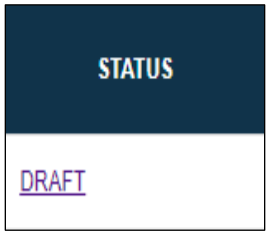
- Additional Contact Name: (optional field) Enter an additional contact information for individuals associated with the listing. For more information visit: *Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov).*
- Email: (optional field) Provide the additional 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."

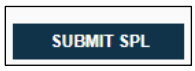
14. Once the system has completed validation the status, '**VALIDATION IN PROGRESS**', will change to '**READY FOR SUBMISSION**'.

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

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

4.4.3.2 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."

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**'

    - **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.

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

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

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

4.4.3.4 Submission Failed

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

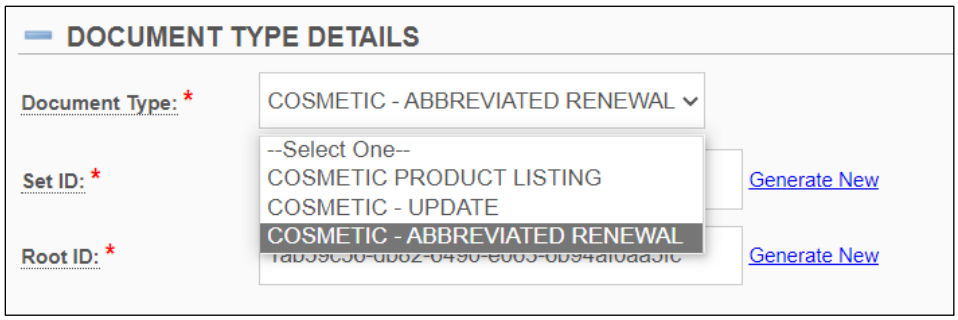
22. Click '**VALIDATION FAILURE**', the system will provide a list of errors that need to be fixed before submitting the SPL:

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

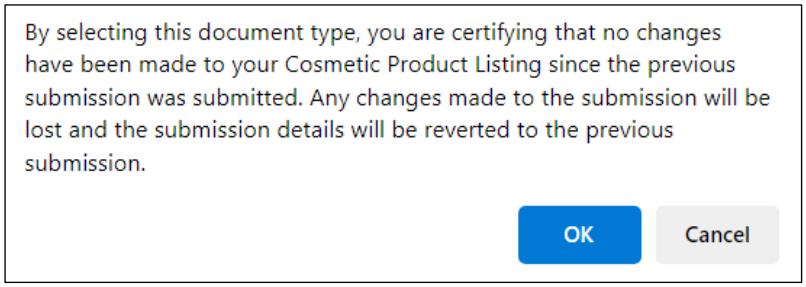
4.4.4 Abbreviated Renewal Listing

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**'.



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.



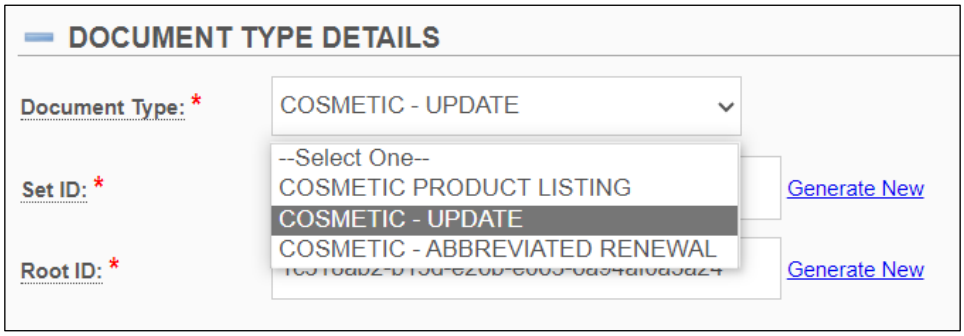
2. After selecting '**OK**', the fields for Product, Ingredient and Facility Listing of the Cosmetic Product, Confirmation Statement, and Additional Contact Information for Authorized Agent will be grayed out and can no longer undergo changes.

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.**"



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

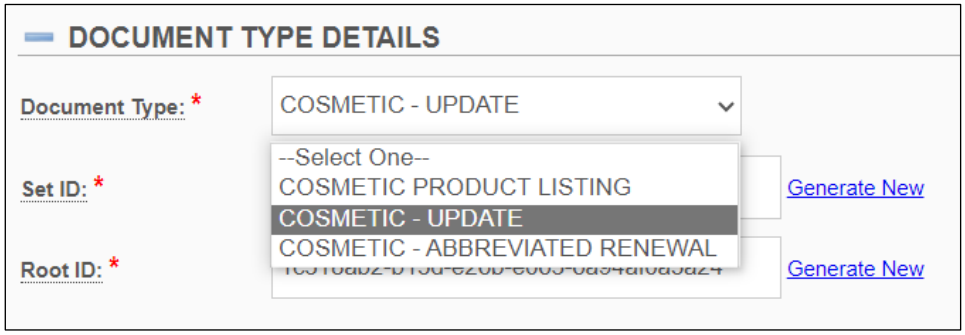
    If you need to update one of the above fields, then you will need to submit an INITIAL-Cosmetic Product Listing. Then, you will need to discontinue the products from the previous submission (see 4.4.5.1 Discontinue).
3. Refer to the steps from Sections 4.4.3.1 – 4.4.3.5 for Submit to FDA instructions.

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:

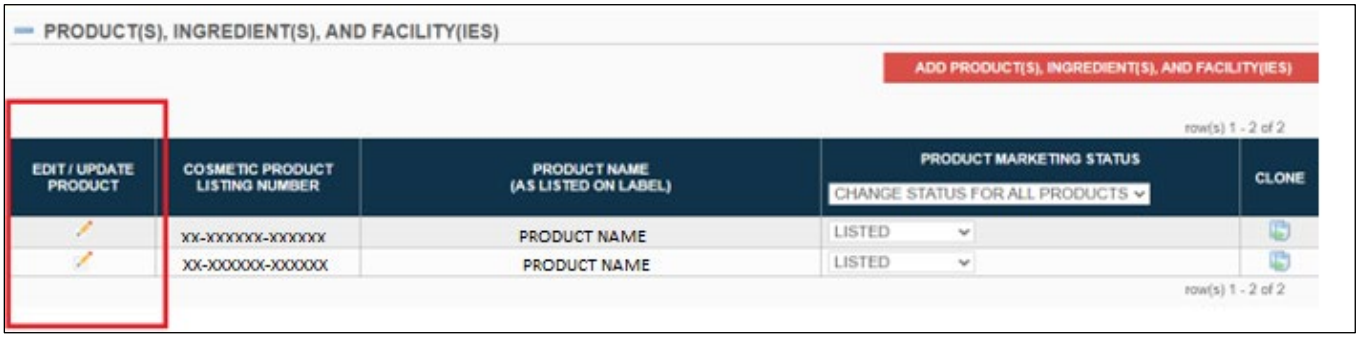
1. Open an existing submission that has been previously accepted.
2. Click '**CREATE NEW VERSION**'

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



Option 1 – Edit/Update Product

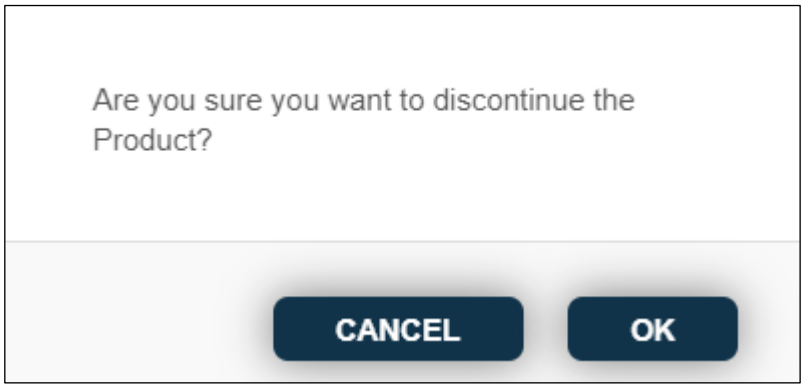
a. Locate the EDIT/UPDATE PRODUCT column under the PRODUCT(S), INGREDIENT(S), AND FACILITY(IES) section.



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

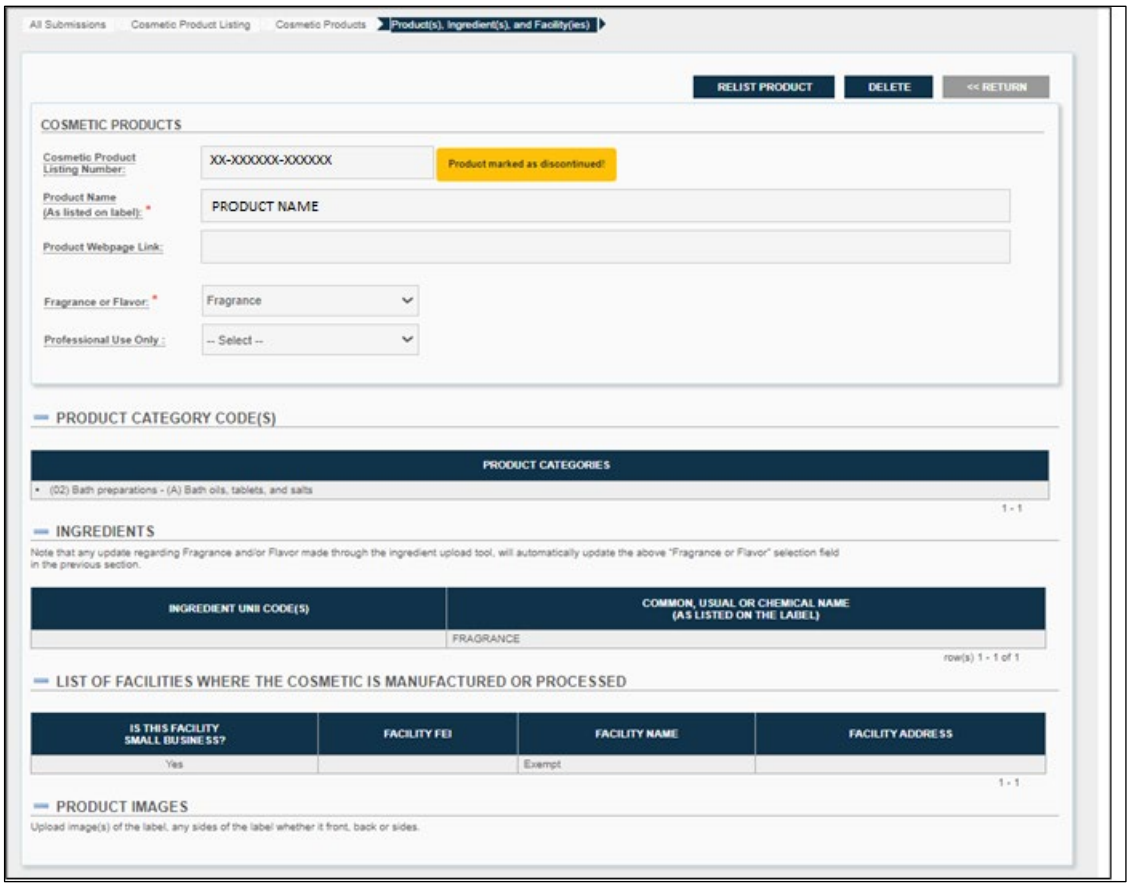
c. Select 'DISCONTINUE PRODUCT' to discontinue the product.

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.

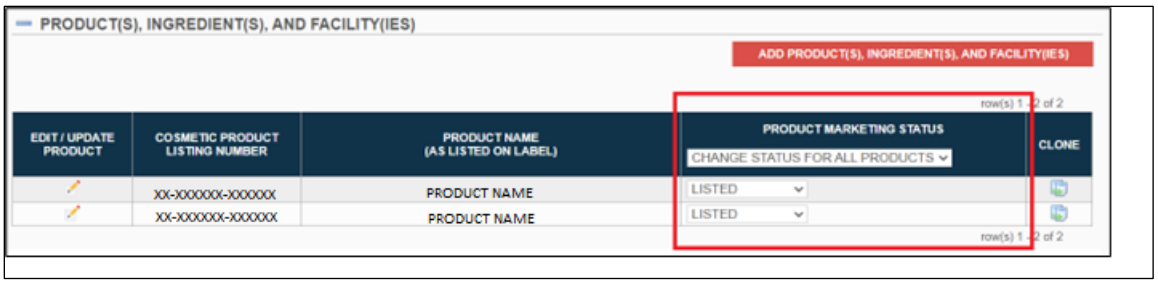
Using the pencil icon, you can re-enter into the selected DISCONTINUED product to view that the product is marked as discontinued. A yellow message will appear next to the Cosmetic Product Listing Number stating, "Product marked as discontinued!"



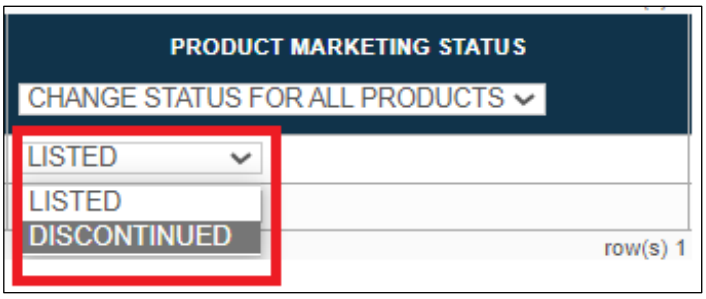
PLEASE NOTE: Once a product is discontinued, no additional edits can be made on the page unless the product is RELISTED. Please see section 4.4.5.2 Relist for additional instructions.

Option 2 – Product Marketing Status

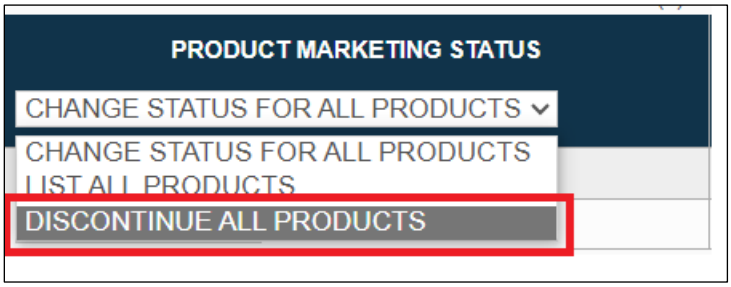
e. Locate the PRODUCT MARKETING STATUS column under the PRODUCT(S), INGREDIENT(S), AND FACILITY(IES) section.



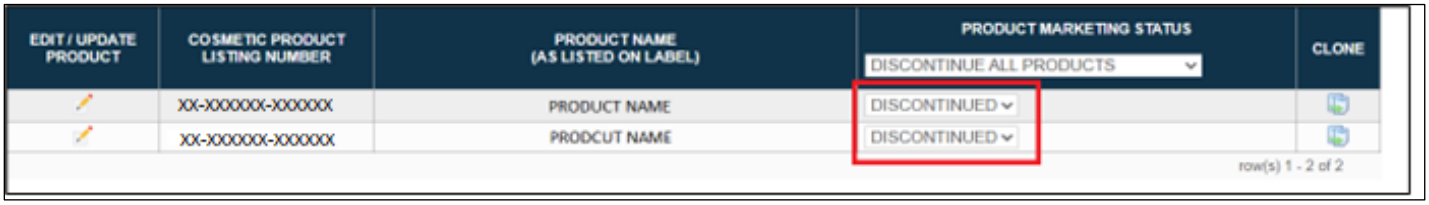
i. Identify the listed products you wish to discontinue. In the PRODUCT STATUS column, click the drop-down menu and select 'DISCONTINUED'.



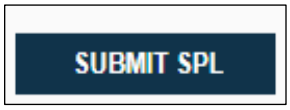
ii. If you wish to discontinue all the LISTED products, select 'DISCONTINUE ALL PRODUCTS'



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

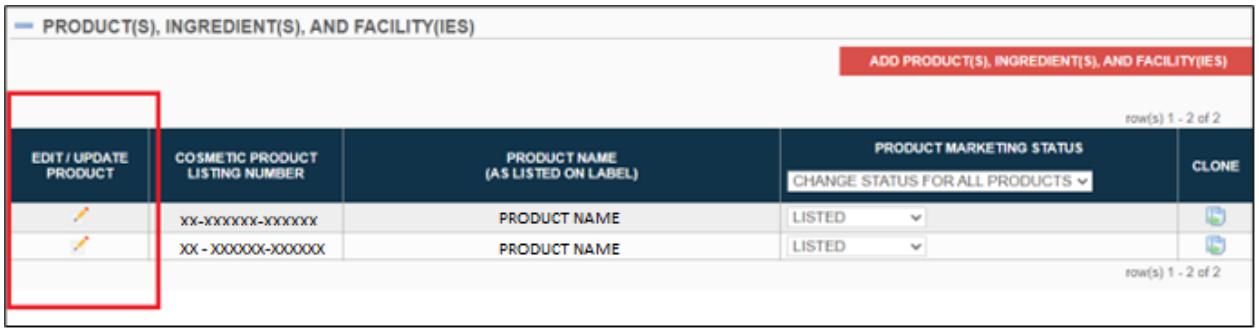


h. Click 'SAVE AS DRAFT' or 'SAVE AND VALIDATE' located at the top right of this page to save your selection(s). This will change your products to 'DISCONTINUED'. To submit your data to the FDA, select 'SUBMIT SPL'.



Option 3 – Delete

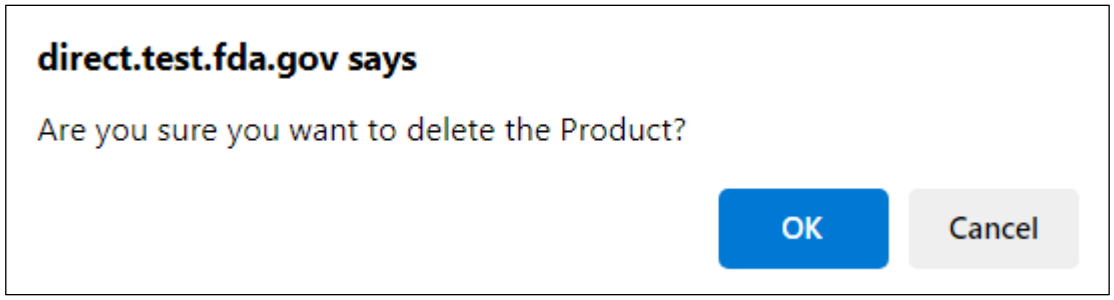
i. Locate the EDIT/UPDATE PRODUCT column under the PRODUCT(S), INGREDIENT(S), AND FACILITY(IES) section.



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.

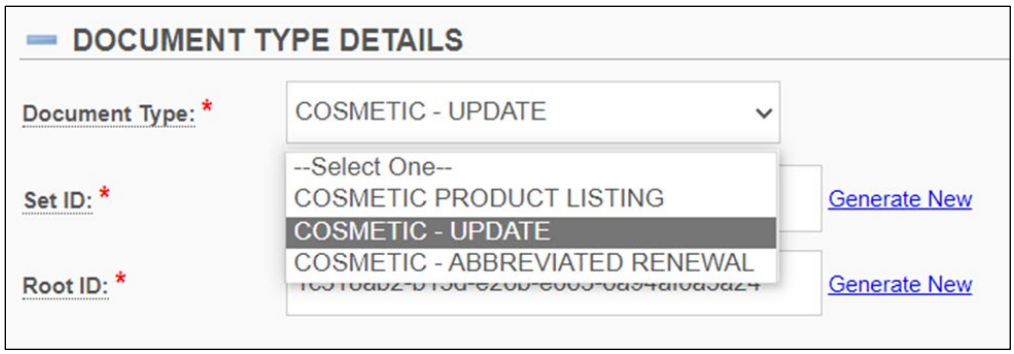
4. Refer to the steps from Sections 4.4.3.1 – 4.4.3.5 for Submit to FDA instructions.

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:

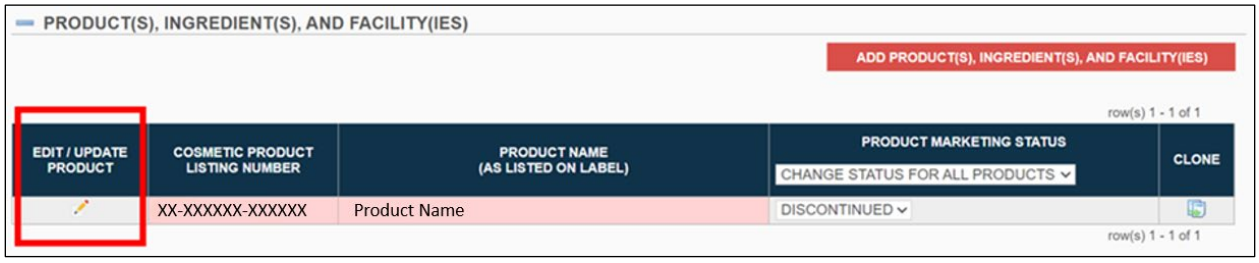
1. Open an existing submission that has been previously accepted.
2. Click '**CREATE NEW VERSION**'

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

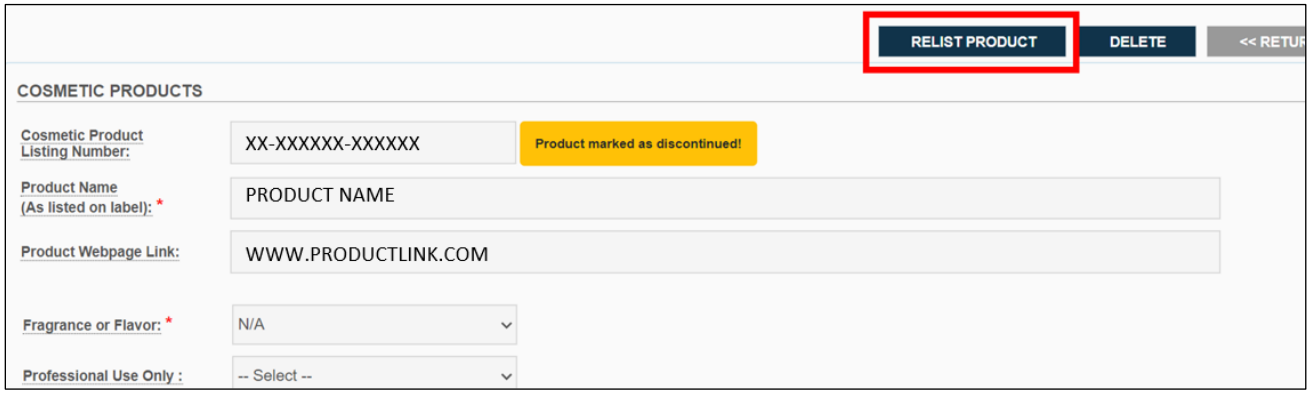


Option 1 – Edit/Update Product

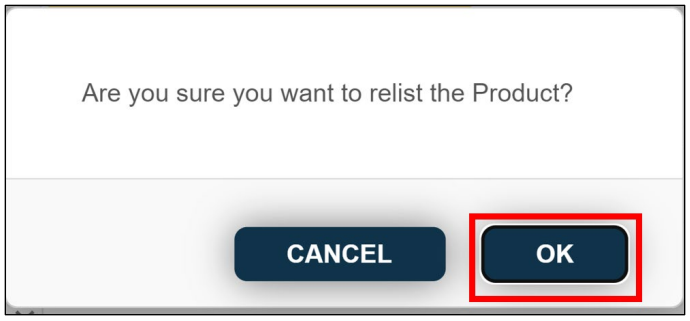
a) Locate the EDIT/UPDATE PRODUCT column under the PRODUCT(S), INGREDIENT(S), AND FACILITY(IES) section. Click on the pencil icon of the product you would wish to relist.



b) Click on 'RELIST PRODUCT'.

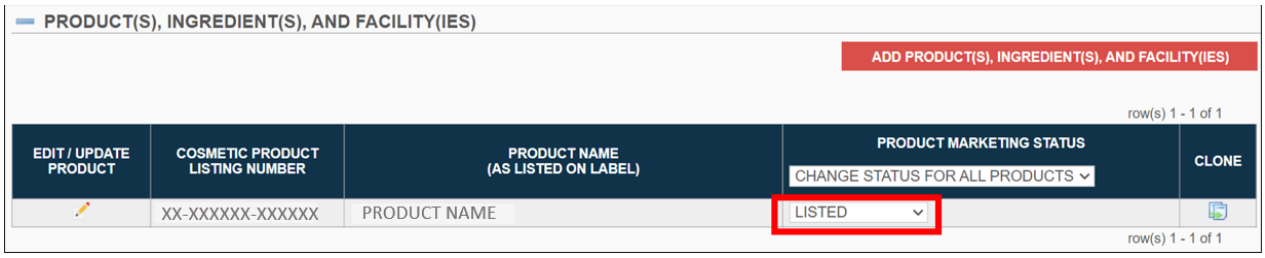


c) To relist the product, click 'OK' when prompted.



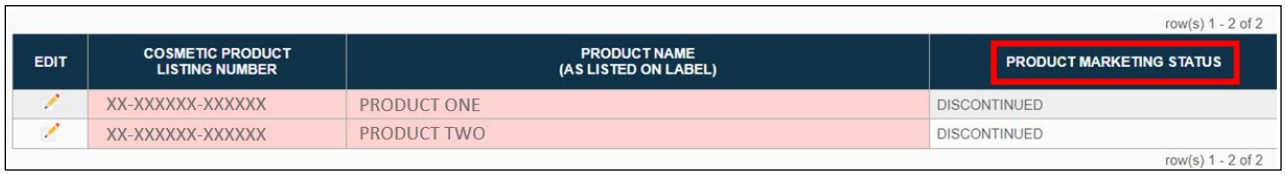
d) After clicking 'OK', you will be taken back to the Cosmetic Product Listing page and a green message will appear across your screen stating, "Cosmetic Product Relisted."

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



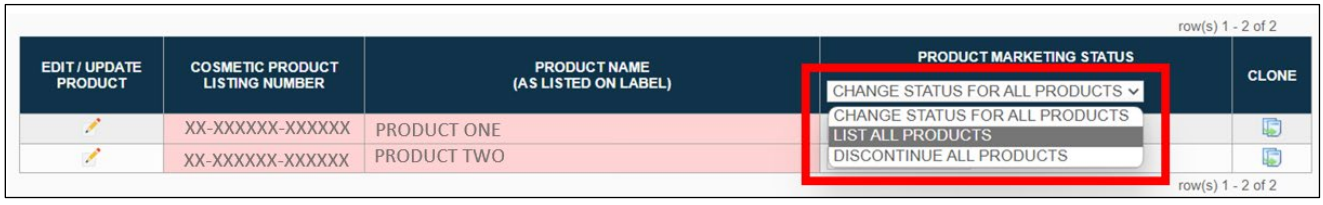
Option 2 – Product Marketing Status

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



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

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



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 MODI 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:

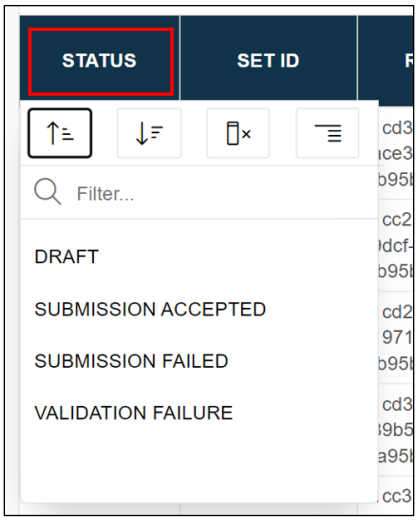
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	RESPONSIBLE PERSON NAME	DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE	

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:

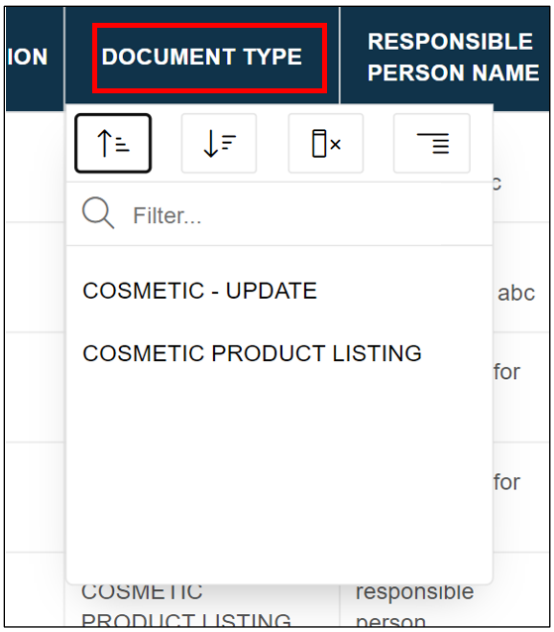
1. Clicking the 'Status' header will display a dropdown of all status types tied to your submissions:



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		,'-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:

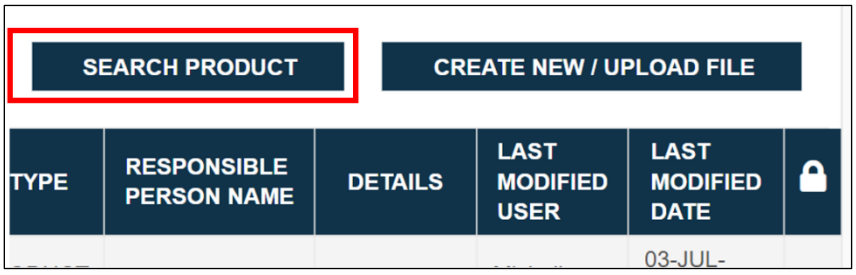


Icon	Description
	Sort ascending
	Sort descending
	Hide column
	Clearly separate each submission

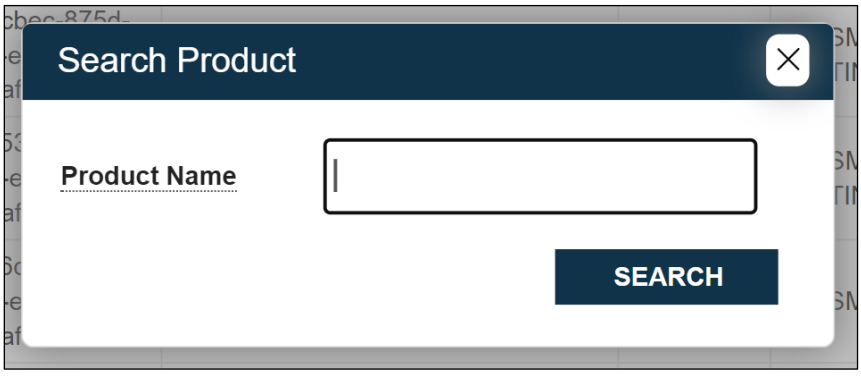
5.5.2.2 Search Product

A product can be searched by name:

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



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

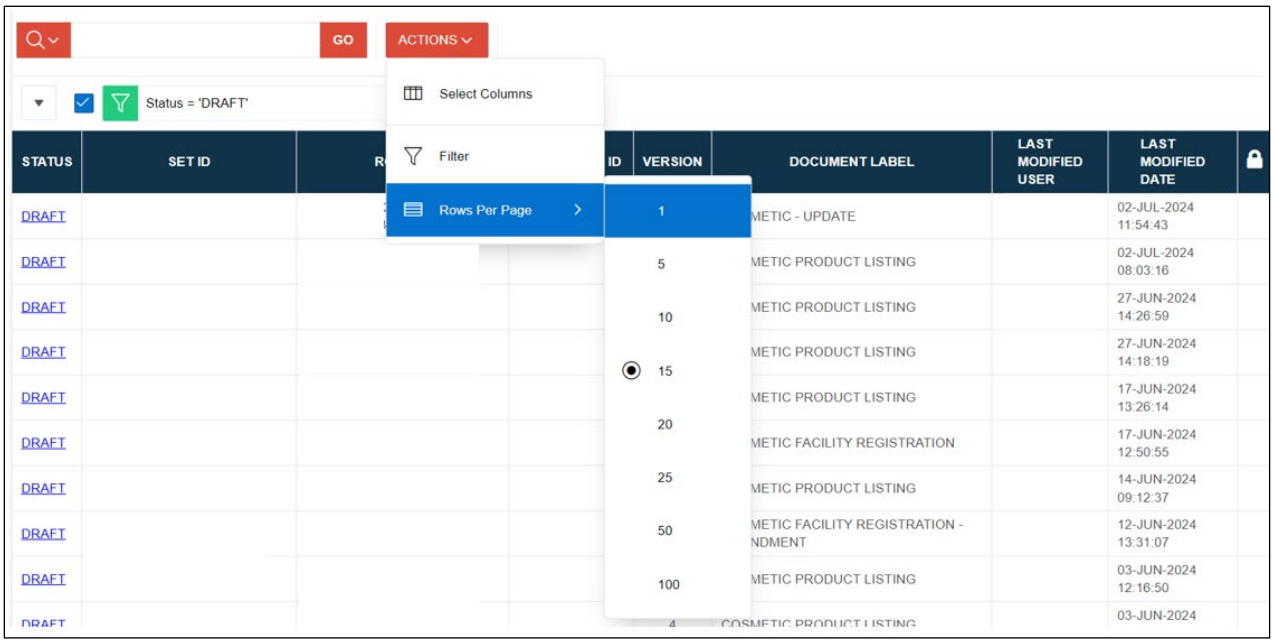


3. The page will update immediately with your filter.

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':



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