

COSMETICS *DIRECT*

PRODUCT LISTING

Tutorial

APRIL 2024

Cosmetics Direct Home Page

Home page of Cosmetics Direct after creating an account within FDA Direct.

SUBMISSIONS:
Two types of selections are shown here: Registration of Cosmetic Product Facility and Cosmetic Product Listing. Depending on the account created, account holder may have additional form selections.

ALL SUBMISSIONS ← The ability to view all the previous submissions based on user's access.

SELF-HELP:
Articles and weblinks are provided for additional information.

MANAGE ACCOUNT:
Manage sub-users of the account and update profile information. 'MANAGE USERS' element is available for Admin users only

Navigation and Content:

- Left Sidebar:**
 - COSMETIC REGISTRATION AND LISTING**
 - REGISTRATION OF COSMETIC PRODUCT FACILITY
 - COSMETIC PRODUCT LISTING
 - SELF-HELP**
 - Structured Product Labeling Resources
 - UNII Search
 - Requests UNII
 - DUNS Search
 - FEI Search Portal
 - Registration and Listing of Cosmetic Product Facilities and Products Industry Guidance
 - Tutorials
 - MANAGE ACCOUNT**
 - EDIT USER PROFILE
 - MANAGE USERS
- Top Navigation:** All Submissions
- Search and Filter:** Search bar with 'GO' button and 'ACTIONS' dropdown.
- Table Headers:** STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, DOCUMENT LABEL, LAST MODIFIED USER, LAST MODIFIED DATE, and a lock icon.



Cosmetic Product Listing

Cosmetic Product Listing Home Page

Home page of the Cosmetics Product Listing after logging into FDA Direct and selecting Cosmetic Product Listing under Cosmetic Registration and Listing.

SUBMISSIONS:
Two types of selections are shown here: Registration of Cosmetic Product Facility and Cosmetic Product Listing. Depending on the account created, account holder may have additional form selections.

The ability to view all the previous registration of cosmetic product facility submissions based on user's access.

SEARCH PRODUCT BY PRODUCT NAME

CREATE NEW/UPLOAD FILE

SELF-HELP:
Articles and weblinks are provided for additional information.

MANAGE ACCOUNT:
Manage sub-users of the account and update profile information. 'MANAGE USERS' element is available for Admin users only.

Navigation and Content:
 - Top Left: FDA Direct Cosmetics
 - Top Center: SUBMISSIONS: (Callout)
 - Top Right: Search Product, CREATE NEW/UPLOAD FILE (Callout)
 - Left Sidebar: COSMETIC REGISTRATION AND LISTING, SELF-HELP, MANAGE ACCOUNT
 - Main Content: COSMETIC PRODUCT LISTING, Search bar, ACTIONS dropdown, Table headers (STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, DOCUMENT TYPE, RESPONSIBLE PERSON NAME, DETAILS, LAST MODIFIED USER, MODIFIED DATE, Lock icon)
 - Bottom: FDA Home | Br... | sk | FAQs, Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy



Create a New Product Listing or Upload an Existing File

Create a New Cosmetic Product Listing or Upload an Existing File

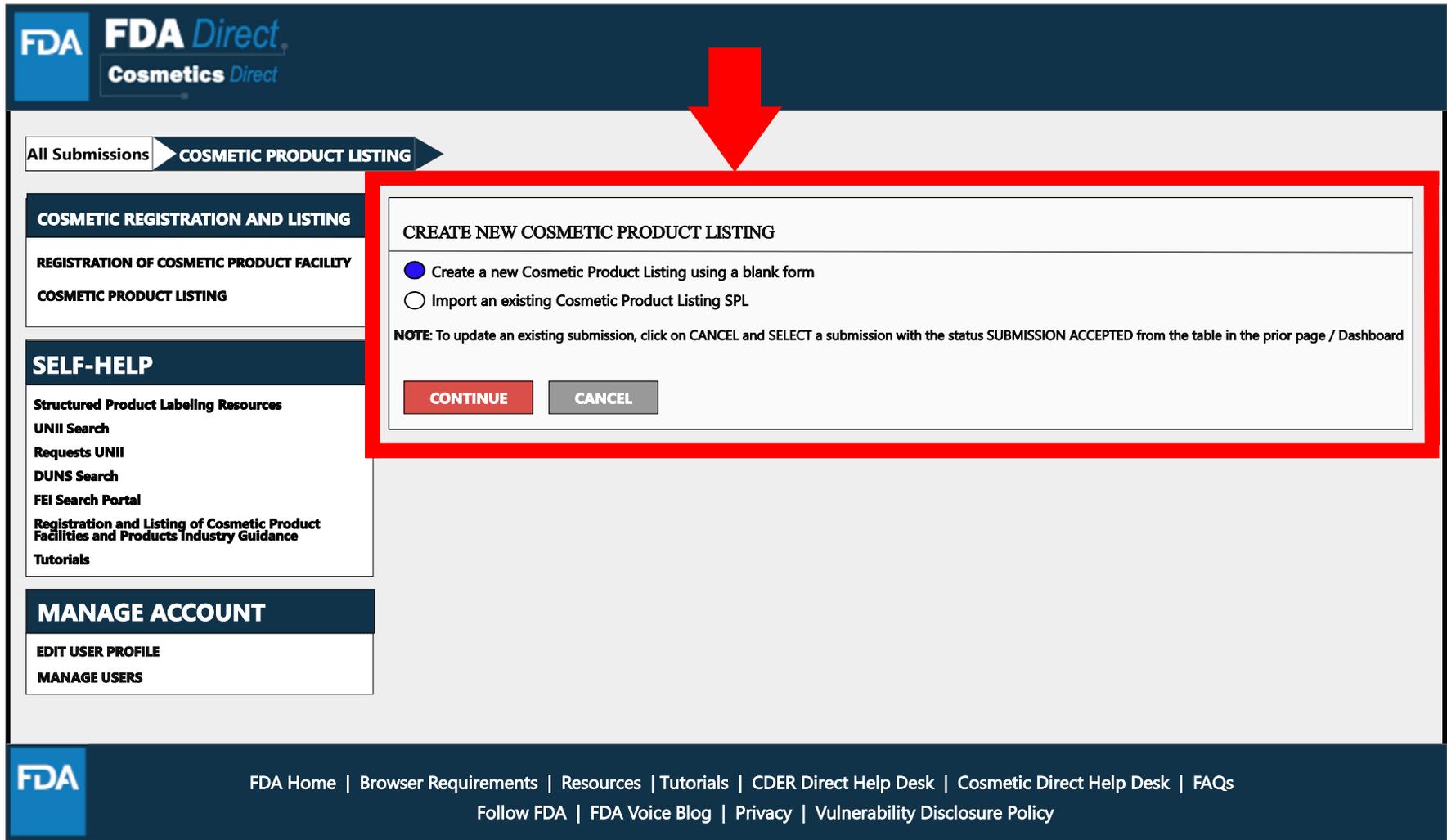


Selecting the **CREATE NEW/UPLOAD FILE** box from the **Cosmetic Product Listing home page** will direct a user to the option of creating an initial Cosmetic Product Listing using a blank form or importing an FDA-accepted SPL stored on your computer in a valid XML zip file. SPL (Structured Product Labeling) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information. Importing an existing Cosmetic Product Listing SPL is beneficial for bulk submission.

The screenshot shows the FDA Direct Cosmetics Direct interface. At the top left is the FDA logo and 'FDA Direct Cosmetics Direct'. A navigation bar shows 'All Submissions' and 'COSMETIC PRODUCT LISTING'. A sidebar on the left contains sections for 'COSMETIC REGISTRATION AND LISTING' (with sub-items: 'REGISTRATION OF COSMETIC PRODUCT FACILITY', 'COSMETIC PRODUCT LISTING'), 'SELF-HELP' (with sub-items: 'Structured Product Labeling Resources', 'UNII Search', 'Requests UNII', 'DUNS Search', 'FEI Search Portal', 'Registration and Listing of Cosmetic Product Facilities and Products Industry Guidance', 'Tutorials'), and 'MANAGE ACCOUNT' (with sub-items: 'EDIT USER PROFILE', 'MANAGE USERS'). The main content area is titled 'CREATE NEW COSMETIC PRODUCT LISTING' and contains two radio button options: 'Create a new Cosmetic Product Listing using a blank form' and 'Import an existing Cosmetic Product Listing SPL'. A note below the options states: 'NOTE: To update an existing submission, click on CANCEL and SELECT a submission with the status SUBMISSION ACCEPTED from the table in the prior page / Dashboard'. At the bottom of the main content area are two buttons: 'CONTINUE' and 'CANCEL'. A large red arrow points from the top of the page down to the 'CREATE NEW COSMETIC PRODUCT LISTING' section, which is also highlighted with a red border.

Create a New Cosmetic Product Listing

Create an Initial Cosmetic Product Listing using a blank form.



The screenshot shows the FDA Direct Cosmetics Direct interface. At the top left, the FDA logo and 'FDA Direct Cosmetics Direct' are displayed. Below this, a navigation bar shows 'All Submissions' and 'COSMETIC PRODUCT LISTING'. The main content area is divided into three sections: 'COSMETIC REGISTRATION AND LISTING', 'SELF-HELP', and 'MANAGE ACCOUNT'. The 'COSMETIC REGISTRATION AND LISTING' section contains 'REGISTRATION OF COSMETIC PRODUCT FACILITY' and 'COSMETIC PRODUCT LISTING'. The 'SELF-HELP' section includes 'Structured Product Labeling Resources', 'UNII Search', 'Requests UNII', 'DUNS Search', 'FEI Search Portal', 'Registration and Listing of Cosmetic Product Facilities and Products Industry Guidance', and 'Tutorials'. The 'MANAGE ACCOUNT' section includes 'EDIT USER PROFILE' and 'MANAGE USERS'. The 'CREATE NEW COSMETIC PRODUCT LISTING' form is highlighted with a red box and contains the following text:

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

Buttons: **CONTINUE** (red), **CANCEL** (grey)

At the bottom of the page, the FDA logo is on the left, and the following text is centered: 'FDA Home | Browser Requirements | Resources | Tutorials | CDER Direct Help Desk | Cosmetic Direct Help Desk | FAQs | Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy'.

Document Type Details Section

Set ID and Root ID are auto-generated, and the Effective Date is the date the submission is created, but users can modify it. Once an SPL has been submitted, this date cannot be changed by users.

FDA Direct
Cosmetics Direct

All Submissions > **COSMETIC PRODUCT LISTING** > **COSMETIC PRODUCTS**

SAVE AS DRAFT <<RETURN

Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out this Cosmetic Product Listing Submission Form. A Red asterisk (*) indicate required fields. 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: * fd8c4f0b-ca3a-82e2-e053-6394a90aa8de [Generate New](#)

Version Number: * 1

Root ID: * fe8b3cc9-aaa9-9846-e053-6b94af0a347d [Generate New](#)

Effective Date: * 06-20-2023

+ PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT

+ CONFIRMATION

+ ADDITIONAL CO

Set ID and Root ID are auto-generated, and Effective Date is the date the submission is created, but users can modify it. Once an SPL has been submitted, this date cannot be edited by users.

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Document Type Tool Tips

A ***RED*** asterisk indicates a field is mandatory. A dashed underline indicates help text (tool-tips) if clicked.

The screenshot shows the 'Document Type' selection interface. Red arrows point from callout boxes to specific fields: 'Document Type', 'Set ID', 'Root ID', 'Version Number', and 'Effective Date'. Each field has a corresponding tool-tip box with an 'X' icon in the top right corner.

Document Type (X)
COSMETIC PRODUCT LISTING-(INITIAL): The responsible person of a cosmetic product that is marketed on December 29, 2022, must submit a cosmetic product listing, or ensure such submission is made, not later than December 29, 2023, or for a cosmetic product that is first marketed after December 29, 2022, within 120 days of marketing such product in interstate commerce (section 607(c) (2) of the FD&C Act). Consistent with the approach for registration of a facility that starts manufacturing or processing cosmetic products after December 29, 2022 (section 607(a)(1)(B) of the FD&C Act), FDA expects the product listing for a cosmetic product to be submitted within 120 days after marketing the product, or within 120 days after December 29, 2023, whichever is later.
Note: On November 8, 2023, FDA issued a guidance for industry titled "Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing." This guidance explains that FDA does not intend to enforce the requirements under section 607 of the FD&C Act related to cosmetic product listing until July 1, 2024.
COSMETIC-UPDATE(CHANGES TO LISTING or DISCONTINUATION OF LISTING) (ANNUAL): The responsible person must provide any updates to such listing annually (CHANGES TO LISTING or DISCONTINUATION OF LISTING) (section 607(c)(5) of the FD&C Act). This includes an update that the product was discontinued.
COSMETIC-ABBREVIATED RENEWAL: FDA is providing for an abbreviated process for the renewal of any cosmetic product listing, as required under section 607(c)(3), for which there has been no change since the responsible person submitted the previous listing. For more information visit: Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)

Version Number (X)
 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 (X)
 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.

Set ID (X)
 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.

Root ID (X)
 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.

Form Fields:
 Document Type:
 Set ID: *
 Root ID:
 Version Number: * [1]
 Effective Date: * [06-20-2023] [Calendar Icon]

Document Type Details

By selecting the drop-down (v), three document types options will appear: COSMETIC PRODUCT LISTING (initial), COSMETIC – UPDATE, and COSMETIC – ABBREVIATED RENEWAL.

FDA Direct
Cosmetics Direct

All Submissions > COSMETIC PRODUCT LISTING > COSMETIC PRODUCTS >

DOCUMENT TYPE DETAILS

Document Type: v

Set ID: *

Root ID: *

Version Number: *

Effective Date: *

+ COSMETIC PRODUCTS

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out the field. For assistance with validation errors and general questions regarding electronic registration and listing of cosmetics, visit www.fda.gov/cosmetics.

SAVE AS DRAFT <<RETURN

Risk (*) indicate required fields.
@fda.hhs.gov.

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A Guide that will help the user understand different submission stages such as, VALIDATE SPL or SUBMIT SPL.

Document Type: v

Set ID: *

Root ID: *

Document Type Details: Abbreviated Renewal

Depending on which document type is selected, an ALERT box will appear as shown below.

The screenshot shows the FDA Direct interface for document type details. A red-bordered alert box is overlaid on the form, containing the following text: "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." The alert box has "OK" and "Cancel" buttons. Below the alert, the "DOCUMENT TYPE DETAILS" section is visible. The "Document Type" dropdown is set to "COSMETIC - ABBREVIATED RENEWAL". A red arrow points to this dropdown. Other form fields include "Set ID" (fd8c4f0b-ca3a-82e2-e053-6394a90aa8de), "Root ID" (fe8b3cc9-aaa9-9846-e053-6b94af0a347d), "Submission Number" (1), and "Effective Date" (06-20-2023). Below the details section are expandable sections for "COSMETIC PRODUCTS", "CONFIRMATION STATEMENT", and "ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT". The footer contains navigation links: FDA Home | Browser Requirements | Resources | Tutorials | CDER Direct Help Desk | Cosmetic Direct Help Desk | FAQs | Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy.

Product, Ingredient, and Facility Listing of The Cosmetic Product Details



- Enter the responsible person as listed on the label information.
- Select “ADD PRODUCT(S), INGREDIENT (s), and FACILITY(ies) to add the product information.

The screenshot shows the 'Cosmetic Product Listing' form on the FDA Direct website. The form is titled 'DOCUMENT TYPE DETAILS' and contains several sections. A red box highlights the 'PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT' section, which includes a question about small business status, a 'Type of Business' dropdown (with options MANUFACTURER, PACKER, DISTRIBUTOR), and input fields for 'Responsible Person Name', 'Responsible Person Phone Number', and 'Responsible Person D&B D-U-N-S Number'. A red arrow points to the 'Responsible Person Name' field. Below this section is a red button labeled 'ADD PRODUCT(S), INGREDIENT(S), and FACILITY(IES)'. The form also includes sections for 'CONFIRMATION STATEMENT' and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. The footer contains navigation links for FDA Home, Browser Requirements, Resources, Tutorials, CDER Direct Help Desk, Cosmetic Direct Help Desk, and FAQs, along with a 'Follow FDA' link and a 'Vulnerability Disclosure Policy' link.

FDA Direct Cosmetics Direct

All Submissions > COSMETIC PRODUCT LISTING > COSMETIC PRODUCTS >

SAVE AS DRAFT <<RETURN

Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out this Cosmetic Product Listing Submission form. A Red asterisk (*) indicate required fields. For assistance with validation errors and general questions regarding electronic registration and listing of cosmetic product facilities and products, contact cosmeticsdirect@fda.hhs.gov.

+ DOCUMENT TYPE DETAILS

- PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT

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): *

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

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

Parent Company Name (if applicable):

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

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

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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Select Product Category Code(s)



- To add one or multiple **PRODUCT CATEGORY CODE(S)**, click the **‘MANAGE CATEGORIES’** button in *Product Category Code(s)* section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section.

FDA Direct
Cosmetics Direct

All Submissions > COSMETIC PRODUCT LISTING > COSMETIC PRODUCTS > **PRODUCT(S), INGREDIENT(S), and FACILITY(IES)**

SAVE PRODUCT << RETURN

COSMETIC PRODUCTS

Cosmetic Product Listing Number:

Product Name (As listed on label): *

Product Webpage Link:

Fragrance or Flavor: -- Select --

Professional Use: -- Select --

PRODUCT CATEGORY CODE(S)

MANAGE CATEGORIES

INGREDIENTS

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

MANAGE INGREDIENTS

LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

ADD FACILITY

PRODUCT IMAGES

Upload image(s) of the label, any sides of the label whether it front, back or sides.

Drag and Drop

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

UPLOAD CANCEL

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

Product Category Code(s) Section



- A selection window titled *COSMETIC PRODUCT CATEGORIES* will display.
- Select all that apply.
- Click on the + icon in front of each category to display additional elements.

FDA **FDA Direct**
Cosmetics Direct

All Submissions > COSMETIC PRODUCT LISTING > COSMETIC PRODUCTS > PRODUCT(S), INGREDIENT(S), and FACILITY(IES) > **COSMETIC PRODUCT CATEGORIES**

SAVE CATEGORIES << RETURN

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

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

- (01) Baby products
 - (A) Baby shampoos
 - (B) Lotions, oils, powders, and creams
 - (C) Baby wipes
- (D) Other baby products
 - 1. Leave-on
 - 2. Rinse-off
- + (02) Bath preparations
- + (03) Eye makeup preparations (other than children's eye makeup preparations)
- + (04) Children's eye makeup preparations
- + (05) Fragrance preparations
- + (06) Hair preparations (non-coloring)
- + (07) Hair coloring preparations
- + (08) Makeup preparations (not eye)(other than makeup preparations for children)
- + (09) Makeup preparations for children (not eye)
- + (10) Manicuring preparations
- + (11) Oral products
- + (12) Personal cleanliness
- + (13) Shaving preparations
- + (14) Skin care preparations (creams, lotions, powder, and sprays)
- + (15) Suntan preparations
- + (16) Tattoo preparations
- (17) Other preparations (i.e., those preparations that do not fit another category)

Product Category Code(s)

After clicking 'SAVE CATEGORIES', all the selections 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.

The screenshot displays the FDA Direct Cosmetics Direct interface. At the top, there is a breadcrumb trail: **All Submissions** > **COSMETIC PRODUCT LISTING** > **COSMETIC PRODUCTS** > **PRODUCT(S), INGREDIENT(S), and FACILITY(IES)**. In the top right corner, there are buttons for **SAVE PRODUCT** and **<< RETURN**.

The main content area is titled **COSMETIC PRODUCTS** and contains several input fields:

- Cosmetic Product Listing Number:** (text input)
- Product Name (As listed on label):*** (text input)
- Product Webpage Link:** (text input)
- Fragrance or Flavor:*** (dropdown menu with "-- Select --")
- Professional Use Only :** (dropdown menu with "-- Select --")

Below this section, the **PRODUCT CATEGORY CODE(S)** tab is highlighted with a red box and a red arrow. To the right of this tab is a **MANAGE CATEGORIES** button. Underneath, a dark blue bar contains the text **PRODUCT CATEGORIES**. Below this bar, a list of categories is shown, including:

- (01) Baby products - (A) Baby shampoos

 The page number **1 - 1** is visible in the bottom right corner of this section.

At the bottom of the interface, there are expandable sections:

- + INGREDIENTS**
- + LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED**
- + PRODUCT IMAGES**

The footer of the page includes the FDA logo and the following text:

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Select Ingredients

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

FDA Direct Cosmetics Direct

All Submissions > COSMETIC PRODUCT LISTING > COSMETIC PRODUCTS > **PRODUCT(S), INGREDIENT(S), and FACILITY(IES)**

SAVE PRODUCT << RETURN

COSMETIC PRODUCTS

Cosmetic Product Listing Number:

Product Name (As listed on label): *

Product Webpage Link:

Fragrance or Flavor: * -- Select --

Professional only: -- Select --

— PRODUCT CATEGORY CODE(S)

— **INGREDIENTS**

MANAGE CATEGORIES

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.

— LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

ADD FACILITY

— PRODUCT IMAGES

Upload image(s) of the label, any sides of the label whether it front, back or sides.

Drag and Drop

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

UPLOAD CANCEL

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Cosmetic Ingredients Tab

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

- The ingredient list can be downloaded, edited, re-arranged, deleted, and uploaded.
- Select the **UPLOAD** button beneath the **DRAG AND DROP** in the **UPLOAD INGREDIENT FILE** section to replace the current Ingredient section.

The screenshot displays the FDA Direct Cosmetics Direct interface. At the top, there is a navigation breadcrumb: All Submissions > COSMETIC PRODUCT LISTING > COSMETIC PRODUCTS > PRODUCT(S), INGREDIENT(S), and FACILITY(IES) > **COSMETIC INGREDIENTS**. Below the breadcrumb are three buttons: **SAVE INGREDIENTS**, **DELETE INGREDIENTS**, and **<< RETURN**.

The main section is titled **INGREDIENTS**. A note states: "Fill in all INGREDIENTS that are included in this product or upload a prefilled ingredients file in the section below. Common, usual or chemical name will auto populate as you type along with its UNII. If the ingredient does not auto-populate, continue typing and select ADD. Ingredients can be re-ordered using drag and drop. Select an ingredient then move it into the new location." Below the note is a search field labeled "Ingredient UNII-Name:" with a search icon and an **ADD** button.

Below the search field is a table with the following structure:

INGREDIENT UNII CODE(S)	COMMON, USUAL OR CHEMICAL NAME (AS LISTED ON THE LABEL)	
<input type="text"/>	<input type="text"/>	1

Ingredients

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.

The screenshot shows the FDA Direct Cosmetics Direct interface. The breadcrumb trail is: All Submissions > COSMETIC PRODUCT LISTING > COSMETIC PRODUCTS > **PRODUCT(S), INGREDIENT(S), and FACILITY(IES)**. The 'COSMETIC PRODUCTS' section contains fields for: Cosmetic Product Listing Number, Product Name (As listed on label), Product Webpage Link, Fragrance or Flavor, and Professional Use Only. Below this is a red-bordered section for 'INGREDIENTS' with a 'MANAGE INGREDIENTS' button. A red arrow points from the 'Fragrance or Flavor' dropdown to the 'INGREDIENTS' section. The ingredients table is as follows:

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

Below the ingredients table are sections for 'LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED' and 'PRODUCT IMAGES'. The footer contains navigation links: FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs | Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy.

Selecting List of Facilities Where The Cosmetic is Manufactured or Processed



- To add the **LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED**, click the ‘**ADD FACILITY**’ button in **LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED** section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section.

The screenshot displays the FDA Direct Cosmetics Direct interface. At the top, the navigation bar includes 'All Submissions', 'COSMETIC PRODUCT LISTING', 'COSMETIC PRODUCTS', and 'PRODUCT(S), INGREDIENT(S), and FACILITY(IES)'. The main content area is titled 'COSMETIC PRODUCTS' and contains several sections: 'COSMETIC PRODUCTS' (with input fields for Listing Number, Product Name, and Product Webpage Link), 'PRODUCT CATEGORY CODE(S)', 'INGREDIENTS', 'LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED' (highlighted with a red box), and 'PRODUCT IMAGES'. A red arrow points from the 'LIST OF FACILITIES' section to the 'ADD FACILITY' button, which is also highlighted with a red box. The 'ADD FACILITY' button is located in a sidebar on the right side of the page, with other buttons like 'MANAGE CATEGORIES' and 'MANAGE INGREDIENTS' above it. The bottom of the page features the FDA logo and a footer with links to FDA Home, Browser Requirements, Resources, Tutorials, Help Desk, FAQs, Follow FDA, FDA Voice Blog, Privacy, and Vulnerability Disclosure Policy.



List of Facilities Where The Cosmetic is Manufactured or Processed IS NOT Exempt From Registration

If “NO” is selected for, “*Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?*” the FEI (FDA Establishment Identifier) is mandatory, and the name/address is greyed.

FDA **FDA Direct**
Cosmetics Direct

All Submissions > COSMETIC PRODUCT LISTING > COSMETIC PRODUCTS > PRODUCT(S), INGREDIENT(S), and FACILITY(IES) > **COSMETIC FACILITY**

SAVE FACILITY << **RETURN**

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

Facility FEI: *

Facility Name:

Facility Country:

Facility Street Address:

Facility City:

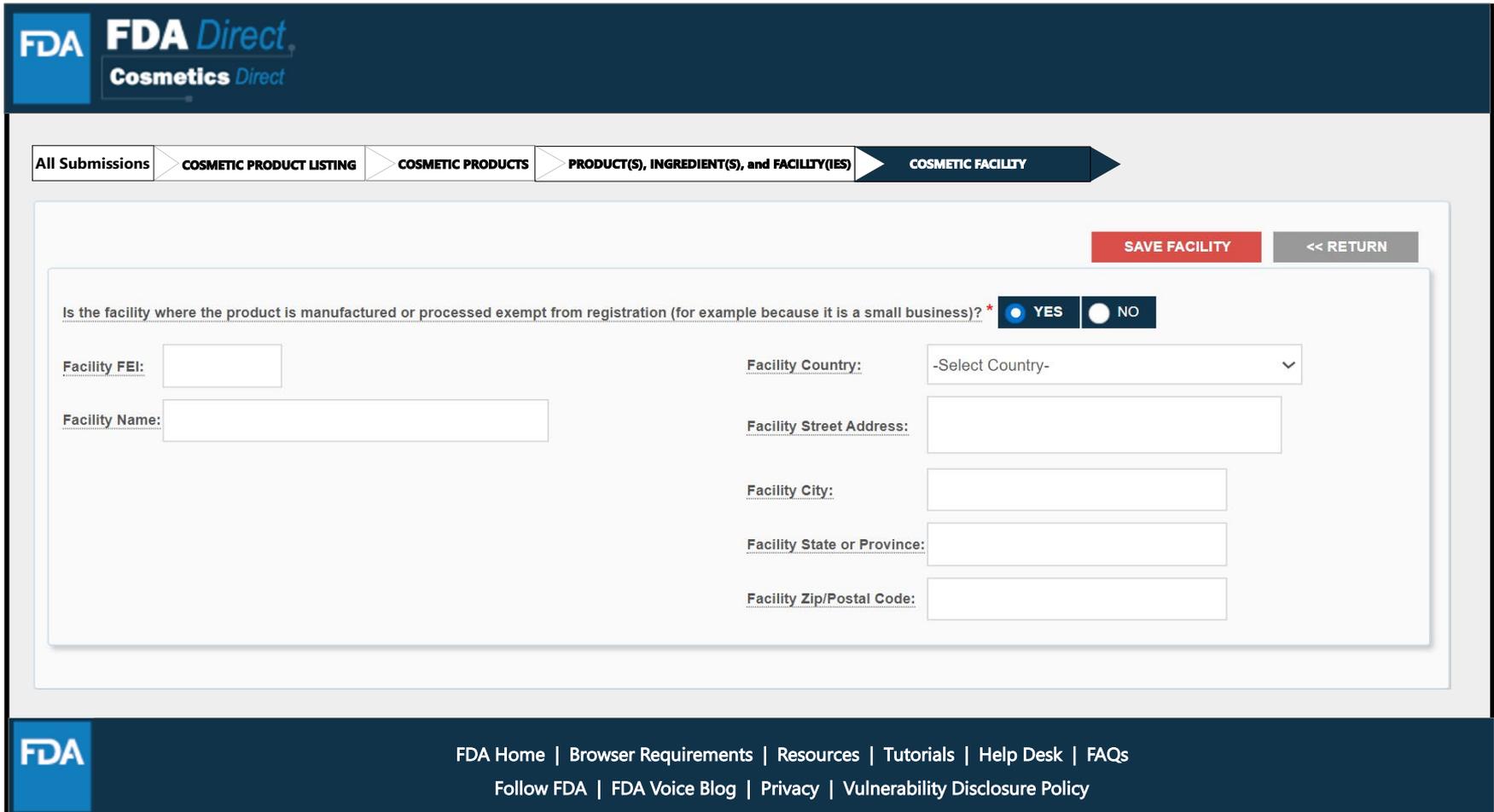
Facility State or Province:

Facility Zip/Postal Code:

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List of Facilities Where The Cosmetic is Manufactured or Processed IS Exempt From Registration

If “YES” is selected for, “*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.



The screenshot shows the 'COSMETIC FACILITY' form in the FDA Direct Cosmetics Direct system. The breadcrumb trail at the top indicates the navigation path: All Submissions > COSMETIC PRODUCT LISTING > COSMETIC PRODUCTS > PRODUCT(S), INGREDIENT(S), and FACILITY(IES) > COSMETIC FACILITY. The form includes a 'SAVE FACILITY' button and a '<< RETURN' button. The main question is 'Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?' with radio buttons for 'YES' (selected) and 'NO'. Below this are several optional input fields: Facility FEI, Facility Name, Facility Country (a dropdown menu currently showing '-Select Country-'), Facility Street Address, Facility City, Facility State or Province, and Facility Zip/Postal Code.

List of Facilities Where The Cosmetic is Manufactured or Processed



- Once complete, click '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.

The screenshot shows the FDA Direct Cosmetics Direct interface. The breadcrumb navigation is: All Submissions > COSMETIC PRODUCT LISTING > COSMETIC PRODUCTS > PRODUCT(S), INGREDIENT(S), and FACILITY(IES). The 'SAVE PRODUCT' and '<< RETURN' buttons are visible. The 'COSMETIC PRODUCTS' section contains fields for 'Cosmetic Product Listing Number', 'Product Name (As listed on label)*', 'Product Webpage Link', 'Fragrance or Flavor*', and 'Professional Use Only'. Below this is a red arrow pointing to the 'LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED' section, which is highlighted with a red border. This section includes an 'ADD FACILITY' button and a table with the following data:

EDIT	IS THIS FACILITY SMALL BUSINESS?	FACILITY FEI	FACILITY NAME	FACILITY ADDRESS
	No	0000000000		

At the bottom of the table, it says '1 - 1'. Below the table is a '+ PRODUCT IMAGES' section. The footer contains the FDA logo and links: FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs | Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy.

Product Images



- Upload an image of the label on any side of the label, whether it is front, back, or side, by selecting or dragging and dropping the image.
- The image must be in a .jpg format.
- Additionally, if you are uploading more than one image, ensure that the naming convention for each image is different/unique.

The screenshot shows the FDA Direct Cosmetics Direct interface. At the top, there is a navigation breadcrumb: All Submissions > COSMETIC PRODUCT LISTING > COSMETIC PRODUCTS > PRODUCT(S), INGREDIENT(S), and FACILITY(IES). Below this, there are buttons for 'SAVE PRODUCT' and '<< RETURN'. The main form area is titled 'COSMETIC PRODUCTS' and contains several input fields: 'Cosmetic Product Listing Number:', 'Product Name (As listed on label): *', 'Product Webpage Link:', 'Fragrance or Flavor: *' (with a dropdown menu), and 'Professional Use Only:' (with a dropdown menu). Below the form, there are sections for 'PRODUCT CATEGORY CODE(S)', 'INGREDIENTS', and 'LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED', each with a corresponding 'MANAGE' or 'ADD' button. The 'PRODUCT IMAGES' section is highlighted with a red box and a red arrow pointing to it. It contains the text 'Upload image(s) of the label, any sides of the label whether it front, back or sides.' and a 'Drag and Drop' area with a camera icon and the text 'Image of Product Label (Attach images of the front and back product labels by selecting the icon)'. Below this are 'UPLOAD' and 'CANCEL' buttons.

Product, Ingredient and Facility Listing of The Cosmetic Product

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

- AFTER selecting SAVE PRODUCT, the overall product details will be displayed under **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)**.
- ANY similar PRODUCT with common ingredient(s) can be **CLONED** by selecting the CLONE icon.
- If any edit needs to be made, select the icon under the EDIT tab.

FDA Direct Cosmetics Direct

All Submissions > COSMETIC PRODUCT LISTING > COSMETIC PRODUCTS > [User Icon]

SAVE AS DRAFT <<RETURN

Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out this Cosmetic Product Listing Submission Form. A Red asterisk (*) indicate required fields. For assistance with validation errors and general questions regarding electronic registration and listing of cosmetic product facilities and products, contact cosmeticsdirect@fda.hhs.gov.

+ DOCUMENT TYPE DETAILS

— PRODUCT, INGREDIENT AND FACILITY LISTING OF THE COSMETIC PRODUCT

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): *

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

Parent Company Name (if applicable):

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

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

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

row(s) 1 - 1 of 1

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

row(s) 1 - 1 of 1

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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Confirmation Statement

A dashed underline indicates help text (tool-tips) if clicked on, as shown below.

FDA Direct Cosmetics Direct

HOME > COSMETIC PRODUCT LISTING

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 Cosmetic Product Listing Submission Form. Red asterisk indicate required fields. For general questions regarding electronic registration and listing of cosmetic product facilities and products, contact eRLC@fda.hhs.gov.

+ DOCUMENT TYPE DETAILS

+ COSMETIC PRODUCTS

- CONFIRMATION STATEMENT

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

WARNING: A willfully false statement is a criminal offense, U.S. Code, Title 18, Section 1001.

AGREE

After understanding the confirmation statement. Select AGREE

Name of Submitter

Date (MM/DD/YYYY)

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

Name of Submitter (optional field) Enter the full name of the submitter

Date (optional field) Enter today's date, two digit month two digit day and four digit year

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Additional Contact Information for Authorized Agent

A dashed underline indicates help text (tool-tips) if clicked on, as shown below.

The screenshot shows the FDA Direct Cosmetics Direct interface. The main navigation bar includes 'HOME', 'COSMETIC PRODUCT LISTING', and a user icon. Below the navigation bar are buttons for 'SAVE AS DRAFT', 'SAVE AND VALIDATE', 'DELETE', and '<< RETURN'. A note states: 'Click on the Data element name for each field below to display instructions and helpful hints for filling out this Cosmetic Product Listing Submission Form. Red asterisk indicate required fields. For general questions regarding electronic registration and listing of cosmetic product facilities and products, contact eRLC@fda.hhs.gov.'

The main content area has three expandable sections: 'DOCUMENT TYPE DETAILS', 'COSMETIC PRODUCTS', and 'CONFIRMATION STATEMENT'. The 'CONFIRMATION STATEMENT' section is expanded, and the 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT' sub-section is highlighted with a red box. A red arrow points from this section to a zoomed-in view on the right.

The zoomed-in view shows the following fields:

- Additional Contact Name** (optional field) Provide an additional contact name
- Email** (optional field) Provide the additional contact person's email address
- Phone Number** (optional field) Provide the additional contact person's phone number including the area or the country code
- Phone Extension** (optional Field)

The bottom of the page features the FDA logo and navigation links: 'FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs' and 'Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy'.

Completed

After filling in all the required information, select **SAVE AND VALIDATE** to identify any errors.

OR

Select **SUBMIT SPL** for the form to be submitted to FDA.



Upload an Existing File

Upload an Existing File

To upload a file, select **Import an existing Cosmetic Product Listing SPL**. Importing an existing Cosmetic Product Listing SPL is beneficial for bulk submission.

The screenshot shows the FDA Direct Cosmetics Direct interface. The top navigation bar includes 'HOME' and 'COSMETIC PRODUCT LISTING'. A red arrow points to the 'COSMETIC PRODUCT LISTING' tab. The main content area is titled 'CREATE AN INITIAL COSMETIC PRODUCT LISTING' and contains two radio button options: 'Create an initial Cosmetic Product Listing using a blank form' (unselected) and 'Import an existing Cosmetic Product Listing SPL' (selected). A red border highlights this section. Below the options is a 'NOTE' and two buttons: 'CONTINUE' and 'CANCEL'. The left sidebar contains sections for 'SUBMISSIONS', 'SELF-HELP', and 'MANAGE ACCOUNT'. The bottom footer contains navigation links and the FDA logo.

FDA Direct Cosmetics Direct

HOME ► **COSMETIC PRODUCT LISTING**

SUBMISSIONS

REGISTRATION OF COSMETIC PRODUCT FACILITY
COSMETIC PRODUCT LISTING

SELF-HELP

FEI Search Portal (fda.gov)
Registration and Listing of Cosmetic Facilities and Products: Guidance for Industry (fda.gov)
Search for UNILs: precision.fda.gov/unilsearch
For UNIL requests contact: FDA-SRS@fda.hhs.gov.
Structured Product Labeling Resources | FDA
DUNSLink (dnb.com)

MANAGE ACCOUNT

EDIT USER PROFILE
MANAGE USERS

CREATE AN INITIAL COSMETIC PRODUCT LISTING

Create an initial 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**

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Upload a File

A user can upload a pre-existing ZIP file; this file 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.

The screenshot shows the FDA Direct Cosmetics Direct interface. At the top, there is a navigation bar with 'HOME' and 'COSMETIC PRODUCT LISTING'. The main content area is titled 'UPLOAD COSMETIC PRODUCT LISTING'. It features a section for 'Cosmetic Product Listing File' with a folder icon and the instruction 'Select a file or drop one here.' Below this, a note states: '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 referenced in the xml whose names end in ".jpg".' Two buttons are present: 'UPLOAD' (highlighted with a red box and a red arrow) and 'CANCEL'.

Upload a File (Example)

The content in the red box is an example of what a zip file could be; it may contain .xml file and image (jpg) files.

FDA Direct
Cosmetics Direct

HOME > COSMETIC PRODUCT LISTING

SUBMISSIONS

- REGISTRATION OF COSMETIC PRODUCT FACILITY
- COSMETIC PRODUCT LISTING

SELF-HELP

- FEI Search Portal (fda.gov)
- Registration and Listing of Cosmetic Facilities and Products: Guidance for Industry (fda.gov)
- Search for UNILs: precision.fda.gov/unilsearch
- For UNIL requests contact: FDA-SRS@fda.hhs.gov.
- Structured Product Labeling Resources | FDA
- DUNSLink (dnb.com)

MANAGE ACCOUNT

- EDIT USER PROFILE
- MANAGE USERS

UPLOAD COSMETIC PRODUCT LISTING

Cosmetic Product Listing File

dcba860b1f-6bae-123a-e032-6f94af0ac444

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 referenced in the xml whose names end in ".jpg".

UPLOAD **CANCEL**

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Zip File (Example)

An example to what an XML format could look like.

```
<?xml version="1.0" encoding="UTF-8"?>
<?xml-stylesheet href="https://www.accessdata.fda.gov/spl/stylesheet/spl.xsl" 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"/>
```

Upload a File (Submission)



After **UPLOADING A FILE** (XML ZIP FILE), the system will auto-fill all the data and the form will be ready to save and validate to check for any errors. This is an easy way to submit multiple Cosmetic Product Listing under one submission ID.

VALIDATE SPL: A popup will appear that says, “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.”

Select **SUBMIT SPL** for the form to be submitted to FDA. The Submit SPL box is a help tool that can guide a user through the process.

FDA Direct
Cosmetics Direct

All Submissions > COSMETIC PRODUCT LISTING > SPL Submission

Note: Click on the Data element name for each field below to display instructions and help for filling out this field. For assistance with validation errors and general questions regarding electronic registration of cosmetic products, click on the help icon.

- + DOCUMENT TYPE DETAILS
- + COSMETIC PRODUCTS
- + CONFIRMATION STATEMENT
- + ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

Submit SPL
Submit SPL to FDA.
Next Disable Tour

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.
Next

A Guide that will help the user understand different submission stages such as, VALIDATE SPL or SUBMIT SPL.

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34

Product Listing Status Examples

Listing Status: Validation in Progress

After SAVE AND VALIDATE, the Cosmetic Product Listing home page will have the following details as shown below. The status will be in **VALIDATION IN PROGRESS**.

FDA FDA Direct
Cosmetics Direct

HOME ▶ COSMETIC PRODUCT LISTING

SUBMISSIONS

REGISTRATION OF COSMETIC PRODUCT FACILITY

COSMETIC PRODUCT LISTING

COSMETIC PRODUCT LISTING

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

GO
ACTIONS ▼

CREATE NEW/UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
VALIDATION IN PROGRESS	fd850b1f-7bcd-165a-e053-6b65af0ac496	dcb860b1f-6bae-123a-e032-6f94af0ac444		1	INITIAL	Cosmetic Beauty (Different Color Aloe Gels)	DETAILS	First name Last name	07-JUN-2023 02:53:31

SELF-HELP

FEI Search Portal (fda.gov)

Registration and Listing of Cosmetic Facilities and Products: [Guidance for Industry \(fda.gov\)](https://www.fda.gov/guidance/industry)

Search for UNII: precision.fda.gov/unii/search

For UNII requests contact: FDA-SRS@fda.hhs.gov.

Structured Product Labeling Resources | [FDA](https://www.fda.gov/oc/structured-product-labeling)

DUNSLink ([dnb.com](https://www.dnb.com))

MANAGE ACCOUNT

EDIT USER PROFILE

MANAGE USERS

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

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Listing Status: Ready for Submission

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. Once the system has completed an INITIAL VALIDATION, the status **VALIDATION IN PROGRESS** will change to **READY FOR SUBMISSION**.

The screenshot shows the FDA Direct Cosmetics Direct web application. The main navigation bar includes 'HOME' and 'COSMETIC PRODUCT LISTING'. The left sidebar contains sections for 'SUBMISSIONS', 'SELF-HELP', and 'MANAGE ACCOUNT'. The main content area is titled 'COSMETIC PRODUCT LISTING' and contains a search bar with a 'GO' button and an 'ACTIONS' dropdown. A red arrow points to the search bar. Below the search bar is a table with one row of data. The table has columns for STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, DOCUMENT TYPE, TITLE, PRODUCT DETAILS, LAST MODIFIED USER, and LAST MODIFIED DATE. The first row shows a status of 'READY FOR SUBMISSION' and a title of 'Cosmetic Beauty (Different Color Aloe Gels)'. A red box highlights the table.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
READY FOR SUBMISSION	fd850b1f-7bcd-165a-e053-6b65af0ac496	dcb860b1f-6bae-123a-e032-6f94af0ac444		1	INITIAL	Cosmetic Beauty (Different Color Aloe Gels)	DETAILS	First name Last name	07-JUN-2023 02:53:31

Listing Status: Ready for Submission to Submit SPL

By clicking on the **READY FOR SUBMISSION**, the listing will be ready for **SUBMIT SPL**.

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

The screenshot shows the FDA Direct Cosmetics Direct interface. At the top left is the FDA logo and 'FDA Direct Cosmetics Direct' text. Below this is a navigation bar with 'HOME' and 'COSMETIC PRODUCT LISTING' (the latter is highlighted with a dark blue arrow). To the right of the navigation bar is a user icon and a 'SUBMIT SPL' button, which is highlighted with a red box and a red arrow pointing down from above. Below the navigation bar is a 'Note' section with a red border and a red arrow pointing left from the right. The note text reads: 'Note: This submission has passed the INITIAL VALIDATION but has NOT been ACTUALLY SUBMITTED TO FDA. Click ON "SUBMIT SPL" to SUBMIT.' Below the note are four expandable sections, each with a blue plus sign and a title: 'DOCUMENT TYPE DETAILS', 'COSMETIC PRODUCTS', 'CONFIRMATION STATEMENT', and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. At the bottom of the page is a footer with the FDA logo and a list of links: 'FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs | Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy'. The page number '38' is located in the bottom right corner.

Listing Status: Submit SPL to Submission Accepted

The status will change to **SUBMISSION ACCEPTED** after listing has been successfully completed. A **SUBMISSION ID** will be given to all **ACCEPTED SUBMISSIONS**.

FDA Direct
Cosmetics Direct

HOME | COSMETIC PRODUCT LISTING

SUBMISSIONS

REGISTRATION OF COSMETIC PRODUCT FACILITY
COSMETIC PRODUCT LISTING

SELF-HELP

FEI Search Portal (fda.gov)
Registration and Listing of Cosmetic Facilities and Products: Guidance for Industry (fda.gov)
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For UNIL requests contact: FDA-SRS@fda.hhs.gov.
Structured Product Labeling Resources | FDA
DUNSLink (dnb.com)

MANAGE ACCOUNT

EDIT USER PROFILE
MANAGE USERS

COSMETIC PRODUCT LISTING

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

Qv GO ACTIONS v CREATE NEW/UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
SUBMISSION ACCEPTED	fd850b1f-7bcd-165a-e053-6b65af0ac496	dcba860b1f-6bae-123e-32-6f94af0ac444	fe1237459100.54893654@direct	1	INITIAL	Cosmetic Beauty (Different Color Aloe Gels)	DETAILS	First name Last name	07-JUN-2023 02:53:31

Listing Status: Submission Accepted to View SPL and Download SPL

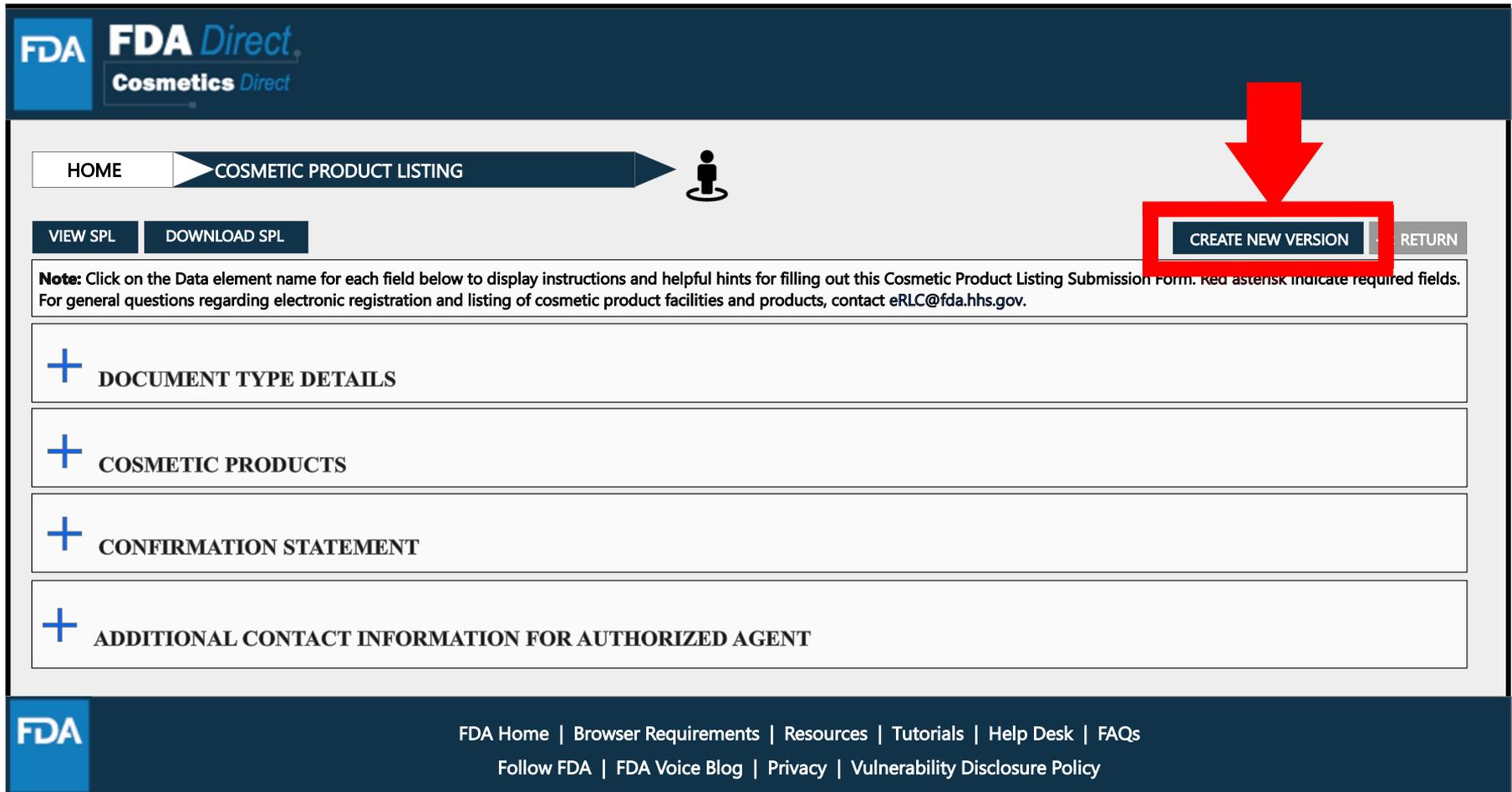


By clicking on the **SUBMISSION ACCEPTED** the system will allow user to **VIEW SPL** and **DOWNLOAD SPL**.

The screenshot displays the FDA Direct Cosmetics Direct interface. At the top left, the logo for FDA Direct Cosmetics Direct is visible. Below the logo, there is a navigation bar with a 'HOME' button and a 'COSMETIC PRODUCT LISTING' button. To the right of the navigation bar is a user profile icon. Below the navigation bar, there are two buttons: 'VIEW SPL' and 'DOWNLOAD SPL', both of which are highlighted with a red box and a red arrow pointing to them. To the right of these buttons are two more buttons: 'CREATE NEW VERSION' 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 Cosmetic Product Listing Submission Form. Red asterisk indicate required fields. For general questions regarding electronic registration and listing of cosmetic product facilities and products, contact eRLC@fda.hhs.gov.' Below the note, there are four expandable sections, each with a plus sign icon and a title: 'DOCUMENT TYPE DETAILS', 'COSMETIC PRODUCTS', 'CONFIRMATION STATEMENT', and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. At the bottom of the page, there is a footer with the FDA logo and a list of links: 'FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs | Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy'.

Clone Successfully Submitted SPL

By clicking on the **CREATE A NEW VERSION**, you can clone a successfully-submitted SPL as a starting point.



The screenshot shows the FDA Direct Cosmetics Direct interface. At the top left is the FDA logo and 'FDA Direct Cosmetics Direct' text. Below this is a navigation bar with 'HOME' and 'COSMETIC PRODUCT LISTING' (the latter is highlighted with a blue arrow). To the right of the navigation bar is a user icon. Below the navigation bar are two buttons: 'VIEW SPL' and 'DOWNLOAD SPL'. To the right of these is a button labeled 'CREATE NEW VERSION', which is highlighted with a red box and a red arrow pointing down to it. To the right of 'CREATE NEW VERSION' is a 'RETURN' button. Below the buttons is a note: 'Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out this Cosmetic Product Listing Submission Form. Red asterisks indicate required fields. For general questions regarding electronic registration and listing of cosmetic product facilities and products, contact eRLC@fda.hhs.gov.' Below the note are four expandable sections, each with a blue plus sign icon and a title: 'DOCUMENT TYPE DETAILS', 'COSMETIC PRODUCTS', 'CONFIRMATION STATEMENT', and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. At the bottom of the page is a footer with the FDA logo and a list of links: 'FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs | Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy'.

Listing Status: Validation Failure

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

The screenshot shows the FDA Direct Cosmetics Direct interface. The main navigation bar includes 'HOME' and 'COSMETIC PRODUCT LISTING'. The left sidebar contains sections for 'SUBMISSIONS', 'SELF-HELP', and 'MANAGE ACCOUNT'. The main content area is titled 'COSMETIC PRODUCT LISTING' and contains a search bar with a red arrow pointing to the search input field. Below the search bar is a table with one row of data. The table has columns for STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, DOCUMENT TYPE, TITLE, PRODUCT DETAILS, LAST MODIFIED USER, and LAST MODIFIED DATE. The STATUS column contains the text 'VALIDATION FAILURE' in blue. The TITLE column contains 'Cosmetic Beauty (Different Color Aloe Gels)'. The PRODUCT DETAILS column contains a link labeled 'DETAILS'. The LAST MODIFIED DATE column contains '07-JUN-2023 02:53:31'. A red box highlights the table area.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
VALIDATION FAILURE	fd850b1f-7bcd-165a-e053-6b65af0ac496	dcba860b1f-6bae-123a-e032-6f94af0ac444		1	INITIAL	Cosmetic Beauty (Different Color Aloe Gels)	DETAILS	First name Last name	07-JUN-2023 02:53:31

Listing Status: Validation Failure (List of Errors)

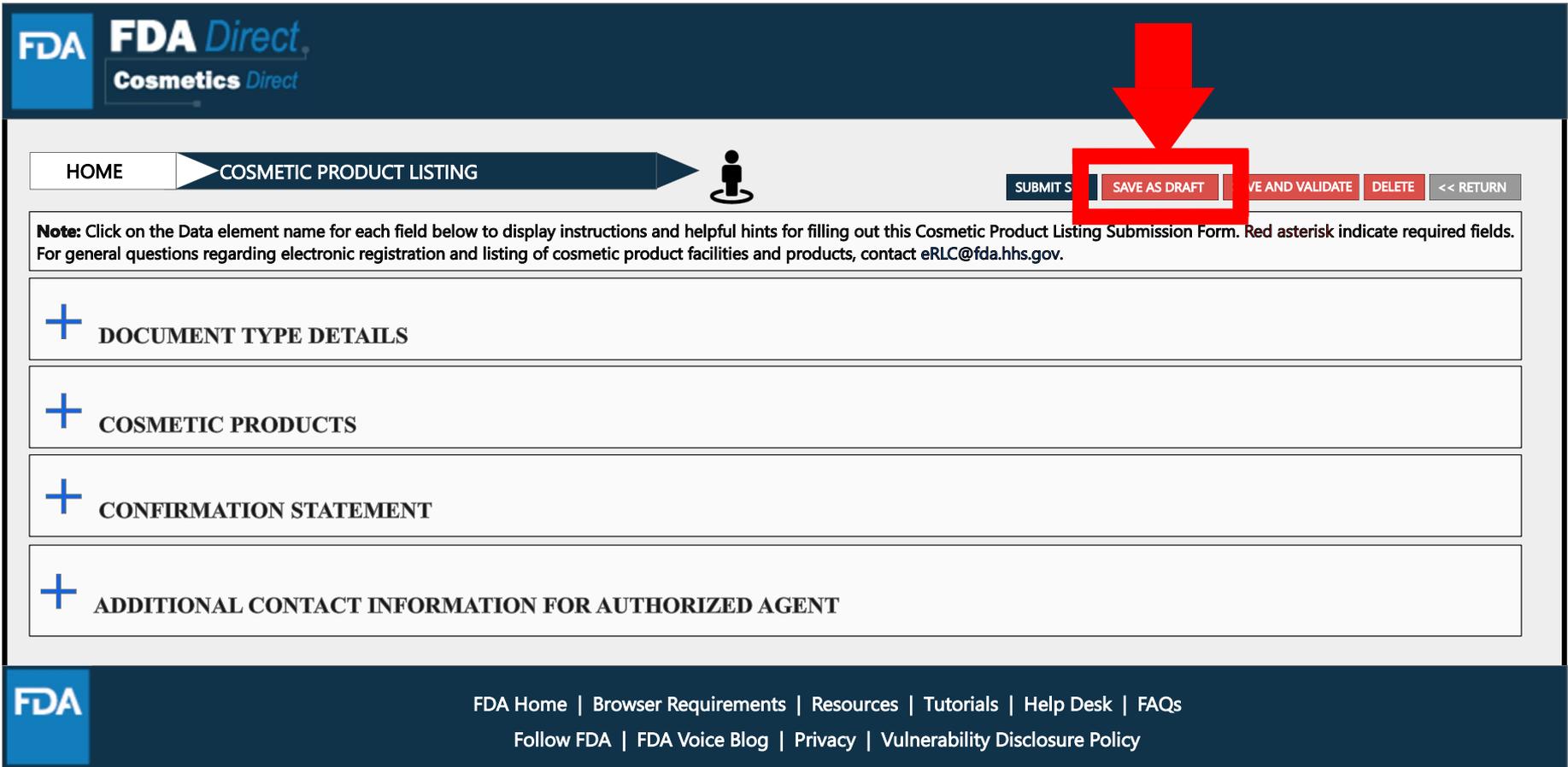


When user selects **VALIDATION FAILURE** status, the system will provide a list of errors that need to be fixed before submitting the SPL. After reviewing and fixing the errors, users can select **SUBMIT SPL** to resubmit the SPL or **SAVE AND VALIDATE** to check for any additional errors.

The screenshot shows the FDA Direct Cosmetics Direct interface. At the top left, the logo reads "FDA FDA Direct Cosmetics Direct". A prominent red banner at the top contains the message: "# ERRORS HAVE OCCURRED" with a close button (X) on the right. Below this, two lines of text provide instructions: "* Error Facility FEI Number : (Go to error)" and "* After reviewing and fixing these errors, select Submit SPL or Save and Validate to resubmit the SPL and check for any additional errors." Below the banner is a navigation bar with "HOME" and "COSMETIC PRODUCT LISTING" (the latter is highlighted with a blue arrow). To the right of the navigation bar are buttons for "SUBMIT SPL", "SAVE AS DRAFT", "SAVE AND VALIDATE", "DELETE", and "<< RETURN". Below the navigation bar is a note: "Note: Click on [redacted] element name for each field below to display instructions and helpful hints for filling out this Cosmetic Product Listing Submission Form. Red asterisk indicate required fields. For general questions regarding electronic registration and listing of cosmetic product facilities and products, contact eRLC@fda.hhs.gov." Below the note are four expandable sections, each with a blue plus sign icon: "DOCUMENT TYPE DETAILS", "COSMETIC PRODUCTS", "CONFIRMATION STATEMENT", and "ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT". A red arrow points from the "DOCUMENT TYPE DETAILS" section up to the "HOME" button in the navigation bar. At the bottom of the page is a footer with the FDA logo and a list of links: "FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs" and "Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy".

Listing Status: Save As Draft

By selecting **SAVE AS DRAFT** from any screen during the process of cosmetic product listing, the system will save all information and will bring the user back to the home page. The status will be in **DRAFT**.



The screenshot shows the FDA Direct Cosmetics Direct interface. At the top left, the logo reads "FDA Direct Cosmetics Direct". The navigation bar includes "HOME" and "COSMETIC PRODUCT LISTING" with a right-pointing arrow. A user icon is visible in the center. On the right side of the navigation bar, there are several buttons: "SUBMIT S...", "SAVE AS DRAFT" (highlighted with a red box and a red arrow), "SAVE AND VALIDATE", "DELETE", and "<< RETURN". Below the navigation bar, a note states: "Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out this Cosmetic Product Listing Submission Form. Red asterisk indicate required fields. For general questions regarding electronic registration and listing of cosmetic product facilities and products, contact eRLC@fda.hhs.gov." The main content area contains four expandable sections, each with a plus sign icon and a title: "DOCUMENT TYPE DETAILS", "COSMETIC PRODUCTS", "CONFIRMATION STATEMENT", and "ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT". The footer contains the FDA logo and a list of links: "FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs | Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy".

Listing Status: Draft

The registration of cosmetic product facility home page will have the following details as shown below. The status will be in **DRAFT**.

FDA FDA Direct
Cosmetics Direct

HOME
▶ COSMETIC PRODUCT LISTING

SUBMISSIONS

REGISTRATION OF COSMETIC PRODUCT FACILITY
COSMETIC PRODUCT LISTING

SELF-HELP

FEI Search Portal (fda.gov)
Registration and Listing of Cosmetic Facilities and Products: Guidance for Industry (fda.gov)
Search for UNILs: precision.fda.gov/unilsearch
For UNIL requests contact: FDA-SRS@fda.hhs.gov.
Structured Product Labeling Resources | FDA
DUNSLink (dnb.com)

MANAGE ACCOUNT

EDIT USER PROFILE
MANAGE USERS

COSMETIC PRODUCT LISTING

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

GO
ACTIONS ▾

CREATE NEW/UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
DRAFT	fd850b1f-7bcd-165a-e05 3-6b65af0ac496	dcba860b1f-6bae-123a-e0 32-6f94af0ac444		1	INITIAL	Cosmetic Beauty (Different Color Aloe Gels)	DETAILS	First name Last name	07-JUN-2023 02:53:31