

COSMETICS *DIRECT*

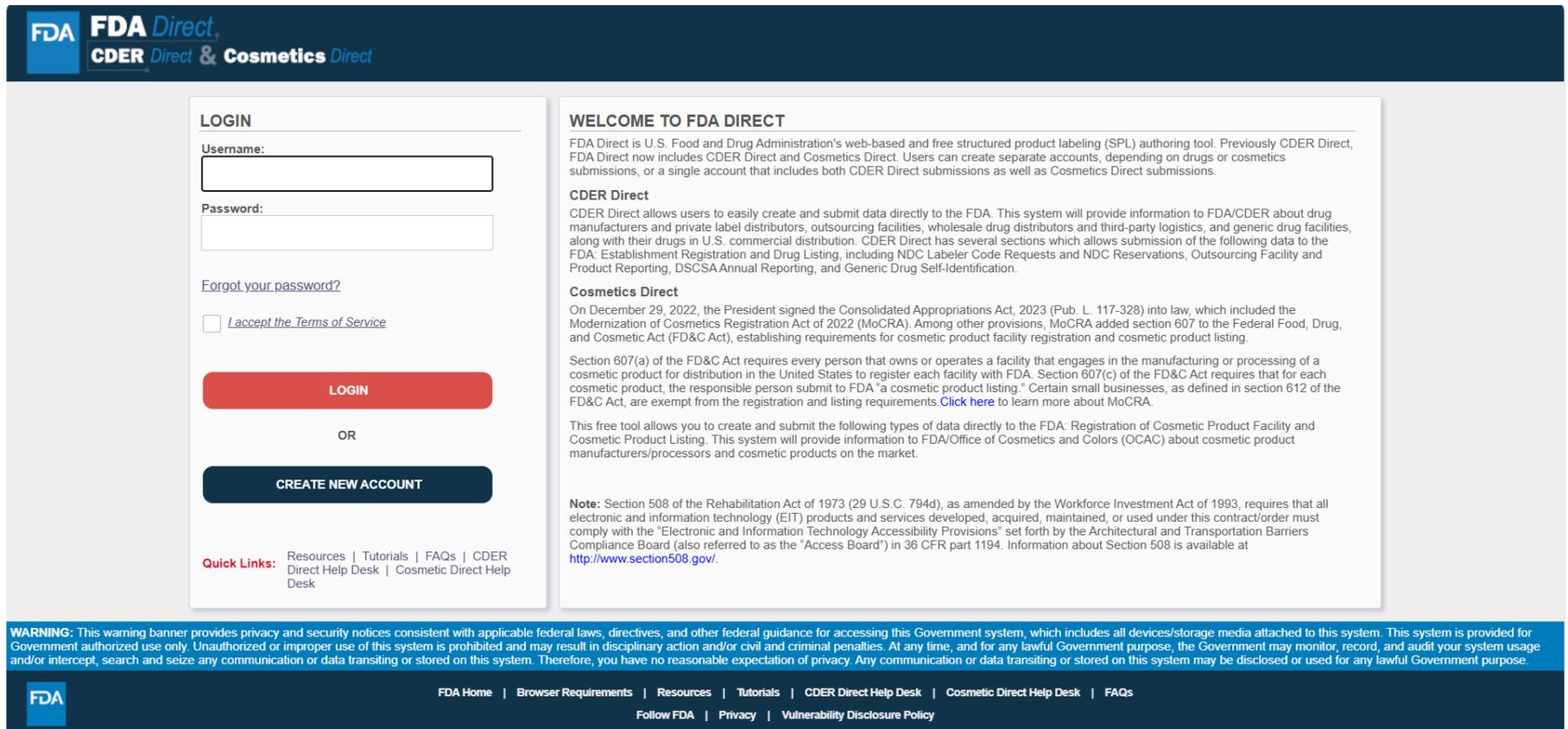
Product Listing Tutorial

February 2026

Welcome to the Cosmetics Direct Product Listing Tutorial.

This guide provides the essential information you need to submit, update, discontinue, relist and/or delete a Cosmetic Product Listing using Cosmetics Direct.

For technical support, email the eRLC Help Desk at CosmeticsDirect@fda.hhs.gov.



The screenshot shows the FDA Direct login interface. At the top left is the FDA logo and the text "FDA Direct, CDER Direct & Cosmetics Direct". The main content is divided into two columns. The left column is titled "LOGIN" and contains a "Username:" field, a "Password:" field, a "Forgot your password?" link, a checkbox for "I accept the Terms of Service", a red "LOGIN" button, an "OR" separator, and a dark blue "CREATE NEW ACCOUNT" button. Below the login fields is a "Quick Links:" section with links to Resources, Tutorials, FAQs, CDER Direct Help Desk, and Cosmetic Direct Help Desk. The right column is titled "WELCOME TO FDA DIRECT" and contains introductory text about FDA Direct, sections for "CDER Direct" and "Cosmetics Direct", and a "Note" about Section 508 of the Rehabilitation Act of 1973. At the bottom of the page is a blue warning banner and a footer with navigation links.

LOGIN

Username:

Password:

[Forgot your password?](#)

[I accept the Terms of Service](#)

LOGIN

OR

CREATE NEW ACCOUNT

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

WELCOME TO FDA DIRECT

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

CDER Direct

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

Cosmetics Direct

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

Section 607(a) of the FD&C Act requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility with FDA. Section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person submit to FDA "a cosmetic product listing." Certain small businesses, as defined in section 612 of the FD&C Act, are exempt from the registration and listing requirements. [Click here](#) to learn more about MoCRA.

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

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

WARNING: This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes all devices/storage media attached to this system. This system is provided for Government authorized use only. Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties. At any time, and for any lawful Government purpose, the Government may monitor, record, and audit your system usage and/or intercept, search and seize any communication or data transiting or stored on this system. Therefore, you have no reasonable expectation of privacy. Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

FDA Home | [Browser Requirements](#) | [Resources](#) | [Tutorials](#) | [CDER Direct Help Desk](#) | [Cosmetic Direct Help Desk](#) | [FAQs](#)

Follow FDA | [Privacy](#) | [Vulnerability Disclosure Policy](#)

Click [here](#) to access the FDA Direct portal.

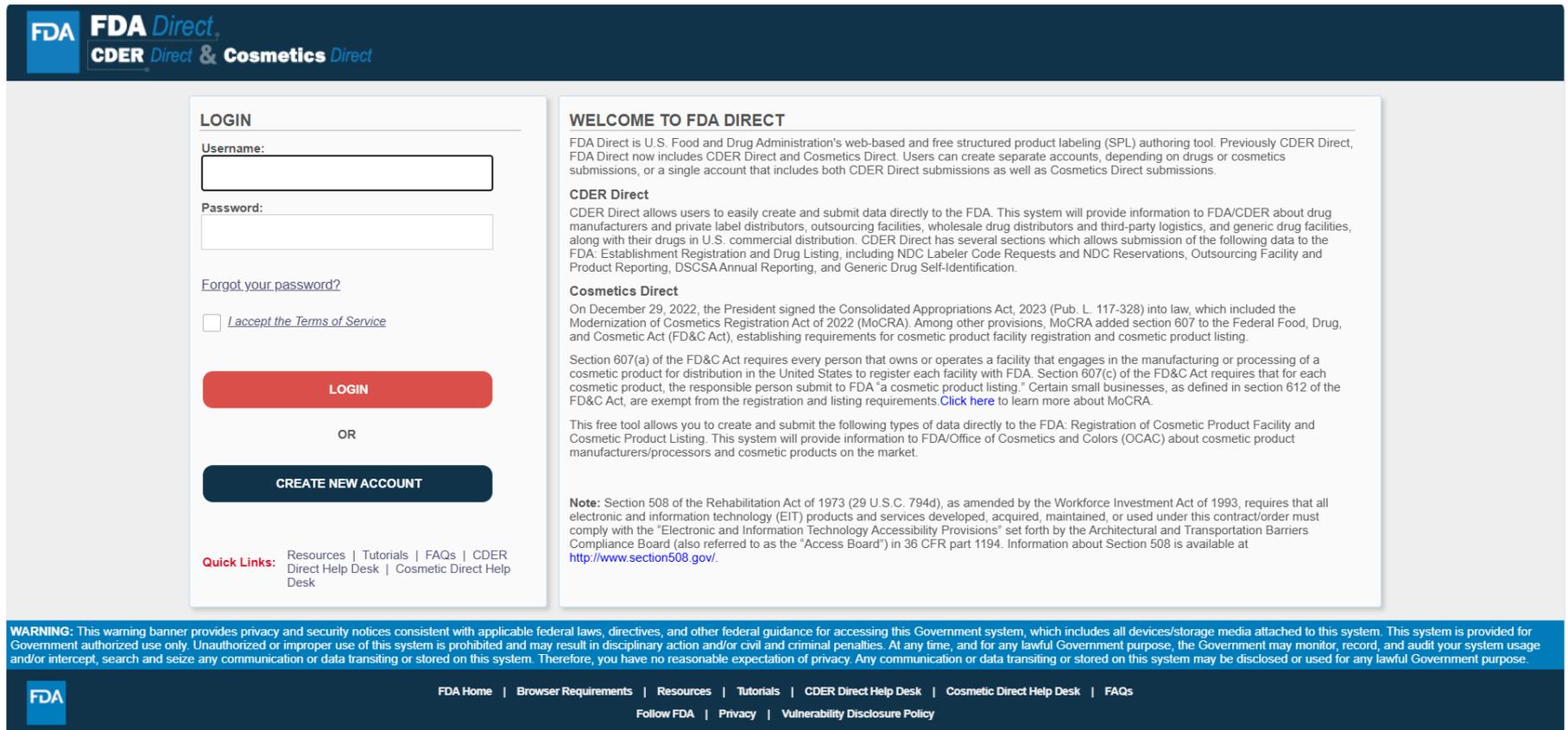
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CREATING A NEW COSMETIC PRODUCT LISTING

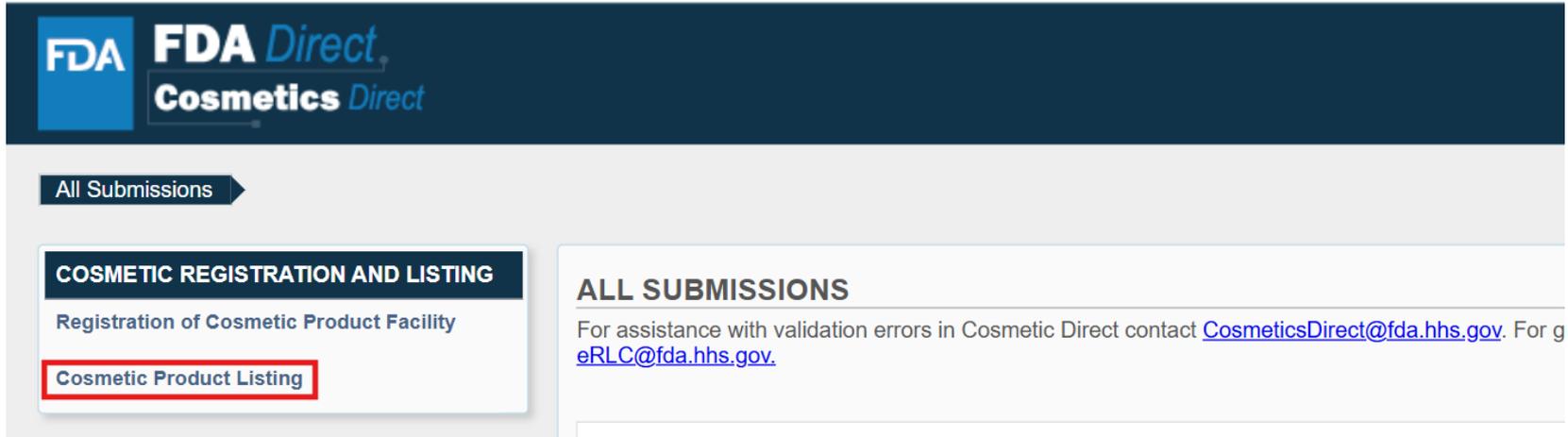
Step 1. Navigate to Cosmetics Direct via <https://direct.fda.gov>.

Step 2. Enter your log-in credentials, accept the terms of service, and click ‘**LOGIN**’.



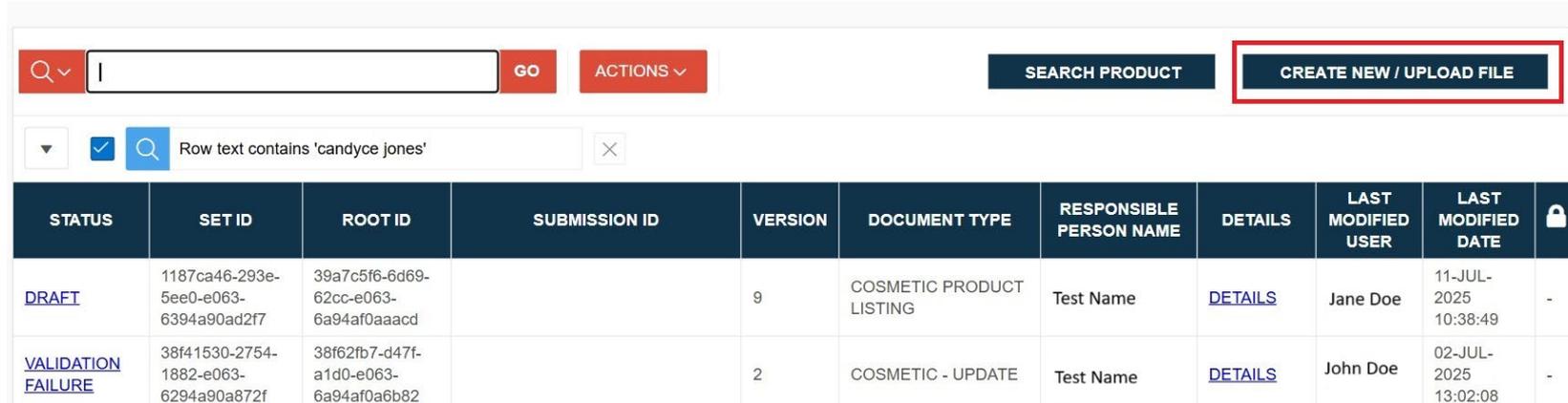
The screenshot shows the FDA Direct login interface. On the left, there is a 'LOGIN' section with fields for 'Username:' and 'Password:', a 'Forgot your password?' link, a checkbox for 'I accept the Terms of Service', and three buttons: 'LOGIN' (red), 'OR', and 'CREATE NEW ACCOUNT' (dark blue). Below these is a 'Quick Links' section with links to Resources, Tutorials, FAQs, CDER Direct Help Desk, and Cosmetic Direct Help Desk. On the right, a 'WELCOME TO FDA DIRECT' section provides an overview of the system, including sections for 'CDER Direct' and 'Cosmetics Direct', and a 'Note' regarding Section 508 of the Rehabilitation Act of 1973. At the bottom, a blue warning banner states that the system is for authorized use only and that any communication or data may be disclosed or used for a lawful purpose. The footer contains navigation links for FDA Home, Browser Requirements, Resources, Tutorials, CDER Direct Help Desk, Cosmetic Direct Help Desk, FAQs, Follow FDA, Privacy, and Vulnerability Disclosure Policy.

Step 3. Select ‘Cosmetic Product Listing’.



The screenshot shows the FDA Direct Cosmetics Direct interface. At the top left, there is a navigation menu with 'All Submissions' selected. Below this, there are two main sections. The left section is titled 'COSMETIC REGISTRATION AND LISTING' and contains two sub-items: 'Registration of Cosmetic Product Facility' and 'Cosmetic Product Listing', which is highlighted with a red box. The right section is titled 'ALL SUBMISSIONS' and contains a text block with contact information: 'For assistance with validation errors in Cosmetic Direct contact CosmeticsDirect@fda.hhs.gov. For eRLC@fda.hhs.gov.' Below this is a table with columns for STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, DOCUMENT TYPE, RESPONSIBLE PERSON NAME, DETAILS, LAST MODIFIED USER, LAST MODIFIED DATE, and a lock icon.

Step 4. Click on ‘CREATE NEW/UPLOAD FILE’.



The screenshot shows the FDA Direct Cosmetics Direct interface. At the top, there is a search bar with a magnifying glass icon and a 'GO' button. To the right of the search bar is an 'ACTIONS' dropdown menu. Below the search bar, there is a 'SEARCH PRODUCT' button and a 'CREATE NEW / UPLOAD FILE' button, which is highlighted with a red box. Below the buttons, there is a search filter section with a dropdown arrow, a checked checkbox, a magnifying glass icon, and the text 'Row text contains 'candyce jones''. Below the search filter is a table with columns for STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, DOCUMENT TYPE, RESPONSIBLE PERSON NAME, DETAILS, LAST MODIFIED USER, LAST MODIFIED DATE, and a lock icon.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	RESPONSIBLE PERSON NAME	DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE	
DRAFT	1187ca46-293e-5ee0-e063-6394a90ad2f7	39a7c5f6-6d69-62cc-e063-6a94af0aaacd		9	COSMETIC PRODUCT LISTING	Test Name	DETAILS	Jane Doe	11-JUL-2025 10:38:49	-
VALIDATION FAILURE	38f41530-2754-1882-e063-6294a90a872f	38f62fb7-d47f-a1d0-e063-6a94af0a6b82		2	COSMETIC - UPDATE	Test Name	DETAILS	John Doe	02-JUL-2025 13:02:08	-

Note: A user can upload an existing Cosmetic Product Listing SPL (Structured Product Labeling), a ZIP file that may contain both the .xml file and image (jpg) files. SPL is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information. For more information regarding SPL, utilize the SPL Resources link provided under SELF-HELP.

Step 5. To upload a Cosmetic Product Listing SPL File, select ‘**Import an existing Cosmetic Product Listing SPL**’ and then ‘**CONTINUE**’.

CREATE NEW COSMETIC PRODUCT LISTING

Create a new Cosmetic Product Listing using a blank form

Import an existing Cosmetic Product Listing SPL

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

CONTINUE CANCEL

Step 6. Select ‘**Cosmetic Product Listing File**’. Locate and select the Registration of Cosmetic Product Listing zip file to upload into Cosmetics Direct and click ‘**UPLOAD**’.

UPLOAD COSMETIC PRODUCT LISTING FILE

 **Cosmetic Product Listing File**
Select a file or drop one here.

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

UPLOAD CANCEL

Example of Uploading a Cosmetic Product Listing File:

This is an example of a zip file.

Please ‘**UPLOAD**’ a zip file that contains the SPL file with the name as the root id followed by ‘.xml’.

UPLOAD COSMETIC PRODUCT LISTING FILE


1803842e-7470-9f50-e063-6294a90a690b.zip ✕
355.53 KB

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

UPLOAD
CANCEL

An example to what .xml format could look like:

```

<?xml version="1.0" encoding="UTF-8"?>
<?xml-stylesheet href="https://www.accessdata.fda.gov/spl/stylesheet/spl.xml" type="text/xsl"?>
<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:hl7-org:v3 https://www.accessdata.fda.gov/spl/schema/spl.xsd">
  <id root="fd8c4f0b-ca3b-82e2-e053-6394a90aa8de"/>
  <code code="51725-0" codeSystem="2.16.840.1.113883.6.1" displayName="COSMETIC PRODUCT LISTING"/>
  <effectiveTime value="[DATE]"/>
  <setId root="fd8c4f0b-ca3a-82e2-e053-6394a90aa8de"/>
  <versionNumber value="1"/>
  <author>
    <time/>
    <assignedEntity>
      <representedOrganization>
        <assignedEntity>
          <assignedOrganization>
            <id root="1.3.6.1.4.1.519.1" extension="314988747"/>
          </assignedOrganization>
        </assignedEntity>
      </representedOrganization>
    </assignedEntity>
  </author>
</document>

```

Step 7. Proceed to Slides #[10](#) through [#24](#) and update the submission details by following the instructions.

Step 8. Submit the SPL to FDA following the instructions in Slide [#25](#).

Step 9. To click on ‘**Create a new Cosmetic Product Listing using a blank form**’, select that option and then click ‘**CONTINUE**’.

CREATE NEW COSMETIC PRODUCT LISTING

Create a new Cosmetic Product Listing using a blank form

Import an existing Cosmetic Product Listing SPL

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

CONTINUE **CANCEL**

Step 10. The ‘**DOCUMENT TYPE**’ drop-down menu automatically defaults to ‘**COSMETIC PRODUCT LISTING**’. The other information under ‘**DOCUMENT TYPE DETAILS**’ (Set ID, Root ID, Version Number, Effective Date) will automatically populate.

NOTE: The effective date is the date the submission is created, which can be edited by users until the SPL is submitted and accepted by FDA. However, the system will only use the actual registration date accepted by FDA. It also provides a date reference to the SPL version. Select the date by clicking on the calendar icon.

DOCUMENT TYPE DETAILS

Document Type: * COSMETIC PRODUCT LISTING

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

Root ID: * COSMETIC-ABBREVIATED RENEWAL [Generate New](#)

Version Number: * 1

Effective Date: * 02-06-2026 

Step 11. Enter the information for **PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT.**

PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT

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

Responsible Person (as listed on label):

Type of Business: MANUFACTURER PACKER DISTRIBUTOR

Responsible Person Name (as listed on label): *

Parent Company Name (if applicable):

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

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

Quick Tip! Clicking on a field name that has a dotted underline will bring up 'Help Text' to provide more information.

Fields with the red asterisk (*) are required.

PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT

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

Responsible Person (as listed on label):

Type of Business: MANUFACTURER PACKER DISTRIBUTOR

Responsible Person(as listed on label)

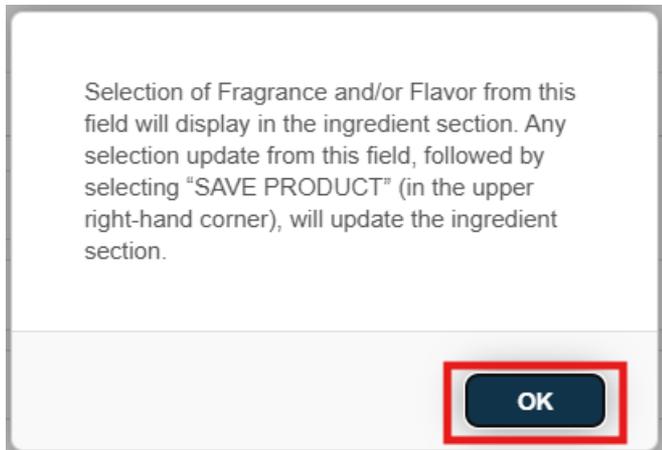
(Optional) The manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product.
For more information visit: [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#).

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

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

Add all required information by selecting ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES).

Note: An information banner will pop-up when ‘**FRAGRANCE OR FLAVOR**’ selection is made, as shown below:



Step 12. The next section is ‘**PRODUCT CATEGORY CODE(S)**’, including Primary Product Categories, Secondary Product Categories, and Tertiary Product Categories (when applicable). Click the ‘**MANAGE CATEGORIES**’ button.



Step 13. After clicking the ‘**MANAGE CATEGORIES**’ button, a selection window titled ‘**COSMETIC PRODUCT CATEGORIES**’ will display. Select the applicable product category or categories for this product name. Each primary product category has a secondary product category. A secondary product category can have a tertiary product category (e.g., Leave on or rinse-off). Click on the plus (+) icon in front of each Primary Product Category to display additional Secondary and/or Tertiary Product Categories (when applicable).

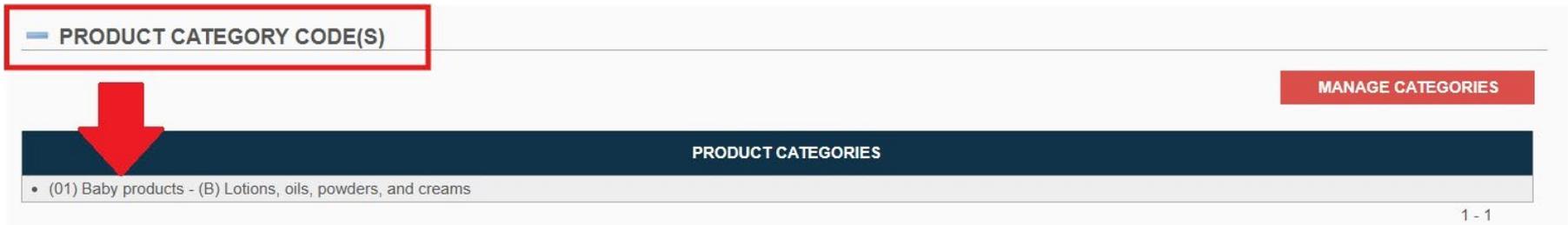
SAVE CATEGORIES
<< RETURN

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

Select the product category or categories for this product name. Each main product category has a sub-product category. A sub-product category can have sub-sub product category, select the one that applies to this product name. (e.g., leave-on or rinse-off).

- + (01) Baby products
- + (02) Bath preparations
- + (03) Eye makeup preparations (other than children's eye makeup preparations)
- + (04) Children's eye makeup preparations
- + (05) Fragrance preparations
- + (06) Hair preparations (non-coloring)
- (07) Hair coloring preparations Primary Product Category
 - (A) Hair dyes and colors (all types requiring caution statement and patch test)
 - (B) Hair tints
 - (C) Hair rinses (coloring) Secondary Product Category
 - 1. Leave-on > Tertiary Product Category
 - 2. Rinse-off
 - + (D) Hair shampoos (coloring)
 - (E) Hair color sprays (aerosol)
 - (F) Hair lighteners with color
 - (G) Hair bleaches
 - (H) Eyelash and eyebrow dyes
 - + (I) Other hair coloring preparations
- + (08) Makeup preparations (not eye)(other than makeup preparations for children)
- + (09) Makeup preparations for children (not eye)
- + (10) Manicuring preparations
- + (11) Oral products
- + (12) Personal cleanliness
- + (13) Shaving preparations
- + (14) Skin care preparations (creams, lotions, powder, and sprays)
- + (15) Suntan preparations
- + (16) Tattoo preparations
- (17) Other preparations (i.e., those preparations that do not fit another category)

Step 14. After clicking 'SAVE CATEGORIES' all the selection(s) that was made on the previous page will be displayed under the 'PRODUCT CATEGORY CODE(S)' tab in the 'PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)' section.



PRODUCT CATEGORY CODE(S)

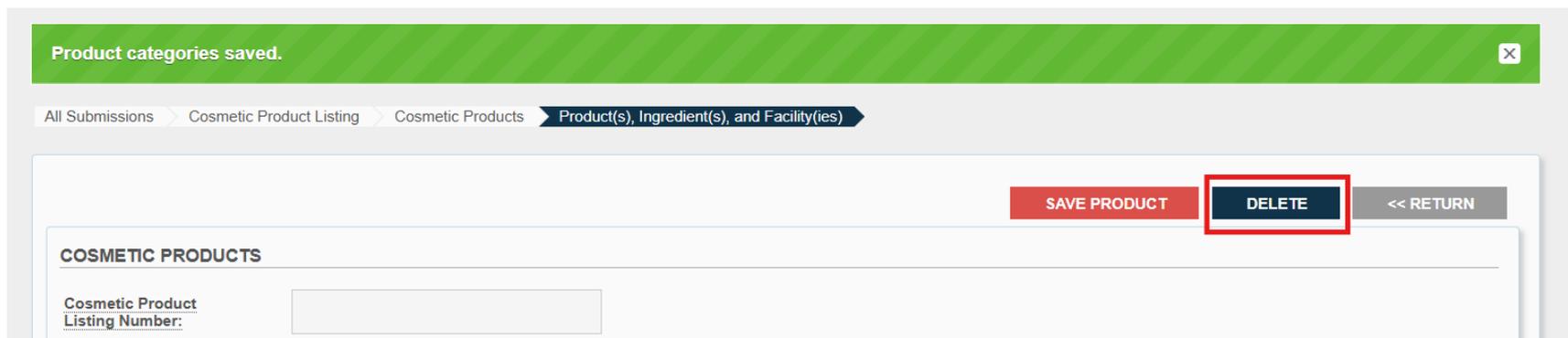
MANAGE CATEGORIES

PRODUCT CATEGORIES

- (01) Baby products - (B) Lotions, oils, powders, and creams

1 - 1

Note: 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.



Product categories saved. [X]

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

SAVE PRODUCT DELETE << RETURN

COSMETIC PRODUCTS

Cosmetic Product Listing Number: [input field]

Step 15. To add **PRODUCT INGREDIENTS**, click the ‘**MANAGE INGREDIENTS**’ button in **INGREDIENTS** section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section.

Note: Any updates to Fragrance and/or Flavor will need to be made in the previous section, **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)**. Changes made there will automatically appear in the ingredient list.

INGREDIENTS

MANAGE INGREDIENTS

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

INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (PREFERABLY IN THE ORDER AS LISTED ON THE LABEL)
	FLAVOR

row(s) 1 - 1 of 1

Step 16. A blank template titled COSMETIC INGREDIENTS will display. Ingredients can be searched, added or uploaded, in the **INGREDIENTS** section.

Fill in all the ingredients that are included in this product (preferably in the order as listed on the 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’.

NOTE:

- Adding UNII codes is optional.
- If there are multiple ingredients, each ingredient needs to be entered separately.

Step 17. An ingredient can be deleted by selecting the ‘X’ on the left-most column. As an example, shown below:

Common, usual, chemical name * or UNII:

	INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (PREFERABLY IN THE ORDER AS LISTED ON THE LABEL)	
		FRAGRANCE	1
	ZBP1YXW0H8	LAVENDER OIL	2
	059QF0KO0R	WATER	3
	PDC6A3C0OX	GLYCERIN	4

Step 18. Ingredients can be re-ordered using the drag and drop feature. Select an ingredient then move it into the new location.

	INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (PREFERABLY IN THE ORDER AS LISTED ON THE LABEL)	
		FRAGRANCE	1
	ZBP1YXW0H8	LAVENDER OIL	2
	059QF0KO0R	WATER	3
	PDC6A3C0OX	GLYCERIN	4

Step 19a. To download current ingredient list with its UNII CODE(S) from the **INGREDIENTS** section, click the **‘DOWNLOAD CURRENT INGREDIENT LIST’**, as shown below:

DOWNLOAD CURRENT INGREDIENT LIST

UPLOAD INGREDIENT FILE

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

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



Drag and Drop
Select a file or drop one here.

UPLOAD
CANCEL

Step 19b. An EXCEL ingredient template (.xlsx) prefilled with the current ingredient list or blank Excel ingredient template (if creating a new cosmetic product listing using a blank form) will download to update, edit or prepare an appropriate ingredient list that can be uploaded into the system. EXCEL template with ingredient list can also be used for your review and/or reference. UNII's should be entered in the first column and ingredient names in the second column. Then ‘SAVE’ it on to the computer.

PLEASE NOTE: DO NOT enter CAS numbers instead of UNII's. CAS numbers will not be recognized by the system.

	A	B
1	INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME
2		FRAGRANCE
3	ZBP1YXW0H8	LAVENDER OIL
4	059QF0K00R	WATER
5	PDC6A3C00X	GLYCERIN
6		

Step 20. To upload the completed template to replace the previous ingredient list, click the ‘**DRAG AND DROP**’ button in the ‘**UPLOAD INGREDIENT FILE**’ section. Select the ingredient EXCEL FILE saved on the computer, then select the ‘**UPLOAD**’ button.

DOWNLOAD CURRENT INGREDIENT LIST

UPLOAD INGREDIENT FILE

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

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



Drag and Drop
Select a file or drop one here.

UPLOAD
CANCEL

Step 21. Once all the INGREDIENT(S) are listed, select ‘**SAVE INGREDIENTS**’.

SAVE INGREDIENTS
DELETE INGREDIENTS
<< RETURN

INGREDIENTS

Note: Enter the common name, usual name or chemical name of each INGREDIENT that is included in this product preferably in the order as listed on the label. Optional UNII can also be entered to search ingredient(s). Common, usual or chemical name will auto populate as you type along with its UNII. If the ingredient does not auto-populate, continue typing and select ADD. Each row should only contain one ingredient. Ingredients can be re-ordered using the drag and drop feature by selecting an ingredient then moving it into the new location.

Common, usual, chemical name* or UNII: ADD

	INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (PREFERABLY IN THE ORDER AS LISTED ON THE LABEL)	
		FRAGRANCE	1
✖	ZBP1YXW0H8	LAVENDER OIL	2
✖	059QF0K00R	WATER	3
✖	PDC6A3C0OX	GLYCERIN	4

Step 22. 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:

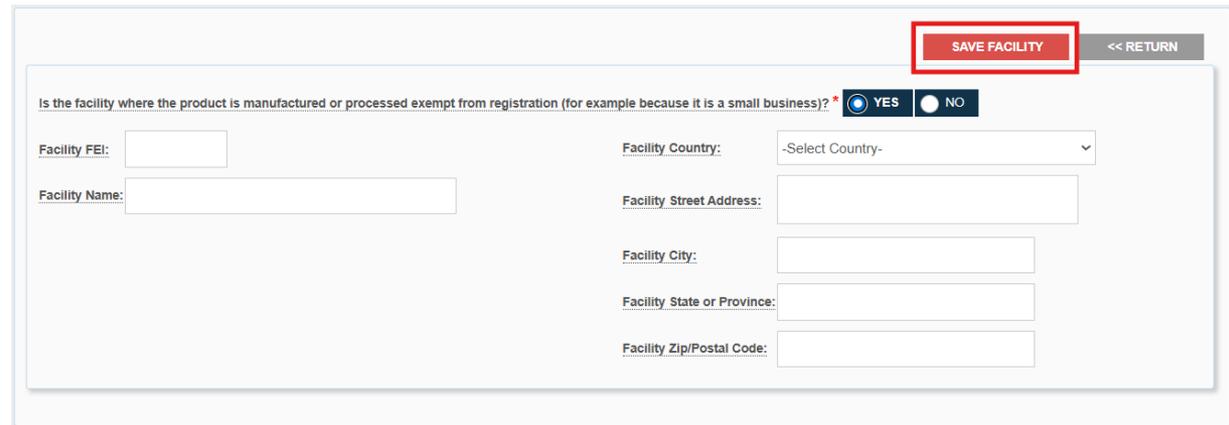


Step 23. To add your facility(ies) where the cosmetic product is manufactured or processed, under the **'PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)'** section, click the **'ADD FACILITY'** button in **'LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED'** section, as shown below. A red asterisk (*) indicates a required field throughout the submission process.



Step 24. Fill in 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.

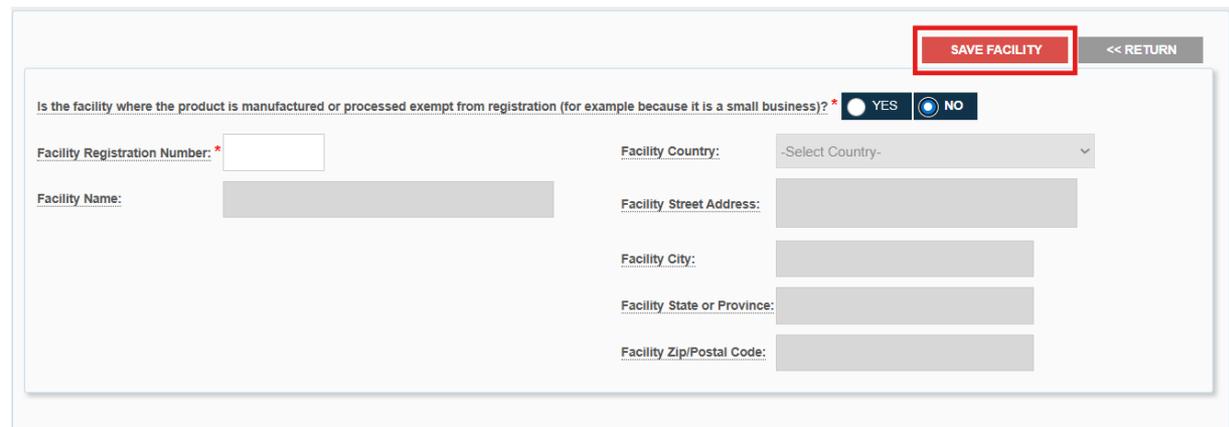
If ‘YES’ is selected for the question, “**Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?**”, then all data fields are optional.



The screenshot shows a form titled "SAVE FACILITY" with a "<< RETURN" button. The question "Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?" has the "YES" radio button selected. The form contains the following fields:

- Facility FEI: [Text input field]
- Facility Country: [-Select Country- dropdown menu]
- Facility Name: [Text input field]
- Facility Street Address: [Text input field]
- Facility City: [Text input field]
- Facility State or Province: [Text input field]
- Facility Zip/Postal Code: [Text input field]

If ‘NO’ is selected for the question, “**Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?**”, then the ‘Facility FEI’ number is mandatory, and the name/address fields are greyed out.



The screenshot shows the same "SAVE FACILITY" form, but with the "NO" radio button selected. The "Facility Registration Number:" field is marked with a red asterisk and is a required text input field. The "Facility Name:", "Facility Street Address:", "Facility City:", "Facility State or Province:", and "Facility Zip/Postal Code:" fields are all greyed out, indicating they are optional.

Once complete, click 'SAVE FACILITY'.

Step 25. 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.

— LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

[ADD FACILITY](#)

EDIT	IS THIS FACILITY SMALL BUSINESS?	FACILITY FEI / REGISTRATION NUMBER	FACILITY NAME	FACILITY ADDRESS
	No	1285749685		

1 - 1

Step 26. Multiple FACILITY(IES) can be added by selecting the ‘**ADD FACILITY**’ on the top right, as shown below.

— LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

[ADD FACILITY](#)

EDIT	IS THIS FACILITY SMALL BUSINESS?	FACILITY FEI / REGISTRATION NUMBER	FACILITY NAME	FACILITY ADDRESS
	No	1285749685		

1 - 1

Step 27. In the ‘**Product Images**’ section, you may upload an image(s) of the label(s) whether it be the front or back label by clicking on the drag and drop area to select an image from your computer or dragging the file from your computer onto this area. Once the file has been selected from your computer, click the ‘**UPLOAD**’ button. The image must have a file extension of .jpg.

PLEASE NOTE: It is important that the image uploaded is in .JPG format. The max image size allowed is 1MB. The .jpg file must be a valid .jpg file format and the name should consist of letters (a-z, A-Z) and/or numbers (0-9). Special characters and symbols are not allowed. Additionally, if you are uploading more than one image, the name for each image file should be unique.

PRODUCT IMAGES

(Optional field) Upload an image(s) of the label, whether it be the front or back label by clicking on the drag and drop area to select an image from your computer, or dragging the file from your computer onto this area. Once the file has been selected from your computer, click the ‘Upload’ button. **PLEASE NOTE:** Image must be a .JPG format. File name with special characters will not be accepted. The maximum size for each image is 1MB. If uploading more than one image, ensure that the file name for each image is unique.



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

UPLOAD **CANCEL**

After clicking ‘**UPLOAD**’, an ‘**Image uploaded successfully!**’ banner will appear at the top of the screen as confirmation.



Step 28. Return to the top of the page and select ‘**SAVE PRODUCT**’, the overall product details will be displayed under **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)**.

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

SAVE PRODUCT
DELETE
<< RETURN

COSMETIC PRODUCTS

Cosmetic Product Listing Number:

Step. 29 ANY PRODUCT within the submission can be CLONED by selecting the ‘**CLONE**’ icon. If any edits need to be made, select the icon under the ‘**EDIT**’ tab.

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

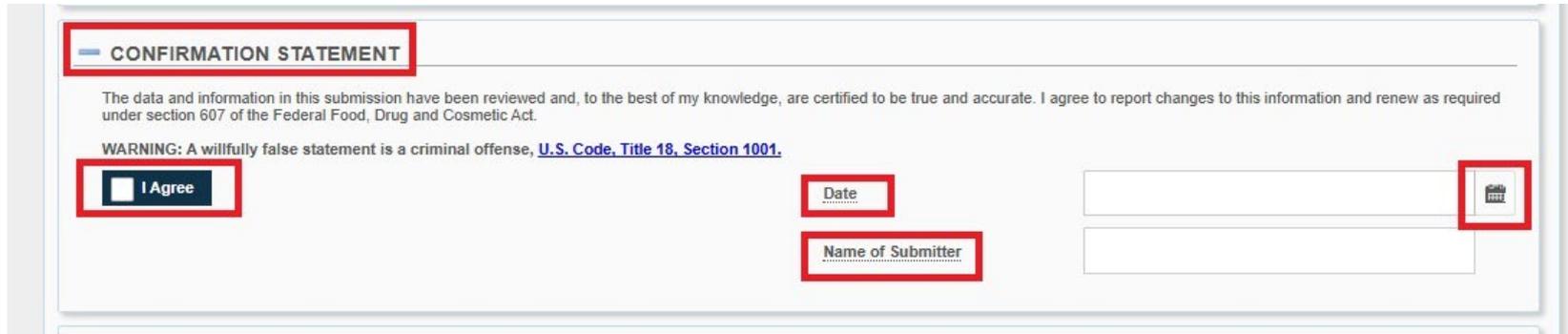
ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)

row(s) 1 - 2 of 2

EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS CHANGE STATUS FOR ALL PRODUCTS ▾	CLONE
		Baby Silk	LISTED ▾	
		Baby Silk Oil	LISTED ▾	

row(s) 1 - 2 of 2

Step 30. In the ‘**CONFIRMATION STATEMENT**’ section, fill in the following optional blank fields: Click on the calendar icon to select the date. Enter the full ‘**NAME OF THE SUBMITTER**’. Click ‘**AGREE**’ after reading and understanding the confirmation statement.



CONFIRMATION STATEMENT

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

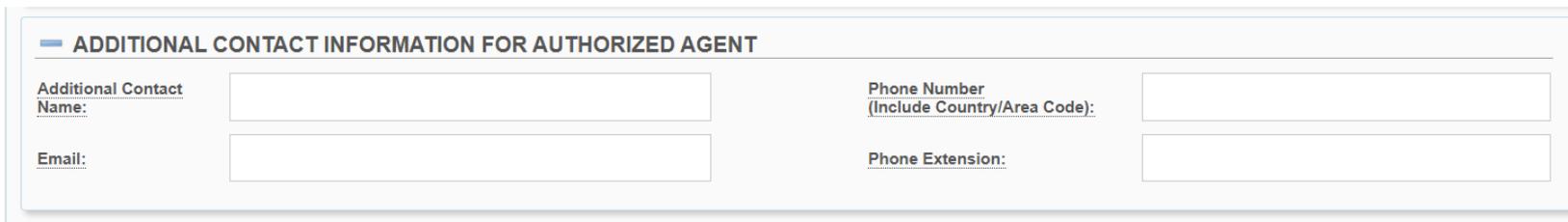
WARNING: A willfully false statement is a criminal offense, [U.S. Code, Title 18, Section 1001](#).

I Agree

Date

Name of Submitter

Step 31. If you would like to list additional contact information for an authorized agent, complete the ‘**ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT**’ section.



ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

Additional Contact Name:

Email:

Phone Number (Include Country/Area Code):

Phone Extension:

NOTE for Step 30 and Step 31: If you enter information into any field in this section, all other fields in the section will also need to be entered.

Step 32. Return to the top of the SPL Submission page where you can do the following:

- ‘**SUBMIT SPL**’ button will send the submission to FDA for additional validation and processing.



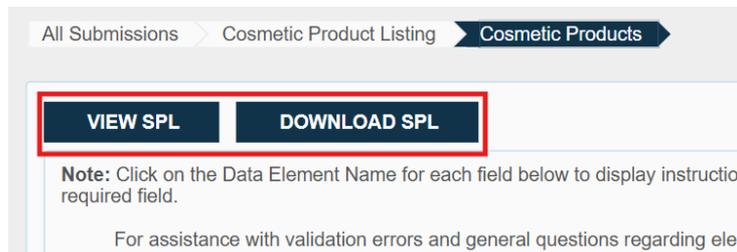
- After clicking on ‘SUBMIT SPL’, the submission undergoes an automated, technical validation indicated by the status of ‘AWAITING ACCEPTANCE’. In addition, a ‘SUBMISSION ID’ will be generated automatically whenever an SPL is submitted to FDA.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	RESPONSIBLE PERSON NAME	DETAILS
AWAITING ACCEPTANCE	4a81b10c-4f53-ce8c-e063-6a94af0a7aa1	4a81b10c-4f54-ce8c-e063-6a94af0a7aa1		1	COSMETIC PRODUCT LISTING	Test Name	DETAILS

- If the submission passes technical validation, the status will change to ‘SUBMISSION ACCEPTED’. To view and/or download an accepted submission, click on ‘SUBMISSION ACCEPTED’.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	RESPONSIBLE PERSON NAME	DETAILS
SUBMISSION ACCEPTED	4a81b10c-4f53-ce8c-e063-6a94af0a7aa1	4a81b10c-4f54-ce8c-e063-6a94af0a7aa1	cmxxxxxx.xxxxxx@direct	1	COSMETIC PRODUCT LISTING	Test Name	DETAILS

- Then click on ‘**VIEW SPL**’ and/or ‘**DOWNLOAD SPL**’.



- If the submission fails technical validation, the status will change to **‘SUBMISSION FAILED’**.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE
SUBMISSION FAILED	1f8dd1ef-5308-1990-e063-6394a90a8eeb	334db542-7ce1-b473-e063-6a94af0ac53d	cm8104562397.6720534189@direct	2	COSMETIC PRODUCT LISTING

- Click on **‘SUBMISSION FAILED’** to view and correct the errors identified. **ONCE CORRECTED**, click on **‘SUBMIT SPL’** to resubmit the SPL or **‘SAVE AND VALIDATE’** to recheck for errors.

1 ERROR HAS OCCURRED ✕

- Error in Cosmetic Product : Hair Dye Black Shampoo ([Go to error](#))

- ‘**SAVE AS DRAFT**’ button allows you to save your work, preserving your progress without submitting it to the FDA.



- Clicking ‘**SAVE AS DRAFT**’ from any screen during the cosmetic product listing process saves all entered information and redirects you to the homepage. The ‘**STATUS**’ will display ‘**DRAFT**’.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	RESPONSIBLE PERSON NAME	DETAILS
DRAFT	39d655aa-818a-c43a-e063-6a94af0aa14d	39d655aa-818b-c43a-e063-6a94af0aa14d		1	COSMETIC PRODUCT LISTING	-	DETAILS

- **‘SAVE AND VALIDATE’**: You can check your SPL for an initial validation before submitting to FDA. This option is only for an initial validation of your SPL before submitting to FDA. It scans for certain errors prior to the actual submission but does not automatically submit your SPL to FDA, even if it passes the initial validation. To submit your data to the FDA, select “Submit SPL”.



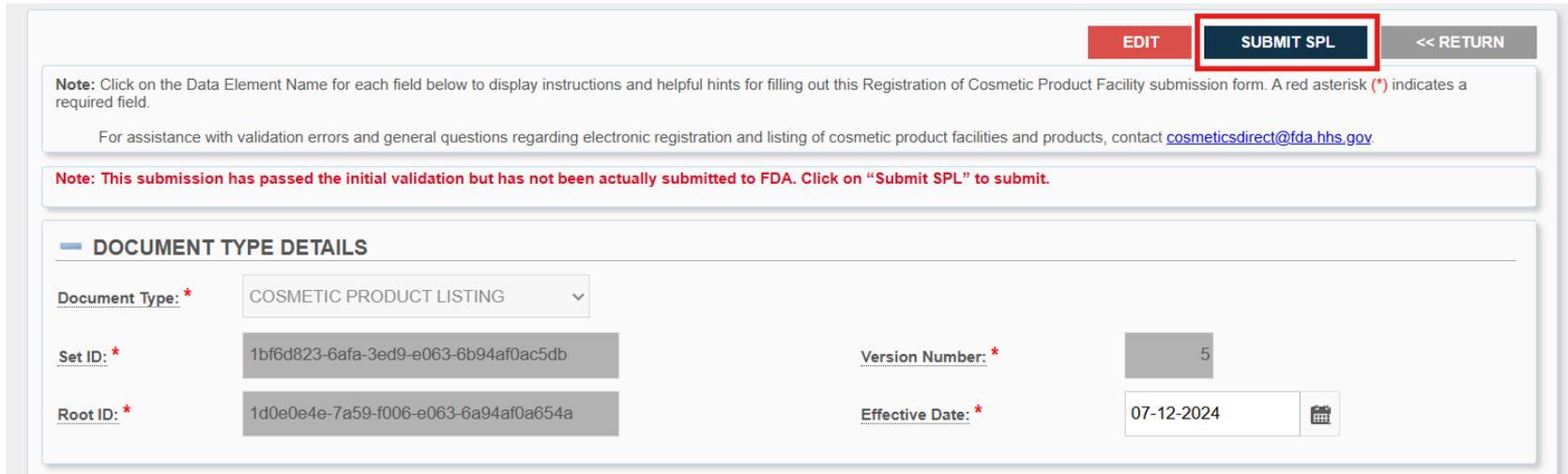
- Clicking **‘SAVE AND VALIDATE’** will automatically change the status to **‘VALIDATION IN PROGRESS’**.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	RESPONSIBLE PERSON NAME	DETAILS
VALIDATION IN PROGRESS	0f04f613-5b3d-e094-e063-6294a90a430d	4a90777c-83af-3559-e063-6a94af0aaf05		3	COSMETIC PRODUCT LISTING	Test Name	DETAILS

- Once the system completes the initial validation, the status **‘VALIDATION IN PROGRESS’** will change to **‘READY FOR SUBMISSION’**. Click **‘READY FOR SUBMISSION’** to proceed.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	RESPONSIBLE PERSON NAME
READY FOR SUBMISSION	0f04f613-5b3d-e094-e063-6294a90a430d	4a90777c-83af-3559-e063-6a94af0aaf05		3	Cosmetic Product Listing	Test Name

- This will open the submission. 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.



EDIT **SUBMIT SPL** << RETURN

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

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

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

DOCUMENT TYPE DETAILS

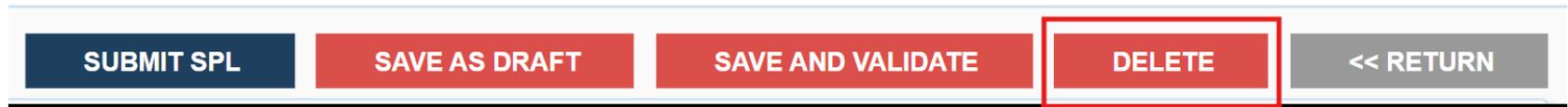
Document Type: *	COSMETIC PRODUCT LISTING		
Set ID: *	1bf6d823-6afa-3ed9-e063-6b94af0ac5db	Version Number: *	5
Root ID: *	1d0e0e4e-7a59-f006-e063-6a94af0a654a	Effective Date: *	07-12-2024

- After clicking **‘SUBMIT SPL’** the below message will appear:

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. X

- **‘DELETE’**: Delete will remove the submission from your account.

NOTE: Submissions with the status **‘SUBMISSION ACCEPTED’** can not be deleted.



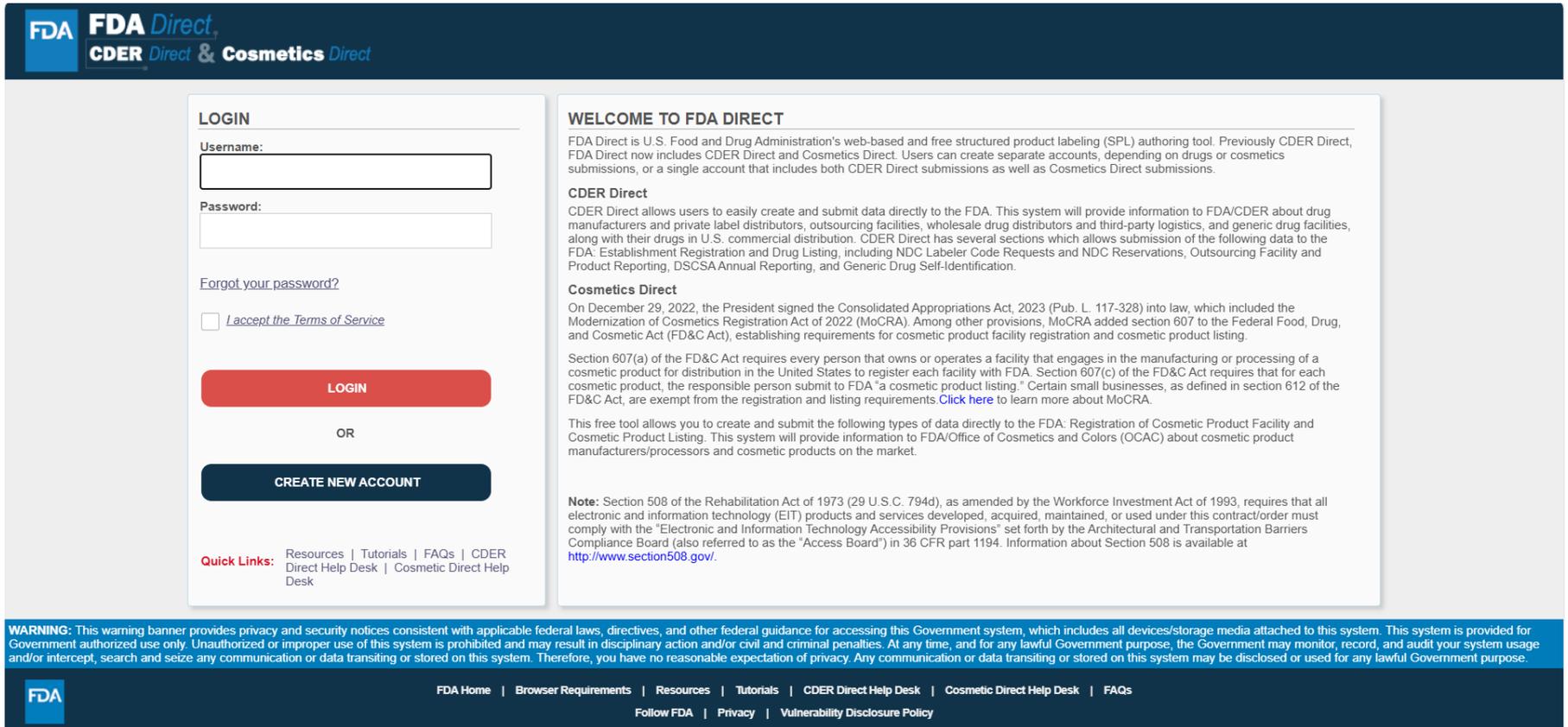
- **‘RETURN’**: Click **‘RETURN’** at any time to return to the Cosmetic Product Listing main page.



**RENEWING A
COSMETIC PRODUCT LISTING
WITHOUT CHANGES
(ABBREVIATED RENEWAL)**

Step 1. Navigate to Cosmetics Direct via <https://direct.fda.gov>.

Step 2. Enter your log-in credentials, accept the terms of service, and click ‘**LOGIN**’.



The screenshot shows the FDA Direct login interface. At the top left is the FDA logo and the text "FDA Direct, CDER Direct & Cosmetics Direct". The main content area is split into two columns. The left column contains a login form with fields for "Username:" and "Password:", a "Forgot your password?" link, a checkbox for "I accept the Terms of Service", a red "LOGIN" button, an "OR" separator, and a dark blue "CREATE NEW ACCOUNT" button. Below the form are "Quick Links" for Resources, Tutorials, FAQs, CDER Direct Help Desk, and Cosmetic Direct Help Desk. The right column is titled "WELCOME TO FDA DIRECT" and contains introductory text about the system, sections for "CDER Direct" and "Cosmetics Direct", and a "Note" regarding Section 508 of the Rehabilitation Act of 1973. A red warning banner at the bottom of the page provides privacy and security notices. The footer contains navigation links for FDA Home, Browser Requirements, Resources, Tutorials, CDER Direct Help Desk, Cosmetic Direct Help Desk, and FAQs, along with links for Follow FDA, Privacy, and Vulnerability Disclosure Policy.

LOGIN

Username:

Password:

[Forgot your password?](#)

[I accept the Terms of Service](#)

LOGIN

OR

CREATE NEW ACCOUNT

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

WELCOME TO FDA DIRECT

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

CDER Direct

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

Cosmetics Direct

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

Section 607(a) of the FD&C Act requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility with FDA. Section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person submit to FDA "a cosmetic product listing." Certain small businesses, as defined in section 612 of the FD&C Act, are exempt from the registration and listing requirements. [Click here](#) to learn more about MoCRA.

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

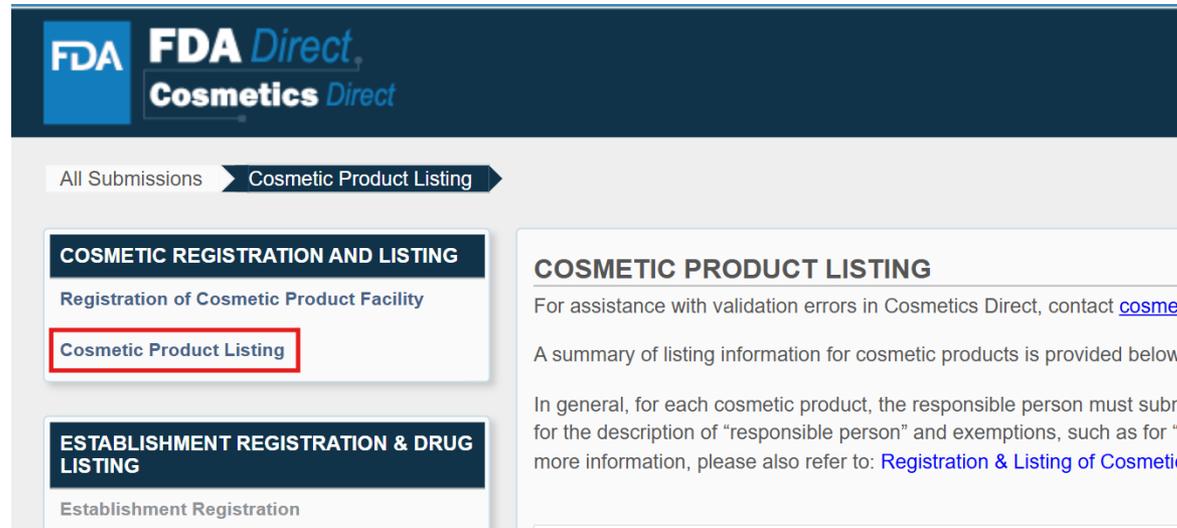
Note: Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1993, requires that all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic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

WARNING: This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes all devices/storage media attached to this system. This system is provided for Government authorized use only. Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties. At any time, and for any lawful Government purpose, the Government may monitor, record, and audit your system usage and/or intercept, search and seize any communication or data transiting or stored on this system. Therefore, you have no reasonable expectation of privacy. Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

FDA Home | Browser Requirements | Resources | Tutorials | CDER Direct Help Desk | Cosmetic Direct Help Desk | FAQs

Follow FDA | Privacy | Vulnerability Disclosure Policy

Step 3. Select ‘Cosmetic Product Listing’.



The screenshot shows the FDA Direct Cosmetics Direct interface. At the top, there are navigation tabs for 'All Submissions' and 'Cosmetic Product Listing'. Below this, there are two main sections: 'COSMETIC REGISTRATION AND LISTING' and 'ESTABLISHMENT REGISTRATION & DRUG LISTING'. Under 'COSMETIC REGISTRATION AND LISTING', there are two sub-sections: 'Registration of Cosmetic Product Facility' and 'Cosmetic Product Listing', which is highlighted with a red box. The 'ESTABLISHMENT REGISTRATION & DRUG LISTING' section has a sub-section for 'Establishment Registration'. On the right side, there is a 'COSMETIC PRODUCT LISTING' section with introductory text and a link to contact support.

Step 4. Click on ‘SUBMISSION ACCEPTED’ on the most recently accepted Cosmetic Product Listing submission that you wish to renew.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	RESPONSIBLE PERSON NAME	DETAILS
SUBMISSION ACCEPTED	1187ca46-293e-5ee0-e063-6394a90ad2f7	39e48963-6f40-b29b-e063-6b94af0a6acf	cmXXXXXXXXXXXX@direct	9	COSMETIC - UPDATE	Test Name	DETAILS

Step 5. Click on ‘**CREATE NEW VERSION**’ to generate an updated version of the SPL for review.

All Submissions > Cosmetic Product Listing > **Cosmetic Products**

VIEW SPL **DOWNLOAD SPL** **CREATE NEW VERSION** << RETURN

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

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

DOCUMENT TYPE DETAILS

Document Type: *	COSMETIC PRODUCT LISTING		
Set ID: *	1187ca46-293e-5ee0-e063-6394a90ad2f7	Version Number: *	8
Root ID: *	389307a8-f4bb-1f7d-e063-6a94af0a3e5d	Effective Date: *	06-27-2025 

Step 6. Select ‘COSMETIC PRODUCT LISTING – ABBREVIATED RENEWAL’ from the ‘DOCUMENT TYPE’ drop-down menu.

SPL has been successfully cloned. ✕

All Submissions > Cosmetic Product Listing > **Cosmetic Products** 

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

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

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

DOCUMENT TYPE DETAILS

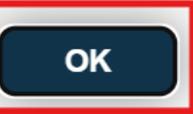
Document Type: *	--Select One--				
Set ID: *	--Select One--	Generate New	Version Number: *	2	
Root ID: *	COSMETIC-ABBREVIATED RENEWAL	Generate New	Effective Date: *	02-06-2026	
	COSMETIC PRODUCT LISTING				
	COSMETIC UPDATE				

Step 7. A pop-up will appear stating,

“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 draft changes made to your submission will be lost, and submission details will be reverted to the previous submission.”

Select, ‘**OK**’ to proceed.

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

A dark blue, rounded rectangular button with the word "CANCEL" in white, uppercase letters.A dark blue, rounded rectangular button with the word "OK" in white, uppercase letters. The button is highlighted with a red rectangular border.

Step 8. Review your information to ensure no update is needed and the current information is still accurate.

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

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

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DOCUMENT TYPE DETAILS

<u>Document Type:</u> *	COSMETIC-ABBREVIATED RENEWAL ▾		
<u>Set ID:</u> *	48f9bc31-6a2d-1adc-e063-6b94af0a6849	Generate New	<u>Version Number:</u> * <input style="width: 50px;" type="text" value="2"/>
<u>Root ID:</u> *	4a2b9a37-7c70-fa35-e063-6b94af0a0dd9	Generate New	<u>Effective Date:</u> * <input style="width: 100px;" type="text" value="02-06-2026"/>

PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT

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

Type of Business:

MANUFACTURER
 PACKER
 DISTRIBUTOR

Grayed out fields cannot be edited.

<u>Responsible Person (as listed on label):</u>	
<u>Responsible Person Name (as listed on label):</u> *	Responsible Person
<u>Parent Company Name (if applicable):</u>	
<u>Responsible Person Phone Number (Include Country/Area Code):</u> *	1-999-9999
<u>Responsible Person D&B D-U-N-S Number for Address Listed on the Product Label:</u>	

Step 9. In the ‘**CONFIRMATION STATEMENT**’ section, fill in the following optional blank fields: Click on the calendar icon to select the date. Enter the full ‘**NAME OF THE SUBMITTER**’. Click ‘**AGREE**’ after reading and understanding the confirmation statement.

PLEASE NOTE: If you enter information into any field in this section, all other fields in the section will also need to be entered.



CONFIRMATION STATEMENT

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

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

I Agree

Date 

Name of Submitter

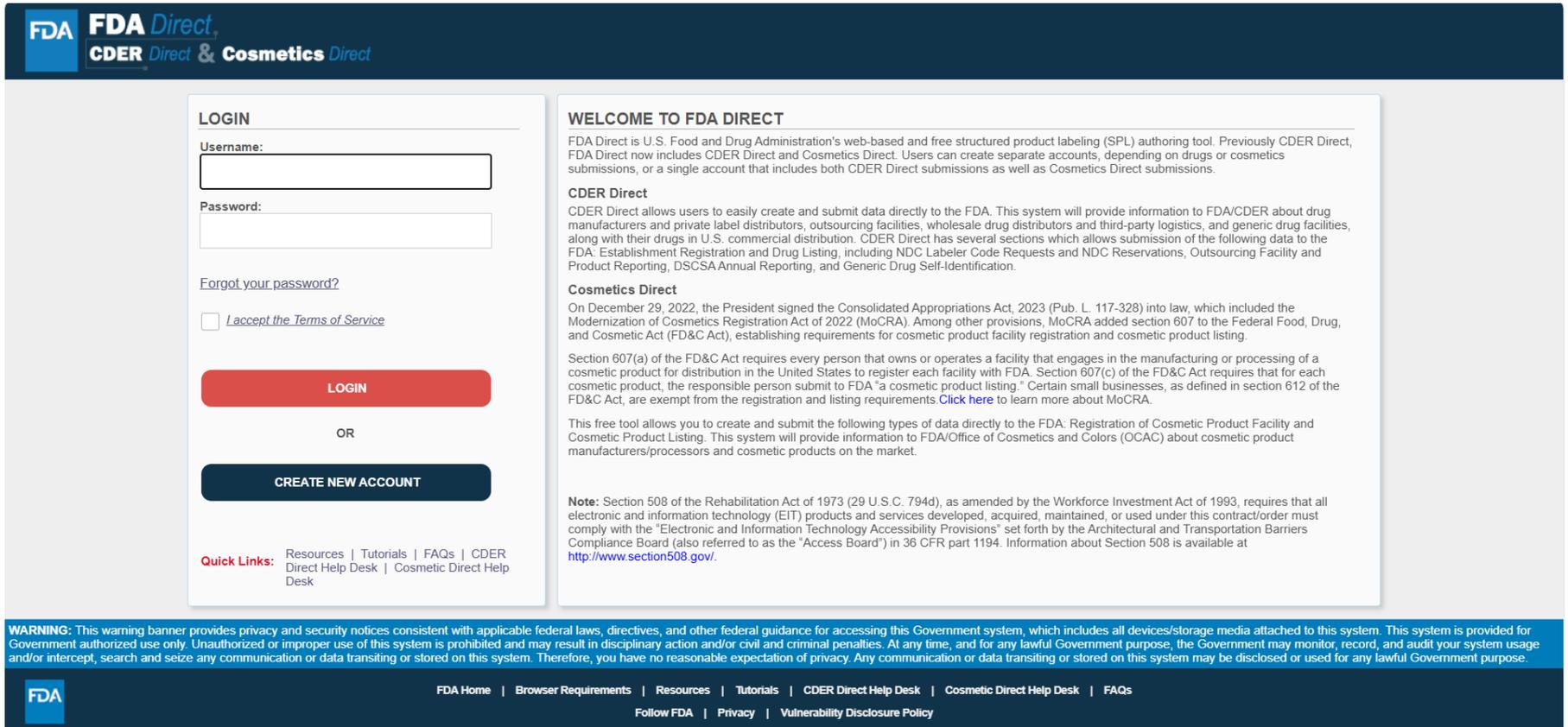
Step 10. Click ‘**SUBMIT SPL**’ to submit your SPL to FDA.

SUBMIT SPL

UPDATING A COSMETIC PRODUCT LISTING

Step 1. Navigate to Cosmetics Direct via <https://direct.fda.gov>.

Step 2. Enter your log-in credentials, accept the terms of service, and click ‘**LOGIN**’.



The screenshot shows the FDA Direct login interface. At the top left is the FDA logo and the text "FDA Direct, CDER Direct & Cosmetics Direct". The main content area is split into two columns. The left column is titled "LOGIN" and contains a form with fields for "Username:" and "Password:". Below the password field is a link "Forgot your password?" and a checkbox for "I accept the Terms of Service". There are two buttons: a red "LOGIN" button and a dark blue "CREATE NEW ACCOUNT" button. At the bottom of the left column are "Quick Links" for Resources, Tutorials, FAQs, CDER Direct Help Desk, and Cosmetic Direct Help Desk. The right column is titled "WELCOME TO FDA DIRECT" and contains introductory text about the system, sections for "CDER Direct" and "Cosmetics Direct", and a "Note" about Section 508 of the Rehabilitation Act of 1973. A red warning banner at the bottom of the page provides privacy and security notices.

LOGIN

Username:

Password:

[Forgot your password?](#)

[I accept the Terms of Service](#)

LOGIN

OR

CREATE NEW ACCOUNT

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

WELCOME TO FDA DIRECT

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CDER Direct

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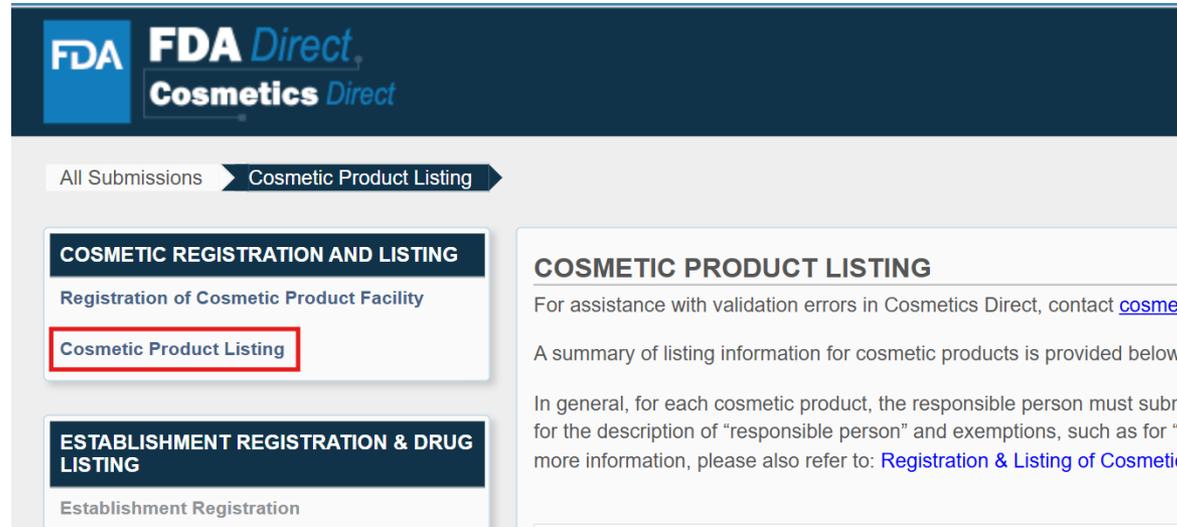
Note: Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1993, requires that all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic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

WARNING: This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes all devices/storage media attached to this system. This system is provided for Government authorized use only. Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties. At any time, and for any lawful Government purpose, the Government may monitor, record, and audit your system usage and/or intercept, search and seize any communication or data transiting or stored on this system. Therefore, you have no reasonable expectation of privacy. Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

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**Step 3. Select
'Cosmetic Product
Listing'.**

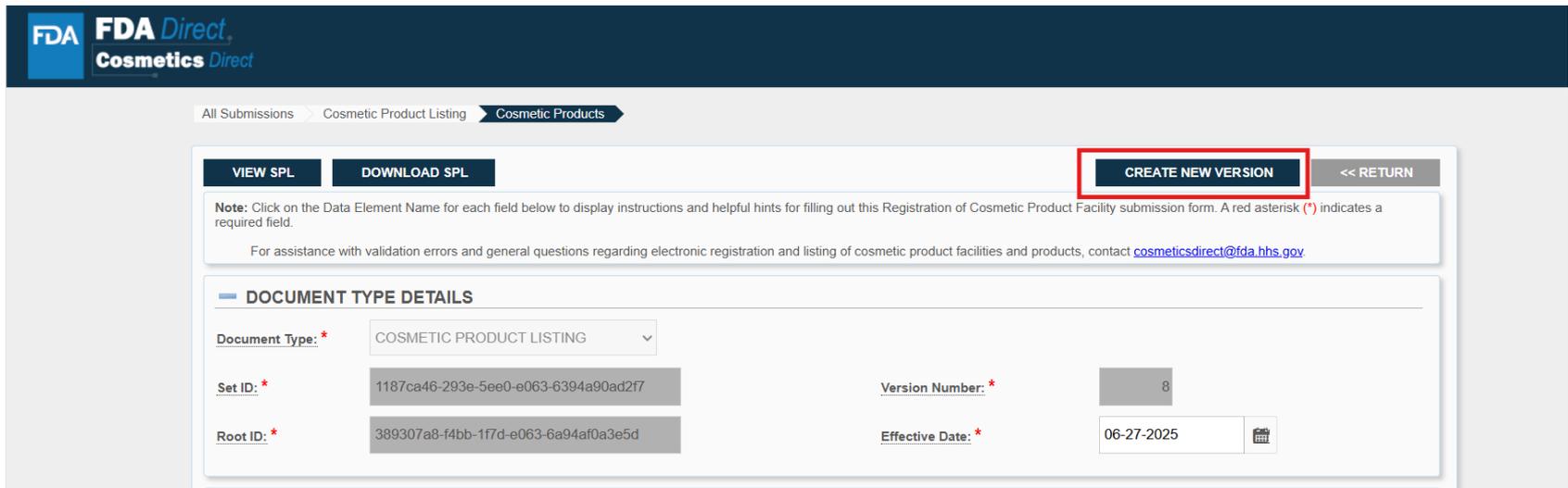


The screenshot shows the FDA Direct Cosmetics Direct interface. At the top, there are navigation tabs for 'All Submissions' and 'Cosmetic Product Listing'. Below this, there are two main sections: 'COSMETIC REGISTRATION AND LISTING' and 'ESTABLISHMENT REGISTRATION & DRUG LISTING'. Under 'COSMETIC REGISTRATION AND LISTING', there are two sub-sections: 'Registration of Cosmetic Product Facility' and 'Cosmetic Product Listing', which is highlighted with a red box. The 'ESTABLISHMENT REGISTRATION & DRUG LISTING' section has a sub-section for 'Establishment Registration'. To the right, there is a 'COSMETIC PRODUCT LISTING' section with introductory text and a link to 'cosmeti'.

**Step 4. Click on
'SUBMISSION
ACCEPTED' on
the most recently
accepted Cosmetic
Product Listing
submission that
you wish to update.**

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	RESPONSIBLE PERSON NAME	DETAILS	M
SUBMISSION ACCEPTED	1187ca46-293e-5ee0-e063-6394a90ad2f7	39e48963-6f40-b29b-e063-6b94af0a6acf	cmXXXXXXXXXXXX@direct	9	COSMETIC - UPDATE	Test Name	DETAILS	C Ji

Step 5. Click on ‘**CREATE NEW VERSION**’ to generate an updated version of the SPL to make any necessary changes.



The screenshot shows the FDA Direct Cosmetics Direct interface. At the top left, the logo reads "FDA Direct Cosmetics Direct". Below the logo, there are navigation tabs: "All Submissions", "Cosmetic Product Listing", and "Cosmetic Products". The "Cosmetic Products" tab is active. Below the tabs, there are four buttons: "VIEW SPL", "DOWNLOAD SPL", "CREATE NEW VERSION" (highlighted with a red box), and "<< RETURN". Below the buttons, there is a note: "Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Registration of Cosmetic Product Facility submission form. A red asterisk (*) indicates a required field." Below the note, there is a link: "For assistance with validation errors and general questions regarding electronic registration and listing of cosmetic product facilities and products, contact cosmeticsdirect@fda.hhs.gov". Below the link, there is a section titled "DOCUMENT TYPE DETAILS". This section contains four fields: "Document Type:" with a dropdown menu showing "COSMETIC PRODUCT LISTING"; "Set ID:" with a text input field containing "1187ca46-293e-5ee0-e063-6394a90ad2f7"; "Version Number:" with a text input field containing "8"; and "Root ID:" with a text input field containing "389307a8-f4bb-1f7d-e063-6a94af0a3e5d". There is also an "Effective Date:" field with a date input field containing "06-27-2025" and a calendar icon.

Step 6. Under ‘DOCUMENT TYPE’, select ‘COSMETIC PRODUCT LISTING – UPDATE’.

SPL has been successfully cloned. ✕

All Submissions > Cosmetic Product Listing > **Cosmetic Products** 

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

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

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

DOCUMENT TYPE DETAILS

Document Type: *	--Select One--		
Set ID: *	--Select One-- COSMETIC PRODUCT LISTING	Generate New	Version Number: * <input type="text" value="9"/>
Root ID: *	COSMETIC - UPDATE COSMETIC - ABBREVIATED RENEWAL	Generate New	Effective Date: * <input type="text" value="07-14-2025"/> 

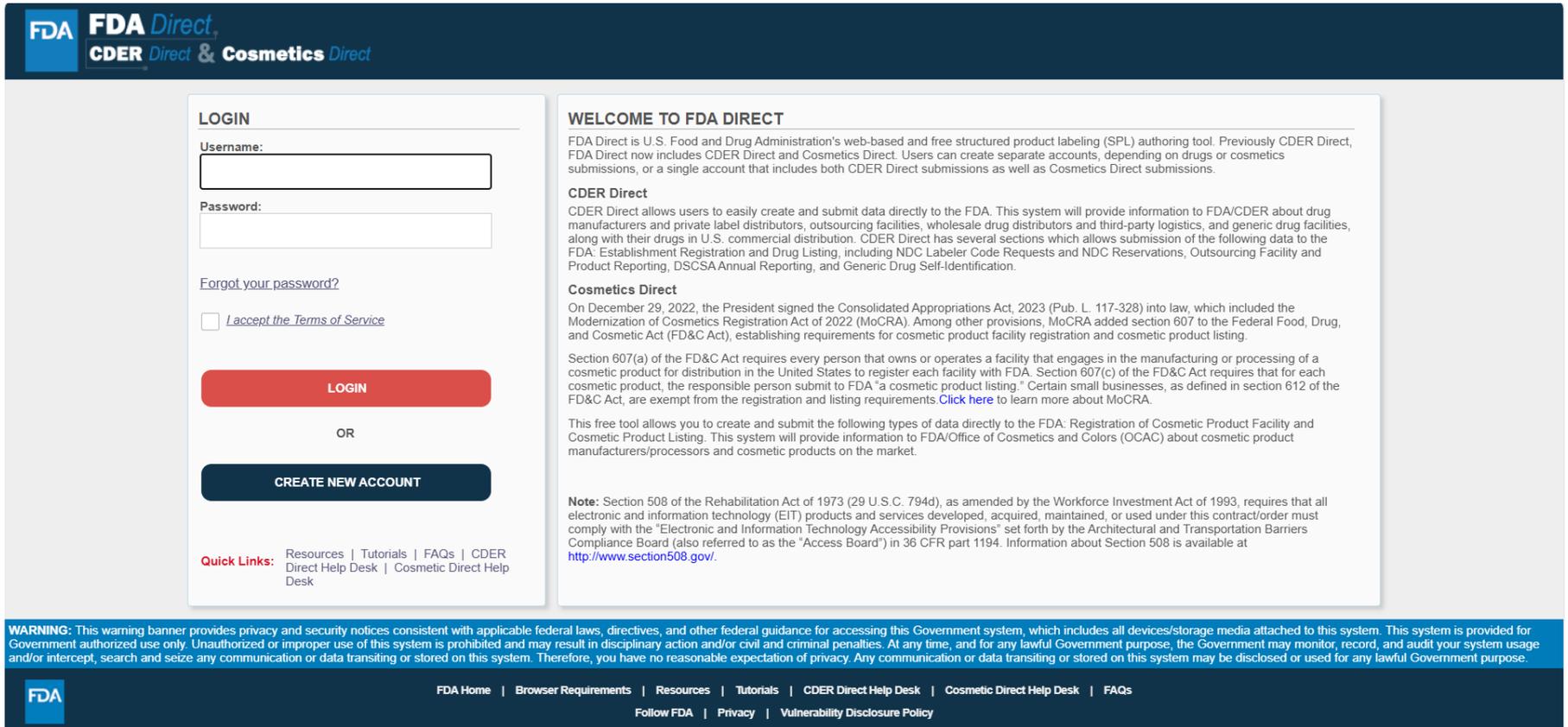
Step 7. Update the submission details using the instructions in Slide [#10](#) – Slide [#24](#).

Step 8. Submit the SPL to FDA following the instructions in Slide [#25](#).

DISCONTINUING A COSMETIC PRODUCT LISTING

Step 1. Navigate to Cosmetics Direct via <https://direct.fda.gov>.

Step 2. Enter your log-in credentials, accept the terms of service, and click ‘**LOGIN**’.



The screenshot shows the FDA Direct login interface. At the top left is the FDA logo and the text "FDA Direct, CDER Direct & Cosmetics Direct". The main content area is split into two columns. The left column contains a login form with fields for "Username:" and "Password:", a "Forgot your password?" link, a checkbox for "I accept the Terms of Service", a red "LOGIN" button, an "OR" separator, and a dark blue "CREATE NEW ACCOUNT" button. Below the form are "Quick Links" for Resources, Tutorials, FAQs, CDER Direct Help Desk, and Cosmetic Direct Help Desk. The right column is titled "WELCOME TO FDA DIRECT" and contains introductory text about the system, sections for "CDER Direct" and "Cosmetics Direct", and a "Note" regarding Section 508 of the Rehabilitation Act. A blue warning banner at the bottom of the page provides privacy and security notices.

LOGIN

Username:

Password:

[Forgot your password?](#)

[I accept the Terms of Service](#)

LOGIN

OR

CREATE NEW ACCOUNT

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

WELCOME TO FDA DIRECT

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

CDER Direct

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

Cosmetics Direct

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

Section 607(a) of the FD&C Act requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility with FDA. Section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person submit to FDA "a cosmetic product listing." Certain small businesses, as defined in section 612 of the FD&C Act, are exempt from the registration and listing requirements. [Click here](#) to learn more about MoCRA.

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

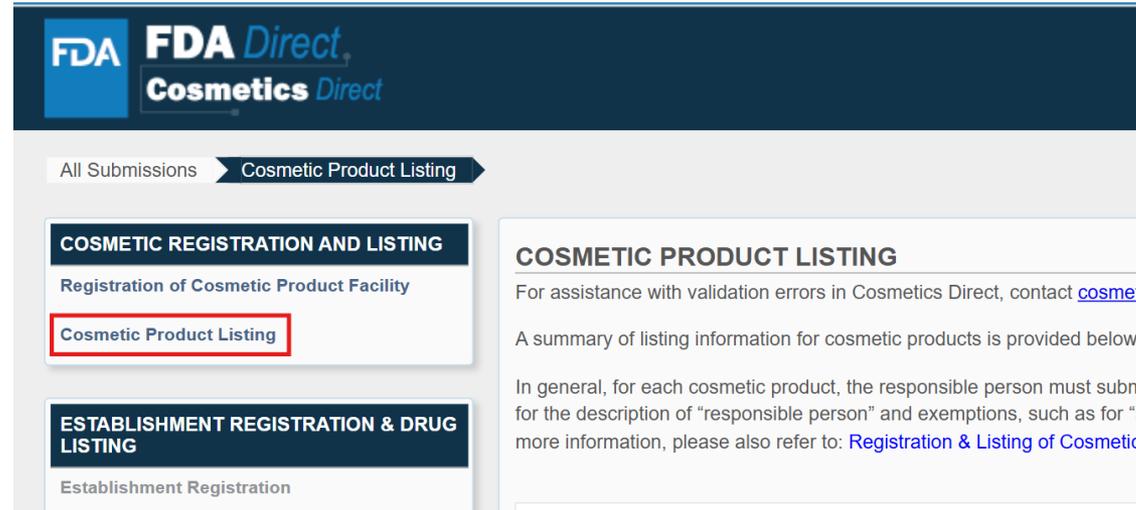
Note: Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1993, requires that all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic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

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Step 3. Select ‘Cosmetic Product Listing’.

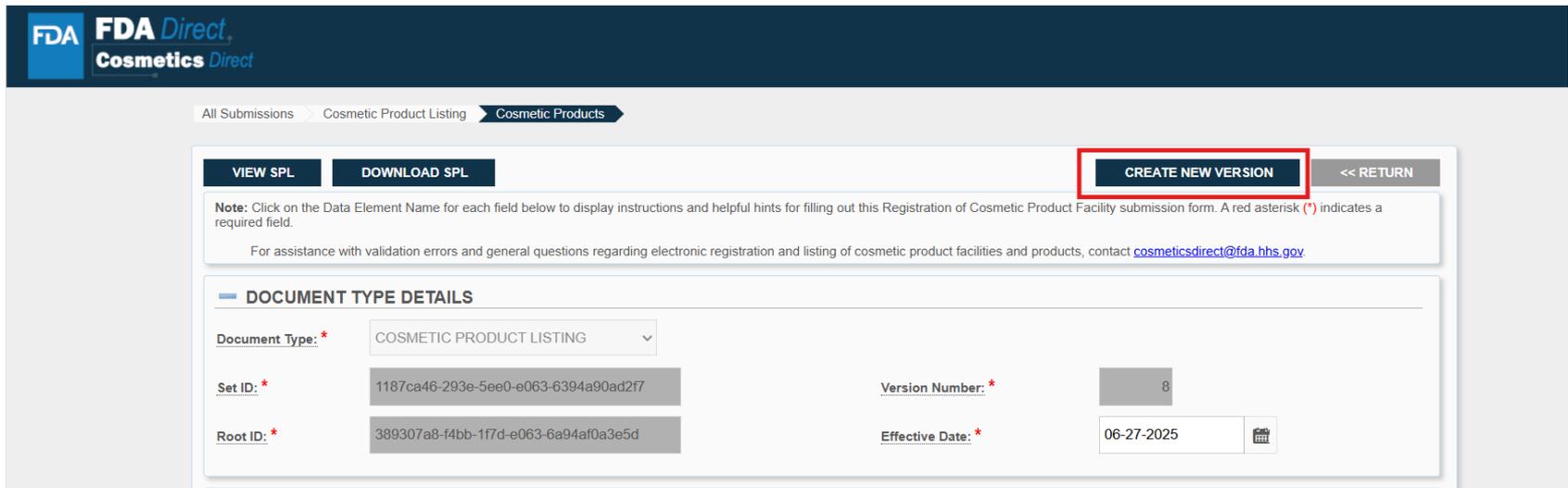


The screenshot shows the FDA Direct Cosmetics Direct interface. At the top, there are navigation tabs for 'All Submissions' and 'Cosmetic Product Listing'. Below this, there are two main sections: 'COSMETIC REGISTRATION AND LISTING' and 'ESTABLISHMENT REGISTRATION & DRUG LISTING'. Under 'COSMETIC REGISTRATION AND LISTING', there are three sub-items: 'Registration of Cosmetic Product Facility', 'Cosmetic Product Listing' (highlighted with a red box), and 'Cosmetic Product Listing'. Under 'ESTABLISHMENT REGISTRATION & DRUG LISTING', there is one sub-item: 'Establishment Registration'. To the right, the 'COSMETIC PRODUCT LISTING' section contains text about validation errors and a link to 'cosmeti', and a summary of listing information for cosmetic products.

Step 4. Click on ‘SUBMISSION ACCEPTED’ on the most recently accepted Cosmetic Product Listing submission containing the product(s) you wish to discontinue.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	RESPONSIBLE PERSON NAME	DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
SUBMISSION ACCEPTED	1187ca46-293e-5ee0-e063-6394a90ad2f7	39e48963-6f40-b29b-e063-6b94af0a6acf	cmXXXXXXXXXXXXXXXX@direct	9	COSMETIC - UPDATE	Test Name	DETAILS	Candyce Jones	14-JUL-2025 09:35:08

Step 5. Click on ‘**CREATE NEW VERSION**’, unlocking the SPL to review the SPL and make any updates.



The screenshot shows the FDA Direct Cosmetics Direct interface. At the top left, the logo reads "FDA Direct Cosmetics Direct". A breadcrumb trail indicates the current location: "All Submissions > Cosmetic Product Listing > Cosmetic Products". Below this, there are four buttons: "VIEW SPL", "DOWNLOAD SPL", "CREATE NEW VERSION" (highlighted with a red box), and "<< RETURN".

A note below the buttons states: "Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Registration of Cosmetic Product Facility submission form. A red asterisk (*) indicates a required field." Below the note is a link for assistance: "For assistance with validation errors and general questions regarding electronic registration and listing of cosmetic product facilities and products, contact cosmeticsdirect@fda.hhs.gov".

The main section is titled "DOCUMENT TYPE DETAILS" and contains the following fields:

Document Type: *	COSMETIC PRODUCT LISTING		
Set ID: *	1187ca46-293e-5ee0-e063-6394a90ad2f7	Version Number: *	8
Root ID: *	389307a8-f4bb-1f7d-e063-6a94af0a3e5d	Effective Date: *	06-27-2025

Step 6. Under ‘DOCUMENT TYPE’, select ‘COSMETIC PRODUCT LISTING – UPDATE’.

All Submissions > Cosmetic Product Listing > **Cosmetic Products** 

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

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

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

DOCUMENT TYPE DETAILS

Document Type: *	--Select One--		
Set ID: *	--Select One-- COSMETIC PRODUCT LISTING	<input type="button" value="Generate New"/>	Version Number: * <input type="text" value="9"/>
Root ID: *	COSMETIC - UPDATE COSMETIC - ABBREVIATED RENEWAL	<input type="button" value="Generate New"/>	Effective Date: * <input type="text" value="07-14-2025"/> 

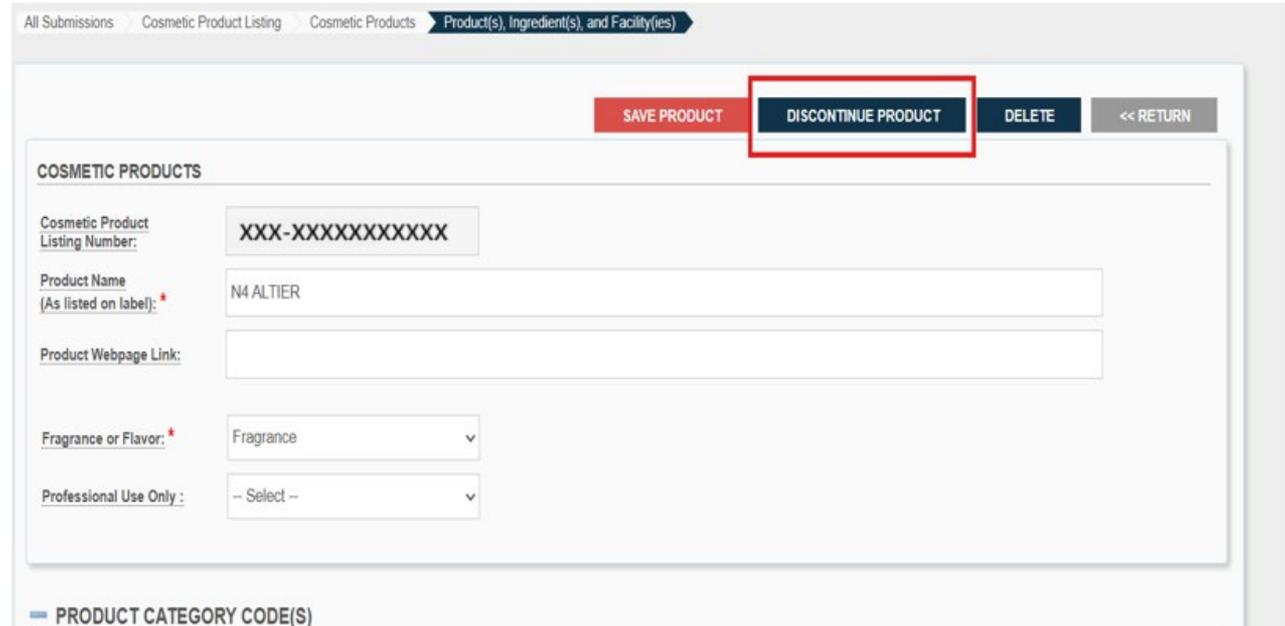
Option 1 – Edit/Update Product

Step 7. 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 discontinue.

PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)				
ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)				
row(s) 1 - 61 of 61				
EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	XX-XXXXXXXX	Product Name	CHANGE STATUS FOR ALL PRODUCTS ▾ LISTED ▾	
	XX-XXXXXXXX	Product Name 1	LISTED ▾	

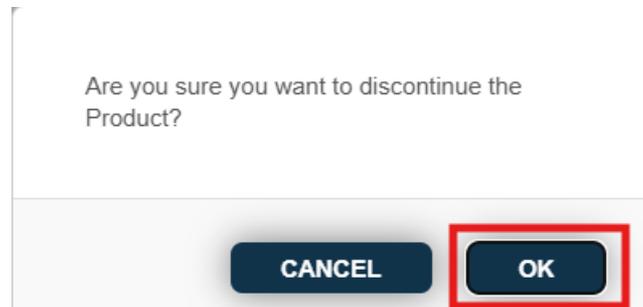
Option 1 – Edit/Update Product (continued)

Step 8. Select ‘**DISCONTINUE PRODUCT**’ to discontinue the product.



The screenshot shows a web interface for managing cosmetic products. At the top, there are navigation tabs: 'All Submissions', 'Cosmetic Product Listing', 'Cosmetic Products', and 'Product(s), Ingredient(s), and Facility(es)'. Below the tabs, there are four buttons: 'SAVE PRODUCT' (red), 'DISCONTINUE PRODUCT' (dark blue, highlighted with a red box), 'DELETE' (dark blue), and '<< RETURN' (grey). The main content area is titled 'COSMETIC PRODUCTS' and contains a form with the following fields: 'Cosmetic Product Listing Number:' with a text input containing 'XXX-XXXXXXXXXXXX'; 'Product Name (As listed on label):*' with a text input containing 'N4 ALTIER'; 'Product Webpage Link:' with an empty text input; 'Fragrance or Flavor: *' with a dropdown menu showing 'Fragrance'; and 'Professional Use Only:' with a dropdown menu showing '-- Select --'. At the bottom of the form, there is a link for 'PRODUCT CATEGORY CODE(S)'.

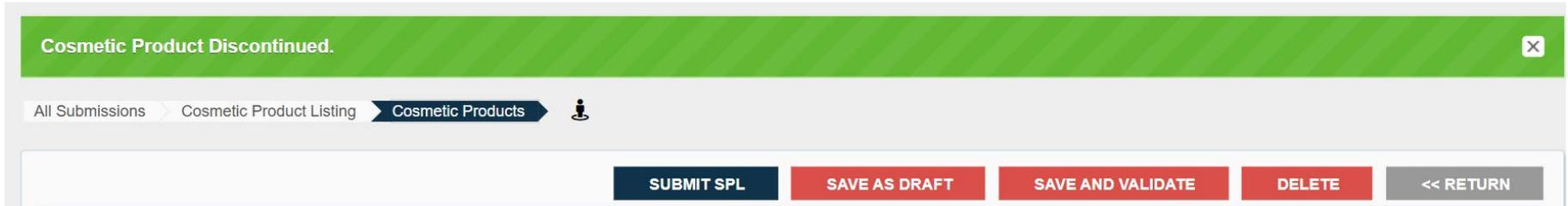
PLEASE NOTE: The following message will appear, “Are you sure you want to discontinue the Product?” Select, ‘**OK**’ to proceed.



The screenshot shows a confirmation dialog box with the text: "Are you sure you want to discontinue the Product?". At the bottom of the dialog, there are two buttons: 'CANCEL' (dark blue) and 'OK' (dark blue, highlighted with a red box).

Option 1 – Edit/Update Product (continued)

Step 9. After selecting ‘OK’, a green message will appear across your screen stating, “Cosmetic Product Discontinued.”



Cosmetic Product Discontinued. [X]

All Submissions > Cosmetic Product Listing > Cosmetic Products [User Icon]

[SUBMIT SPL] [SAVE AS DRAFT] [SAVE AND VALIDATE] [DELETE] [RETURN]

The discontinued product will be shaded red, and the Product Marketing Status will list the product as ‘DISCONTINUED’.

FACILITY(IES)

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

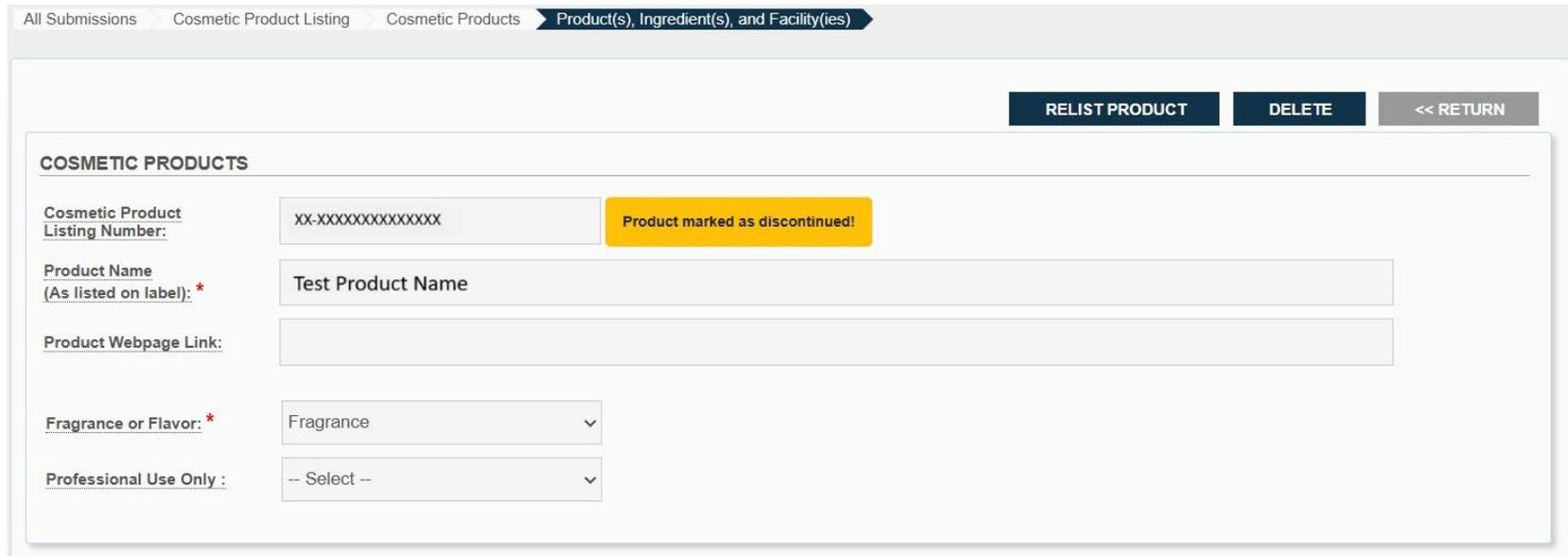
row(s) 1 - 2 of 2

PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
deep conditioner	DISCONTINUED ▾	
hair shampoo	LISTED ▾	

row(s) 1 - 2 of 2

Option 1 – Edit/Update Product (continued)

Step 10. Using the pencil icon, you can re-enter the selected DISCONTINUED product to view its details. A yellow highlighted message “Product marked as discontinued!” will also appear next to the Cosmetic Product Listing Number to mark the product as discontinued.



The screenshot shows a web interface for editing a product listing. At the top, there are navigation tabs: 'All Submissions', 'Cosmetic Product Listing', 'Cosmetic Products', and 'Product(s), Ingredient(s), and Facility(ies)'. On the right side, there are three buttons: 'RELIST PRODUCT', 'DELETE', and '<< RETURN'. The main form area is titled 'COSMETIC PRODUCTS' and contains the following fields:

- Cosmetic Product Listing Number:** A text input field containing 'XX-XXXXXXXXXXXXXX'. To its right is a yellow highlighted box with the text 'Product marked as discontinued!'.
- Product Name (As listed on label): *** A text input field containing 'Test Product Name'.
- Product Webpage Link:** An empty text input field.
- Fragrance or Flavor: *** A dropdown menu with 'Fragrance' selected.
- Professional Use Only :** A dropdown menu with '-- Select --' selected.

PLEASE NOTE: Once a product is discontinued, no additional edits can be made on the page unless the product is ‘RELISTED’. See Slide [#58](#) for ‘RELIST PRODUCT’ instructions.

After completing ‘Option 1’, proceed to ‘Step 19’.

Option 2 – Product Marketing Status

Step 11. Locate the ‘**PRODUCT MARKETING STATUS**’ column under the ‘**PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)**’ section.

— PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)				
ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)				
EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	53-XXXXXXXXXXXX	Body Wash XYZ	CHANGE STATUS FOR ALL PRODUCTS ▾	
	53-XXXXXXXXXXXX	Body Oil 123	LISTED ▾	
			LISTED ▾	

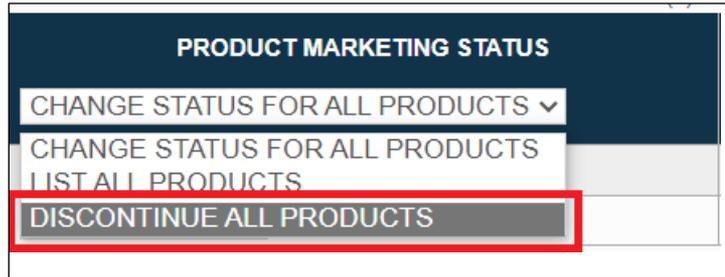
Step 12. Identify the listed products you wish to discontinue. In the **PRODUCT STATUS** column, click the drop-down menu and select '**DISCONTINUED**'.

PRODUCT MARKETING STATUS	CLONE
CHANGE STATUS FOR ALL PRODUCTS ▾	
LISTED ▾	
LISTED	
DISCONTINUED	

EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	53-XXXXXXXXXXXX	Body Wash XYZ	DISCONTINUED ▾	
	53-XXXXXXXXXXXX	Body Oil 123	LISTED ▾	

Option 2 – Product Marketing Status (continued)

Step 13. If you wish to discontinue all the **‘LISTED’** products, select **‘DISCONTINUE ALL PRODUCTS’**.



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

PRODUCT MARKETING STATUS		CLONE
DISCONTINUE ALL PRODUCTS		
DISCONTINUED		
DISCONTINUED		
DISCONTINUED		
DISCONTINUED		
DISCONTINUED		
DISCONTINUED		
DISCONTINUED		
DISCONTINUED		
DISCONTINUED		

Option 2 – Product Marketing Status (continued)

Step 14. Click ‘SAVE AS DRAFT’ or ‘SAVE AND VALIDATE’ located at the top right of this page to save your selection(s).

All Submissions > Cosmetic Product Listing > **Cosmetic Products** 

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

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

After completing ‘Option 2’, proceed to ‘Step 19’.

Option 3 – Delete

Step 15. 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 ‘DELETE’.

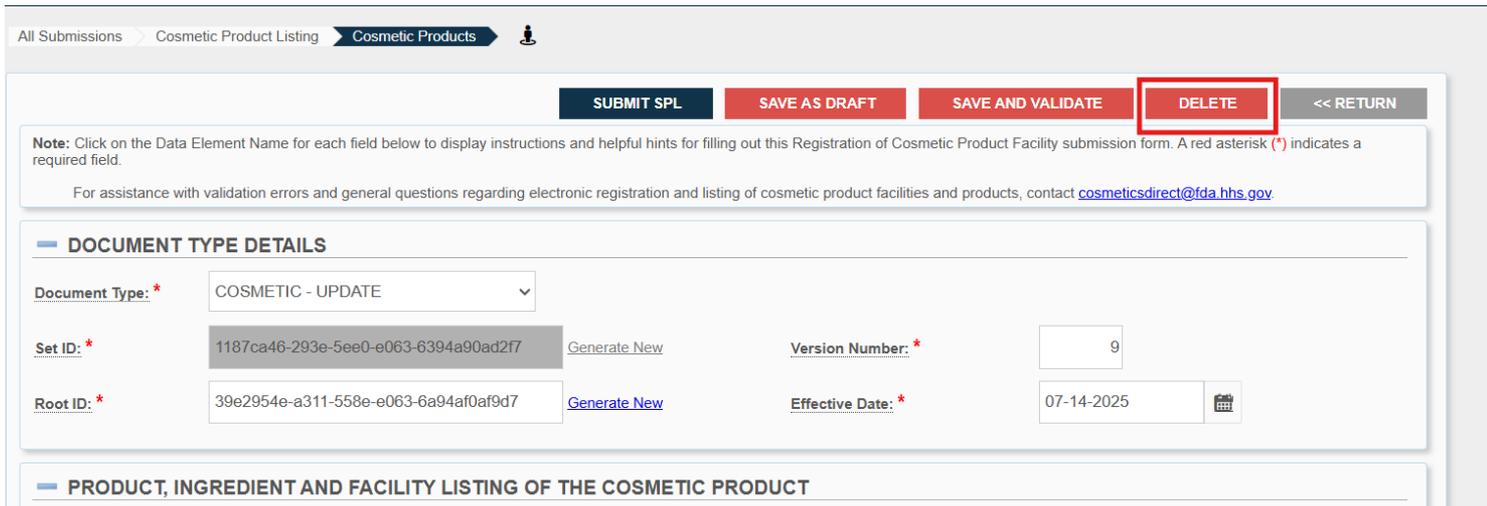
— PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)

row(s) 1 - 61 of 61

EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	XXXXXXXXXXXXX	PRODUCT A	CHANGE STATUS FOR ALL PRODUCTS <input type="button" value="v"/>	
	XXXXXXXXXXXXX	PRODUCT B	LISTED <input type="button" value="v"/>	

Option 3 – Delete (continued)

Step 16. Select ‘DELETE’ to delete the product from the SPL file.



All Submissions > Cosmetic Product Listing > Cosmetic Products > 

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

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

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DOCUMENT TYPE DETAILS

Document Type: * COSMETIC - UPDATE

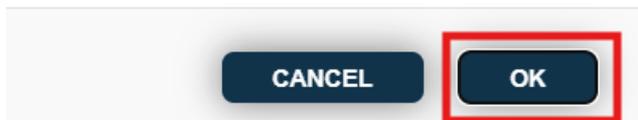
Set ID: * 1187ca46-293e-5ee0-e063-6394a90ad2f7 [Generate New](#) **Version Number:** * 9

Root ID: * 39e2954e-a311-558e-e063-6a94af0af9d7 [Generate New](#) **Effective Date:** * 07-14-2025 

PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT

Step 17. 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.

Are you sure you want to delete the Product?



CANCEL **OK**

Option 3 – Delete (continued)

Step 18. After selecting ‘OK’, the product will be removed from your SPL submission. A green message will appear across your screen stating, ‘**Cosmetic Product Deleted.**’

A horizontal green notification bar with a white close button (an 'X' in a square) on the right side. The text 'Cosmetic Product Deleted.' is written in white on the left side of the bar.

Cosmetic Product Deleted.

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

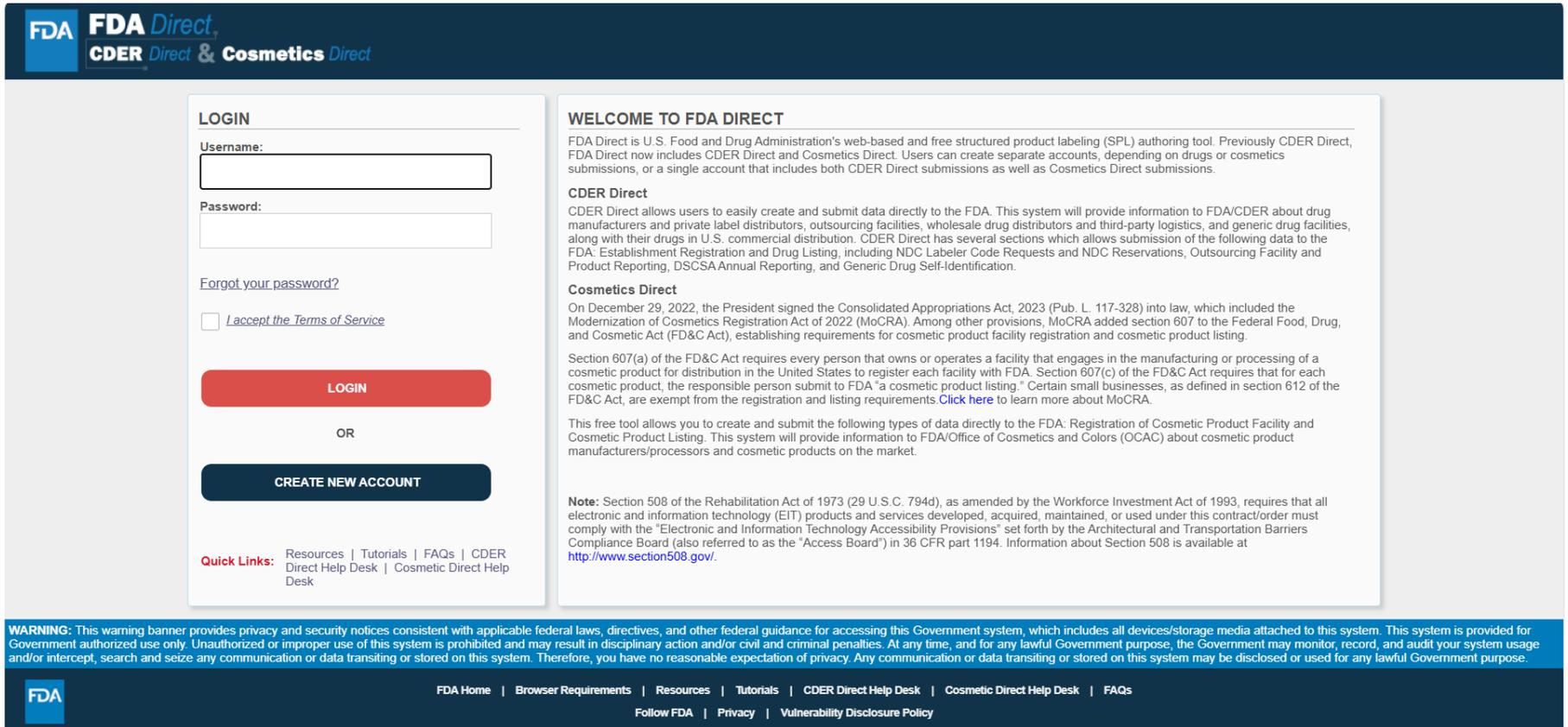
NOTE: Once deleted, a product is permanently removed from the SPL and cannot be retrieved for relisting. The SPL must contain at least one product in order to pass validation.

Step 19. Submit the SPL to FDA following the instructions in Slide [#25](#).

RELISTING A COSMETIC PRODUCT LISTING

Step 1. Navigate to Cosmetics Direct via <https://direct.fda.gov>.

Step 2. Enter your log-in credentials, accept the terms of service, and click ‘**LOGIN**’.



The screenshot shows the FDA Direct login interface. At the top left is the FDA logo and the text "FDA Direct, CDER Direct & Cosmetics Direct". The main content area is split into two columns. The left column is titled "LOGIN" and contains a form with fields for "Username:" and "Password:". Below the password field is a link "Forgot your password?". There is a checkbox for "I accept the Terms of Service". Two buttons are present: a red "LOGIN" button and a dark blue "CREATE NEW ACCOUNT" button. At the bottom of the left column are "Quick Links" for Resources, Tutorials, FAQs, CDER Direct Help Desk, and Cosmetic Direct Help Desk. The right column is titled "WELCOME TO FDA DIRECT" and contains introductory text about the system, sections for "CDER Direct" and "Cosmetics Direct", and a "Note" regarding Section 508 of the Rehabilitation Act of 1973. A blue warning banner at the bottom of the page contains text about privacy and security notices.

LOGIN

Username:

Password:

[Forgot your password?](#)

[I accept the Terms of Service](#)

LOGIN

OR

CREATE NEW ACCOUNT

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

WELCOME TO FDA DIRECT

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

Section 607(a) of the FD&C Act requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility with FDA. Section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person submit to FDA "a cosmetic product listing." Certain small businesses, as defined in section 612 of the FD&C Act, are exempt from the registration and listing requirements. [Click here](#) to learn more about MoCRA.

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

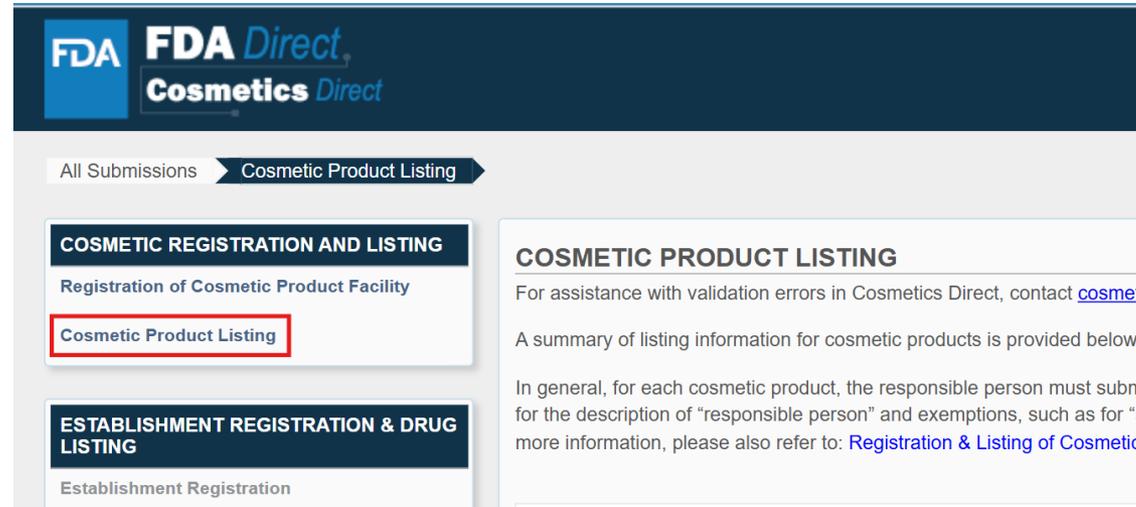
Note: Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1993, requires that all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic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

WARNING: This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes all devices/storage media attached to this system. This system is provided for Government authorized use only. Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties. At any time, and for any lawful Government purpose, the Government may monitor, record, and audit your system usage and/or intercept, search and seize any communication or data transiting or stored on this system. Therefore, you have no reasonable expectation of privacy. Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

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Step 3. Select ‘Cosmetic Product Listing’.

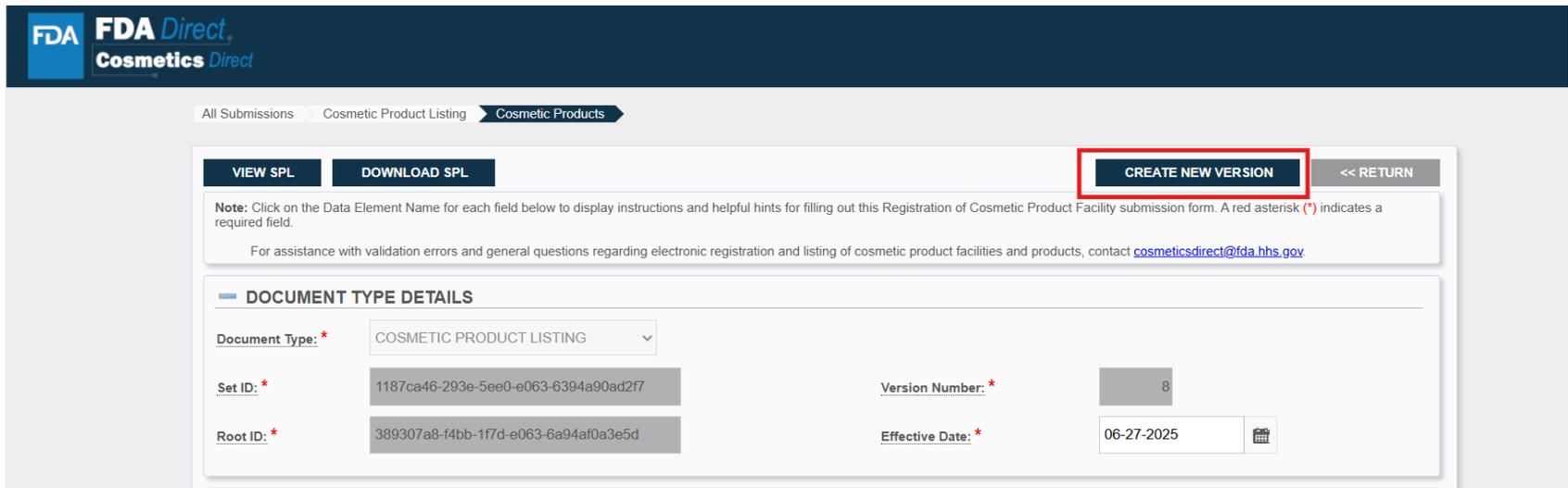


The screenshot shows the FDA Direct Cosmetics Direct interface. At the top, there are navigation tabs for 'All Submissions' and 'Cosmetic Product Listing'. Below this, there are two main sections: 'COSMETIC REGISTRATION AND LISTING' and 'ESTABLISHMENT REGISTRATION & DRUG LISTING'. Under 'COSMETIC REGISTRATION AND LISTING', there are three sub-sections: 'Registration of Cosmetic Product Facility', 'Cosmetic Product Listing' (highlighted with a red box), and 'Cosmetic Product Listing'. Under 'ESTABLISHMENT REGISTRATION & DRUG LISTING', there is one sub-section: 'Establishment Registration'. On the right side, there is a section titled 'COSMETIC PRODUCT LISTING' with a sub-header 'For assistance with validation errors in Cosmetics Direct, contact [cosmeti](#)'. Below this, there is a paragraph: 'A summary of listing information for cosmetic products is provided below. In general, for each cosmetic product, the responsible person must submit for the description of "responsible person" and exemptions, such as for "s more information, please also refer to: [Registration & Listing of Cosmetic](#)'.

Step 4. Click on ‘SUBMISSION ACCEPTED’ on the most recently accepted Cosmetic Product Listing submission containing the product(s) you wish to relist.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	RESPONSIBLE PERSON NAME	DETAILS
SUBMISSION ACCEPTED	1187ca46-293e-5ee0-e063-6394a90ad2f7	39e48963-6f40-b29b-e063-6b94af0a6acf	cmXXXXXXXXXXXX@direct	9	COSMETIC - UPDATE	Test Name	DETAILS

Step 5. Click on ‘**CREATE NEW VERSION**’, unlocking the SPL to review the SPL and make any updates.



The screenshot shows the FDA Direct Cosmetics Direct interface. At the top left, the logo reads "FDA Direct Cosmetics Direct". Below the logo, there are navigation tabs: "All Submissions", "Cosmetic Product Listing", and "Cosmetic Products".

Below the navigation tabs, there are four buttons: "VIEW SPL", "DOWNLOAD SPL", "CREATE NEW VERSION" (highlighted with a red box), and "<< RETURN".

Below the buttons, there is a note: "Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Registration of Cosmetic Product Facility submission form. A red asterisk (*) indicates a required field." Below the note, there is a link: "For assistance with validation errors and general questions regarding electronic registration and listing of cosmetic product facilities and products, contact cosmeticsdirect@fda.hhs.gov".

Below the note, there is a section titled "DOCUMENT TYPE DETAILS". This section contains the following fields:

Document Type: *	COSMETIC PRODUCT LISTING		
Set ID: *	1187ca46-293e-5ee0-e063-6394a90ad2f7	Version Number: *	8
Root ID: *	389307a8-f4bb-1f7d-e063-6a94af0a3e5d	Effective Date: *	06-27-2025

Step 6. Under ‘DOCUMENT TYPE’, select ‘COSMETIC PRODUCT LISTING – UPDATE’.

All Submissions > Cosmetic Product Listing > **Cosmetic Products** 

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

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

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

DOCUMENT TYPE DETAILS

Document Type: *	--Select One--			
Set ID: *	--Select One-- COSMETIC PRODUCT LISTING	Generate New	Version Number: *	9
Root ID: *	COSMETIC - UPDATE COSMETIC - ABBREVIATED RENEWAL	Generate New	Effective Date: *	07-14-2025 

Option 1 – Edit/Update Product

Step 7. 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 want to relist.

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

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

row(s) 1 - 61 of 61

EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS CHANGE STATUS FOR ALL PRODUCTS ▾	CLONE
	XX-XXXXXXXXXX	Product Name	DISCONTINUED ▾	
	53-583913-079606	SOLO NAVY MEN	LISTED ▾	

Step 8. Click on ‘**RELIST PRODUCT**’.

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

RELIST PRODUCT
DELETE
<< RETURN

COSMETIC PRODUCTS

Cosmetic Product Listing Number: 53-12345678987 Product marked as discontinued!

Product Name (As listed on label): *

Product Webpage Link:

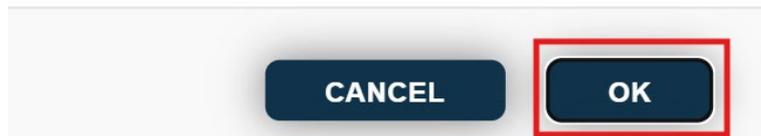
Fragrance or Flavor: *

Professional Use Only:

Option 1 – Edit/Update Product (continued)

Step 9. To relist the product, click ‘OK’ when prompted.

Are you sure you want to relist the Product?



Step 10. After clicking ‘OK’, you will be taken back to the Cosmetic Product Listing page and a green message will appear across your screen stating, ‘Cosmetic Product Relisted’.



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

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

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

row(s) 1 - 61 of 61

EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
			CHANGE STATUS FOR ALL PRODUCTS ▾	
	XX-XXXXXXXXXX	Product Name	LISTED ▾	
	XX-XXXXXXXXXX	Test Product B	LISTED ▾	

After completing ‘Option 1’, proceed to ‘Step 15’.

Option 2 – Product Marketing Status

Step 11. Locate the ‘**PRODUCT MARKETING STATUS**’ column under the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section.

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

Step 12. Identify the discontinued product you want to relist. In the **PRODUCT STATUS** column, click the drop- down menu and select ‘**LISTED**’.

EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS
	XX-XXXXXX-XXXXXX	PRODUCT ONE	DISCONTINUE ALL PRODUCTS ▾
	XX-XXXXXX-XXXXXX	PRODUCT TWO	<div style="border: 2px solid red; padding: 2px;"> DISCONTINUED ▾ LISTED ▾ LISTED DISCONTINUED </div>

Option 2 – Product Marketing Status (continued)

Step 13. If you want to relist all discontinued products, click the drop-down menu and locate ‘**LIST ALL PRODUCTS**’.

EDIT / UPDATE PRODUCT	COSMETIC PRODUCT LISTING NUMBER	PRODUCT NAME (AS LISTED ON LABEL)	PRODUCT MARKETING STATUS	CLONE
	XX-XXXXXX-XXXXXX	PRODUCT ONE	<div style="border: 2px solid red; padding: 2px;"> CHANGE STATUS FOR ALL PRODUCTS ▾ CHANGE STATUS FOR ALL PRODUCTS LIST ALL PRODUCTS DISCONTINUE ALL PRODUCTS </div>	
	XX-XXXXXX-XXXXXX	PRODUCT TWO		

PRODUCT MARKETING STATUS	CLONE
<div style="border: 2px solid red; padding: 2px;"> LIST ALL PRODUCTS ▾ </div>	
<div style="border: 2px solid red; padding: 2px;"> LISTED ▾ </div>	
<div style="border: 2px solid red; padding: 2px;"> LISTED ▾ </div>	

Step 14. 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 ‘LISTED’

Step 15. Submit the SPL to FDA following the instructions in Slide [#25](#).

ASSISTANCE WITH VALIDATION ERRORS

For assistance with validation errors received in Cosmetics Direct, contact [**CosmeticsDirect@fda.hhs.gov**](mailto:CosmeticsDirect@fda.hhs.gov).