U.S. Food and Drug Administration

USER'S GUIDE

to FDA Direct

July 2024

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1 FDA DIRECT

1.1 Overview

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

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

1.2 Account Types

1.2.1 CDER Direct Account

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

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

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

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

1.2.2 Cosmetics Direct Account

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

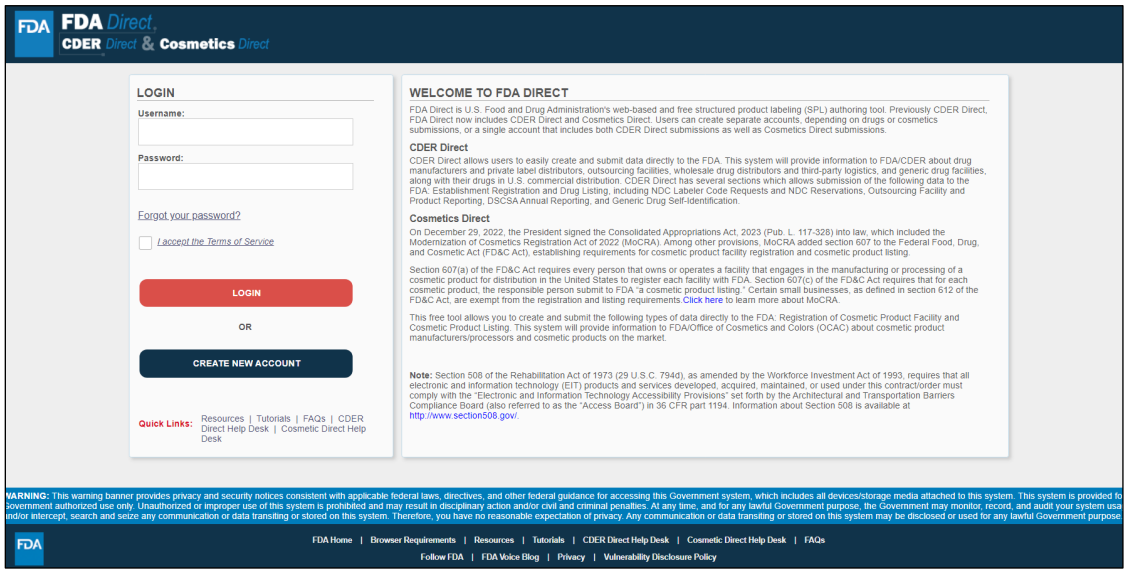
- *Registration of Cosmetic Product Facility*
- *Cosmetic Product Listing*

1.2.3 'Combined' Account – CDER Direct & Cosmetics Direct

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

2 ACCOUNTS

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



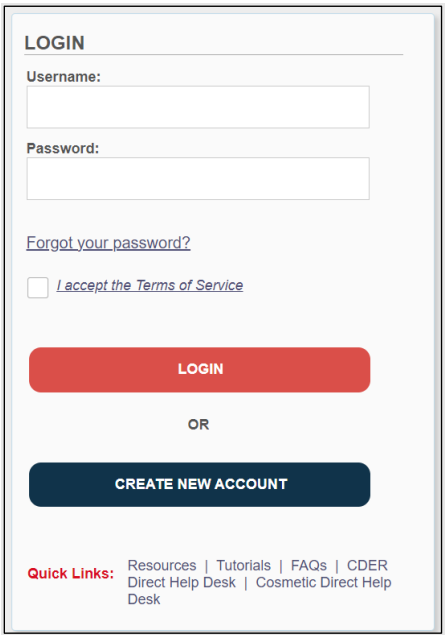
At the bottom of the Login area, there are ***Quick Links*** that can provide you with further assistance on various topics:

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

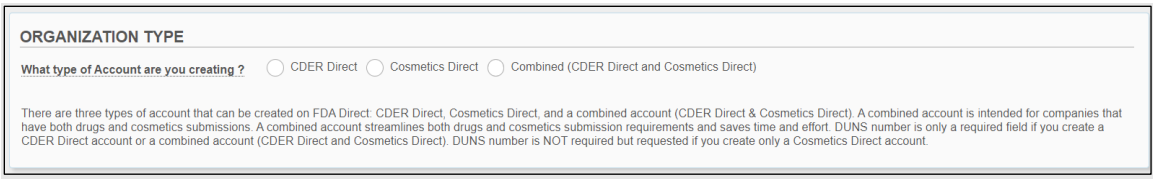
2.2 Account Creation

Follow these steps to create a new account:

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

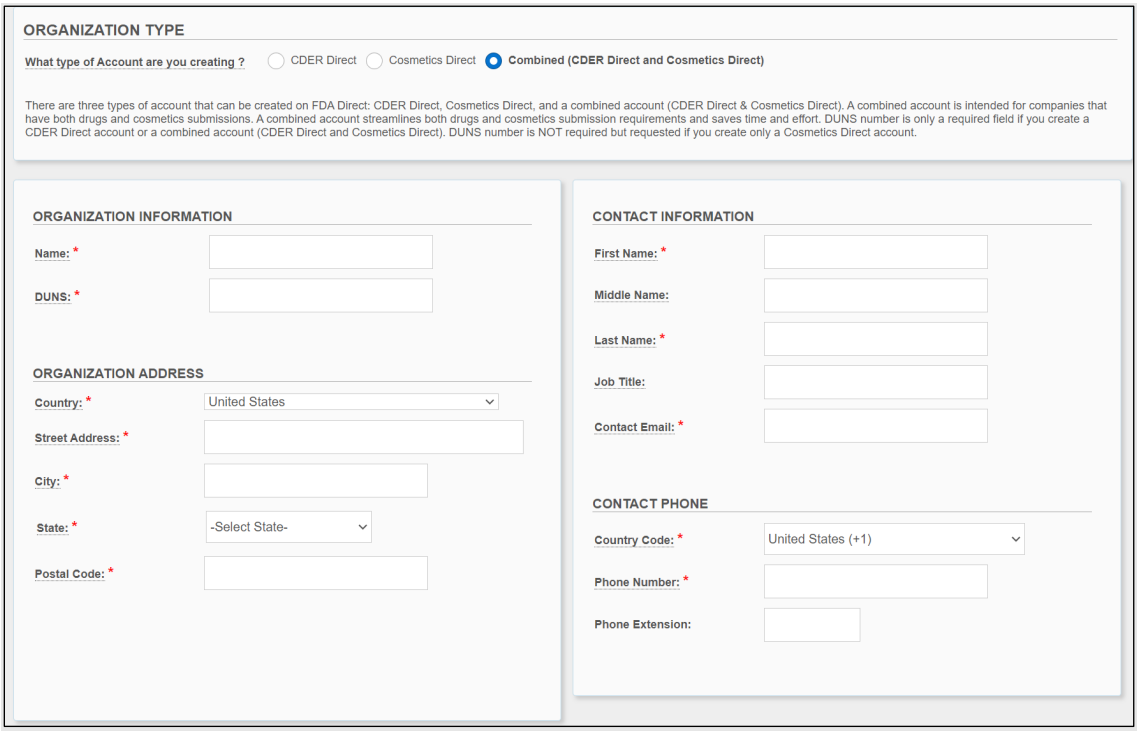


2. Select your desired account type. This can be changed after account creation:



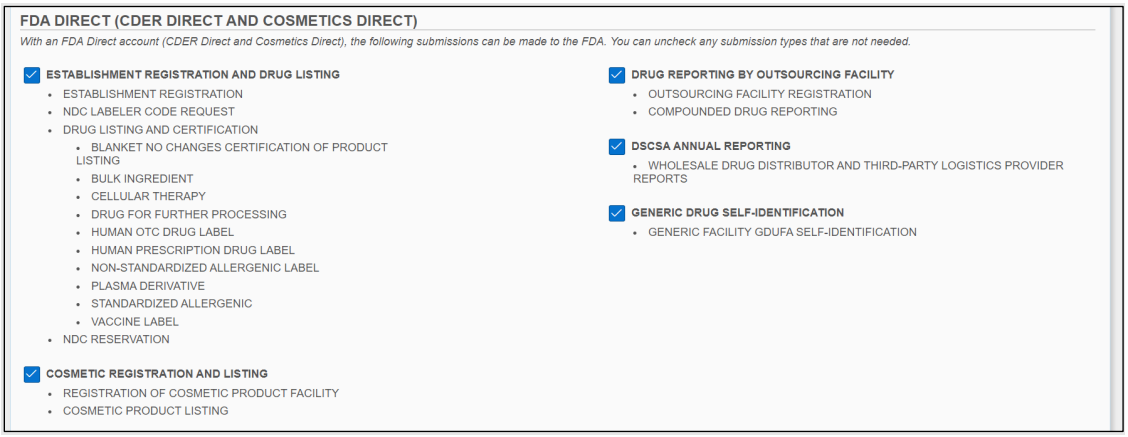
- **CDER Direct –** Select this option to register and list for human drugs or biological products. You will have access to drug-related submission forms such as *Establishment Registration and Drug Listing*, *Outsourcing Facility Registration and Product Reporting*, *DSCSA Annual Reporting,* and *Generic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

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

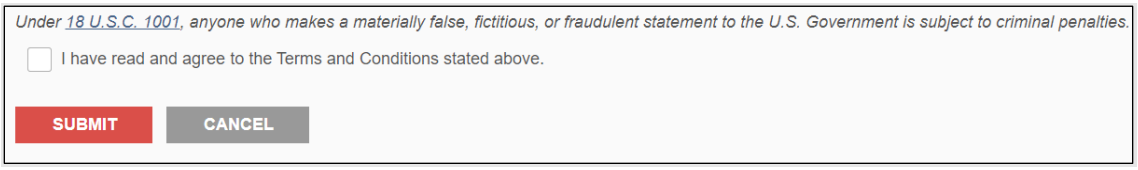


***The DUNS field is <u>optional</u> in Cosmetics Direct account creation only.**

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.

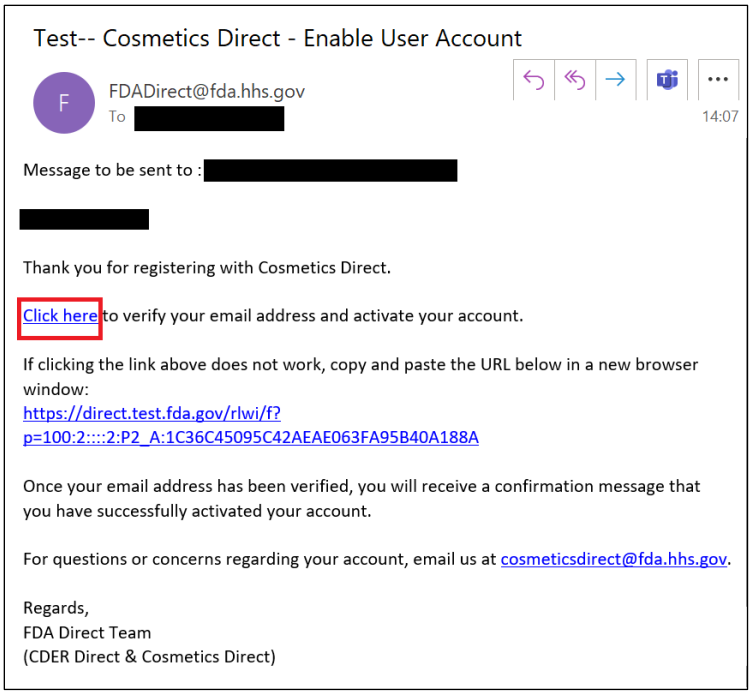
   If you still have not received your activation email after 5-10 minutes, you can contact the Help Desk at:

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

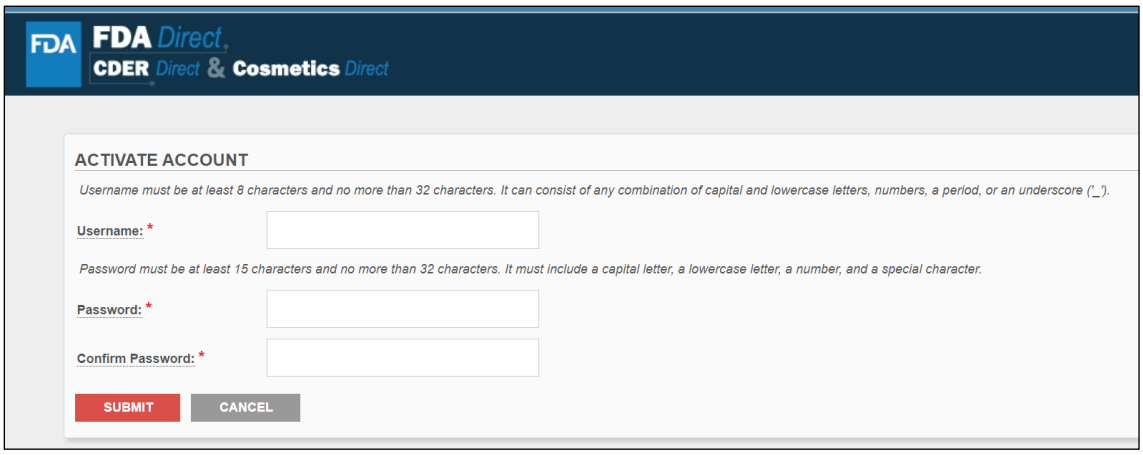
     OR

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

7. Click the link in the activation email:



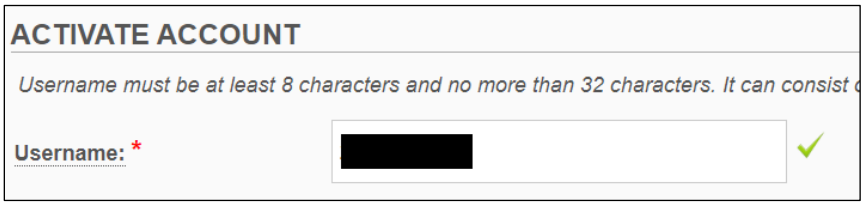
8. The link will open the FDA Direct website in your browser. Enter your desired Username and Password:



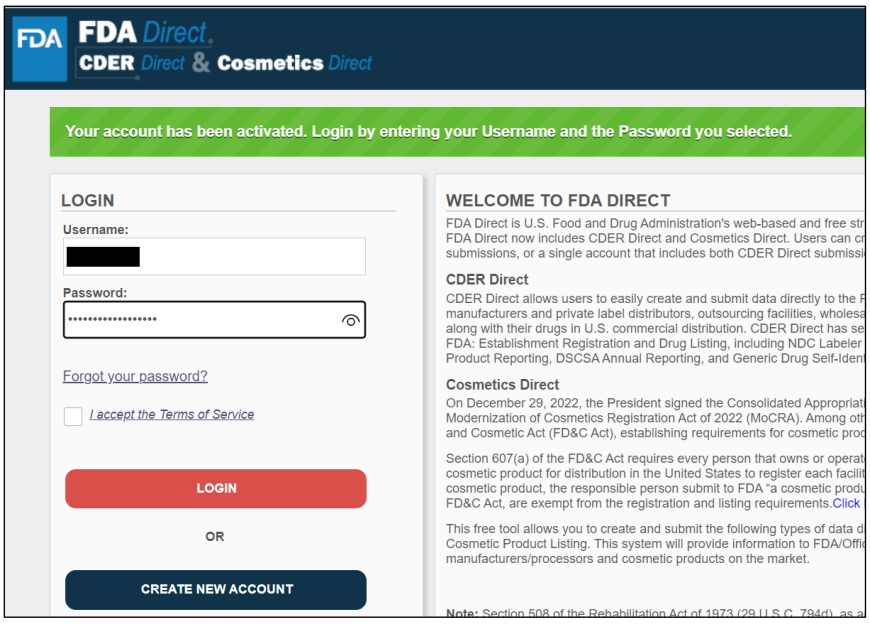
Usernames must be within 8-32 characters in length. Passwords must be between 15-32 characters long, and include at least **one** of the following:

- Capital letter
- Lowercase letter
- Number
- Special character

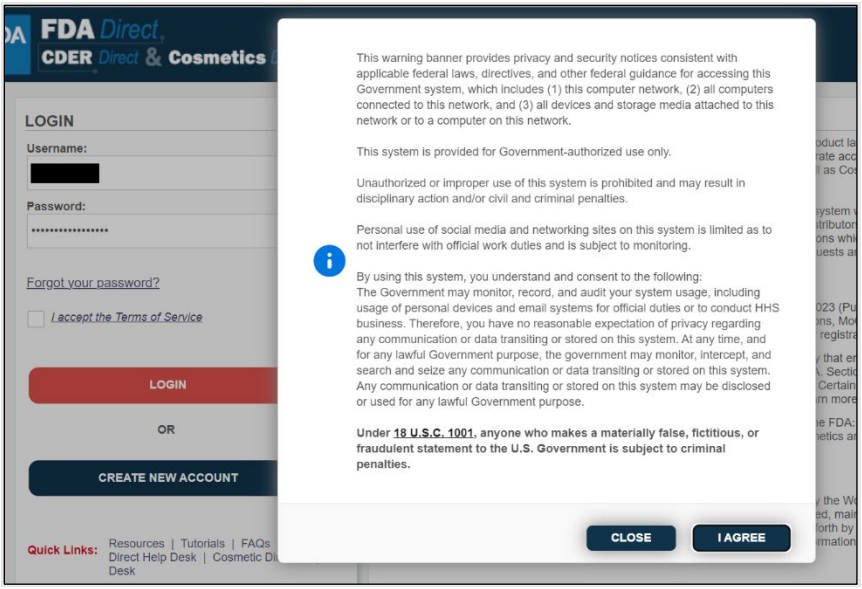
A green checkmark will indicate that your username is acceptable:



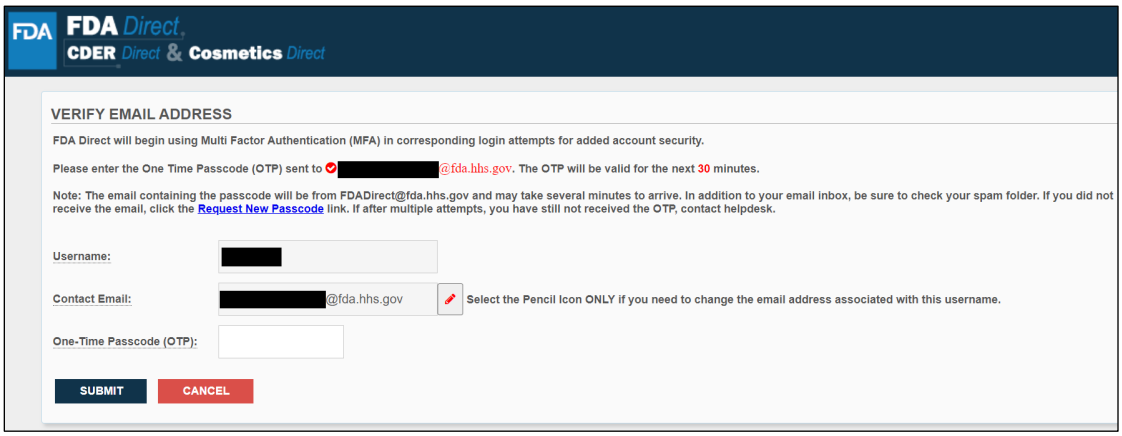
9. Click '**Submit**' when all information has been entered.
10. You will be redirected to the FDA Direct login page. A green banner at the top of the page will confirm your account activation. Enter your new username and password:



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

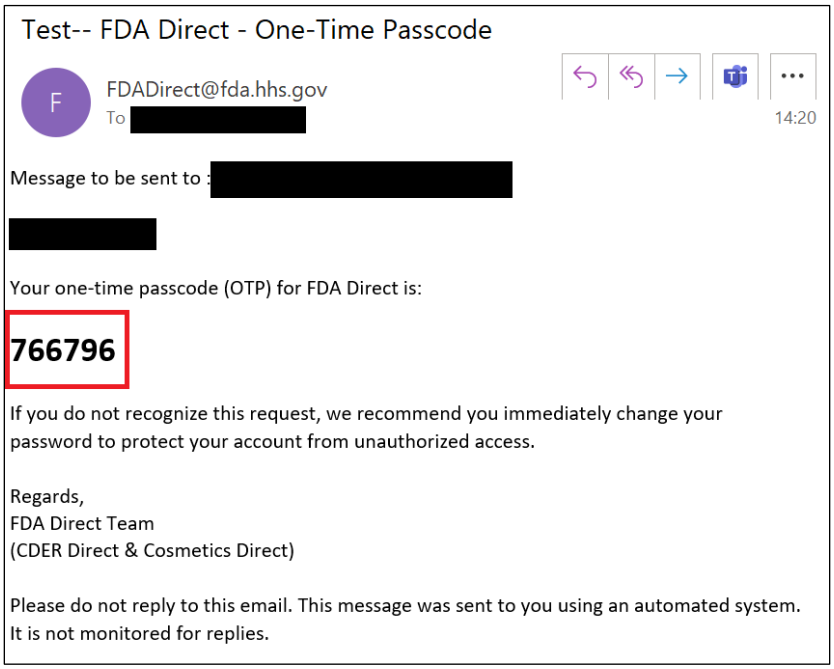


12. The FDA uses **MFA (Multi-Factor Authentication)** for security verification. The 'Verify Email Address' screen below will only display once, immediately after your initial login to your new account:



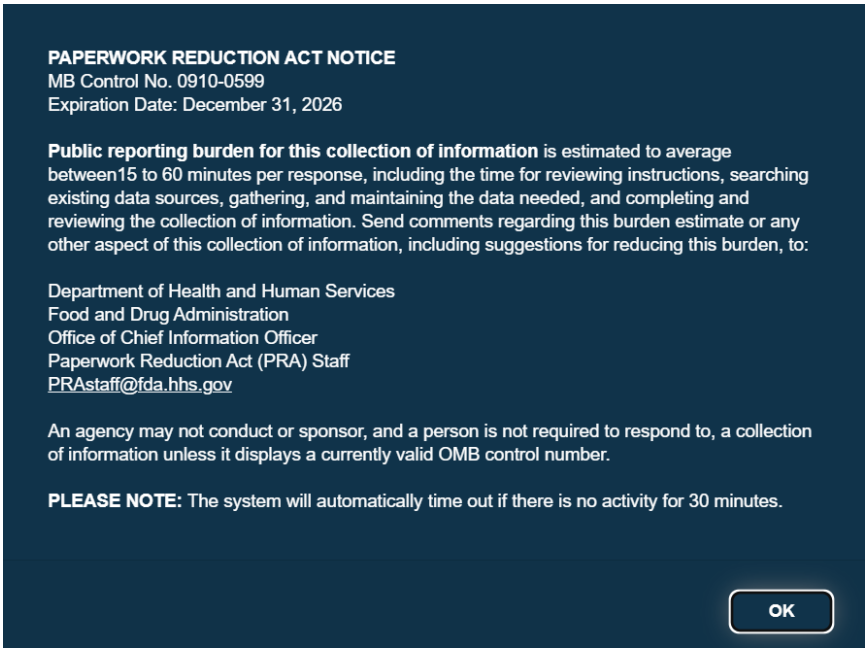
***Click the pencil icon beside your email address to update your email address, or change it later in the Account Management settings (see Section 2.4)**

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

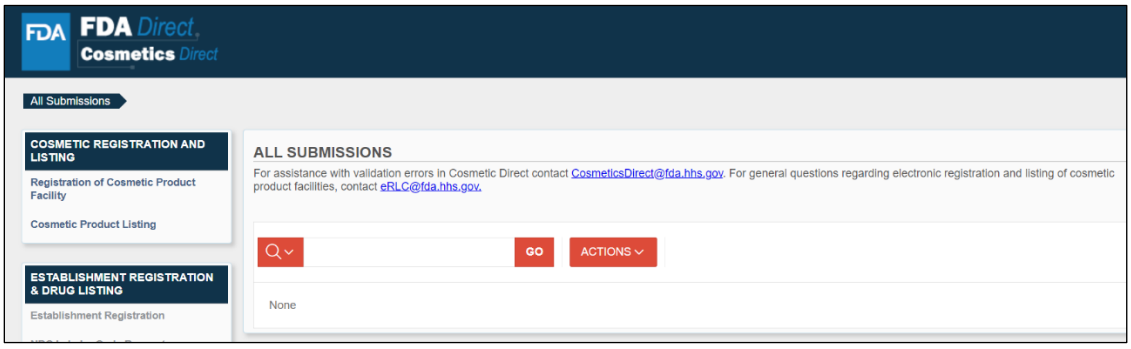


14. Enter the passcode from your email into the OTP field:

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



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

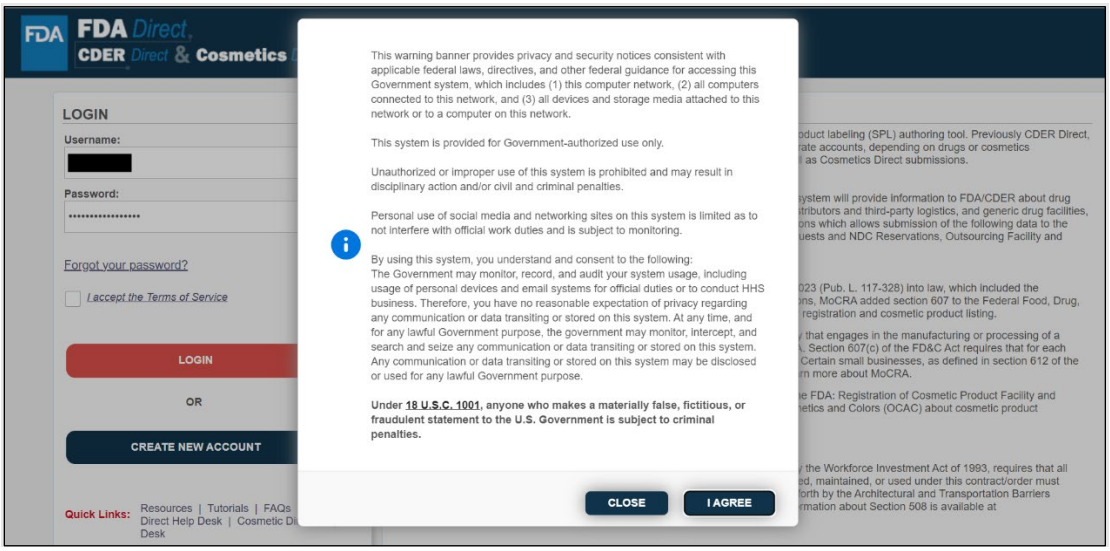


2.3 Account Login

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

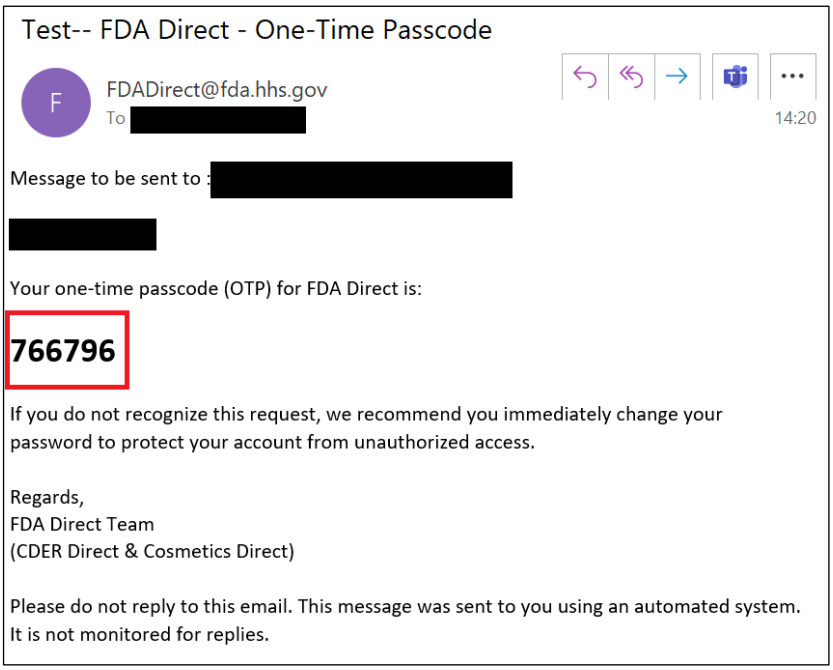
To log in to FDA Direct and access your account:

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

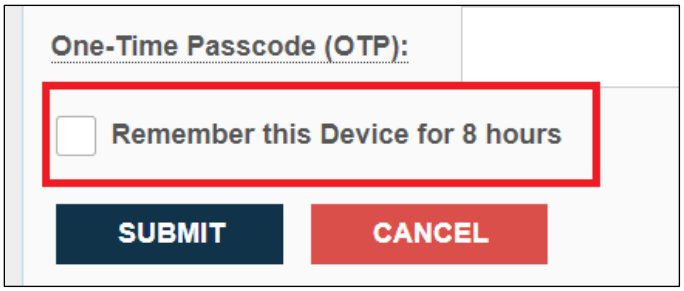


3. Click the 'Login' button. If this is your **first time logging in for the day**, you will be redirected to the 'Verification Code' page:

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



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



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

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

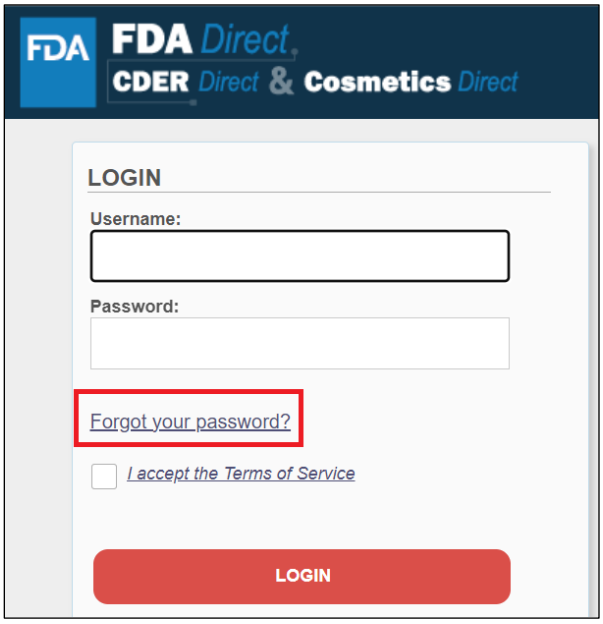
6. Click '**Submit**.' You will then be taken to your account main page.
7. If you have a Cosmetics account or a Combined account, a Paperwork Reduction Act (PRA) banner will display. Click '**OK**' to continue.

   You are now logged in to your account.

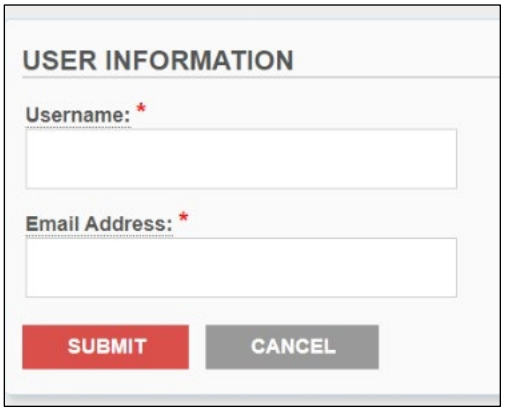
2.3.1 Forgot Password

If you forgot your password, do the following:

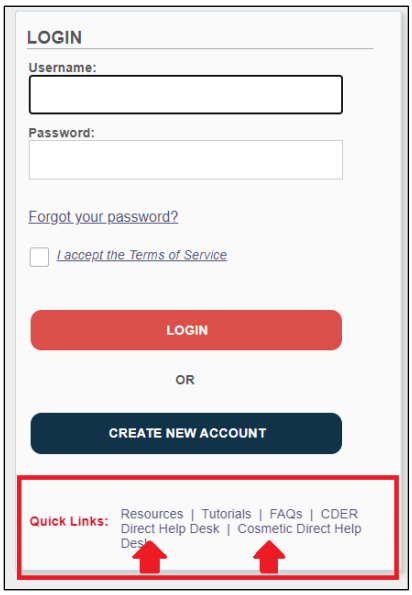
1. Go to the FDA Direct homepage (http://direct.fda.gov/) and click '*Forgot Password*':



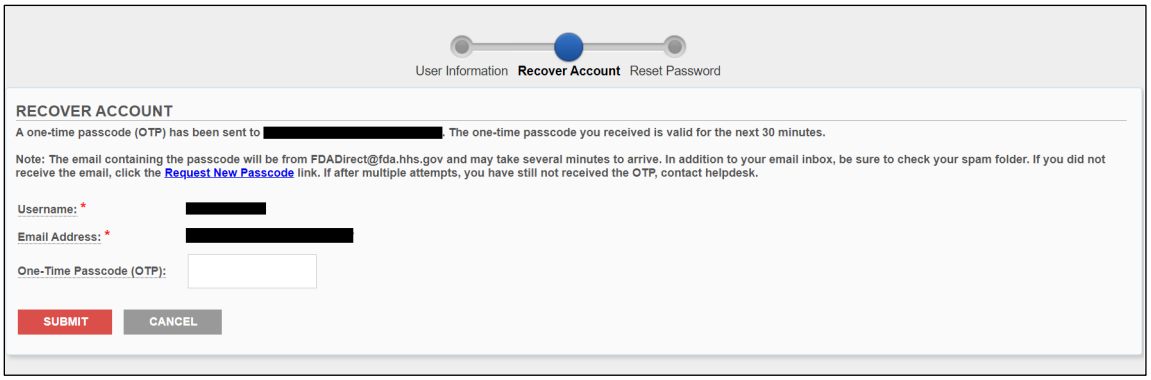
2. Enter your username and your email address in the next page:



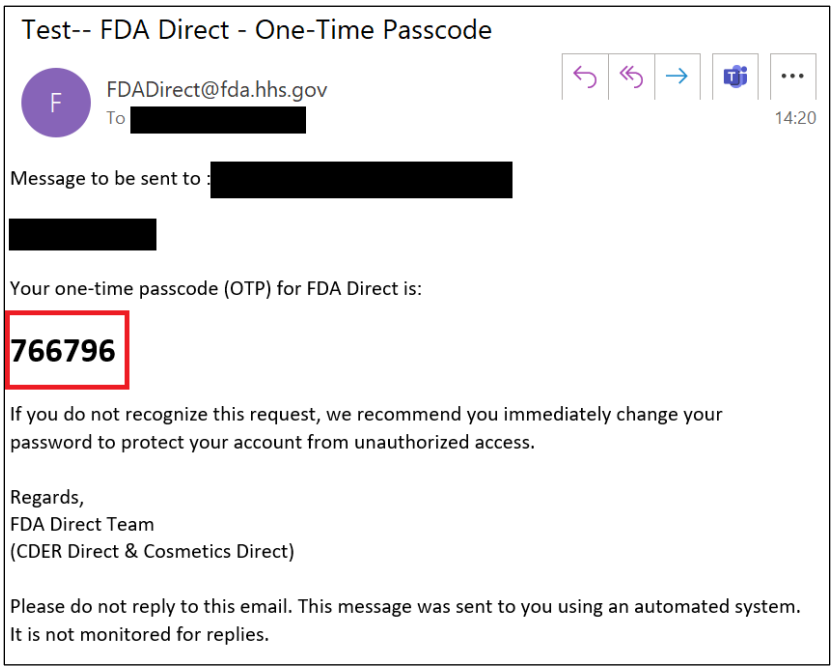
IMPORTANT: If you do not remember one or both of these details, you must contact the Help Desk by returning to the FDA homepage and clicking one of the Help Desk links in the ***Quick Links*** section:



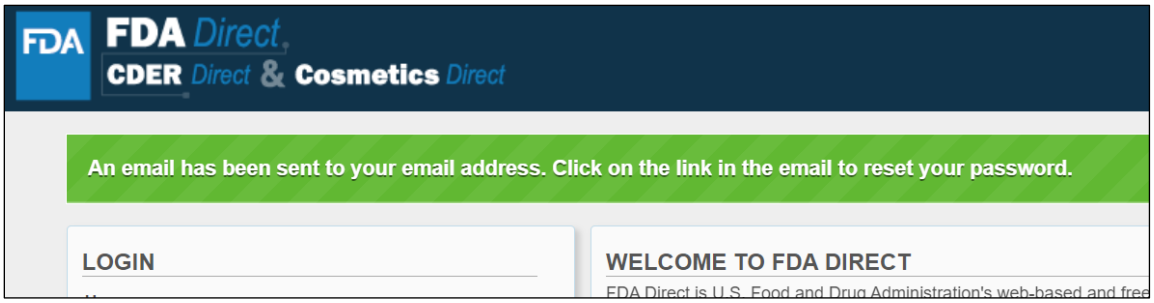
3. On the 'Recover Account' page, you will be notified that a One-Time Passcode (OTP) has been emailed to the email address associated with your account:



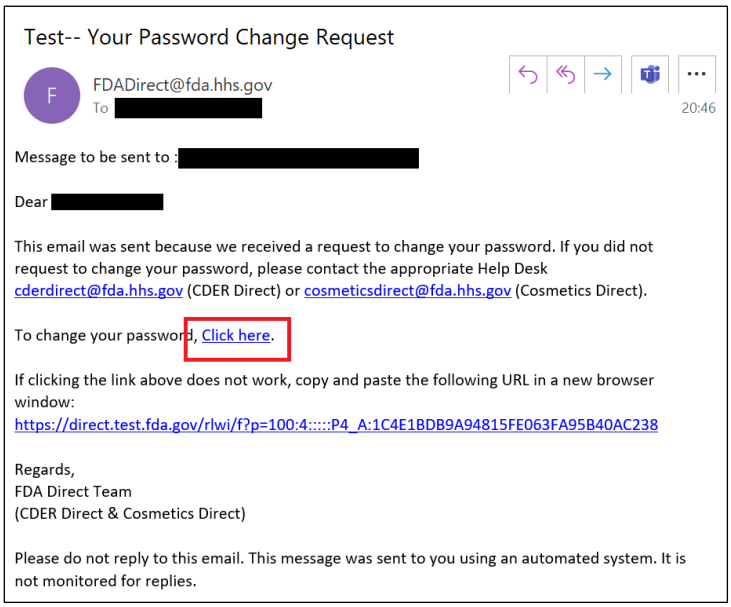
4. Check your email address for the OTP. If you have not received an email after several minutes, you can click the '**Request New Passcode**' link (shown above) to send another code.



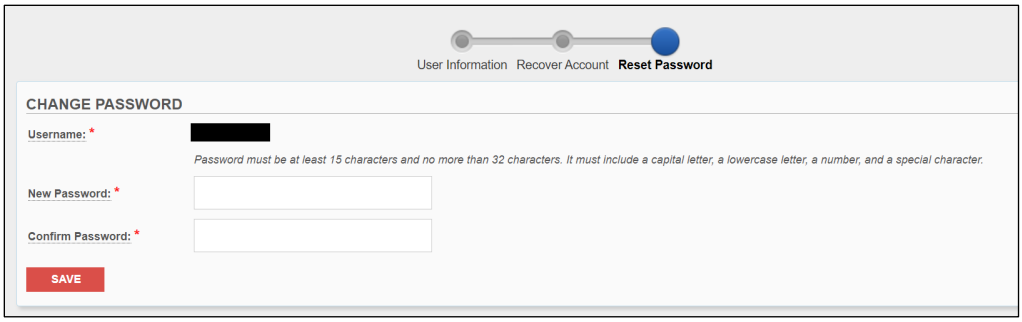
5. Enter the OTP and you will be returned to the FDA homepage with a confirmation notice:



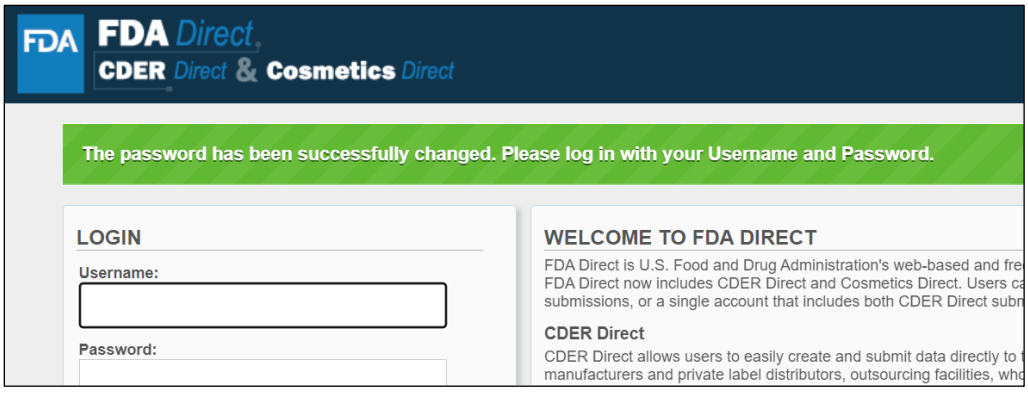
6. Check your email inbox for the reset email and click the link to reset your password:



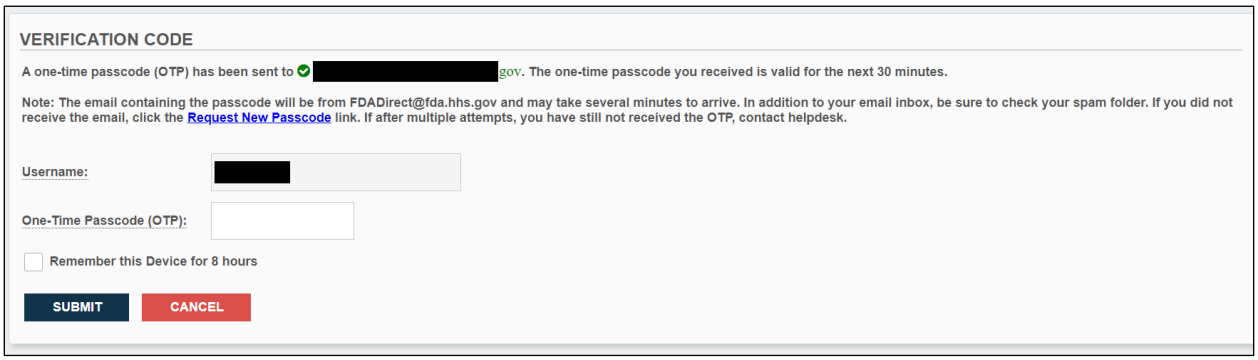
7. Enter a new password in the 'Reset/Change Password' then click '**Save**':



8. Another confirmation will display:



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

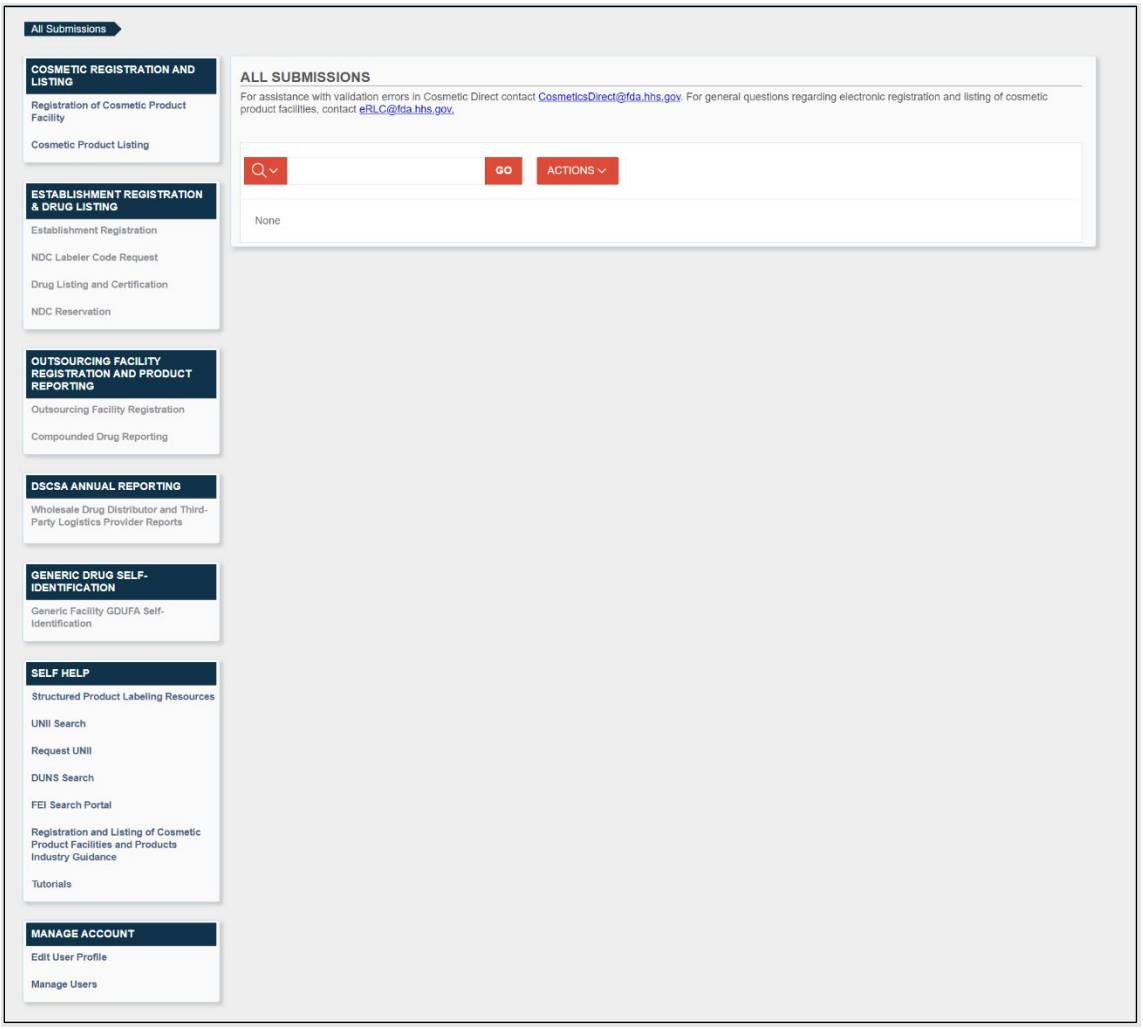


10. Check your email one last time for a One-Time Passcode. Enter the passcode from that email, check the '*Remember This Device For 8 Hours'* box, and finally click '**Submit**.'

    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:

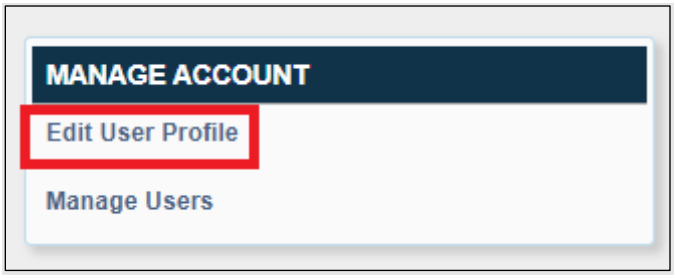


- The left menu displays all available submission forms in FDA Direct. Access to certain forms is limited based on both your account type (Cosmetic/CDER/Combined) and any de-selections made in Section 2.2: Account Creation. Greyed out areas of the menu indicate you do not have access to a particular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

2.4.1 Edit Profile

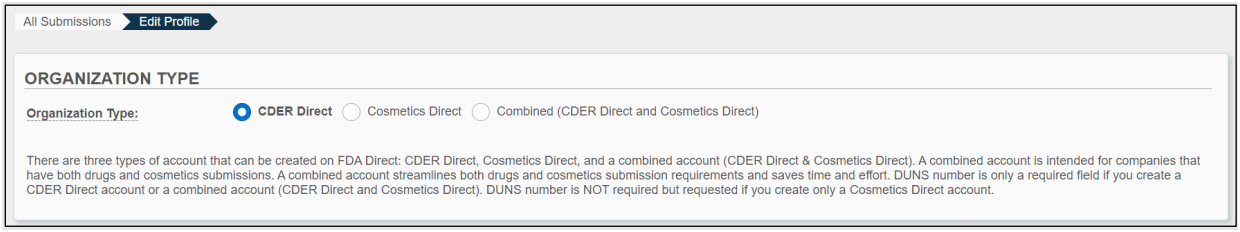
To change your account type (Cosmetics Direct, CDER Direct, or Combined) log in to FDA Direct.

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



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

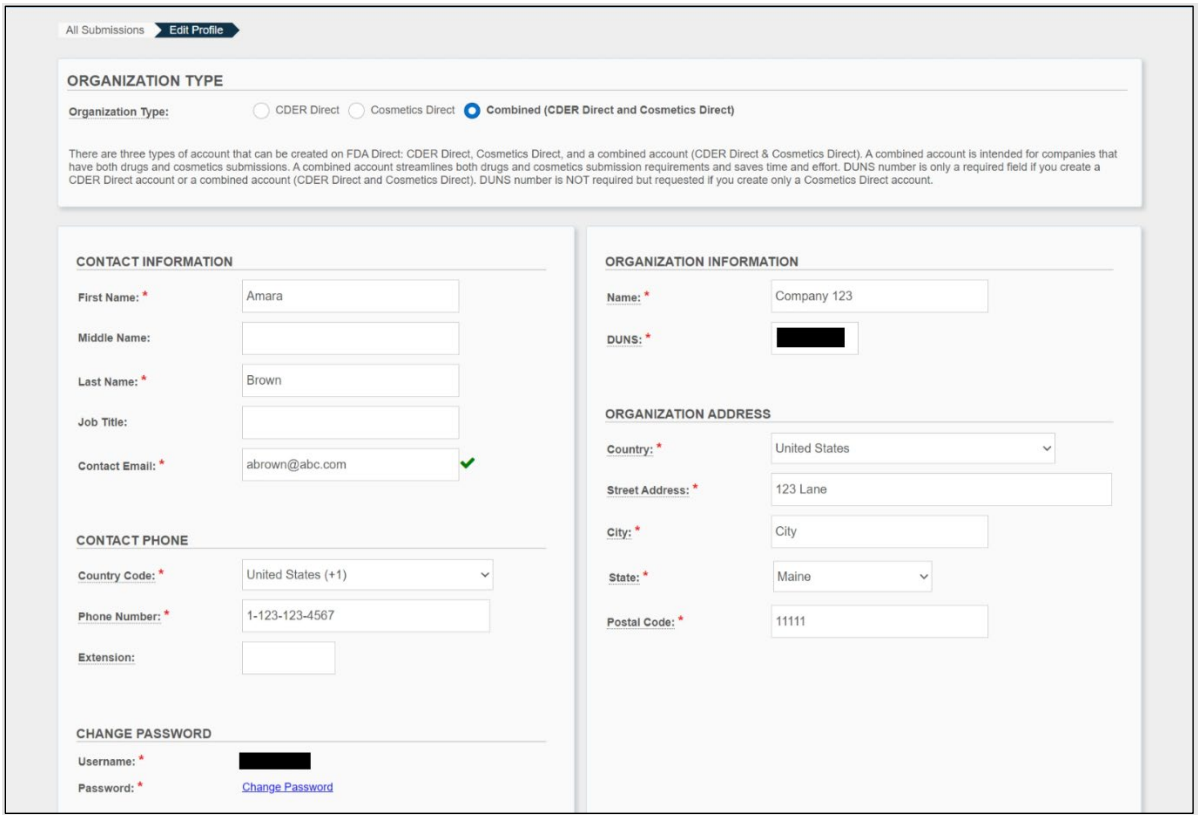
Select the desired account type:



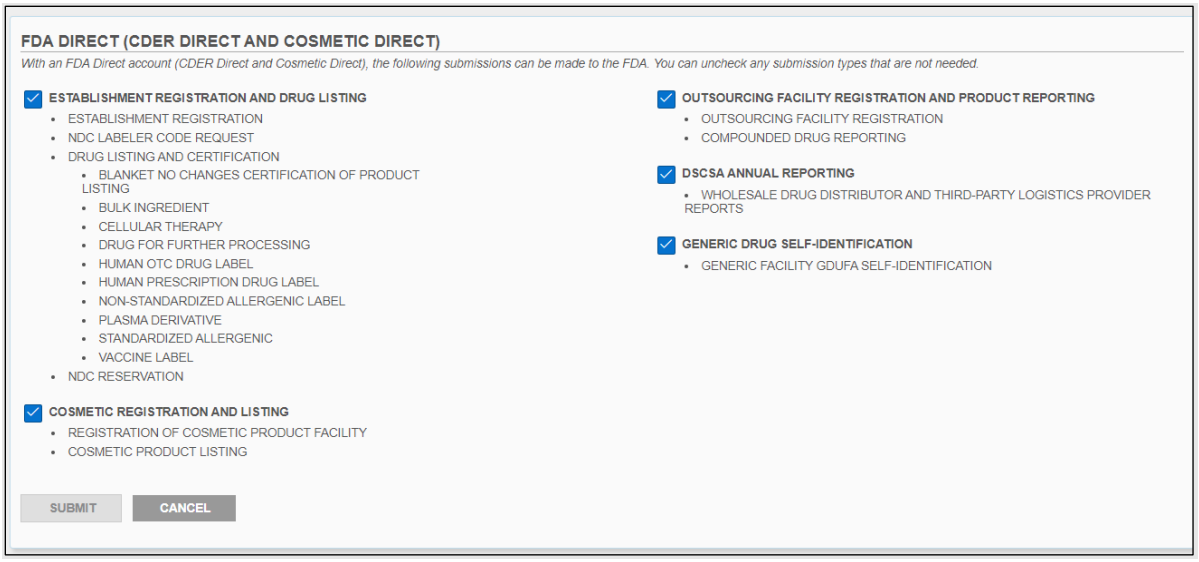
***If you are converting from a Cosmetics Direct account to a CDER Direct or Combined account, you must enter a valid DUNS number to successfully switch accounts.**

You can modify the following in the next section:

- Contact Information
- Organization Information
- Account Password



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



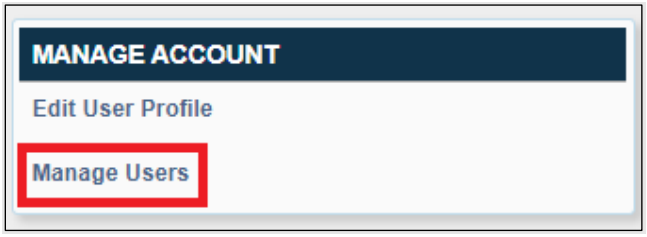
Click '**Submit**' to finalize all changes made, or '**Cancel**' to abandon your changes.

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.

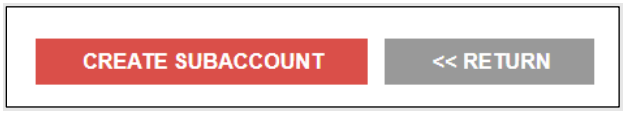
Log in to FDA Direct. Scroll to the bottom of your account main page and select '**Manage Users**' under the Section 2.4: Account Management section:



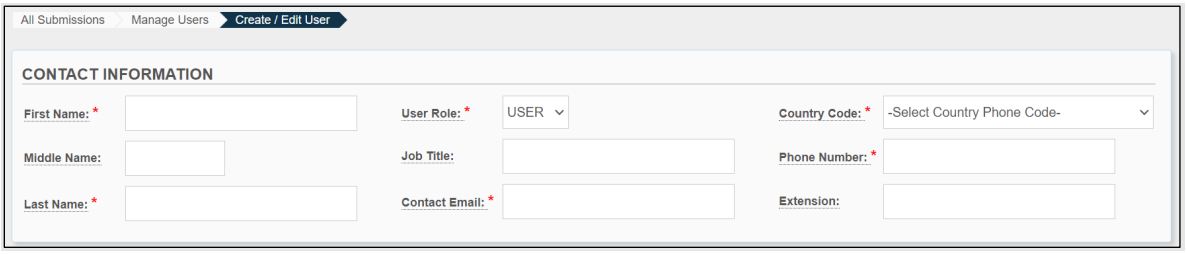
If you have already created subaccounts, they will display in a list. Otherwise, the page will be empty:

2.5.1 Creating A Subaccount:

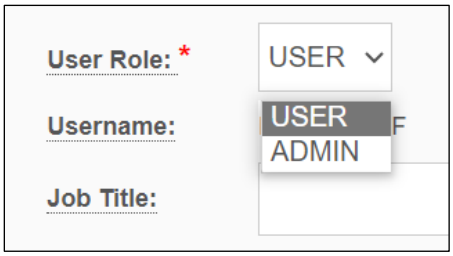
1. Click the '**Create Subaccount**' button



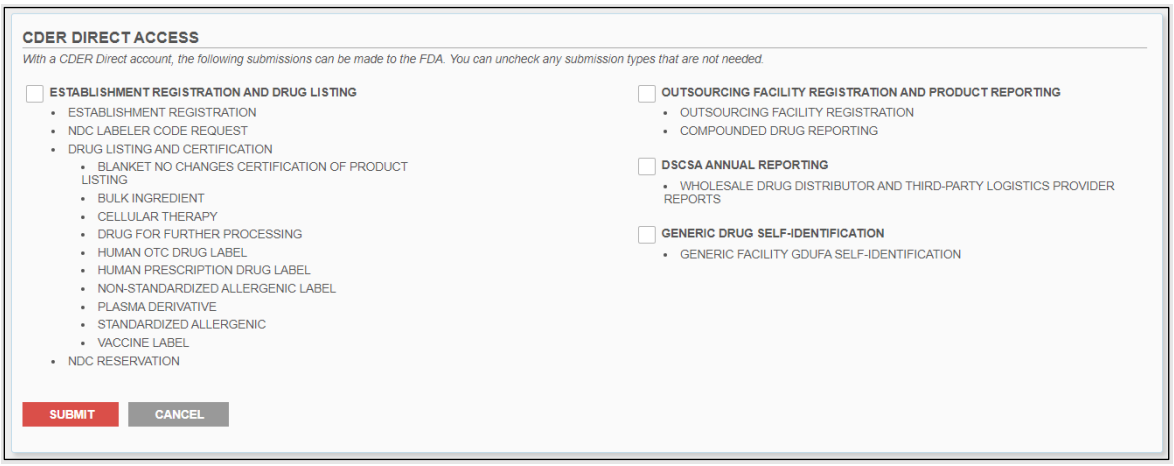
2. Enter all required fields for the subaccount user:

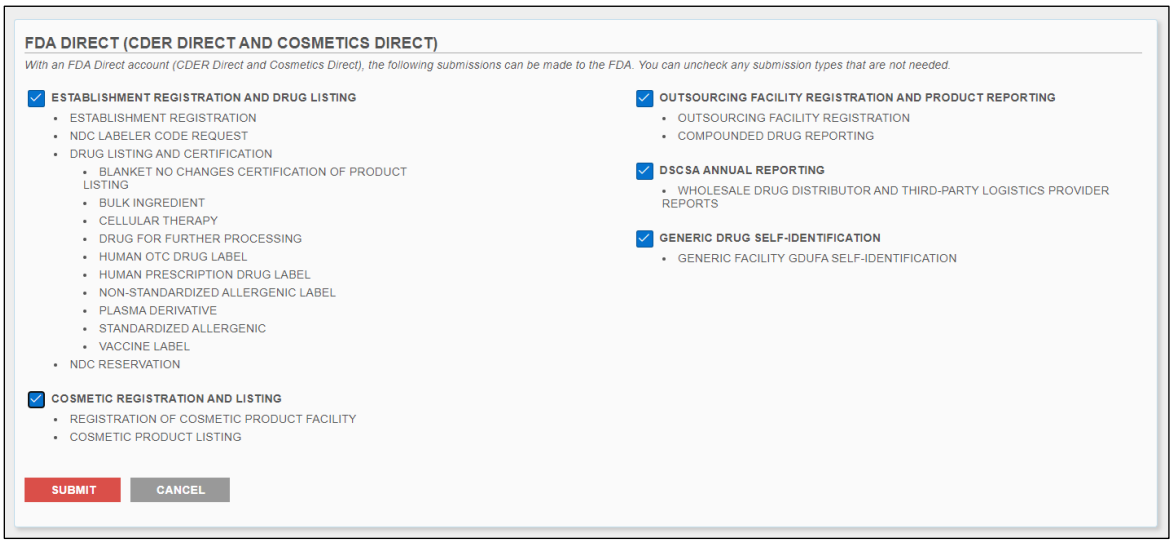


3. Select the '**User Role**' dropdown. This will determine whether the subaccount will have full access (Admin) or limited access (User).

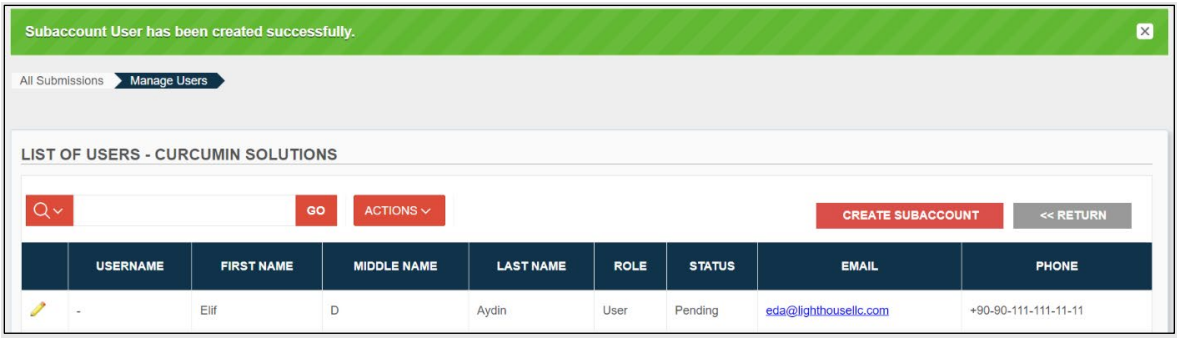


4. Select which forms the subaccount will have access to. This view will differ based on your organizational account type, which is modifiable in Section 2.4.1: Edit Profile. Click the form checkboxes then click '**Submit**.'





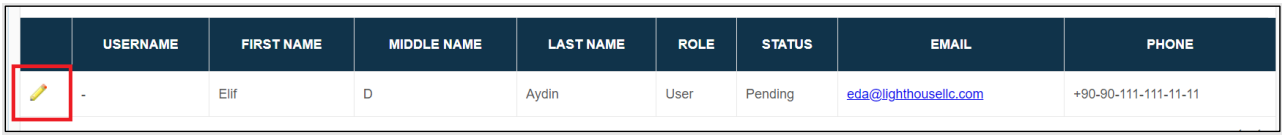
5. Subaccount creation confirmation will display at the top of the page, and the new user will be listed immediately:



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

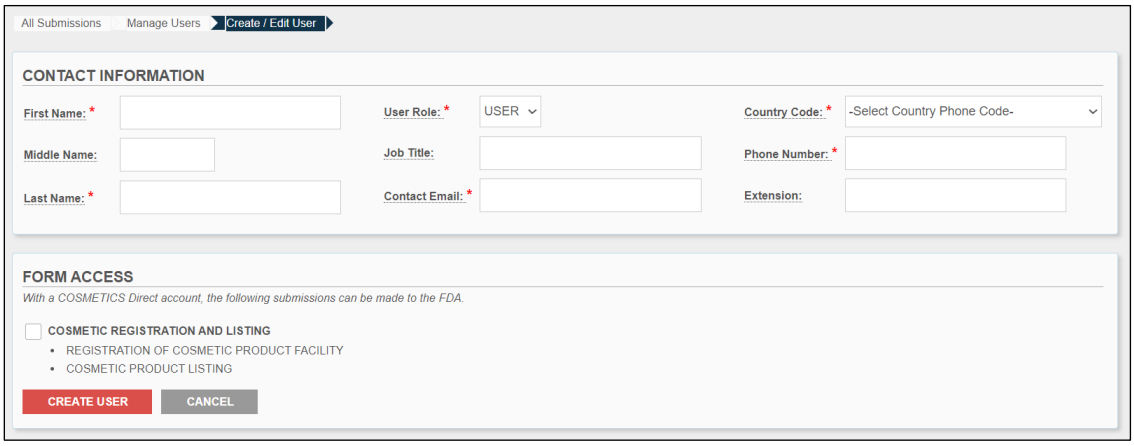
2.5.2 Managing A Subaccount

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:

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:

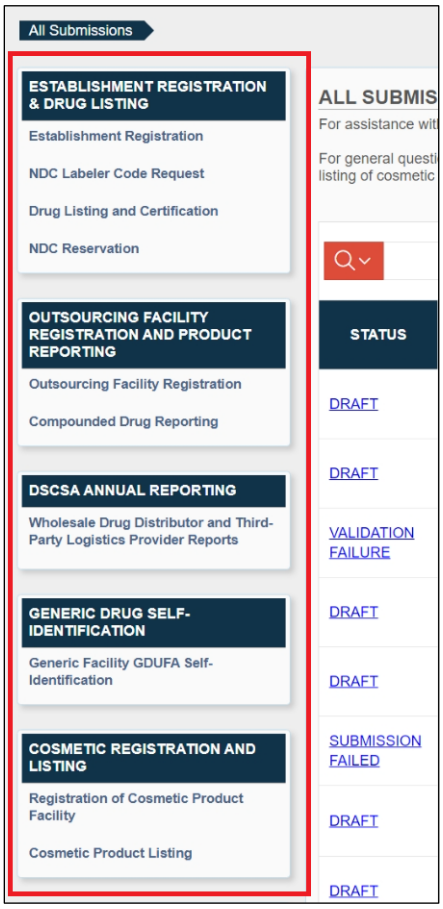
   c. Make any necessary changes, then return to the top and click '**Submit**.'

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

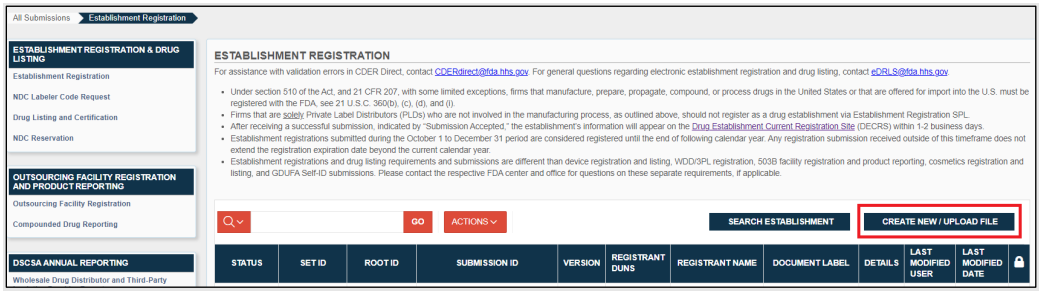
   Recommended if you already have a completed SPL submission file that is ready for submission to the FDA. The file must be in XML format and compressed into a zip file. Changes can be made to the file once it has been uploaded to FDA Direct.

   To upload a completed file into FDA Direct:

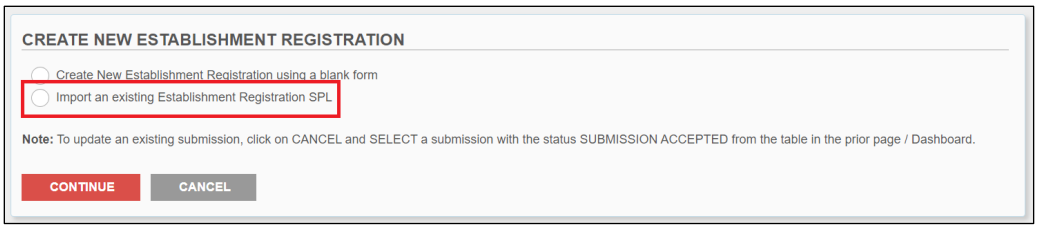
   a. Select your submission category from the menu on the left:



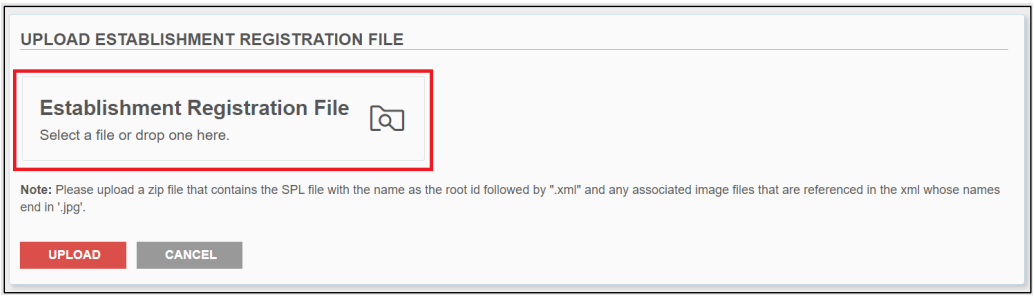
   b. Click '**Create New/Upload File**':



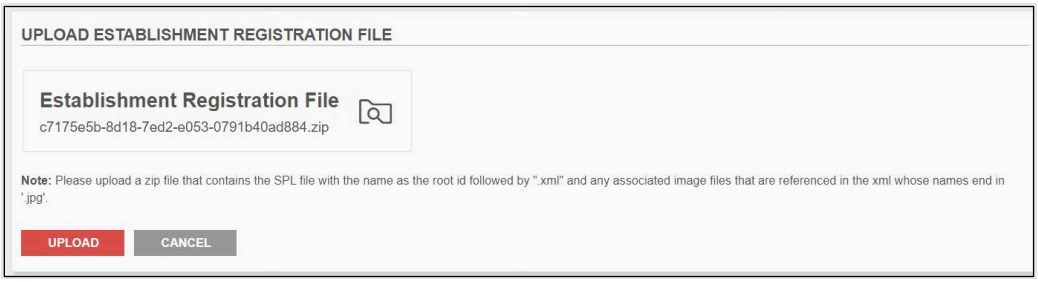
c. Select the '**Import an existing**' option then click '**Continue**':



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



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



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

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

3.2 Submission Statuses

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

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

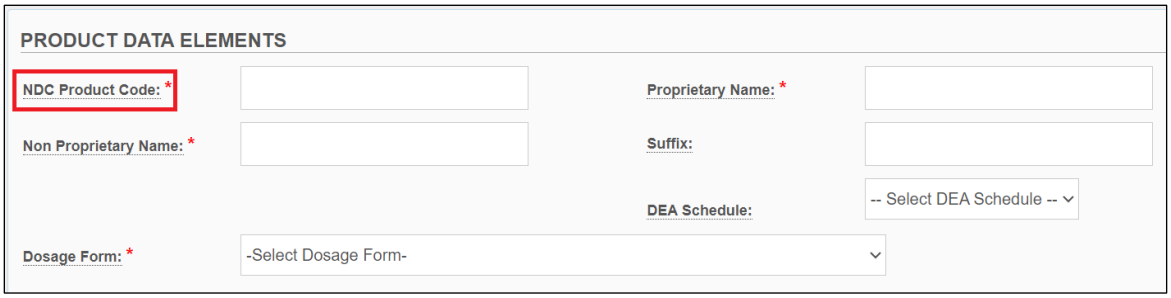
At the top of every submission is a pre-generated set of information:

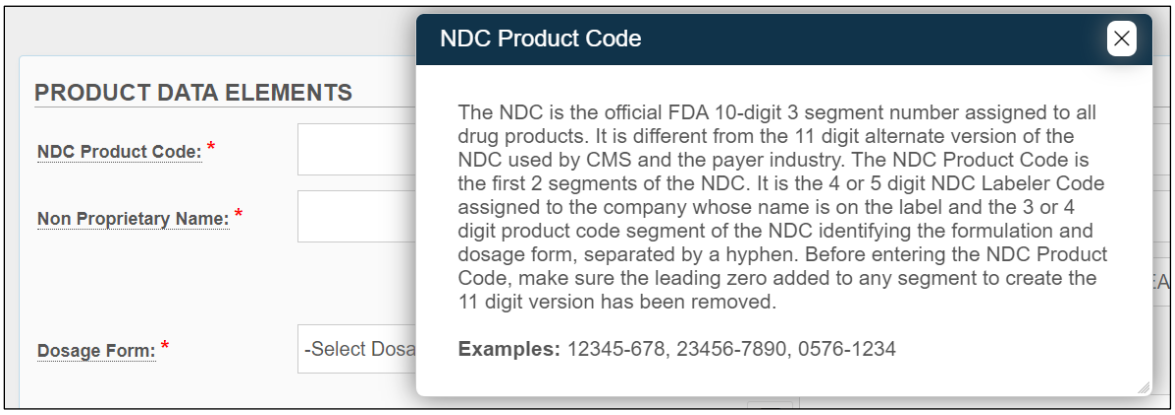
1. Set ID: A 'Globally Unique Identifier' (GUID) that remains the same for each submission 'set,' which is a group of submission versions. When you submit a different version of a submission, the set ID stays the same through each new version.
2. Root ID: A GUID that is generated uniquely for every single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

3.4 Submission Help

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

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



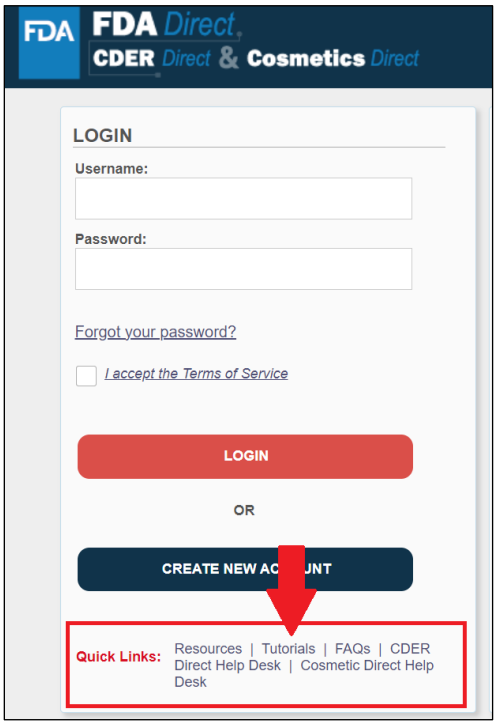


2. Tutorials/User Guide: This User Guide provides complete and detailed information on all aspects of FDA Direct. It is recommended for first-time users of FDA Direct.

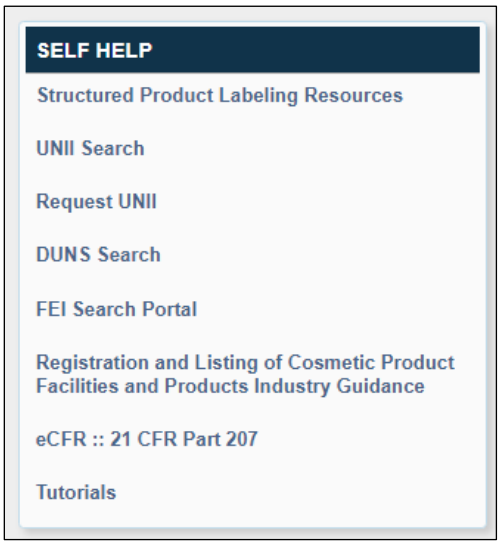
   Tutorials will show you how to complete specific actions like creating an account or submitting a drug product listing. They are less detailed than this User Guide, and in slideshow format. Recommended for users familiar with FDA Direct who may want a quick refresher.

   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).

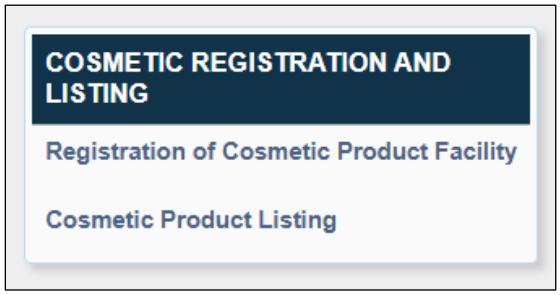
4 COSMETIC REGISTRATION AND LISTING

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. To learn more about MoCRA, visit https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022-mocra.

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



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

4.2 Document Types

4.2.1 Registration of Cosmetic Facility

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

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

  - **PLEASE NOTE:** Cosmetic Facility Registration (Initial) is preselected when entering the SPL application.
  - **Additional note**: On November 8, 2023, FDA issued a guidance for industry titled "Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing." This guidance explains that FDA does not intend to enforce the requirements under section 607 of the FD&C Act related to cosmetic product facility registration until July 1, 2024.

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

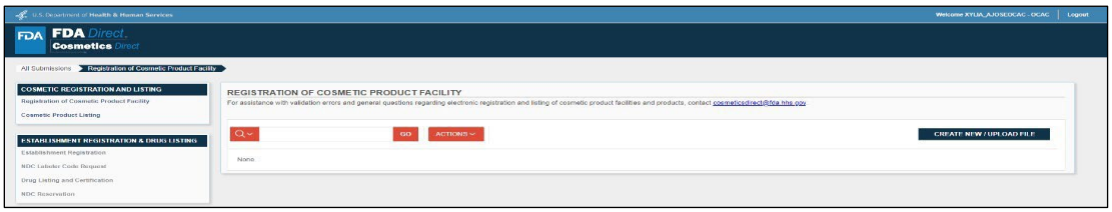
4.2.2 Cosmetic Product Listing

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

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

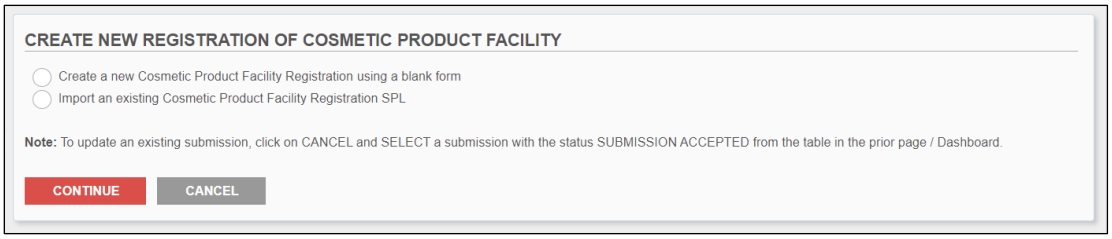
4.3 Registering a New Cosmetic Product Facility

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

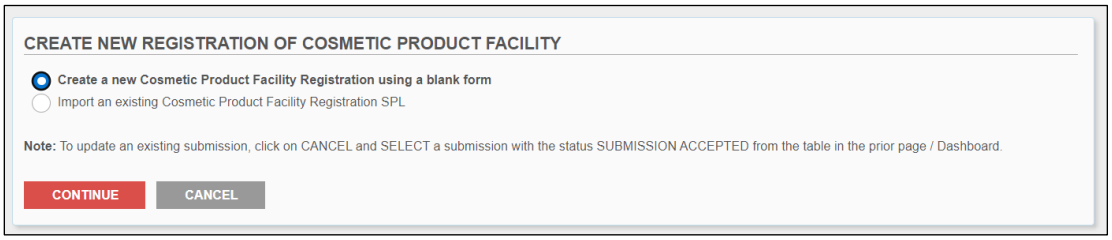


3. Click '**Create New/Upload File**':

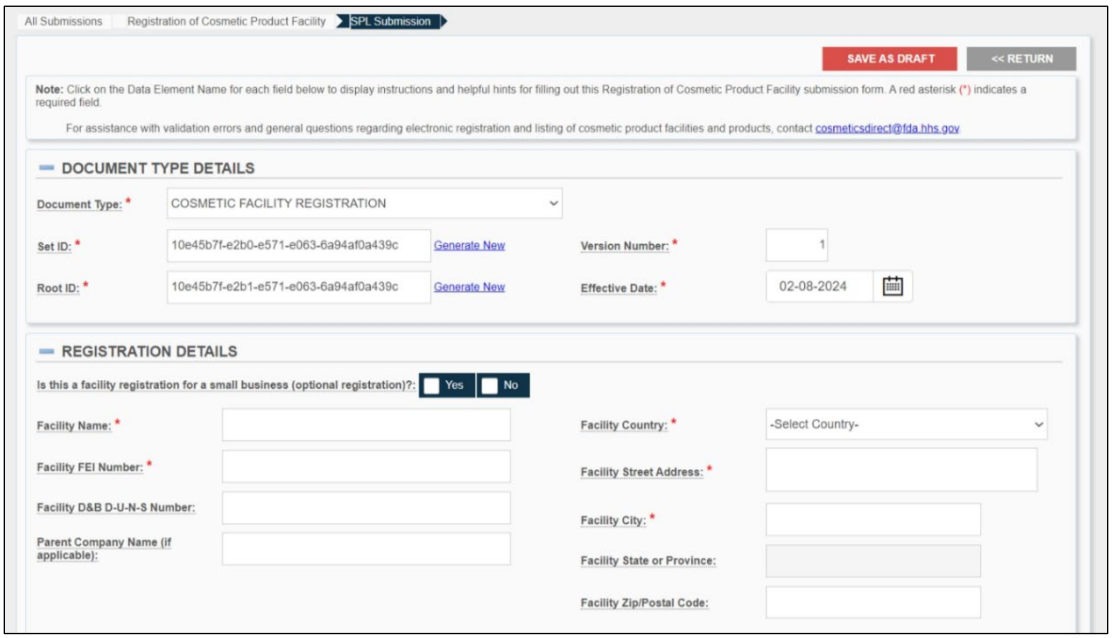
You will be given two options:



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

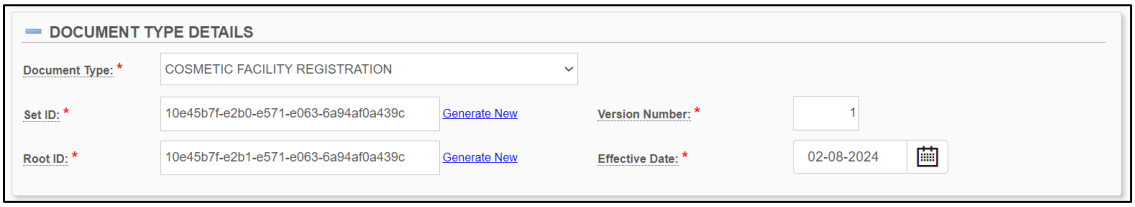


5. A blank template will display with required fields marked with a red (*) and optional fields:



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.

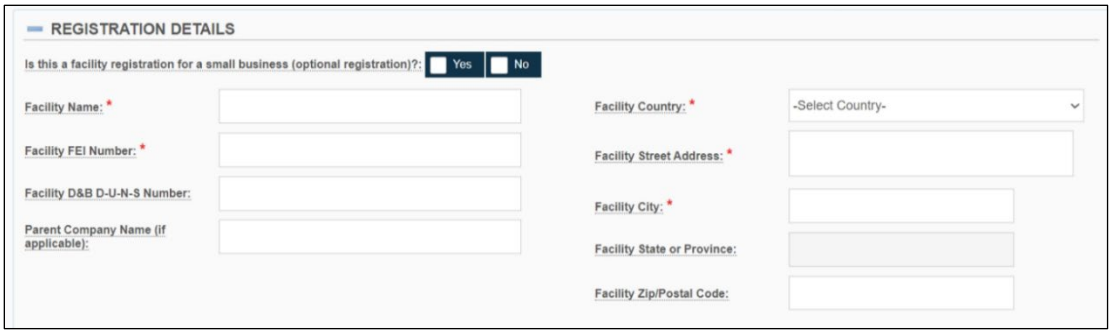
a. Set ID*: **This field is auto generated by the system.** The Set ID uniquely identifies a group of versions of an SPL submission. When an SPL submission changes, a new Root ID is assigned to the new SPL submission, but the Set ID in the original SPL submission also is used. The Set ID is a Globally 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.

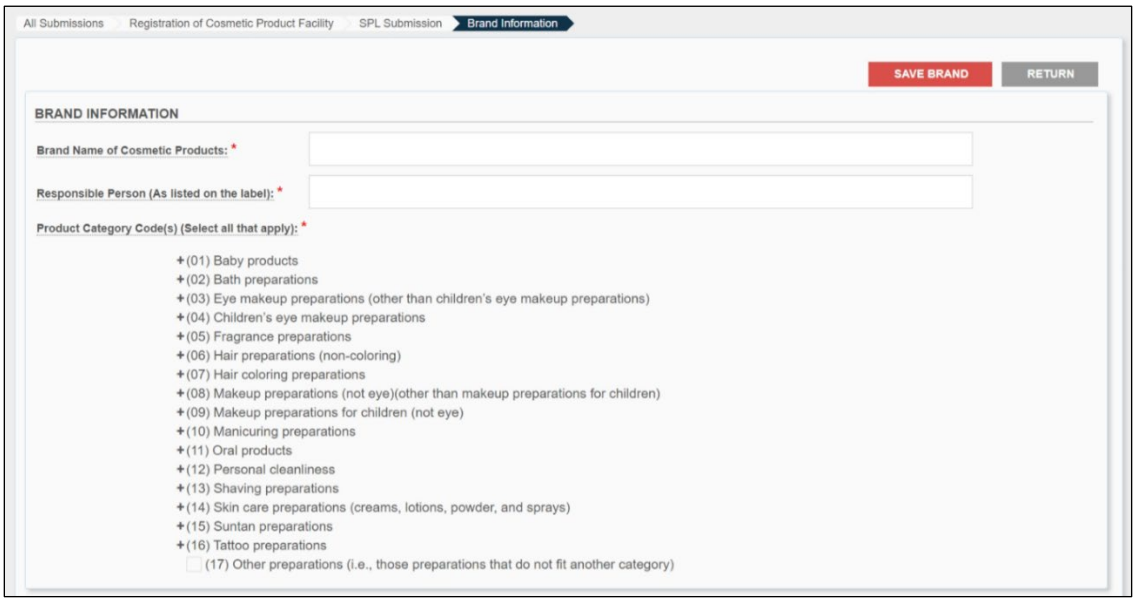
c. U.S. Agent Phone Number (Include Country/Area Code) *: For foreign facilities, enter the U.S. agent telephone number including the country code and the area code. The format for Phone number should be <Area Code>-<Subscriber Number>. For example, in the U.S. the phone number would be 1-999-9999999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

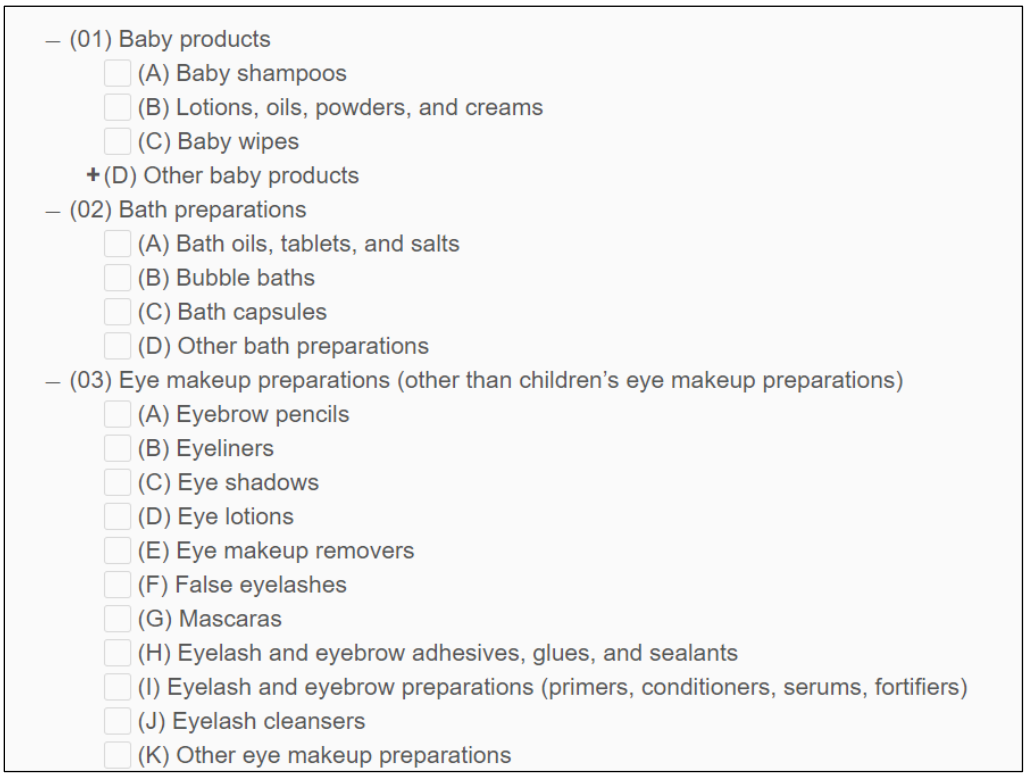


a. Brand Name of Cosmetic Product*: Enter brand names under which cosmetic products manufactured or processed in the facility are sold.

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

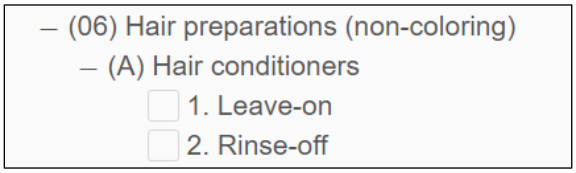
c. Product Category Code(s) (Select all that apply) *: Select the product category or categories for this brand name. Each main product category has a sub-product category. And some sub-product categories have sub-sub product categories, select the one that applies to this brand name. (i.e., leave-on 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):

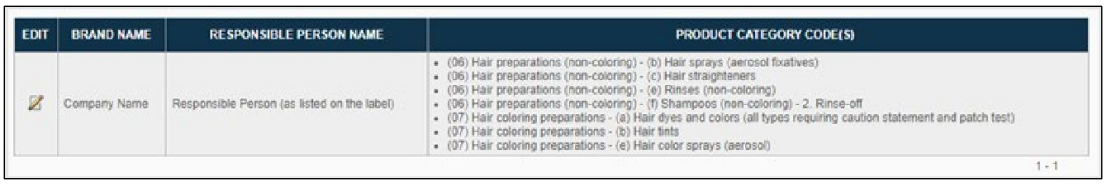
- Leave-on
- Rinse-off



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

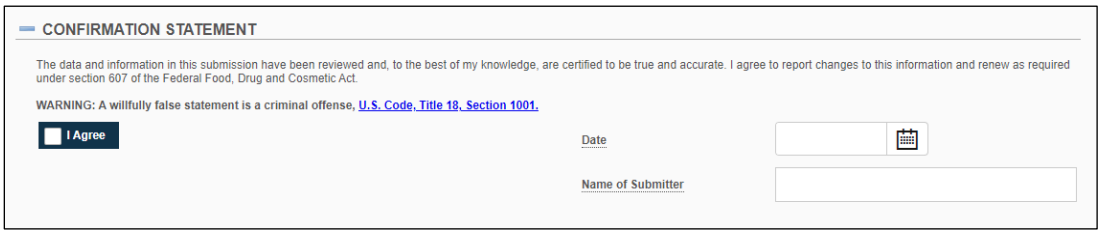
15. The platform will return to the SPL Submission page with the verification banner 'Product brand saved.'

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.

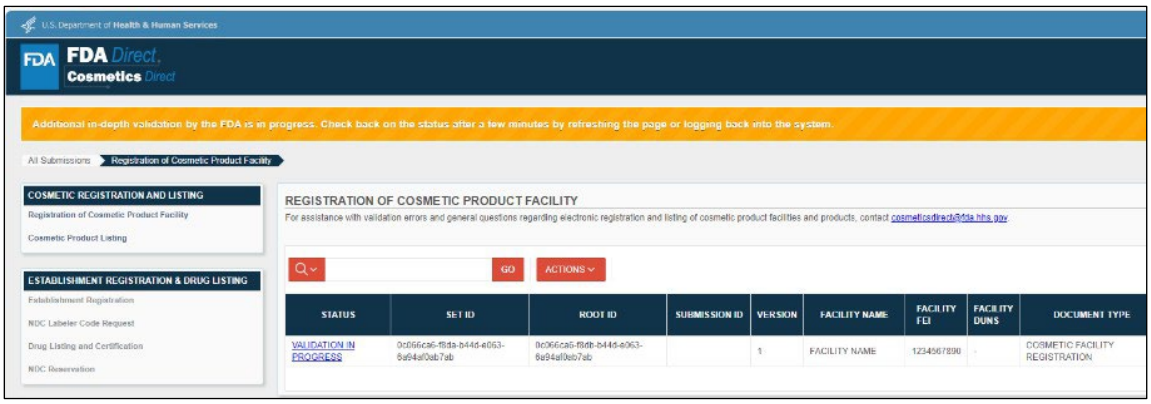
d. '**DELETE**'

- Delete will remove the submission from your account.

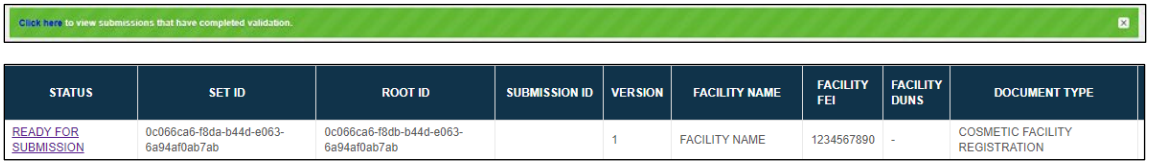
21. Click '**RETURN**' at any time to return to the Registration of Cosmetic Product Facility main page.

4.3.1 Save and Validate

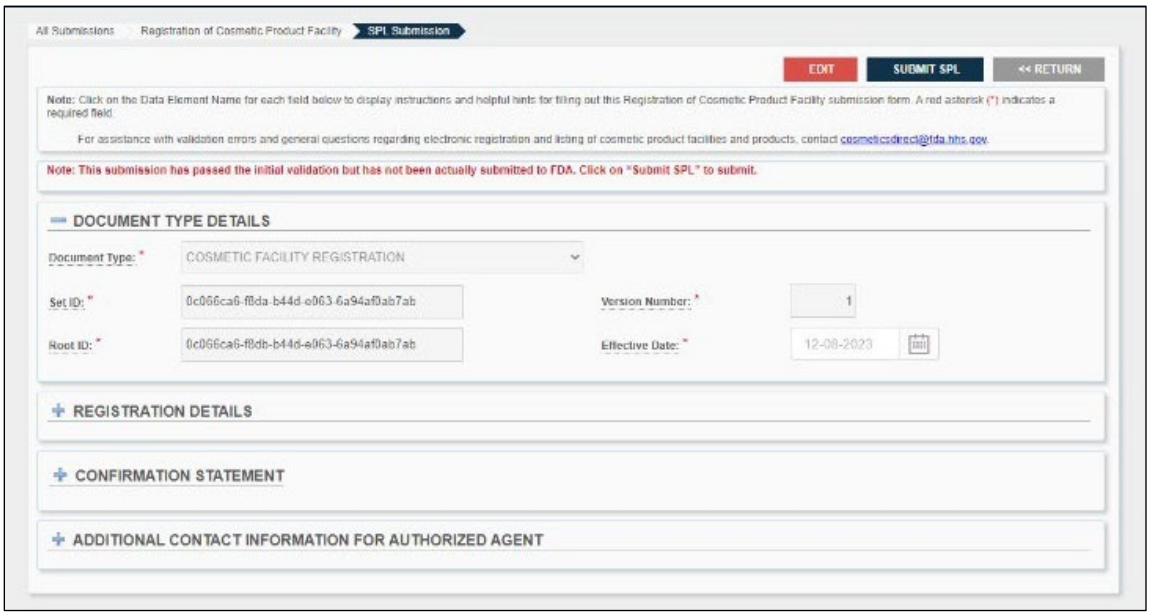
1. Click '**SAVE AND VALIDATE**' if you want to check for errors within your SPL. To submit your SPL to FDA, skip to Section 4.3.2: Submit to FDA.
    a. **PLEASE NOTE:** This option is only for an initial validation of your SPL before submitting to FDA. It does not automatically submit your SPL to FDA,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



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



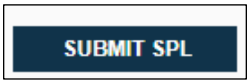
    a. If the system finds any errors, the status field will change to '**VALIDATION FAILURE**', see Section 4.3.5: Validation Failure for additional details.
4. Click '**READY FOR SUBMISSION**', the homepage will change to reflect the following:



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

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



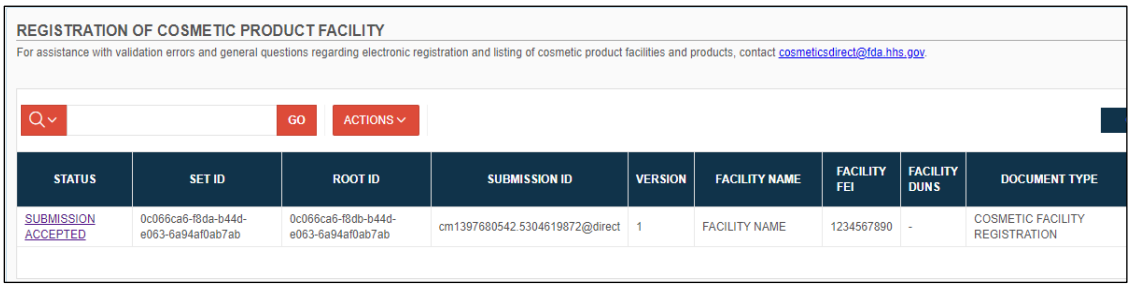
a. A green message will appear across your screen stating, "Your submission has been sent to FDA for additional validation and processing. Check the status of your submission after a few minutes by refreshing the page or logging back into the system. You will also receive an email from FDA when the processing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

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

4.3.3 Submission Accepted

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

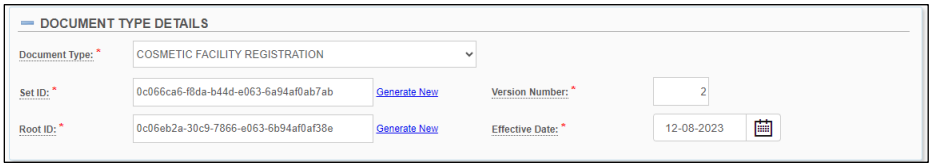
   Please Note: A '**SUBMISSION ID**' does not always mean that the submission was in fact accepted by FDA. The '**Submission ID**' will also appear with '**Awaiting Acceptance**' and '**Submission Failure**.'



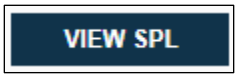
2. Click on '**SUBMISSION ACCEPTED**' to **VIEW SPL** and **DOWNLOAD SPL**.

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

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

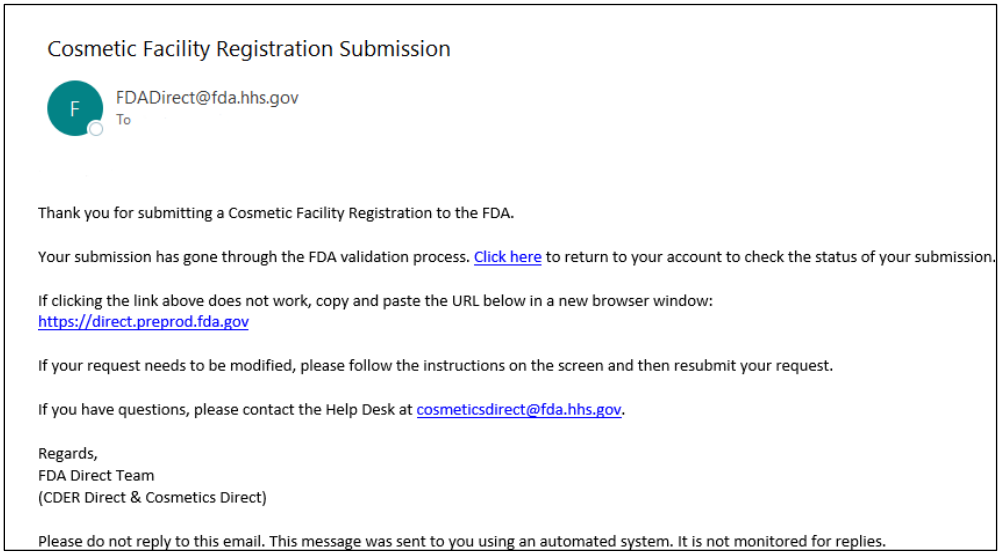


b. To view your SPL, click '**VIEW SPL**'



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.

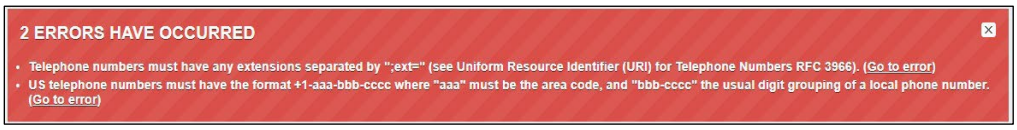
e. A '**SUBMISSION ACCEPTED**' status will appear in the status column of your SPL submission if it has been successfully submitted to the FDA. At this point, the process is finished and there is no further action needed unless you need to make any changes to your registration.

4.3.4 Submission Failed

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

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

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

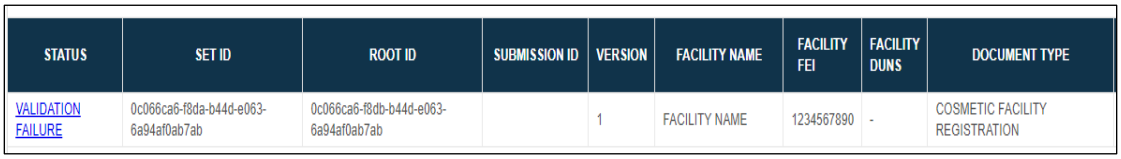


b. Submit again and your submission will once again be '**AWAITING ACCEPTANCE**.'

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

4.3.5 Validation Failure

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



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

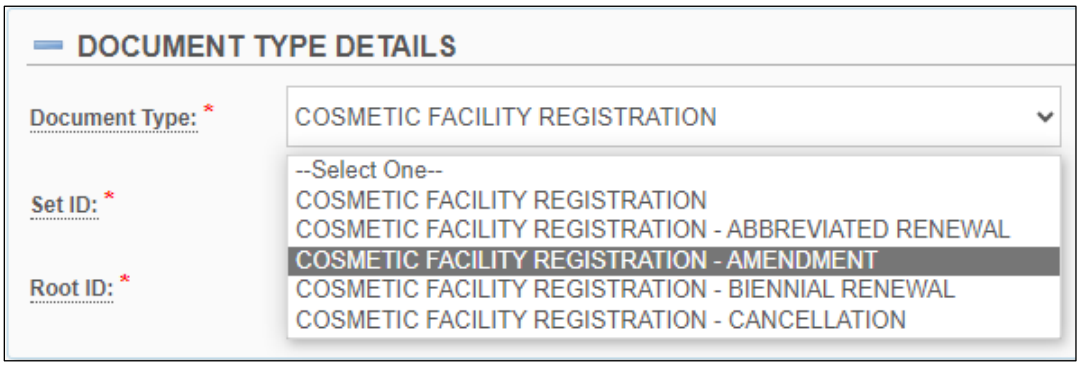
2. Click '**VALIDATION FAILURE**', the system will provide a list of errors that need to be fixed before submitting the SPL:

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

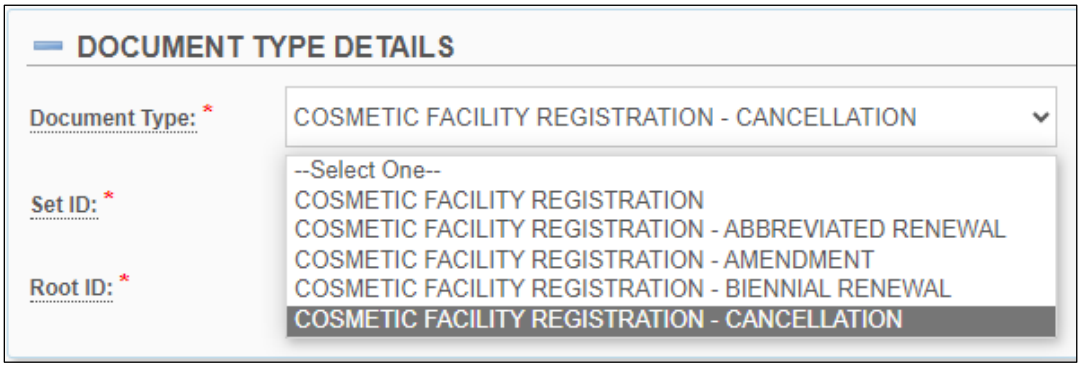


2. Repeat the steps in Section 4.3.3.
3. Refer to the steps in Section 4.3.2 for Submit to FDA instructions.

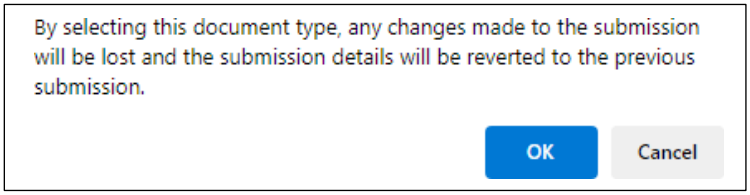
4.3.7 Amending Cosmetic Product Facility Cancellation

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**':

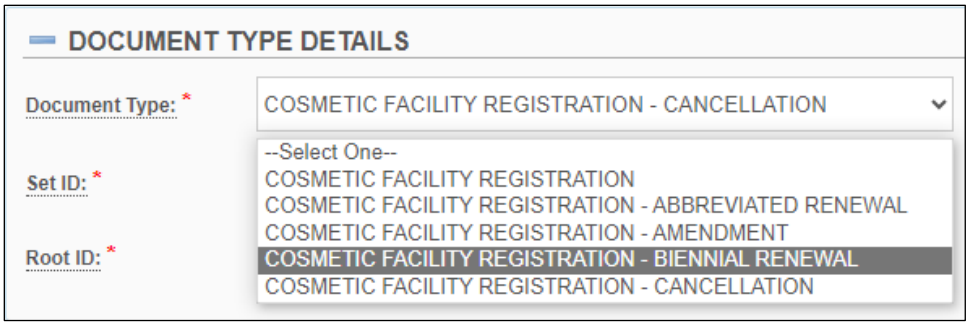


2. After selecting '**OK**', the fields for Registration Details, Confirmation Statement, and Additional Contact Information for Authorized Agent will be grayed out and can no longer undergo changes.
3. Click '**SUBMIT SPL**' to submit your cancellation request to FDA.

4.3.8 Biennial Cosmetic Product Facility Registration Renewal

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

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

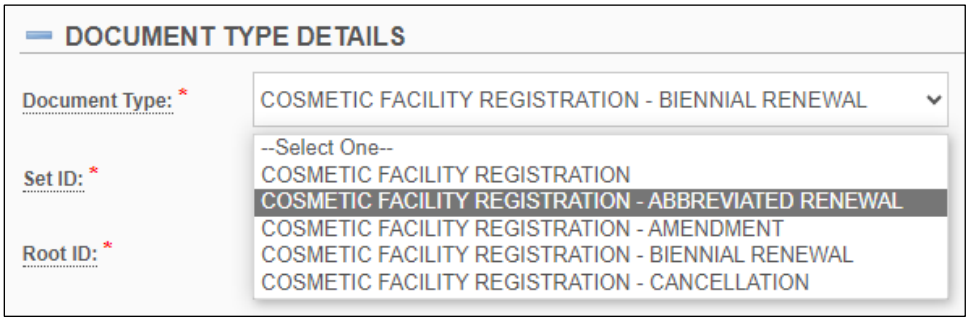


2. Repeat the steps in Section 4.3.3.
3. Refer to the steps in Section 4.3.2 for Submit to FDA instructions.

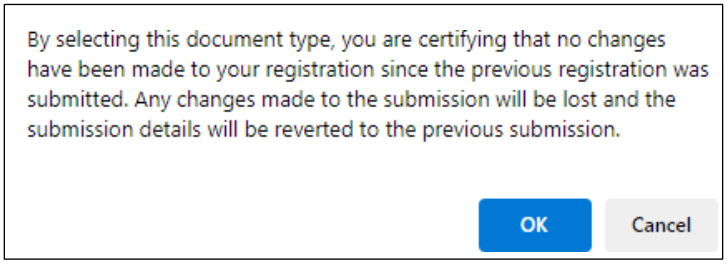
4.3.9 Abbreviated Cosmetic Product Facility Registration

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

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



   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.

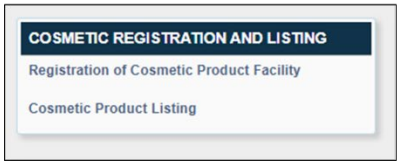


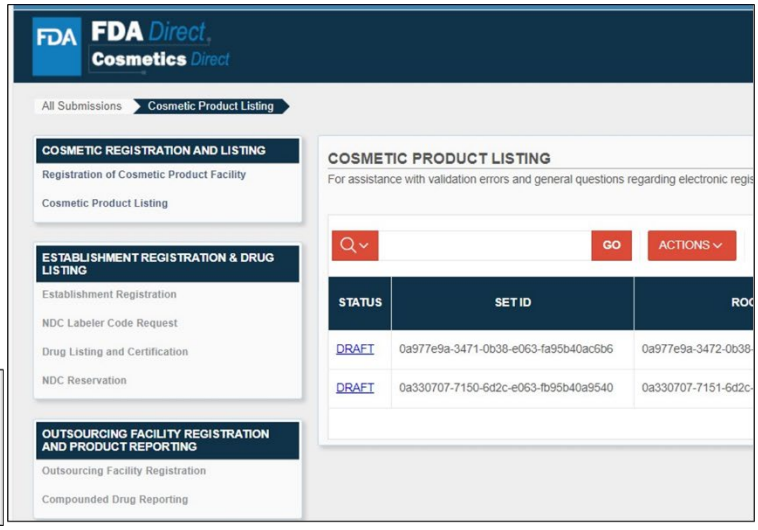
2. After selecting '**OK**', the fields for Registration Details, Confirmation Statement, and Additional Contact Information for Authorized Agent will be grayed out and can no longer undergo changes.
3. Click '**SUBMIT SPL**' to submit your request to FDA.

4.4 Cosmetics Product Listing

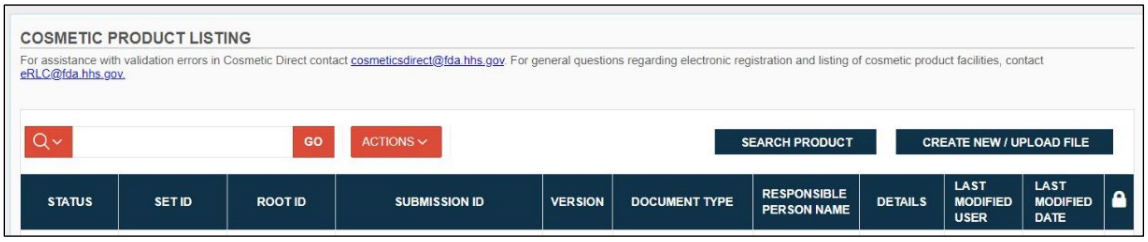
4.4.1 New Cosmetics Product Listing

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.



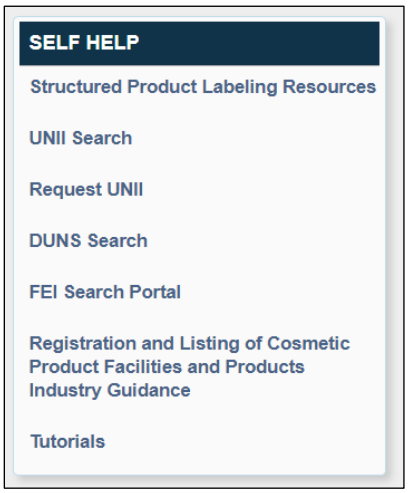


3. Navigate to the Cosmetic Product Listing Home Page AFTER selecting '**Cosmetic Product Listing**' under *Cosmetic Registration and Listing* section, on the left side of the FDA Direct menu. This will navigate the user to the **Cosmetic Product Listing Home Page**. The **Cosmetic Product Listing Home 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.

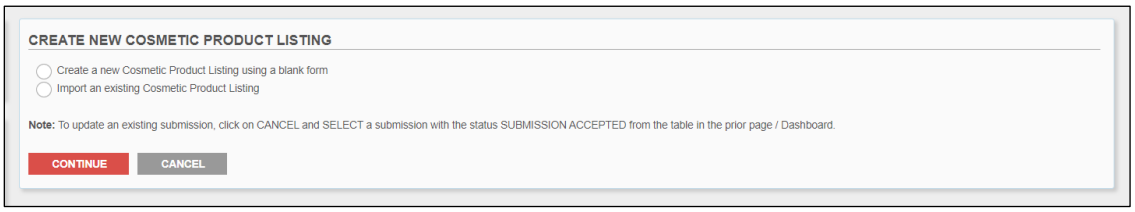
d. A product can be searched by select the **SEARCH PRODUCT** box next to **CREATE NEW/UPLOAD FILE**.

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:

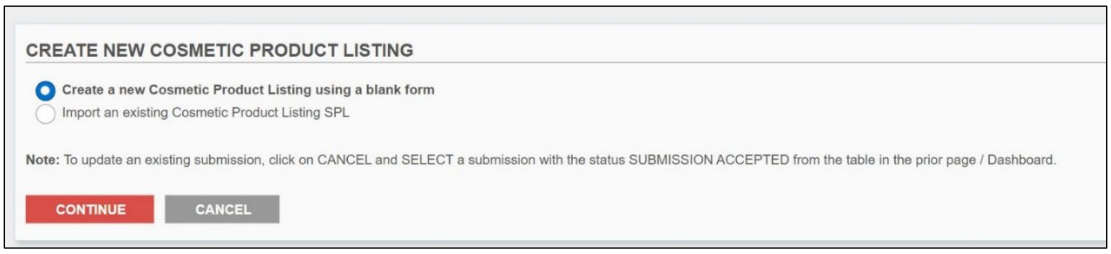
      - The facility registration number (FEI) of each facility where the cosmetic product is manufactured or processed:
        - **PLEASE NOTE:** The responsible person will need to obtain the relevant facility registration number(s) for each facility where its cosmetic products are manufactured or processed, 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:

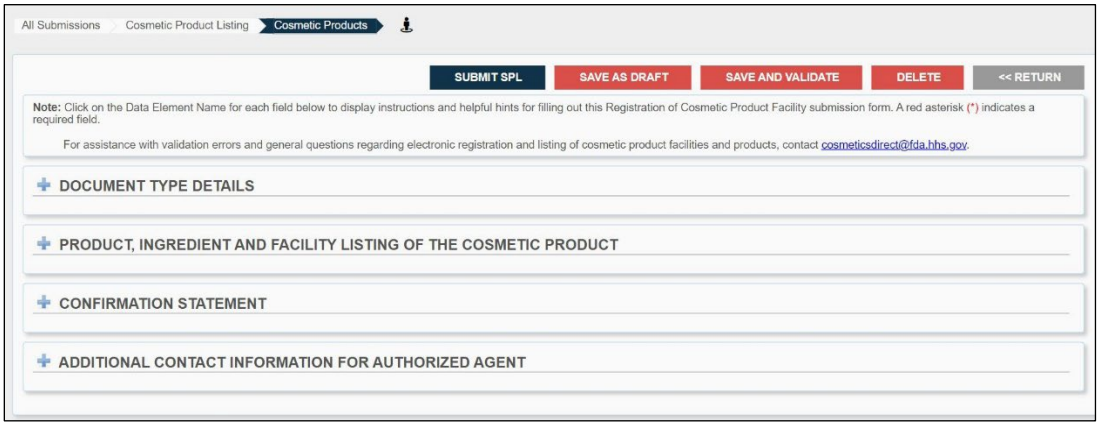
- Parent company name (if applicable)
- Type of business (as listed on the label), i.e., manufacturer, packer, or distributor.
- Image of the label (currently jpg files are accepted)
- Product webpage link
- Whether the cosmetic product is for professional use only
- Responsible person DUNS Number for 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:



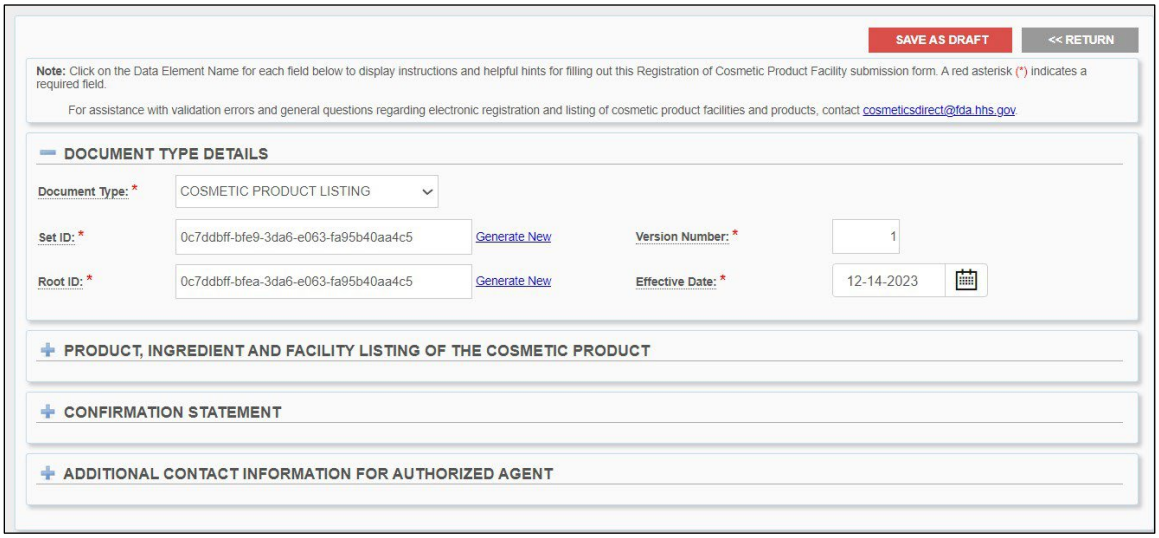
6. Enter the required information as indicated by red asterisk (*) throughout the submission process.
    a. **PLEASE NOTE:** For assistance with validation errors in Cosmetic Direct contact CosmeticsDirect@fda.hhs.gov. For general questions regarding electronic registration and listing of cosmetic product 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**: This will guide the user to Cosmetics Product Listing Submissions home page without saving your changes.

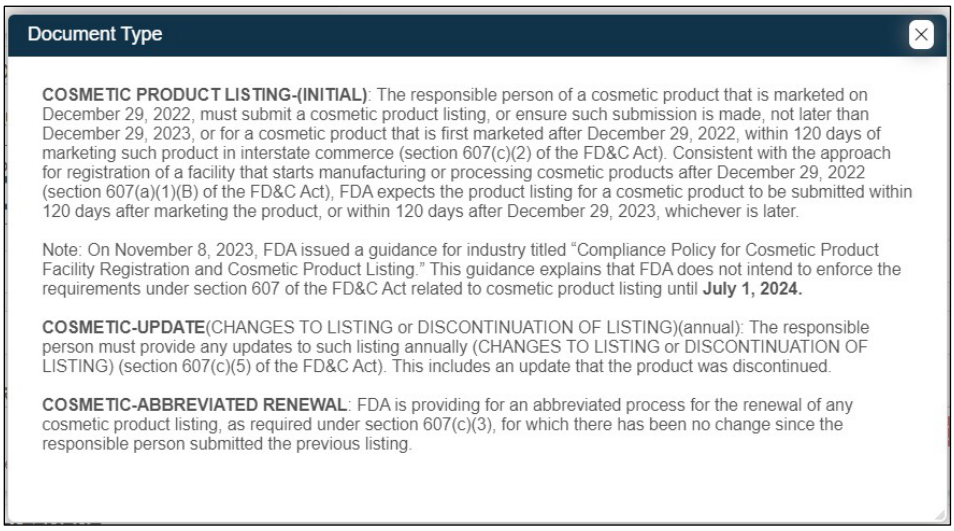
8. Select the **' +'** to open or '-' to close the **DOCUMENT TYPES** section of the **COSMETIC PRODUCT LISTING** to focus one section at a time, a red asterisk (*) indicates a required field throughout the submission process: 



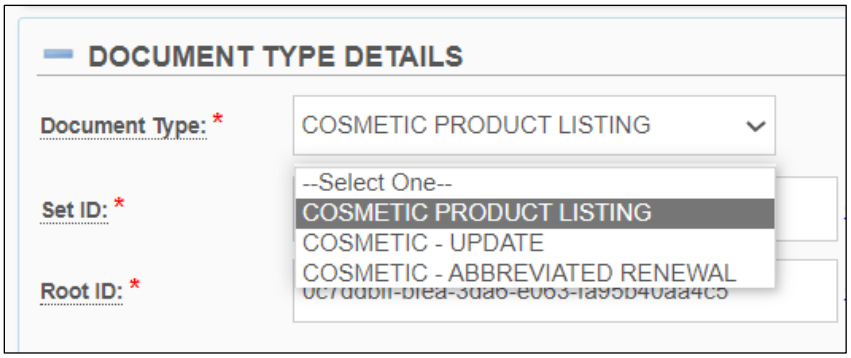
a. **PLEASE NOTE:** The **DOCUMENT TYPE** of the **DOCUMENT TYPE DETAILS** section is preselected to COSMETIC PRODUCT LISTING, which is the (**INITIAL**) submission. The **Set ID, Root ID, Version Number, and Effective Date** fields will always auto-populate for the **INITIAL SUBMISSION**:

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:

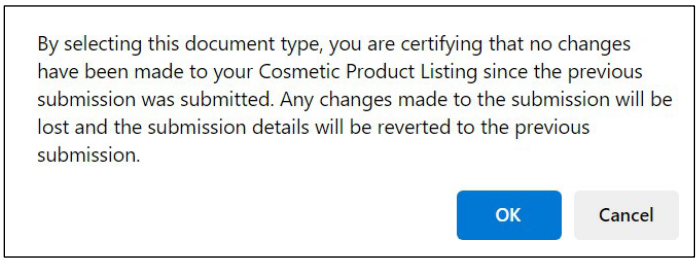


a. DOCUMENT TYPES INFORMATION*:

- **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:

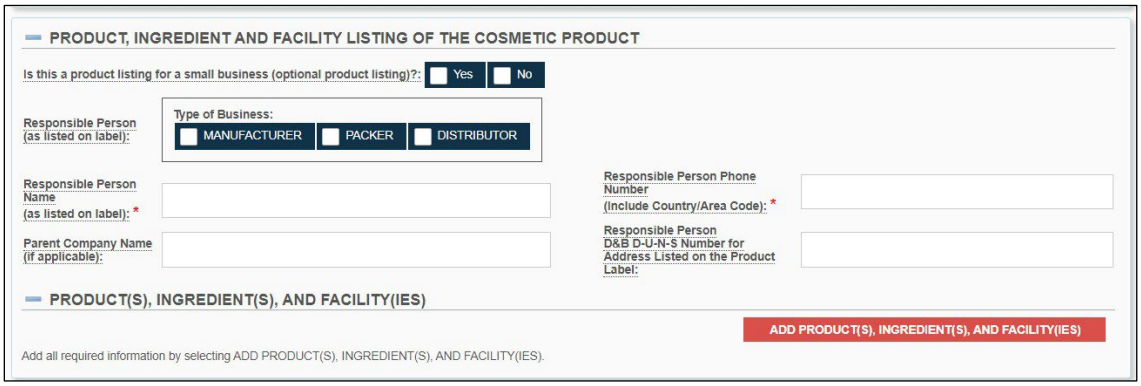
- **SET ID***: The Set ID uniquely identifies a group of versions of an SPL submission. When an SPL submission changes, a new Root ID is assigned to the new SPL submission, but the Set ID in the original SPL submission also is used. The Set ID is a Globally Unique Identifier (GUID). A GUID is a string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

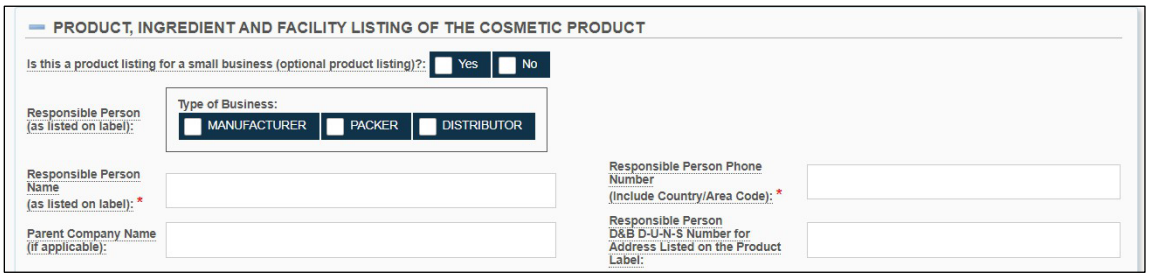
- **EFFECTIVE DATE***: The date the submission is created, users can modify it. However, the system will only use the actual registration date submitted to FDA. It also provides a date reference to the SPL version. Select the date by clicking on the calendar icon. Once an SPL has been submitted, this 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 (FDA.gov).

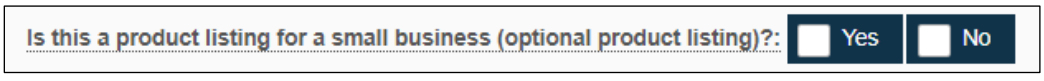
13. Fill in all the blank fields in the **RESPONSIBLE PERSON** section of the **PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT** section, a red asterisk (*) indicates a required field throughout the submission process:



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).

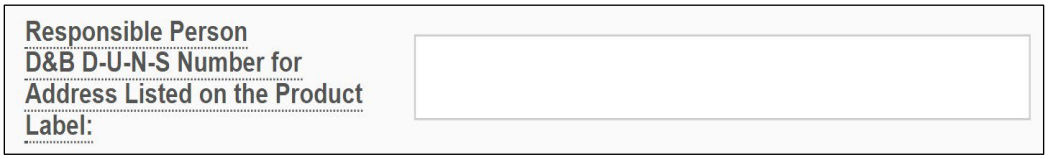
c. Responsible Person Name (as Listed on the label) *: Enter the responsible person name as it appears on the label.

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

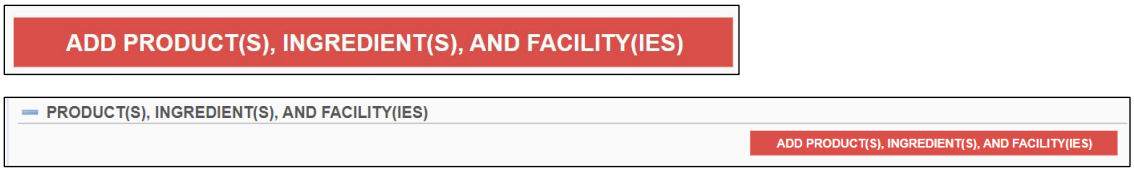
b. Responsible Person D&B D-U-N-S Number for Address Listed on the Product Label: (optional) Enter the existing 9- digit DUNS number of the address listed on the product label. Obtain a DUNS number: https://www.dnb.com



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,**

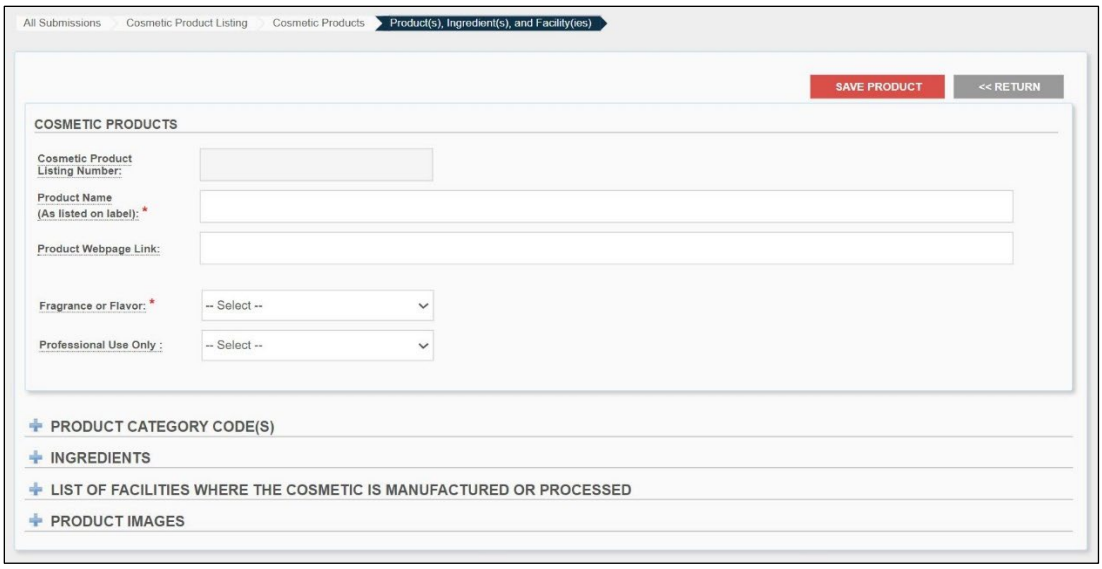
INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT section as shown below, a red asterisk (*) indicates a required field throughout the submission process:



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.

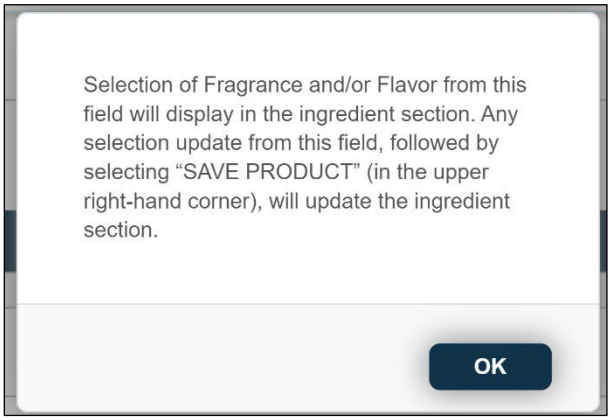
   a. Product Listing Number*: This 14-digit number will be generated by the system for each cosmetic product submission after acceptance. **PLEASE NOTE: THE PRODUCT LISTING NUMBER WILL BE GENERATED AFTER A SUBMISSION HAS BEEN ACCPETED BY FDA.**

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.

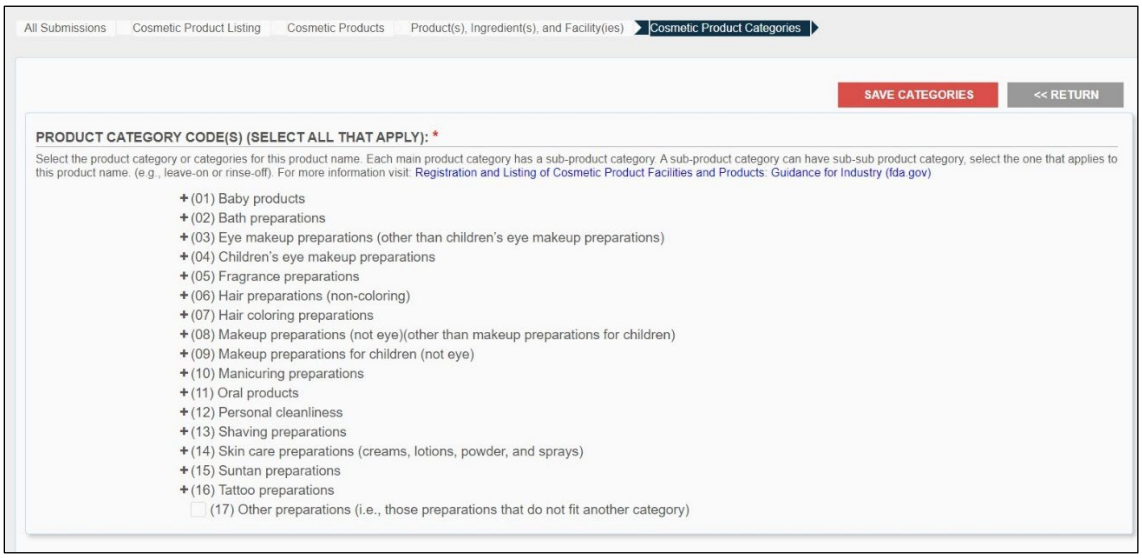
- **PLEASE NOTE:** An INFORMATION BANNER will pop up when FRAGRANCE OR FLAVOR SELECTION is made, as shown below:



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:

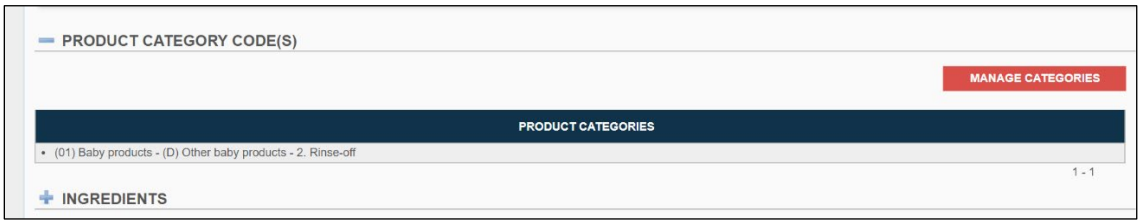
- (01) is considered a main product category (e.g. any section that begins with (#) are main product category).
- (A) to (D) are considered sub- product categories (e.g., any section that begins with (capital letter) are a sub-product category).
- 1. and 2. are considered a sub-sub product (e.g., any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

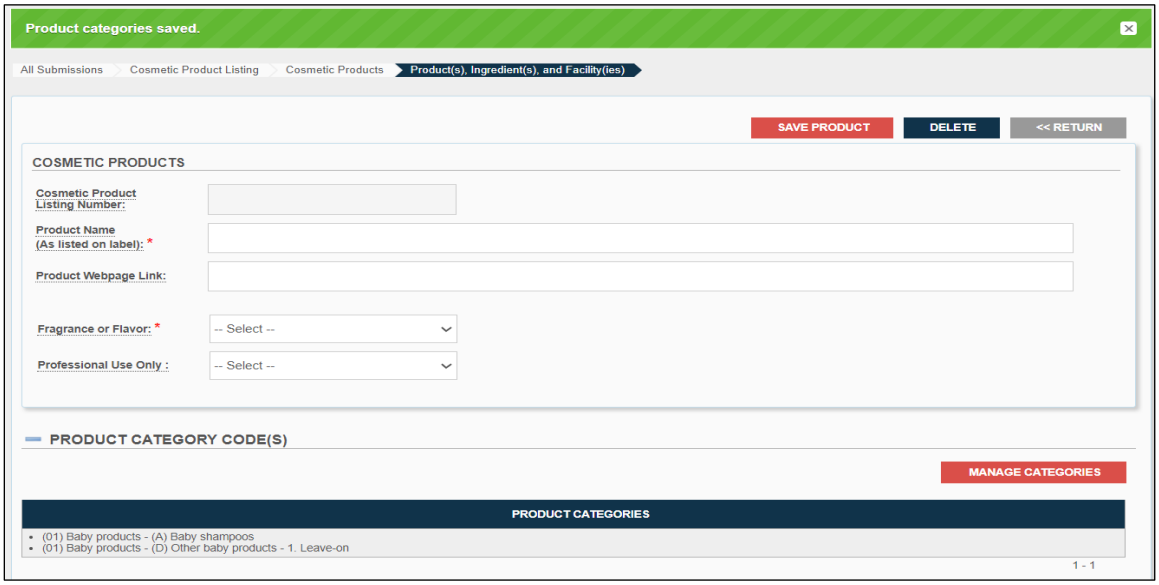
c. **PLEASE NOTE:** Any combination can be selected, EXCEPT leave-on and rinse-off (one or the other may be selected). However, if sub-product category has been selected, then a sub-sub product category must be selected.

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:

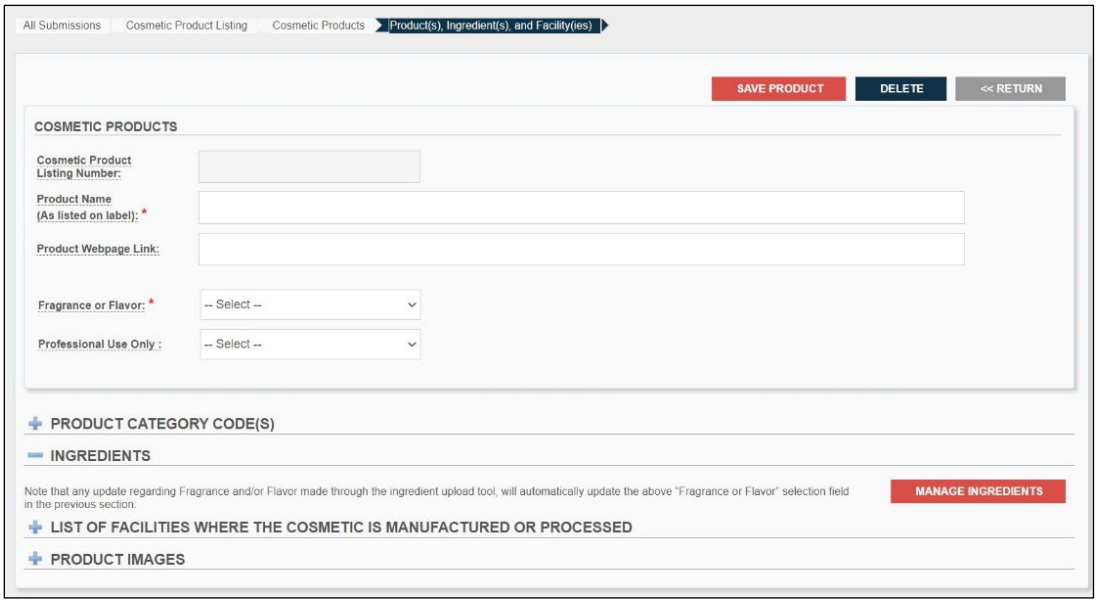


a. At this point, the option to '**DELETE**' this product tab on the upper right hand will appear along with **'SAVE PRODUCT'** and **'RETURN'** as shown below.

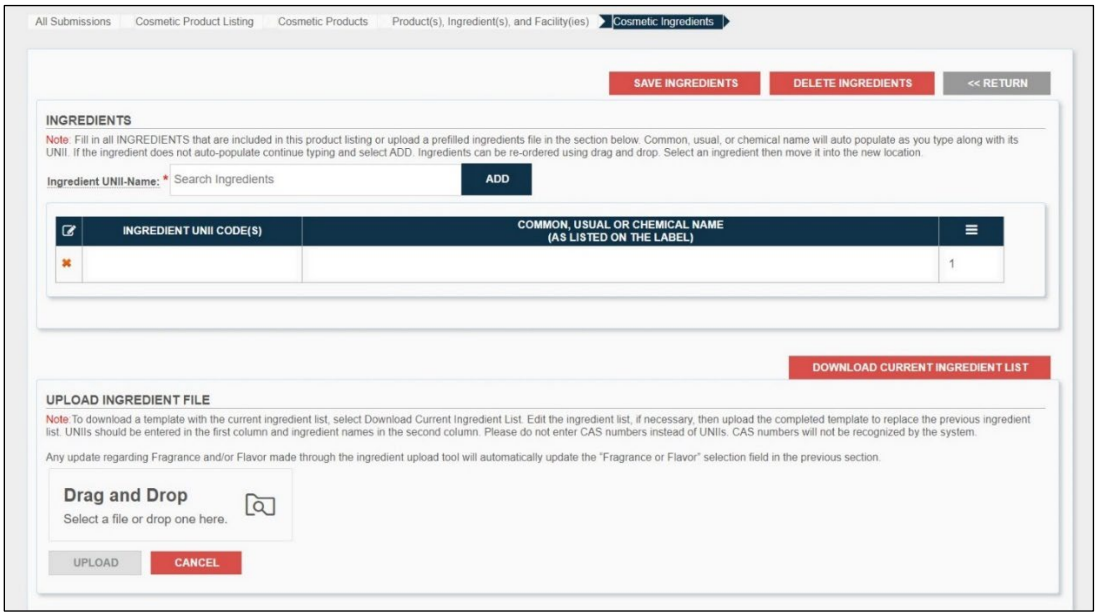


7. To add **PRODUCT INGREDIENTS** section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section, click the '**MANAGE INGREDIENTS**' button in ***INGREDIENTS***

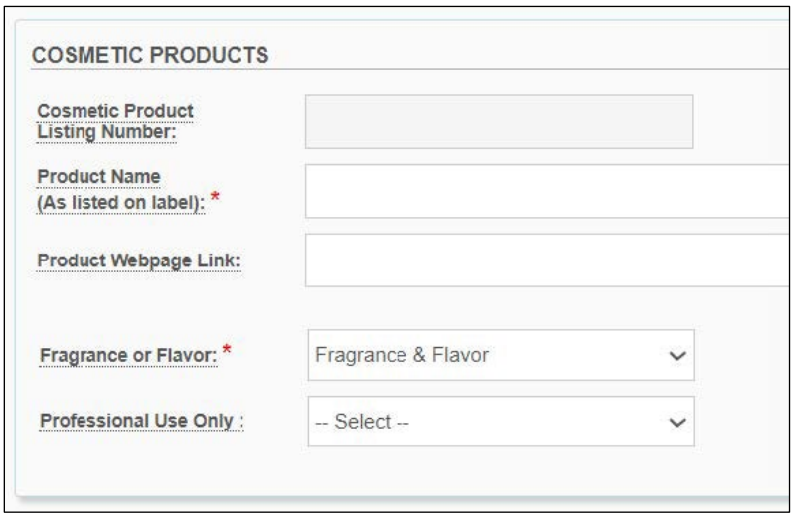
section, as shown below. A red asterisk (*) indicates a required field throughout the submission process.

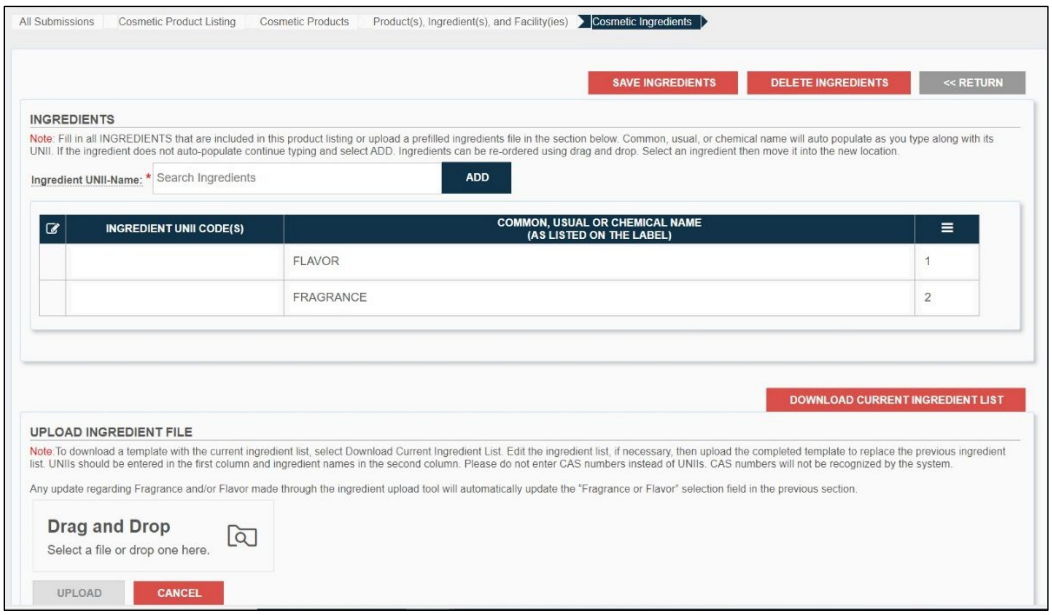


8. A blank template titled *COSMETIC INGREDIENTS* will display. Ingredients can be searched, added or uploaded, in the **INGREDIENTS** section., A red asterisk (*) indicates a required field throughout the submission process:



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:





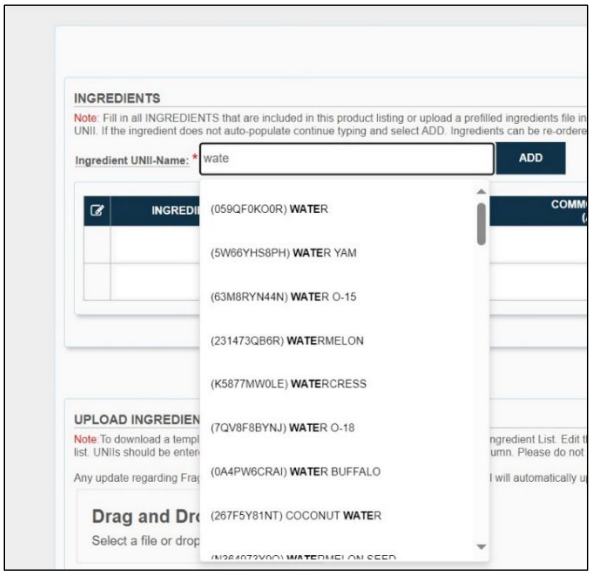
9. Fill in all the ingredients that are included in this product (as listed on label). Common, usual, or chemical name will auto-populate as you type along with its UNII. If an ingredient does not auto-populate, continue typing and select **ADD**.

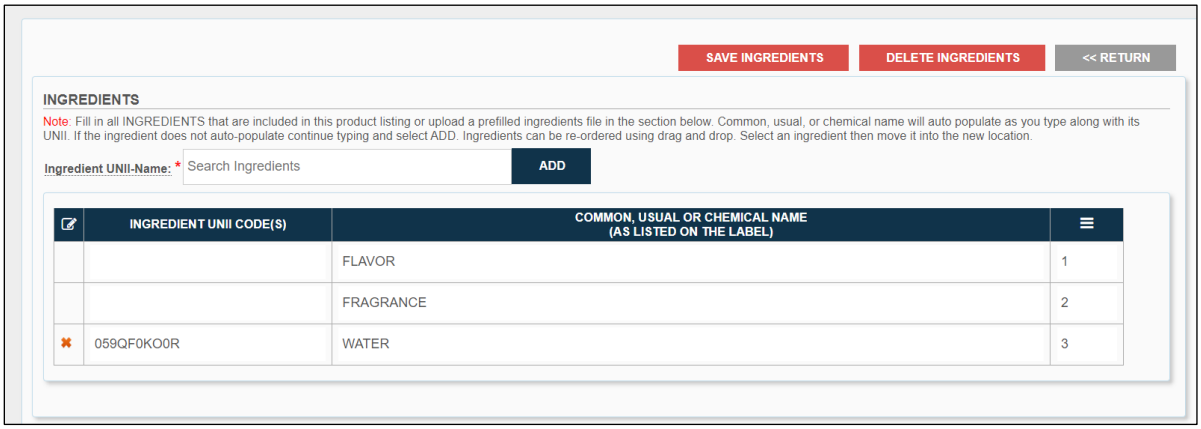
    a. **PLEASE NOTE:**

    - 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.

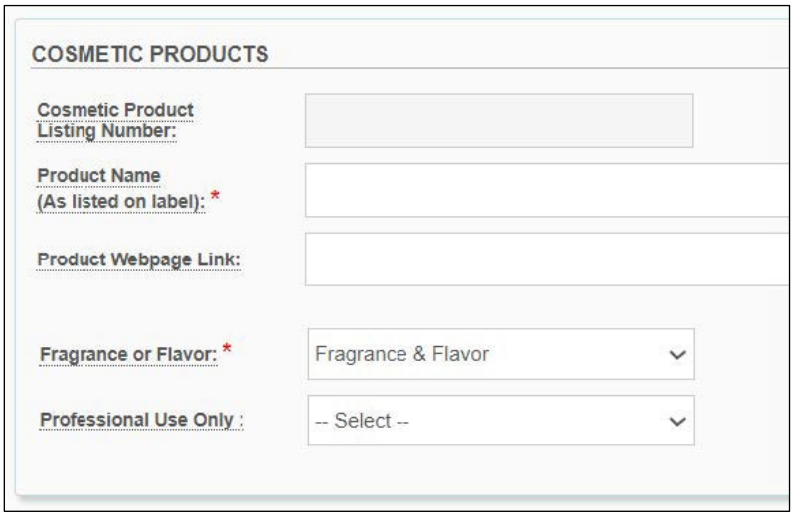
An example is shown below:



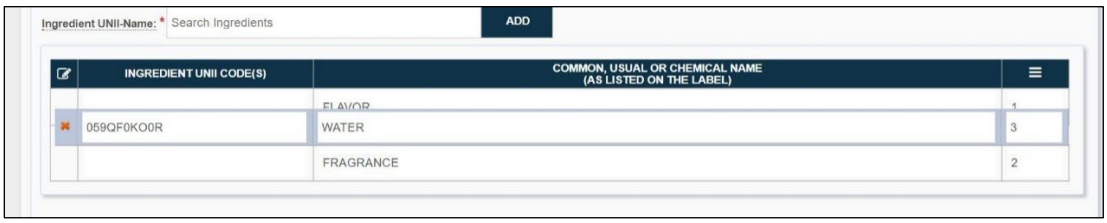


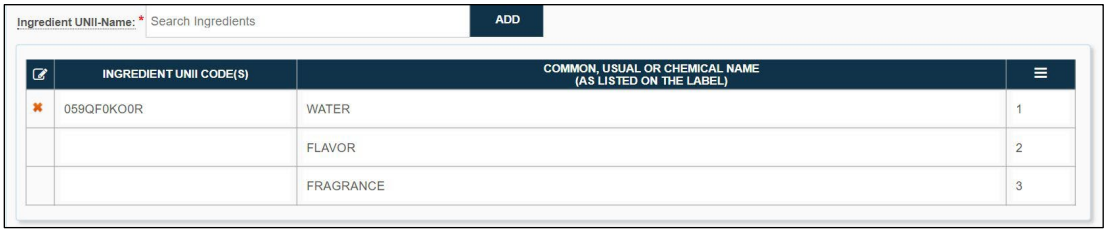
10. An ingredient can be deleted by selecting the **X** on the left-most column. As an example, shown below:

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.

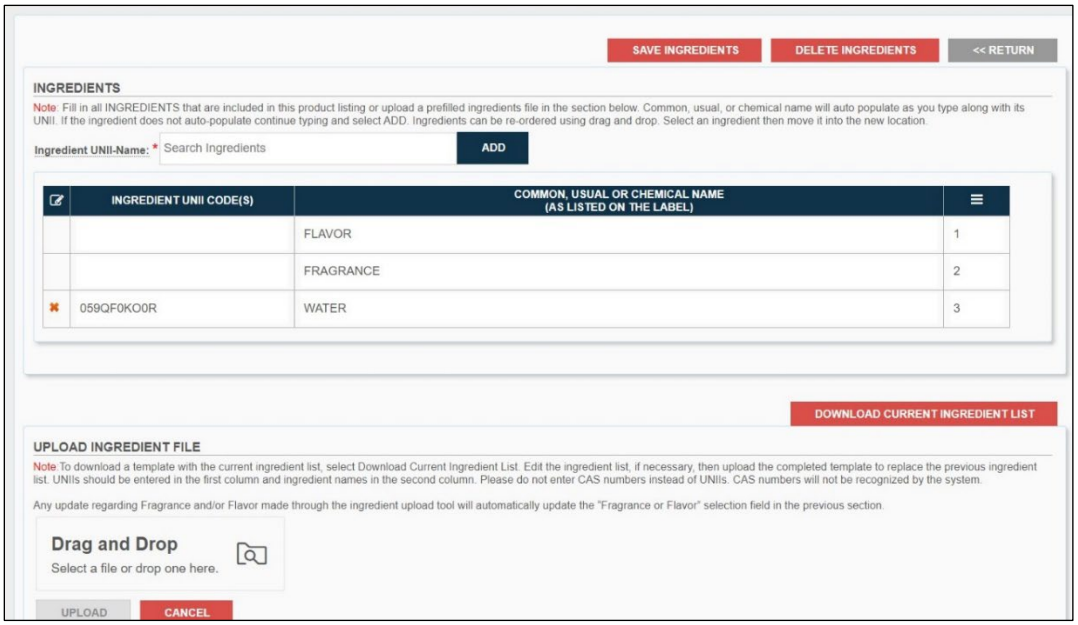


11. **Ingredients** can be **re-ordered** using the **drag and drop feature**. Select an ingredient then move it into the new location as shown below:

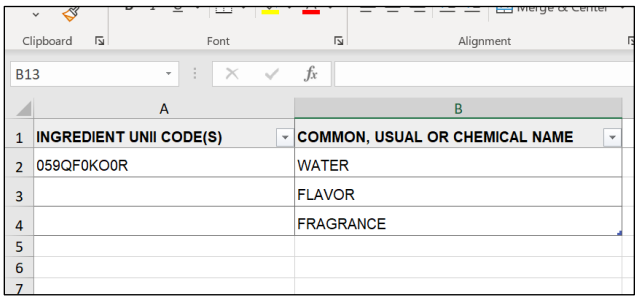




12. To download current ingredient list with its UNII CODE(S) from the **INGREDIENTS** section, click the '**DOWNLOAD CURRENT INGREDIENT LIST**', as shown below:



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

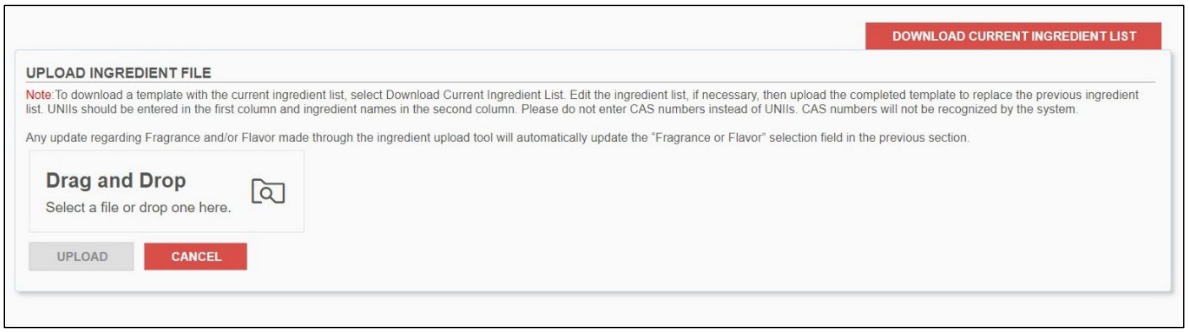


13. Edit the ingredient list, if necessary, then upload the completed template to replace the previous ingredient list. UNIIs should be entered in the first column and ingredient names in the second column.

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

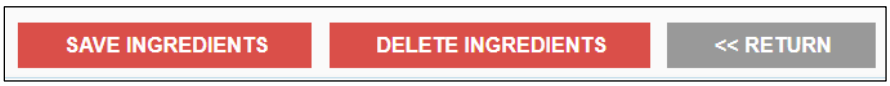
14. SAVE it on to the computer.

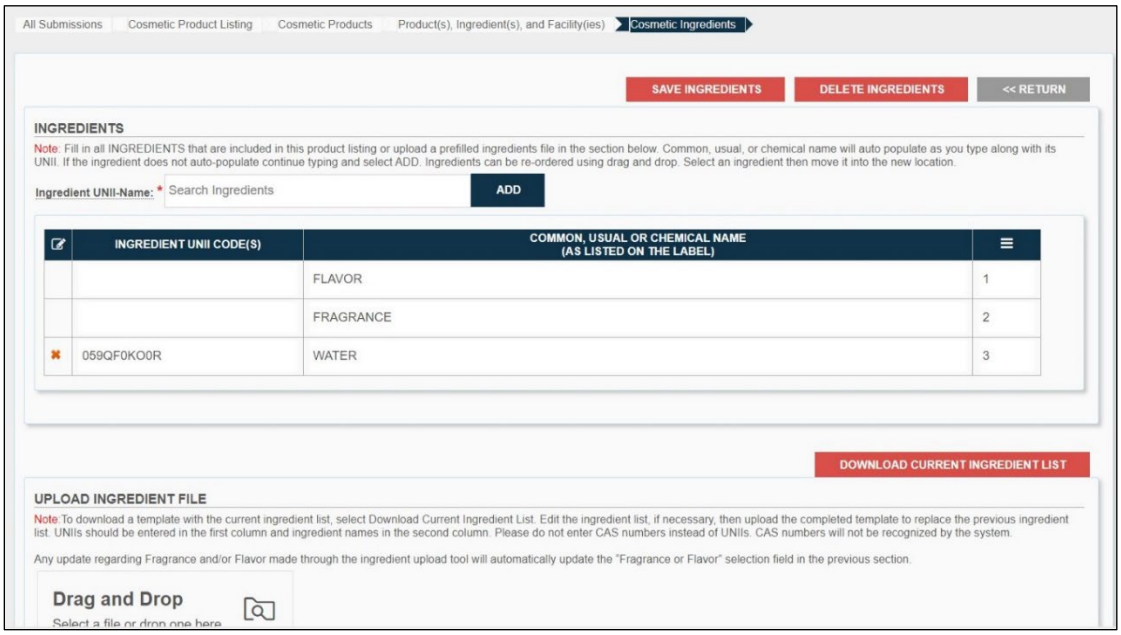
15. Upload the completed template to replace the previous ingredient list**,** by selecting the UPLOAD button underneath the DRAG AND DROP in the UPLOAD INGREDIENT FILE section. As shown below:

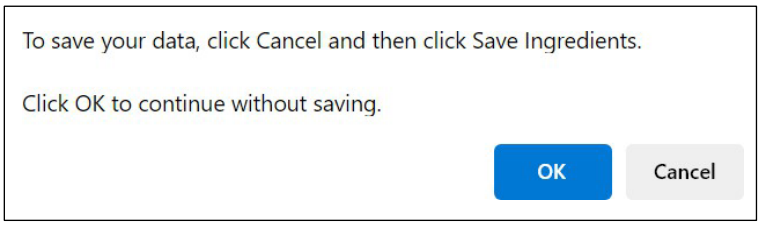


a. **PLEASE NOTE:** Any update regarding Fragrance and/or Flavor made through the ingredient upload tool, will automatically update the above "Fragrance or Flavor" selection field in the previous section.

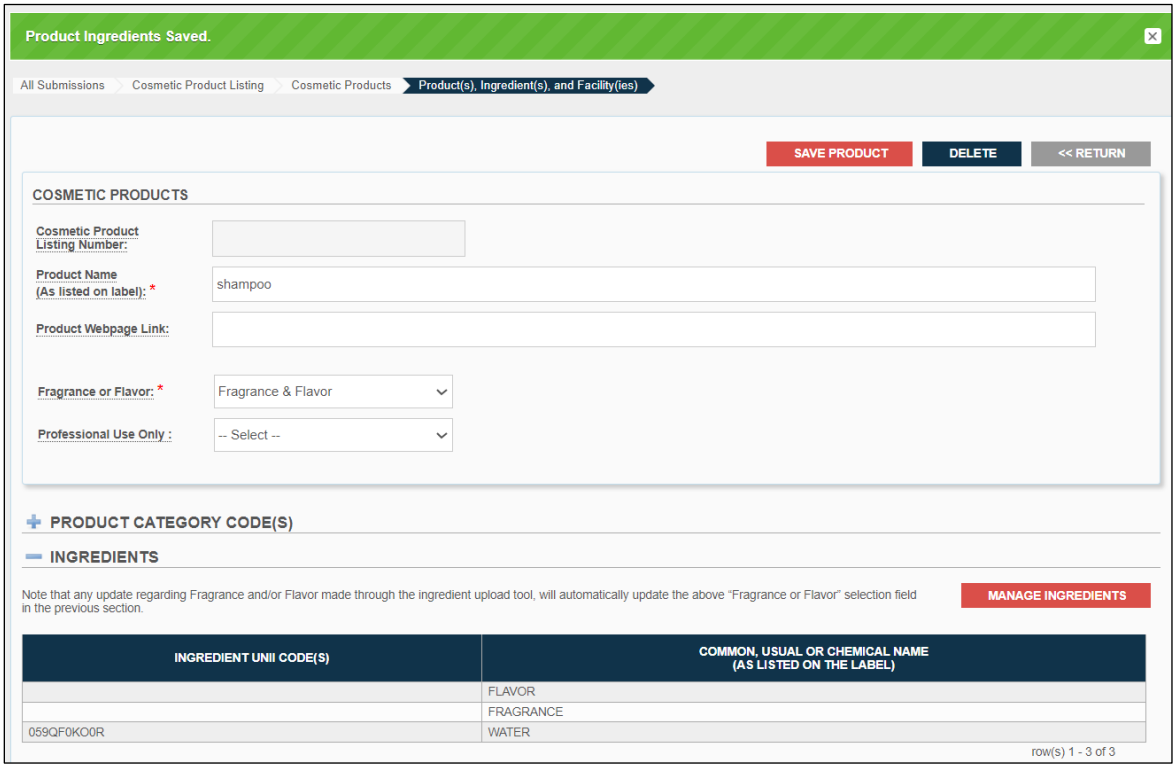
16. Once all the **INGREDIENT(S)** are listed, select **SAVE INGREDIENTS.** If the user chooses to delete the ingredient's list, select **DELETE INGREDIENT**. By selecting RETURN, a warning banner will appear. As an example, shown below:



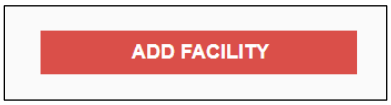


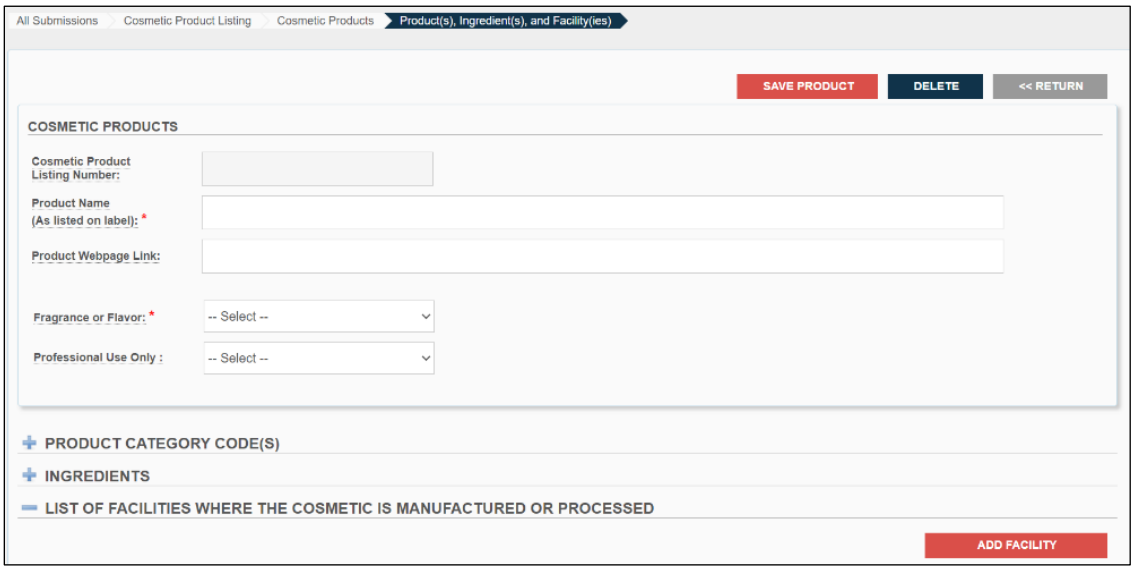


17. After clicking '**SAVE INGREDIENTS**' all the INGREDIENTS that were listed on the previous page will be listed under the ingredients tab in the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section with a saved banner on the top of the page, as shown below:

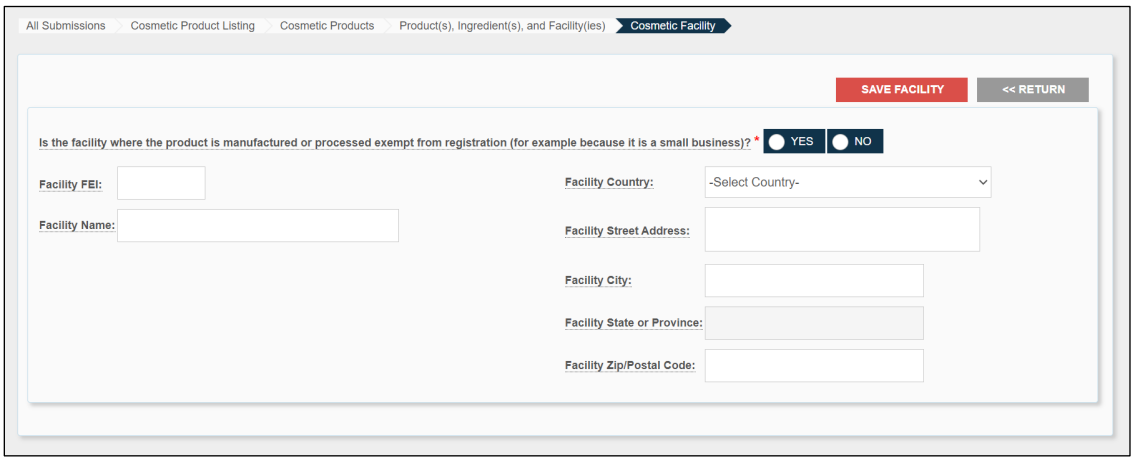


18. To add the **LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED,** section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section, click the '**ADD FACILITY**' button in ***LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED*** section, as shown below. A red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

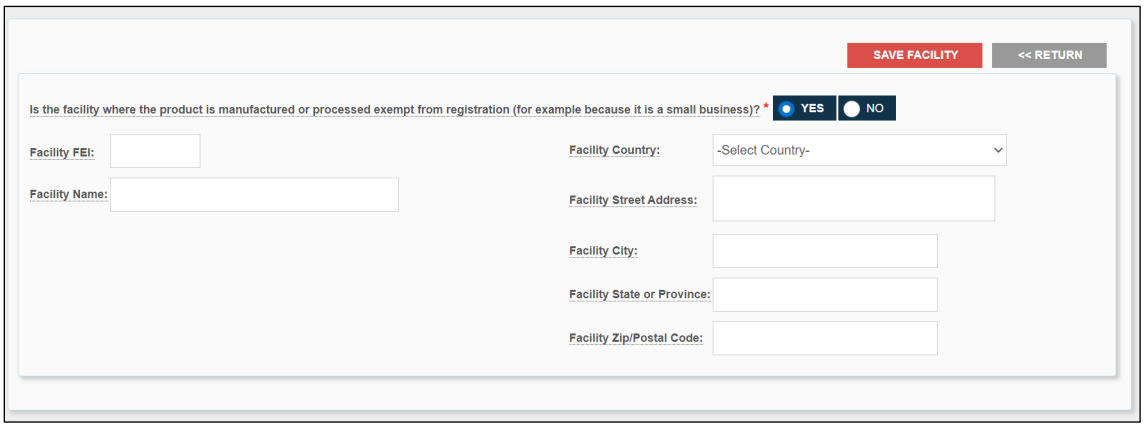
c. Facility FEI: Enter the existing 7 to 10-digit facility FEI number. The FEI number is a unique identifier assigned by the FDA to identify firms associated with FDA-regulated products. To facilitate the registration process, the owner or operator of a facility will need to obtain an FEI number before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

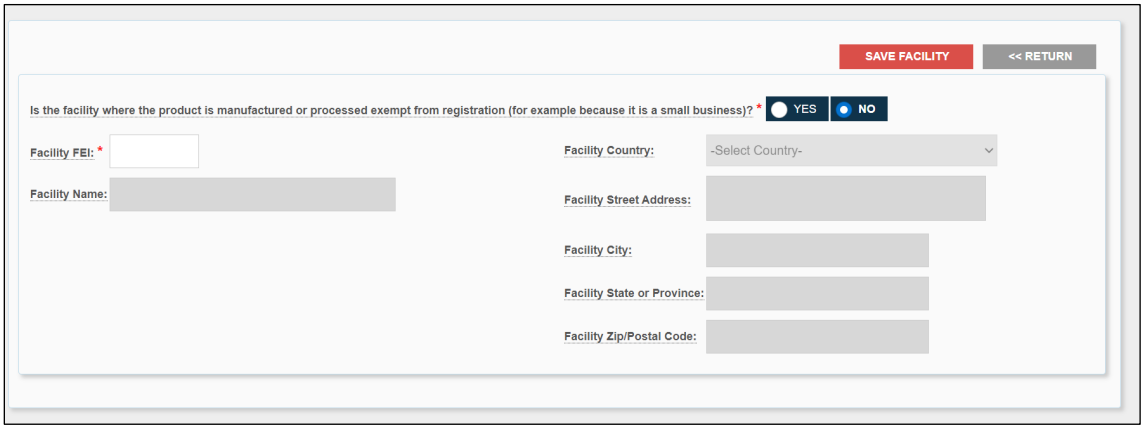
- Facility Name: Enter the complete name of the existing facility.
- Facility country: Select facility's country name where the facility is physically located.
- Facility Street Address: Enter the complete information of the street where the facility is physically located.
- Facility City: Enter the 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)

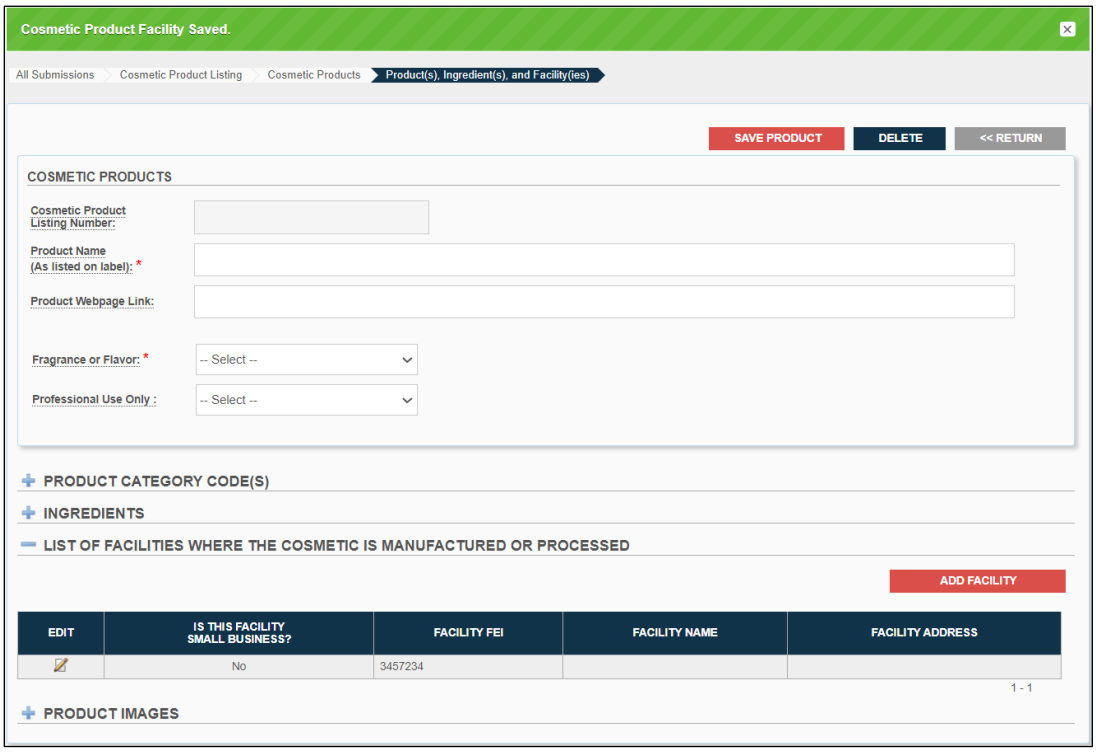
20. If selected **YES** to the question, "***Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?"*** all data fields are optional. As shown below:



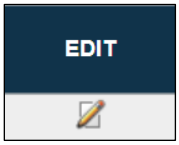
21. If selected **NO** to the question, "***Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?"*** the FEI is mandatory, and the name/address is greyed. As shown below:

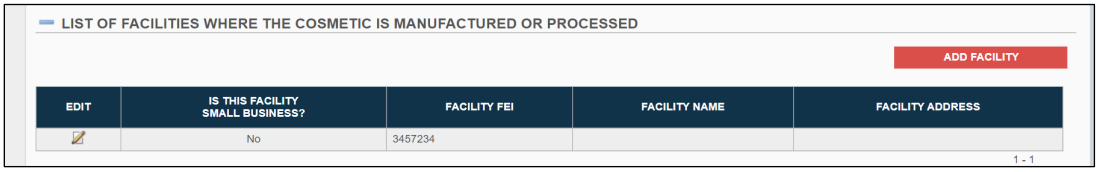


22. Once complete, clicking '**SAVE FACILITY**' and the FACILITY will be saved on the previous page under the **LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED** tab in the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section with a saved banner on the top of the page, as shown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

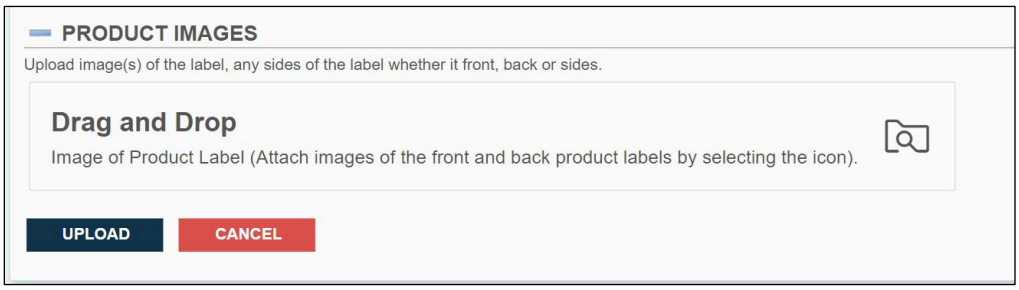




   a. Multiple **FACILITY(IES)** can be added by selecting the **ADD FACILITY** on the top right, as shown above.

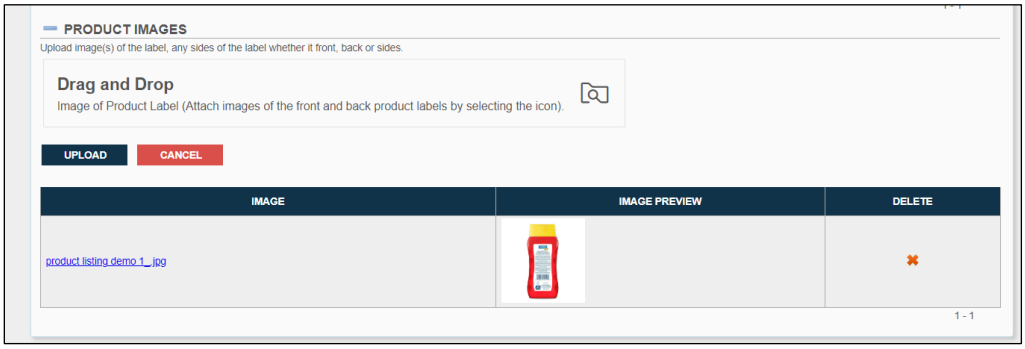
24. The **PRODUCT IMAGES** section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section, a red asterisk (*) indicates a required field throughout the submission process:

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 .jpg format.

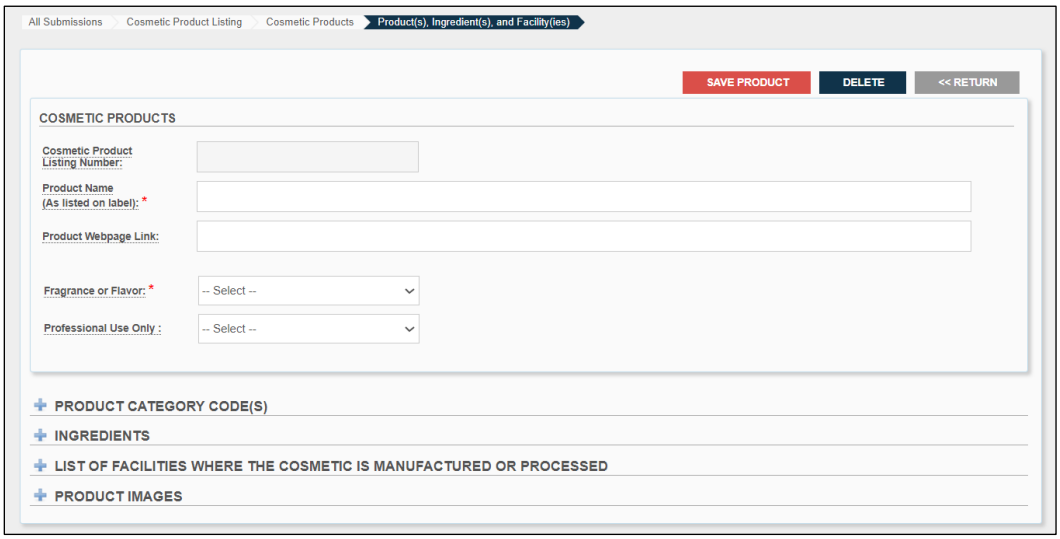


b. **PLEASE NOTE:** The image must be uploaded in .JPEG format. The max image size allowed is 1MB. Please make sure that the image is a true jpg without special characters. They must be valid jpg file and the name should consist of letters (a-z, A-Z) and/or numbers (0-9). Special characters and symbols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

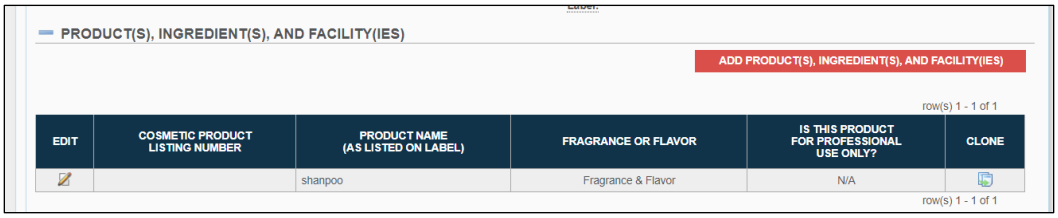
c. The image will display under the **PRODUCT IMAGES** section under **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES),** as shown below:



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:

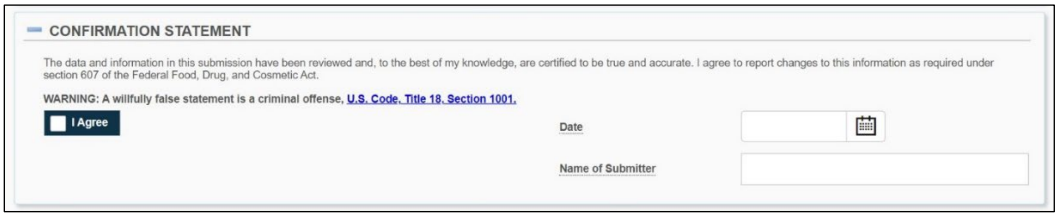


a. Multiple **PRODUCT** can be added by selecting the **ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)**on the top right, as shown above.

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>.

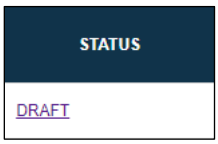
- Phone Extension: (optional field) Enter additional contact person's phone extension, if any.

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

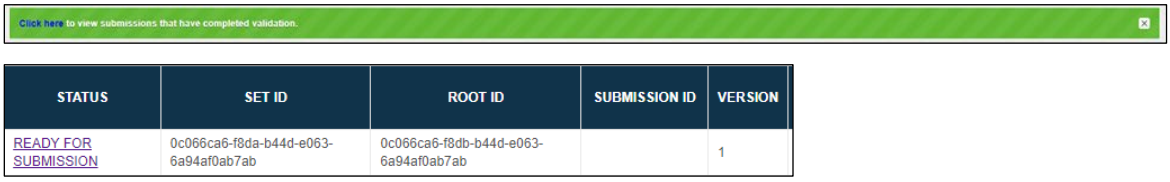
1. Click '**SAVE AND VALIDATE**' if you want to check for errors with your SPL. To submit your SPL to FDA,

   a. **PLEASE NOTE:** This option is only for an initial validation of your SPL before submitting to FDA. It does not automatically submit your SPL to FDA, even if it

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

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

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

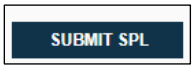


4. Click '**READY FOR SUBMISSION**', the homepage will change to reflect the following:

   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.*'

4.4.3.2 Submit SPL to FDA

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



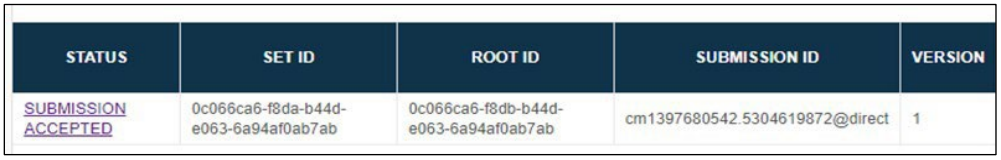
   a. A green message will appear across your screen stating, "Your submission has been sent to FDA for additional validation and processing. Check the status of your submission after a few minutes by refreshing the page or logging back into the system. You will also receive an email from FDA when the processing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

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

4.4.3.3 Submission Accepted

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

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



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

2. Click on '**SUBMISSION ACCEPTE**D' 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

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

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

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

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

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

4.4.3.5 Validation Failure

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

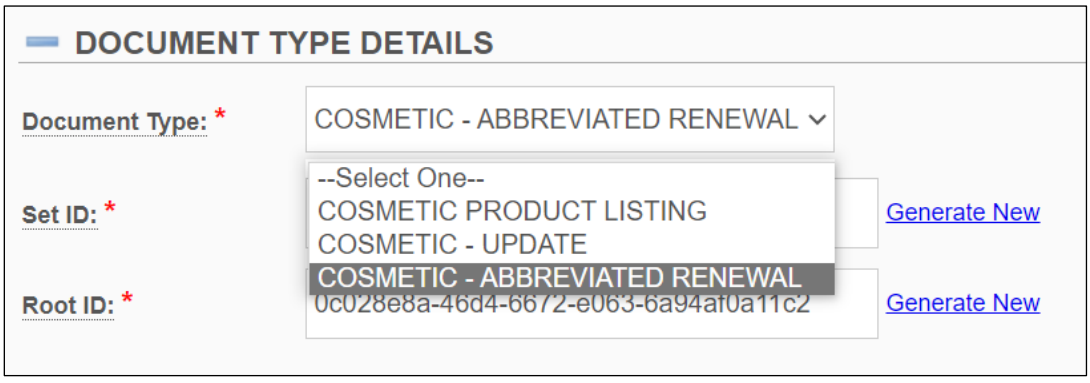
2. Click '**VALIDATION FAILURE**', the system will provide a list of errors that need to be fixed before submitting the SPL:

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

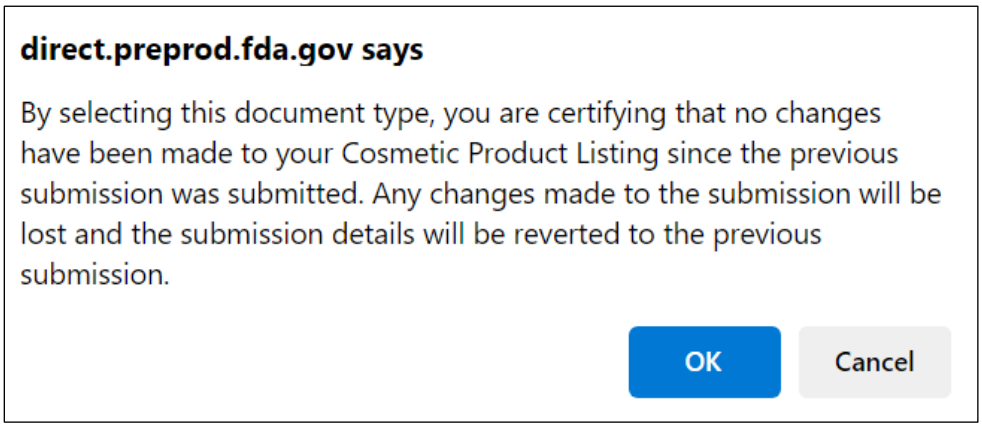
4.4.4 Abbreviated Renewal Listing

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

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



   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 in Sections 4.4.3.1 – 4.4.3.5 for Submit to FDA instructions.

4.4.5 Cosmetic – Update

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

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

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

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

- Product Name
- Ingredients (including fragrance, color, and flavor)
- Product Categories
- Responsible Person

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

4.4.5.1 Discontinue

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

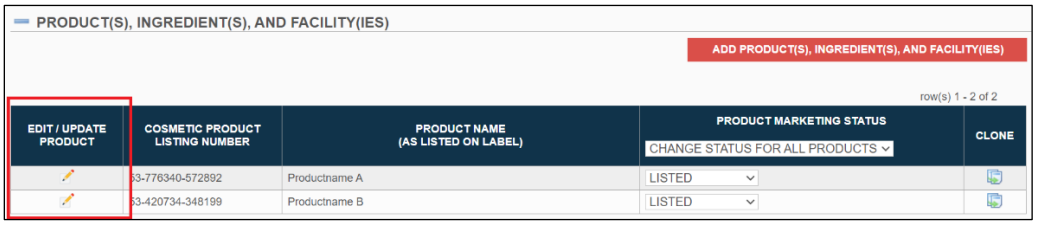
There are three ways to discontinue a product from your SPL submission:

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

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

Option 1 – Edit/Update Product

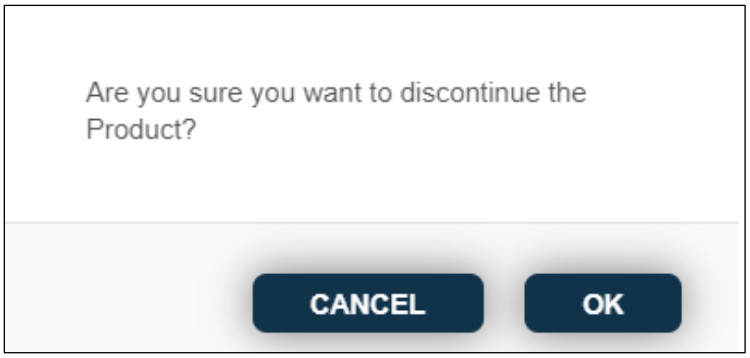
a. Locate the EDIT/UPDATE PRODUCT column under the PRODUCT(S), INGREDIENT(S), AND FACILITY(IES) section.



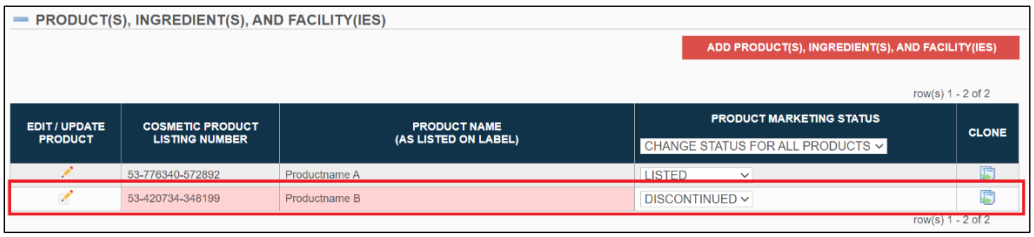
b. Click on the pencil icon of the product you would wish to discontinue.

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

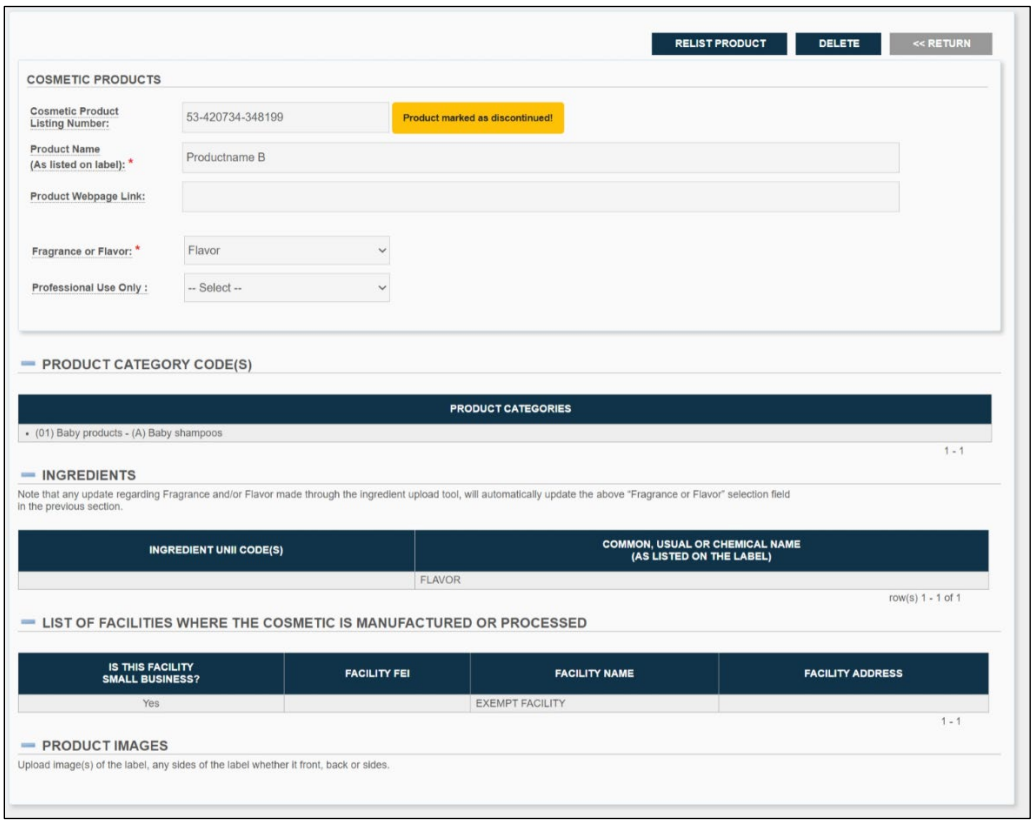
- **PLEASE NOTE:** The following message will appear, "Are you sure you want to discontinue the Product?" Select, '**OK**' to proceed.



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.



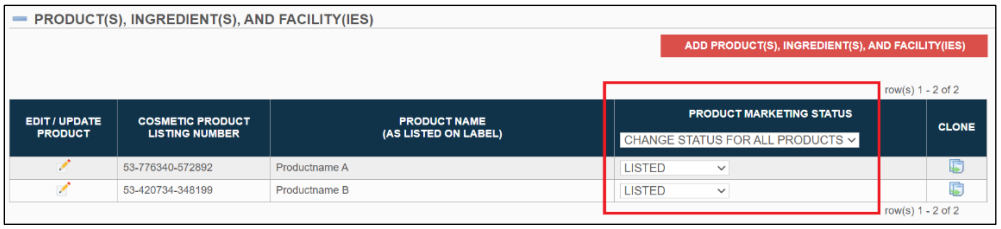
e. Using the pencil icon, you can re-enter into the selected DISCONTINUED product to view that the product is marked as discontinued. A yellow message will appear next to the Cosmetic Product Listing Number stating, "Product marked as discontinued!"



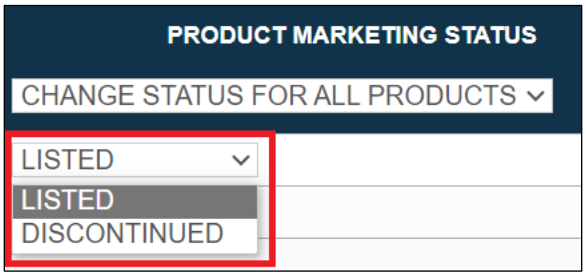
- **PLEASE NOTE:** Once a product is discontinued, no additional edits can be made on the page unless the product is RELISTED. Please see section 4.4.5.2 Relist for additional instructions.

Option 2 – Product Marketing Status

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

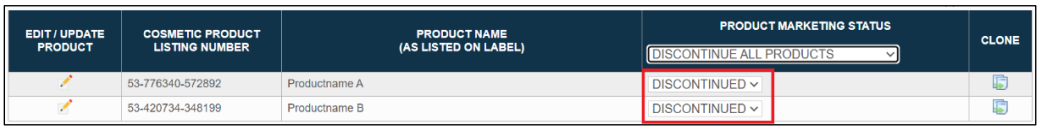


g. Identify the listed products you wish to discontinue. In the PRODUCT STATUS column, click the drop-down menu and select '**DISCONTINUED**'.

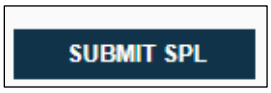


h. If you wish to discontinue all the LISTED products, select '**DISCONTINUE ALL PRODUCTS**'

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

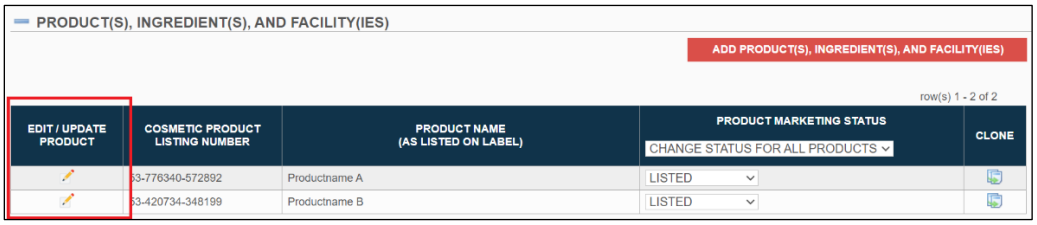


j. Click '**SAVE AS DRAFT**' or '**SAVE AND VALIDATE**' located at the top right of this page to save your selection(s). This will change your products to '**DISCONTINUED**'. To submit your data to the FDA, select '**SUBMIT SPL**'.



Option 3 – Delete

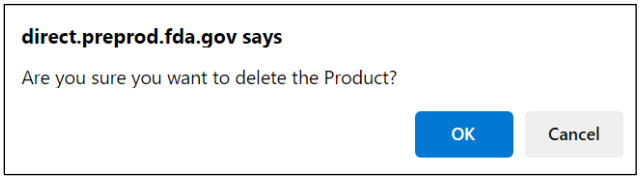
k. Locate the EDIT/UPDATE PRODUCT column under the PRODUCT(S), INGREDIENT(S), AND FACILITY(IES) section.



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

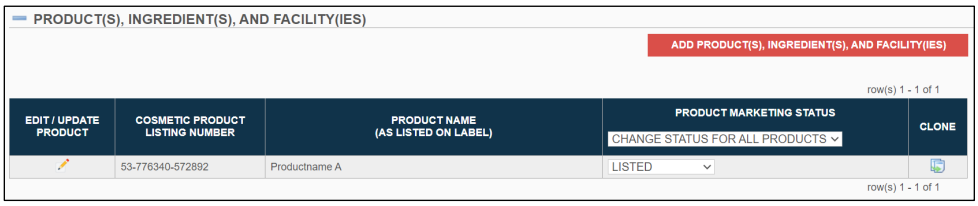
m. Select '**DELETE**', to delete the product from the SPL file.

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



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

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



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:

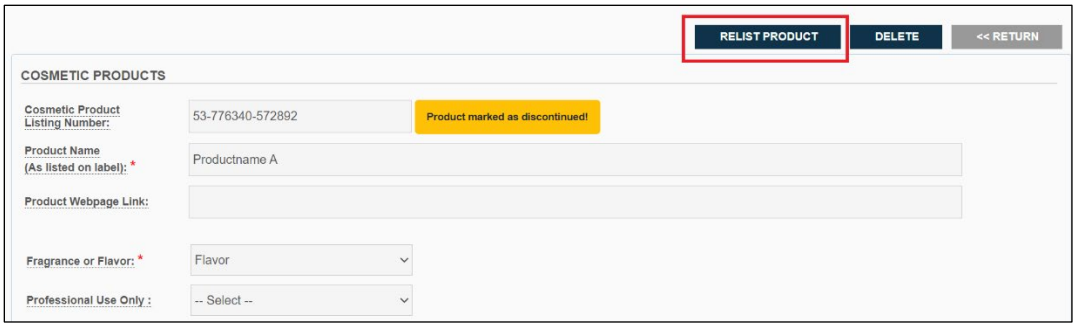
1. Open an existing submission that has been previously accepted.
2. Click '**CREATE NEW VERSION**'

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

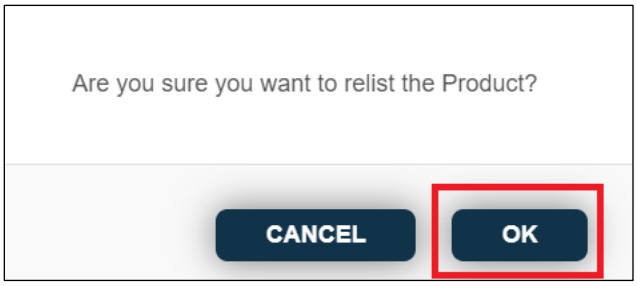
<u>Option 1 – Edit/Update Product</u>

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.

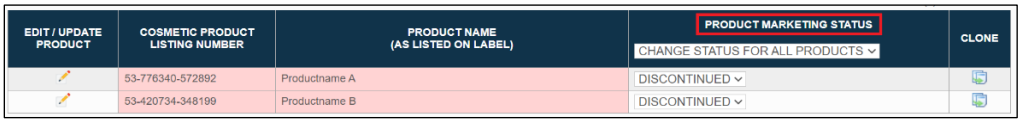


d. After clicking '**O**K', you will be taken back to the Cosmetic Product Listing page and a green message will appear across your screen stating, "Cosmetic Product Relisted."

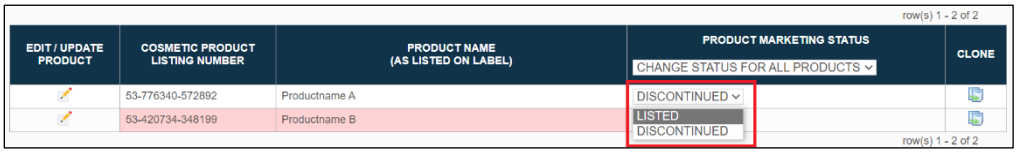
e. Under PRODUCT(S), INGREDIENT(S), AND FACILITY(IES), the product will now show as 'LISTED.'

Option 2 – Product Marketing Status

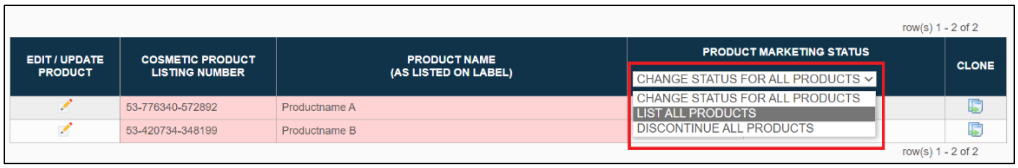
f. Locate the PRODUCT MARKETING STATUS column under the PRODUCT(S), INGREDIENT(S), AND FACILITY(IES) section.



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



h. 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.

4.5 Filters

4.5.1 Cosmetic Facility Registration

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

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

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

4.5.2 Cosmetic Product Listing

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

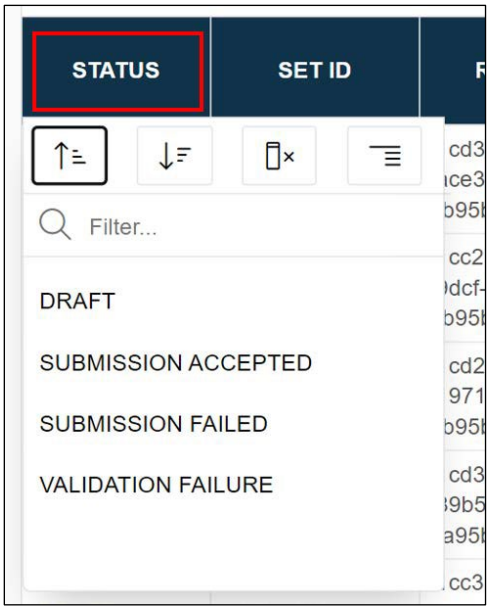
1. Status: The current status of your submissions. For further explanation of the different status types, see Section 3.2: Submission Statuses.
2. Set ID: A 'Globally Unique Identifier' (GUID) that remains the same for each submission 'set,' which is a group of submission versions. When you submit a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

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

4.5.2.1 Filtering on Column Header

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

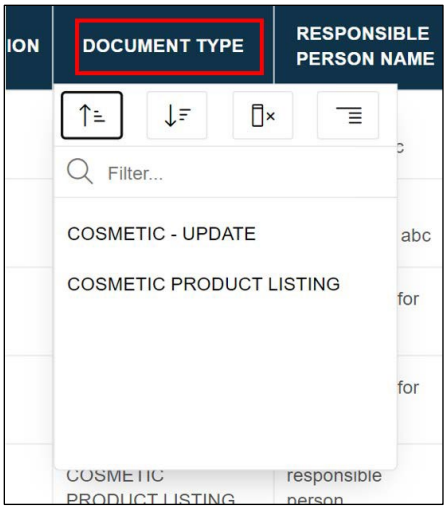
1. Clicking the 'Status' header will display a dropdown of all status types tied to your submissions:



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

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

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



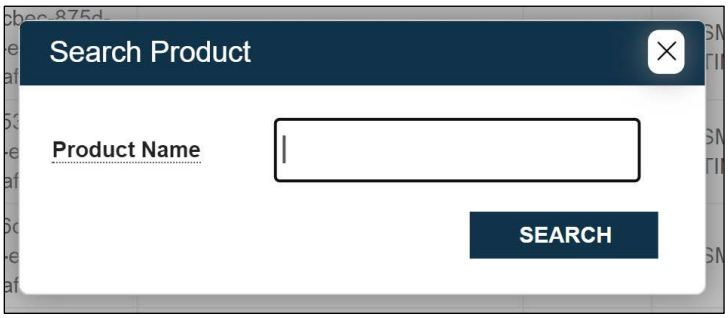
Icon	Description
	Sort ascending
	Sort descending
	Hide column
	Clearly separate each submission

4.5.2.2 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**'.

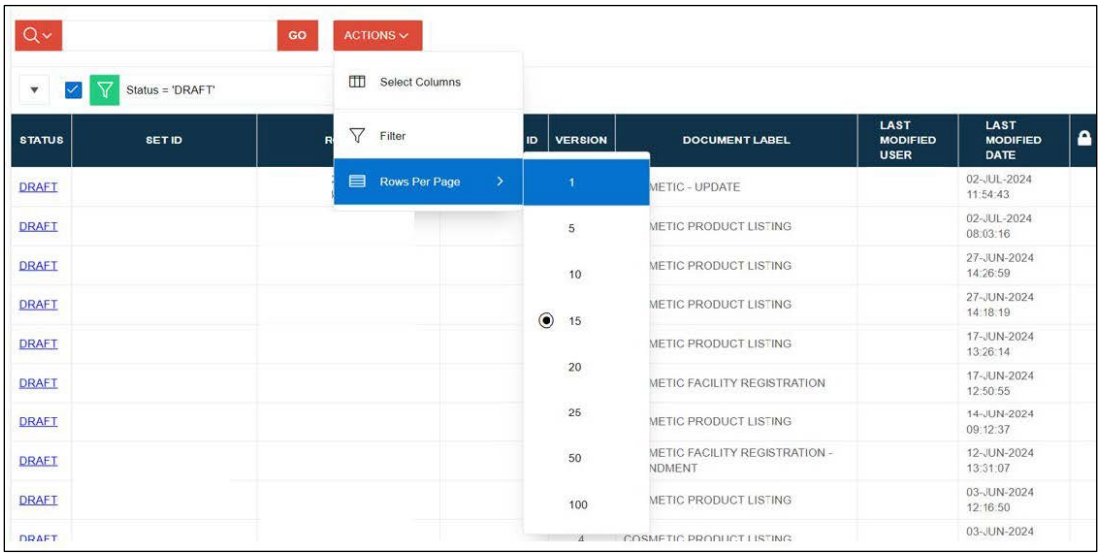


3. The page will update immediately with your filter.

4.5.2.3 Rows Per Page

To adjust the number of submissions visible per page:

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



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

5 DRUG REGISTRATION AND LISTING

5.1 Drug Establishment Registration SPL

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

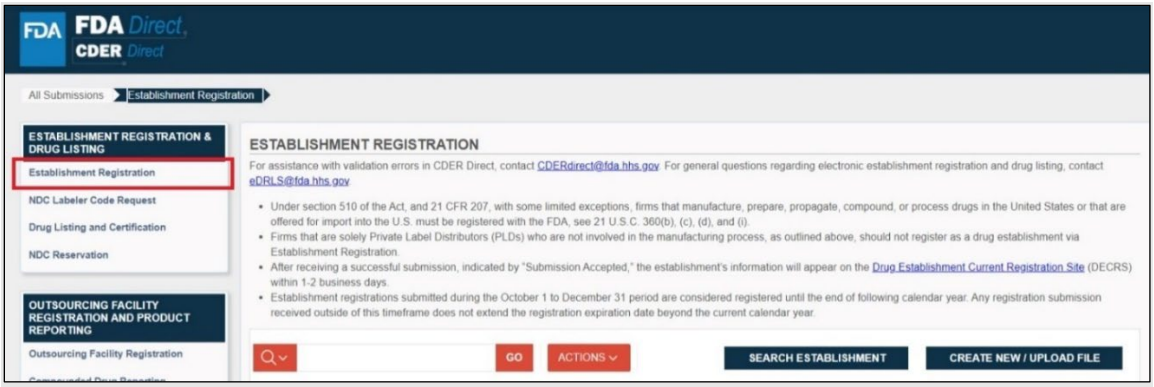
The Establishment Registration SPL submission template can be used for the following purposes:

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

5.1.1 Registering a New Drug Establishment

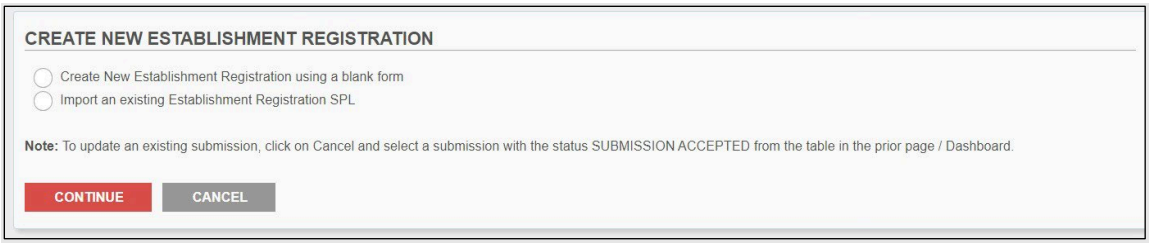
To use the Establishment Registration SPL:

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



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

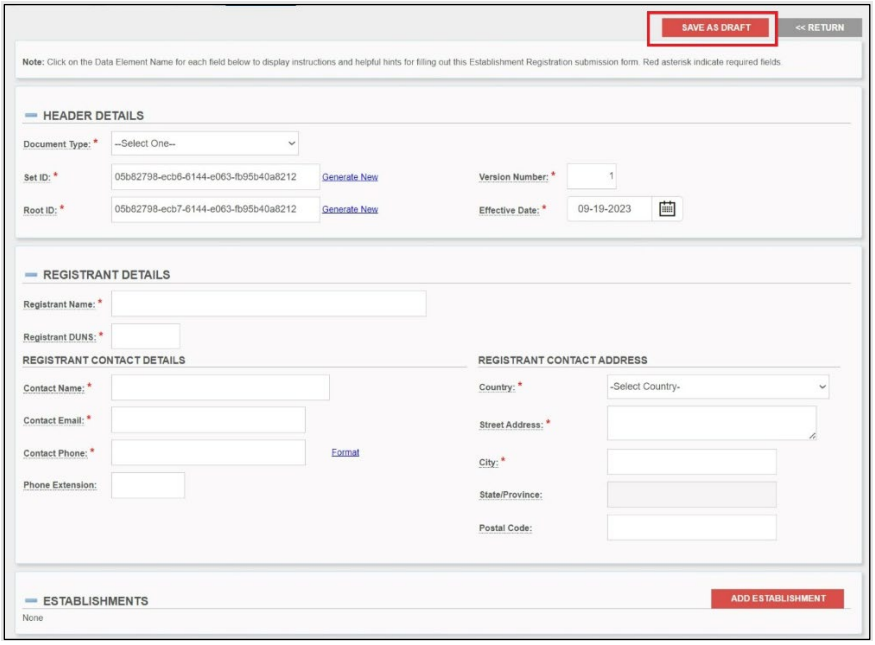
4. You will be given two options:



   a. To upload a file from your computer directly, follow the steps outlined in Section 3: Submission Information. Then skip to Step 12 below to continue editing.

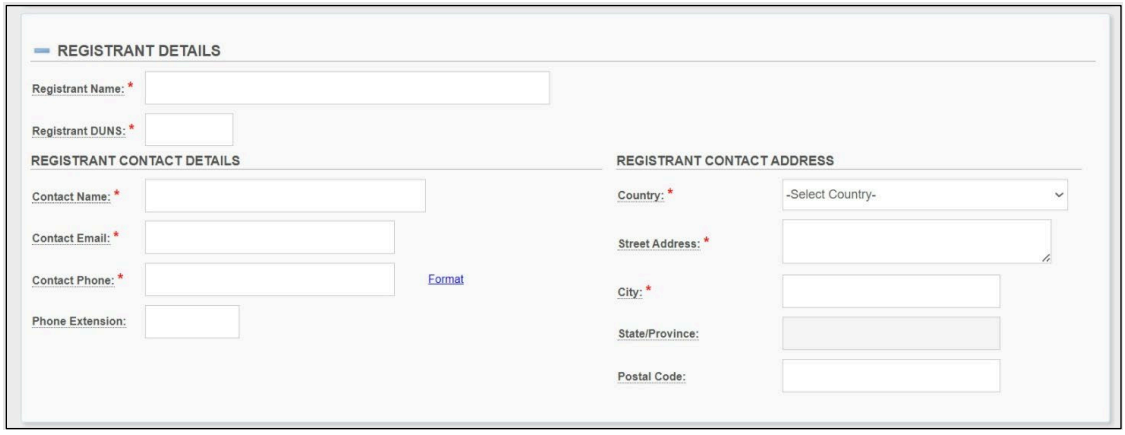
5. To create an SPL submission using a blank template, select the '**Create New Establishment Registration using a blank form**' option.

6. Click '**Continue**' and a blank template will display:



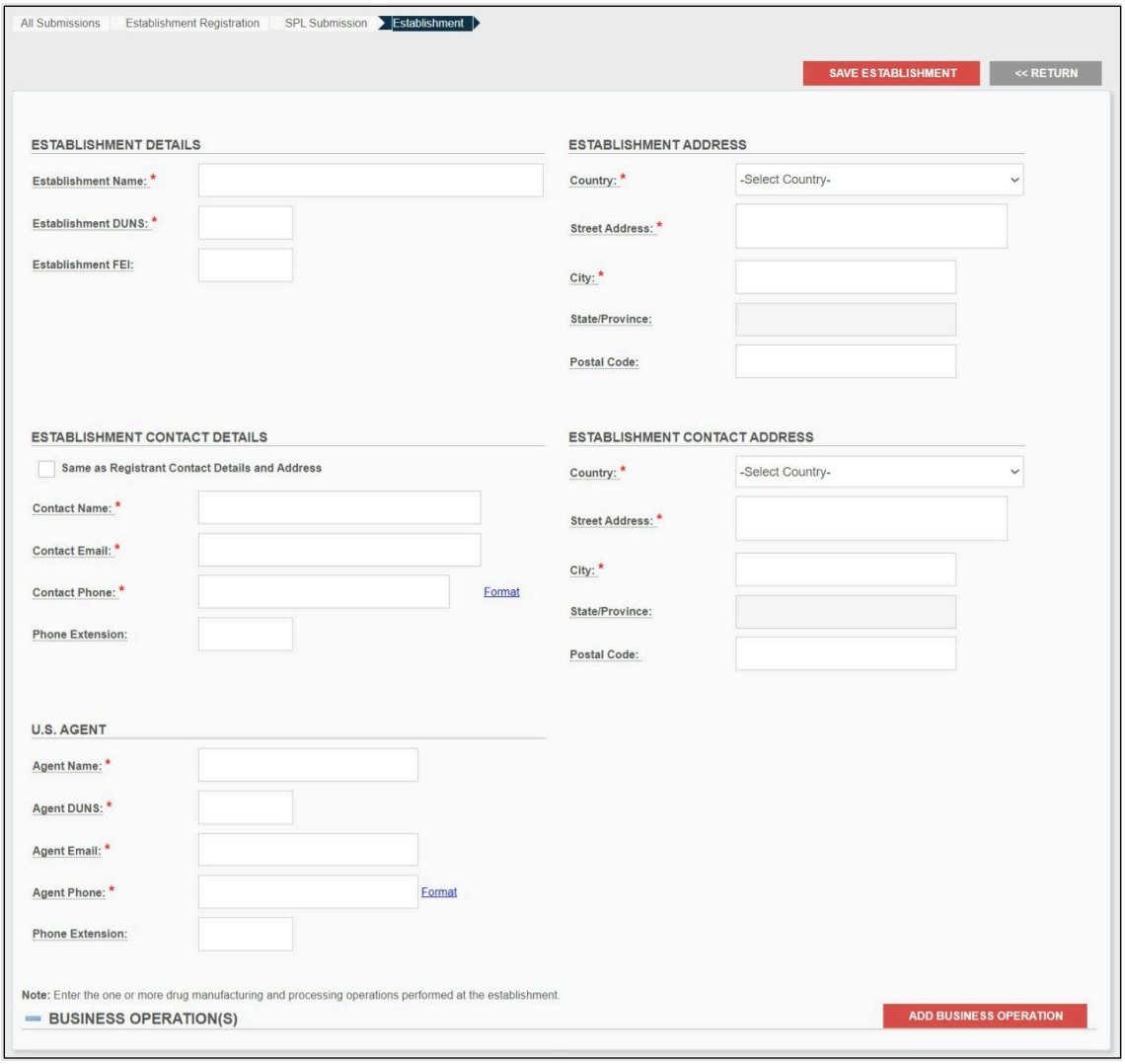
7. Selecting the '**Save As Draft**' button on the top right will save your work without submitting it. The '**Return**' button will send you back to the main Establishment Registration page without saving your changes.
8. Select '**Establishment Registration**' from the *Document Type* dropdown:

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

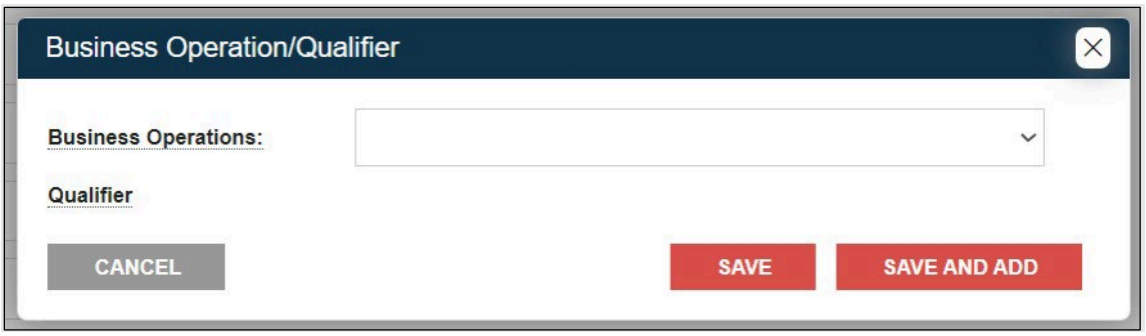


10. To add multiple establishments, click the '**Add Establishment**' button at the bottom of the page:

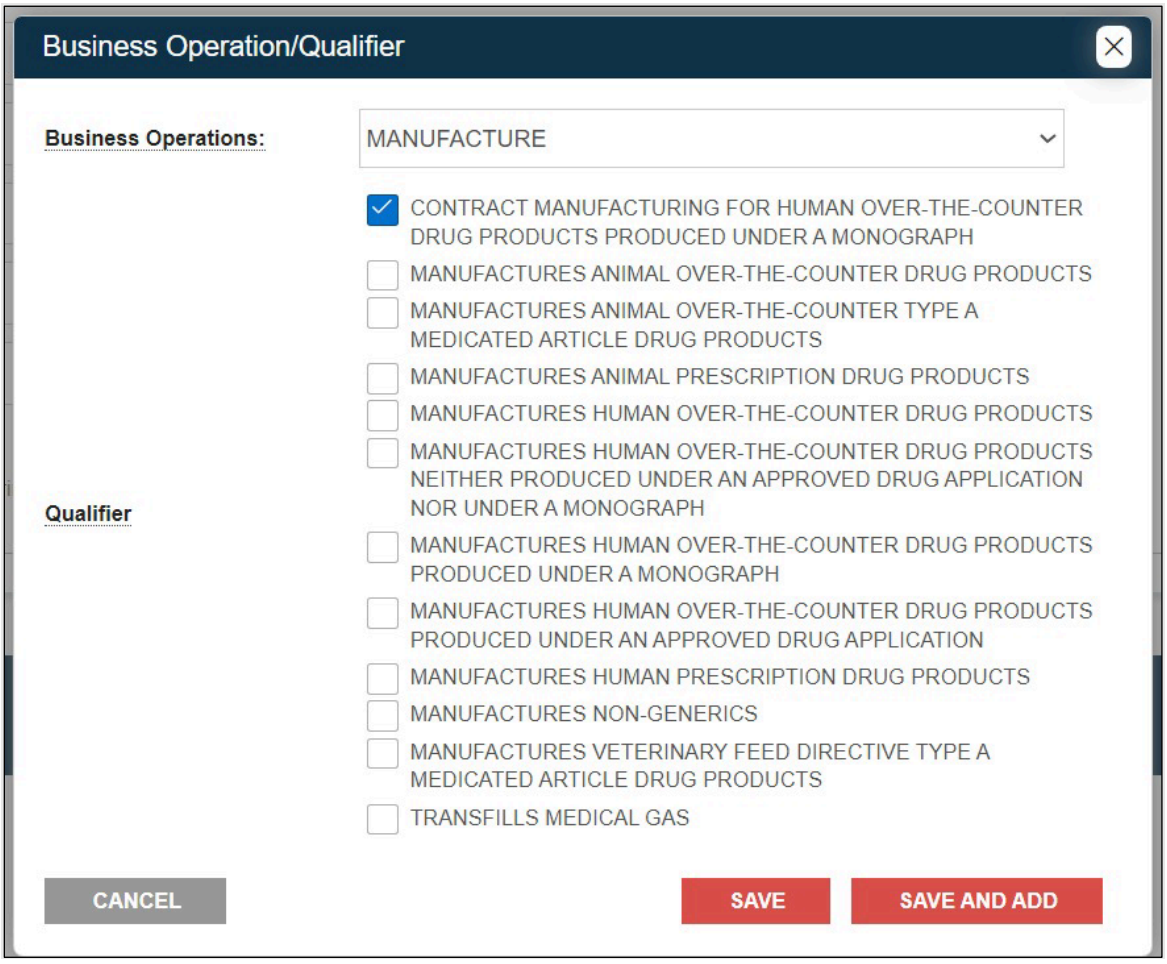
11. You will be shown a separate form. Fill in all the necessary fields:



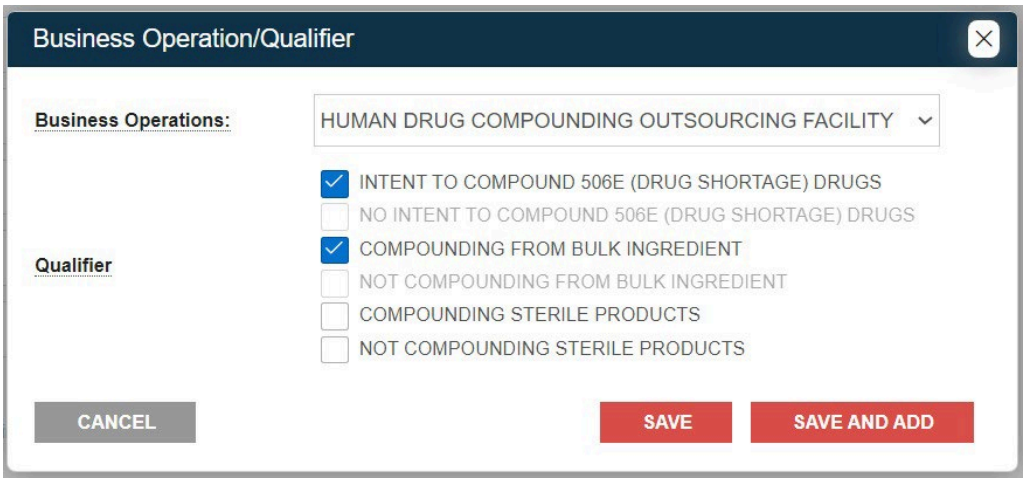
12. At the bottom of the page, click the '**Add Business Operation**' button. A dialog box will display:



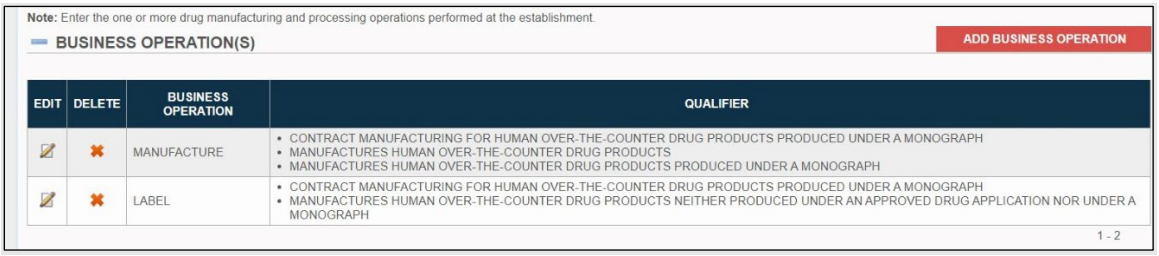
13. Select your business operations from the dropdown. Check all qualifier boxes that apply:



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



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



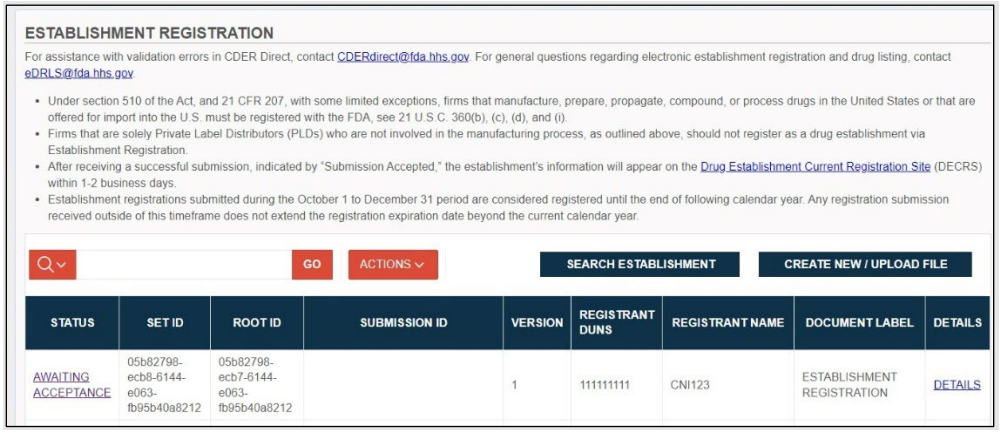
15. Return to the top of the page and select '**Save Establishment**' when finished. You will be returned to the main entry page, with the newly added establishment(s) listed at the bottom. Click the pencil icon to make edits to the establishment:

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

    a. '**Save As Draft**' – Save your entry and return to the main Establishment Registration page. No submission will be made.

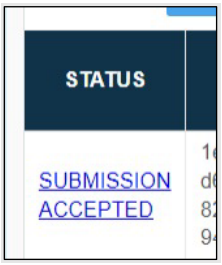
    b. '**Save And Validate**' - Save your entry + validate. This will check your submission for errors prior to submitting to the FDA. Validation may take some time. If you are ready to submit your SPL, you may skip this step entirely.

    c. '**Submit SPL**' - Submit your Establishment Registration to the FDA. You will then be returned to the Establishment Registration main page where you can view your pending submission(s) status:



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

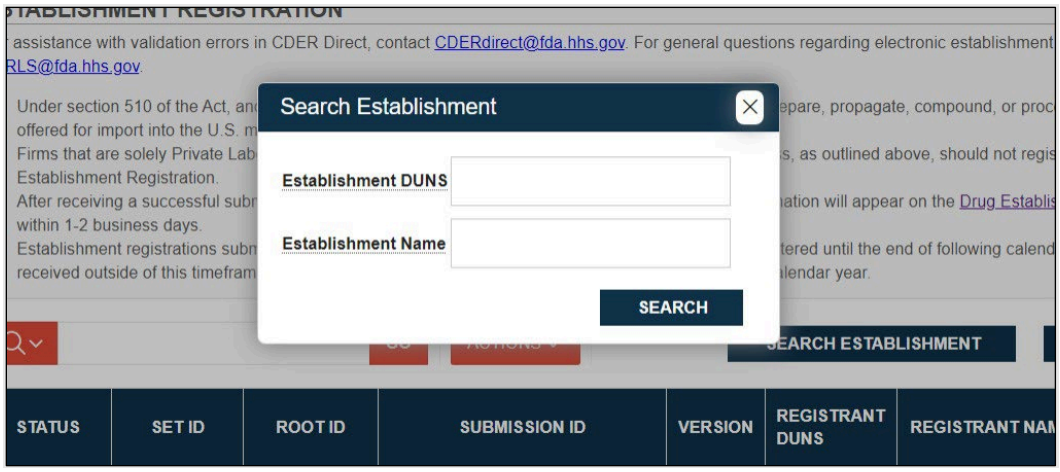
17. Click '**Return**' at any time to return to the main Establishment Registration page.
18. The *Status* field should read '*Submission Accepted*' when your submission has been validated and accepted by the FDA. You will receive an email to your account email address when the submission status changes.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



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

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

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



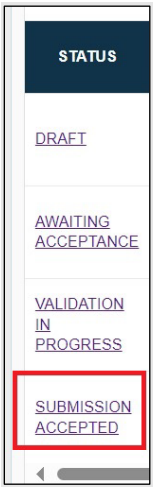
c. Click '**Search**' and your results will populate.

d. See Section 9.2: Searching and Filtering for additional help with filters and searching multiple establishments.

5.1.2 De-Registering a Drug Establishment

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

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



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

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

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

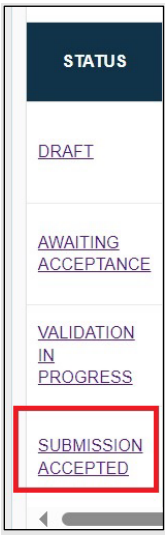
c. Click '**Submit SPL**' at the top right of the page and you will be taken to the *Establishment Registration* page. An email will be sent to your account email address to confirm your establishment de-registration/out of business status.

3. Click '**Create New/Upload File**' on the *Establishment Registration* page.
   a. Select '**Import an Existing Establishment Registration SPL**' and click '**Continue.**'
   b. See Steps (b-c) in the previous section.

5.1.3 No Changes to Establishment Registration

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

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



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

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

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

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

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

   a. Select '**Import an Existing Establishment Registration SPL**' and click '**Continue.**'

   b. See Steps 3(b)-3(c) in the previous section.

5.2 Drug NDC Labeler Code Request

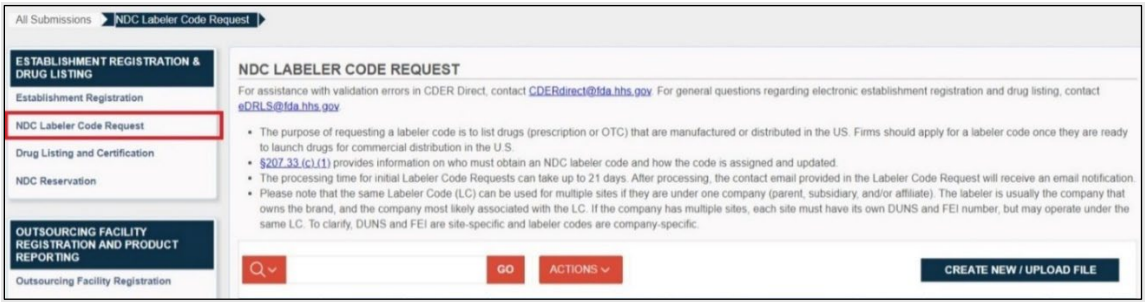
A drug **NDC Labeler Code Request** SPL submission will allow you to list drugs (prescription or OTC) that are manufactured or distributed in the United States. Use this only when you are ready to launch your drug products for commercial registration in the U.S. The same labeler code may be used for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

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

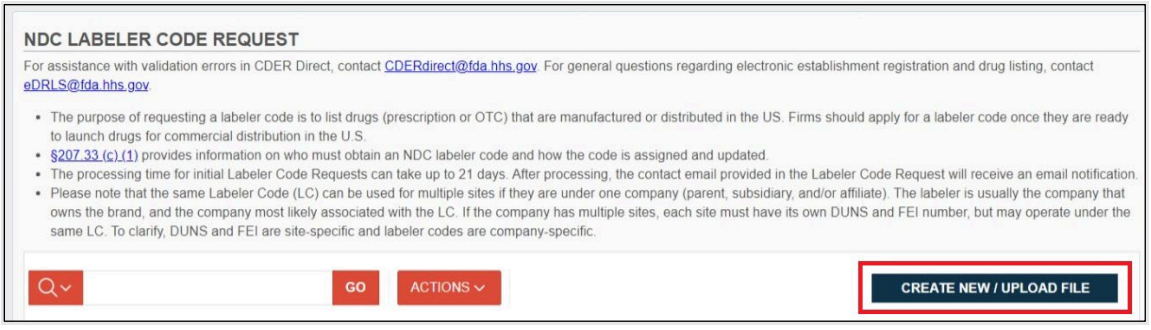
- Registration - Requesting a new NDC Labeler Code, or confirming or updating labeler code details.
- Inactivation – Suspend use of an existing NDC Labeler Code.

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

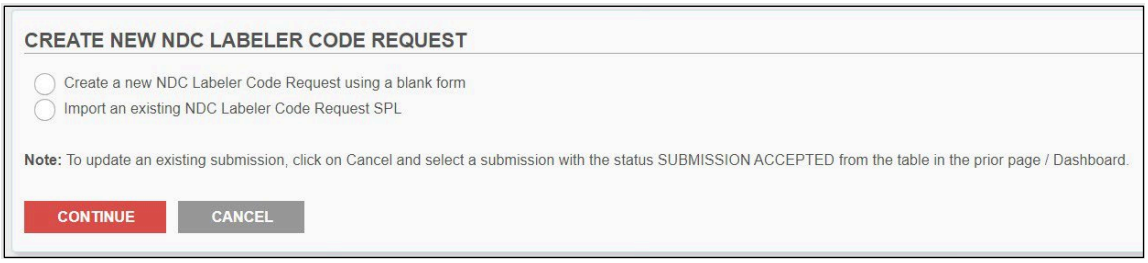
1. Log in to FDA Direct.
2. Select '**NDC Labeler Code Request**' under the *Establishment Registration & Drug Listing* section:



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



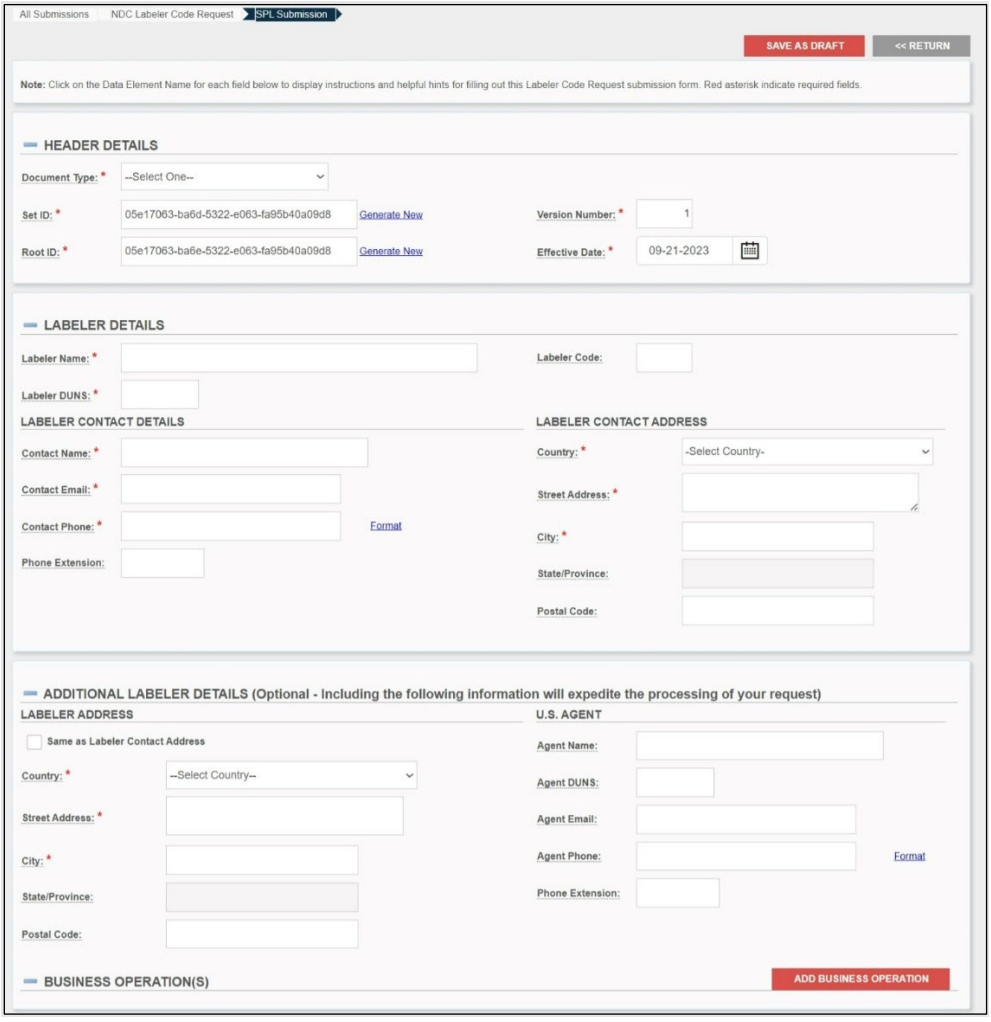
4. You will be given two options:



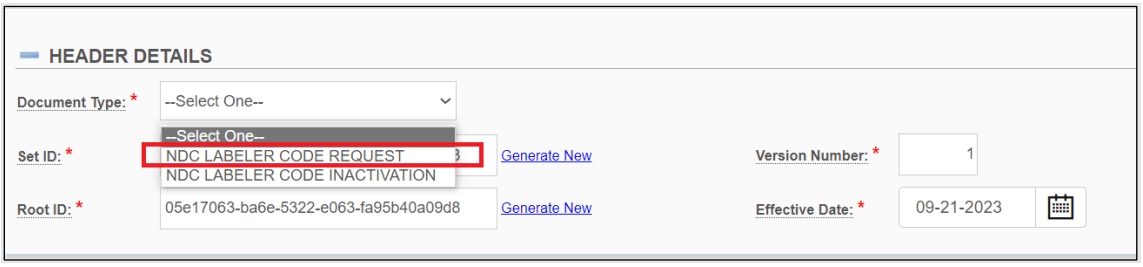
a. To upload a file from your computer directly, follow the steps outlined in Section 3: Submission Information. Then skip to Step 11 below and continue the instructions.

5. To create an SPL submission using a blank template, select the '**Create a new NDC Labeler Code Request using a blank form**' option.

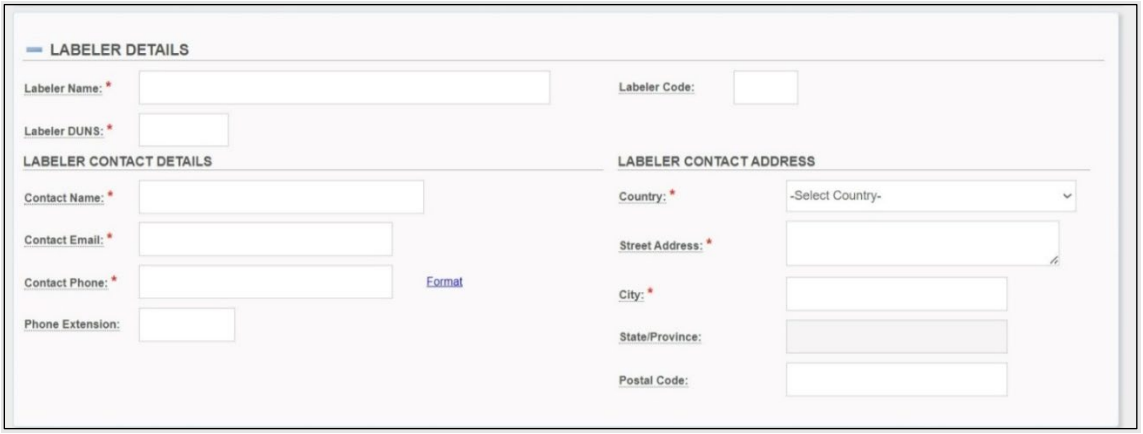
6. Click '**Continue**' and a blank template will display:



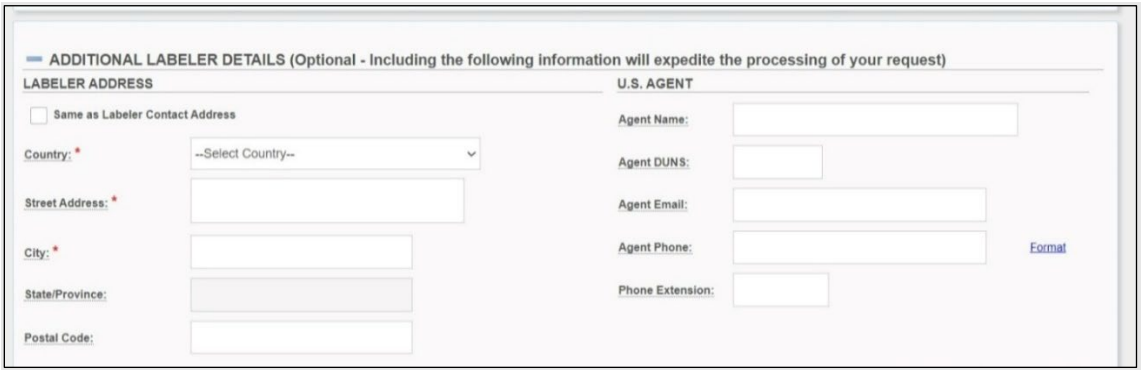
7. Selecting the '**Save Draft**' button at any time will save your work without submitting it. The '**Return**' button will send you back to the main NDC Labeler Code Request page without saving your changes.
8. Select '**NDC Labeler Code Request**' from the *Document Type* dropdown:



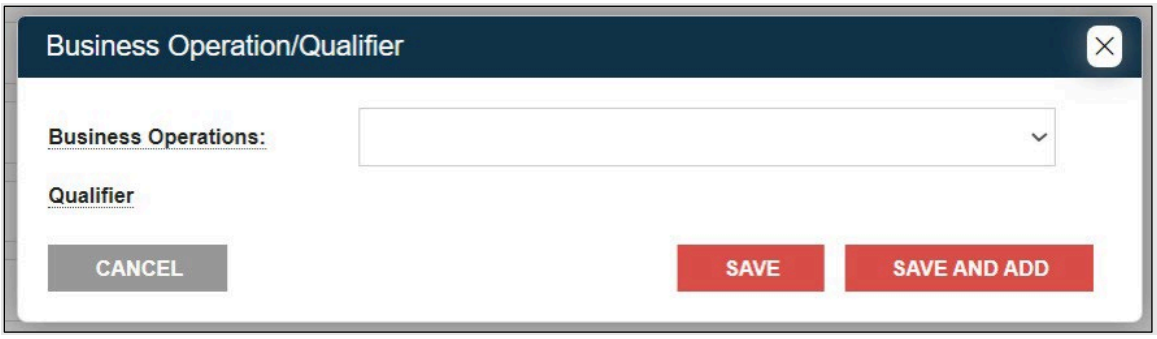
9. Fill in all blank fields in the *Labeler Details* section. If you are requesting a labeler code, leave the "Labeler Code" field blank:



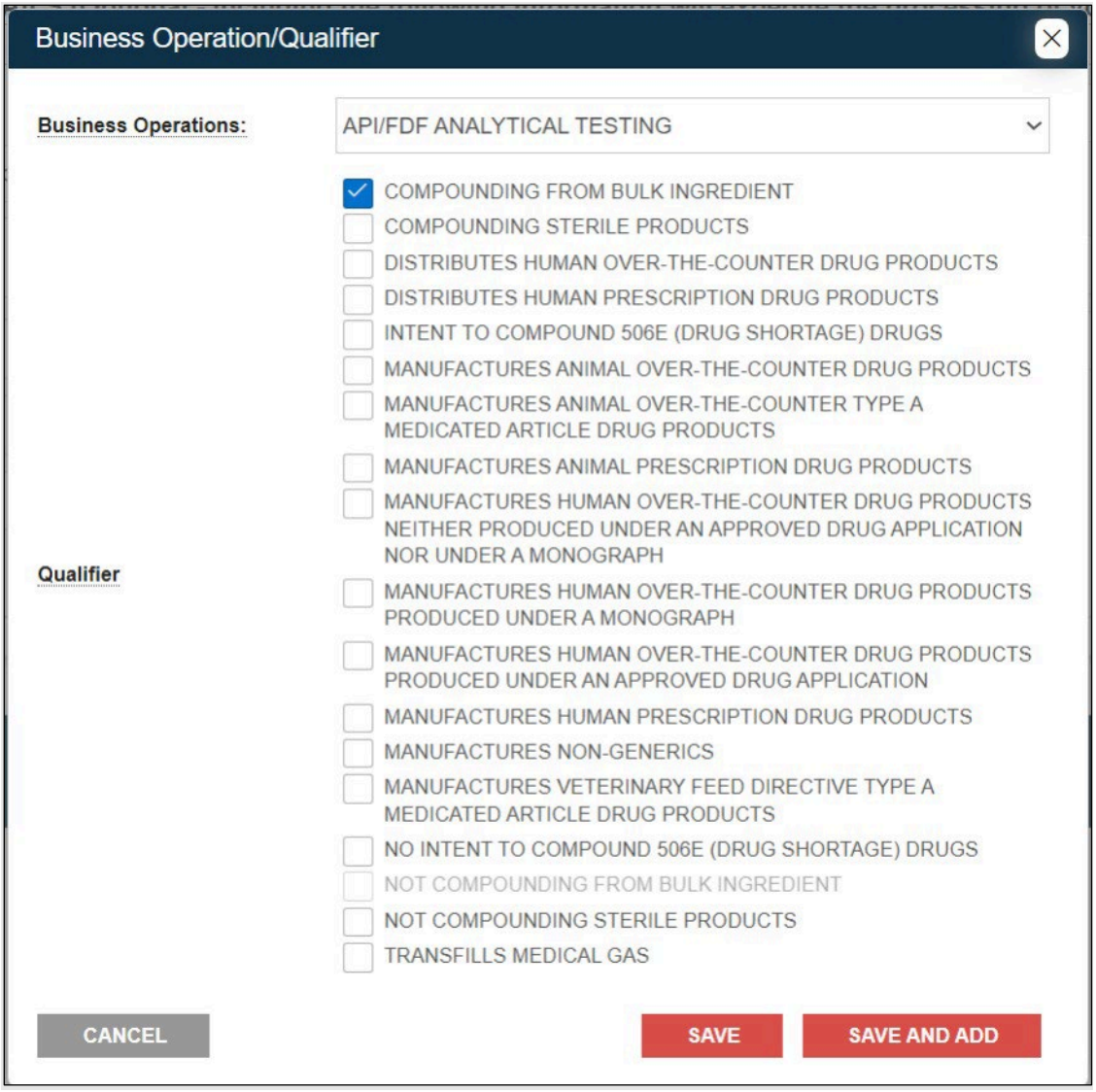
10. Information provided in the *Additional Labeler Details* section is optional, but including this information will expedite the processing of your NDC Labeler Code request:



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

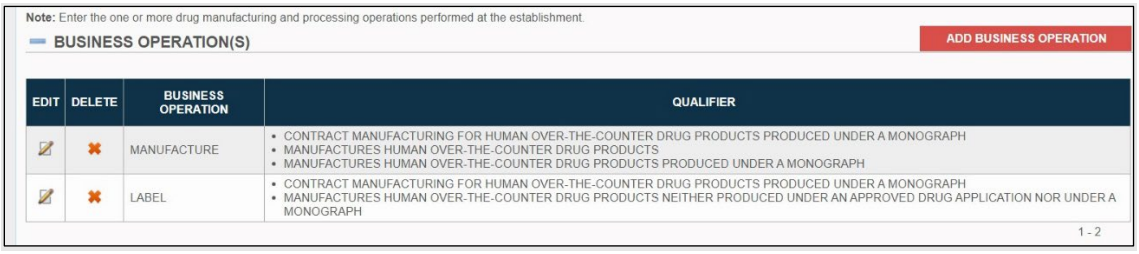


12. Select your business operations from the dropdown. Check all qualifier boxes that apply:



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

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



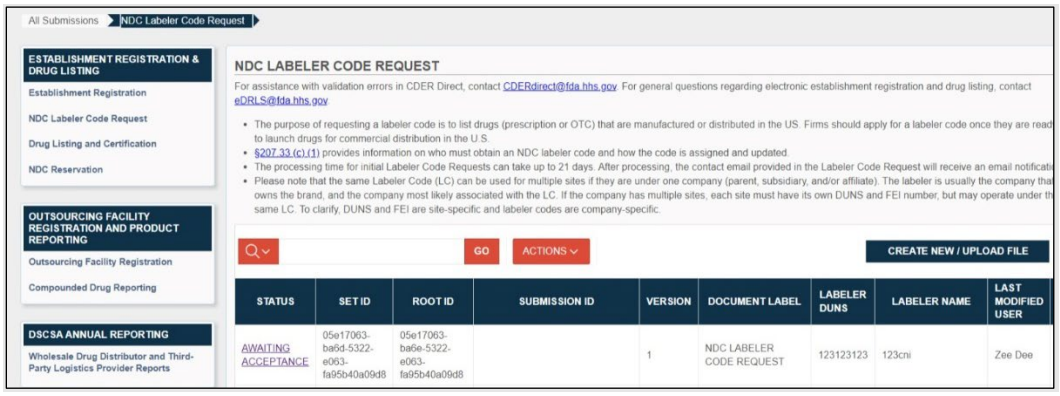
14. Click the pencil icon to make edits to any of the Business Operations or click the X to delete the specified operation.

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

    a. '**Save As Draft**' – Save your entry and return to the main NDC Labeler Code Request page. No submission will be made.

    b. '**Save And Validate**' - Save your entry + validate. This will check your submission for errors prior to submitting to the FDA. Validation may take some time. If you are ready to submit your SPL, you may skip this step entirely.

    c. '**Submit SPL**' - Submit your NDC Labeler Code Request to the FDA. You will then be returned to the NDC Labeler Code Request main page where you can view your pending submission(s) status:

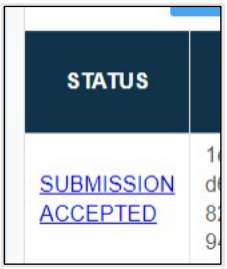


    d. '**Delete**' – Delete your draft entry completely.

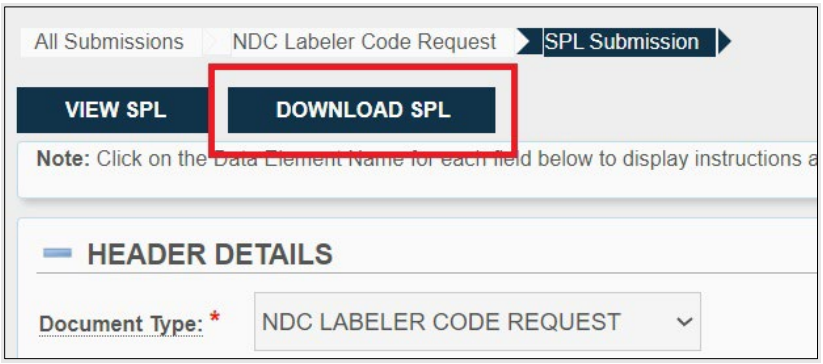
16. The *Status* field on the NDC Labeler Code Request main page should read '*Submission Accepted*' when your submission has been validated and accepted by the FDA.

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

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



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

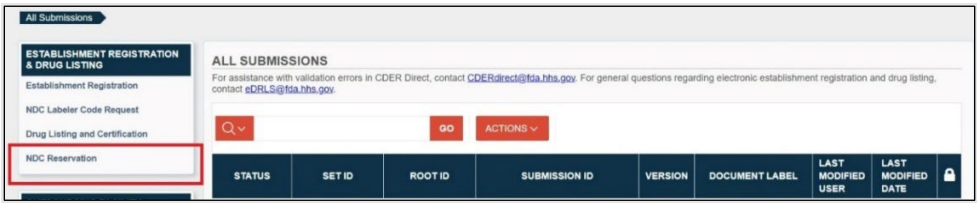


5.3 Drug NDC Reservation

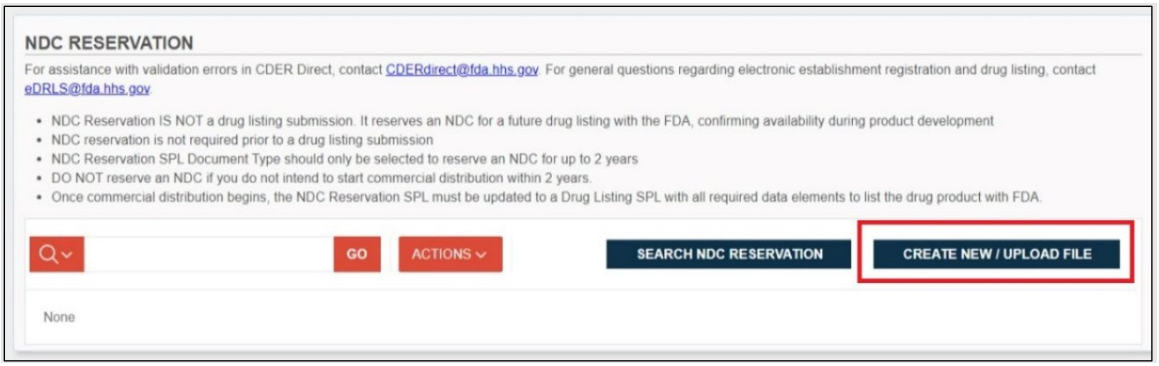
A drug **NDC Reservation** SPL submission reserves an NDC for a *future* drug listing with the FDA without requiring all data elements to be provided. It is *NOT* a drug listing submission. This submission template should only be used if you intend to begin commercial distribution within 2 years, as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

To reserve an NDC, do the following:

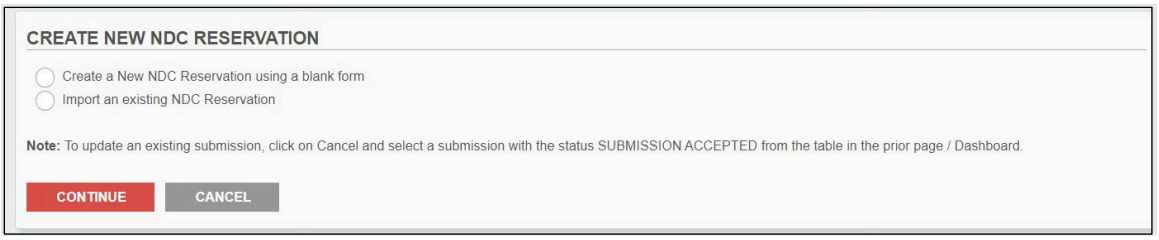
1. Log in to FDA Direct.
2. Select '**NDC Reservation**' under *Establishment Registration & Drug Listing*:



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



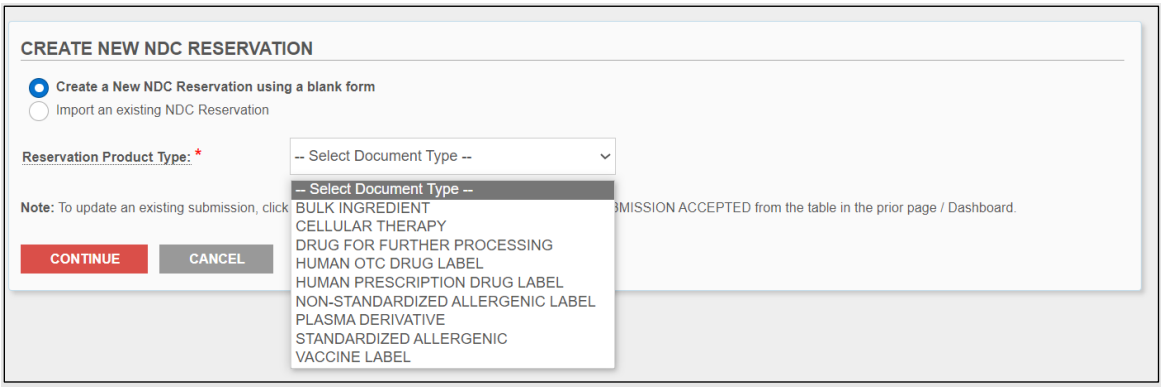
4. You will be given two options:



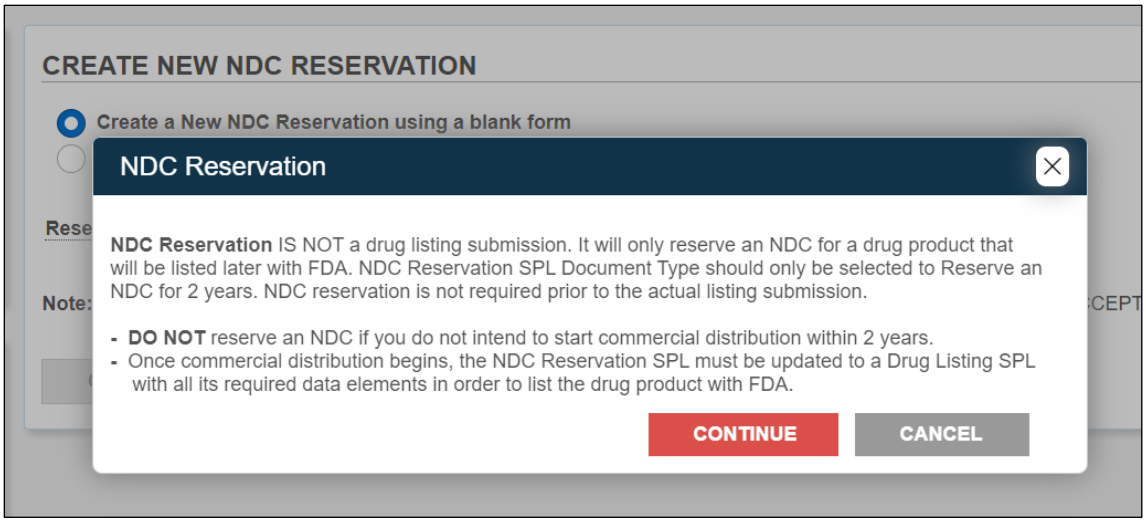
   a. To upload a file from your computer directly, follow the steps outlined in Section 3: Submission Information. Then skip to Step 9 below to continue the instructions.

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

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



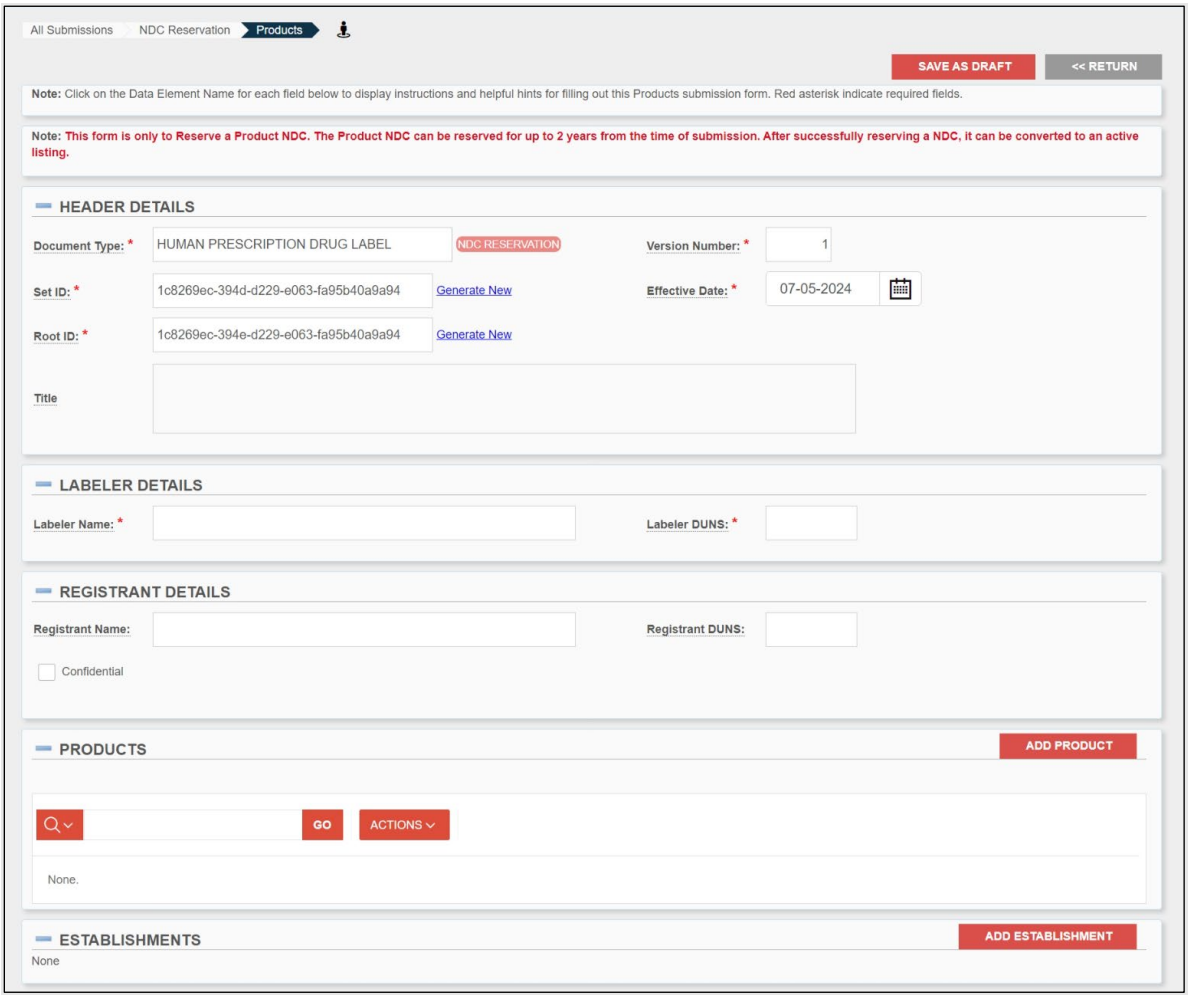
7. An informational dialog box will appear:



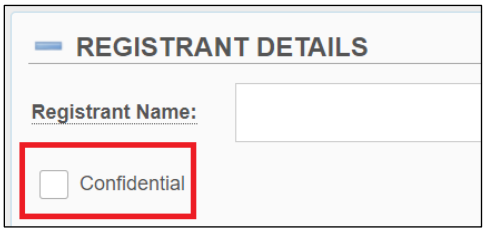
IMPORTANT: An NDC Reservation IS NOT a drug listing submission. It will only reserve an NDC for a drug product that will be listed later with FDA. The NDC Reservation SPL Document Type should only be selected to reserve an NDC for 2 years. An NDC reservation is not required prior to the actual listing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

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

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

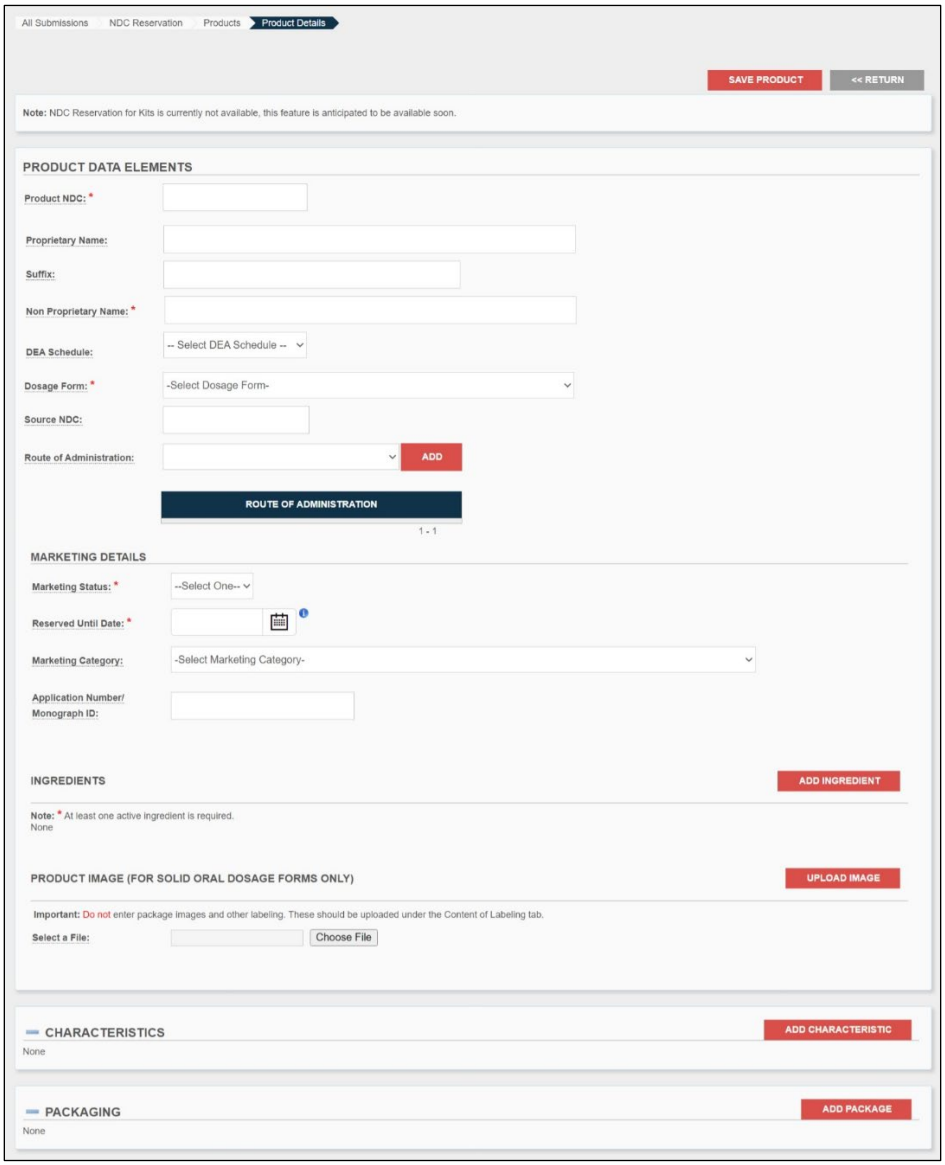


9. Fill out the *Labeler Details* section.
10. The *Registrant Details* section is optional. Clicking the '**Confidential**' check box in this section will keep this submission from being visible to the public:



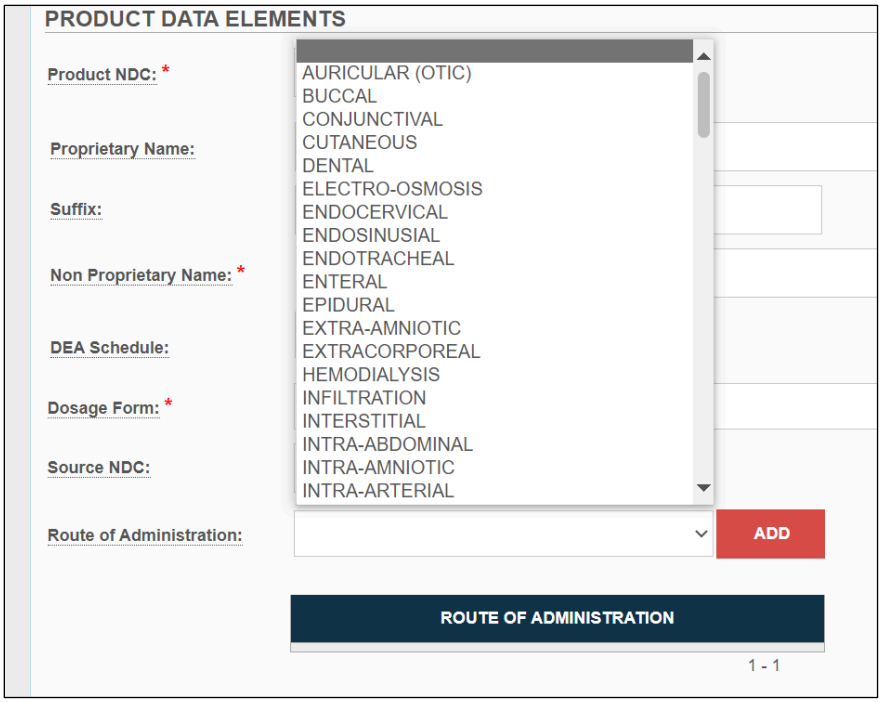
11. To add products, click the '**Add Product**' button at the bottom of the template:

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

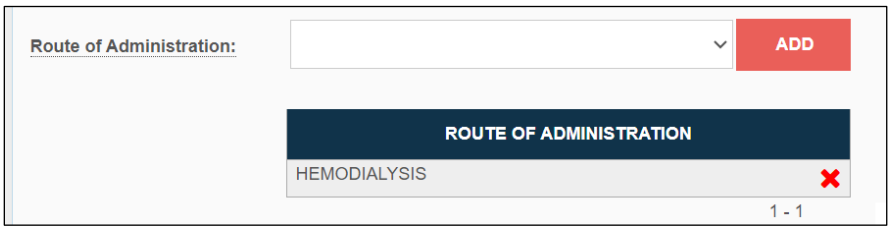


13. Fill out the requested information in the *Product Data Elements* section.

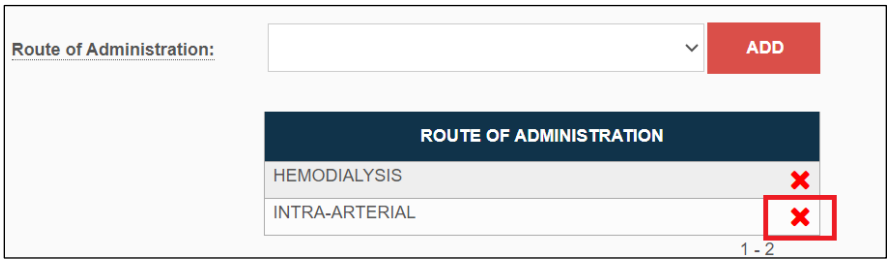
a. To add a '**Route of Administration**,' select the dropdown and choose from the list:



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

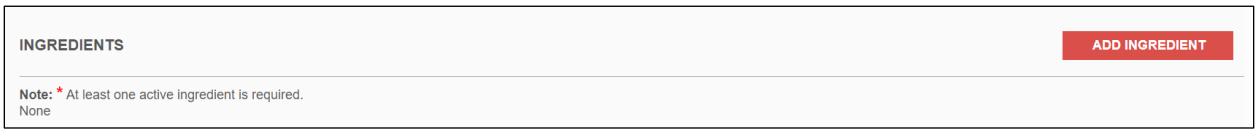


c. To remove a selection, simply click the 'X' beside a route of administration:

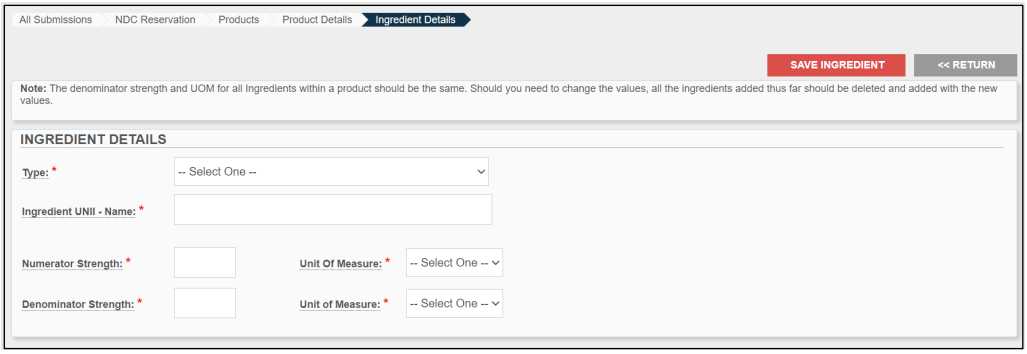


14. Enter information into the *Marketing Details* section.

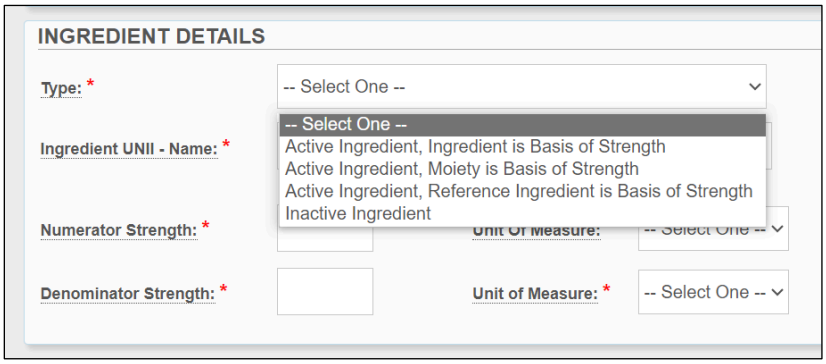
15. To '**Add An Ingredient**,' click the button under the *Ingredients* section:



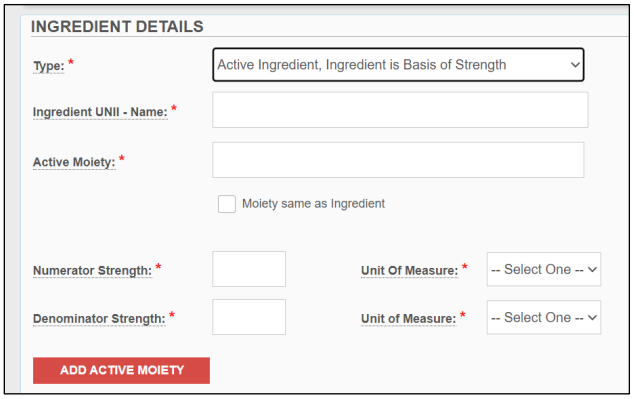
a. You will be taken to a separate page where you can enter information about a single ingredient:



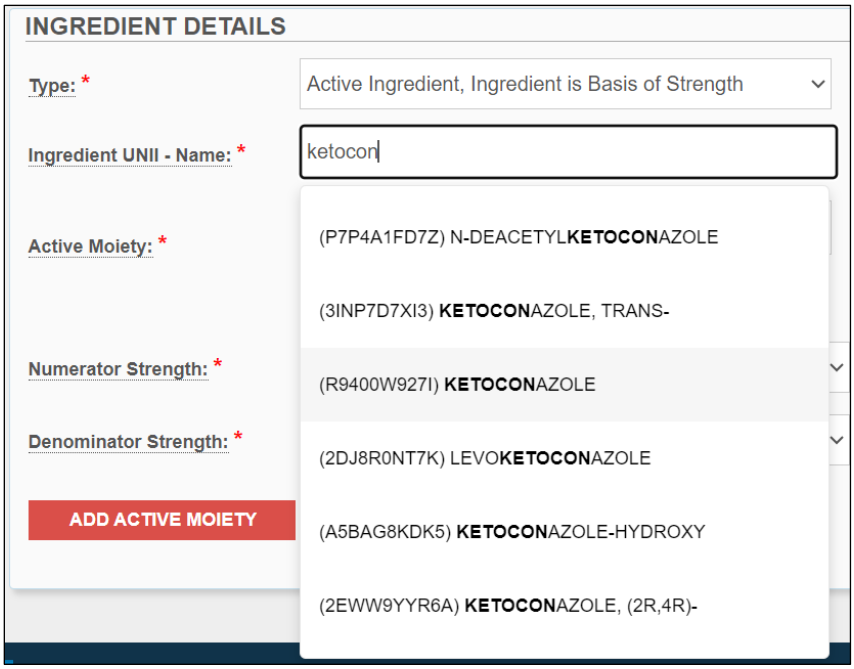
b. Select the dropdown for '**Type**':



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



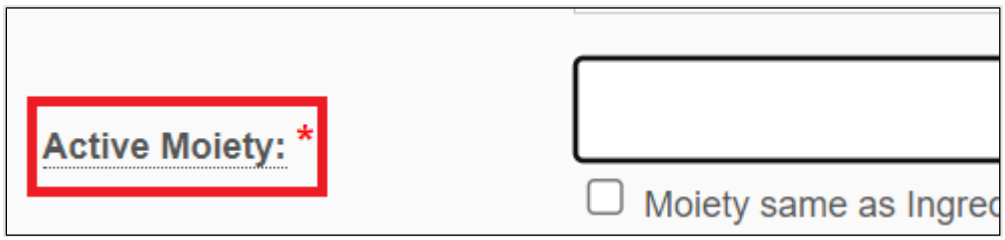
d. Enter an Ingredient UNII, or simply begin typing the ingredient name into the empty field:

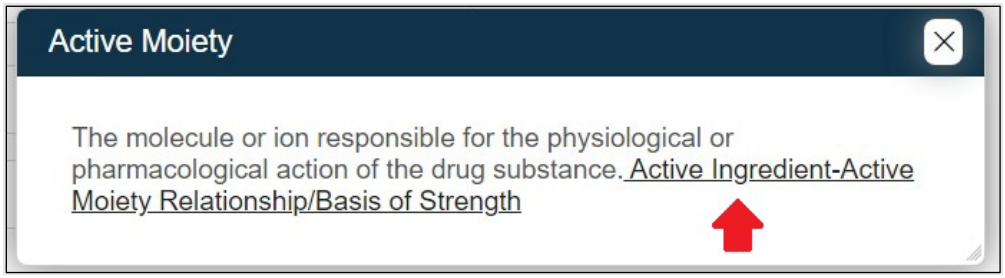


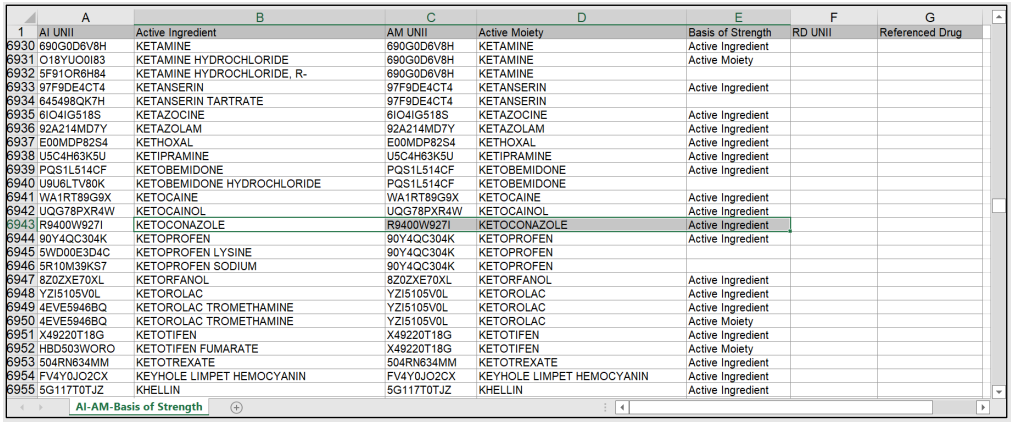
e. If the ingredient and moiety are the same, simply click the checkbox labeled 'Moiety Same As Ingredient' to automatically copy the ingredient to the active moiety field.

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

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



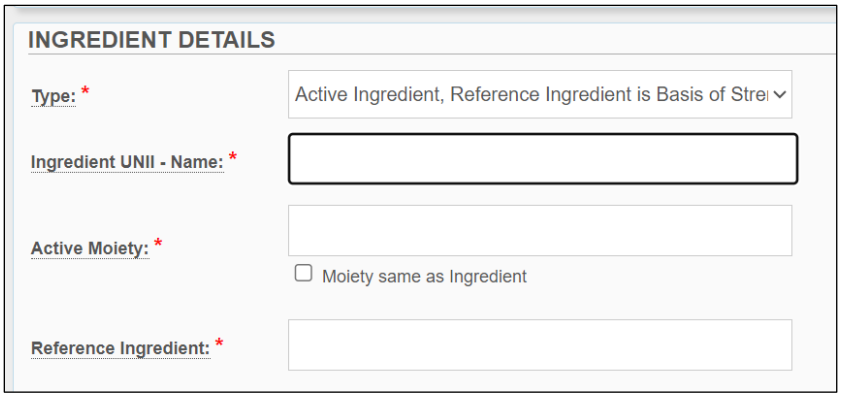




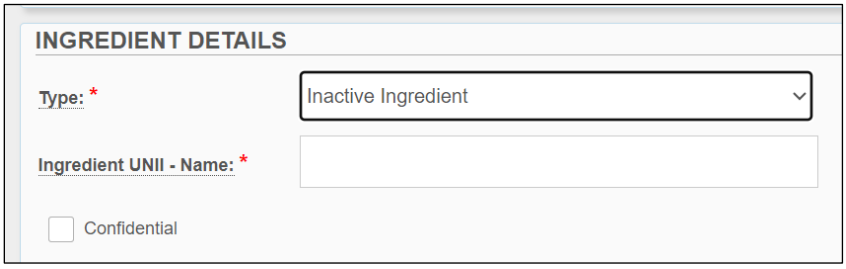
	A	B	C	D	E	F	G
1	AI UNII	Active Ingredient	AM UNII	Active Moiety	Basis of Strength	RD UNII	Referenced Drug
6930	690G0D6V8H	KETAMINE	690G0D6V8H	KETAMINE	Active Ingredient		
6931	O18YUO0I83	KETAMINE HYDROCHLORIDE	690G0D6V8H	KETAMINE	Active Moiety		
6932	5F91OR6H84	KETAMINE HYDROCHLORIDE, R-	690G0D6V8H	KETAMINE			
6933	97F9DE4CT4	KETANSERIN	97F9DE4CT4	KETANSERIN	Active Ingredient		
6934	645498QK7H	KETANSERIN TARTRATE	97F9DE4CT4	KETANSERIN			
6935	6IO4IG518S	KETAZOCINE	6IO4IG518S	KETAZOCINE	Active Ingredient		
6936	92A214MD7Y	KETAZOLAM	92A214MD7Y	KETAZOLAM	Active Ingredient		
6937	E00MDP82S4	KETHOXAL	E00MDP82S4	KETHOXAL	Active Ingredient		
6938	U5C4H63K5U	KETIPRAMINE	U5C4H63K5U	KETIPRAMINE	Active Ingredient		
6939	PQS1L514CF	KETOBEMIDONE	PQS1L514CF	KETOBEMIDONE	Active Ingredient		
6940	U9U6LTV80K	KETOBEMIDONE HYDROCHLORIDE	PQS1L514CF	KETOBEMIDONE			
6941	WA1RT89G9X	KETOCAINE	WA1RT89G9X	KETOCAINE	Active Ingredient		
6942	UQG78PXR4W	KETOCAINOL	UQG78PXR4W	KETOCAINOL	Active Ingredient		
6943	R9400W927I	KETOCONAZOLE	R9400W927I	KETOCONAZOLE	Active Ingredient		
6944	90Y4QC304K	KETOPROFEN	90Y4QC304K	KETOPROFEN	Active Ingredient		
6945	5WD00E3D4C	KETOPROFEN LYSINE	90Y4QC304K	KETOPROFEN			
6946	5R10M39KS7	KETOPROFEN SODIUM	90Y4QC304K	KETOPROFEN			
6947	8Z0ZXE70XL	KETORFANOL	8Z0ZXE70XL	KETORFANOL	Active Ingredient		
6948	YZI5105V0L	KETOROLAC	YZI5105V0L	KETOROLAC	Active Ingredient		
6949	4EVE5946BQ	KETOROLAC TROMETHAMINE	YZI5105V0L	KETOROLAC	Active Ingredient		
6950	4EVE5946BQ	KETOROLAC TROMETHAMINE	YZI5105V0L	KETOROLAC	Active Moiety		
6951	X49220T18G	KETOTIFEN	X49220T18G	KETOTIFEN	Active Ingredient		
6952	HBD503WORO	KETOTIFEN FUMARATE	X49220T18G	KETOTIFEN	Active Moiety		
6953	504RN634MM	KETOTREXATE	504RN634MM	KETOTREXATE	Active Ingredient		
6954	FV4Y0JO2CX	KEYHOLE LIMPET HEMOCYANIN	FV4Y0JO2CX	KEYHOLE LIMPET HEMOCYANIN	Active Ingredient		
6955	5G117T0TJZ	KHELLIN	5G117T0TJZ	KHELLIN	Active Ingredient		

AI-AM-Basis of Strength

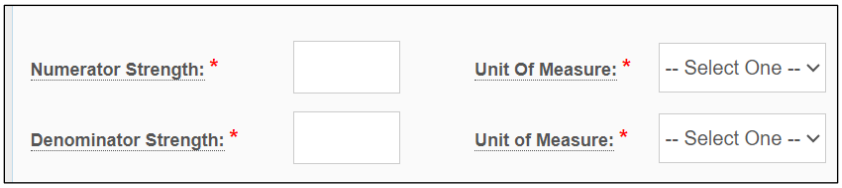
g. If you selected the third '**Type**' option 'Reference Ingredient is Basis of Strength', a Reference Ingredient field will display below the Active Moiety field:



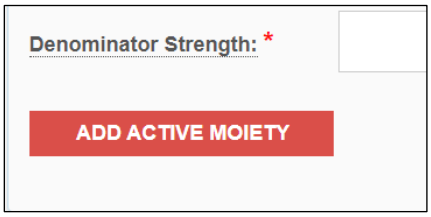
h. If you selected the 'Inactive Ingredient' option for '**Type**,' a checkbox labeled 'Confidential' will appear below the Ingredient UNII field:



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



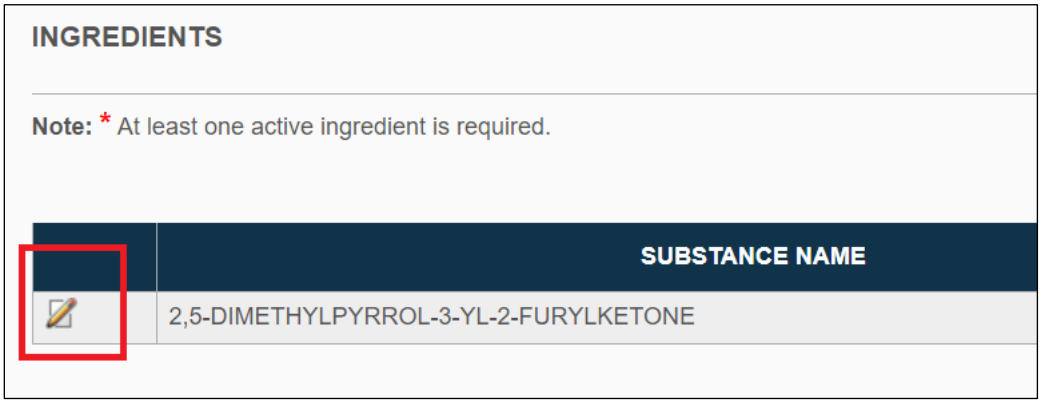
j. For all ingredient types (except 'Inactive Ingredient'), you will have the option to click the button '**Add Active Moiety**' to add additional active moieties:



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

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

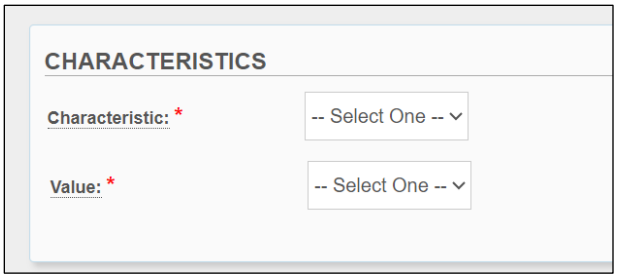
m. You can edit an ingredient on the Product Details page by clicking the pencil icon:



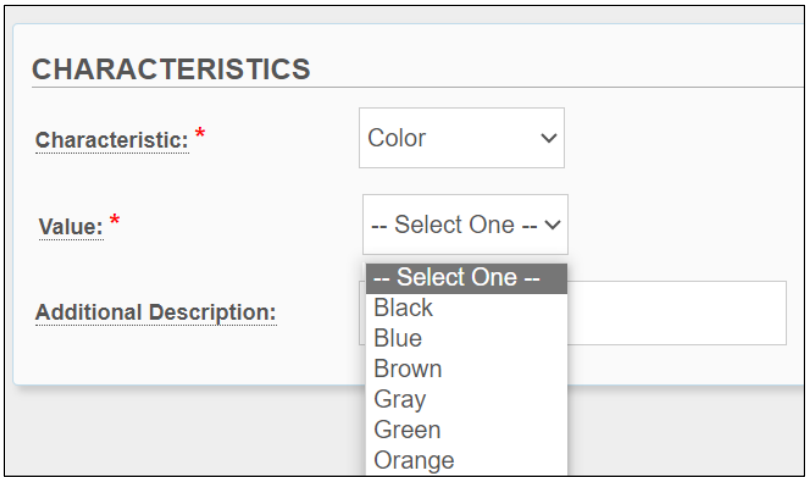
16. If your product is a **<u>solid oral dosage form</u>** ***only***, add a product image (JPG format):

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

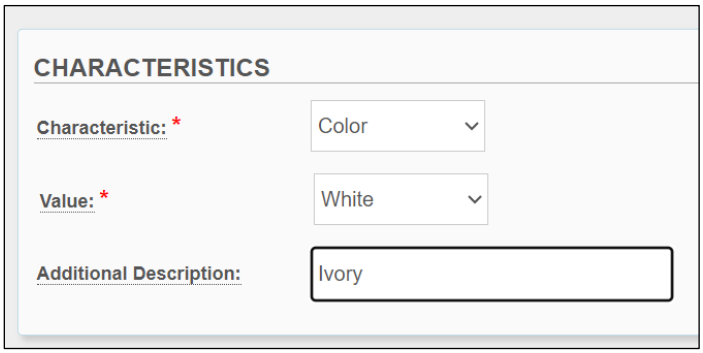
a. You will be sent to a separate *Characteristics* page:



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



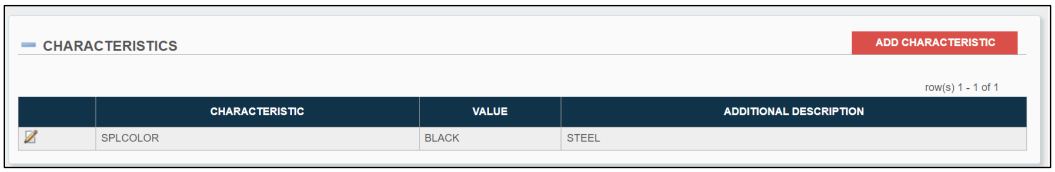
c. You can enter more specific details for a selected characteristic in the '**Additional Description**' field, which can include shades of colors ("ivory" white) or shape variations (triangle with "rounded edges"):



d. Click '**Save Characteristic**' on the top right of the page when finished. You will be returned to the Product Details page.

e. Only one characteristic can be entered at a time, so repeat the above steps to add additional characteristics.

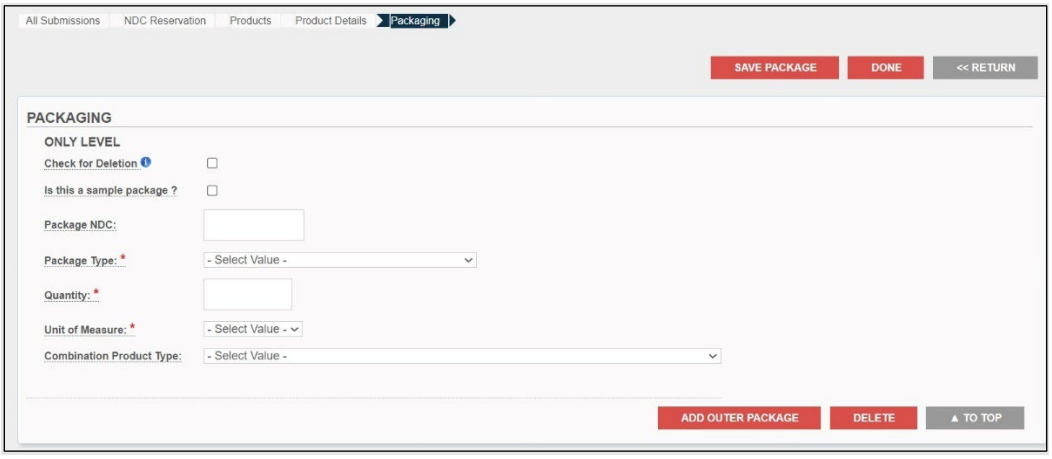
f. To edit a characteristic, click the pencil icon beside the selected characteristic on the Product Details page (toward the bottom of the page):



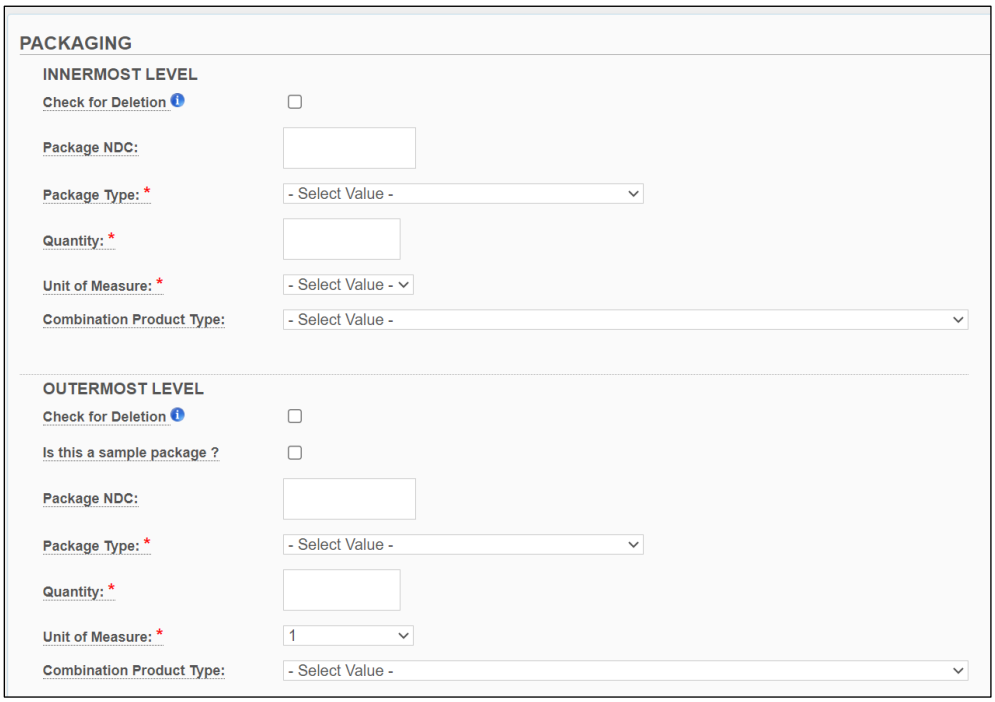
18. To add a Package:

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

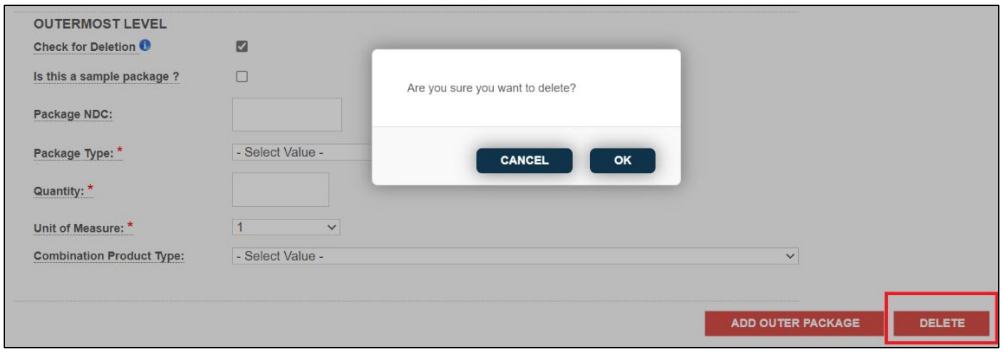
b. Enter all applicable data for the inner package:



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

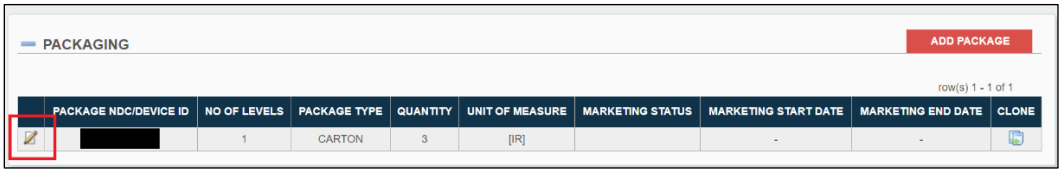


d. To delete an outer package, click the '**Check for Deletion**' checkbox and then select the '**Delete**' button:

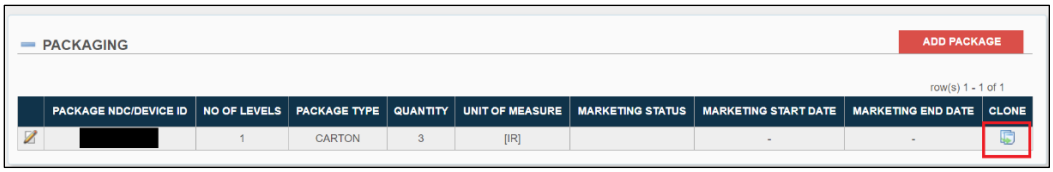


e. When finished, click '**Save Package**' at the top of the page to save your changes and return to the product details page.

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

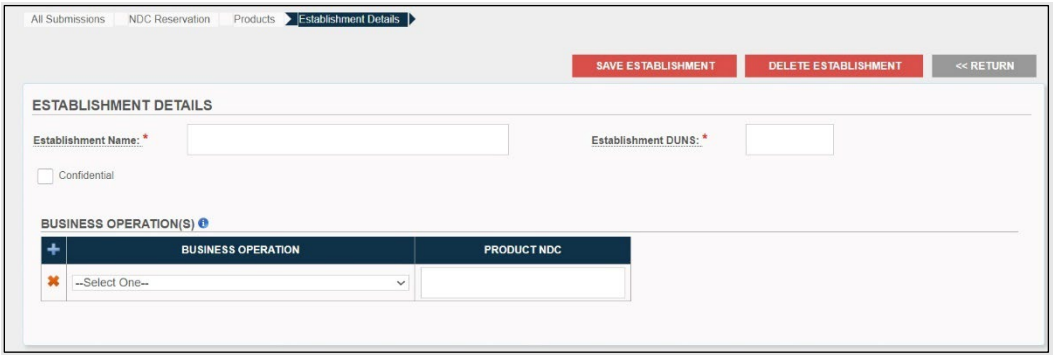


g. To make an exact duplicate of a package you previously created, click the '**Clone**' icon:



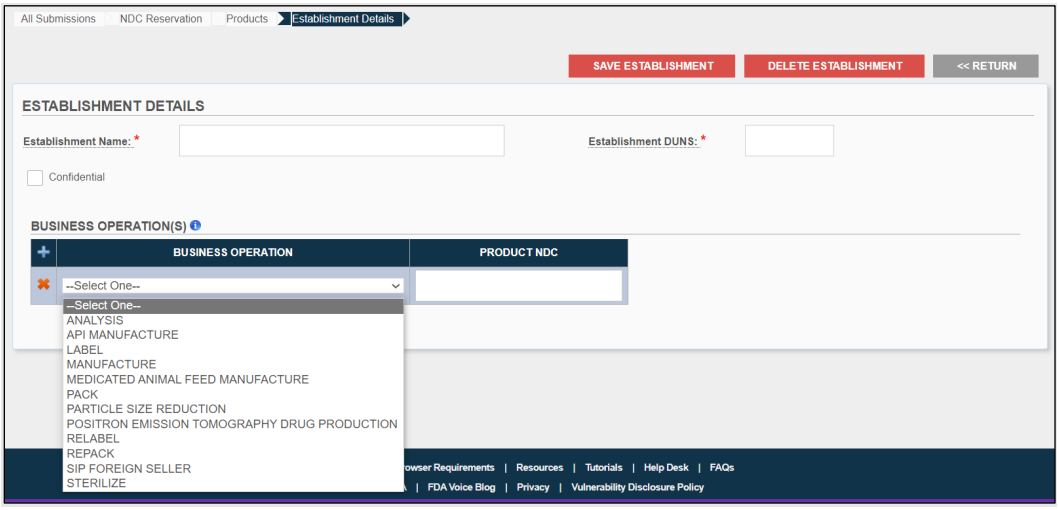
19. Repeat Steps 11-18 to add more products.

20. Navigate to the *Establishments* section at the bottom of the page. To enter an establishment, click the '**Add Establishment**' button. You will be sent to a separate page:

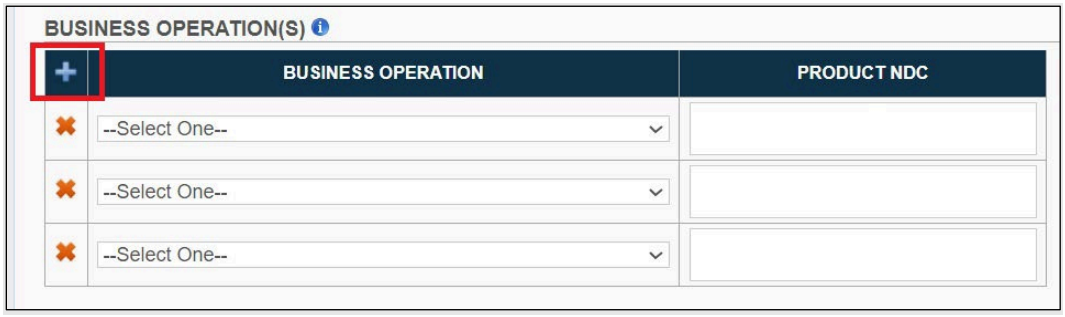


a. Enter your Establishment Name and DUNS.

b. Select your business operation(s) from the dropdown and input the product NDC for each operation:



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



d. Click '**Save Establishment**' button to save your work and return to the previous page. Click '**Delete Establishment**' to delete your establishment addition(s) and return to the previous page. The '**Return**' button will send you back to the previous page without saving the establishment changes.

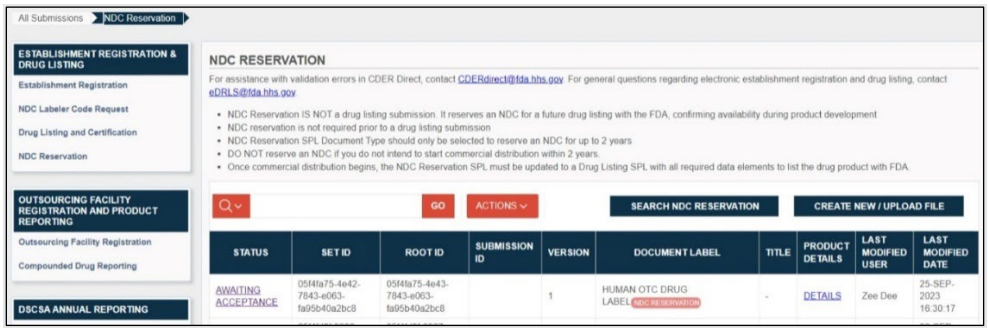
21. All added establishment details will display under the *Establishments* section:

22. When all fields have been entered to your satisfaction, you can do the following:

a. '**Save As Draft**' – Save your entry and return to the main NDC Reservation page. No submission will be made.

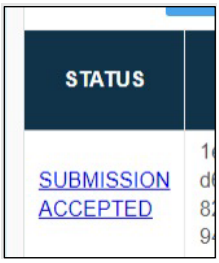
b. '**Save And Validate**' - Save your entry + validate. This will check your submission for errors prior to submitting to the FDA. Validation may take some time. If you are ready to submit your SPL, you may skip this step entirely.

c. '**Submit SPL**' - Submit your NDC Reservation SPL submission to the FDA. You will then be returned to the NDC Reservation main page where you can view your pending submission(s) status:



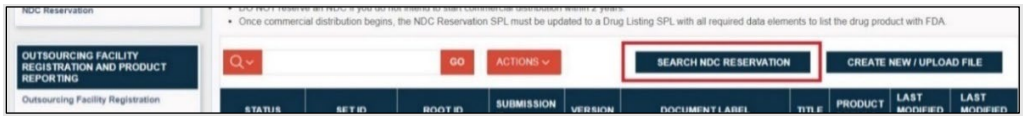
d. '**Delete**' – Delete your entry draft completely.

23. Click '**Return**' at any time to return to the main NDC Reservation page.
24. The *Status* field should read '*Submission Accepted*' when your submission has been validated and accepted by the FDA. You will receive an email to your account email address when the submission status changes.
25. Once your submission has been accepted, you will be able to download a copy of the submission as a zip file. Go to the main NDC Reservation page and click the latest '*Submission Accepted*' text link:

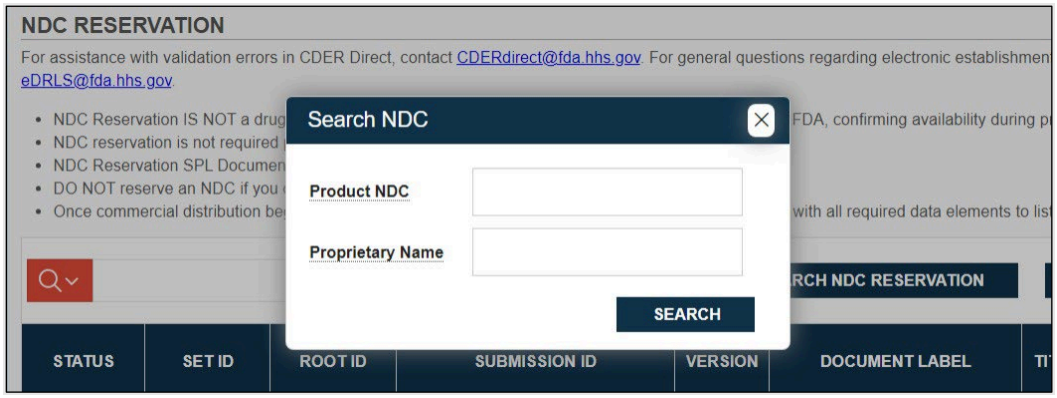


26. Click '**Download SPL**' on the top left of the page to download the zip file. You can also select '**View SPL**' for a quick look at your submission.

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



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



c. Click '**Search**' and your results will populate.

d. See Section 9.2: Searching and Filtering for additional help with filters and searching multiple reservations.

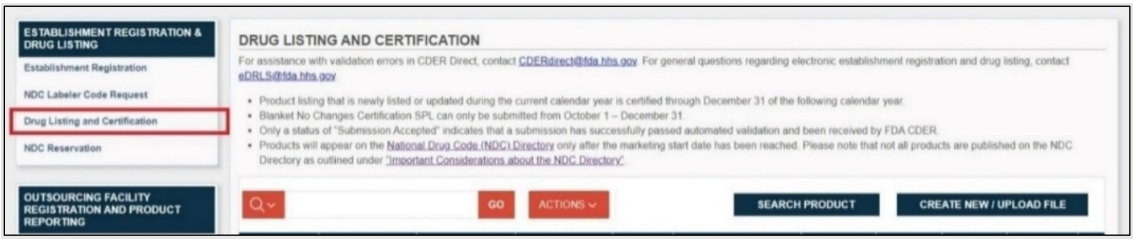
5.4 Drug Product Listing and Certification

A **Drug Product Listing and Certification** SPL submission will allow you to list and certify your drug products. This includes the following types of drugs:

- Bulk Ingredient
- Cellular Therapy
- Drug For Further Processing
- Human OTC Drug Label
- Human Prescription Drug Label
- Non-Standardized Allergenic
- Plasma Derivative
- Standardized Allergenic
- Vaccine Label

To list a drug product with the FDA:

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



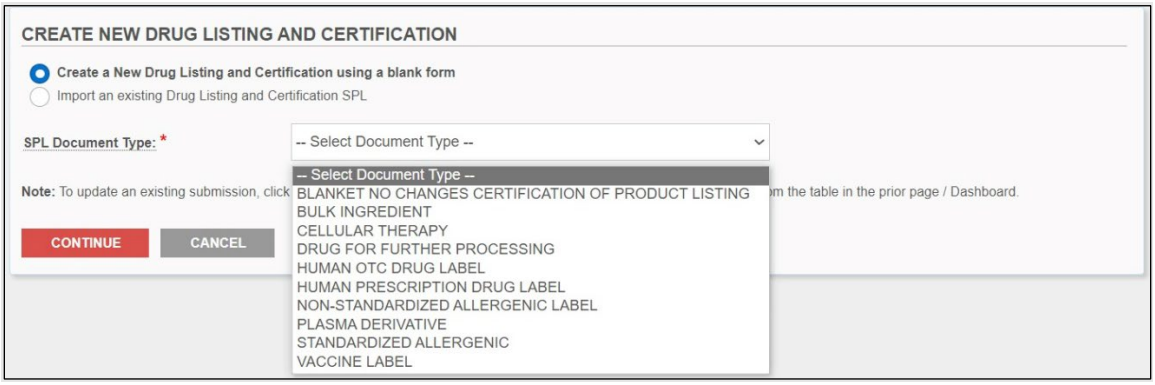
3. Click '**Create New/Upload File**' on the Drug Listing and Certification main page:

4. You will be given two options:

   a. To upload a file from your computer directly, follow the steps outlined in Section 3: Submission Information. Then skip to Step 8 below and continue the instructions.

5. To create a new drug listing SPL submission using a blank template, select the '**Create a new Drug Listing and Certification using a blank form**' option.

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

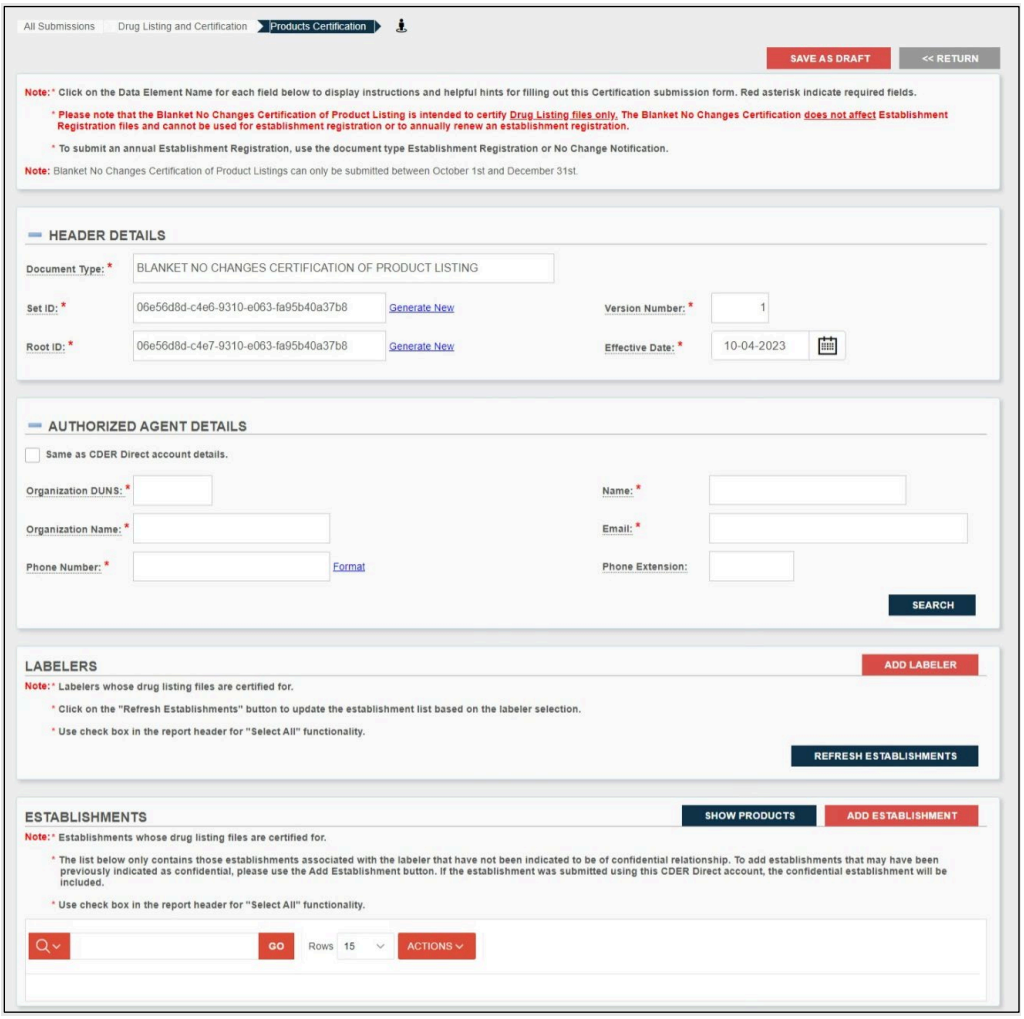


7. For most document types, skip to Step 10.

8. For the '**Blanket No Changes Certification of Product Listing**' document type **only**, complete the following:

    a. Select '**Blanket No Changes Certification of Product Listing**' from the *Document Type* dropdown, then press '**Continue**.'

    b. A blank template will display:



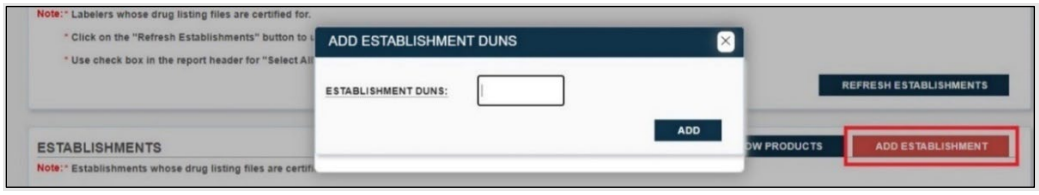
    c. All fields in the *Header Details* section will be automatically generated.

    d. To name yourself as the Authorized Agent, select the '**Same as CDER Direct account details**' checkbox, and the fields will populate automatically:

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

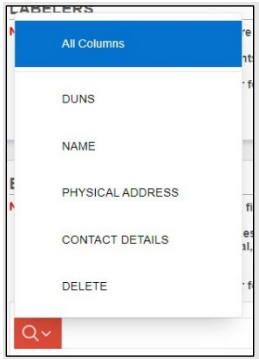
f. Click '**Refresh Establishments**' to update the following section with establishment data based on your labeler code entries.

g. If an establishment has been marked as confidential, their data must be added via the '**Add Establishment**' button:



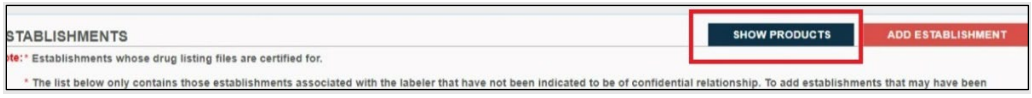
"If the establishment was submitted using this CDER Direct account, the confidential establishment will be included."

h. To search on an establishment, enter a partial or full search term. This can be the establishment DUNS, the establishment name, establishment's physical address, or contact details. You can also search under a specific column instead of all of them (default):

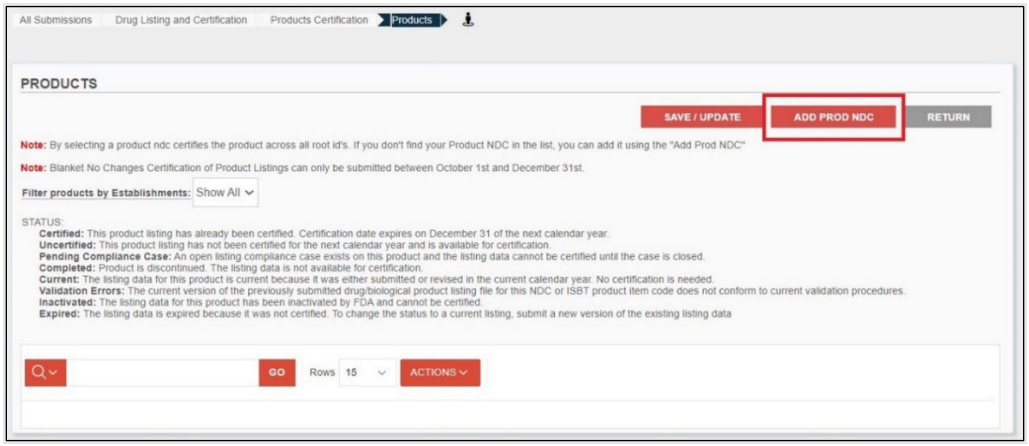


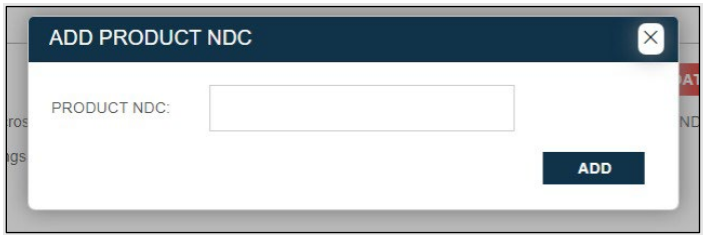
i. For more advanced search and filtering options, see Section 9.2: Searching and Filtering.

j. Click the '**Show Products**' button under the *Establishments* section:



k. You can add a product via the '**Add Prod NDC**' button if your product does not display at the bottom of the *Products* page:

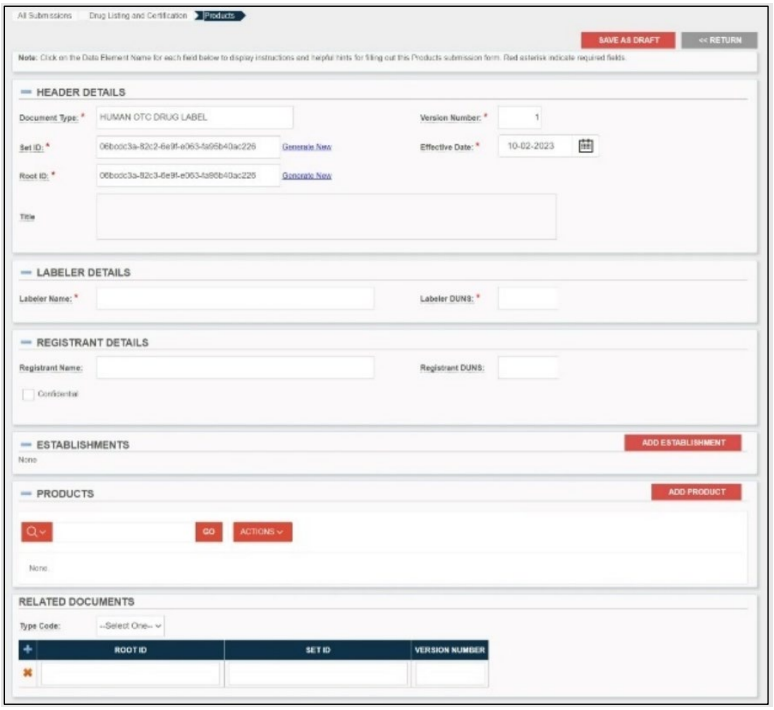




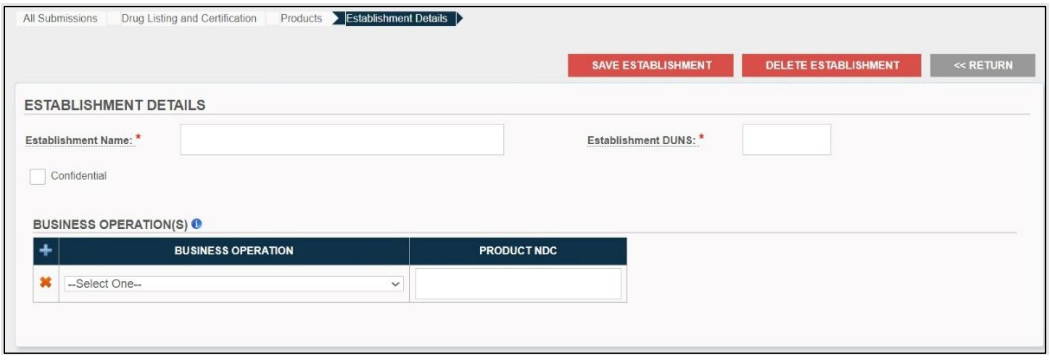
l. Your product will then display below the search bar. Click the '**Save/Update**' button at the top of the page to be returned to the previous *Products Certification* page.

m. Skip to Step 25 when you are ready to submit.

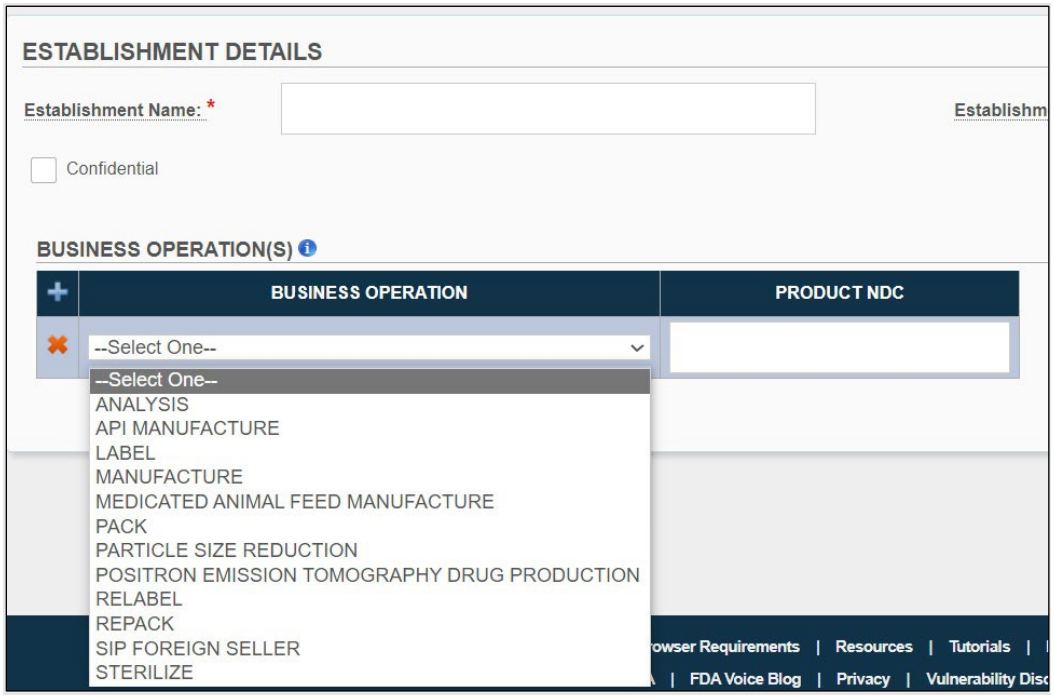
9. For all other document types (***not*** the Blanket No-Change type): select your document type, press '**Continue**' and a blank template will display:



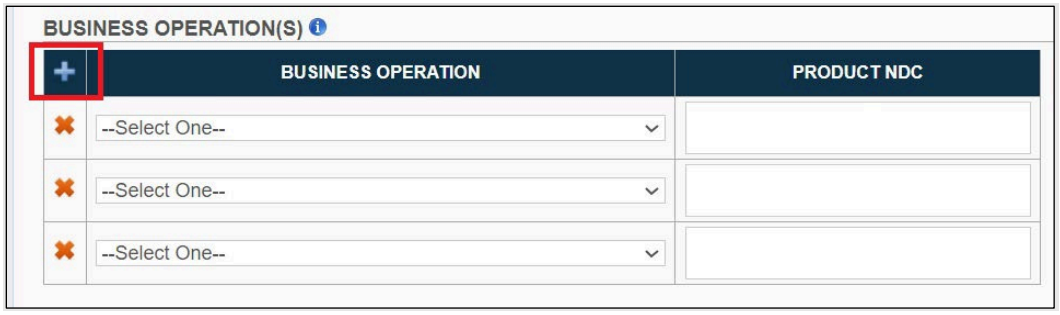
10. Fill out all applicable fields.
11. To keep this submission from being made visible to the public, click the '**Confidential**' check box under *Registrant Details*.
12. To enter an establishment, click the '**Add Establishment**' button under the *Establishments* section. You will be sent to a separate page:



a. Enter your Establishment Name and DUNS.
b. Select your business operation(s) from the dropdown and input the product NDC for each operation:



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



d. Click '**Save Establishment**' button to save your work and return to the previous page.

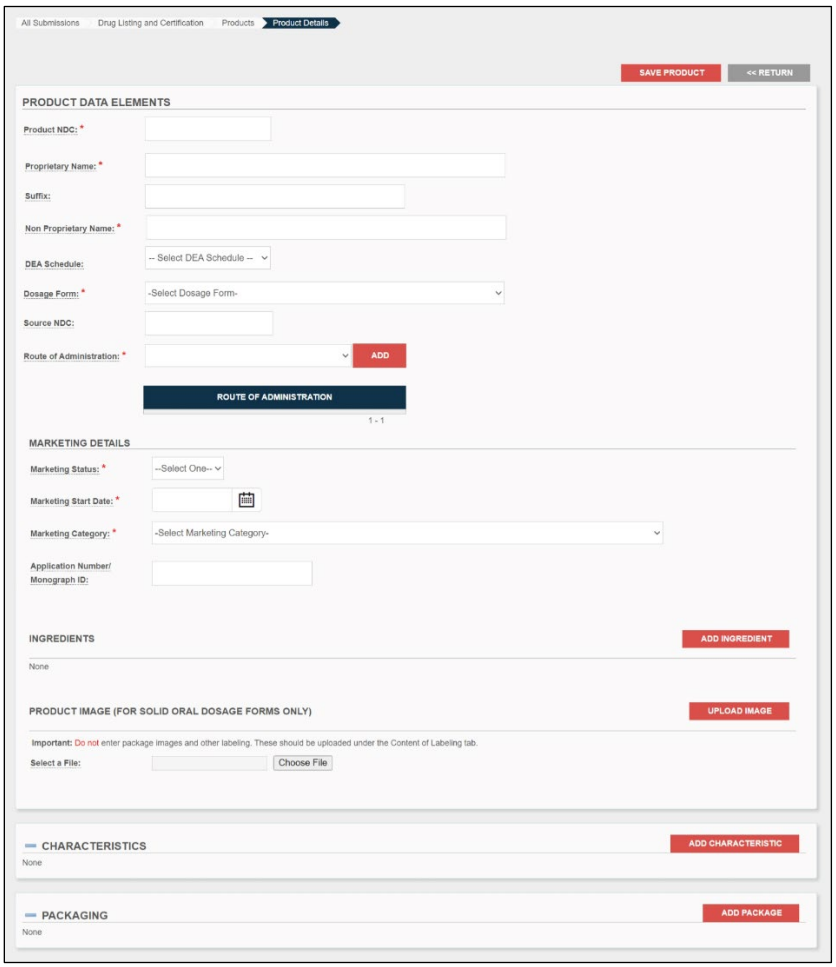
e. Click '**Delete Establishment**' to delete your establishment addition(s) and return to the previous page.

f. The '**Return**' button will send you back to the previous page without saving the establishment changes.

13. All added establishment details will display under the *Establishments* section:

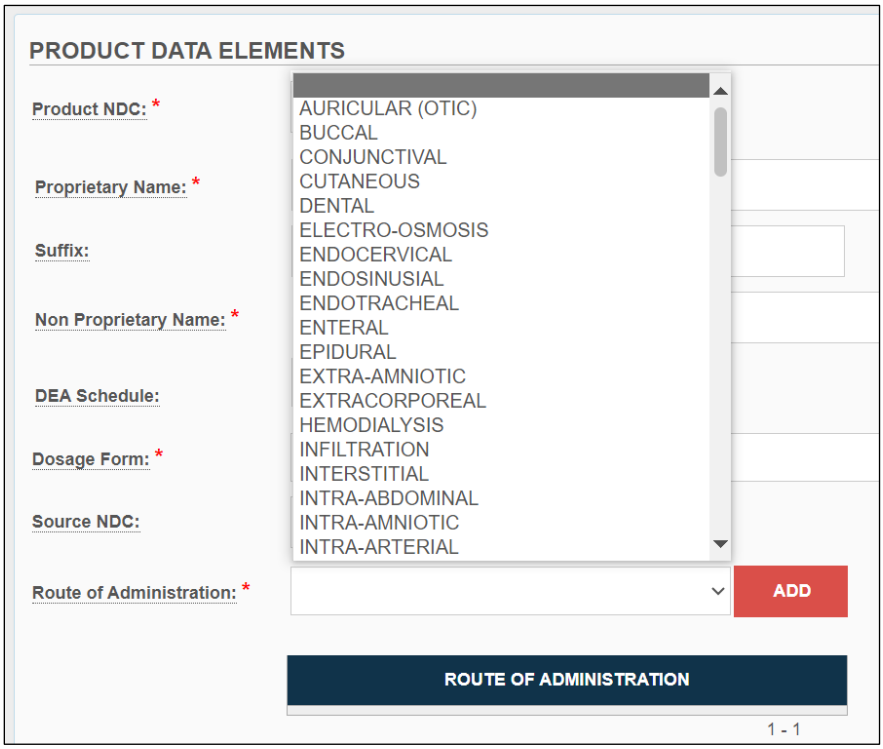
14. To add products, click the '**Add Product**' button:

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

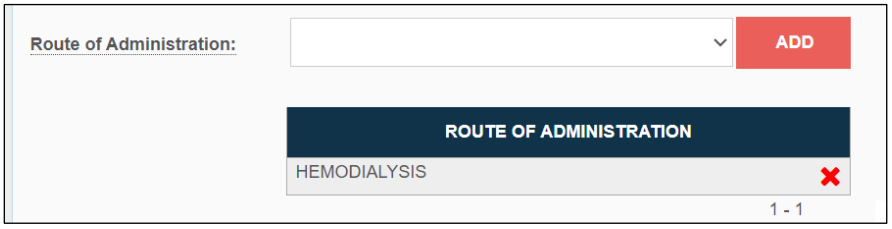


16. Fill out the requested information in the *Product Data Elements* section.

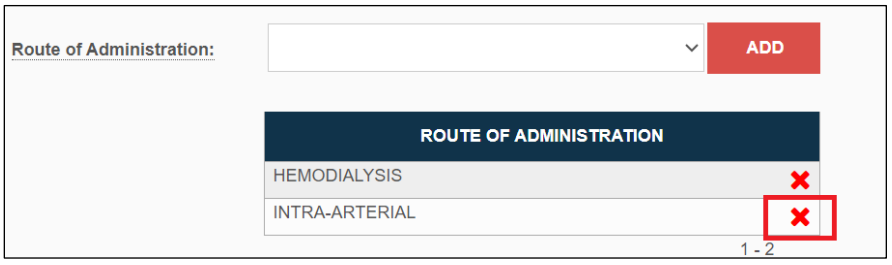
    a. To add a '**Route of Administration**,' select the dropdown and choose from the list:



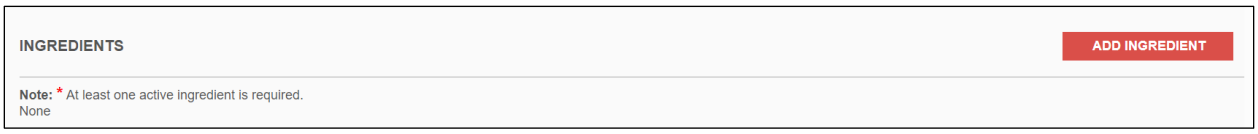
    b. Click the '**Add**' button and your selection will appear in the Route of Administration box.



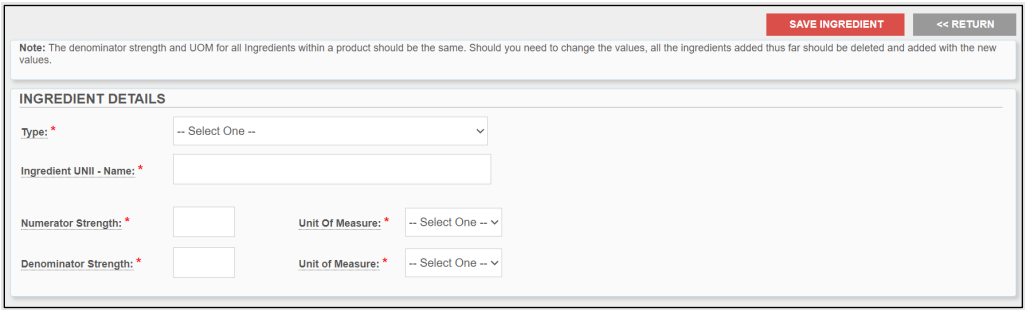
    c. To remove a selection, simply click the 'X' beside a route of administration:



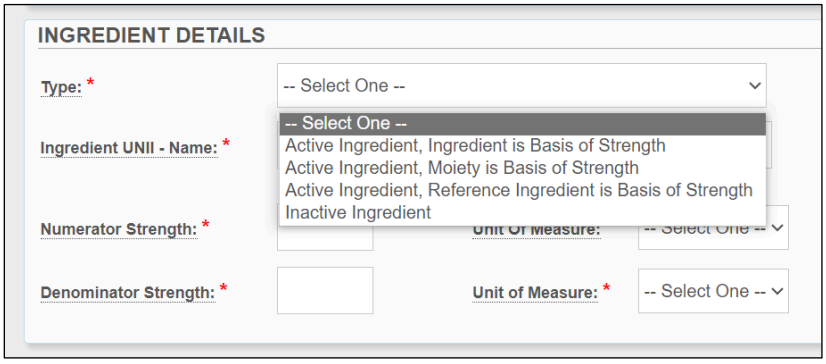
17. Enter information into the *Marketing Details* section.
18. To '**Add An Ingredient**,' click the button under the *Ingredients* section:



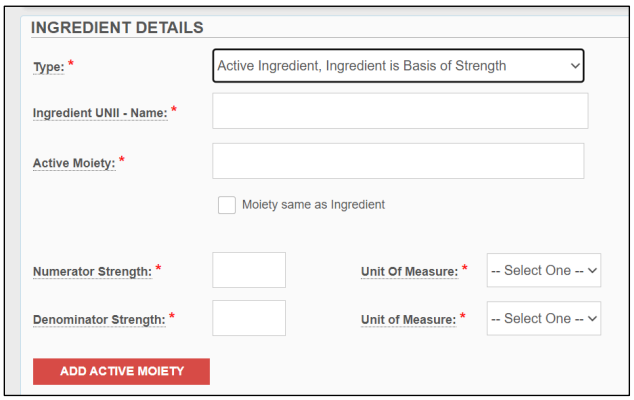
a. You will be taken to a separate page where you can enter information about a single ingredient:



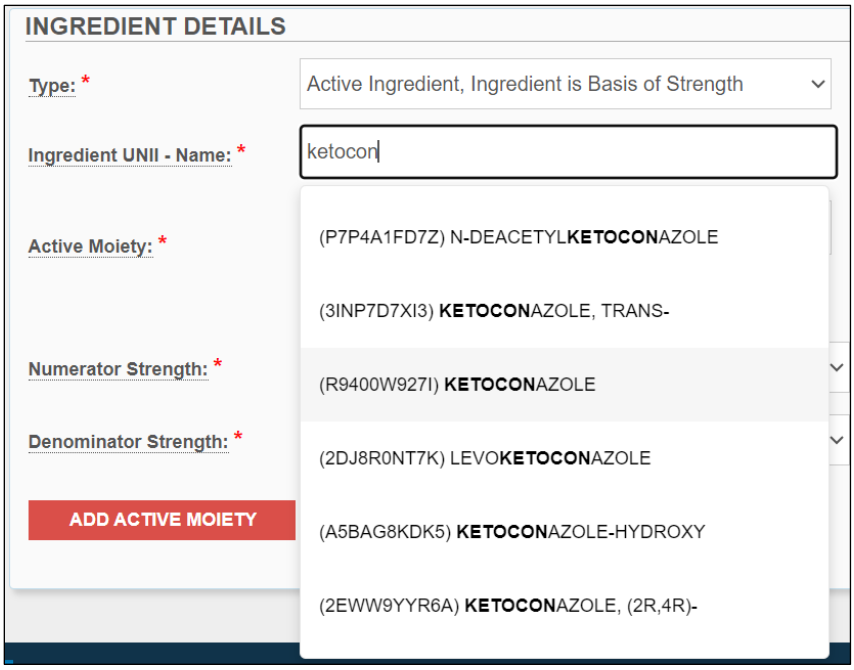
b. Select the dropdown for '**Type**':



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



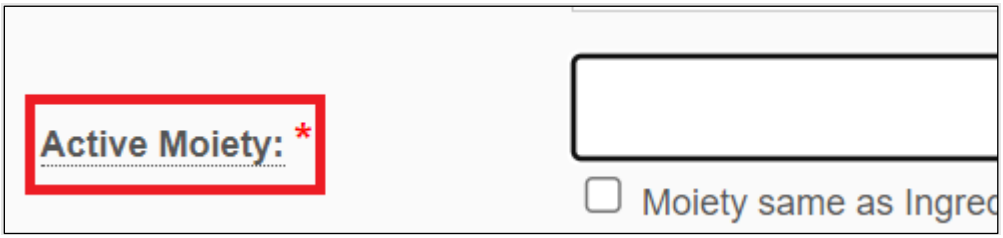
d. Enter an Ingredient UNII, or simply begin typing the ingredient name into the empty field:

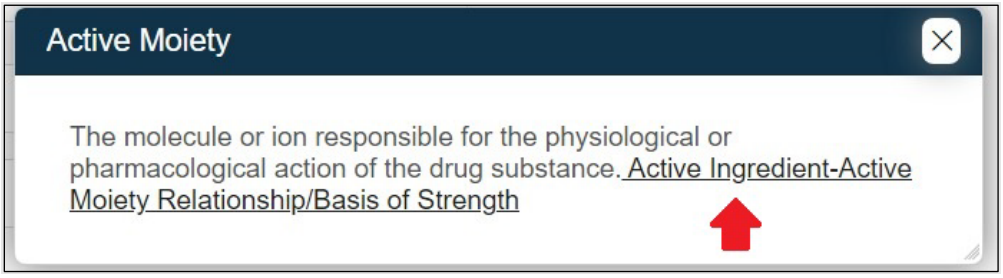


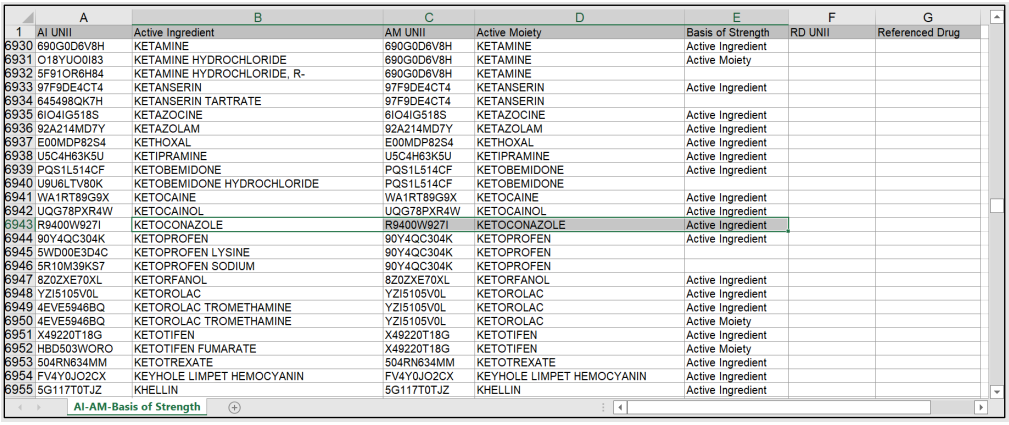
e. If the ingredient and moiety are the same, simply click the checkbox labeled 'Moiety Same As Ingredient' to automatically copy the ingredient to the active moiety field.

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

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



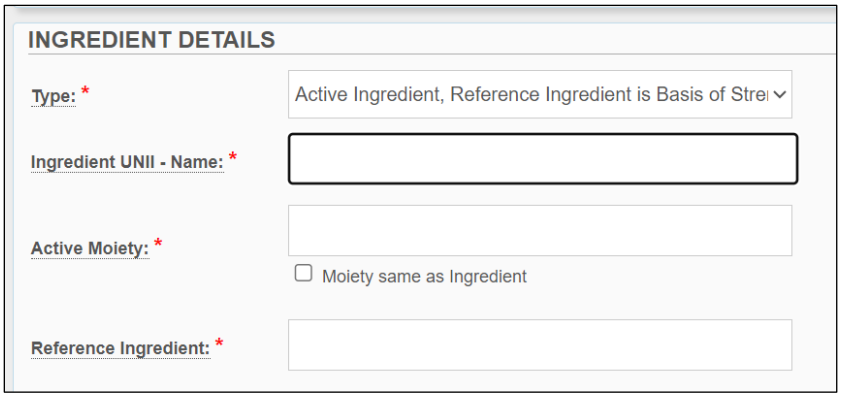




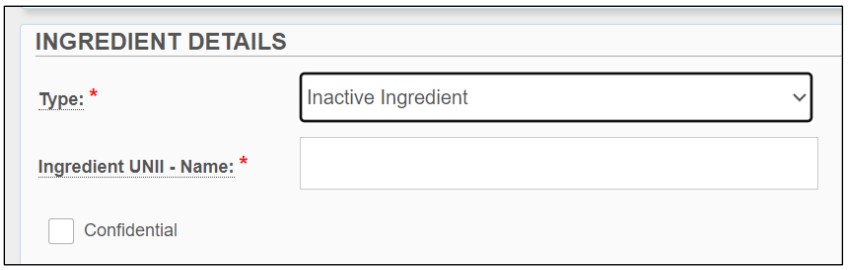
	A	B	C	D	E	F	G
1	AI UNII	Active Ingredient	AM UNII	Active Moiety	Basis of Strength	RD UNII	Referenced Drug
6930	690G0D6V8H	KETAMINE	690G0D6V8H	KETAMINE	Active Ingredient		
6931	O18YUO0I83	KETAMINE HYDROCHLORIDE	690G0D6V8H	KETAMINE	Active Moiety		
6932	5F91OR6H84	KETAMINE HYDROCHLORIDE, R-	690G0D6V8H	KETAMINE			
6933	97F9DE4CT4	KETANSERIN	97F9DE4CT4	KETANSERIN	Active Ingredient		
6934	645498QK7H	KETANSERIN TARTRATE	97F9DE4CT4	KETANSERIN			
6935	6IO4IG518S	KETAZOCINE	6IO4IG518S	KETAZOCINE	Active Ingredient		
6936	92A214MD7Y	KETAZOLAM	92A214MD7Y	KETAZOLAM	Active Ingredient		
6937	E00MDP82S4	KETHOXAL	E00MDP82S4	KETHOXAL	Active Ingredient		
6938	U5C4H63K5U	KETIPRAMINE	U5C4H63K5U	KETIPRAMINE	Active Ingredient		
6939	PQS1L514CF	KETOBEMIDONE	PQS1L514CF	KETOBEMIDONE	Active Ingredient		
6940	U9U6LTV80K	KETOBEMIDONE HYDROCHLORIDE	PQS1L514CF	KETOBEMIDONE			
6941	WA1RT89G9X	KETOCAINE	WA1RT89G9X	KETOCAINE	Active Ingredient		
6942	UQG78PXR4W	KETOCAINOL	UQG78PXR4W	KETOCAINOL	Active Ingredient		
6943	R9400W927I	KETOCONAZOLE	R9400W927I	KETOCONAZOLE	Active Ingredient		
6944	90Y4QC304K	KETOPROFEN	90Y4QC304K	KETOPROFEN	Active Ingredient		
6945	5WD00E3D4C	KETOPROFEN LYSINE	90Y4QC304K	KETOPROFEN			
6946	5R10M39KS7	KETOPROFEN SODIUM	90Y4QC304K	KETOPROFEN			
6947	8Z0ZXE70XL	KETORFANOL	8Z0ZXE70XL	KETORFANOL	Active Ingredient		
6948	YZI5105V0L	KETOROLAC	YZI5105V0L	KETOROLAC	Active Ingredient		
6949	4EVE5946BQ	KETOROLAC TROMETHAMINE	YZI5105V0L	KETOROLAC	Active Ingredient		
6950	4EVE5946BQ	KETOROLAC TROMETHAMINE	YZI5105V0L	KETOROLAC	Active Moiety		
6951	X49220T18G	KETOTIFEN	X49220T18G	KETOTIFEN	Active Ingredient		
6952	HBD503WORO	KETOTIFEN FUMARATE	X49220T18G	KETOTIFEN	Active Moiety		
6953	504RN634MM	KETOTREXATE	504RN634MM	KETOTREXATE	Active Ingredient		
6954	FV4Y0JO2CX	KEYHOLE LIMPET HEMOCYANIN	FV4Y0JO2CX	KEYHOLE LIMPET HEMOCYANIN	Active Ingredient		
6955	5G117T0TJZ	KHELLIN	5G117T0TJZ	KHELLIN	Active Ingredient		

AI-AM-Basis of Strength

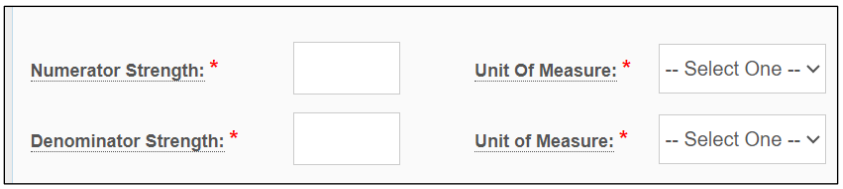
g. If you selected the third '**Type**' option 'Reference Ingredient is Basis of Strength', a Reference Ingredient field will display below the Active Moiety field:



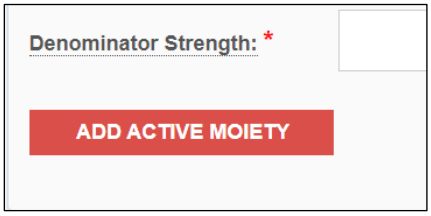
h. If you selected the 'Inactive Ingredient' option for '**Type**,' a checkbox labeled 'Confidential' will appear below the Ingredient UNII field:



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



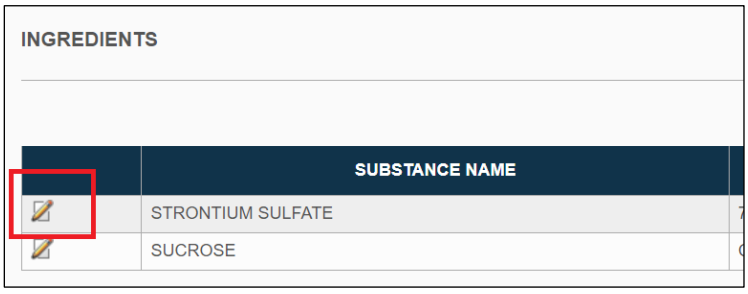
j. For all ingredient types (except 'Inactive Ingredient'), you will have the option to click the button '**Add Active Moiety**' to add additional active moieties:



k. To add more ingredients, redo Step 18 above.

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

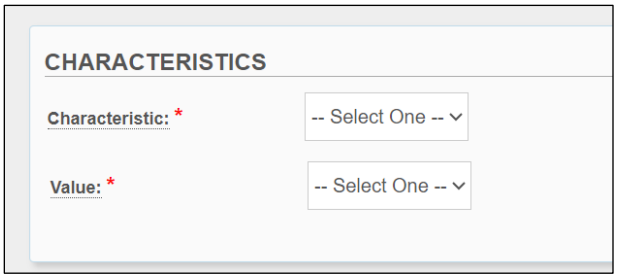
m. You can edit an ingredient on the Product Details page by clicking the pencil icon:



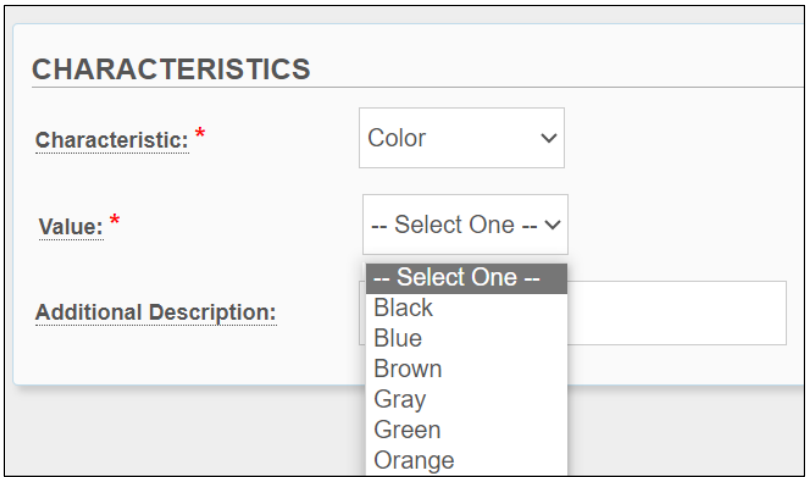
19. If your product is a **solid oral dosage form** ***only***, add a product image (JPG format):

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

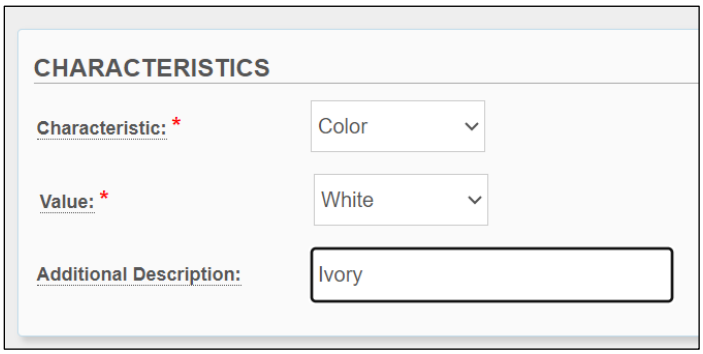
a. You will be sent to a separate *Characteristics* page:



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



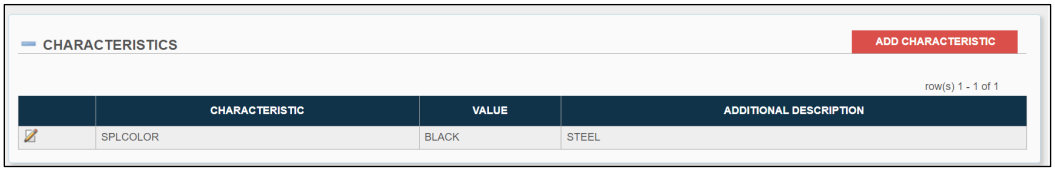
c. You can enter more specific details for a selected characteristic in the '**Additional Description**' field, which can include shades of colors ("ivory" white) or shape variations (triangle with "rounded edges"):



d. Click '**Save Characteristic**' on the top right of the page when finished. You will be returned to the Product Details page.

e. Only one characteristic can be entered at a time, so repeat the above steps to add additional characteristics.

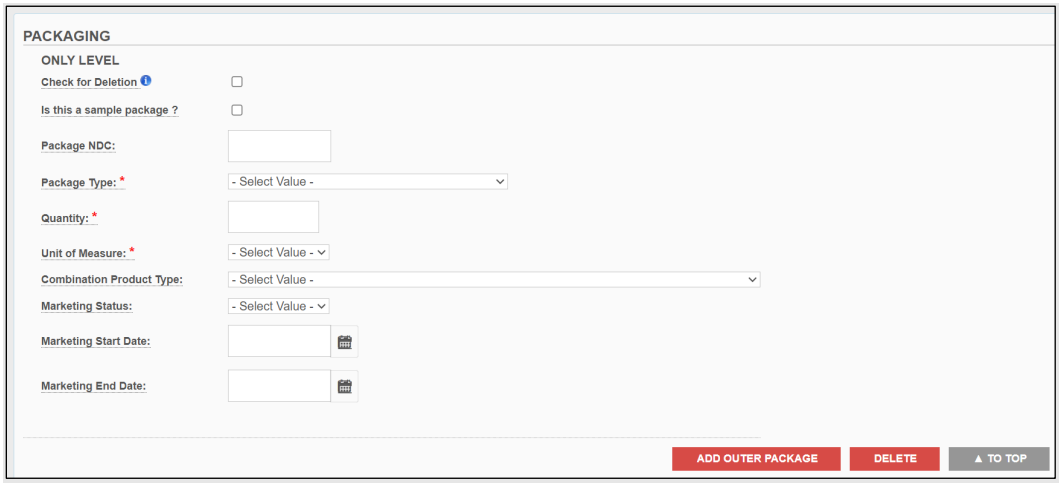
f. To edit a characteristic, click the pencil icon beside the selected characteristic on the Product Details page (toward the bottom of the page):



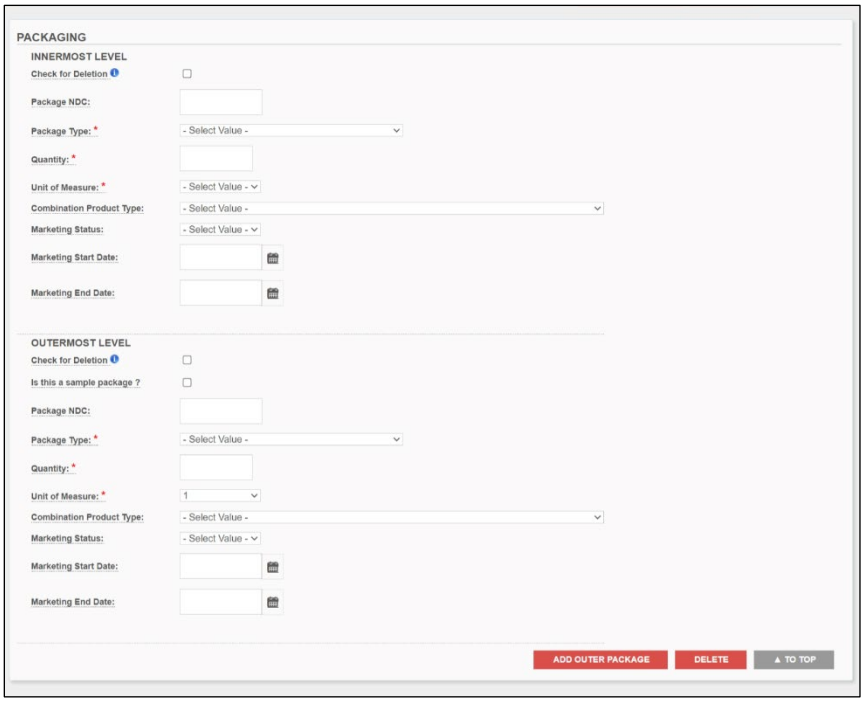
21. To add a Package:

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

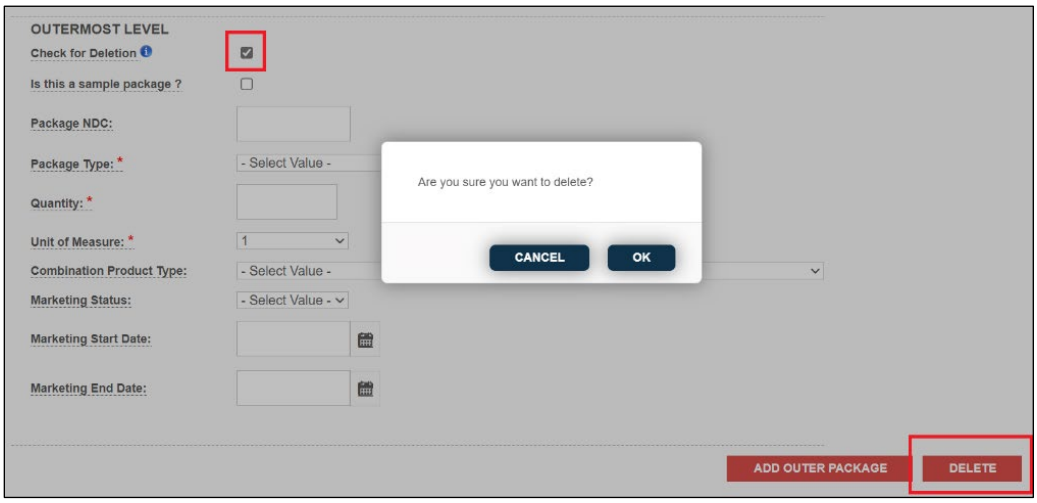
b. Enter all applicable data for the inner package:



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

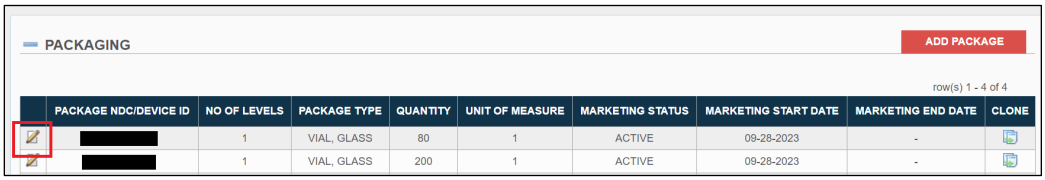


d. To delete an outer package, click the '**Check for Deletion**' checkbox and then select the '**Delete**' button:

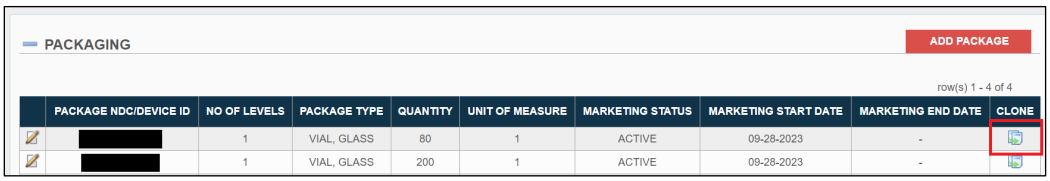


e. When finished, click '**Save Package**' at the top of the page to save your changes and return to the product details page.

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



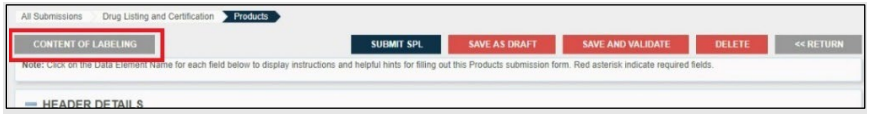
g. To make an exact duplicate of a package you previously created, click the '**Clone**' icon:



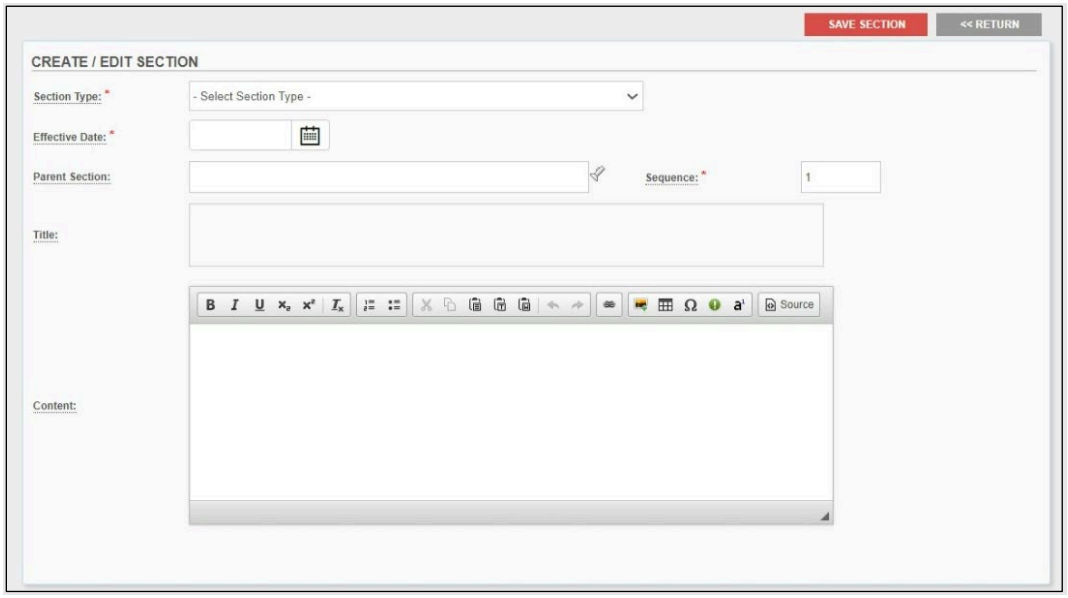
22. Repeat Steps 16-21 to add more products.

23. Once you are back on the product details page, enter the Content of Labeling information:

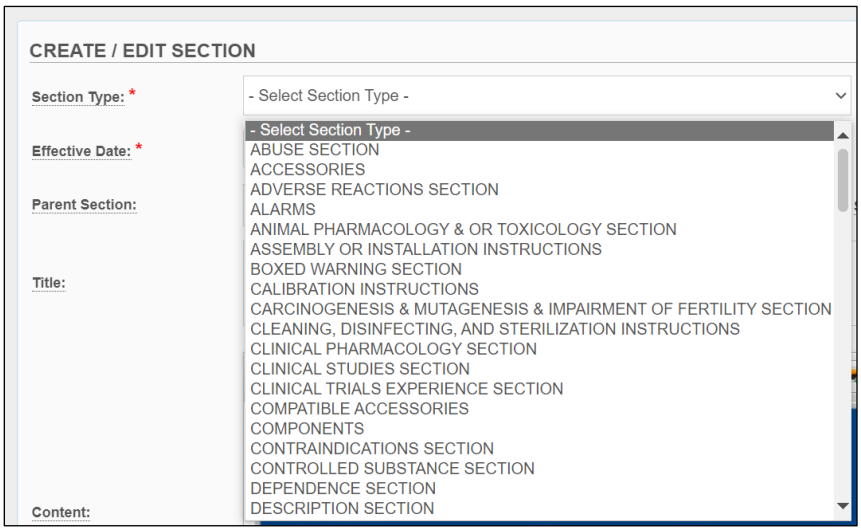
a. Click the '**Content of Labeling**' button at the top:



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



c. Clicking the '**Section Type**' dropdown will display a list of packaging sections, which will act as headings for your label. For each section/heading that applies to your label, add the appropriate label graphic and text (as explained later).



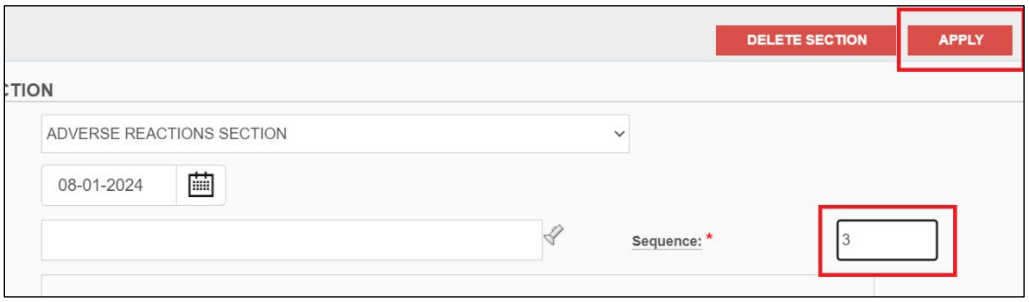
d. '**Effective Date**' is the date this labeling change/submission will occur.

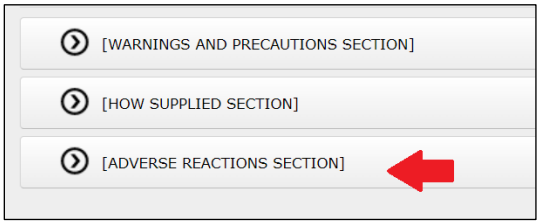
e. The '**Sequence**' field allows you to organize your label sections (headings) so that they display in the appropriate order. Here is an example list of three sections that were created in Content of Labeling:

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

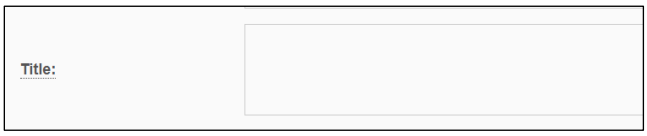
Each section is automatically assigned the next number in numerical order (2, 3, 4, etc). If you need to reorganize any existing or new sections so that they display in a different order, simply change the number in the '**Sequence**' field of a desired section.

In the example below, the 'Adverse Reactions Section' previously at the top was moved to the bottom by simply entering '3' into that section's '**Sequence**' field then clicking '**Apply**':



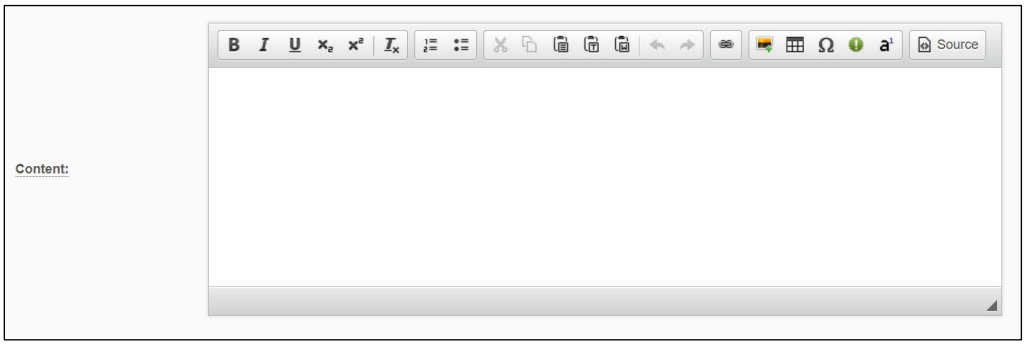


f. Choose a title for your section. If you don't enter anything, whatever you selected from the '**Section Type**' dropdown will become the title.



g. Some Section Types will have a '**Highlight Text**' box. This box only displays for certain section types. Enter information there, if applicable.

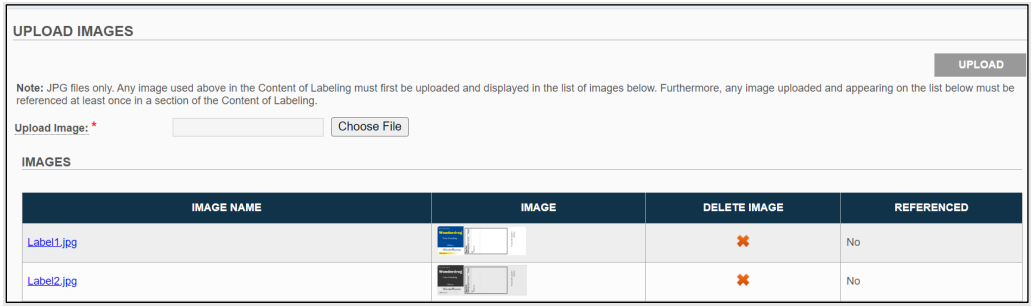
h. The '**Content**' box is intended for text and graphics that pertain to the '**Section Type.**' If you chose 'Adverse Reactions' as a section type, you must enter images and/or text that are appropriate for that section of your labeling.



i. To upload a product label image, click '**Choose File**' to select an image from your computer. The extension/ending of the file MUST be a **.jpg no larger than 1MB**.

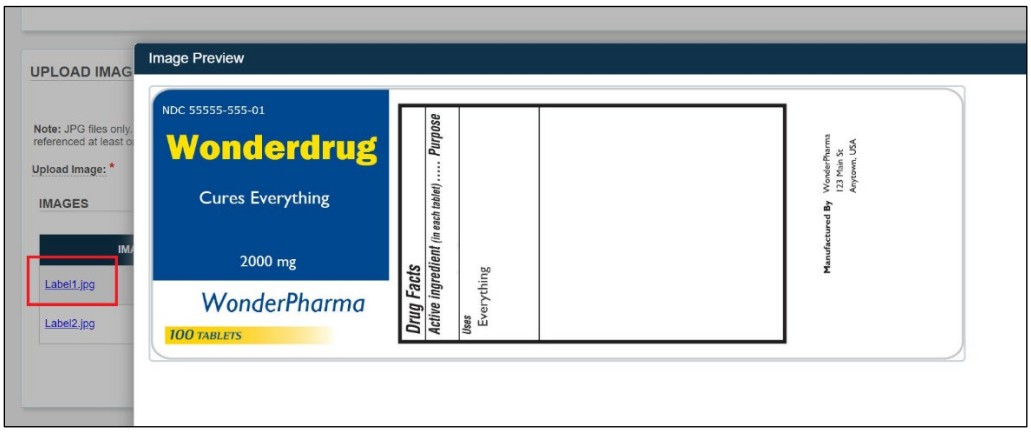
j. When you have selected a JPG image from your computer, click the '**Upload**' button. Only one image can be uploaded at a time.

k. Your image(s) will display in the *Images* section:

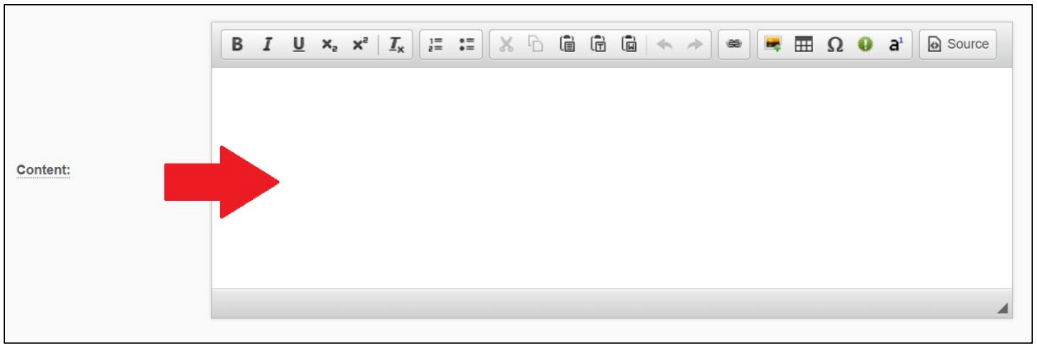


l. Click the red **X** beside an image to delete the image. Doing this will cause images to disappear or not display properly if they have been used ("referenced") in a section.

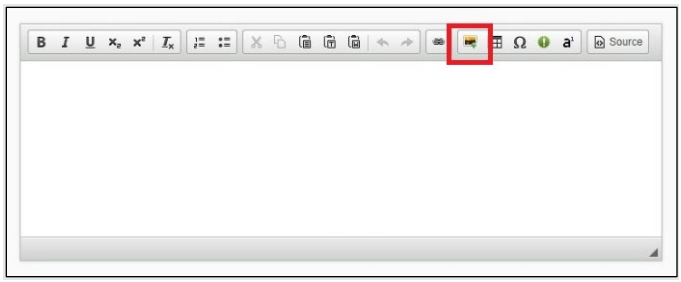
m. Click the name of the image to display a closeup preview:



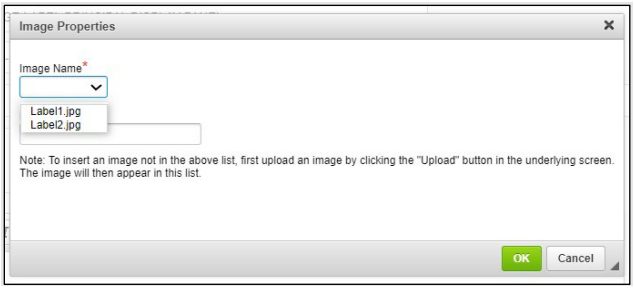
n. You must now "reference" your image(s) before you can submit your SPL. To reference an image, go back up to the *Create/Edit* section and click anywhere inside the '**Content**' box:



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

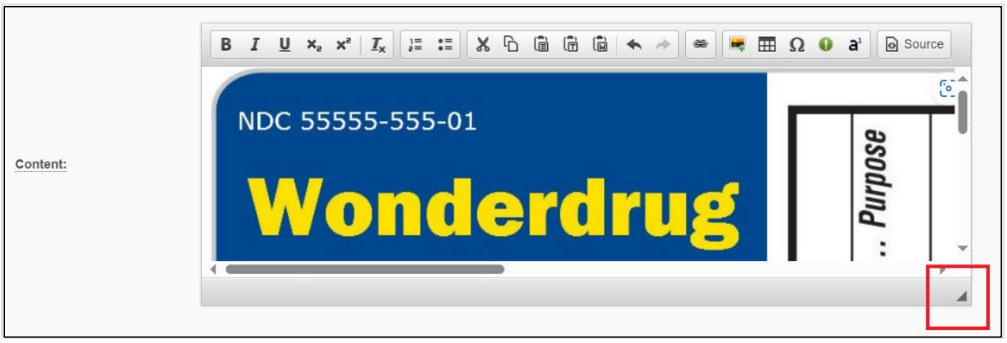


p. A popup box will display. Your previously uploaded image(s) will now be available to select from the dropdown:



q. Next, add some Image Text. This is alt text (description text for an image that is not visible anywhere but can be picked up and read by screen reading technology).

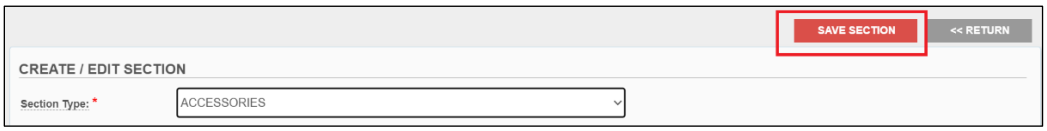
r. Click '**OK.**' Your image will now display within the Content box. Click and drag the corner arrow to view more of the image:



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

If you delete an image from the *Images* section, it will be automatically removed from each 'Content' section in every Content of Labeling entry that references it!

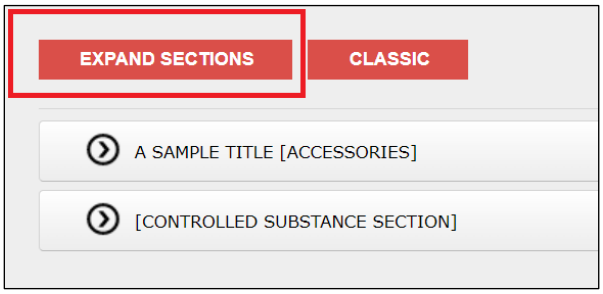
s. When you are finished, click the '**Save Section**' button at the top right of the page to save your new section:



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

u. To add another section to this list, click the '**Add Section**' button:

v. If you have at least one section created, clicking the '**Expand Sections**' button (top left) will automatically display the full contents of all of your sections listed:



w. Click '**Collapse Sections**' (top left) to close all entries.

x. You also have the option to switch between '**Classic**' and '**Enhanced**' (top left button) mode, which simply changes the look of the lists.

y. See Section 9.1 for additional help with the Content of Labeling section.

z. When you are finished with Content of Labeling, click the '**Return**' button at the top right of the page. You will be sent back to the product details page.

24. **IMPORTANT:** This is an **optional section** and should ***NOT*** be used unless you are familiar with FDA core documents, as this will allow you to append or replace core documents.

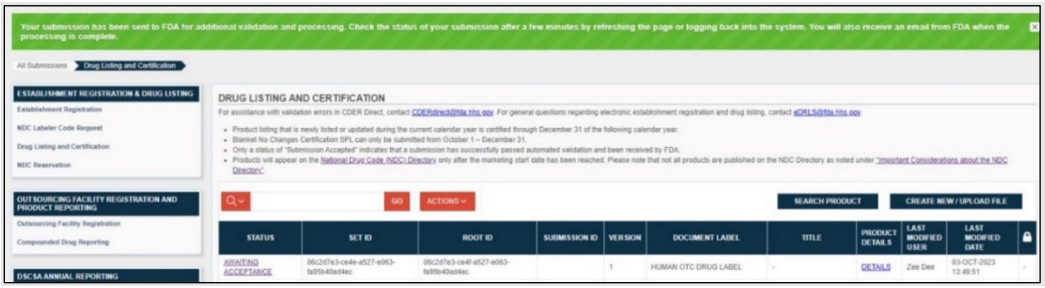
25. Repeat Steps 15-22 to add more products.

26. When all fields have been entered to your satisfaction, you can do the following:

a. '**Save As Draft**' – Save your entry and return to the main Drug Listing and Certification page. No submission will be made.

b. '**Save And Validate**' - Save your entry + validate. This will check your submission for errors prior to submitting to the FDA. Validation may take some time. If you are ready to submit your SPL, you may skip this step entirely.

c. '**Submit SPL**' - Submit your Drug Listing and Certification SPL submission to the FDA. You will then be returned to the Drug Listing and Certification main page where you can view your pending submission(s) status:

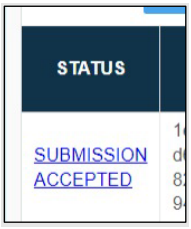


d. '**Delete**' – Delete your entry draft completely.

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

28. The *Status* field should now read '*Submission Accepted,*' indicating that your submission has been validated and accepted by the FDA. You will receive an email to your account email address when the submission status changes.

29. Once your submission has been accepted, you will be able to download a copy of the submission as a zip file. Go to the main Drug Listing and Certification page and click the latest '*Submission Accepted*' text link:

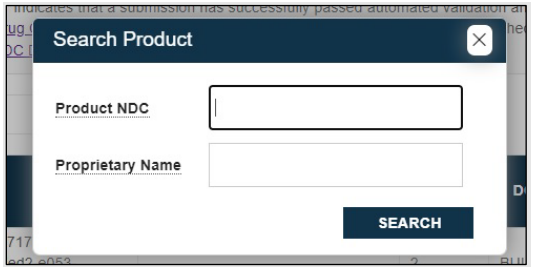


30. Click '**Download SPL**' on the top left of the page to download the zip file. You can also select '**View SPL**' for a quick look at your submission.

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

    a. Click '**Search Product**' on the Drug Listing and Certification main page:

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



    c. Click '**Search**' and your results will populate.

    d. See Section 9.2: Searching and Filtering for additional help with filters and searching multiple products.

6 OUTSOURCING FACILITY REGISTRATION AND COMPOUNDED PRODUCT REPORTING

6.1 Outsourcing Facility Registration

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

- Establishment Registration: Registering a facility for the first time.
- Establishment De-Registration: Dissolving a facility's registration.
- Out of Business: De-registering a facility due to going out of business.
- No Change Notification: Informing the FDA that no changes have occurred since the previous facility registration submission was made.

For more information on outsourcing facilities and compounded products, visit the FDA's *Information for Outsourcing Facilities* website.

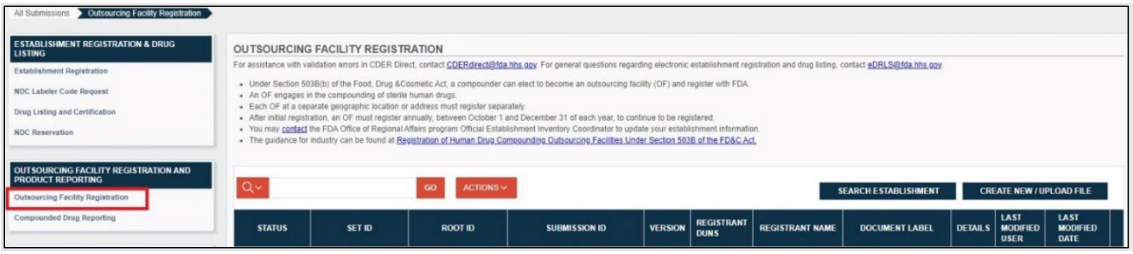
6.1.1 Registering A New Outsourcing Facility

The '**Outsourcing Facility Registration**' SPL submission is used by outsourcing facilities who compound human drugs. A facility is considered an "outsourcing facility" (according to *Section 503B of the FD&C Act*) if the facility:

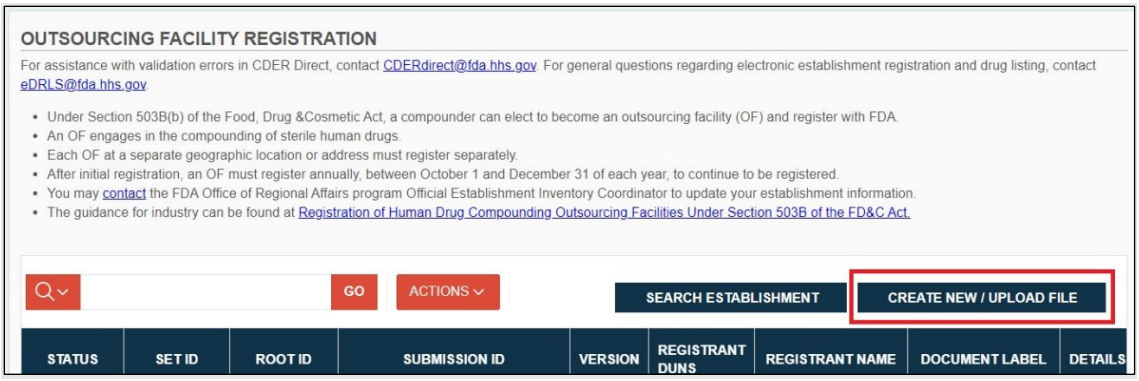
- is engaged in the compounding of sterile drugs (and may also compound non-sterile drugs);
- has elected to register as an outsourcing facility;
- complies with all of the requirements of section 503B;
- is not required to be a licensed pharmacy, but compounding must be by or under the direct supervision of a licensed pharmacist; and
- may or may not obtain prescriptions for identified individual patients.

To submit an '**Outsourcing Facility Registration**' SPL, do the following:

1. Log in to FDA Direct.
2. Select '**Outsourcing Facility Registration**' under the *Outsourcing Facility Registration and Product Reporting* section:



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

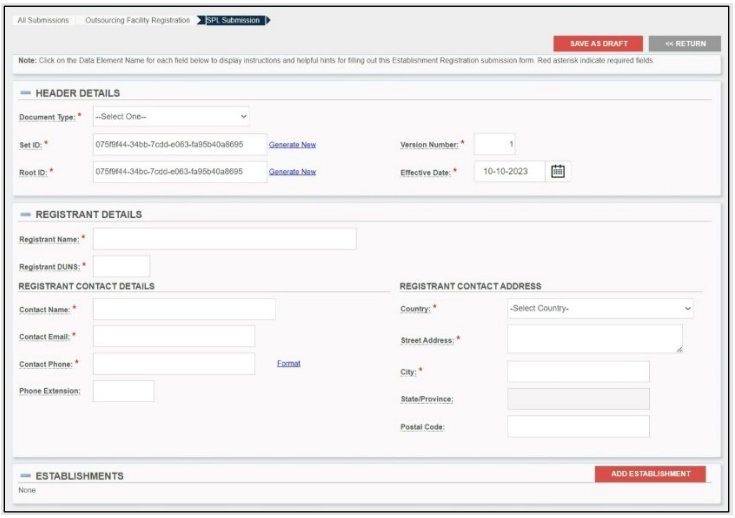


4. You will be given two options:

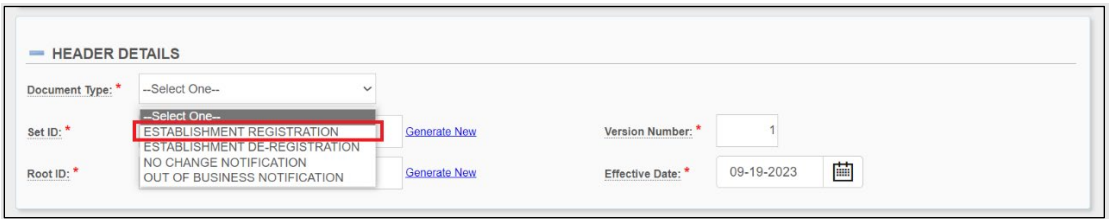
   a. To upload a file from your computer directly, follow the steps outlined in Section 3: Submission Information. Then skip to Step 9 below and continue the instructions.

5. To create a new outsourcing facility registration using a blank template, select the '**Create New Outsourcing Facility Registration using a blank form**' option.

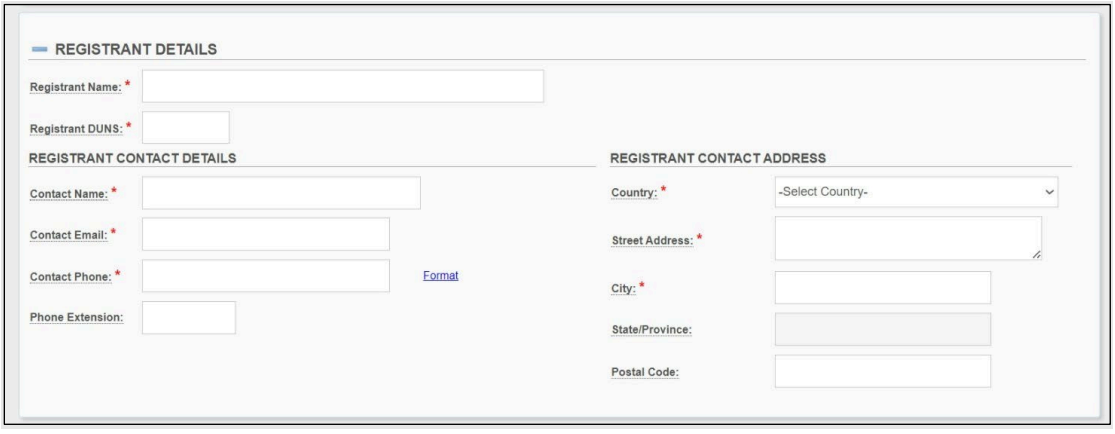
6. Click '**Continue**' and a blank template will display:



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

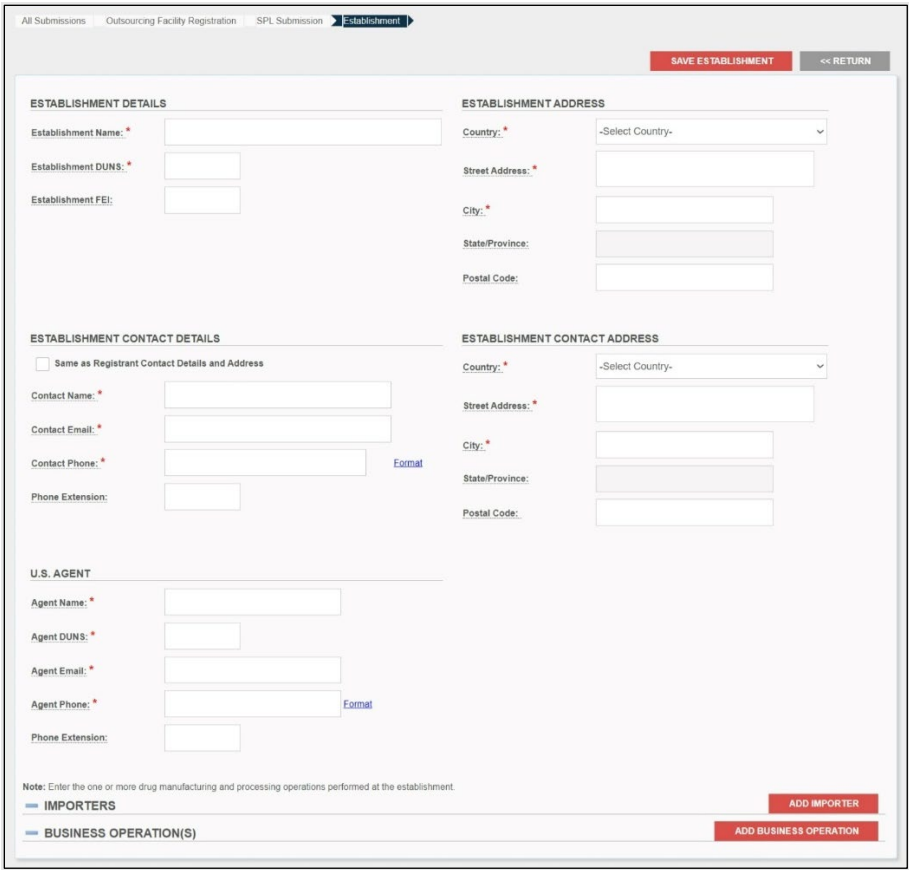


9. Fill in all blank fields in the *Registrant Details* section:

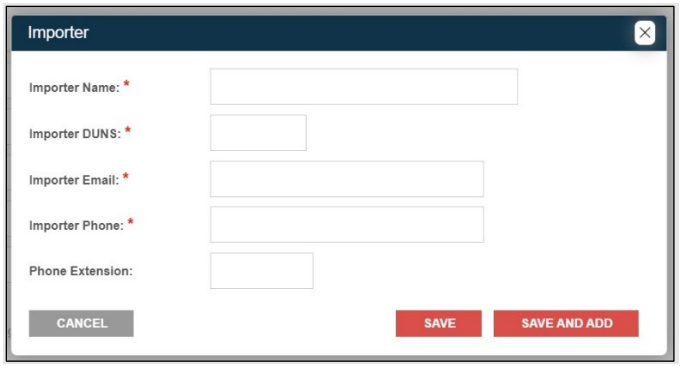


10. To add multiple establishments, click the '**Add Establishment**' button at the bottom of the page:

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

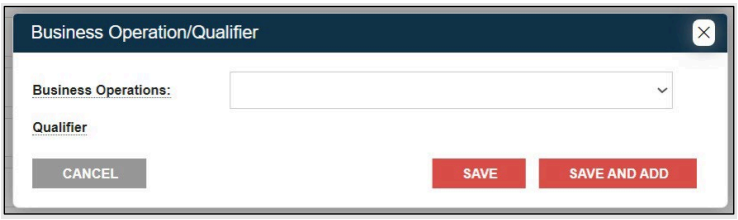


12. At the bottom of the page, click the '**Add Importer**' button. A popup box will display:

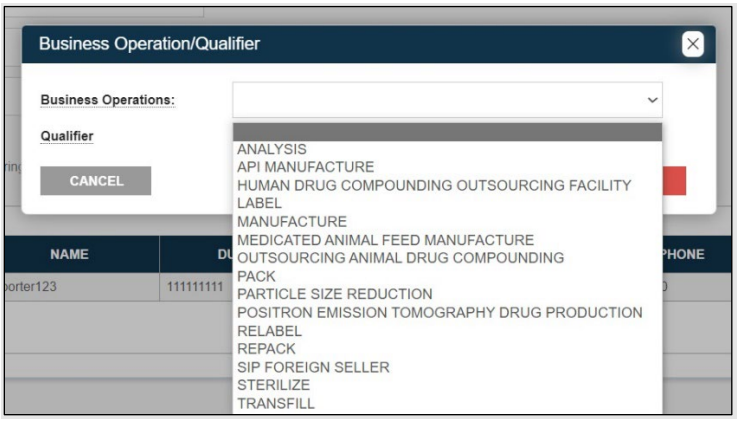


13. Enter importer details then either click '**Save And Add**' to keep the window open and add another importer, or select '**Save**' to close the window and finish your entry. Your information will display under the *Importers* section:

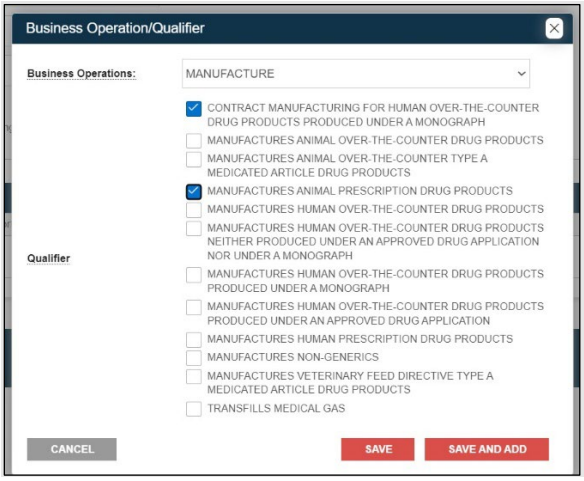
14. Click the '**Add Business Operation**' button. A dialog box will display:



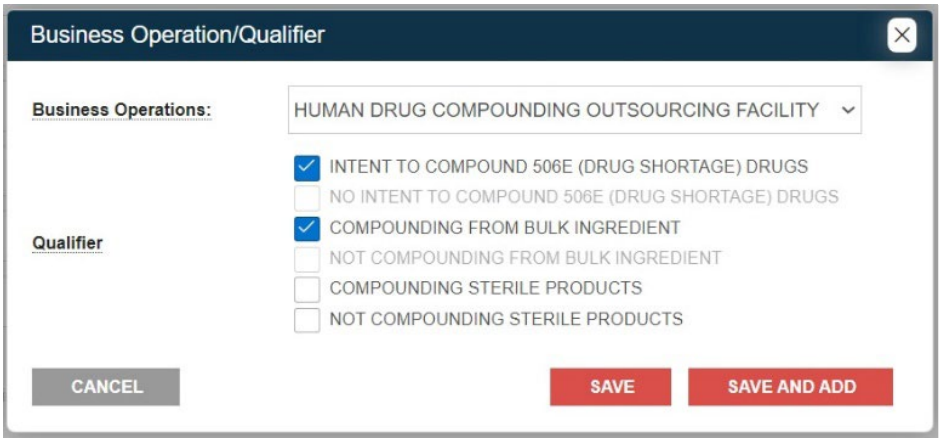
15. Select your business operation from the dropdown:



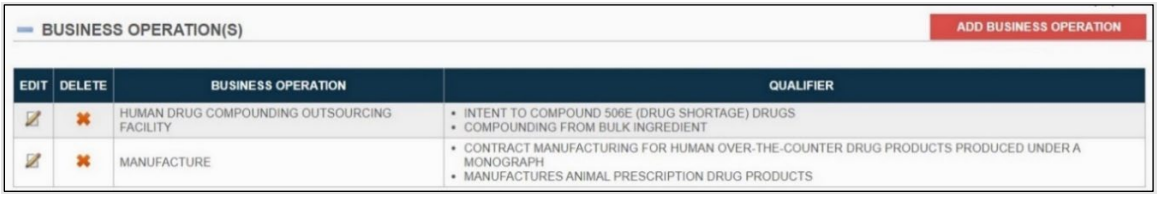
16. Check all qualifier boxes that apply to your selected business operation:



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



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



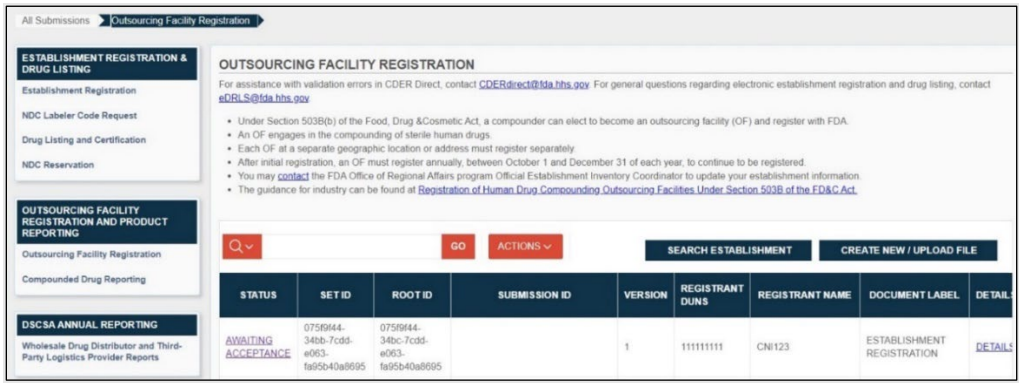
18. Return to the top of the page and select '**Save Establishment**' when finished. You will be returned to the initial template entry page, with the newly added establishment(s) listed at the bottom. Click the pencil icon to make edits to the establishment:

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

    a. '**Save As Draft**' – Save your entry and return to the main Outsourcing Facility Registration page. No submission will be made.

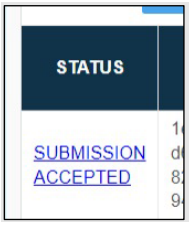
    b. '**Save And Validate**' - Save your entry + validate. This will check your submission for errors prior to submitting to the FDA. Validation may take some time. If you are ready to submit your SPL, you may skip this step entirely.

    c. '**Submit SPL**' - Submit your Outsourcing Facility Registration submission to the FDA. You will then be returned to the Outsourcing Facility Registration main page where you can view your pending submission(s) status:

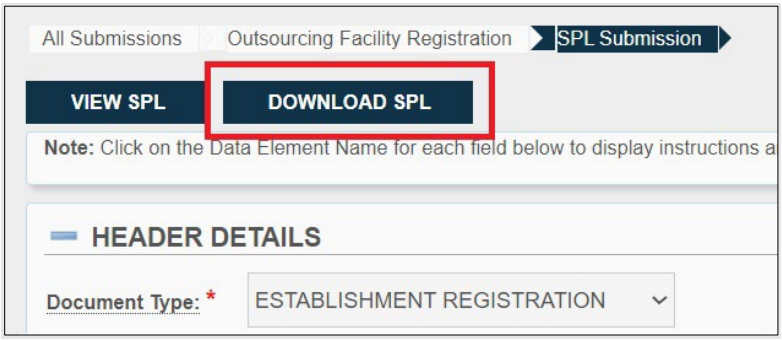


d. '**Delete**' – Delete your draft entry completely.

20. Click '**Return**' at any time to return to the main Outsourcing Facility Registration page.
21. The *Status* field should read '*Submission Accepted*' when your submission has been validated and accepted by the FDA. You will receive an email to your account email address when the submission status changes.
22. Once your submission has been accepted, you will be able to download a copy of the submission as a zip file. Go to the main Outsourcing Facility Registration page and click the latest '*Submission Accepted*' text link:

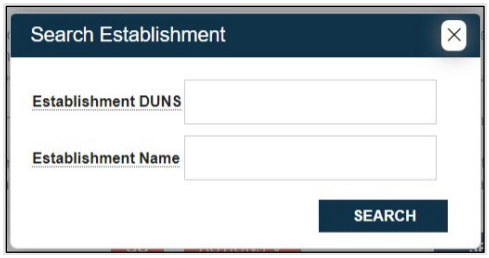


23. Click '**Download SPL**' on the top left of the page to download the zip file. You can also select '**View SPL**' for a quick look at your submission.



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

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



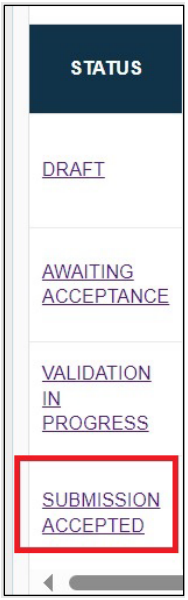
c. Click '**Search**' and your results will populate.

d. See Section 9.2: Searching and Filtering for additional help with filters and searching multiple establishments.

6.1.2 De-Registering An Outsourcing Facility

There are two ways to de-register an outsourcing facility with the FDA:

1. Go to the *Outsourcing Facility Registration* page.
2. Find the most recent submission with the '*Submission Accepted*' status and select the link:



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

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

- **Establishment De-Registration**

  OR

- **Out Of Business Notification**

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

3. Click '**Create New/Upload File**' on the *Outsourcing Facility Registration* page.
   a. Select '**Import an Existing Establishment Registration SPL**' and click '**Continue.**'
   b. See Step 2(b)-2(c) in the previous section.

6.1.3 No Change To Outsourcing Facility Registration

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

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

6.2 Compounded Drug Reporting

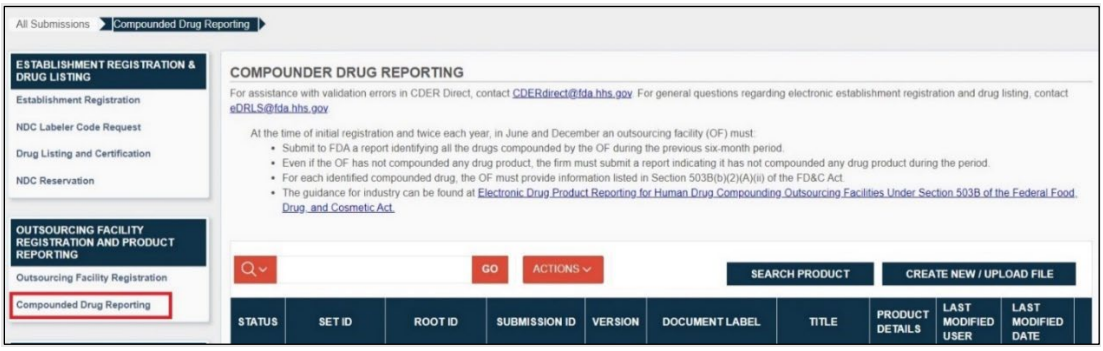
The '**Compounded Drug Reporting**' SPL submission is used to identify all sterile and non-sterile drugs compounded at an outsourcing facility during the previous six-month period:

- Drug product reports submitted between June 1 and June 30 of each year must report drug products produced from December 1 through May 31.
- Drug product reports submitted between December 1 and December 30 of each year must report drug products produced from June 1 through November 30.

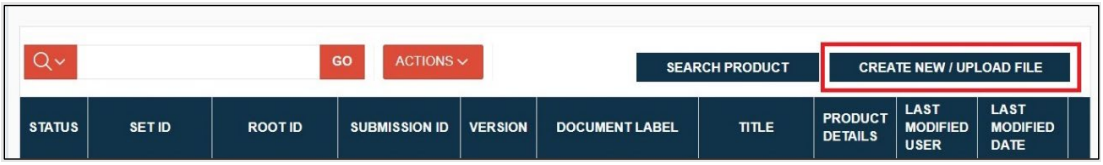
For further information, visit the FDA's Human Drug Compounding Registration and Product Reporting Procedures website.

To submit a '**Compounded Drug Reporting**' SPL, do the following:

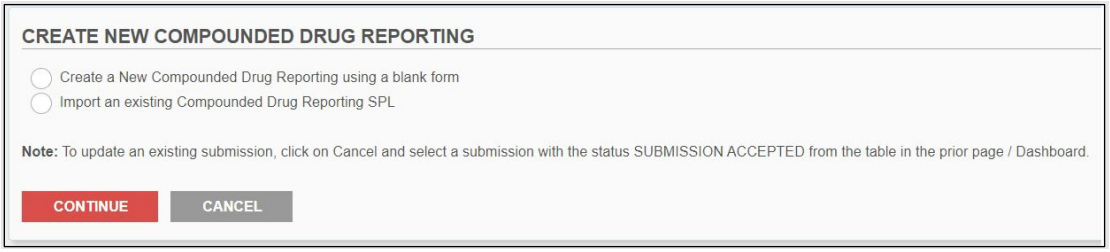
2. Log in to FDA Direct.
3. Select '**Compounded Drug Reporting**' under *Outsourcing Facility Registration And Product Reporting*:



4. Click '**Create New/Upload File**' on the Compounded Drug Reporting main page:

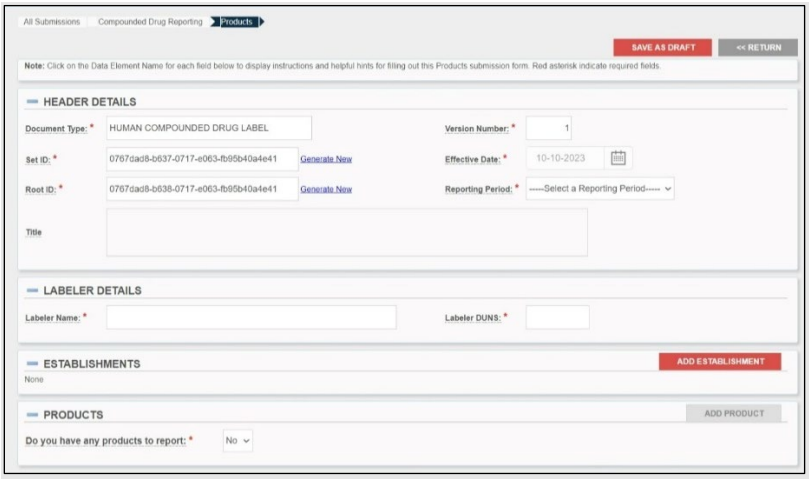


5. You will be given two options:

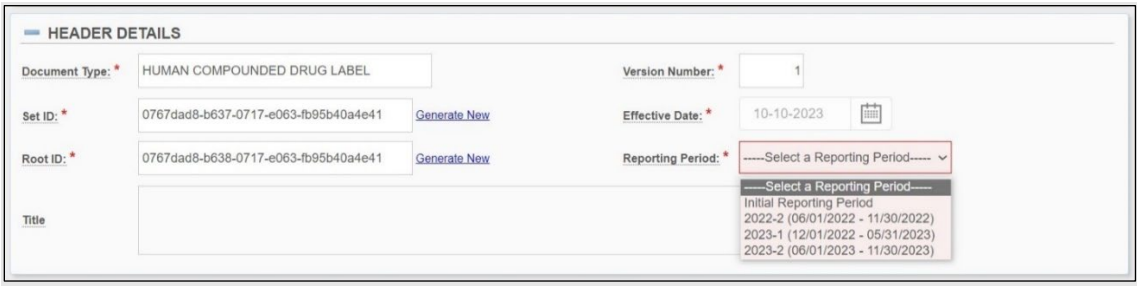


a. To upload a file from your computer directly, follow the steps outlined in Section 3: Submission Information. Then skip to Step 9 below and continue the instructions.

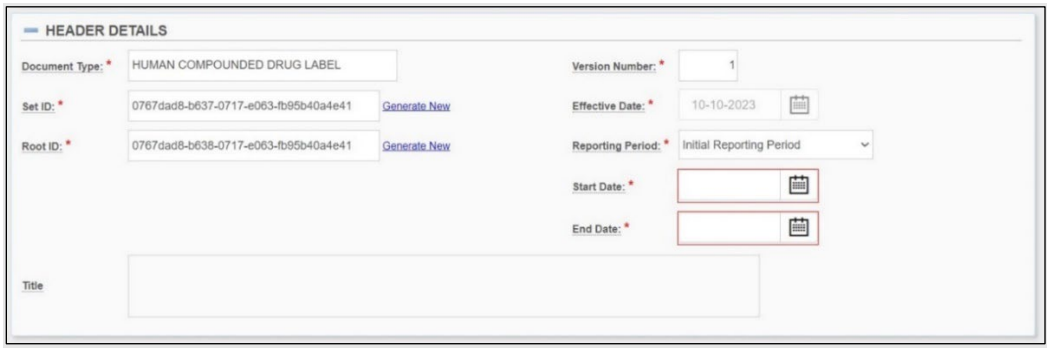
6. To create a new compounded drug submission using a blank template, select the '**Create a new Compounded Drug Reporting using a blank form**' option.
7. A blank template will display:



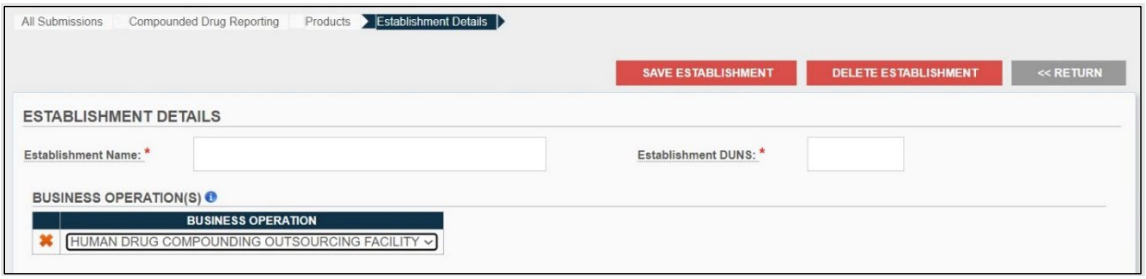
8. Enter your '**Reporting Period**' in the *Header Details* section:



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



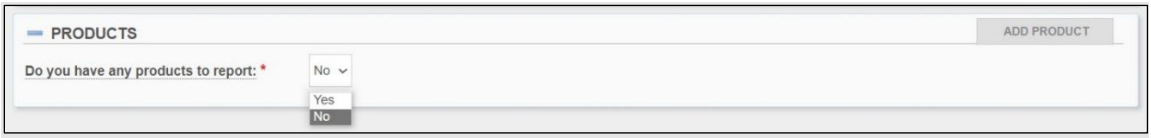
9. If this is not for an initial reporting period, select the appropriate date range from the dropdown.
10. Go to the *Establishments* section of the page.
11. Enter an establishment by clicking the '**Add Establishment**' button. You will be sent to a separate page:



    a. Enter your Establishment Name and DUNS.
    b. The 'Human Drug Compounding Outsourcing Facility' business operation is automatically selected.
    c. Click the '**Save Establishment**' button to save your work and return to the previous page.
    d. Click '**Delete Establishment**' to delete your establishment addition(s) and return to the previous page.
    e. The '**Return**' button will send you back to the previous page without saving the establishment changes.

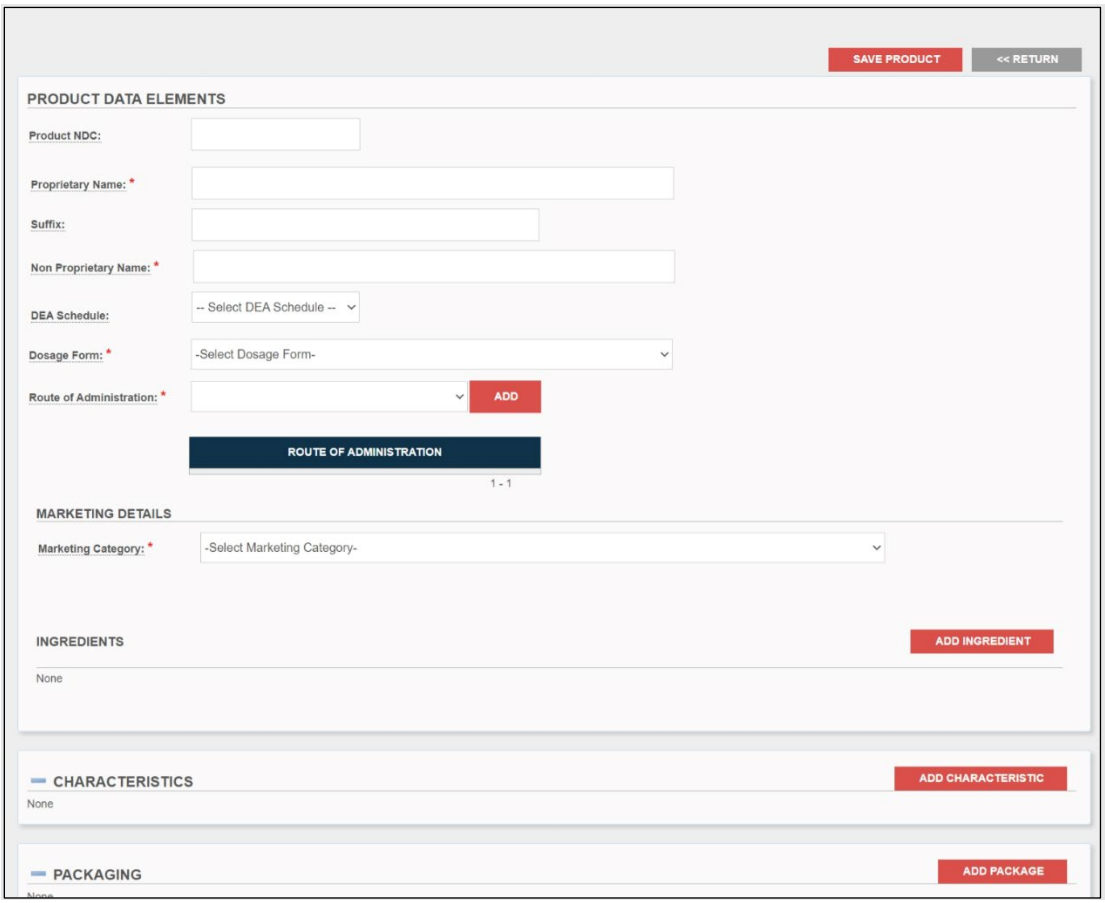
12. If you added an establishment, you will be returned to the previous page where you can view the establishment. You can click the pencil icon at any time to edit the establishment details:

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

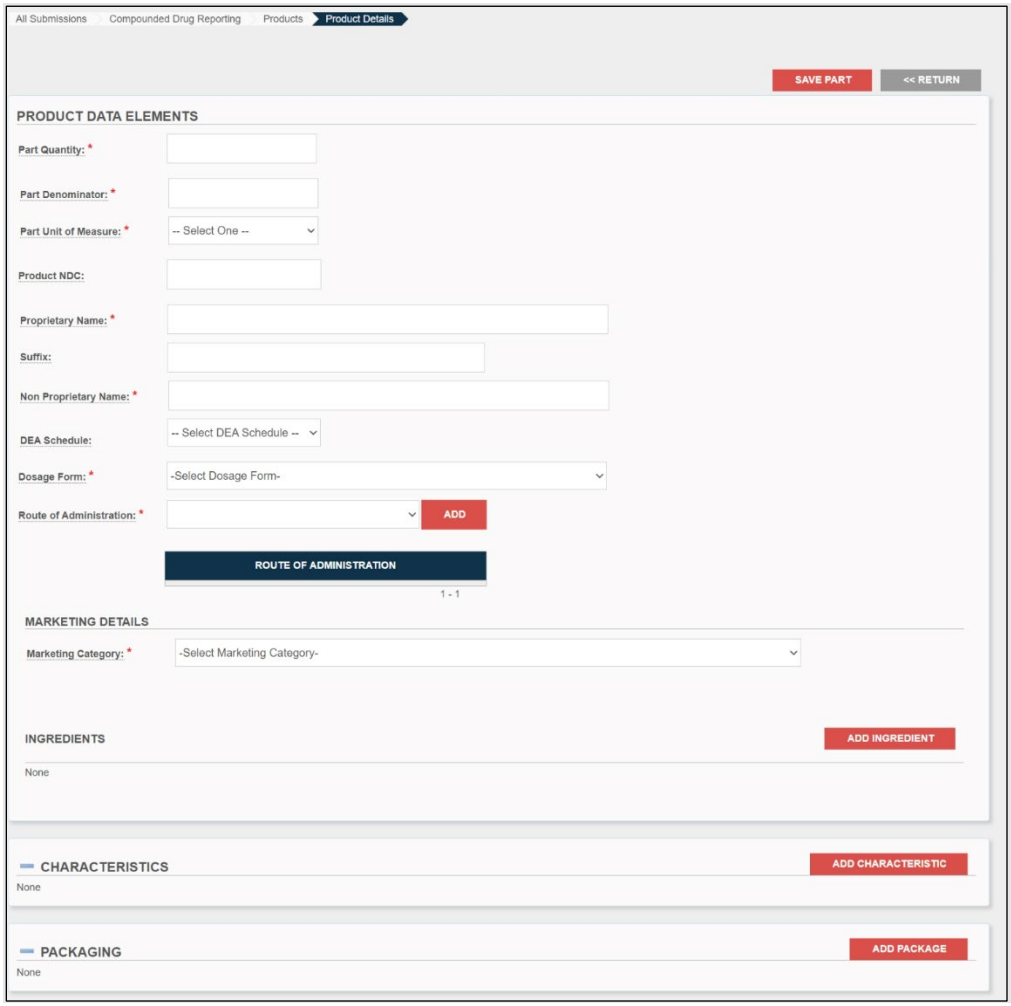


14. If you selected 'Yes' from the dropdown above, click the '**Add Product**' button:

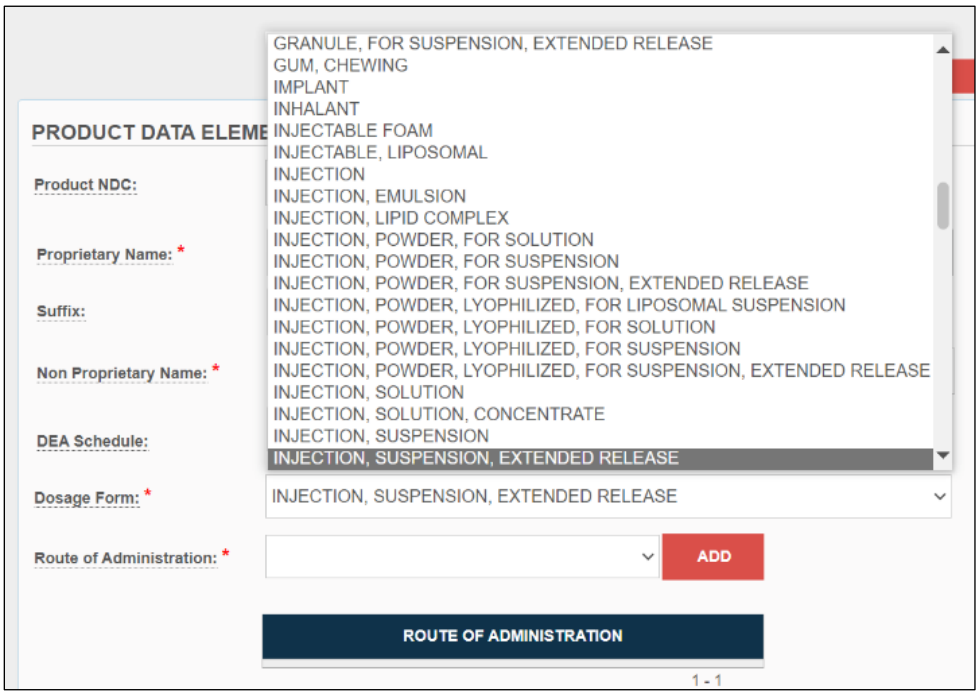
15. A blank template will display. Enter all fields applicable. If you are unsure about what to enter for any of the fields, click the underlined text beside the blank fields for more information.



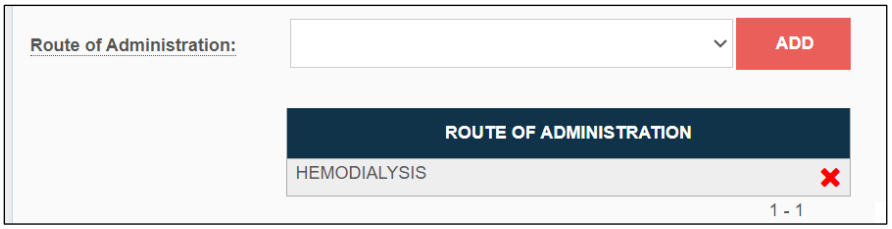
a. Select the dosage under the '**Dosage Form**' dropdown. If you select 'Kit', you have the option to add a part via separate form:



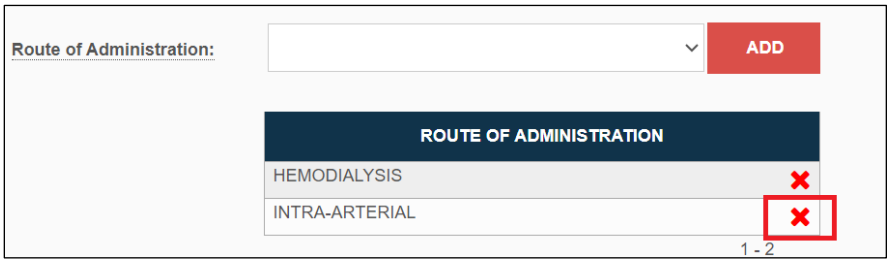
b. To add a '**Route of Administration,**' select the dropdown and choose from the list:



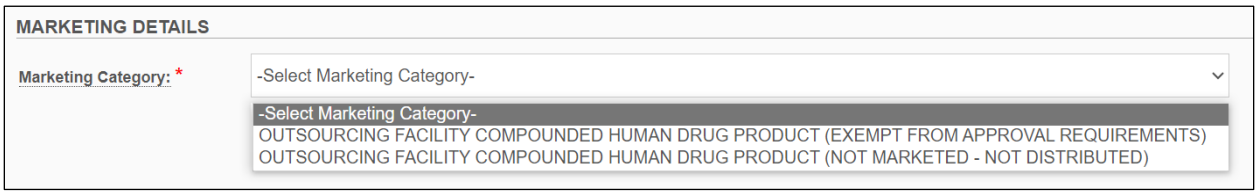
c. Click the 'Add' button and your selection will appear in the Route of Administration box.



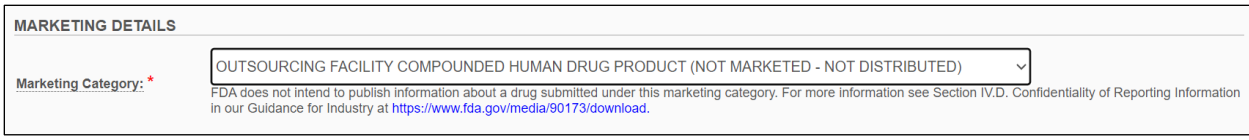
d. To remove a selection, simply click the 'X' beside a route of administration:



16. Enter the marketing category in the *Marketing Details* section:

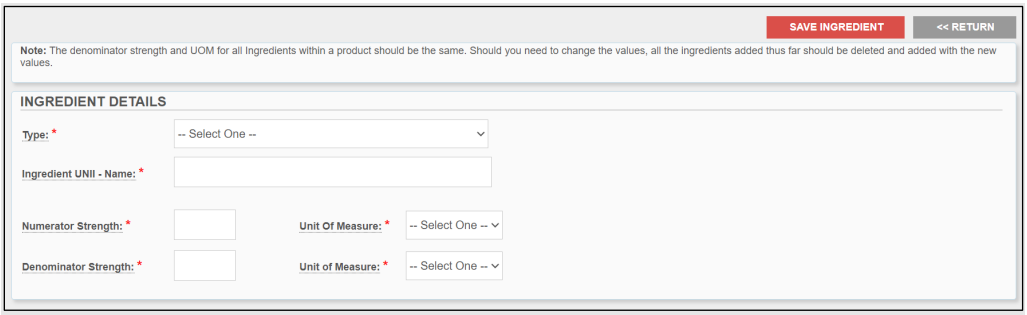


a. If you select '**Not Marketed – Not Distributed**,' you will receive a notice:

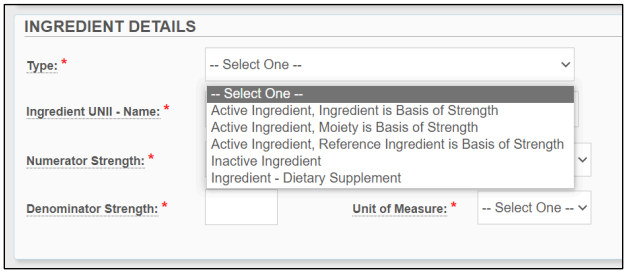


17. Next click '**Add Ingredient**' in the *Ingredients* section:

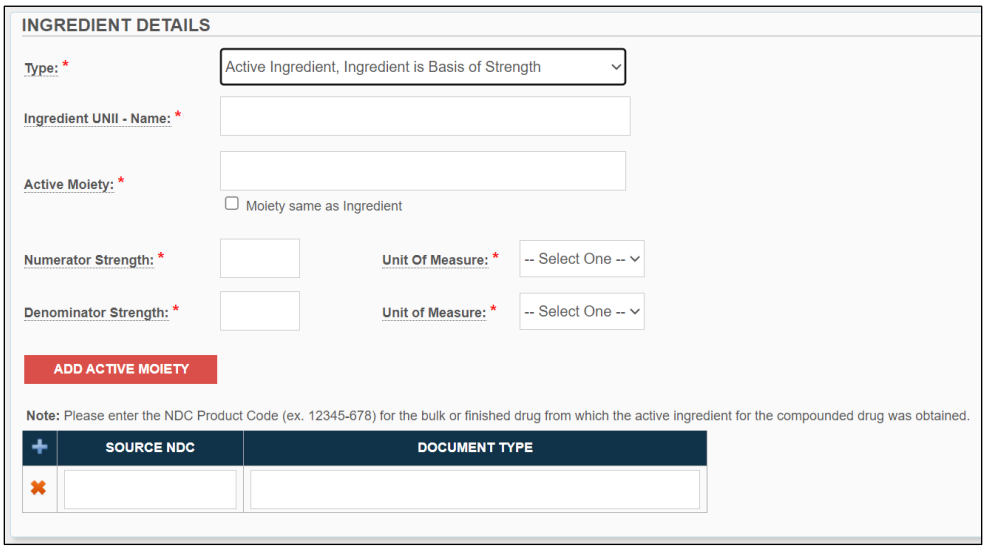
a. You will be taken to a separate page where you can enter information about a single ingredient:



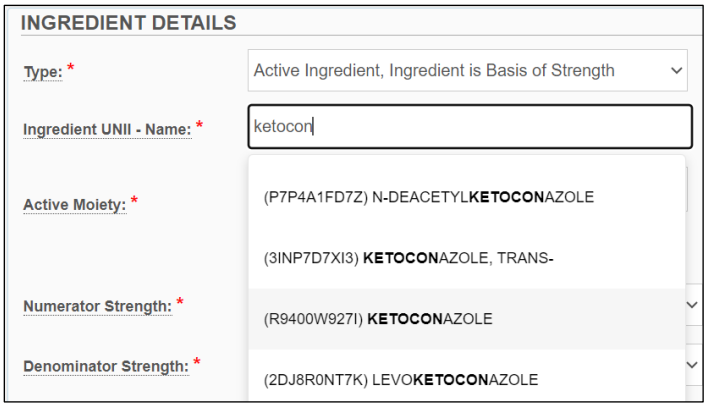
b. Select the dropdown for '**Type**':



e. Selecting either of the first two Active Ingredient options 'Ingredient is Basis of Strength' or 'Moiety is Basis of Strength' will display the '**Active Moiety**' field and a checkbox, along with a section to add source NDCs:

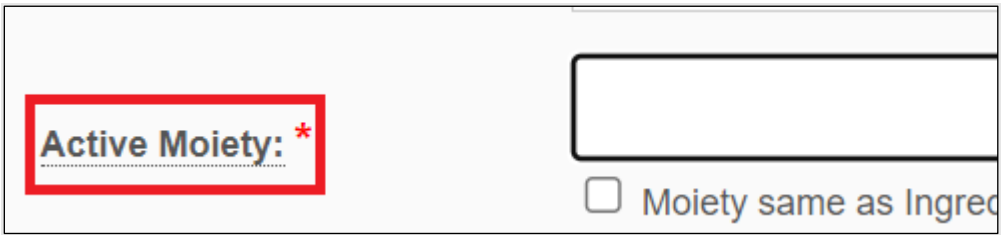


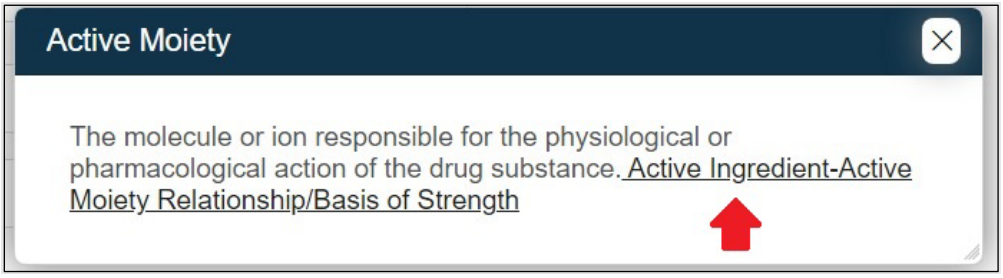
f. Enter an Ingredient UNII, or simply begin typing the ingredient name into the empty field:

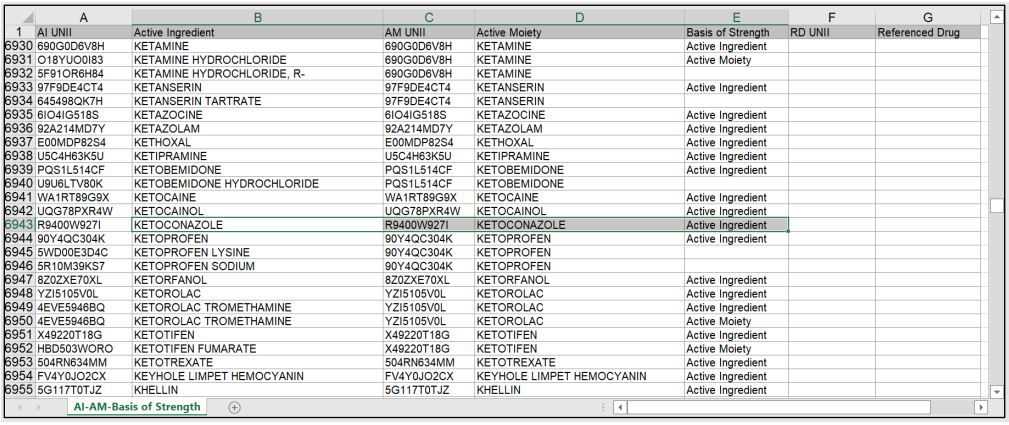


g. If the ingredient and moiety are the same, simply click the checkbox labeled 'Moiety Same As Ingredient' to automatically copy the ingredient to the active moiety field.

h. If you are unsure of the active moiety in your ingredient, you can click the underlined 'Active Moiety' helptext link. A box will display with a download link entitled 'Active Ingredient-Active Moiety Relationship/Basis of Strength.' This will download a zip file to your computer that contains a spreadsheet with a full active ingredient list and corresponding active moieties:



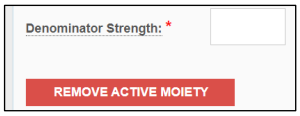




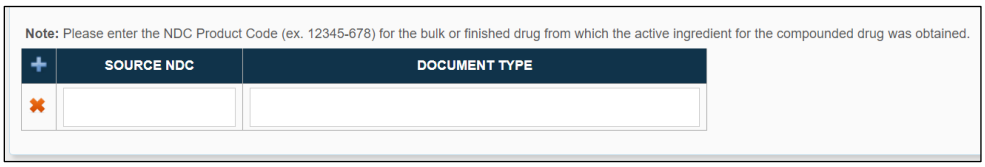
	A	B	C	D	E	F	G
1	AI UNII	Active Ingredient	AM UNII	Active Moiety	Basis of Strength	RD UNII	Referenced Drug
6930	690G0D6V8H	KETAMINE	690G0D6V8H	KETAMINE	Active Ingredient		
6931	O18YUO0I83	KETAMINE HYDROCHLORIDE	690G0D6V8H	KETAMINE	Active Moiety		
6932	5F91OR6H84	KETAMINE HYDROCHLORIDE, R-	690G0D6V8H	KETAMINE			
6933	97F9DE4CT4	KETANSERIN	97F9DE4CT4	KETANSERIN	Active Ingredient		
6934	645498QK7H	KETANSERIN TARTRATE	97F9DE4CT4	KETANSERIN			
6935	6IO4IG518S	KETAZOCINE	6IO4IG518S	KETAZOCINE	Active Ingredient		
6936	92A214MD7Y	KETAZOLAM	92A214MD7Y	KETAZOLAM	Active Ingredient		
6937	E00MDP82S4	KETHOXAL	E00MDP82S4	KETHOXAL	Active Ingredient		
6938	U5C4H63K5U	KETIPRAMINE	U5C4H63K5U	KETIPRAMINE	Active Ingredient		
6939	PQS1L514CF	KETOBEMIDONE	PQS1L514CF	KETOBEMIDONE	Active Ingredient		
6940	U9U6LTV80K	KETOBEMIDONE HYDROCHLORIDE	PQS1L514CF	KETOBEMIDONE			
6941	WA1RT89G9X	KETOCAINE	WA1RT89G9X	KETOCAINE	Active Ingredient		
6942	UQG78PXR4W	KETOCAINOL	UQG78PXR4W	KETOCAINOL	Active Ingredient		
6943	R9400W927I	KETOCONAZOLE	R9400W927I	KETOCONAZOLE	Active Ingredient		
6944	90Y4QC304K	KETOPROFEN	90Y4QC304K	KETOPROFEN	Active Ingredient		
6945	5WD00E3D4C	KETOPROFEN LYSINE	90Y4QC304K	KETOPROFEN			
6946	5R10M39KS7	KETOPROFEN SODIUM	90Y4QC304K	KETOPROFEN			
6947	8Z0ZXE70XL	KETORFANOL	8Z0ZXE70XL	KETORFANOL	Active Ingredient		
6948	YZI5105V0L	KETOROLAC	YZI5105V0L	KETOROLAC	Active Ingredient		
6949	4EVE5946BQ	KETOROLAC TROMETHAMINE	YZI5105V0L	KETOROLAC	Active Ingredient		
6950	4EVE5946BQ	KETOROLAC TROMETHAMINE	YZI5105V0L	KETOROLAC	Active Moiety		
6951	X49220T18G	KETOTIFEN	X49220T18G	KETOTIFEN	Active Ingredient		
6952	HBD503WORO	KETOTIFEN FUMARATE	X49220T18G	KETOTIFEN	Active Moiety		
6953	504RN634MM	KETOTREXATE	504RN634MM	KETOTREXATE	Active Ingredient		
6954	FV4Y0JO2CX	KEYHOLE LIMPET HEMOCYANIN	FV4Y0JO2CX	KEYHOLE LIMPET HEMOCYANIN	Active Ingredient		
6955	5G117T0TJZ	KHELLIN	5G117T0TJZ	KHELLIN	Active Ingredient		

AI-AM-Basis of Strength

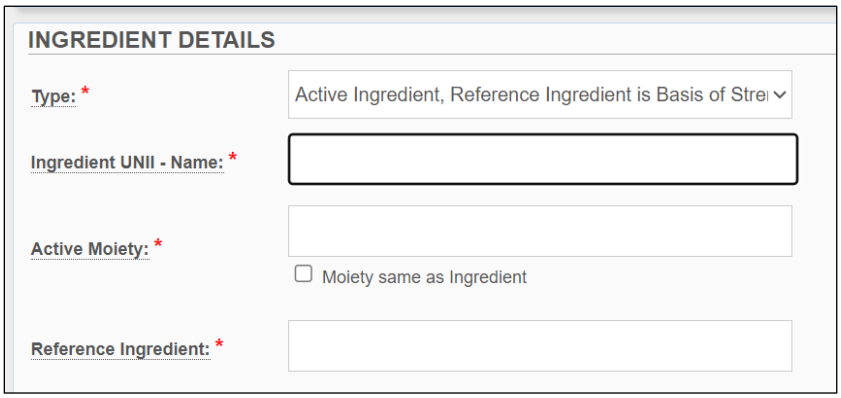
i. Click the 'Add Active Moiety' button to add another moiety. Click the button again to remove that moiety.



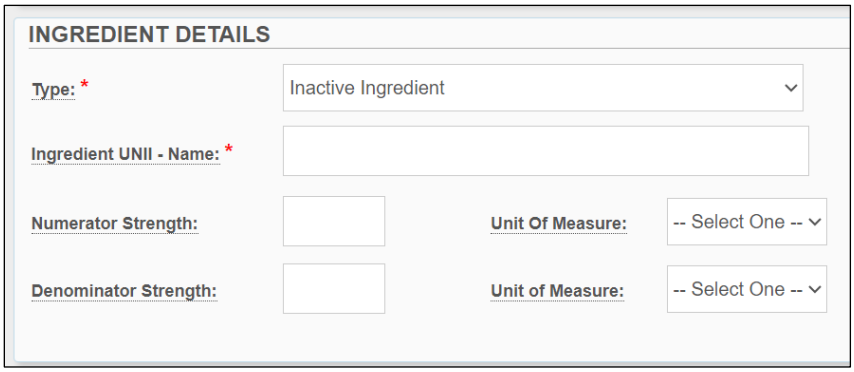
j. Add the source NDC Product Code at the bottom of the page. You can click the '+' button to add more source NDCs, or the 'X' button to remove them:



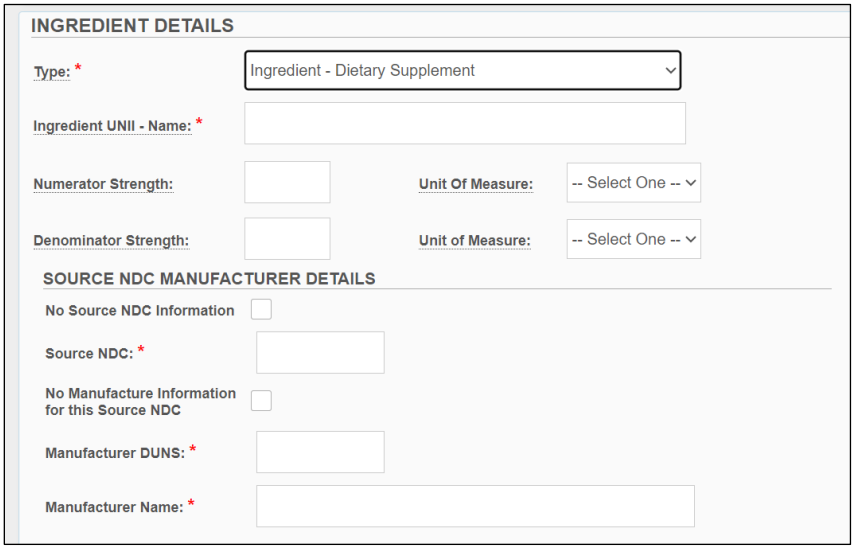
k. If you selected the third '**Type**' option 'Reference Ingredient is Basis of Strength', a Reference Ingredient field will display below the Active Moiety field:



l. If you selected the 'Inactive Ingredient' option for '**Type**,' the 'Numerator/Denominator Strength' fields will not be required:

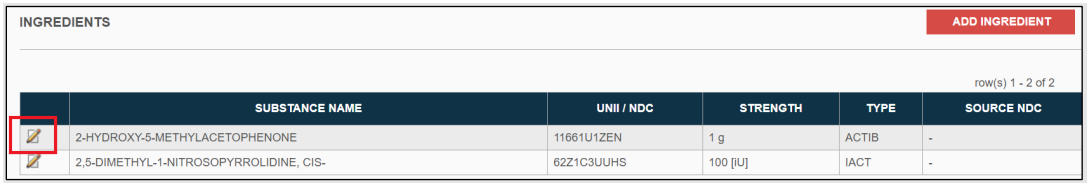


m. If you selected the 'Dietary Supplement' option for '**Type**,' the *Source NDC Manufacturer Details* section will display:



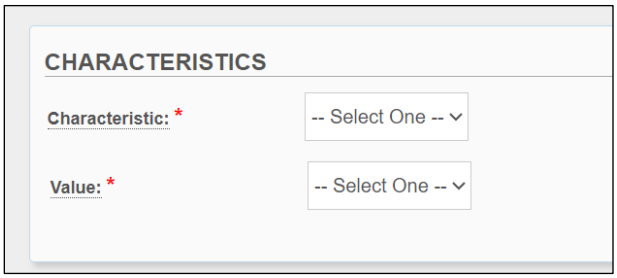
n. When finished with your ingredient entry, click '**Save Ingredient**' at the top right of the page. This will return you to the Product Details page.

o. To add more ingredients, re-do Step 17. You can edit an ingredient on the Product Details page by clicking the pencil icon:

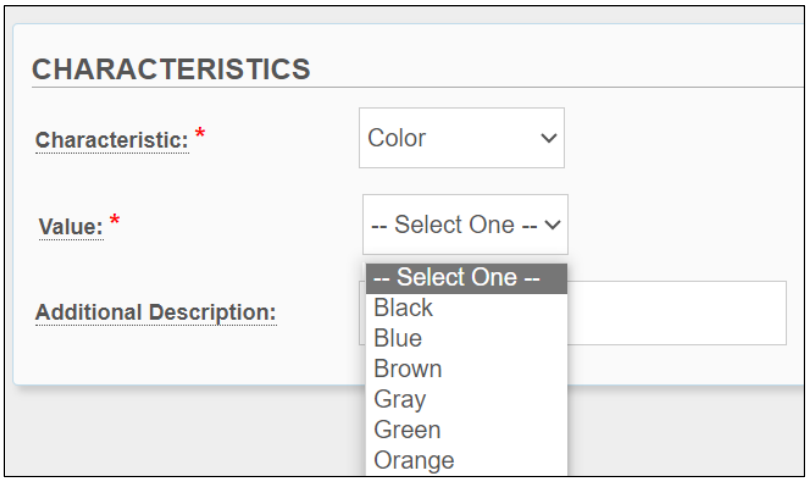


18. Next, click '**Add Characteristic**' to enter color/flavor/score/shape/imprint/size details:

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



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

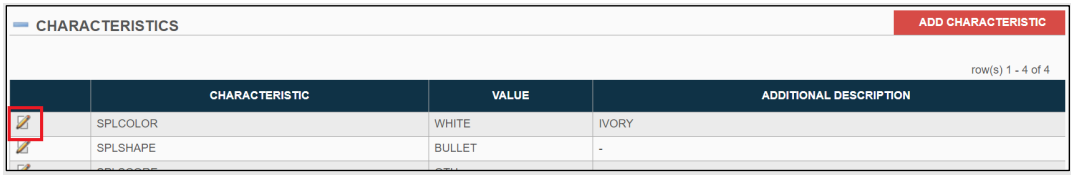


c. You can enter more specific details for a selected characteristic in the '**Additional Description**' field, which can include shades of colors ("ivory" white) or shape variations (triangle with "rounded edges"):

d. Click '**Save Characteristic**' on the top right of the page when finished. You will be returned to the Product Details page.

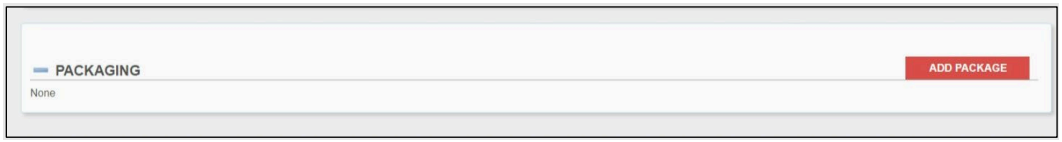
e. Only one characteristic can be entered at a time, so repeat Step 18 to add additional characteristics.

f. To edit a characteristic, click the pencil icon beside the selected characteristic on the Product Details page:

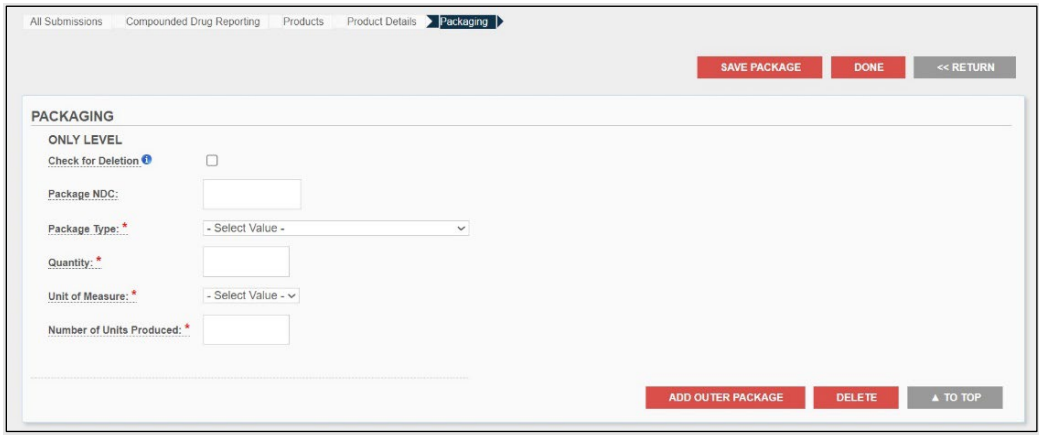


19. To add a Package:

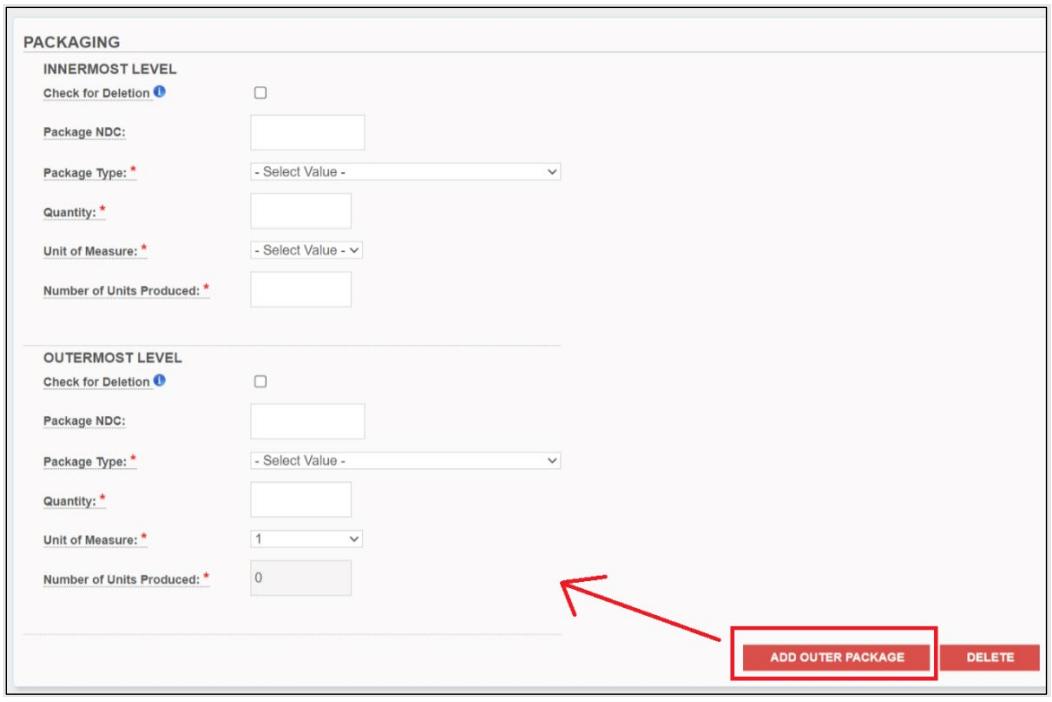
a. Click '**Add Package**' at the bottom of the product details page:



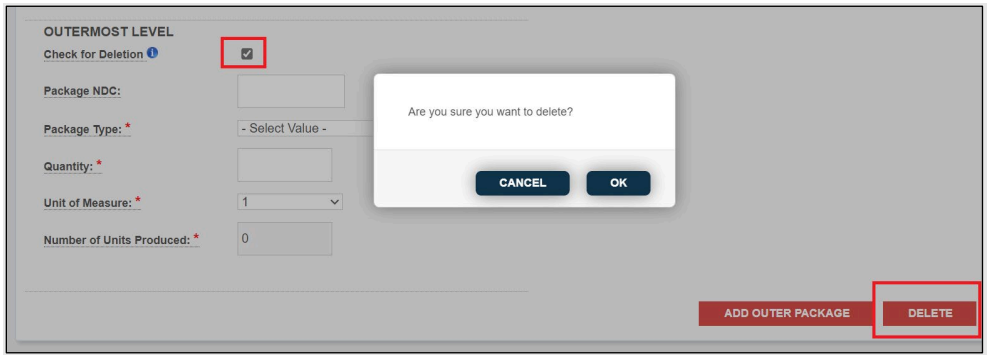
b. Enter all applicable data for the package:



c. If there are multiple layers of packaging, click the '**Add Outer Package**' button at the bottom of the page (you can click this button multiple times):

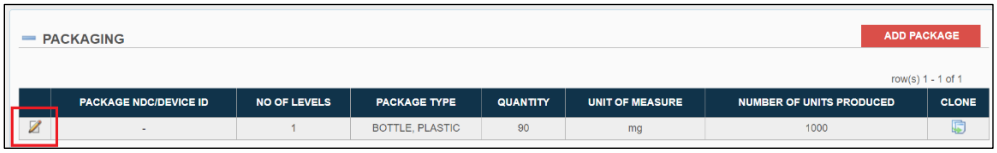


d. To delete an outer package, click the '**Check For Deletion**' checkbox and then select the '**Delete**' button. A popup box will ask for confirmation to delete:



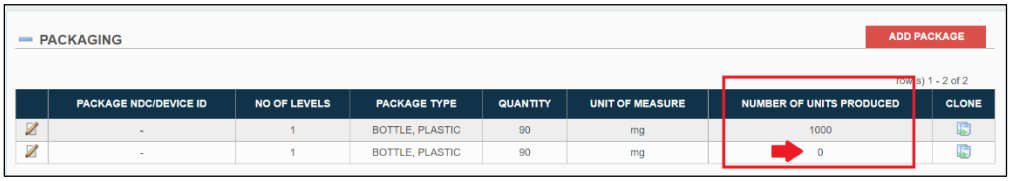
e. When finished, click '**Save Package**' at the top of the page to return to the Product Details page.

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



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

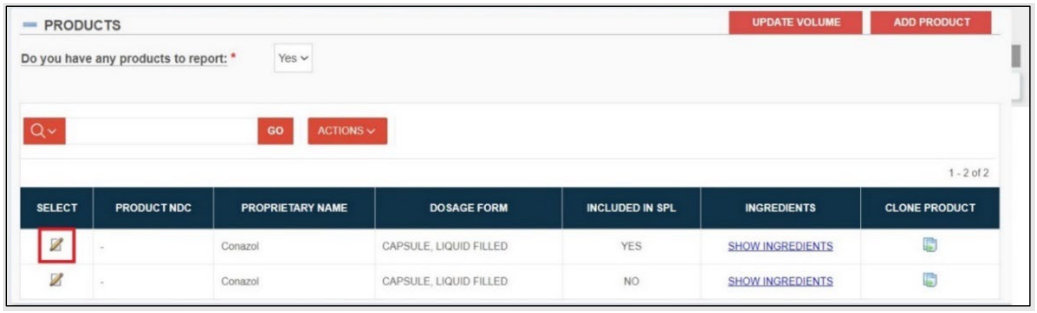
IMPORTANT: When cloning, don't forget to add the 'Number of Units Produced'! The number **does not** carry over to the new package:



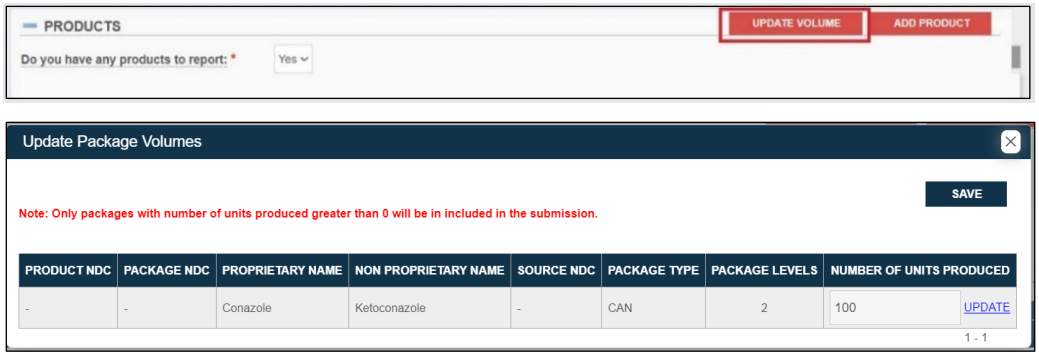
20. Repeat Steps 13-19 to add more products.

21. Click '**Save Product**' at the top right of the Product Details page. This will return you to the Products page, where you can edit a product:

    a. Click the pencil icon beside a product to go to its Product Details page and make edits:



b. You can also edit the number of units produced for all of your products by clicking the '**Update Volume**' button:

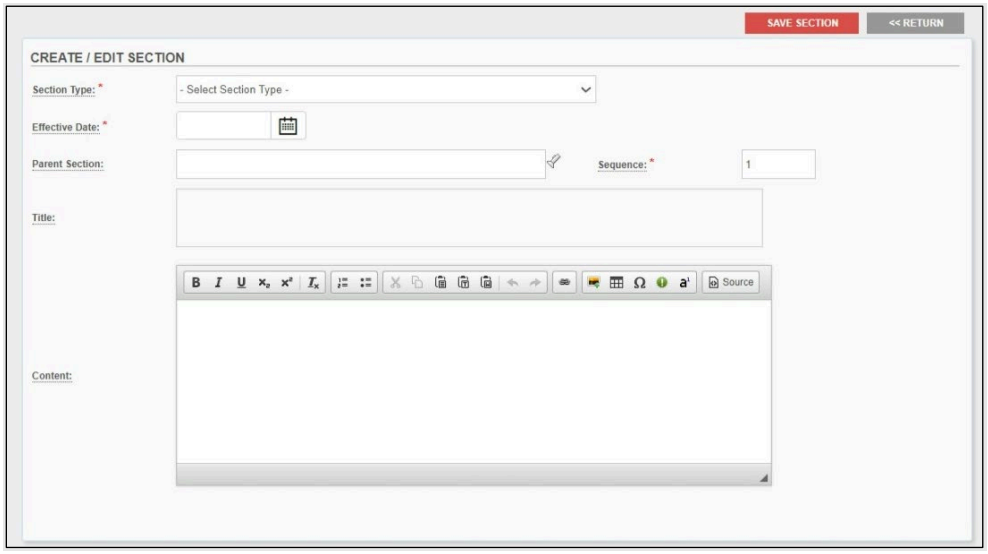


22. Back on the Products page, enter the Content of Labeling information:

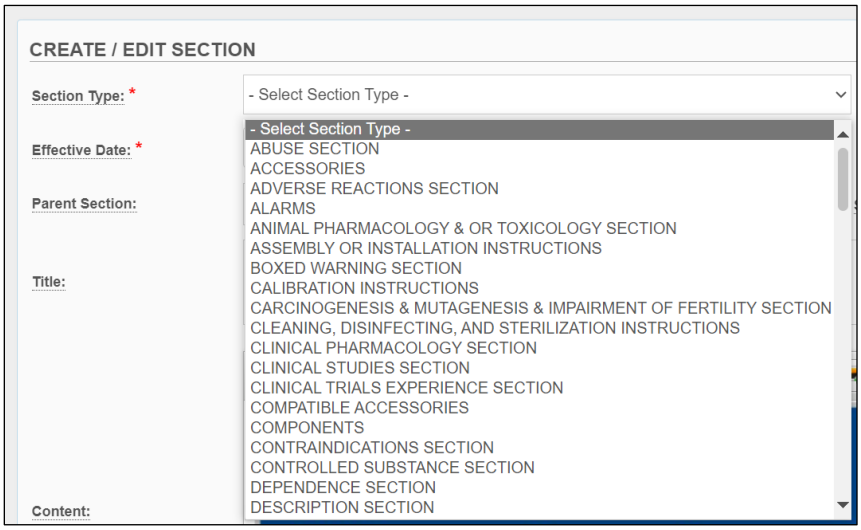
a. Click the '**Content of Labeling**' button at the top:

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

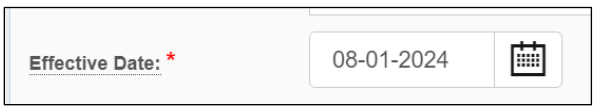
c. A blank template will display. Fill in all applicable fields:



d. Clicking the '**Section Type**' dropdown will display a list of packaging sections, which will act as headings for your label. For each section/heading that applies to your label, add the appropriate label graphic and text (as explained later).



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

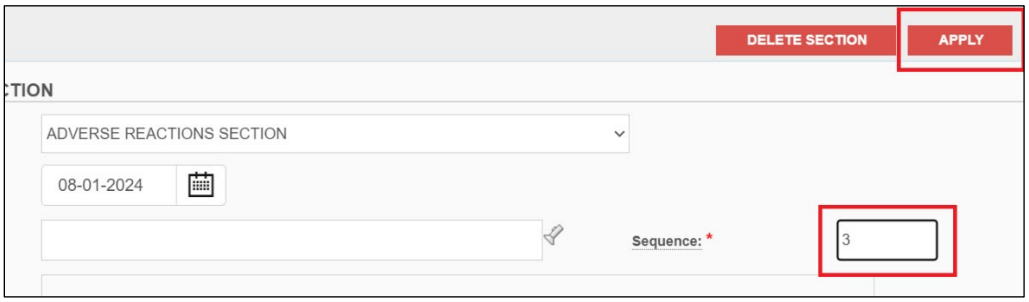


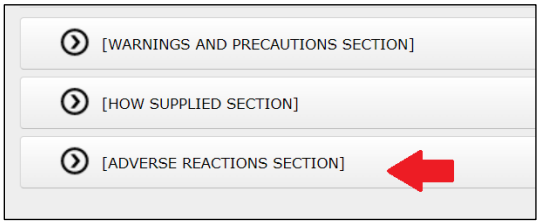
f. The '**Sequence**' field allows you to organize your label sections (headings) so that they display in the appropriate order. Here is an example list of three sections that were created in Content of Labeling:

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

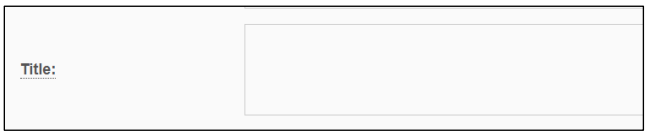
Each section is automatically assigned the next number in numerical order (2, 3, 4, etc). If you need to reorganize any existing or new sections so that they display in a different order, simply change the number in the 'Sequence' field of a desired section.

In the example below, the 'Adverse Reactions Section' previously at the top was moved to the bottom by simply entering '3' into that section's 'Sequence' field then clicking 'Apply':



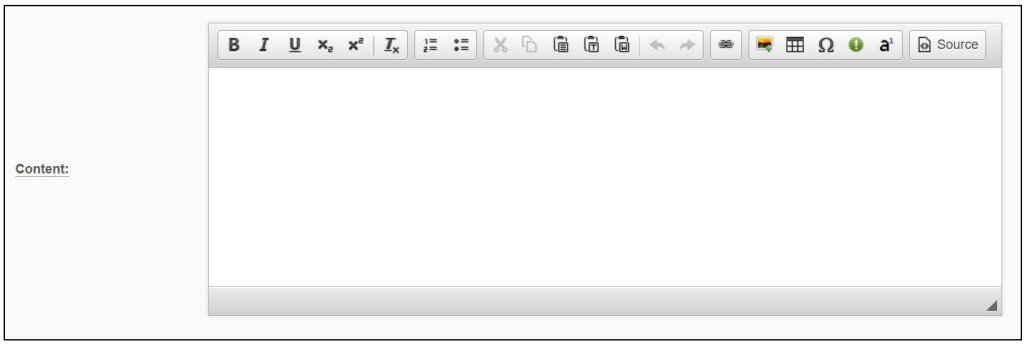


g. Choose a title for your section. If you don't enter anything, whatever you selected from the '**Section Type**' dropdown will become the title.



h. The '**Highlighted Text**' box only displays for certain section types. Enter information there, if applicable.

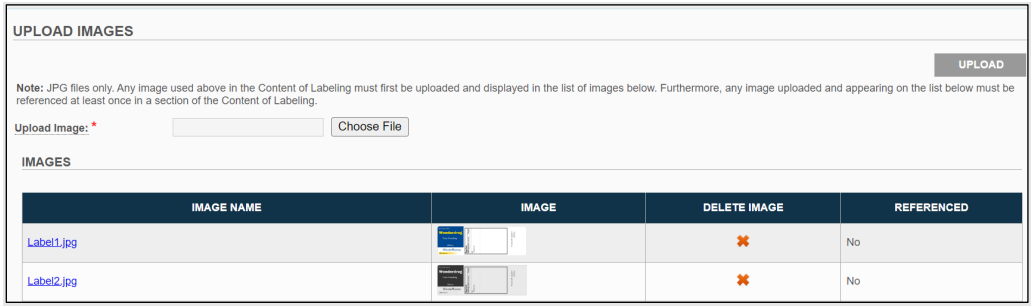
i. The '**Content**' box is intended for text and graphics that pertain to the '**Section Type.**' If you chose 'Adverse Reactions' as a section type, you must enter images and/or text that are appropriate for that section of your labeling.



j. To upload a product label image, click '**Choose File**' to select an image from your computer. The extension/ending of the file MUST be a **.jpg no larger than 1MB**.

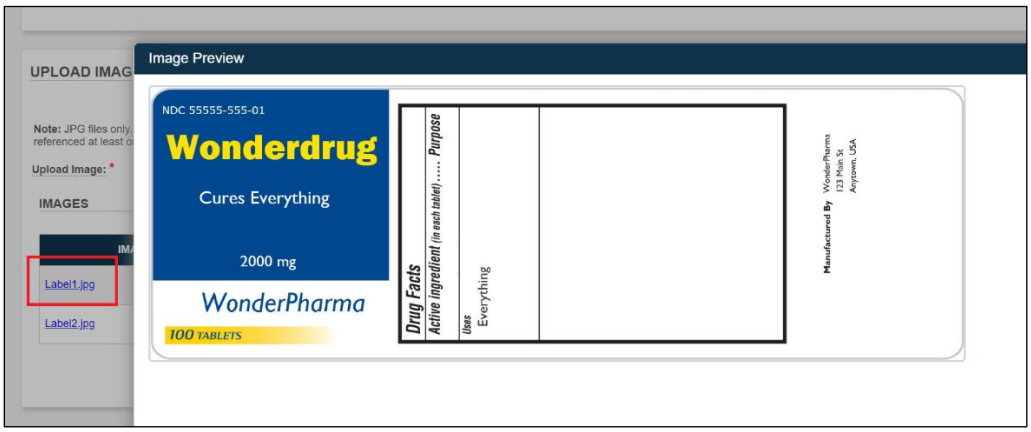
k. When you have selected a JPG image from your computer, click the '**Upload**' button. Only one image can be uploaded at a time.

l. Your image(s) will display in the *Images* section:

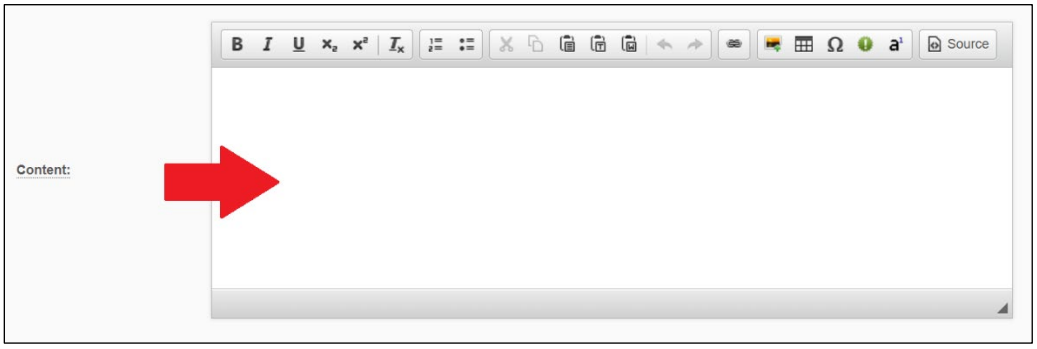


m. Click the red **X** beside an image to delete the image. Doing this will cause images to disappear or not display properly if they have been used ("referenced") in a section.

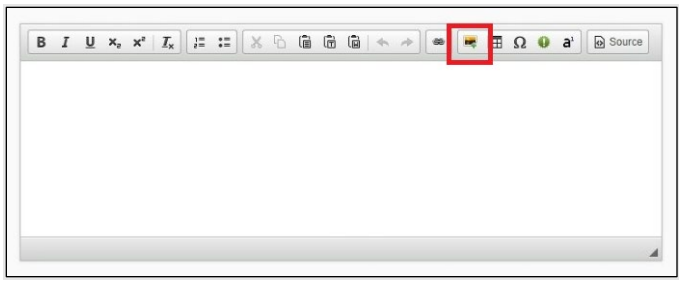
n. Click the name of the image to display a closeup preview:



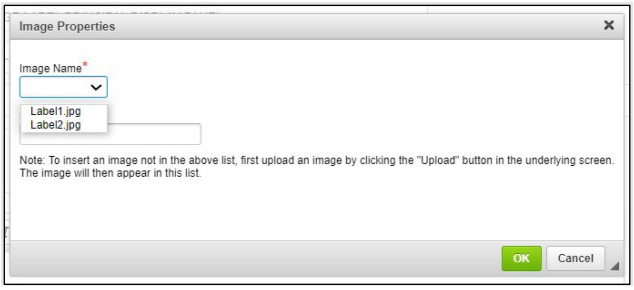
o. Click You must now "reference" your image(s) before you can submit your SPL. To reference an image, go back up to the *Create/Edit* section and click anywhere inside the '**Content**' box:



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

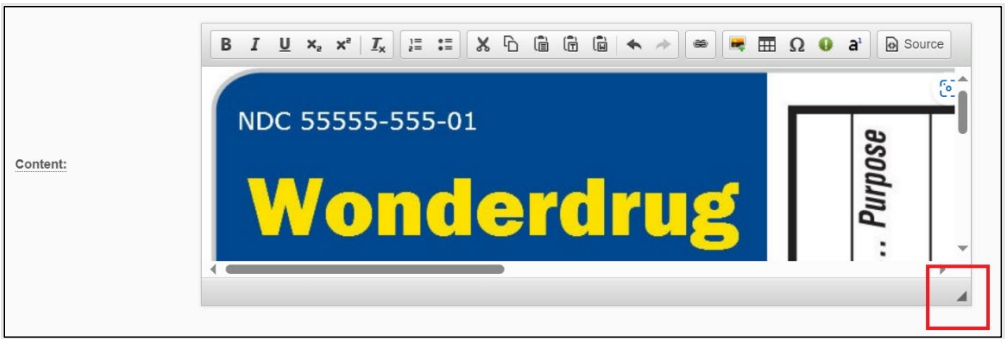
q. 

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



s. Next, add some Image Text. This is alt text (description text for an image that is not visible anywhere but can be picked up and read by screen reading technology).

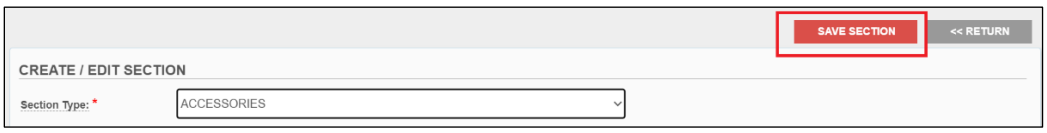
t. Click '**OK**.' Your image will now display within the Content box. Click and drag the corner arrow to view more of the image:



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

If you delete an image from the *Images* section, it will be automatically removed from each 'Content' section in every Content of Labeling entry that references it!

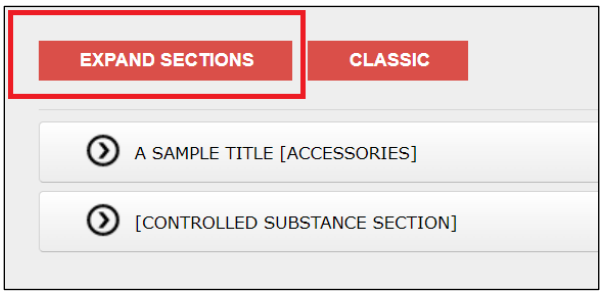
u. When you are finished, click the '**Save Section**' button at the top right of the page to save your new section:



v. You will be returned to the main Content of Labeling list page. Clicking '**Edit**' will allow you to modify an existing section:

w. To add another section to this list, click the '**Add Section**' button:

x. If you have at least one section created, clicking the '**Expand Sections**' button (top left) will automatically display the full contents of all of your sections listed:



y. Click '**Collapse Sections**' (top left) to close all entries.

z. You also have the option to switch between '**Classic**' and '**Enhanced**' (top left button) mode, which simply changes the look of the lists.

aa. See Section 9.1 for additional help with the Content of Labeling section.

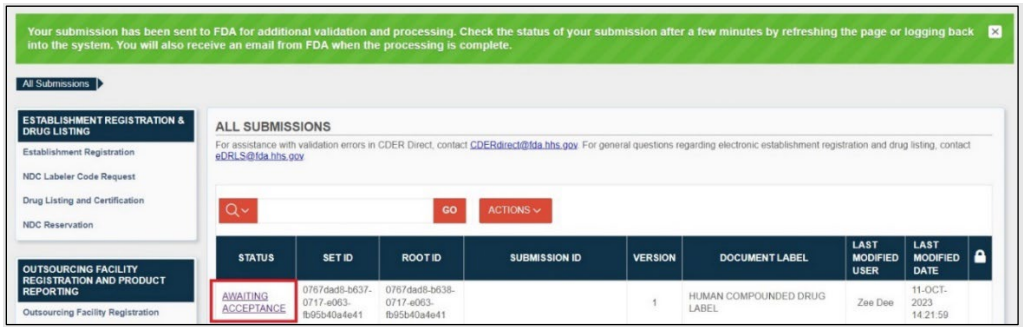
bb. When you are finished with Content of Labeling, click the '**Return**' button at the top right of the page. You will be sent back to the product details page.

23. When all fields have been entered to your satisfaction, you can do the following:

a. '**Save As Draft**' – Save your entry and return to the main Compounded Drug Reporting page. No submission will be made.

b. '**Save And Validate**' - Save your entry + validate. This will check your submission for errors prior to submitting to the FDA. Validation may take some time. If you are ready to submit your SPL, you may skip this step entirely,

c. '**Submit SPL**' - Submit your Compounded Drug Reporting SPL submission to the FDA. You will then be returned to the Compounded Drug Reporting main page where you can view your pending submission(s) status:

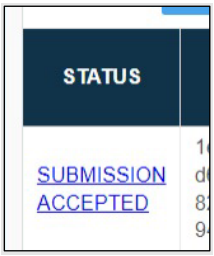


d. '**Delete**' – Delete your entry draft completely.

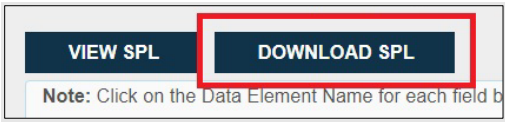
24. Click '**Return**' at any time to return to the main Compounded Product Reporting page.

25. The *Status* field will read '*Submission Accepted*' when your submission has been validated and accepted by the FDA. You will receive an email to your account email address whenever the submission status changes.

26. Once your submission has been accepted, you will be able to download a copy of the submission as a zip file. Go to the main Compounded Drug Reporting page and click the latest '*Submission Accepted*' text link:

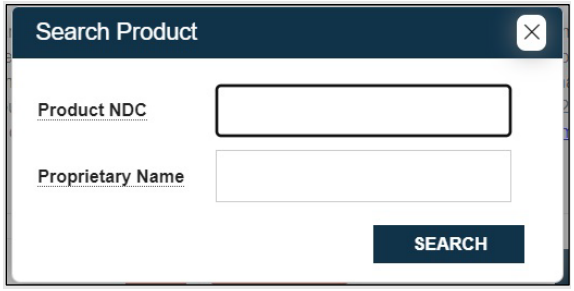


27. Click '**Download SPL**' on the top left of the page to download the zip file. You can also select '**View SPL**' for a quick look at your submission.



28. If you already have multiple Compounded Product Reporting submissions, you can search for a specific submission:
    a. Click '**Search Product**' on the Compounded Product Reporting main page:

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



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

7 WHOLESALE DRUG DISTRIBUTOR AND THIRD-PARTY LOGISTICS PROVIDER REPORTS

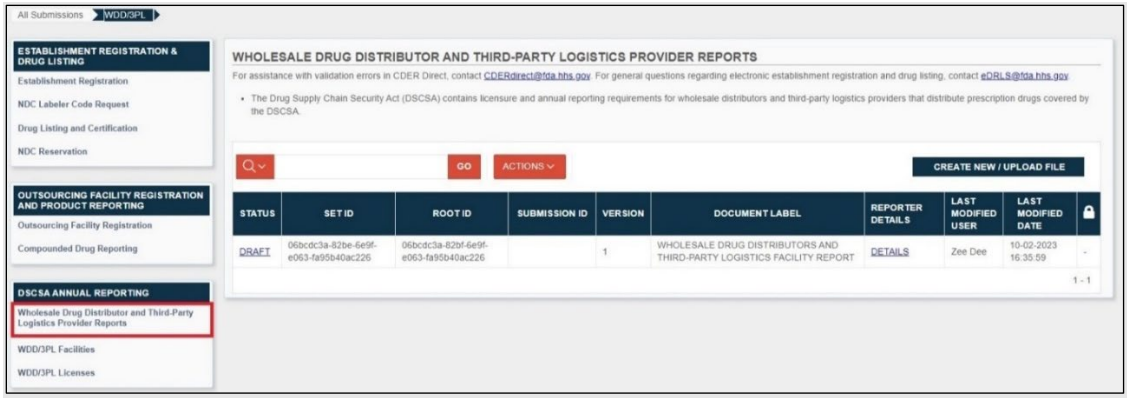
A **Wholesale Drug Distributor And Third Party Logistics Provider Reports** (WDD/3PL) SPL submission can be used for wholesale distributors and third-party logistics providers that distribute prescription drugs covered by the Drug Supply Chain Security Act (DSCSA).

The **WDD/3PL** SPL submission template can be used for the following purposes:

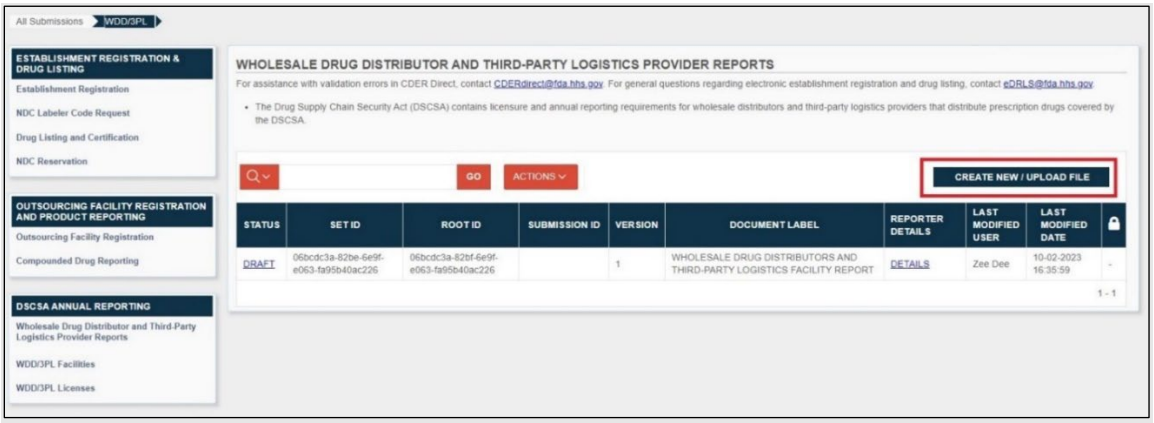
- Facility Reporting: Reporting facility information.
- Withdrawal of Facility Reporting: Removing previously reported facility information.
- Out of Business: De-registering due to going out of business.

To submit a WDD/3PL SPL, do the following:

1. Log in to FDA Direct.
2. Select '**Wholesale Drug Distributor And Third Party Logistics Provider Reports**' under the *DSCSA Annual Reporting* section:



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

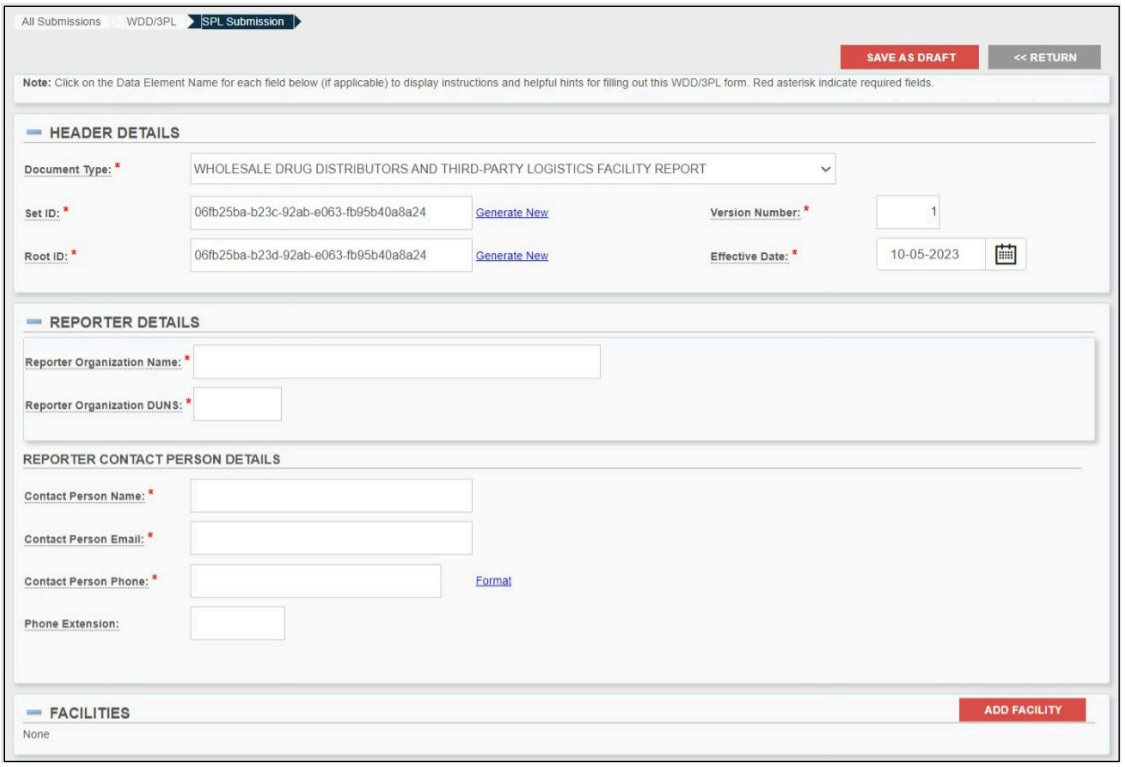


4. You will be given two options:

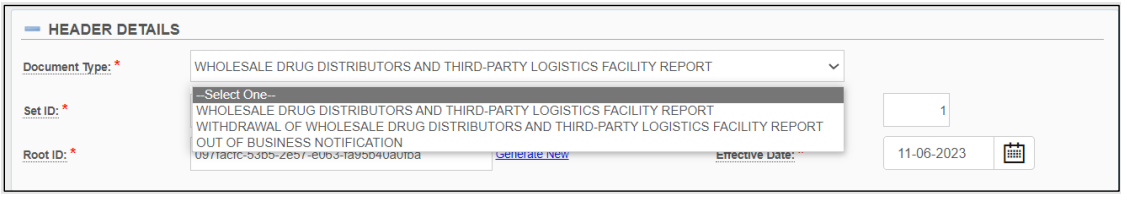
   a. To upload a file from your computer directly, follow the steps outlined in Section 3: Submission Information. Then skip to Step 7 below and continue the instructions.

5. To create a new WDD/3PL submission using a blank template, select the '**Create a new Wholesale Drug Distribution and Third Party Logistics using a blank form**' option.

6. Click '**Continue**' and a blank template will display:



7. Selecting the '**Save Draft**' button at any time will save your work without submitting it. The '**Return**' button will send you back to the main WDD/3PL Provider Reports page without saving your changes.
8. In the *Header Details* section, select one of the options from the dropdown:

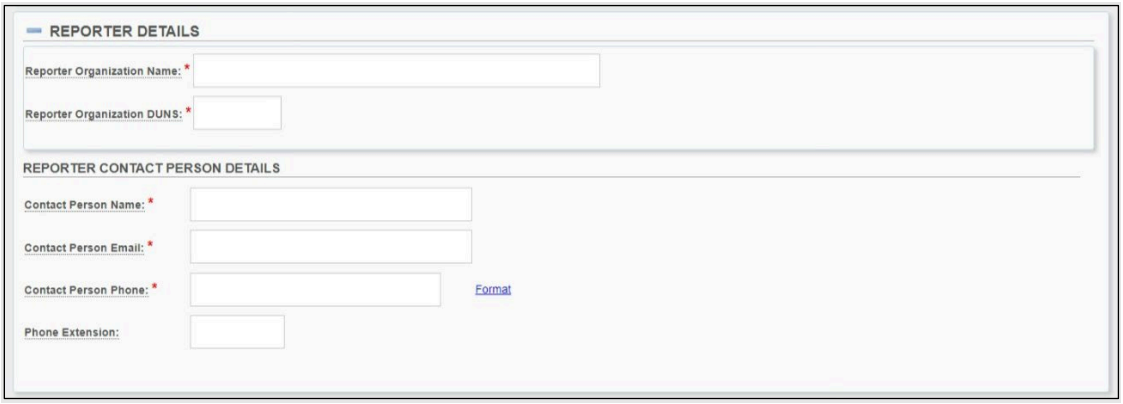


9. To enter a **Withdrawal** or an **Out Of Business** submission, select the option that applies from the dropdown.
    a. Enter your submission Root ID and/or Set ID.

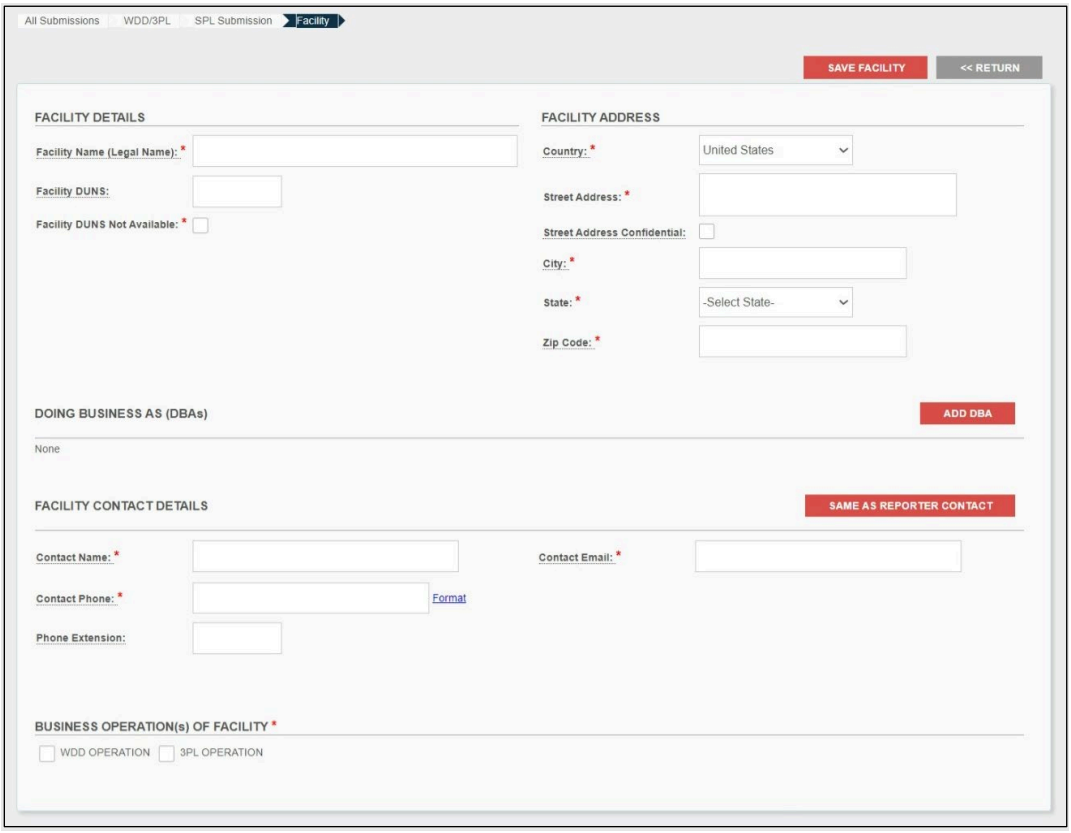
    IMPORTANT: This step can be skipped **only if you uploaded your submission during** Step 4, as the correct IDs will automatically populate those fields.

    b. Click '**Save As Draft**' at the top. You will be returned to main WDD/3PL page.
    c. Click '**Submit SPL**' when you are ready to send you submission to the FDA.

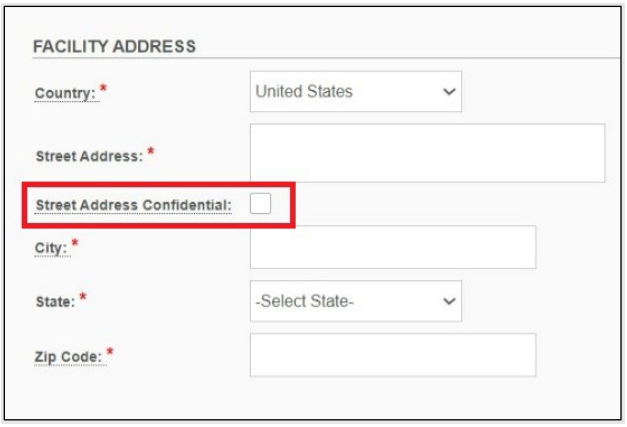
10. To enter a '**Wholesale Drug Distributors and Third-Party Logistics Facility Report**' submission, select the option from the dropdown.
11. Fill in all blank fields in the *Reporter Details* section. The reporter is the company that owns or operates the wholesale distributor or 3PL and is reporting the facility(s) information.



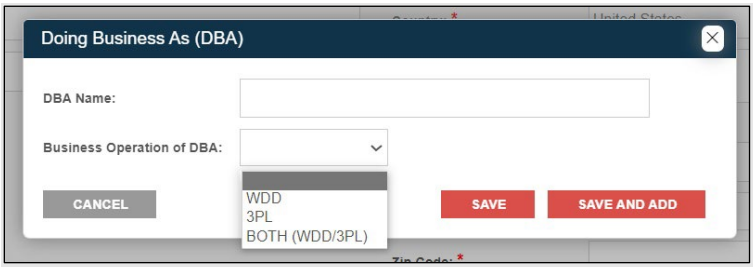
12. At the bottom of the page, click the '**Add Facility**' button. A blank template will display on a new page:



13. Complete the *Facility Details* and *Facility Address* fields. Click the '**Street Address Confidential**' check box if you want to keep the street name private:



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



a. Enter your '**DBA Name**' and select the appropriate business operation from the dropdown.

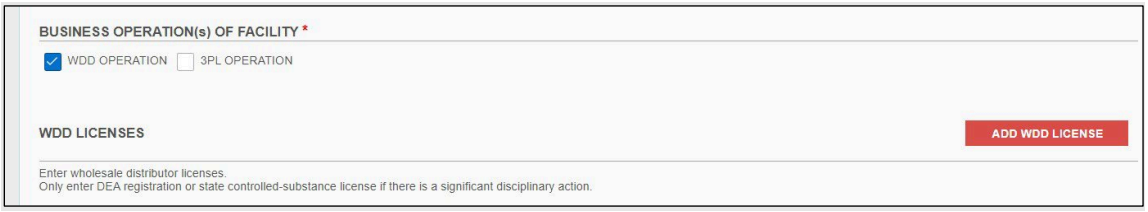
b. To add multiple DBAs without closing the popup, click the '**Save And Add**' button for each new DBA entry.

c. When you are finished adding DBAs, click '**Save**' and you will be returned to the facility page. Your saved DBAs will display under the *Doing Business As* section:

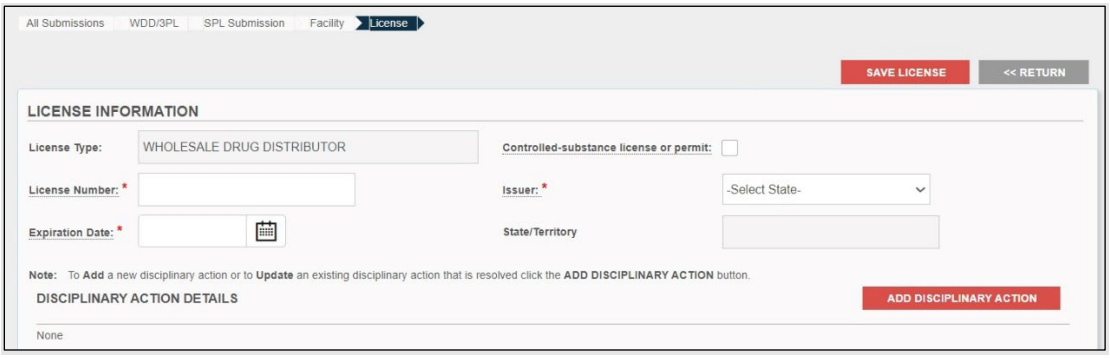
d. Click the pencil icon to make edits to any of the DBAs or click the **X** to delete the specified DBA.

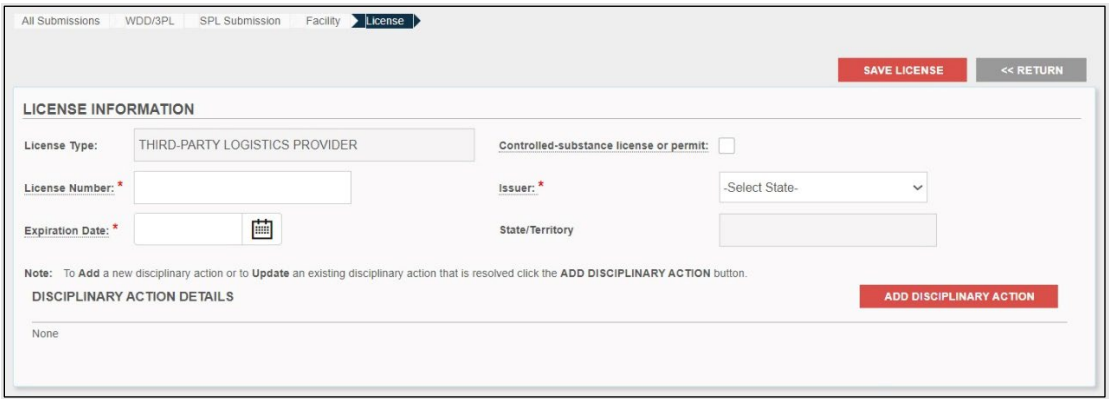
15. Under *Facility Contact Details*, you have the option to select '**Same As Reporter Contact**' to copy over contact information from the initial page (*Reporter Contact Person Details*).

16. To add business operations, select one or both of the check boxes:



17. Click '**Add License**' and you will be taken to a separate page where you will enter licensing information for the specified business operation (WDD or 3PL):





18. If you select the '**Controlled-substance license or permit**' check box, you must enter at least one disciplinary action via the '**Add Disciplinary Action**' button. This will send you to a new page:

a. Fill out the *Action Details* section then upload any relevant document with a '**.pdf**' file extension. Upload a PDF file from your computer by clicking '**Choose File**' then clicking the '**Add Document**' button:

b. Repeat the above step to add additional documents.

c. Once you add a document, it will display at the bottom of this page:

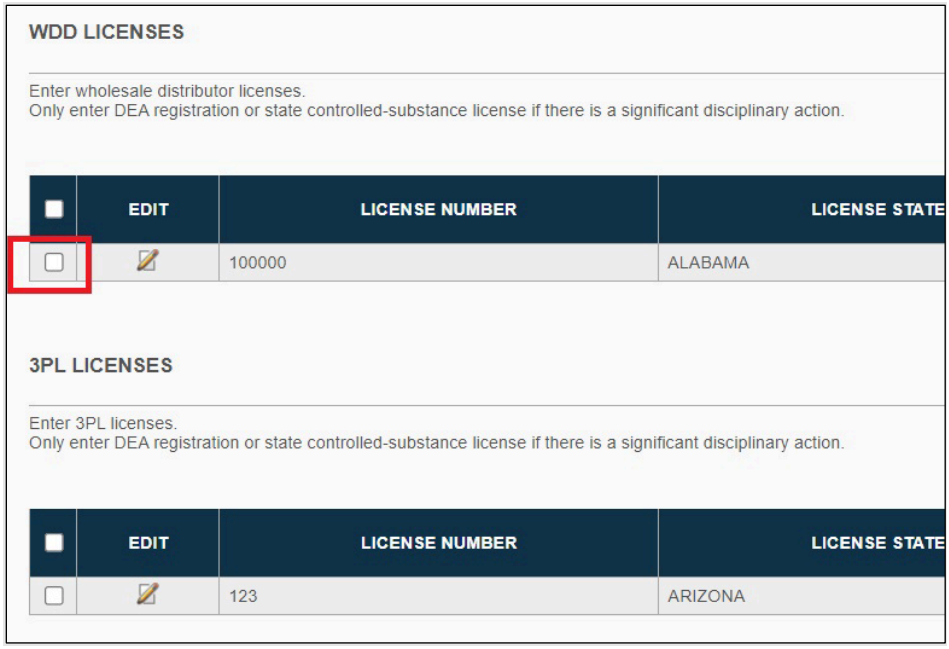
d. Clicking the **X** will delete the uploaded file.

e. When finished, click '**Save Action**' at the top to save your entry and return to the license page. If you do not want to save your changes, simply click the grey '**Return**' button instead.

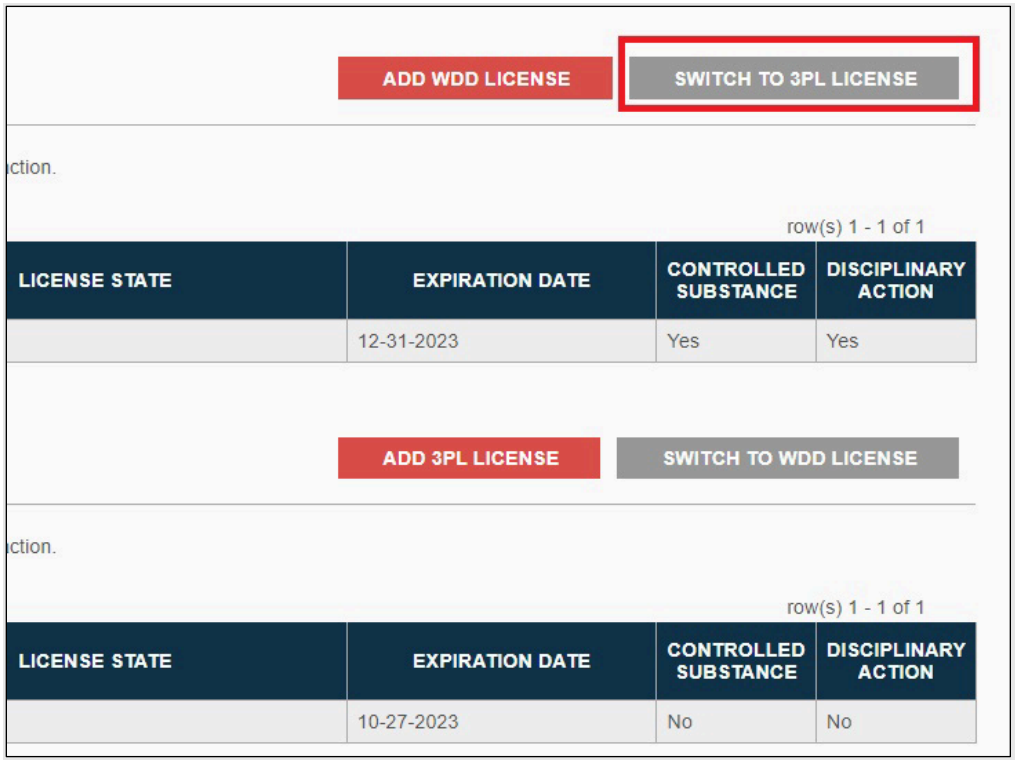
f. You will be sent back to the licensing page.

19. Click '**Save License**' when you are finished making changes. If you do not want to save your entry, click '**Return**'.
20. You will be sent back to the facility page and your licenses will display at the bottom. Click the pencil icon beside each entry to edit a license.
21. If you selected both of the business operations boxes under *Business Operation(s) of Facility*, you have the option to switch between licenses.

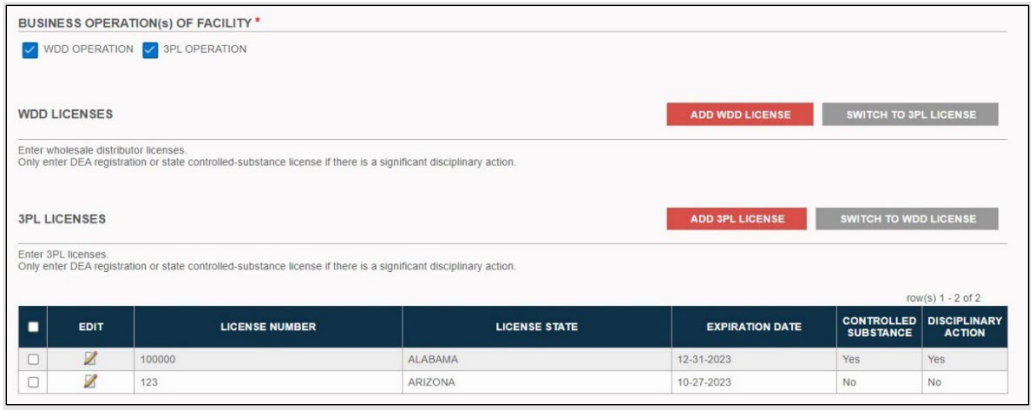
a. To do this, you must first select the checkbox next to the desired license:



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

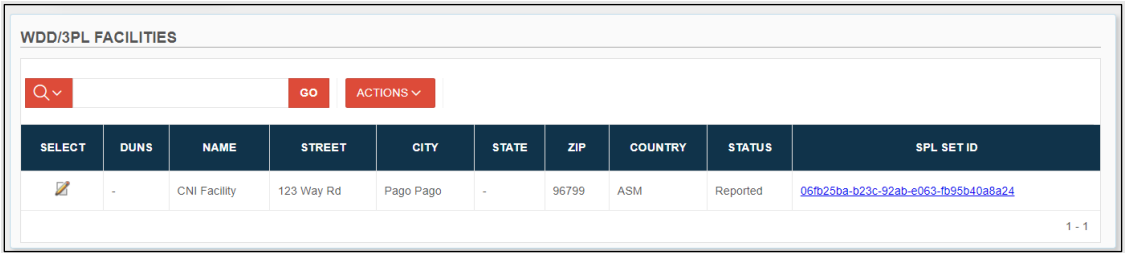


c. Your license will now be moved under the selected license business operation and removed from the previous one:



22. When you are finished editing the facility page, scroll to the top and click '**Save**' to save and return to the initial form page, or '**Return**' to exit the facility page without saving.

23. Your facilities will display at the bottom of the page, and can be edited by clicking the pencil icon beside each facility entry.

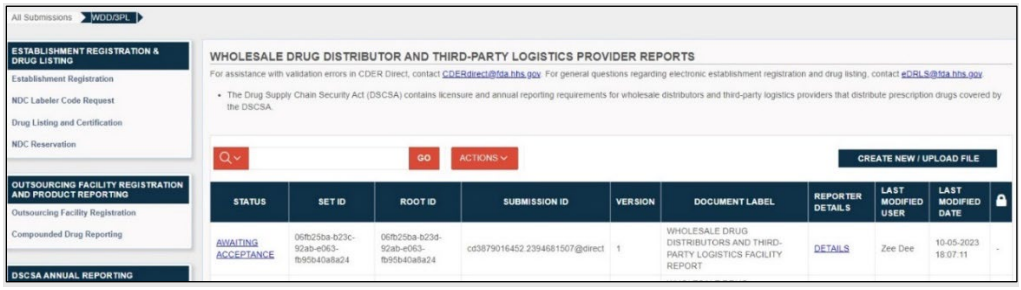


24. When you are fully finished, go to the top of the WDD/3PL submission page where you can do the following:

    a. '**Save As Draft**' – Save your entry and return to the main WDD/3PL Provider Reports page. No submission will be made.

    b. '**Save And Validate**' - Save your entry + validate. This will check your submission for errors prior to submitting to the FDA. Validation may take some time. If you are ready to submit your SPL, you may skip this step entirely.

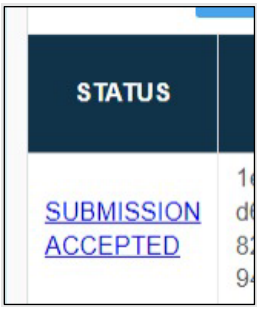
    c. '**Submit SPL**' - Submit your WDD/3PL submission to the FDA. You will then be returned to the WDD/3PL Provider Reports page where you can view your pending submission(s) status:



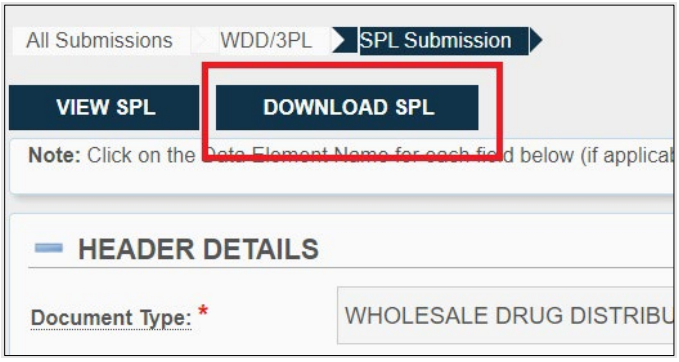
d. '**Delete**' – Delete your draft entry completely.

25. The *Status* field on the WDD/3PL Provider Reports main page should read '*Submission Accepted*' when your submission has been validated and accepted by the FDA. You will receive an email to your account email address when the submission status changes.

26. Once your submission has been accepted, you will be able to download a copy as a zip file. Go to the main WDD/3PL Provider Reports page and click the latest '*Submission Accepted*' text link:

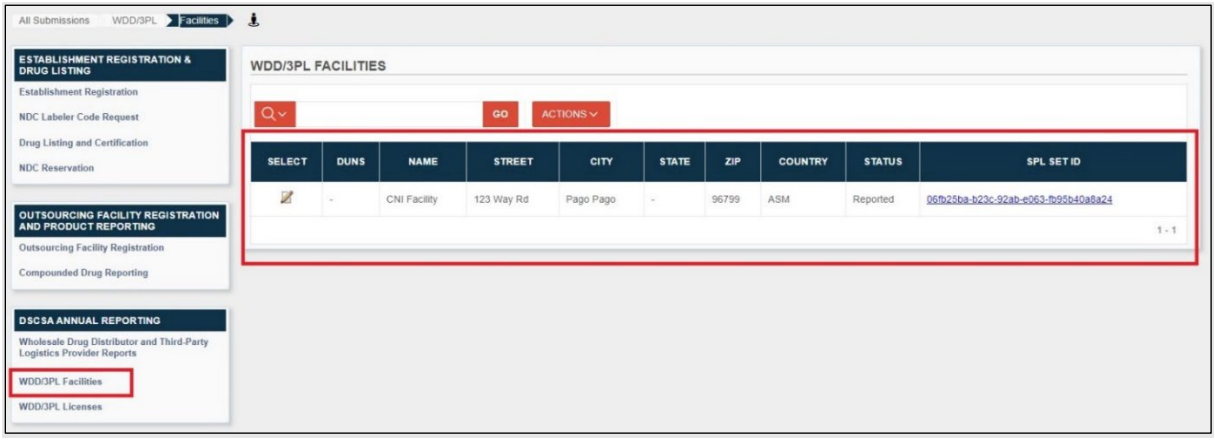


27. Click '**Download SPL**' on the top left of the page to download the zip file. You can also select '**View SPL**' for a quick look at your submission.



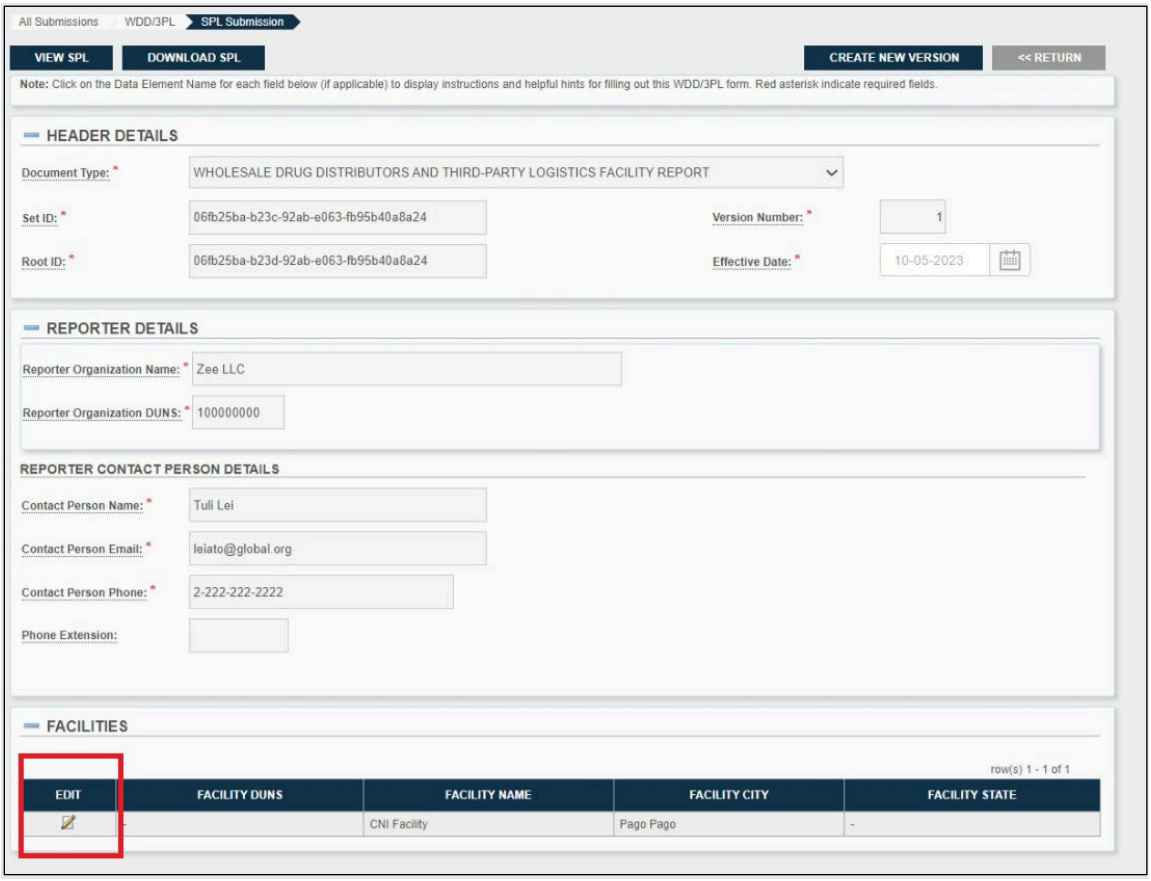
7.1 WDD/3PL Facilities

This section lists all the facilities you have entered in your submissions. Only facilities entered from submissions with the 'Submission Accepted' status will populate in this section:



To view any of your listed facilities:

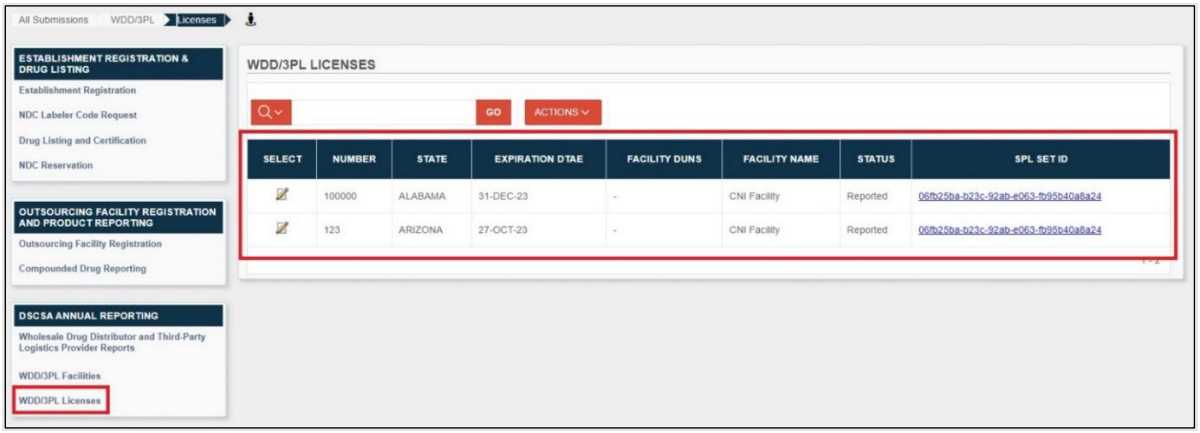
1. Click the pencil icon under the *Select* column (above). You will be redirected to the submission associated with that facility. Click the pencil icon beside the facility:



2. When finished viewing facility information, click the grey '**Return**' button at the top right of each page to return to a previous page.

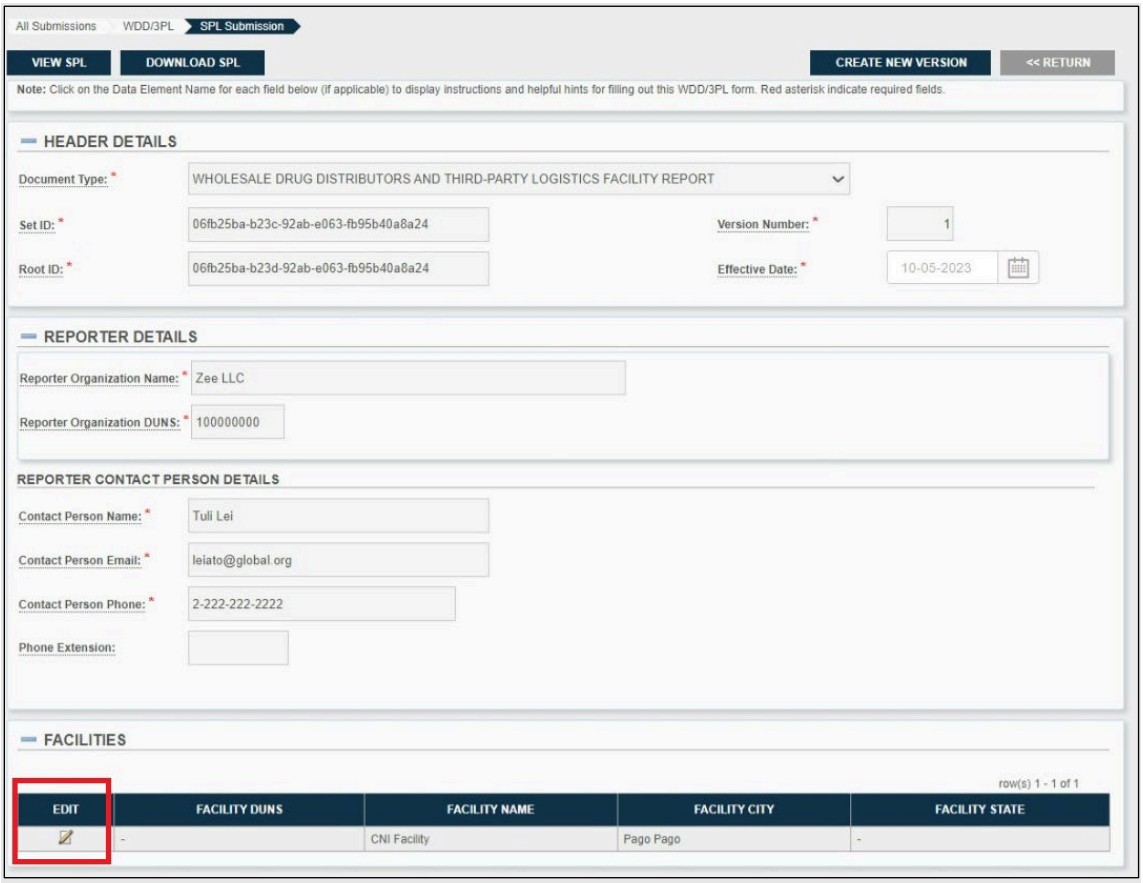
7.2 WDD/3PL Licenses

This section lists all the licenses you have entered in your submissions. Only licenses entered from submissions with the 'Submission Accepted' status will populate in this section:

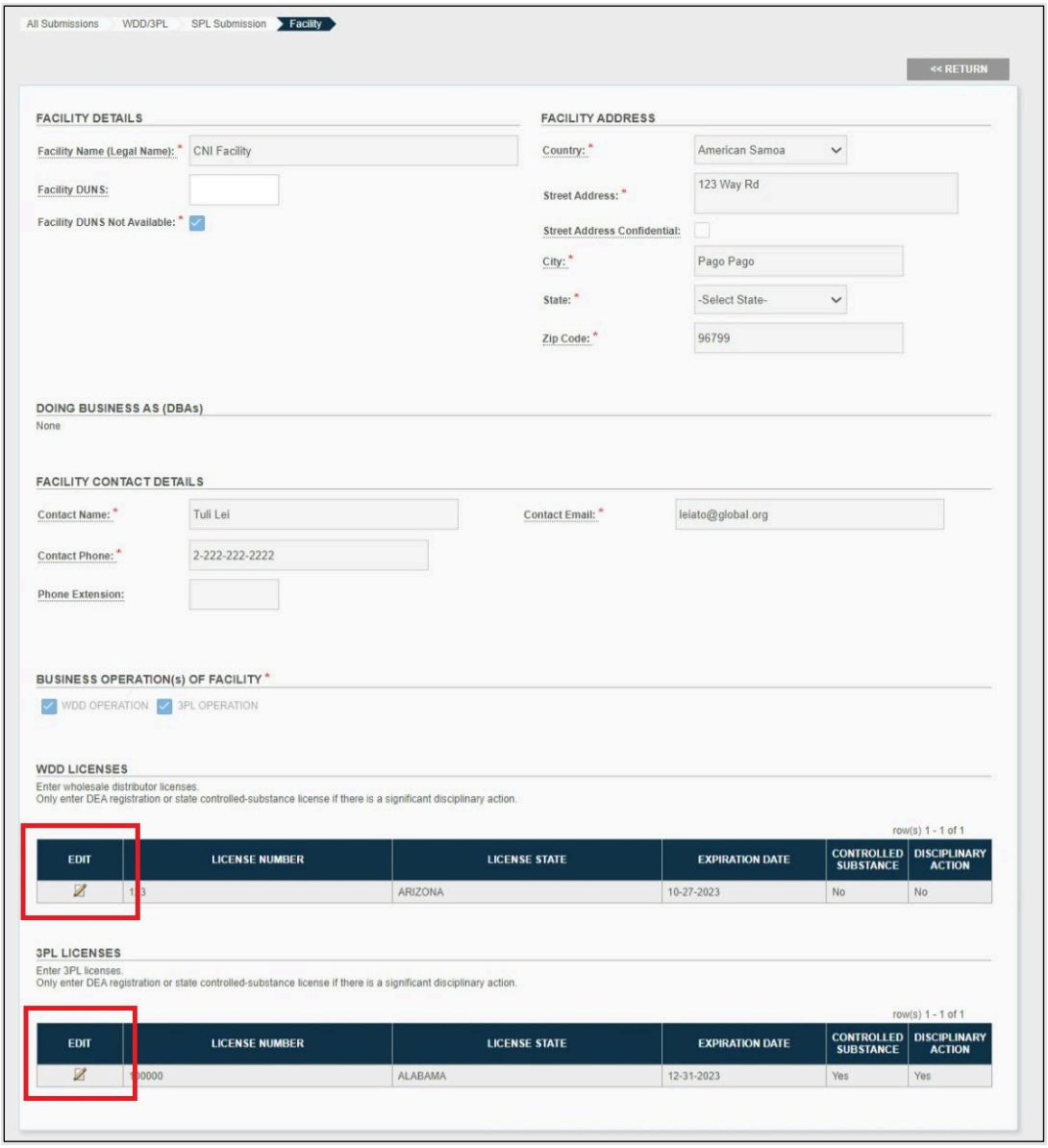


To view any of your listed licenses:

3. Click the pencil icon under the *Select* column (above). You will be redirected to the submission associated with that license. Click the pencil icon beside the facility associated with the license:



4. Select the pencil icon for the desired license, under *Edit:*



5. When finished viewing license information, click the grey '**Return**' button at the top right of each page to return to a previous page.

8 GENERIC FACILITY GDUFA SELF-IDENTIFICATION

8.1 Generic Facility GDUFA Self-Identification

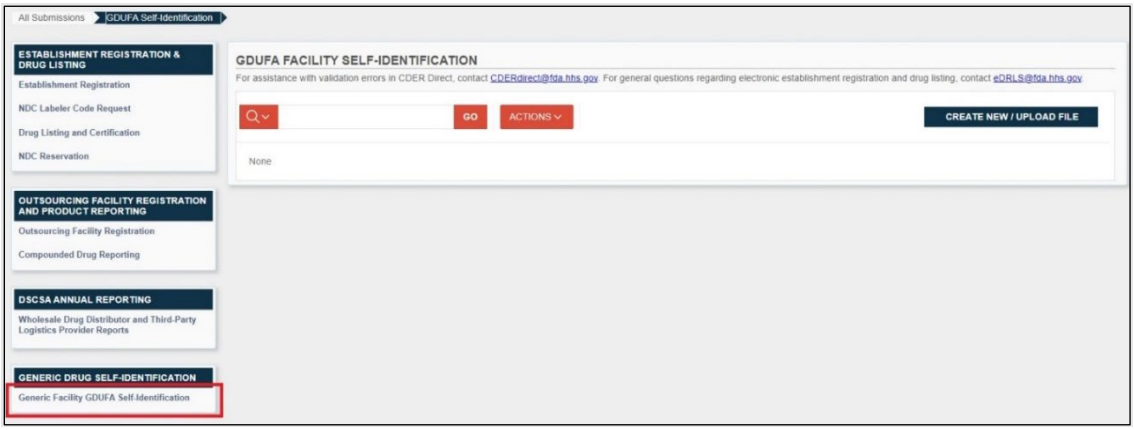
A **Generic Facility GDUFA Self-Identification** SPL submission is intended for human generic drug facilities to provide identification information to the FDA.

You are **required** to self-identify if you represent a generic industry facility/site/organization that is:

- Manufacturing, or intends to manufacture, human generic drug APIs or FDFs, or both.
- A site/organization that packages the FDF of a human generic drug into the primary container/closure system and label the primary container/closure system. (Site/organization)
- A site identified in a generic drug submission and pursuant to a contract with the applicant remove the drug from a primary container/closure system and subdivide the contents into a different primary container/closure system. (Site)
- A bioequivalence (BE)/bioavailability (BA) site identified in a generic drug submission and conducts clinical BE/BA testing, bioanalytical testing of samples collected from clinical BE/BA testing, and/or in vitro BE testing.
- A site that is identified in a generic drug submission and performs testing of one or more attributes or characteristics of the FDF or the API pursuant to a contract with the applicant to satisfy a current good manufacturing practice (CGMP) testing requirement (excludes sites that are testing for research purposes only).
- For more information, see the FDA's Self-Identification FAQ website.

To submit a Generic Facility GDUFA Self-Identification SPL, do the following:

1. Log in to FDA Direct.
2. Select '**Generic Facility GDUFA Self-Identification**' under the *Generic Drug Self-Identification* section:



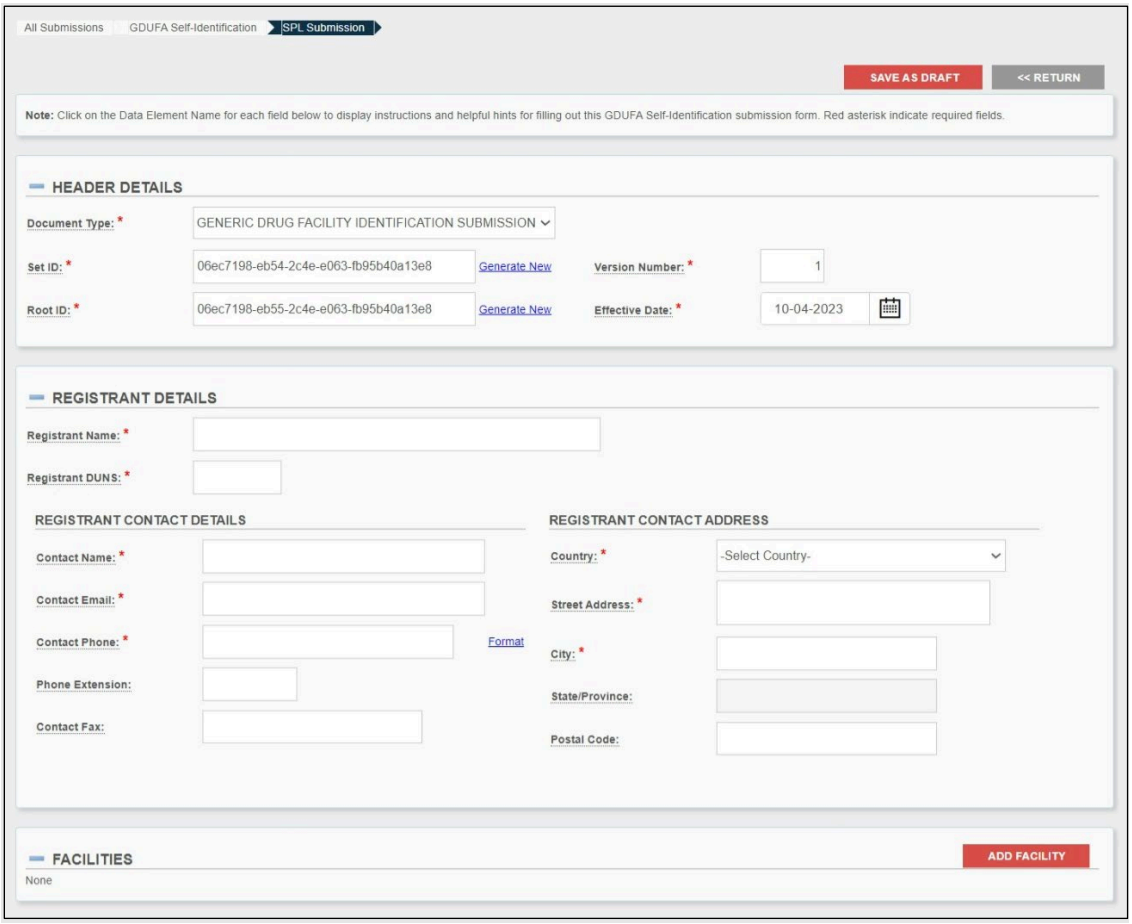
3. Click '**Create New/Upload File**':

4. You will be given two options:

   a. To upload a file from your computer directly, follow the steps outlined in Section 3: Submission Information. Then skip to Step 7 below and continue the instructions.

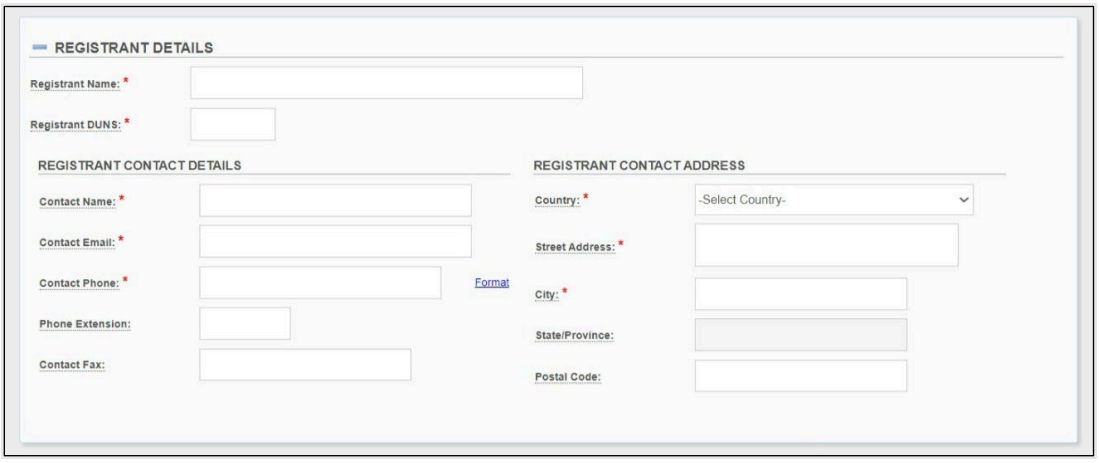
5. To create a new GDUFA submission using a blank template, select the '**Create New Generic Facility GDUFA Self-Identification using a blank form**' option.

6. Click '**Continue**' and a blank template will display:



7. Selecting the '**Save Draft**' button at any time will save your work without submitting it. The '**Return**' button will send you back to the main Generic Facility GDUFA Self-Identification page without saving your changes.

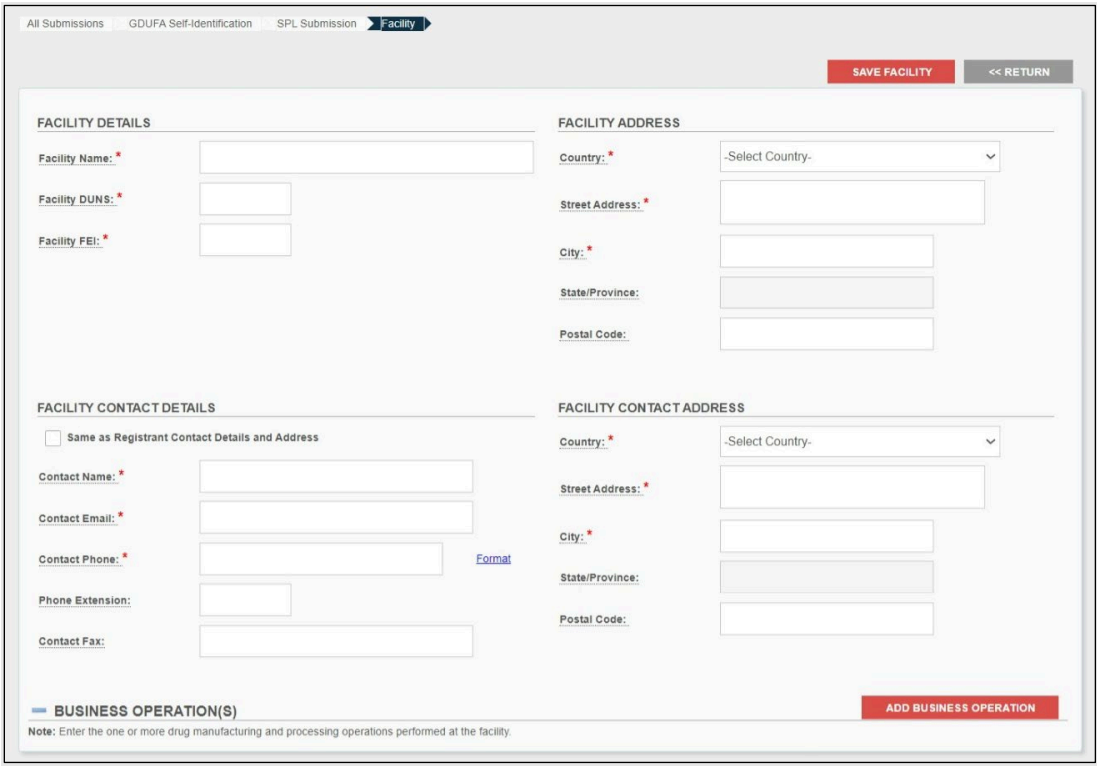
8. Fill in the blank fields in the *Registrant Details* section:



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

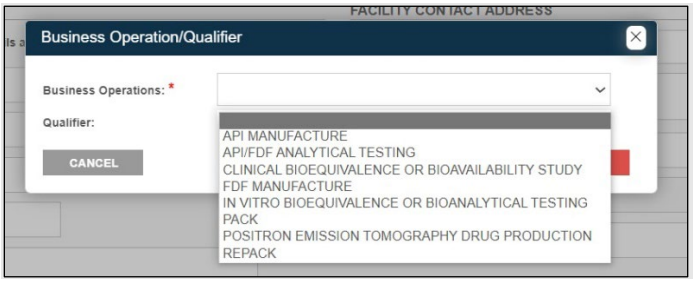
10. Click the '**Add Facility**' button at the bottom of the page, under *Facilities*:

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

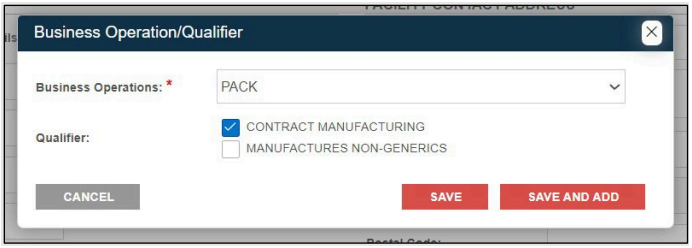


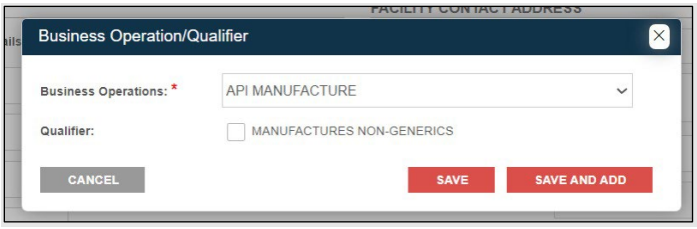
12. Click the '**Add Business Operation**' button at the bottom of this page:

13. A popup box will display. Select the facility's business operation from the '**Business Operations**' dropdown:



14. Depending on your selection, different business qualifiers will display. Click the check box beside any listed qualifier to select it as business operation qualifier(s):



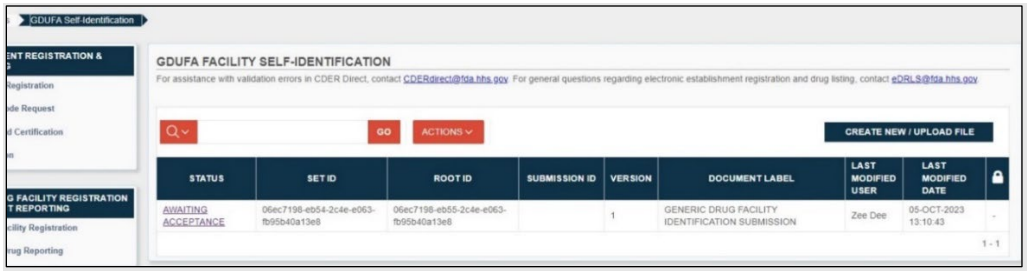


15. To keep adding more business operations without closing the popup box, click '**Save And Add**.' To finish with your selections and close the popup box, click '**Save.**' Your selections will display at the bottom of the page:

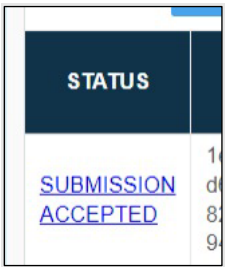
16. Click the pencil icon to make edits to any of the business operations or click the X to delete the specified operation.

17. At the top of the facility page, you can either delete your entry ('**Delete Facility**' button) or add it as a facility ('**Save Facility**'):

18. You will then be sent back to the initial template. Redo Steps 10-17 to add more facilities.
19. Return to the top of the page where you can do the following:
    a. '**Save As Draft**' – Save your entry and return to the main Generic Facility GDUFA Self-Identification page. No submission will be made.
    b. '**Save And Validate**' - Save your entry + validate. This will check your submission for errors prior to submitting to the FDA. Validation may take some time. If you are ready to submit your SPL, you may skip this step entirely.
    c. '**Submit SPL**' - Submit your Generic Facility GDUFA Self-Identification SPL submission to the FDA. You will then be returned to the Generic Facility GDUFA Self-Identification main page where you can view your pending submission(s) status:



    d. '**Delete**' – Delete your draft entry completely.
20. The *Status* field on the Generic Facility GDUFA Self-Identification main page should read '*Submission Accepted*' when your submission has been validated and accepted by the FDA.
21. You will receive an email to your account email address when your submission status has changed. Refresh the main page periodically or log in at a later time.
22. Once your submission has been accepted, you will be able to download a copy of the SPL submission as a zip file. Go to the main Generic Facility GDUFA Self-Identification page and click the latest '*Submission Accepted*' text link:



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

9 USEFUL INFO

9.1 Content of Labeling

This section contains helpful reference when using the Content of Labeling section of FDA Direct.

9.1.1 Text Editing Tools

Several text editing tools available in the text field section:

A description of each of these tools is below:

Icon	Description
B	Bold
I	Italicize
U	Underline
x_2	Create smaller text/superscript
x^2	Create smaller text/subscript
T_x	Remove formatting
1 2	Insert a numbered list
■ ■	Insert a bulleted list
✂	Cut/remove

Icon	Description
T	Paste as plain text
W	Paste from Microsoft Word
↩	Undo the last change
↪	Reapply the last change
🔗	Insert a link/cross-reference to another section
🖼	Add an uploaded image from the Images table
▦	Insert a table
Ω	Insert a special character
!	Identify as a Recent Change

Icon	Description
	Copy
	Paste

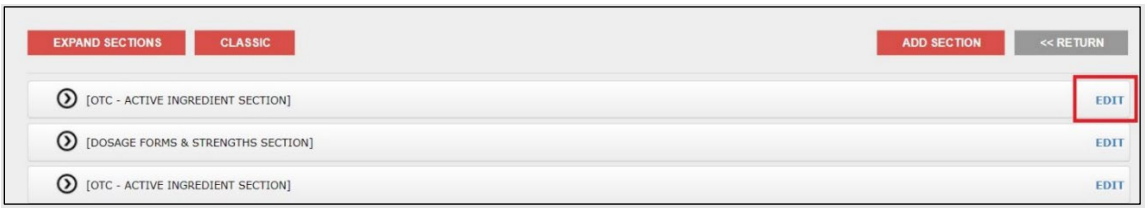
Icon	Description
a[1]	Add a footnote
	Switch to source code

9.1.2 Adding and Deleting Footnotes

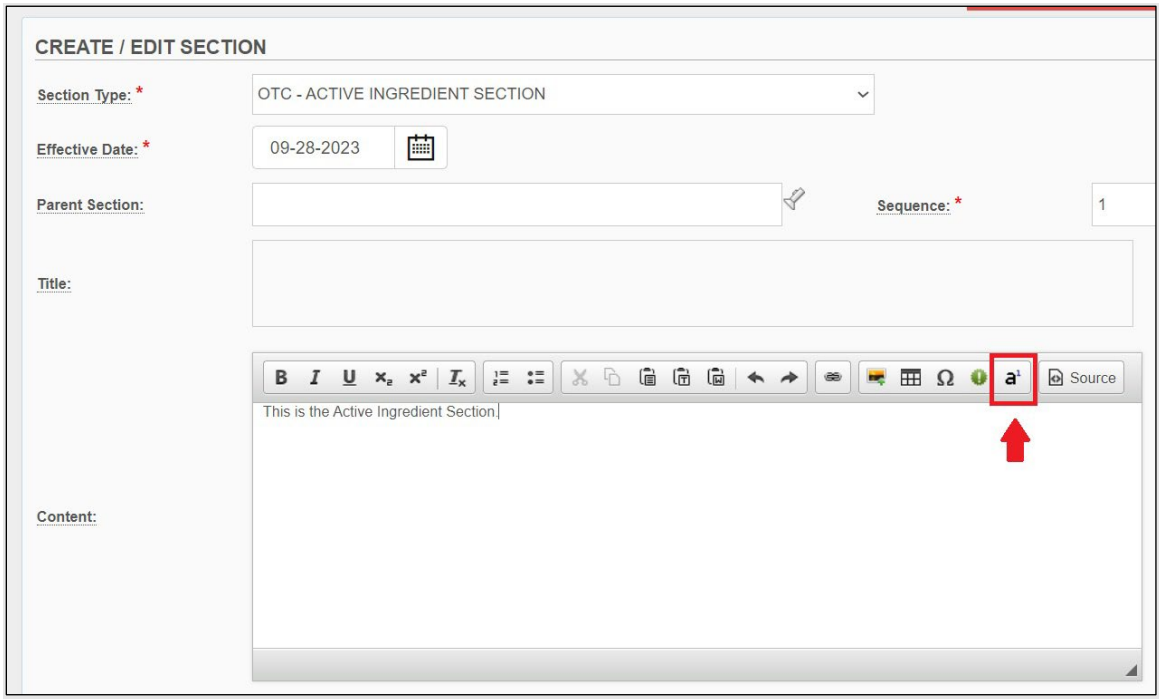
Footnote numbers appear sequentially for sections or subsections, beginning with the number "1". FDA Direct automatically numbers all the footnotes sequentially for the entire label.

To add a footnote:

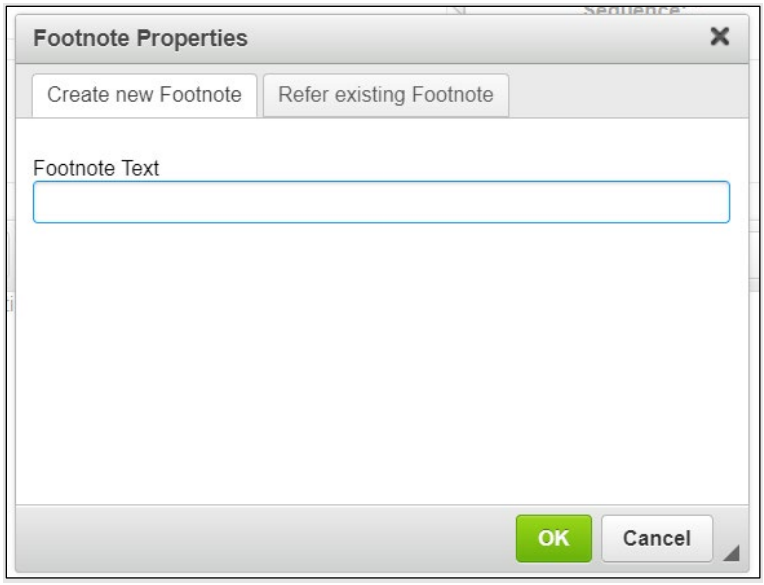
From the Content of Labeling screen, click '**Edit**' on the label you want to make changes to:



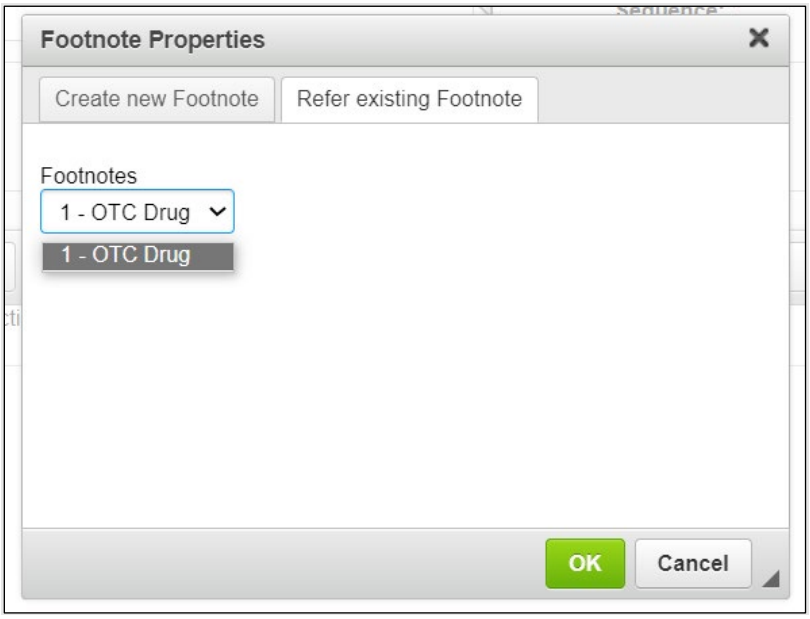
Insert your cursor at the appropriate point in the text and click the 'footnote' icon:



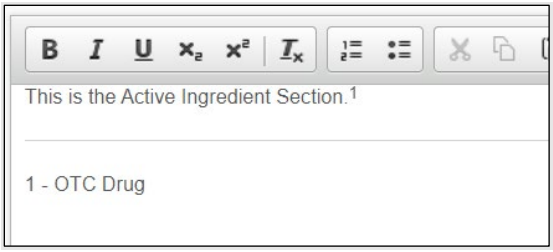
A popup window will display. Enter text for your footnote:



Refer an existing footnote:



Your footnote will display in the text field:

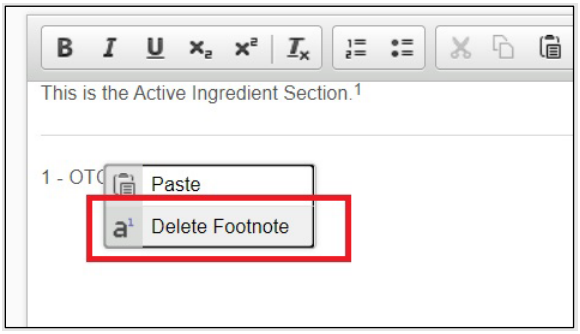


All section footnotes will appear sequentially at the bottom of the text box.

Click '**Apply**' (top right of the page) to save your changes:

To delete a footnote:

a. Place your cursor anywhere within the footnote listed at the bottom of the page, and right-click. Select '**Delete Footnote**':

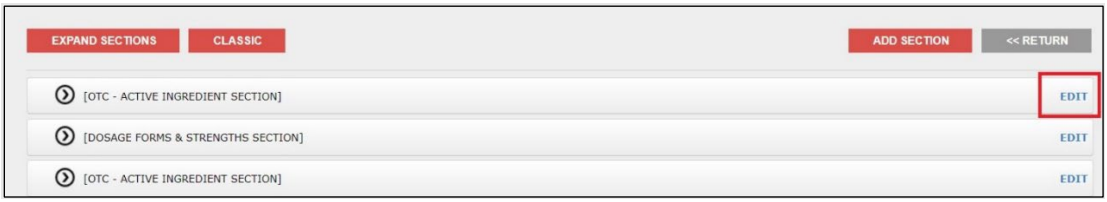
b. 

9.1.3 Links & Cross References

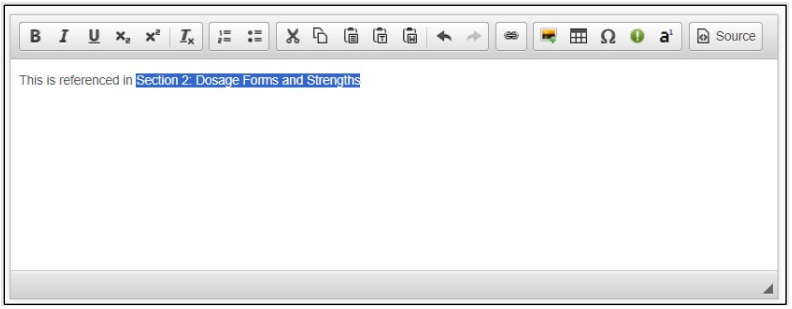
You can create 'links' or 'cross references' which are linked pieces of text that, when clicked, will send you to a different section within a Content of Labeling label.

To create a link/cross reference:

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

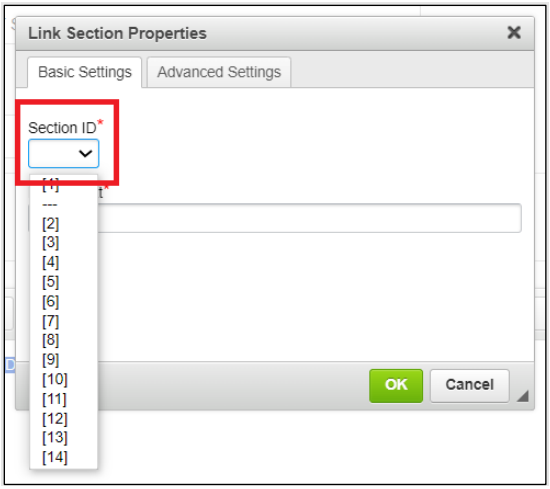


Select/highlight the text you want to make linkable:

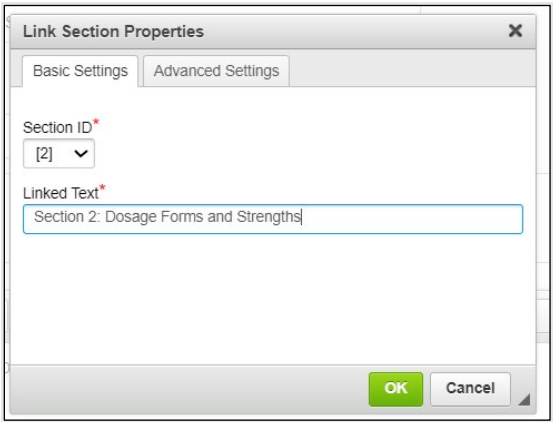


Click the '**link**' icon:

A popup box will display. Click '**Section ID**' for a dropdown list of all your section numbers:

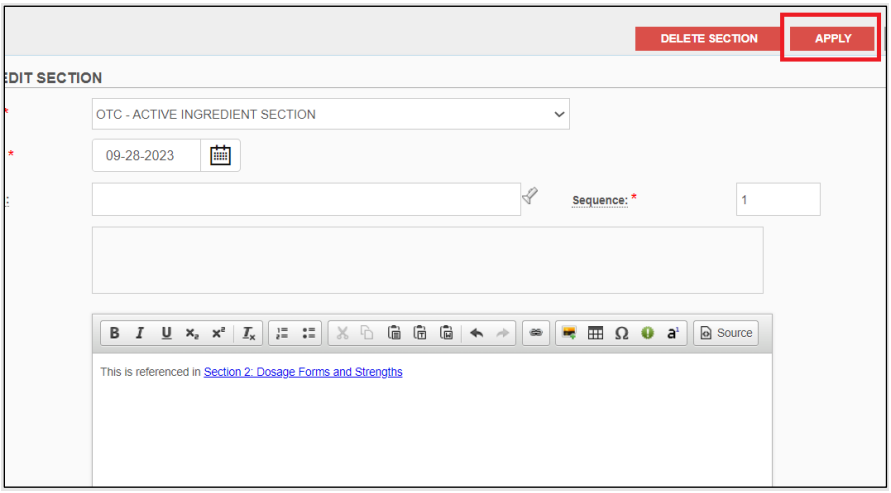


Choose a section number. Then use the '*Linked Text*' field to enter or paste your display text:

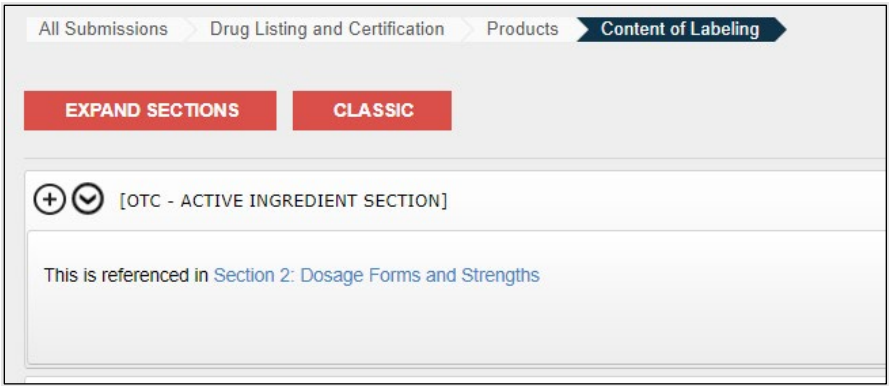


Press the '**OK**' button to save your changes.

The linked text will be underlined in blue. Click '**Apply**' to save your changes:

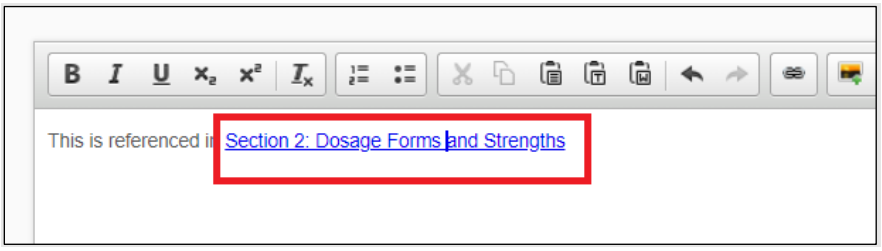


You will be returned to your list of labels where your new link will be available:

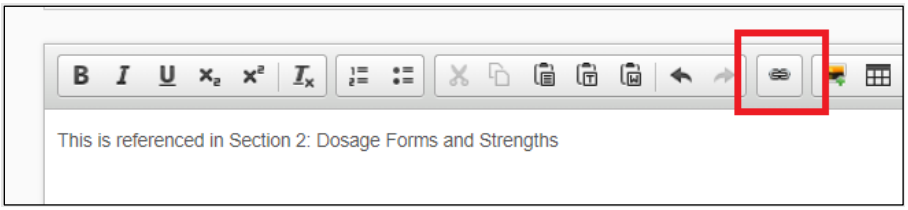


To delete a link/cross-reference:

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



3. Click the '**link**' icon to unlink and revert to standard black text:



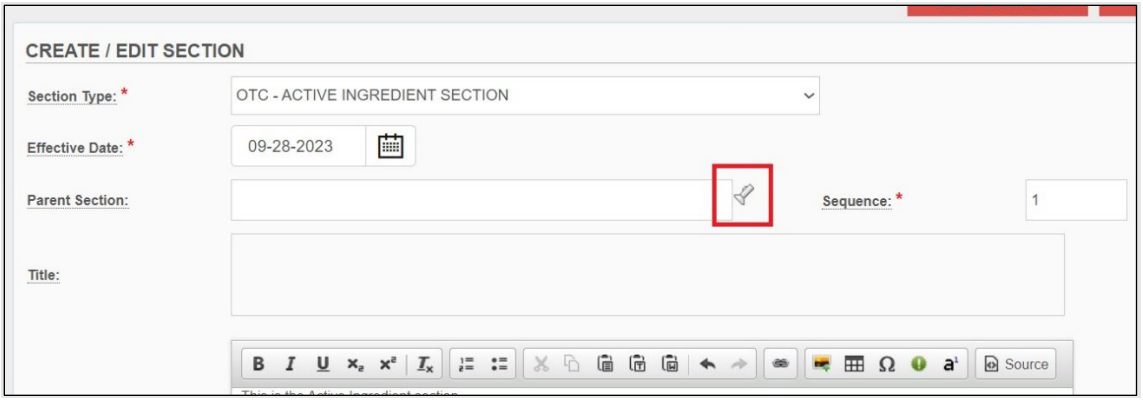
9.1.4 Sections and Subsections

You can create subsections, and alter the positions of both sections and subsections in a product label.

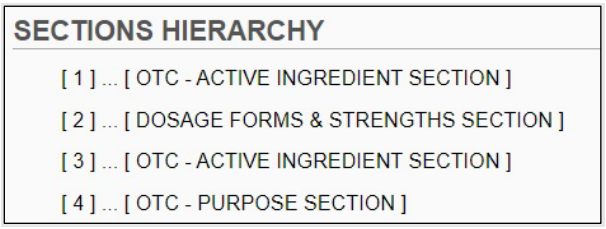
To create a subsection:

1. On the Content of Labeling list page, click '**Edit**' next to the section you want to become a subsection:

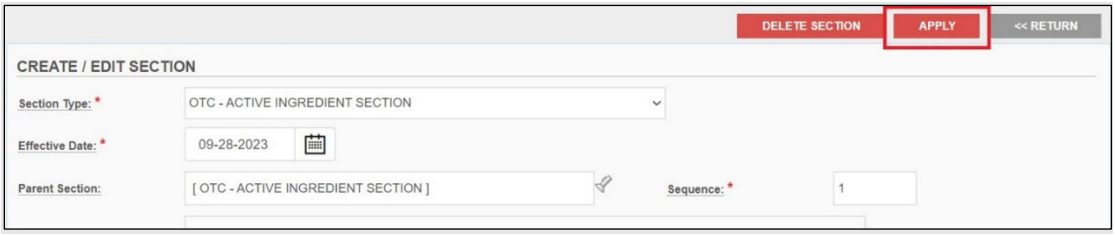
2. Select the 'flashlight' icon next to the '**Parent Section**' field:



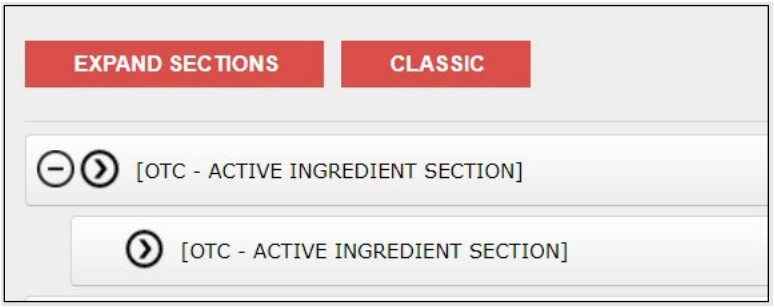
3. The Sections Hierarchy—an ordered list of all your label sections—will display in a new window:



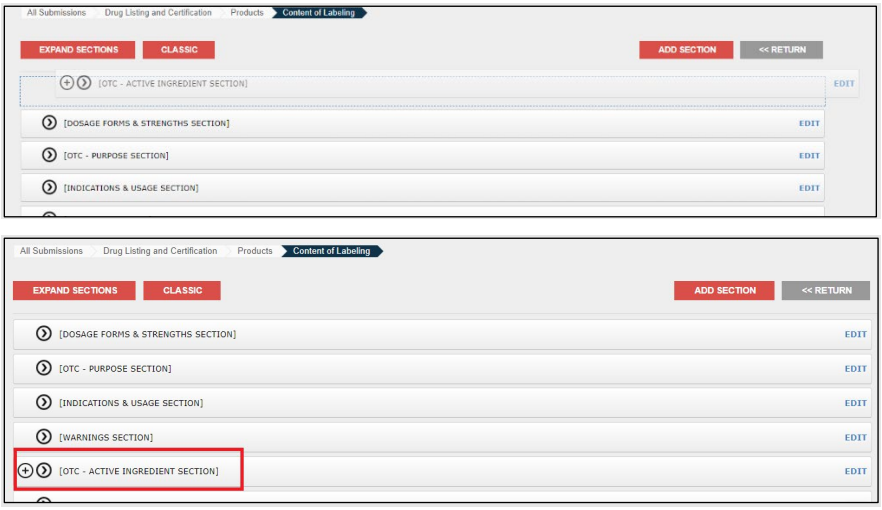
4. Click on the desired section. This section will become the parent section.
5. The window will close automatically and your selection will show up in the '**Parent Section**' field. Click '**Apply**' on the top right of the page:



6. You will be returned to the list page. Click the 'plus' icon on the parent section to view its new subsection:



7. To reorder sections, simply click anywhere on a section then drag and drop it in the new location:



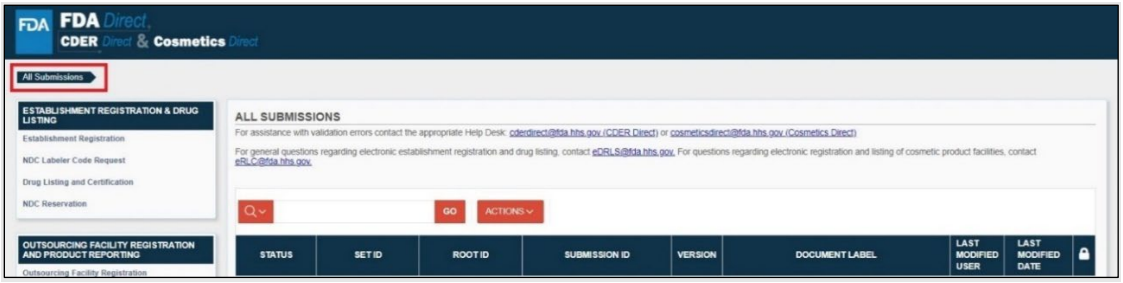
9.2 Searching and Filtering

How to use the search, filter, and sorting features of FDA Direct.

9.2.1 Search

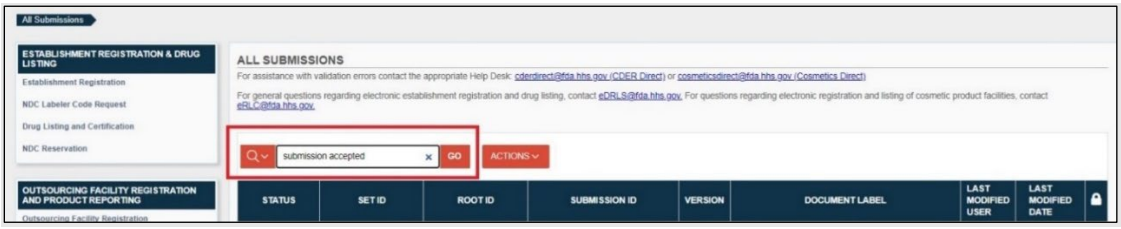
To do a general search on your submissions:

1. Navigate your account main page by clicking the '**All Submissions**' button or by clicking the FDA logo above the button:



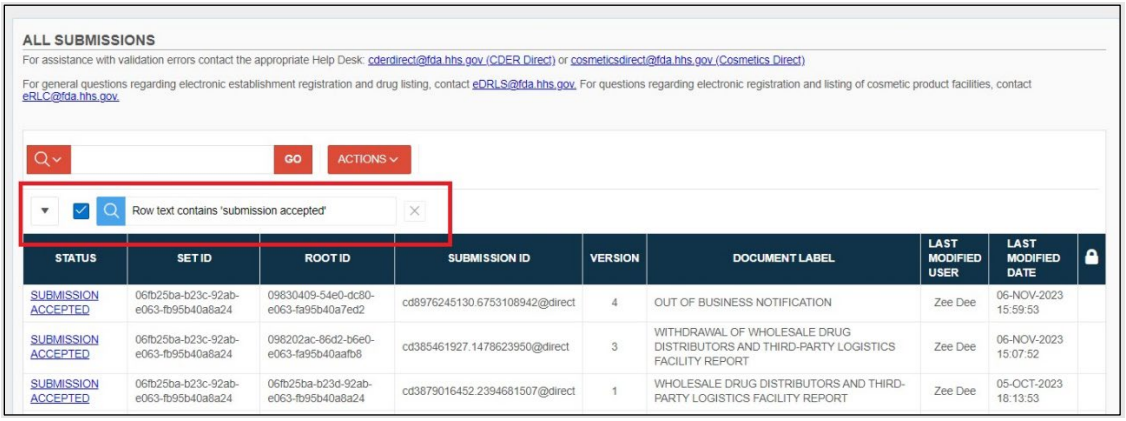
   - This page will list ***all*** submissions you have made since the creation of your account. Click on one of the submission types in the left menu to narrow down your search to a particular submission (ex: 'NDC Labeler Code Request')

2. Click the search area and type in your search term(s). You can type partial or full words, multiple words, and numbers/special characters.

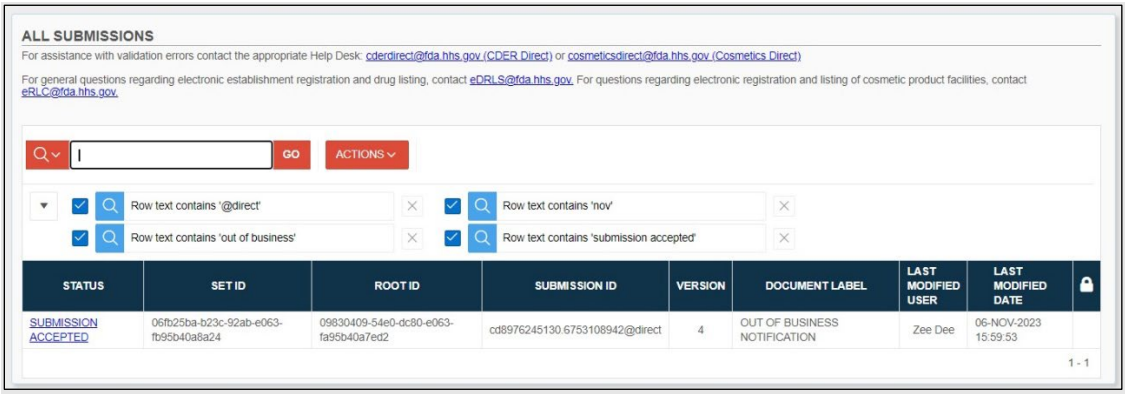


- **<u>IMPORTANT</u>:** This search bar does ***not*** search information within a submission. Only information displayed below the column headers is searchable.

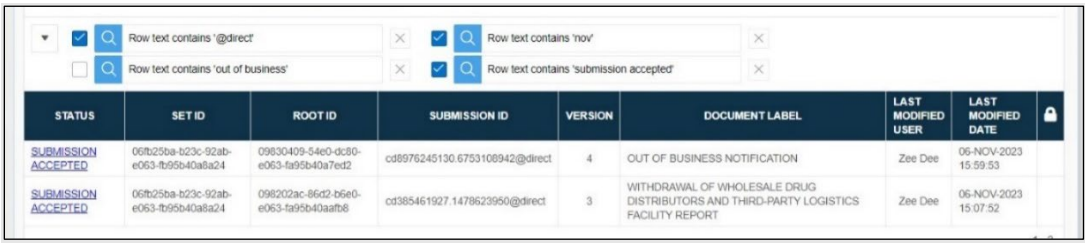
3. Click '**Go**' and your search term will be listed with the results populated below the column headers:



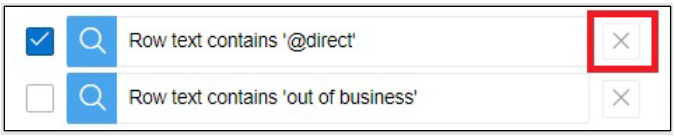
4. You can search multiple terms at once to find your submission(s):



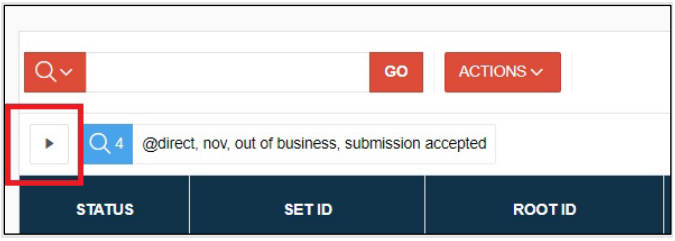
5. Uncheck the box beside search terms you do not want to use. Your search results will be updated immediately:



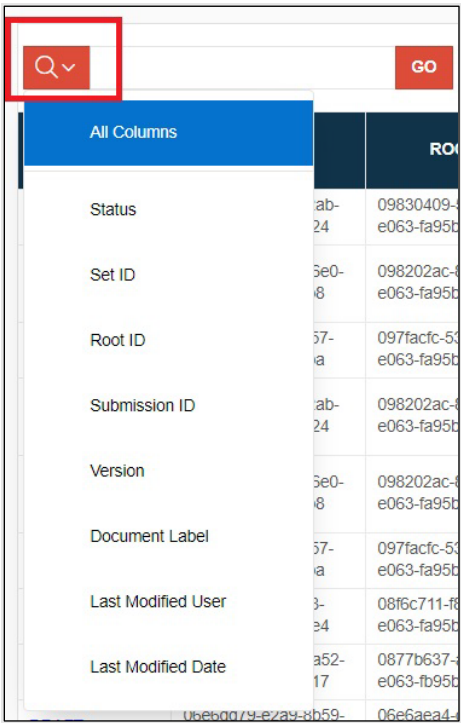
6. Click the 'x' beside a term to remove it completely:



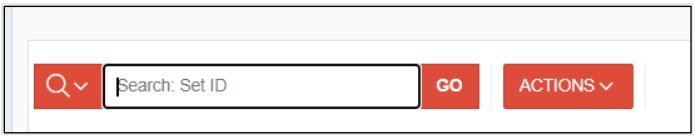
7. If you have multiple search terms taking up space, you can click the arrow to collapse them:



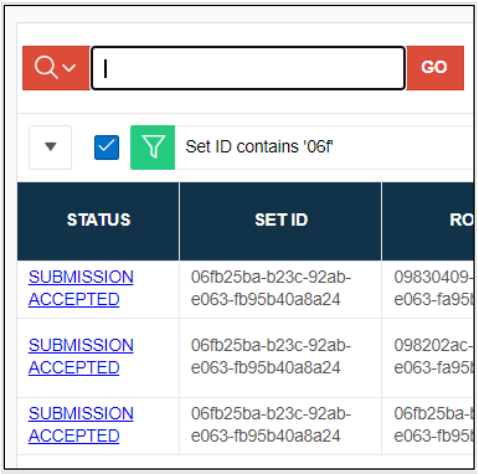
8. You can also search via a specific column header only. This is useful if you need to search by a set ID or root ID. Click the magnifying glass beside the search bar and list of the columns will display:



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



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



11. Search filters are cleared when you log out of FDA Direct.

9.2.2 Filters

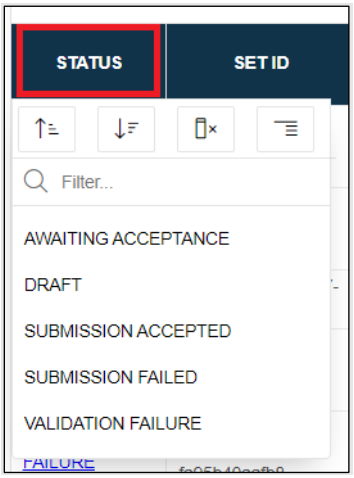
Whenever you log in to FDA Direct, there is always a default column view:

1. Status: The current status of your submissions. For further explanation of the different status types, see Section 3.2: Submission Statuses.
2. Set ID: A 'Globally Unique Identifier' (GUID) that remains the same for each submission 'set,' which is a group of submission versions. When you submit a different version of a submission, the set ID stays the same through each new version.
3. Root ID: Root ID: A GUID that is generated uniquely for every single submission. When you create a new submission, the root ID is always different (unlike the set ID).
4. Submission ID: Unique identifier generated per submission. Also known as the 'Core ID.'
5. Version: A number greater than zero that provides a sequence to the versions of the document. A '1' in this column indicates that it is the first submission. Subsequent versions will increment upwards.
6. Document Label: The submission type. For example, 'Out of Business Notification' or 'Human OTC Drug Label.'
7. Last Modified User: The username of the person who last made changes to a submission.
8. Last Modified Date: The most recent date that changes were made to a submission.

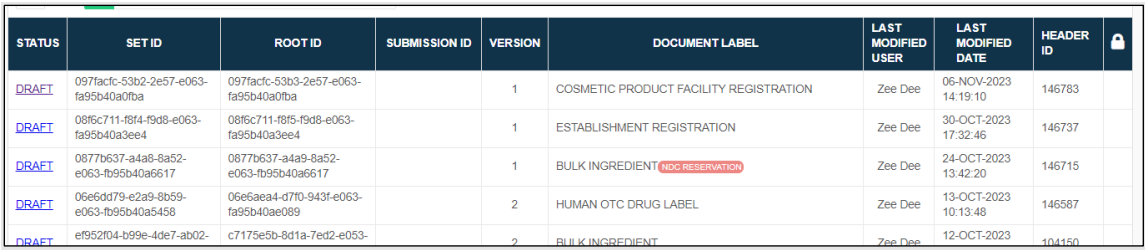
9.2.2.1 Filtering on Column Header

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

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



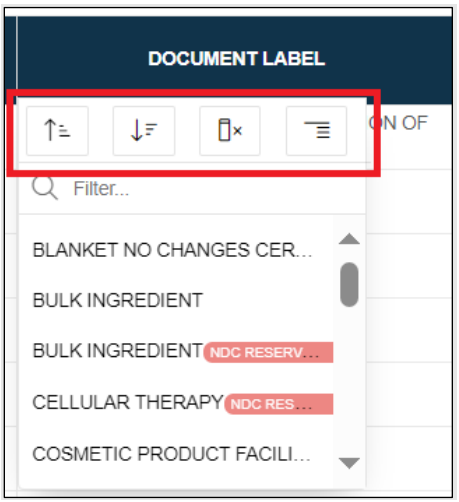
2. Select an option—Draft, for example—and all your submissions currently in that status will be displayed:



STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	HEADER ID
DRAFT	097facfc-53b2-2e57-e063-fa95b40a0fba	097facfc-53b3-2e57-e063-fa95b40a0fba		1	COSMETIC PRODUCT FACILITY REGISTRATION	Zee Dee	06-NOV-2023 14:19:10	146783
DRAFT	08f6c711-f8f4-f9d8-e063-fa95b40a3ee4	08f6c711-f8f5-f9d8-e063-fa95b40a3ee4		1	ESTABLISHMENT REGISTRATION	Zee Dee	30-OCT-2023 17:32:46	146737
DRAFT	0877b637-a4a8-8a52-e063-fb95b40a6617	0877b637-a4a9-8a52-e063-fb95b40a6617		1	BULK INGREDIENT NDC RESERVATION	Zee Dee	24-OCT-2023 13:42:20	146715
DRAFT	06e6dd79-e2a9-8b59-e063-fb95b40a5458	06e6aea4-d7f0-943f-e063-fa95b40ae089		2	HUMAN OTC DRUG LABEL	Zee Dee	13-OCT-2023 10:13:48	146587
DRAFT	ef952f04-b99e-4de7-ab02-	c7175e5b-8d1a-7ed2-e053-		2	BULK INGREDIENT	Zee Dee	12-OCT-2023	104150

Options in the dropdown are pulled only from your data, so available options may differ from the example.

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

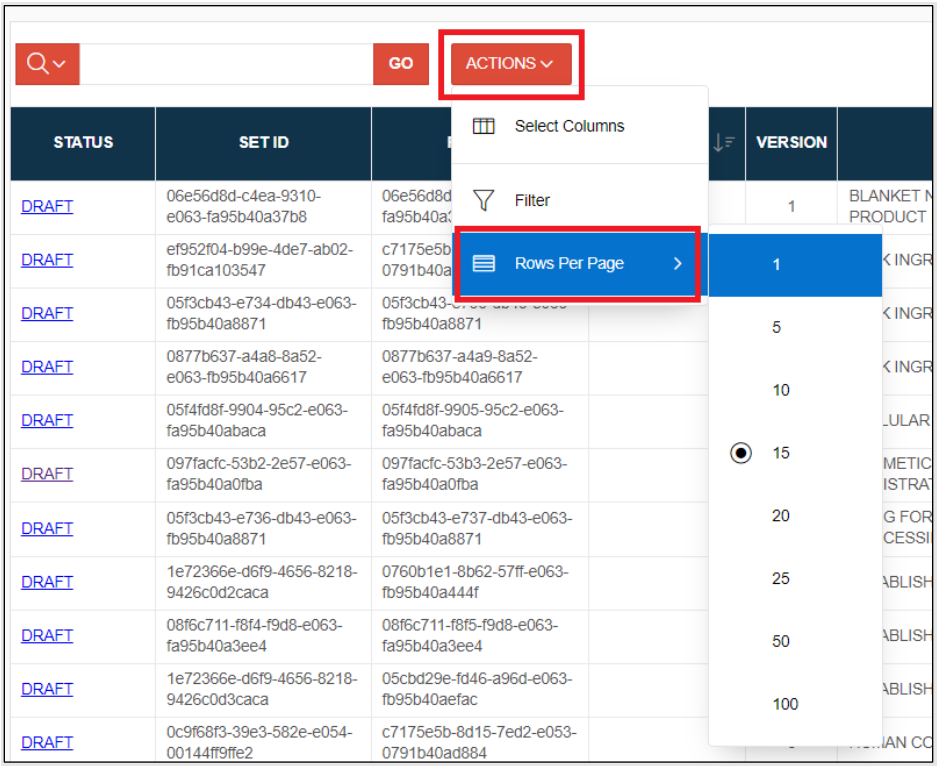


Icon	Description
	Sort ascending
	Sort descending
	Hide column
	Clearly separate each submission

9.2.3 Rows Per Page

To adjust the amount of submissions visible per page:

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



2. You can choose to have 1-100 submissions viewable per page. The page will update immediately after your selection is made.
3. This view resets after you log out. You will need to redo Steps 1-2 when you log back in.