

COSMETICS *DIRECT*

FACILITY REGISTRATION 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 Left:** All Submissions (dropdown arrow)
- Search Bar:** Search icon, input field, GO button, ACTIONS dropdown
- Table Header:**

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	🔒
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Registration of Cosmetic Product Facility

Registration of Cosmetic Product Facility Home Page



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

REGISTRATION OF COSMETIC PRODUCT FACILITY

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. A summary of registration information for cosmetic product facilities is provided below. For more information, please also refer to: Registration & Listing of Cosmetic Product Facilities and Products.

In general, 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 must register each facility (section 607(a)(1) of the FD&C Act). Please refer to FDA's guidance document for the description of "facility" and exemptions, such as for "small business" in the registration context: Guidance for Industry: Registration and Listing of Cosmetic Product Facilities and Products. For more information, please also refer to: Registration & Listing of Cosmetic Product Facilities and Products.

To facilitate the registration process, the owner or operator of a facility will need to obtain an FEI number before submitting the facility registration. To determine if an entity already has an FEI number, please refer to the FEI Search Portal. If your firm does not have an FEI number assigned by FDA, see How can I request an FEI? at FEI Search Portal (fda.gov).

CREATE NEW/UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT TYPE	LAST MODIFIED USER	LAST MODIFIED DATE	LOCK
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SELF-HELP:
Articles and weblinks are provided for additional information.

CREATE NEW/UPLOAD FILE

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

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Create a New Registration or Upload an Existing File

Create a New Registration for Cosmetic Product Facility or Upload an Existing File



Selecting the **CREATE NEW/UPLOAD FILE** box from the **Registration of Cosmetic Product Facility** home page will direct the user to this page, with an option of creating an initial Cosmetic Product Facility Registration using a blank form or importing an FDA-accepted SPL stored on a 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.

The screenshot displays the FDA Direct Cosmetics Direct interface. At the top left, the logo reads "FDA Direct Cosmetics Direct". Below the logo, a navigation bar shows "All Submissions" and "REGISTRATION OF COSMETIC PRODUCT FACILITY". A red arrow points to the "CREATE NEW/UPLOAD FILE" box in the navigation bar. The main content area is highlighted with a red box and contains the following text:

CREATE NEW REGISTRATION OF COSMETIC PRODUCT FACILITY

- Create a new Cosmetic Product Facility Registration using a blank form
- Import an existing Cosmetic Product Facility Registration 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)

The left sidebar contains the following sections:

- 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

The footer contains the following text:

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Create a New Product Facility Registration



Create an Initial Cosmetic Product Facility Registration using a blank form.

The screenshot displays the FDA Direct Cosmetics Direct interface. At the top left, the FDA logo and 'FDA Direct Cosmetics Direct' are visible. A navigation bar shows 'All Submissions' and 'REGISTRATION OF COSMETIC PRODUCT FACILITY'. The main content area is divided into three sections: 'COSMETIC REGISTRATION AND LISTING', 'SELF-HELP', and 'MANAGE ACCOUNT'. The 'COSMETIC REGISTRATION AND LISTING' section is active, showing 'REGISTRATION OF COSMETIC PRODUCT FACILITY' and 'COSMETIC PRODUCT LISTING'. The 'CREATE NEW REGISTRATION OF COSMETIC PRODUCT FACILITY' form is highlighted with a red box and contains the following options:

- Create a new Cosmetic Product Facility Registration using a blank form
- Import an existing Cosmetic Product Facility Registration 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 for 'CONTINUE' and 'CANCEL' are located at the bottom of the form.

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 edited by users.

FDA Direct
Cosmetics Direct

All Submissions > REGISTRATION OF COSMETIC PRODUCT FACILITY > SPL Submission

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

DOCUMENT TYPE DETAILS

Document Type: * -- Select One -- v

Set ID: * fd8c4f0b-ca3a-82e2-e053-6394a90aa8de [Generate New](#)

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

Version Number: * 1

Effective Date: * 06-20-2023

SAVE AS DRAFT <<RETURN

A Guide that will help the user understand different stages such as, SAVE AS DRAFT.

+ REGISTRATION DETAILS

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

Document Type Tool Tips

Document Type

Select one of the document types-

COSMETIC FACILITY REGISTRATION-(INITIAL): Every person that, on December 29, 2022, owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States must register each facility no later than December 29, 2023 (section 607(a)(1)(A) of the FD&C Act).
Every person that owns or operates a facility that first engages, after December 29, 2022, in manufacturing or processing of a cosmetic product for distribution in the United States, must register such facility within 60 days of first engaging in such activity or by February 27, 2024, whichever is later (section 607(a)(1)(B) of the FD&C Act).
Note: On November 8, 2023, FDA issued a guidance for industry titled "Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing." This guidance explains that FDA does not intend to enforce the requirements under section 607 of the FD&C Act related to cosmetic product facility registration until July 1, 2024.

COSMETIC FACILITY REGISTRATION-ABBREVIATED RENEWAL: FDA is providing for an abbreviated renewal of registrations when there have not been any updates to the registration since the most recent facility registration submission, as required under section 607(a)(4) of the FD&C Act.

COSMETIC FACILITY REGISTRATION-AMENDMENT: Every person who is required to register must update their registration within 60 days of any changes to the information required for registration (section 607(a)(4) of the FD&C Act) (an "amended" registration). This includes any changes that result in cancellation of the registration.

COSMETIC FACILITY REGISTRATION-BIENNIAL RENEWAL: Every person who is required to register a facility must renew such registration biennially (i.e., every two years) (section 607(a)(2) of the FD&C Act).

COSMETIC FACILITY REGISTRATION-CANCELLATION: Every person who is required to register must update their registration within 60 days of any changes to the information required for registration (section 607(a)(4) of the FD&C Act). This includes any changes that result in cancellation of the registration.
for more information visit :Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)

Version Number

The Version Number gives sequential order to the different versions of an SPL submission. The version number is a whole number greater than zero, such as 6, 7, or 8. The version number is increased with each change to the SPL submission.

Enter a number greater than zero (0) in the Version Number field.

Effective Date

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

Set ID

This field is auto generated by the system.

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

Root ID

This field is auto generated by the system.

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

Version Number: *

Effective Date: *

Set ID: *

Root ID: *

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Document Type Details



By selecting the drop-down (v), five document type options will appear: COSMETICS FACILITY REGISTRATION-(initial), COSMETICS FACILITY REGISTRATION – ABBREVIATED RENEWAL, COSMETICS FACILITY REGISTRATION – AMENDMENT, COSMETICS FACILITY REGISTRATION – BIENNIAL RENEWAL, and COSMETICS FACILITY REGISTRATION – CANCELLATION

The screenshot shows the 'FDA Direct Cosmetics Direct' interface. At the top, there are navigation links for 'All Submissions', 'REGISTRATION OF COSMETIC PRODUCT FACILITY', and 'SPL Submission'. A 'SAVE AS DRAFT' button and a '<<RETURN' button are also present. A note states: 'Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out this Facility Registration 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.'

The 'DOCUMENT TYPE DETAILS' section is highlighted with a red box. It contains a 'Document Type' dropdown menu with a red arrow pointing to it. The dropdown menu is open, showing the following options: '-- Select One --', '--Select One--', 'COSMETIC FACILITY REGISTRATION', 'COSMETIC FACILITY REGISTRATION - ABBREVIATED RENEWAL', 'COSMETIC FACILITY REGISTRATION - AMENDMENT', 'COSMETIC FACILITY REGISTRATION - BIENNIAL RENEWAL', and 'COSMETIC FACILITY REGISTRATION - CANCELLATION'. To the right of the dropdown, there are fields for 'Version Number' (set to 1) and 'Effective Date' (set to 06-20-2023).

Below the 'DOCUMENT TYPE DETAILS' section, there are expandable sections for 'REGISTRATION STATEMENT', 'CONFIRMATION STATEMENT', and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'.

Document Type Details - Abbreviated renewal



Depending on which document type is selected, an ALERT box will appear. This alert box is for “Abbreviated renewal”

The screenshot shows the FDA Direct interface for 'Cosmetics Direct'. The main heading is 'REGISTRATION OF COSMETIC PRODUCT FACILITY'. A red-bordered alert box is overlaid on the form, containing the text: 'By selecting this document type, you are certifying that no changes have been made to your registration since the previous registration was submitted. Any changes made to the submission will be lost and the submission details will be reverted to the previous submission.' The alert box has 'OK' and 'Cancel' buttons. Below the alert box, the 'DOCUMENT TYPE DETAILS' section is visible. The 'Document Type' dropdown is set to 'COSMETIC FACILITY REGISTRATION - ABBREVIATED RENEWAL'. Other fields include 'Set ID' (fd8c4f0b-ca3a-82e2-e053-6394a90aa8de), 'Root ID' (fe8b3cc9-aaa9-9846-e053-6b94af0a347d), 'Version Number' (1), and 'Effective Date' (06-20-2023). Below this section are expandable sections for 'REGISTRATION DETAILS', '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, and Vulnerability Disclosure Policy.

Document Type Details - Cancellation



Depending on which document type is selected, an ALERT box will appear. This alert box is for “Cancellation”

The screenshot shows the FDA Direct interface for 'Cosmetics Direct'. The breadcrumb trail is 'All Submissions > REGISTRATION OF COSMETIC PRODUCT FACILITY'. A red-bordered alert box is overlaid on the page, containing the following text:

direct.fda.gov says
By selecting this document type, any changes made to the submission will be lost and the submission details will be reverted to the previous submission.

Buttons: OK, Cancel

The main form area is titled 'DOCUMENT TYPE DETAILS' and contains the following fields:

- Document Type:** COSMETIC FACILITY REGISTRATION - CANCELLATION (with a dropdown arrow)
- Set ID:** fd8c4f0b-ca3a-82e2-e053-6394a90aa8de (with a 'Generate New' link)
- Root ID:** fe8b3cc9-aaa9-9846-e053-6b94af0a347d (with a 'Generate New' link)
- Version Number:** 1
- Effective Date:** 06-20-2023 (with a calendar icon)

Below the 'DOCUMENT TYPE DETAILS' section are three expandable sections, each with a plus sign icon:

- REGISTRATION DETAILS
- CONFIRMATION STATEMENT
- ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

The footer contains the FDA logo and the following text: FDA Home | Browser Requirements | Resources | Tutorials | CDER Direct Help Desk | Cosmetic Direct Help Desk | FAQs | Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy

Registration Details Tool-Tips



A dashed underline indicates help text (tool-tips) if clicked on, as listed below. A link is also provided in the tool-tip for more information regarding the registration and listing of cosmetic product facilities and products.

The screenshot shows the 'REGISTRATION OF COSMETIC PRODUCT FACILITY' form in the FDA Direct Cosmetics Direct system. The form is divided into several sections: DOCUMENT TYPE DETAILS, REGISTRATION DETAILS, FACILITY CONTACT DETAILS, FACILITY BRAND NAMES, CONFIRMATION STATEMENT, and ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT. Two tool-tips are highlighted with red boxes and arrows. The first tool-tip, titled 'Is this a facility registration for a small business (optional registration)?', provides information about exemptions for small businesses under Section 612 of the FD&C Act. The second tool-tip, titled 'Facility FEI Number', explains the purpose of the 10-digit facility FEI number and provides instructions on how to obtain one if the firm does not have one assigned by the FDA.

Is this a facility registration for a small business (optional registration)?

(Optional) Indicate whether this registration is for a small business (optional registration) by selecting one of the options provided.

Section 612 of the FD&C Act provides exemptions to certain small businesses from the requirements of section 607 (Registration and Product Listing). However, such exemptions from the requirements of section 607 of the FD&C Act do not apply to any responsible person or facility engaged in the manufacturing or processing of any of the following products listed in section 612(b) of the FD&C Act:

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

For more information visit: [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#).

Facility FEI Number

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

To determine if an entity already has an FEI number, please refer to the [FEI Search Portal](#).

If your firm does not have an FEI number assigned by FDA, see [How can I request an FEI? at FEI Search Portal](#).

For more information visit: [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)

Registration Details



A ***RED*** asterisk indicates field is mandatory.

FDA **FDA Direct**
Cosmetics Direct

All Submissions > REGISTRATION OF COSMETIC PRODUCT FACILITY > SPL Submission

SAVE AS DRAFT <<RETURN

Notes: Click on the Data element name for each field below to display instructions and helpful hints for filling out this Facility Registration 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

- REGISTRATION DETAILS

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

Facility Name: *	<input type="text"/>	Facility Country: *	-Select Country- ▾
Facility FEI Number: *	<input type="text"/>	Facility Street Address: *	<input type="text"/>
Facility D&B D-U-N-S Number:	<input type="text"/>	Facility City: *	<input type="text"/>
Parent Company Name (if applicable):	<input type="text"/>	Facility State or Province:	<input type="text"/>
		Facility Zip/Postal Code:	<input type="text"/>

FACILITY CONTACT DETAILS

Name of the Owner and/or Operator of the Facility: *	<input type="text"/>	Facility Phone Number (Include Country/Area Code): *	<input type="text"/>
Facility Email: *	<input type="text"/>		

US AGENT

U.S. Agent Name (for foreign facilities): *	<input type="text"/>	U.S. Agent Phone Number (Include Country/Area Code): *	<input type="text"/>
U.S. Agent Email (if not available, enter *N/A*) *	<input type="text"/>	U.S. Agent Phone Extension:	<input type="text"/>

- FACILITY BRAND NAMES

ADD BRAND NAME

There are currently no Brand Names associated with this facility. To add a Brand Name, select "Add Brand Name".

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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Registration Details - US Agent



By selecting a country outside the U.S., the U.S. AGENT CONTACT INFORMATION will be needed. A dashed underline indicates help text (tool-tips) if clicked on, as listed below.

FDA Direct Cosmetics Direct

All Submissions > REGISTRATION OF COSMETIC PRODUCT FACILITY > SPL Submission

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 Facility Registration 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

- REGISTRATION DETAILS

Is this a facility registration for a small business (optional registration)?: Yes

Facility Name: *

Facility FEI Number: *

Facility D&B D-U-N-S Number:

Parent Company Name (if applicable):

FACILITY CONTACT DETAILS

Name of the Owner and/or Contact of the Facility: *

Facility Email: *

US AGENT

U.S. Agent Name (for foreign facilities): *

U.S. Agent Phone Number (Include Country/Area Code): *

U.S. Agent Email (if not available, enter "N/A") *

U.S. Agent Phone Extension:

- FACILITY BRAND NAMES

ADD BRAND NAME

There are currently no Brand Names associated with this facility. To add a Brand Name, select "Add Brand Name".

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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Brand Name



Add Brand Name of cosmetic products manufactured or processed at this facility by selecting **ADD BRAND NAME**.

FDA **FDA Direct**
Cosmetics Direct

All Submissions > REGISTRATION OF COSMETIC PRODUCT FACILITY > SPL Submission

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 Facility Registration 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

- REGISTRATION DETAILS

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

Facility Name:* Facility Country:*

Facility FEI Number:* Facility Street Address:*

Facility D&B D-U-N-S Number: Facility City:*

Parent Company Name (if applicable): Facility State or Province:

Facility Zip/Postal Code:

FACILITY CONTACT DETAILS

Name of the Owner and/or Operator of the Facility:* Facility Phone Number (Include Country/Area Code):*

Facility Email:*

US AGENT

U.S. Agent Name (for foreign facilities):* U.S. Agent Phone Number (Include Country/Area Code):*

U.S. Agent Email (if not available, enter "N/A")* U.S. Agent Phone Extension:

- FACILITY BRAND NAMES

ADD BRAND NAME

There are currently no Brand Names associated with this facility. To add a Brand Name, select "Add Brand Name".

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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Brand Names of Cosmetic Product(s) Manufactured or Processed in this Facility



Multiple Brand Names can be submitted by selecting **SAVE BRAND** and then select **ADD BRAND NAME**. Select all the Category Code(s) that apply to this Brand Name. A dashed underline indicates help text (tool-tips) if clicked on, as listed below.

FDA **FDA Direct**
Cosmetics Direct

All Submissions > REGISTRATION OF COSMETIC PRODUCT FACILITY > SPL Submission > **BRAND INFORMATION**

SAVE BRAND << RETURN

BRAND INFORMATION

Brand Name of cosmetic products: *

Responsible Person Name (As listed on the label): *

Product Category Code(s) (Select all that Apply):*

- (01) Baby products.
- (02) Bath preparations.
- (03) Eye makeup preparations (other than children's eye makeup preparations).
- (04) Children's eye makeup preparations.
- (05) Fragrance preparations.
- (06) Hair preparations (non-coloring).
- (07) Hair coloring preparations.
- (08) Makeup preparations (not eye)(other than makeup preparations for children).
- (09) Makeup preparations for children (not eye).
- (10) Manicuring preparations.
- (11) Oral products.
- (12) Personal cleanliness.
- (13) Shaving preparations.
- (14) Skin care preparations, (creams, lotions, powder, and sprays).
- (15) Suntan preparations.
- (16) Tattoo preparations.
- (17) Other preparations (i.e., those preparations that do not fit another category).

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Brand Name of Cosmetic Products

Enter brand names under which cosmetic products manufactured or processed in the facility are sold.
For more information, visit [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)

Responsible Person (As listed on the label)

Enter the responsible person name as it appears on the label.
For more information, visit [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)

Select all product category Code(s)

Select the product category or categories for this brand name. Each main product category has a sub-product category. And some sub-product categories have sub-sub product categories, select the one that applies to this brand name. (i.e., leave-on or rinse-off)
For more information, visit [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)

Brand Name of Cosmetic Product(s) Manufactured or Processed in this Facility (Example)



FDA **FDA Direct**
Cosmetics Direct

All Submissions > REGISTRATION OF COSMETIC PRODUCT FACILITY > SPL Submission > **BRAND INFORMATION**

SAVE BRAND << RETURN

BRAND INFORMATION

Brand Name of cosmetic products: *

Responsible Person Name (As listed on the label): *

Product Category Code(s) (Select all that Apply):*

- (01) Baby products.
- (02) Bath preparations.
- (03) Eye makeup preparations (other than children's eye makeup preparations).
- (04) Children's eye makeup preparations.
- (05) Fragrance preparations.
- (06) Hair preparations (non-coloring).
- (07) Hair coloring preparations.
- (08) Makeup preparations (not eye)(other than makeup preparations for children).
 - (a) Blushers and rouges (all types).
 - (b) Face powders.
 - (c) Foundations.
 - (d) Leg and body paints.
 - (e) Lipsticks and lip glosses.
 - (f) Makeup bases.
 - (g) Makeup fixatives.
 - (h) Other makeup preparations.
 - 1. Traditional applications.
 - 2. Airbrush applications.
- (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).
 - (a) Cleansing (cold creams, cleansing lotions, liquids, and pads).
 - (b) Depilatories.
 - (c) Face and neck (excluding shaving preparations).
 - 1. Leave-on.
 - 2. Rinse-off.
 - (d) Body and hand (excluding shaving preparations).
 - (e) Foot powders and sprays.
 - (f) Moisturizing.
 - (g) Night.
 - (h) Paste masks (mud packs).
 - (i) Skin fresheners.
 - (j) Other skin care preparations.
- (15) Suntan preparations.
- (16) Tattoo preparations.
- (17) Other preparations (i.e., those preparations that do not fit another category).

By selecting the (+) of the MAIN PRODUCT CATEGORY, a SUB PRODUCT CATEGORY will appear & if that sub product category has a SUB-SUB PRODUCT CATEGORY, (+) can be selected.

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Brand Name of Cosmetic Product Manufactured or Processed in this Facility (Example)



The information that was provided in the BRAND NAME TAB will appear under the FACILITY BRAND NAMES section.

FDA **FDA Direct**
Cosmetics Direct

All Submissions > REGISTRATION OF COSMETIC PRODUCT FACILITY > SPL Submission 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 Facility Registration 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

- REGISTRATION DETAILS

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

Facility Name: *

Facility FEI Number: *

Facility D&B D-U-N-S Number:

Parent Company Name (if applicable):

Facility Country: *

Facility Street Address: *

Facility City: *

Facility State or Province:

Facility Zip/Postal Code:

FACILITY CONTACT DETAILS

Name of the Owner and/or Operator of the Facility: *

Facility Phone Number (Include Country/Area Code): *

US AGENT INFORMATION

U.S. Agent Name (for foreign facilities): *

U.S. Agent Phone Number (Include Country/Area Code): *

U.S. Agent Phone Extension:

(if not available, enter "N/A") *

- FACILITY BRAND NAMES ADD BRAND NAME

EDIT	Brand Name	Responsible Person Name	Product Category Code(s)
	BRAND NAME	Responsible Person Name	(08) Makeup preparations (not eye)(other than makeup preparations for children) - (h) Other makeup preparations - 1. Traditional applications.

+ 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 listed below.

FDA Direct Cosmetics Direct

HOME > REGISTRATION OF COSMETIC PRODUCT FACILITY

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 Facility Registration 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

+ REGISTRATION DETAILS

- 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.

AGREE

Date (MM/DD/YYYY)

Name of Submitter

After understanding the confirmation statement. Select AGREE

+ 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 listed below.

FDA Direct Cosmetics Direct

REGISTRATION OF COSMETIC PRODUCT FACILITY

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 Facility Registration 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

+ REGISTRATION DETAILS

+ CONFIRMATION STATEMENT

- **ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT**

Additional Contact Name: **Phone Number**
(Include Area Code/ Country Code)

Email: **Phone Extension**

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Additional Contact Name [X]

(optional field) Enter an Additional contact information for individuals associated with the registration. For more information visit: [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)

Email [X]

(optional field) Provide the additional contact person's email address

Phone Number [X]

(optional field) Provide the additional contact person's phone number including the area or the country code. The format for Phone number should be <Country Code><Area Code><Subscriber Number > For example, in the U.S. the phone number would be 1-999-9999999 or 1-999-999-9999

Phone Extension [X]

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

Completed



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

OR

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

The screenshot displays the 'SPL Submission' stage of the 'REGISTRATION OF COSMETIC PRODUCT FACILITY' process. The breadcrumb trail shows 'All Submissions' > 'REGISTRATION OF COSMETIC PRODUCT FACILITY' > 'SPL Submission'. A navigation bar at the top includes buttons for 'SUBMIT SPL', 'SAVE AND VALIDATE', and 'DELETE', along with a '<< RETURN' button. Below the navigation bar, a 'Note' provides instructions on how to use the data elements. The main content area features four expandable sections: 'DOCUMENT TYPE DETAILS', 'REGISTRATION DETAILS', 'CONFIRMATION STATEMENT', and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. A red box highlights a help guide titled 'A Guide that will help the user understand different submission stages such as, VALIDATE SPL or SUBMIT SPL.' Two other red boxes highlight the 'Submit SPL' and 'Validate SPL' modal windows, which are also pointed to by red arrows from above. The 'Submit SPL' modal has 'Next' and 'Disable Tour' buttons, while the 'Validate SPL' modal has a 'Next' button.

Upload a SPL File

Upload an Existing File



In order to upload a file, select **Import an existing Cosmetic Product Facility Registration SPL**.

The screenshot shows the FDA Direct Cosmetics Direct interface. At the top, there is a navigation bar with the FDA logo and 'FDA Direct Cosmetics Direct'. Below this, there are two tabs: 'All Submissions' and 'REGISTRATION OF COSMETIC PRODUCT FACILITY'. The 'REGISTRATION OF COSMETIC PRODUCT FACILITY' tab is active. On the left side, there are three main sections: 'COSMETIC REGISTRATION AND LISTING', 'SELF-HELP', and 'MANAGE ACCOUNT'. Under 'COSMETIC REGISTRATION AND LISTING', there are two sub-sections: 'REGISTRATION OF COSMETIC PRODUCT FACILITY' and 'COSMETIC PRODUCT LISTING'. Under 'SELF-HELP', there are several links: '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'. Under 'MANAGE ACCOUNT', there are two links: 'EDIT USER PROFILE' and 'MANAGE USERS'. The main content area is titled 'CREATE NEW REGISTRATION OF COSMETIC PRODUCT FACILITY'. It contains two radio button options: 'Create a new Cosmetic Product Facility Registration using a blank form' (unselected) and 'Import an existing Cosmetic Product Facility Registration SPL' (selected). Below these options is a note: '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 this section are two buttons: 'CONTINUE' (red) and 'CANCEL' (grey). A large red arrow points from the top of the page down to the 'Import an existing Cosmetic Product Facility Registration SPL' option, which is also enclosed in a red rectangular box.

Upload a File



User will be able to upload a pre-existing ZIP FILE. This file may contain an xml 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. For more information regarding SPL, utilize the **Structured Product Labeling Resources (SPL)** link provided under **SELF-HELP**.

The screenshot displays the FDA Direct Cosmetics Direct interface. At the top left, the FDA logo and 'FDA Direct Cosmetics Direct' are visible. A navigation bar shows 'All Submissions' and 'REGISTRATION OF COSMETIC PRODUCT FACILITY'. The main content area is titled 'UPLOAD REGISTRATION OF COSMETIC PRODUCT FACILITY FILE'. Below this, the text reads 'Registration of Cosmetic Product Facility File' with a camera icon, followed by 'Select a file or drop one here.' A note specifies: '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 pointing to it) and 'CANCEL'. The left sidebar contains sections for 'COSMETIC REGISTRATION AND LISTING', 'SELF-HELP' (with links like 'Structured Product Labeling Resources', 'UNII Search', etc.), and 'MANAGE ACCOUNT'.

Upload a File (Example)

- 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"

The screenshot shows the FDA Direct Cosmetics Direct interface. The main navigation bar includes "All Submissions" and "REGISTRATION OF COSMETIC PRODUCT FACILITY". The left sidebar contains sections for "COSMETIC REGISTRATION AND LISTING", "SELF-HELP", and "MANAGE ACCOUNT". The main content area is titled "UPLOAD REGISTRATION OF COSMETIC PRODUCT FACILITY FILE". Below this title, there is a section for "Registration of Cosmetic Product Facility File" with a folder icon. A red box highlights the alphanumeric root ID "abcd850b1f-7bce-165a-e053-5e94af0ac123", with a red arrow pointing to it from the right. Below the root ID, 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'." At the bottom of the upload area, there are two buttons: "UPLOAD" (red) and "CANCEL" (grey). The footer contains the FDA logo and a list of links: FDA Home, Browser Requirements, Resources, Tutorials, CDER Direct Help Desk, Cosmetic Direct Help Desk, FAQs, Follow FDA, FDA Voice Blog, Privacy, and Vulnerability Disclosure Policy.

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=" FACILITY
REGISTRATION"/>
  <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"/>
          <name>[COMPANY'S NAME]</name>
          <contactParty>
            <addr>
              <streetAddressLine>[ENTRY THE STREET ADDRESS]</streetAddressLine>
              <city>[ENTRY CITY NAME]</city>
              <postalCode>[ENTRY POSTAL CODE]</postalCode>
              <country>[ENTRY COUNTRY NAME]</country>
            </addr>
            <telecom value="tel:[ENTRY PHONE NUMBER]"/>
            <telecom value="[ENTRY EMAIL ADDRESS]"/>
            <contactPerson>
              <name>[ENTRY FULL NAME]</name>
            </contactPerson>
          </contactParty>
        </assignedEntity>
      </representedOrganization>
    </assignedEntity>
  </contactParty>
</assignedEntity>
```

Upload File (Example)



After **UPLOADING A FILE** (XML ZIP FILE), the system will auto-fill all the fields and the form will be ready to **SAVE AND VALIDATE** to check for any errors.

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

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.

The screenshot displays the FDA Direct Cosmetics Direct interface. At the top, the breadcrumb navigation shows 'All Submissions' > 'REGISTRATION OF COSMETIC PRODUCT FACILITY' > 'SPL Submission'. A user icon is positioned above the 'SPL Submission' step. A note below the breadcrumb reads: 'Note: Click on the Data element name for each field below to display instructions and help hints for filling out this... For assistance with validation errors and general questions regarding electronic registration of cosmetic products, please contact the...'. Below the note are four expandable sections: 'DOCUMENT TYPE DETAILS', 'REGISTRATION DETAILS', 'CONFIRMATION STATEMENT', and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. On the right side, there are two buttons: 'SUBMIT SPL' and 'SAVE AND VALIDATE'. Two red arrows point to these buttons. Below the 'SUBMIT SPL' button is a red-bordered box containing the text: 'A Guide that will help the user understand different submission stages such as, VALADATE SPL or SUBMIT SPL.' To the right of the 'SUBMIT SPL' button is a 'Submit SPL' help box with the text: 'Submit SPL to FDA.' and buttons for 'Next' and 'Disable Tour'. To the right of the 'SAVE AND VALIDATE' button is a 'Validate SPL' help box with the text: '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.' and a 'Next' button. At the bottom of the page, there is a footer with the FDA logo and navigation links: 'FDA Home | Browser Requirements | Resources | Tutorials | CDER Direct Help Desk | Cosmetic Direct Help Desk | FAQs' and 'Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy'.

Registration Status Examples

Registration Status: Validation in Progress



After SAVE AND VALIDATE, the registration of cosmetic product facility home page will have the following details as shown below. The status will be in **VALIDATION IN PROGRESS**.

All Submissions **REGISTRATION OF COSMETIC PRODUCT FACILITY**

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

REGISTRATION OF COSMETIC PRODUCT FACILITY

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.

Q **GO** **ACTIONS** **CREATE NEW/UPLOAD FILE**

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT TYPE	LAST MODIFIED USER	LAST MODIFIED DATE	
VALIDATION IN PROGRESS	fd850b1f-7bcd-165 a-e053-6b65af0ac496	abcd850b1f-7bce-165 a-e053-5e94af0ac123		1	FACILITY NAME	1000125370		COSMETIC FACILITY REGISTRATION	First name Last name	07-JUN-2023 02:53:31	



Registration 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 a quick VALIDATION, the status **VALIDATION IN PROGRESS** will change to **READY FOR SUBMISSION**.

All Submissions **REGISTRATION OF COSMETIC PRODUCT FACILITY**

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

REGISTRATION OF COSMETIC PRODUCT FACILITY

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.

Q GO ACTIONS

CREATE NEW/UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT TYPE	LAST MODIFIED USER	LAST MODIFIED DATE	
READY FOR SUBMISSION	fd850b1f-7bcd-165 a-e053-6b65af0ac496	abcd850b1f-7bce-165 a-e053-5e94af0ac123		1	FACILITY NAME	1000125370		COSMETIC FACILITY REGISTRATION	First name Last name	07-JUN-2023 02:53:31	



Registration Status:



Ready for Submission to Submit SPL

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

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.*

The screenshot displays the FDA Direct Cosmetics Direct interface. At the top left, the logo reads "FDA Direct Cosmetics Direct". The main navigation bar shows "All Submissions" and "REGISTRATION OF COSMETIC PRODUCT FACILITY" with a user icon. On the right, there are buttons for "EDIT", "SUBMIT SPL", and "<< RETURN". A red arrow points to the "SUBMIT SPL" button. Below the navigation, a note states: "Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out this Facility Registration Submission Form. Red asterisk indicate required fields." A large red-bordered box highlights a message: "Note: This submission has passed the INITIAL VALIDATION but has NOT been ACTUALLY SUBMITTED TO FDA. Click ON 'SUBMIT SPL' to SUBMIT." Below this message are four expandable sections: "DOCUMENT TYPE DETAILS", "REGISTRATION DETAILS", "CONFIRMATION STATEMENT", and "ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT". The bottom of the page features a navigation bar with links: "FDA Home | Browser Requirements | Resources | Tutorials | CDER Direct Help Desk | Cosmetic Direct Help Desk | FAQs" and "Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy".



Registration Status: Submit SPL to Submission Accepted

The status will change to **SUBMISSION ACCEPTED** after registration process had been successfully completed. A **SUBMISSION ID** will be given to all **ACCEPTED SUBMISSIONS**.

The screenshot shows the 'REGISTRATION OF COSMETIC PRODUCT FACILITY' page in FDA Direct. The main content area features a table with the following data:

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT TYPE	LAST MODIFIED USER	LAST MODIFIED DATE	
SUBMISSION ACCEPTED	fd850b1f-7bcd-165a-e053-6b65af0ac496	abcd850b1f-7bce-1a-e053-5e94af0ac12	cd6287459103.64893257@direct	1	FACILITY NAME	1000125370		COSMETIC FACILITY REGISTRATION	First name Last name	07-JUN-2023 02:53:31	

Red annotations highlight the 'SUBMISSION ACCEPTED' status and the 'SUBMISSION ID' column. A red box surrounds the entire table, and two red arrows point upwards from below towards the 'SUBMISSION ID' and 'STATUS' columns.



Registration Status: Submission Accepted to View SPL and Download SPL



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

FDA Direct
Cosmetics Direct

All Submissions **REGISTRATION OF COSMETIC PRODUCT FACILITY**

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 Facility Registration Submission Form. Red asterisk indicate required fields. For general questions regarding electronic registration and listing of cosmetic product facilities and products, contact cosmeticsdirect@fda.hhs.gov.

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

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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 'All Submissions' and 'REGISTRATION OF COSMETIC PRODUCT FACILITY'. A user icon is visible. Below the navigation bar are two buttons: 'VIEW SPL' and 'DOWNLOAD SPL'. To the right of these buttons is a red arrow pointing to a red-bordered box containing the 'CREATE NEW VERSION' button and a '<< RETURN' button. Below this is a note: 'Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out this Facility Registration Submission Form. Red asterisk indicate required fields. For general questions regarding electronic registration and listing of cosmetic product facilities and products, contact cosmeticsdirect@fda.hhs.gov.' Below the note are four expandable sections: '+ DOCUMENT TYPE DETAILS', '+ REGISTRATION DETAILS', '+ CONFIRMATION STATEMENT', and '+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. At the bottom is the FDA logo and a footer with links: 'FDA Home | Browser Requirements | Resources | Tutorials | CDER Direct Help Desk | Cosmetic Direct Help Desk | FAQs' and 'Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy'.

Registration Status: Validation Failure



After SAVE AND VALIDATE, the registration of cosmetic product facility home page will have the following details as shown below. The status will be in **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 content area is titled "REGISTRATION OF COSMETIC PRODUCT FACILITY". Below the title, there is a search bar with a "GO" button and an "ACTIONS" dropdown menu. A "CREATE NEW/UPLOAD FILE" button is also visible. A table displays the registration details, with the status "VALIDATION FAILURE" highlighted in blue. A red arrow points to the "VALIDATION FAILURE" status in the table.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT TYPE	LAST MODIFIED USER	LAST MODIFIED DATE	
VALIDATION FAILURE	fd850b1f-7bcd-165a-e053-6b65af0ac496	abcd850b1f-7bce-165a-e053-5e94af0ac123		1	FACILITY NAME	1000125370		COSMETIC FACILITY REGISTRATION	First name Last name	07-JUN-2023 02:53:31	

Registration Status: Validation Failure (List of Errors)



After selecting the **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 FDA logo and 'FDA Direct Cosmetics Direct' are displayed. A prominent red banner at the top contains the message: '# ERRORS HAVE OCCURRED' with a close button (X). Below this, two error messages are listed: '* 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, a navigation bar shows 'All Submission' and 'REGISTRATION OF COSMETIC PRODUCT FACILITY' with a person icon. To the right of the navigation bar are buttons for 'SUBMIT SPL', 'SAVE AS DRAFT', 'SAVE AND VALIDATE', 'DELETE', and '<< RETURN'. A red arrow points to the 'SUBMIT SPL' button. Below the navigation bar is a note: 'Note: Click on the data element name for each field below to display instructions and helpful hints for filling out this Facility Registration Submission Form. Red asterisk indicate required fields. For general questions regarding electronic registration and listing of cosmetic product facilities and products, contact cosmeticsdirect@fda.hhs.gov.' Below the note are four expandable sections, each with a plus sign icon: 'DOCUMENT TYPE DETAILS', 'REGISTRATION DETAILS', 'CONFIRMATION STATEMENT', and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. At the bottom of the page, the FDA logo is on the left, and a navigation bar contains links: 'FDA Home | Browser Requirements | Resources | Tutorials | CDER Direct Help Desk | Cosmetic Direct Help Desk | FAQs'. Below this bar are links: 'Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy'. The page number '37' is in the bottom right corner.

Registration Status: Save as Draft

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

FDA **FDA Direct**
Cosmetics Direct

All Submissions **REGISTRATION OF COSMETIC PRODUCT FACILITY**

SUBMIT 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 Facility Registration Submission Form. Red asterisk indicate required fields. For general questions regarding electronic registration and listing of cosmetic product facilities and products, contact Cosmeticsdirect@fda.hhs.gov.

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

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Registration Status: Draft

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

The screenshot shows the FDA Direct Cosmetics Direct interface. The main content area is titled "REGISTRATION OF COSMETIC PRODUCT FACILITY". Below the title, there is a search bar with a "GO" button and an "ACTIONS" dropdown menu. A "CREATE NEW/UPLOAD FILE" button is also visible. A table displays registration details, with the "STATUS" column highlighted in red and a red arrow pointing to the "DRAFT" status. The table has the following data:

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT TYPE	LAST MODIFIED USER	LAST MODIFIED DATE	
DRAFT	fd850b1f-7bcd-165 a-e053-6b65af0ac496	abcd850b1f-7bce-165 a-e053-5e94af0ac123		1	FACILITY NAME	1000125370		COSMETIC FACILITY REGISTRATION	First name Last name	07-JUN-2023 02:53:31	

Navigation and sidebar elements include: "All Submissions" and "REGISTRATION OF COSMETIC PRODUCT FACILITY" tabs; "COSMETIC REGISTRATION AND LISTING" section with "REGISTRATION OF COSMETIC PRODUCT FACILITY" and "COSMETIC PRODUCT LISTING" links; "SELF-HELP" section with "Structured Product Labeling Resources", "UNII Search", "Requests UNII", "DUNS Search", "FEI Search Portal", and "Registration and Listing of Cosmetic Product Facilities and Products Industry Guidance Tutorials"; and "MANAGE ACCOUNT" section with "EDIT USER PROFILE" and "MANAGE USERS" links.