

COSMETICS *DIRECT*

Electronic Submissions Portal

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FDA DIRECT HOME PAGE

The WELCOME TO FDA DIRECT provides short background info about each (CDER Direct and Cosmetics Direct). First time user can create a new account by selecting the Create New Account.



LOGIN

Username:

Password:

[Forgot your password?](#)

[I accept the Terms of Service](#)

LOGIN [Create New Account](#)

Quick Links: Resources | Tutorials | Help Desk | FAQs

WELCOME TO FDA DIRECT

Structured product labeling (SPL) authoring tool. Previously CDER Direct, FDA Direct now includes Cosmetics Direct. Users can create a single account that includes all of CDER Direct submissions as well as Cosmetics Direct submissions.

CDER Direct

CDER Direct allows users to easily submit the following data to the FDA: Establishment Registration & Drug Listing which includes NDC Labeler Code Requests, Establishment Registration and Product Listing and Certification, Outsourcing Facility and Product Reporting, DSCSA Annual Reporting, Generic Drug Self-Identification.

Cosmetics Direct

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

Section 607(a) of the FD&C Act requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility with FDA no later than 1 year after the date of enactment. In addition to the registration requirements, section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person submit to FDA "a cosmetic product listing." Certain small businesses, as defined in section 612 of the FD&C Act, are exempt from the registration and listing requirements. To learn more about MoCRA, learn more

This free tool allows you to create and submit your submissions directly to the FDA. This system will provide information to FDA/Office of Cosmetics and Colors (OCAC) about cosmetic manufacturers and products in the marketplace.

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

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

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CREATE A NEW ACCOUNT

There are three types of account that can be created: CDER Direct, COSMETICS Direct, and Both (CDER Direct & COSMETICS Direct). DUNS is only a required field if you create a CDER Direct account or Both (CDER Direct and Cosmetics Direct) account. DUNS is NOT required if you create only a COSMETICS Direct account. The system will streamline submissions to save time for the user who has drugs as well as cosmetics to choose both (CDER Direct & COSMETICS Direct) under one functional account.

ORGANIZATION TYPE

What type of Account are you creating ? CDER Direct COSMETICS Direct Both (CDER Direct and COSMETICS Direct)

Lorem Ipsum is simply dummy text of the printing and typesetting industry. Lorem Ipsum has been the industry's standard dummy text ever since the 1500s, when an unknown printer took a galley of type and scrambled it to make a type specimen book. It has survived not only five centuries, but also the leap into electronic typesetting, remaining essentially unchanged. It was popularised in the 1960s with the release of Letraset sheets containing Lorem Ipsum passages, and more recently with desktop publishing software like Aldus PageMaker including versions of Lorem Ipsum.

ORGANIZATION INFORMATION

Name: *

DUNS: *

ORGANIZATION ADDRESS

Country: *

United States

Street Address: *

City: *

State: *

-Select State-

Postal Code:

CONTACT INFORMATION

First Name: *

Middle Name:

Last Name: *

Job Title:

Contact Email: *

CONTACT PHONE

Country Code: *

United States (+1)

Phone Number: *

Phone Extension:

TERMS OF SERVICE

Before logging into the account, the user will have to agree to the terms of service, by selecting **I AGREE** that will pop-up once selecting, *I accept the terms of service*

CDER Direct & Cosmetics Direct

LOGIN

Username:

Password:

[Forgot your password?](#)

I accept the Terms of Service

LOGIN [Create New Account](#)

Quick Links: Resources | Tutorials | Help Des

This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes (1) this computer network, (2) all computers connected to this network, and (3) all devices and storage media attached to this network or to a computer on this network.

This system is provided for Government-authorized use only.

Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties.

Personal use of social media and networking sites on this system is limited as to not interfere with official work duties and is subject to monitoring.



By using this system, you understand and consent to the following:
The Government may monitor, record, and audit your system usage, including usage of personal devices and email systems for official duties or to conduct HHS business. Therefore, you have no reasonable expectation of privacy regarding any communication or data transiting or stored on this system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this system. Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

Under **18 U.S.C. 1001**, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

CLOSE

I AGREE

HOME PAGE WELCOME POP-UP

A burden statement and standard PRA information will appear in the welcome pop-up each time a user logs in. (information is a place holder subject to change)



FDA **FDA Direct**
Cosmetics Direct

HOME

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/uniisearch](#)
- For UNIL requests contact: FDA-SRS@fda.hhs.gov.
- Structured Product Labeling Resources | FDA
- DUNSLink ([dnb.com](#))

MANAGE ACCOUNT

- EDIT USER PROFILE
- MANAGE USERS

WELCOME X

PAPERWORK REDUCTION ACT NOTICE

OMB Control No. 0910-xxxx
Expiration Date: xx/xx/xxxx

Public reporting burden for this collection of information is estimated to average between 15 to 60 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRastaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

PLEASE NOTE: The system will automatically time out if there is no activity for 30 minutes.

COSMETICS DIRECT HOME PAGE

Home page of the 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.

SELF-HELP:

Articles and weblinks are provided for additional information. This box will be available throughout the submission process.

The screenshot shows the FDA Cosmetics Direct home page. At the top left is the FDA logo and 'FDA Direct Cosmetics Direct'. Below this is a 'HOME' button with a right-pointing arrow. The main content area is divided into three columns. The left column has three sections: 'SUBMISSIONS' with links for 'REGISTRATION OF COSMETIC PRODUCT FACILITY' and 'COSMETIC PRODUCT LISTING'; 'SELF-HELP' with links for 'FEI Search Portal (fda.gov)', 'Registration and Listing of Cosmetic Facilities and Products: Guidance for Industry (fda.gov)', 'Search for UNILs: precision.fda.gov/unitsearch', 'For UNIL requests contact: FDA-SRS@fda.hhs.gov', 'Structured Product Labeling Resources | FDA DUNS.com (dnb.com)'; and 'MANAGE ACCOUNT' with links for 'EDIT USER PROFILE' and 'MANAGE USERS'. The middle column has an 'ALL SUBMISSIONS' section with a search bar containing a magnifying glass icon, a 'GO' button, and an 'ACTIONS' dropdown menu. Below the search bar is a table with columns: 'STATUS', 'SET ID', 'ROOT ID', 'SUBMISSION ID', 'VERSION', 'DOCUMENT LABEL', 'LAST MODIFIED USER', 'LAST MODIFIED DATE', and a lock icon. The right column is empty. At the bottom of the page is a footer with the FDA logo and links for 'FDA Home', 'Browser Requirements', 'Resources', 'Tutorials', 'Help Desk', 'FAQs', 'Follow FDA', 'FDA Voice Blog', 'Privacy', and 'Vulnerability Disclosure Policy'. Red arrows point from text boxes to the 'SUBMISSIONS' and 'SELF-HELP' sections, the 'MANAGE ACCOUNT' section, the search bar, and the 'ALL SUBMISSIONS' table.

MANAGE ACCOUNT:

Manage sub-users of the account and update profile information.

The ability to view all the previous product listing submissions based on user's access.

REGISTRATION OF COSMETIC PRODUCT FACILITY

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HOME PAGE: REGISTRATION OF COSMETIC PRODUCT FACILITY

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.

SELF-HELP:

Articles and weblinks are provided for additional information. This box will be available throughout the submission process.

MANAGE ACCOUNT:

Manage sub-users of the account and update profile information.

The ability to view all the previous product listing submissions based on user's access.

CREATE NEW/UPLOAD FILE

The screenshot shows the FDA Direct Cosmetics Direct interface. At the top left is the FDA logo and 'FDA Direct Cosmetics Direct'. Below it are navigation tabs for 'HOME' and 'REGISTRATION OF COSMETIC PRODUCT FACILITY'. The main content area is titled 'REGISTRATION OF COSMETIC PRODUCT FACILITY' and includes a search bar with a 'GO' button and an 'ACTIONS' dropdown. A 'CREATE NEW/UPLOAD FILE' button is located in the top right of the main content area. Below the search bar is a table with columns: STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, FACILITY NAME, FACILITY FEI, FACILITY DUNS, DOCUMENT LABEL, LAST MODIFIED USER, and LAST MODIFIED DATE. On the left side, there are three sections: 'SUBMISSIONS' with links for 'REGISTRATION OF COSMETIC PRODUCT FACILITY' and 'COSMETIC PRODUCT LISTING'; 'SELF-HELP' with links for 'FEI Search Portal (fda.gov)', 'Registration and Listing of Cosmetic Facilities and Products: Guidance for Industry (fda.gov)', 'Search for UNILs: precision.fda.gov/unisearch', 'For UNIL requests contact: FDA-SRS@fda.hhs.gov', 'Structured Product Labeling Resources | FDA', and 'DUNS Link (dnb.com)'; and 'MANAGE ACCOUNT' with links for 'EDIT USER PROFILE' and 'MANAGE USERS'. At the bottom of the page, there is a footer with links for 'FDA Home', 'Browser Requirements', 'Resources', 'Tutorials', 'Help Desk', 'FAQs', 'Follow FDA', 'FDA Voice Blog', 'Privacy', and 'Vulnerability Disclosure Policy'. Red arrows point from the text boxes to the 'SUBMISSIONS' section, the 'SELF-HELP' section, the 'GO' button, the 'CREATE NEW/UPLOAD FILE' button, and the 'MANAGE USERS' link.

CREATE A NEW REGISTRATION
OR UPLOAD AN EXISTING FILE

CREATE A NEW REGISTRATION OR UPLOAD AN EXISTING FILE

Selecting the [CREATE NEW/UPLOAD FILE](#) box, from the [Registration of Cosmetic Product Facility home page](#) will direct 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 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 facility registration SPL will be beneficial for bulk submission

FDA Direct
Cosmetics Direct

HOME > REGISTRATION OF COSMETIC PRODUCT FACILITY

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 UNII: precision.fda.gov/uniisearch
For UNII 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 FACILITY REGISTRATION

Create an initial Cosmetic Product Facility Registration using a blank form

Import an existing Cosmetic Product Facility Registration SPL

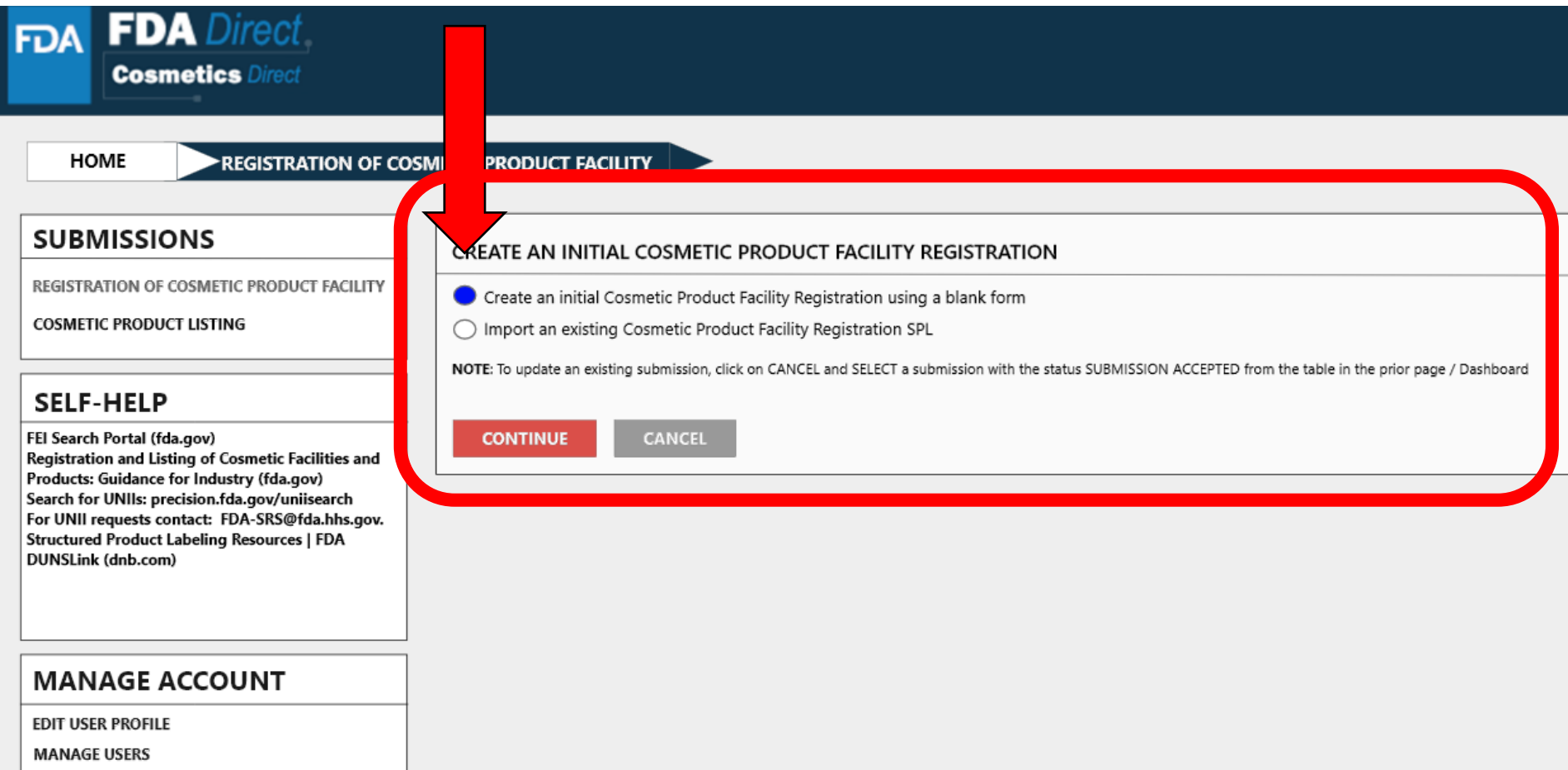
NOTE: To update an existing submission, click on CANCEL and SELECT a submission with the status SUBMISSION ACCEPTED from the table in the prior page / Dashboard

[CONTINUE](#) [CANCEL](#)

FDA Home | [Browser Requirements](#) | [Resources](#) | [Tutorials](#) | [Help Desk](#) | [FAQs](#)
Follow FDA | [FDA Voice Blog](#) | [Privacy](#) | [Vulnerability Disclosure Policy](#)

CREATE A NEW PRODUCT FACILITY REGISTRATION

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



FDA **FDA Direct**
Cosmetics Direct

HOME > REGISTRATION OF COSMETIC PRODUCT FACILITY

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 UNII: precision.fda.gov/uniisearch
For UNII requests contact: FDA-SRS@fda.hhs.gov.
Structured Product Labeling Resources | FDA
[DUNSLink \(dnb.com\)](http://DUNSLink.com)

MANAGE ACCOUNT

EDIT USER PROFILE
MANAGE USERS

CREATE AN INITIAL COSMETIC PRODUCT FACILITY REGISTRATION

Create an initial 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

CONTINUE **CANCEL**

DOCUMENT TYPE DETAILS

Set ID and Root ID are auto-generated, and the Effective Dates 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

HOME | REGISTRATION OF COSMETIC PRODUCT FACILITY |

Note: Click on the help icon for each field below to display instructions and helpful hints for filling out the form. For general information regarding electronic registration and listing of cosmetic product facilities and products, click on the link to the Submission Form. Red asterisk indicate required fields.

DOCUMENT TYPE DETAILS

Document Type: *

Set ID: * [Generate New](#)

Version Number: *

Root ID: * [Generate New](#)

Effective Date: *

+ REGISTRATION DETAILS

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

SAVE AS DRAFT <<RETURN

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

DOCUMENT TYPE TOOL TIPS

Document Type X

Select one of the document types:-

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).

AMENDED:- 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.

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

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

Document Type: * V

Set ID: * [Generate New](#)

Root 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.

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


A dashed underline indicates help text (tool-tips) if clicked on.

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.

Version Number: *

Effective Date: * 

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.

DOCUMENT TYPE DETAILS

By selecting the drop-down (v), Five document type options will appear; initial, amended-changes to registration, amended-cancellation of registration, biennial registration renewal, and abbreviated registration renewal. (First time users will only have INITIAL as an option)



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

Document Type: * -- Select Document Type -- v

Set ID: *

-- Select Document Type --

Version Number: *

1

Root ID: *

INITIAL

Effective Date: *

06-20-2023



AMENDED-CHANGES TO REGISTRATION

AMENDED-CANCELLATION OF REGISTRATION

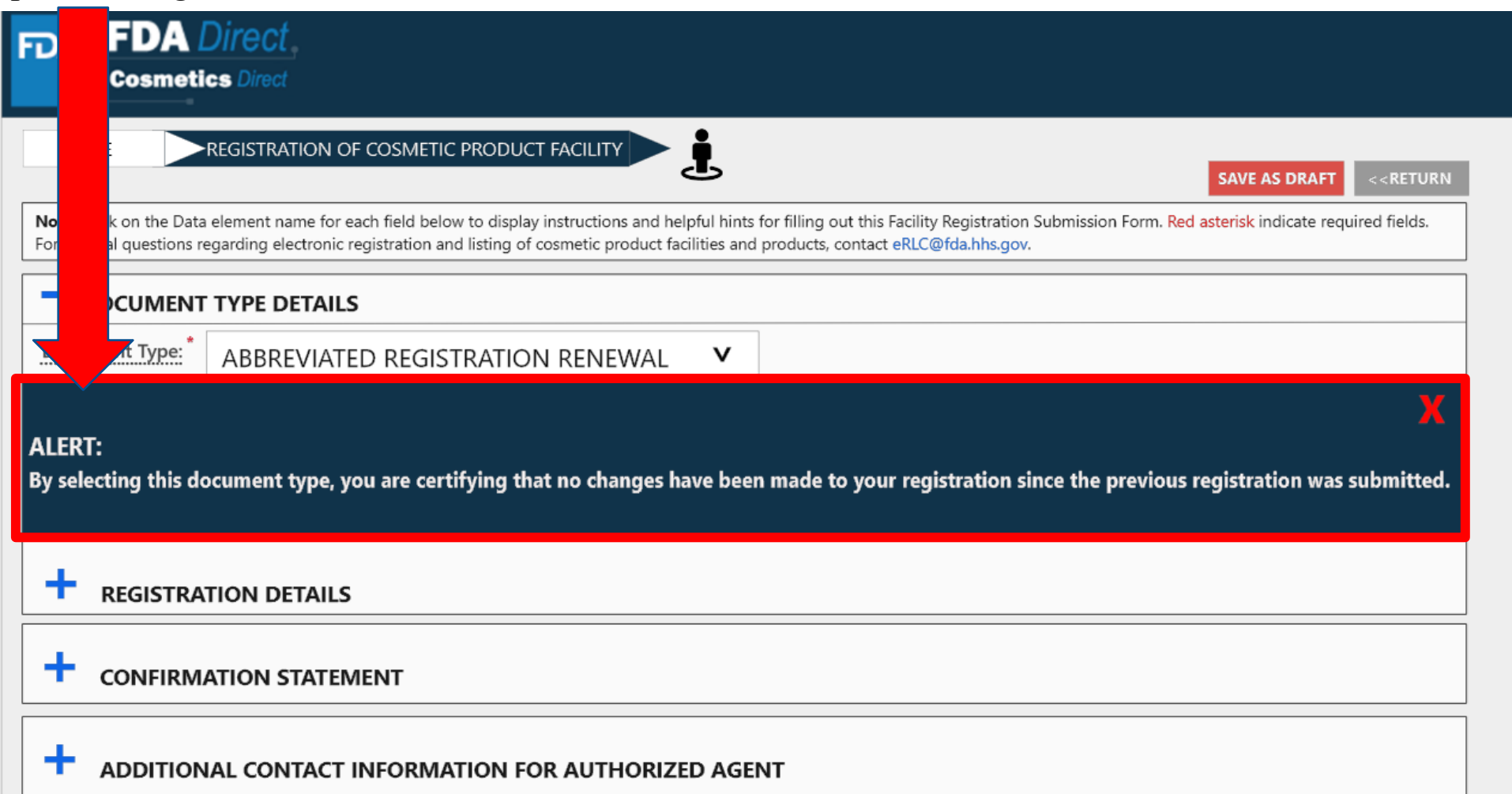
BIENNIAL REGISTRATION RENEWAL

ABBREVIATED REGISTRATION RENEWAL

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

DOCUMENT TYPE DETAILS

Depending on which document type is selected, an ALERT box will appear, “By selecting this document type, you are certifying that no changes have been made to your registration since the previous registration was submitted”



The screenshot shows the 'REGISTRATION OF COSMETIC PRODUCT FACILITY' page on the FDA Direct Cosmetics Direct portal. A red arrow points to the 'Document Type' dropdown menu, which is currently set to 'ABBREVIATED REGISTRATION RENEWAL'. Below this, a dark blue alert box with a red border and a red 'X' icon contains the following text: 'ALERT: By selecting this document type, you are certifying that no changes have been made to your registration since the previous registration was submitted.' Below the alert box are three expandable sections: 'REGISTRATION DETAILS', 'CONFIRMATION STATEMENT', and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'.

FDA Direct
Cosmetics Direct

REGISTRATION OF COSMETIC PRODUCT FACILITY

SAVE AS DRAFT <<RETURN

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 additional questions regarding electronic registration and listing of cosmetic product facilities and products, contact eRLC@fda.hhs.gov.

DOCUMENT TYPE DETAILS

Document Type: * ABBREVIATED REGISTRATION RENEWAL ▼

ALERT:
By selecting this document type, you are certifying that no changes have been made to your registration since the previous registration was submitted.

+ REGISTRATION DETAILS

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

REGISTRATION DETAILS

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

- Small Business** (optional field) Indicate whether your business is a small business by selecting one of the options provided. For more information visit [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)
- Facility Name** Enter the complete name of the existing facility. For more information visit [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)
- Facility FEI Number** Enter the existing facility FEI number. If you need to look-up the FEI number or request an FEI number: <https://www.accessdata.fda.gov/scripts/feportal/index.cfm?action=portal.login> For more information visit [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)
- Facility DUNS Number** (optional field) The existing 9 digital facility DUNS number. Obtain a DUNS number: <https://www.dnb.com> For more information visit [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)
- Parent Company Name** (optional field) Provide the parent company's name if available. For more information visit [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)
- Facility Country** Provide facility's country name (if the country is other than the USA.) For more information visit [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)
- Facility City** Provide the complete name of the city. For more information visit [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)
- Facility Street Address** Provide the complete name of the street. For more information visit [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)
- Facility State or Province** Provide the complete name of the state or province. For more information visit [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)
- Facility Zip/postal Code** Provide the postal code or the zip code. For more information visit [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)
- Facility Email** Provide the facility's email address. For more information visit [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)
- Facility Phone Number** Provide the facility's phone number including the area or the country code. For more information visit [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)
- Facility Owner/Operator** Provide the facility owner's name and/or the name of the facility operator. For more information visit [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)

FDA **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 general questions regarding electronic registration and listing of cosmetic product facilities and products, contact EBLC@fda.hhs.gov.

+ DOCUMENT TYPE DETAILS

- REGISTRATION DETAILS

IS THIS A FACILITY REGISTRATION FOR A SMALL BUSINESS (optional registration)? YES NO

Facility name* Facility DUNS Number*

Facility FEI Number* Parent Company name: (if applicable)

+ FACILITY CONTACT DETAILS

Facility Country* --SELECT COUNTRY-- V Facility City*

Facility Street Address* Facility State or Province*

Facility Zip/Postal code* Facility Phone Number* (Include Area/Country Code)

Facility Email*

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

+ U.S. AGENT CONTACT INFORMATION

- BRAND NAMES

Add FACILITY BRAND NAMES OF COSMETIC PRODUCTS MANUFACTURED OR PROCESSED in this facility. **ADD BRAND NAMES**

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

REGISTRATION DETAILS

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


U.S. Agent Name 
For foreign facilities, provide U.S. AGENT NAME. For more information, visit Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)

U.S. Agent Phone Number 
For foreign facilities, provide U.S. AGENT CONTACT INFORMATION including the area code. For more information, visit Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)

U.S. Agent Email 
For foreign facilities, provide U.S. AGENT CONTACT INFORMATION. If email address not available, enter N/A. For more information, visit Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)

U.S. Agent Phone Extension 
(optional Field) For foreign facilities, provide U.S. AGENT INFORMATION. For more information, visit Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)

FDA **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

IS THIS A FACILITY REGISTRATION FOR A SMALL BUSINESS (optional registration)? YES NO

Facility name* Facility DUNS Number*

Facility FEI Number* Parent Company name: (if applicable)

- FACILITY CONTACT DETAILS

Facility Country* Facility City*

Facility Street Address* Facility State or Province*

Facility Email* Facility Zip/Postal code*

Facility Phone Number* (Include Area/Country Code)

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

- U.S. AGENT CONTACT INFORMATION

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

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

- BRAND NAMES

Add FACILITY BRAND NAME(S) OF COSMETIC PRODUCTS MANUFACTURED OR PROCESSED in this facility. **ADD BRAND NAMES**


+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

BRAND NAME(S)

Add Brand Names of
cosmetic products
manufactured or
processed at this
facility by selecting
**ADD BRAND
NAMES**

FDA **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

IS THIS A FACILITY REGISTRATION FOR A SMALL BUSINESS (optional registration)? YES NO

Facility name: **Facility DUNS Number:**

Facility FEI Number: **Parent Company name: (if applicable)**

- FACILITY CONTACT DETAILS

Facility Country * **Facility City ***

Facility Street Address * **Facility State or Province ***

Facility Email * **Facility Zip/Postal code ***

Facility Phone Number * (Include Area/Country Code)

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

+ U.S. AGENT CONTACT INFORMATION

- BRAND NAMES

Add FACILITY BRAND NAMES OF COSMETIC PRODUCTS MANUFACTURED OR PROCESSED in this facility.

ADD BRAND NAMES

+ CONFIRMATION STATEMENT


+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

BRAND NAME(S) OF COSMETIC PRODUCT(S) MANUFACTURED OR PROCESSED IN THIS FACILITY

Multiple Brand Names
can be submitted by
selecting SAVE AND
ADD MORE BRAND

Select all the
Category code(s) that
applies to this Brand
Name

FDA *FDA Direct*
Cosmetics Direct

HOME > REGISTRATION OF COSMETIC PRODUCT FACILITY > BRAND NAMES 

SAVE AND ADD MORE BRAND SAVE BRAND DELETE BRAND << RETURN

BRAND NAMES OF COSMETIC PRODUCTS MANUFACTURED OR PROCESSED IN THIS FACILITY

Brand Name of cosmetic product: *
.....

Brand Name

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

Responsible Person Name

Select All Product Category Code(s) 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).

BRAND NAME(S) OF COSMETIC PRODUCT(S) MANUFACTURED OR PROCESSED IN THIS FACILITY(EXAMPLE)

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



Brand Name of Cosmetic Product



All 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 Name



The manufacturer, packer, or distributor of a cosmetic product whose name 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)



The product category or categories for each cosmetic product manufactured or processed at the facility. For more information, visit [Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry \(fda.gov\)](#)

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

FDA **FDA Direct**
Cosmetics Direct

HOME > REGISTRATION OF COSMETIC PRODUCT FACILITY > BRAND NAMES >

SAVE AND ADD MORE BRAND SAVE BRAND DELETE BRAND << RETURN

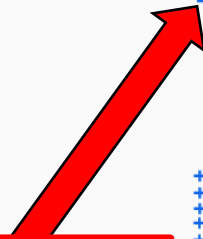
BRAND NAMES OF COSMETIC PRODUCTS MANUFACTURED OR PROCESSED IN THIS FACILITY

Brand Name of cosmetic product: *

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

Select All Product Category Code(s) 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).



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 BRAND NAMES.

FDA **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

IS THIS A FACILITY REGISTRATION FOR A SMALL BUSINESS (optional registration)? YES NO

Facility name* Facility DUNS Number:

Facility FEI Number* Parent Company name:
(If applicable)

- FACILITY CONTACT DETAILS

Facility Country* Facility City*

Facility Street Address* Facility State or Province*

Facility Email* Facility Zip/Postal code*

Facility Phone Number*
(Include Area/Country Code)

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

+ U.S. AGENT CONTACT INFORMATION

- BRAND NAMES

Add FACILITY BRAND NAMES OF COSMETIC PRODUCTS MANUFACTURED OR PROCESSED in this facility. [ADD BRAND NAMES](#)

Brand Names of Cosmetic Products Manufactured or Processed in this Facility *	Responsible Person Name (As listed on label) *	Product Category Code(s) *
<input checked="" type="checkbox"/> Cosmetic Beauty	Responsible Person Name	<ul style="list-style-type: none">(08) Makeup preparations (not eye)(other than makeup preparations for children) - (h) Other makeup preparations - 1. Traditional applications.(14) Skin care preparations, (creams, lotions, powder, and sprays) - (c) Face and neck (excluding shaving preparations) - 1. Leave-on(14) Skin care preparations, (creams, lotions, powder, and sprays) - (f) Moisturizing.

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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

CONFIRMATION STATEMENT

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



Signature of Submitter



(optional field) Use the blank space to provide a signature of the Submitter.

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

FDA **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

Signature of Submitter Name of Submitter

Date (MM/DD/YYYY)

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORITY REPRESENTATIVE

FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs
Follow FDA | FDA Weblog | Privacy | Vulnerability Disclosure Policy

After understanding the confirmation statement. Select AGREE

ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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



FDA **FDA Direct**
Cosmetics Direct

HOME REGISTRATION OF COSMETIC PRODUCT FACILITY

Note: Click on the Data element name for each field below to display instructions and For general questions regarding electronic registration and listing of cosmetic product

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

Additional Contact Name	X
(optional field) Provide an additional contact name	
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	
Phone Extension	X
(optional Field)	

Additional Contact Name:

Phone Number (Include Area Code/ Country Code)

.....

Email:

Phone Extension

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.

FDA Direct
Cosmetics Direct

HOME REGISTRATION OF COSMETIC PRODUCT FACILITY

Note: Click on the D...
For general question...

DOCUM...
REGISTR...
CONFIRMATION STATEMENT
ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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

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 stages such as, VAILADATE SPL or SUBMIT SPL.

UPLOAD A FILE

In order to upload a file, select Import an existing Cosmetic Product Facility Registration SPL. Importing an existing Cosmetic Product Facility Registration SPL will be beneficial for bulk submission.

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/uniisearch
For UNIL requests contact: FDA-SRS@fda.hhs.gov.
Structured Product Labeling Resources | FDA
[DUNSLink \(dnb.com\)](http://DUNSLink.dnb.com)

MANAGE ACCOUNT

EDIT USER PROFILE
MANAGE USERS

CREATE AN INITIAL COSMETIC PRODUCT FACILITY REGISTRATION

- Create an initial 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

CONTINUE

CANCEL

UPLOAD A FILE

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



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 UNII: precision.fda.gov/unii/search
For UNII requests contact: FDA-SRS@fda.hhs.gov.
Structured Product Labeling Resources | FDA (SPL)
DUNSLink (dnb.com)

MANAGE ACCOUNT

EDIT USER PROFILE
MANAGE USERS

UPLOAD COSMETIC PRODUCT FACILITY REGISTRATION FILE

Cosmetic Product Facility Registration File

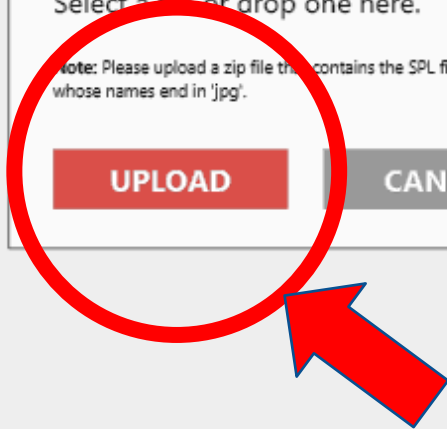


Select a file or drop one here.

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

UPLOAD

CANCEL



UPLOAD A FILE (EXAMPLE)

The content in the red circle is an example to what a zip file could be, may contain .xml file and image (jpg) files.

The screenshot displays the FDA Direct Cosmetics Direct user interface. At the top, the navigation bar includes 'HOME' and 'REGISTRATION OF COSMETIC PRODUCT FACILITY'. The main content area is titled 'UPLOAD COSMETIC PRODUCT FACILITY REGISTRATION FILE'. Below this title, there is a section for 'Cosmetic Product Facility Registration File' with a folder icon. A red circle highlights the alphanumeric string 'd6fbed65-c6ab-a625-e053-2a95af0a20cf', which is an example of a zip file name. A red arrow points to the 'UPLOAD' button. A note below the file name states: 'Note: Please upload the file with the name as the name followed by ".xml" and any associated image files that referenced in the xml whose names end in ".jpg".' The 'UPLOAD' button is red, and the 'CANCEL' button is grey. On the left side, there are three menu sections: 'SUBMISSIONS' (with links for 'REGISTRATION OF COSMETIC PRODUCT FACILITY' and 'COSMETIC PRODUCT LISTING'), 'SELF-HELP' (with links for 'FEI Search Portal (fda.gov)', 'Registration and Listing of Cosmetic Facilities and Products: Guidance for Industry (fda.gov)', 'Search for UNILs: precision.fda.gov/uniisearch', 'For UNIL requests contact: FDA-SRS@fda.hhs.gov', 'Structured Product Labeling Resources | FDA (SPL)', and 'DUNSLink (dnb.com)'), and 'MANAGE ACCOUNT' (with links for 'EDIT USER PROFILE' and 'MANAGE USERS').

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.xml" type="text/xsl"?>
<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:hl7-org:v3 https://www.accessdata.fda.gov/spl/schema/spl.xsd">
  <id root="fd8c4f0b-ca3b-82e2-e053-6394a90aa8de"/>
  <code code="51725-0" codeSystem="2.16.840.1.113883.6.1" displayName=" 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>
```

UPLOAD A FILE (EXAMPLE)

After **UPLOADING A FILE** (XML ZIP FILE), the system will auto-fill all the required fields 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 Facility Registrations under one submission ID.

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. ”

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 is the FDA Direct Cosmetics Direct logo. Below it is a navigation bar with 'HOME' and 'REGISTRATION OF COSMETIC PRODUCT FACILITY'. A red arrow points from a 'TOUR GUIDE' box to a person icon in the navigation bar. The main content area has a 'Note' and a list of sections: DOCUMENT TYPE DETAILS, REGISTRATION DETAILS, CONFIRMATION STATEMENT, and ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT. On the right, there are buttons for 'SUBMIT SPL', 'SAVE AS DRAFT', 'SAVE AND VALIDATE', 'DELETE', and '<< RETURN'. A red box highlights the 'Validate SPL' modal, which contains the text: '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.', and a 'Next' button. A red arrow points from the 'TOUR GUIDE' box to the 'Validate SPL' modal.

FDA Direct Cosmetics Direct

HOME REGISTRATION OF COSMETIC PRODUCT FACILITY

TOUR GUIDE

A Guide that will help the user understand different submission stage such as, VAILADATE SPL.

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

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

+ DOCUMENT TYPE DETAILS

+ REGISTRATION DETAILS

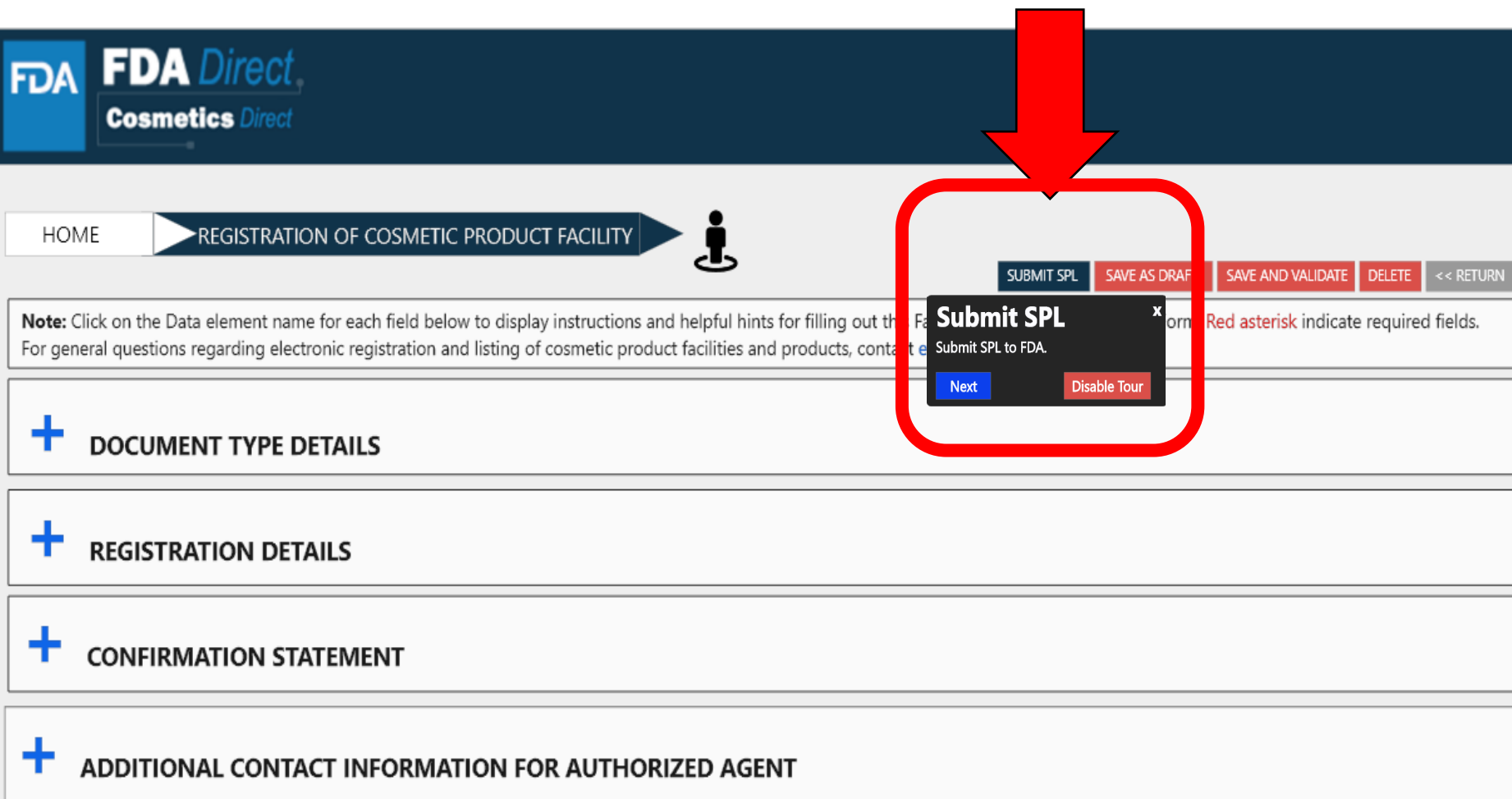
+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

UPLOAD A FILE (EXAMPLE)

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 interface for the 'REGISTRATION OF COSMETIC PRODUCT FACILITY'. At the top left, the 'FDA Direct' and 'Cosmetics Direct' logos are visible. Below the header, there are navigation buttons for 'HOME' and 'REGISTRATION OF COSMETIC PRODUCT FACILITY', along with a user profile icon. A toolbar contains buttons for 'SUBMIT SPL', 'SAVE AS DRAFT', 'SAVE AND VALIDATE', 'DELETE', and '<< RETURN'. A 'Submit SPL' help box is overlaid on the page, containing the text 'Submit SPL to FDA.' and buttons for 'Next' and 'Disable Tour'. A large red arrow points down to the help box, which is also enclosed in a red rounded rectangle. Below the toolbar, a 'Note' provides instructions on how to use the data elements. The main content area consists of four expandable sections: 'DOCUMENT TYPE DETAILS', 'REGISTRATION DETAILS', 'CONFIRMATION STATEMENT', and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. The footer includes 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'.

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](#).

FDA **FDA Direct**
Cosmetics Direct

HOME **REGISTRATION OF COSMETIC PRODUCT FACILITY**

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/uniisearch
For UNIL requests contact: FDA-SRS@fda.hhs.gov.
Structured Product Labeling Resources | FDA
DUNSLink (dnb.com)

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 LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
VALIDATION IN PROGRESS	fd850b1f-7bcd-165a-e053-6b94af0ac496	Rfd850b1f-7bce-165a-e053-6b94af0ac496		1	FACILITY NAME	1000125370		REGISTRATION OF COSMETIC PRODUCT FACILITY	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**.

The screenshot shows the FDA Direct Cosmetics Direct interface. The main heading is 'REGISTRATION OF COSMETIC PRODUCT FACILITY'. Below the heading, there is a search bar with a 'GO' button and an 'ACTIONS' dropdown menu. A table displays the registration details for a facility. A red arrow points to the 'READY FOR SUBMISSION' status in the table. A red box highlights the table area.

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/uniisearch
- For UNIL requests contact: FDA-SRS@fda.hhs.gov
- Structured Product Labeling Resources | FDA DUNSLink (dnb.com)

MANAGE ACCOUNT

- EDIT USER PROFILE
- MANAGE USERS

REGISTRATION OF COSMETIC PRODUCT FACILITY

For assistance with registration errors in Cosmetics Direct contact cosmeticsdirect@fda.hhs.gov. For general questions regarding electronic registration and 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 LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
READY FOR SUBMISSION	fd850b1f-7bcd-165a-e053-6b94af0ac496	Rfd850b1f-7bce-165a-e053-6b94af0ac496		1	FACILITY NAME	1000125370		REGISTRATION OF COSMETIC PRODUCT FACILITY	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.*

FDA **FDA Direct**
Cosmetics Direct

HOME REGISTRATION OF COSMETIC PRODUCT FACILITY

EDIT **SUBMIT SPL** << RETURN

Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out this Facility Registration Submission Form. Red asterisk indicate required fields.

Note: This submission has passed the INITIAL VALIDATION but has NOT been ACTUALLY SUBMITTED TO FDA. Click ON "SUBMIT SPL" to SUBMIT.

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

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.

FDA **FDA Direct**
Cosmetics Direct

HOME **REGISTRATION OF COSMETIC PRODUCT FACILITY**

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/uniisearch
For UNIL requests contact: FDA-SRS@fda.hhs.gov.
Structured Product Labeling Resources | FDA
DUNSLink (dnb.com)

MANAGE ACCOUNT

EDIT USER PROFILE
MANAGE USERS

REGISTRATION OF COSMETIC PRODUCT FACILITY

For assistance with validation errors in Cosmetics Direct contact cosmetics@fda.hhs.gov. For general questions regarding electronic registration and listing of cosmetic product facilities and products, contact direct@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 LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
SUBMISSION ACCEPTED	fd850b1f-7bcd-165a-e053-6b94af0ac496	Rfd850b1f-7bce-165a-e053-6b94af0ac496	cd6287459103.64893257@direct	1	FACILITY NAME	1000125370		REGISTRATION OF COSMETIC PRODUCT FACILITY	First name Last name	07-JUN-2023 02:53:31	

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](#).



HOME > 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 eRLC@fda.hhs.gov.

+ DOCUMENT TYPE DETAILS

+ REGISTRATION DETAILS

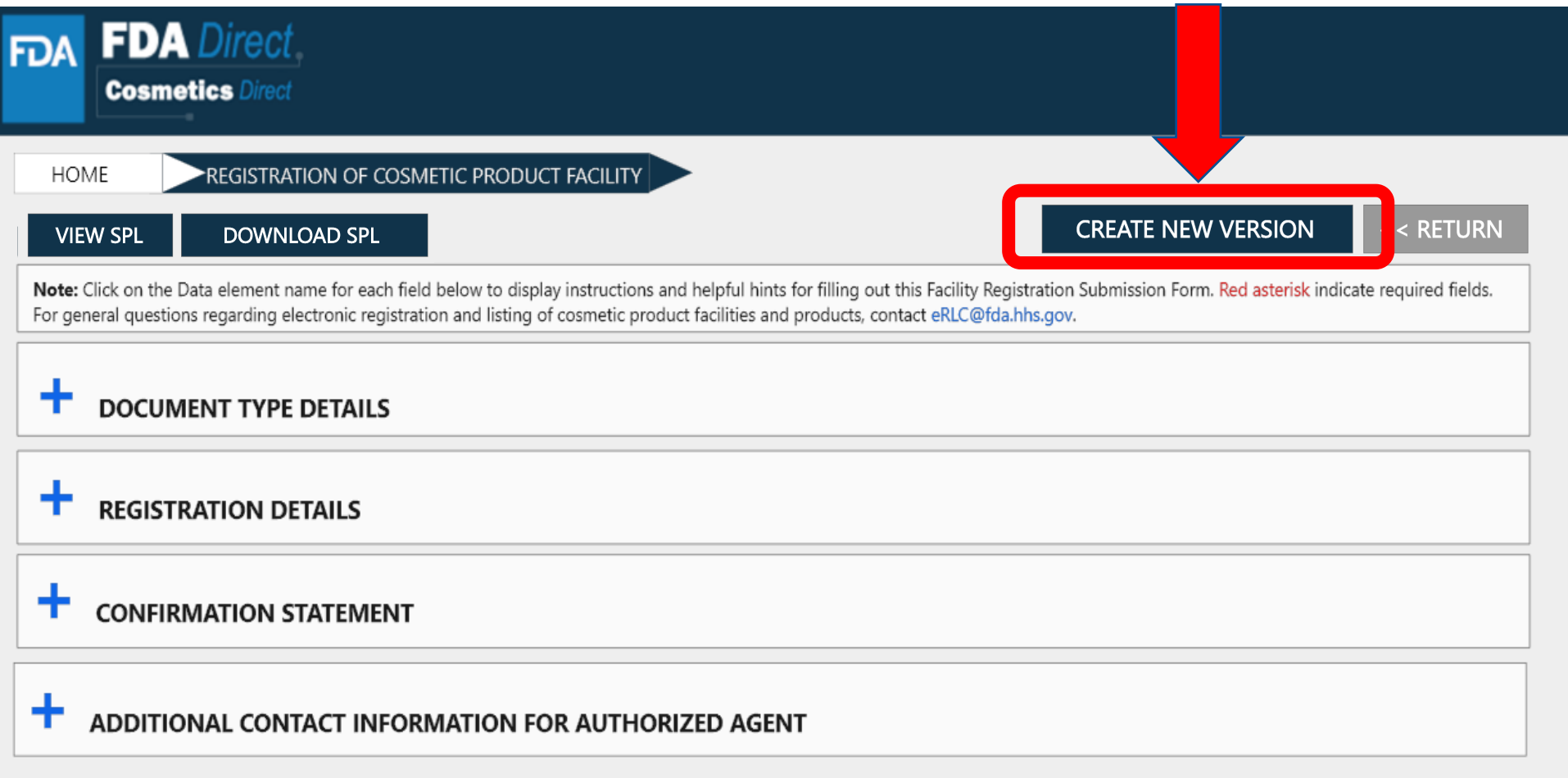
+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT



CREATE A NEW VERSION

By clicking on the [CREATE A NEW VERSION](#), you can clone a successfully-submitted SPL as a starting point.



FDA **FDA Direct**
Cosmetics Direct

HOME ► REGISTRATION OF COSMETIC PRODUCT FACILITY

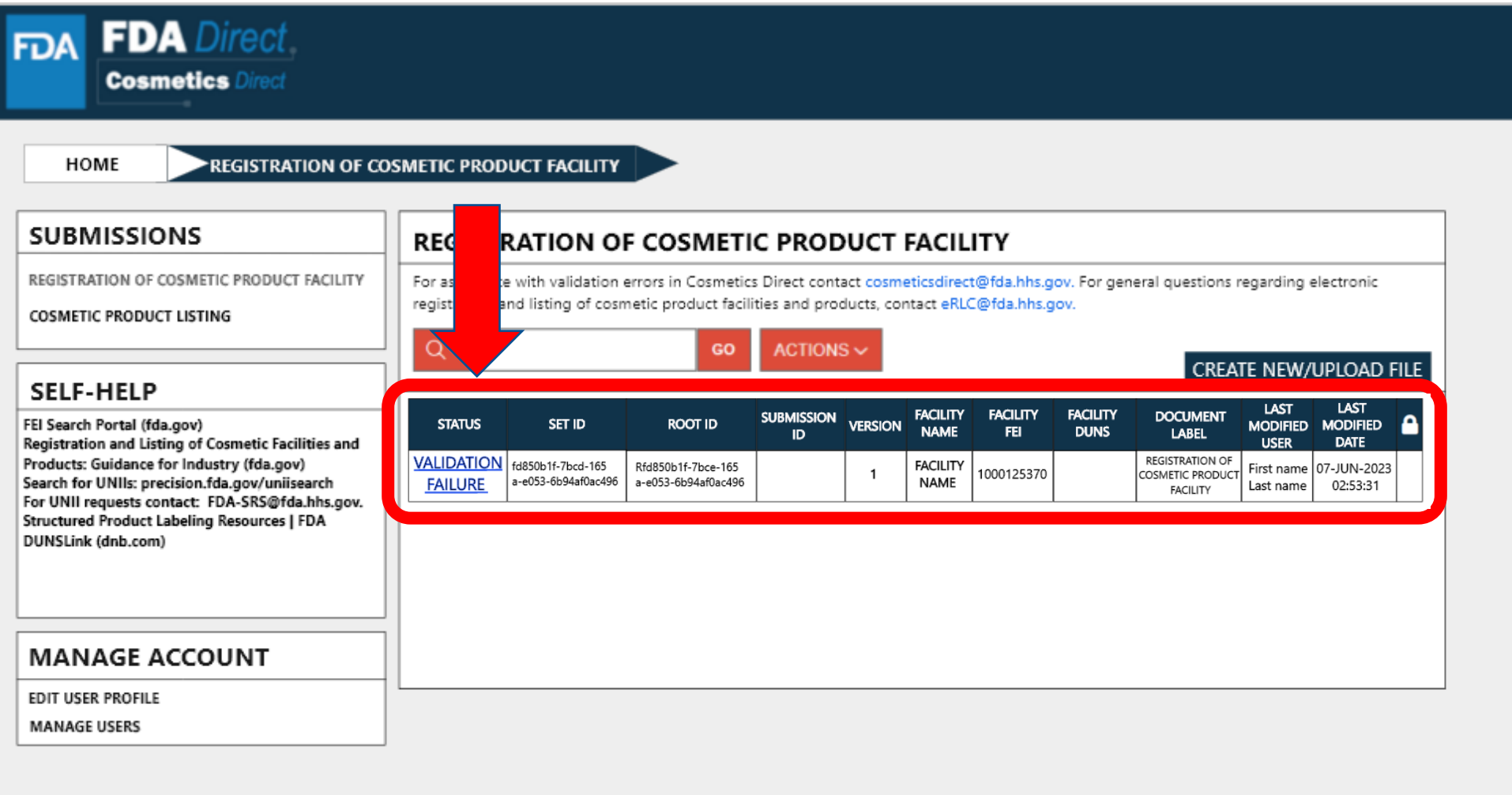
VIEW SPL | DOWNLOAD SPL | **CREATE NEW VERSION** | < RETURN

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 eRLC@fda.hhs.gov.

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

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". A red arrow points to a search bar containing the text "VALIDATION FAILURE". 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, FACILITY NAME, FACILITY FEI, FACILITY DUNS, DOCUMENT LABEL, LAST MODIFIED USER, LAST MODIFIED DATE, and a lock icon. The STATUS column contains the text "VALIDATION FAILURE".

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 UNII: precision.fda.gov/uniisearch
For UNII requests contact: FDA-SRS@fda.hhs.gov.
Structured Product Labeling Resources | FDA DUNSLink (dnb.com)

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.

GO ACTIONS

CREATE NEW/UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
VALIDATION FAILURE	fd850b1f-7bcd-165a-e053-6b94af0ac496	Rfd850b1f-7bce-165a-e053-6b94af0ac496		1	FACILITY NAME	1000125370		REGISTRATION OF COSMETIC PRODUCT FACILITY	First name Last name	07-JUN-2023 02:53:31	

REGISTRATION STATUS: VALIDATION FAILURE

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 displays the FDA Direct Cosmetics Direct interface. At the top left, the logo for FDA Direct Cosmetics Direct is visible. A prominent red error message box is highlighted with a red border and contains the following text:

ERRORS HAVE OCCURRED X

* Error Facility FEI Number : (Go to error)

* 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 error message, the navigation bar includes a "HOME" button and a "REGISTRATION OF COSMETIC PRODUCT FACILITY" button. To the right of the navigation bar are several action buttons: "SUBMIT SPL", "SAVE AS DRAFT", "SAVE AND VALIDATE", "DELETE", and "<< RETURN".

A red arrow points to the "REGISTRATION OF COSMETIC PRODUCT FACILITY" button. Below the navigation bar, a note states: "Note: Click on the Document 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."

The main content area features four expandable sections, each with a blue plus sign icon:

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

REGISTRATION STATUS: 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

HOME REGISTRATION OF COSMETIC PRODUCT FACILITY

SUBMIT SP... **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 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
- + ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

COSMETIC PRODUCT LISTING

Cosmetic Product Listing Home Page.....	44
Create A New Product Listing or Upload An Existing File.....	45
Product Listing Status Examples.....	71

HOME PAGE: COSMETIC PRODUCT 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.

SELF-HELP:

Articles and weblinks are provided for additional information. This box will be available throughout the submission process.

MANAGE ACCOUNT:

Manage sub-users of the account and update profile information.

The ability to view all the previous product listing submissions based on user's access.

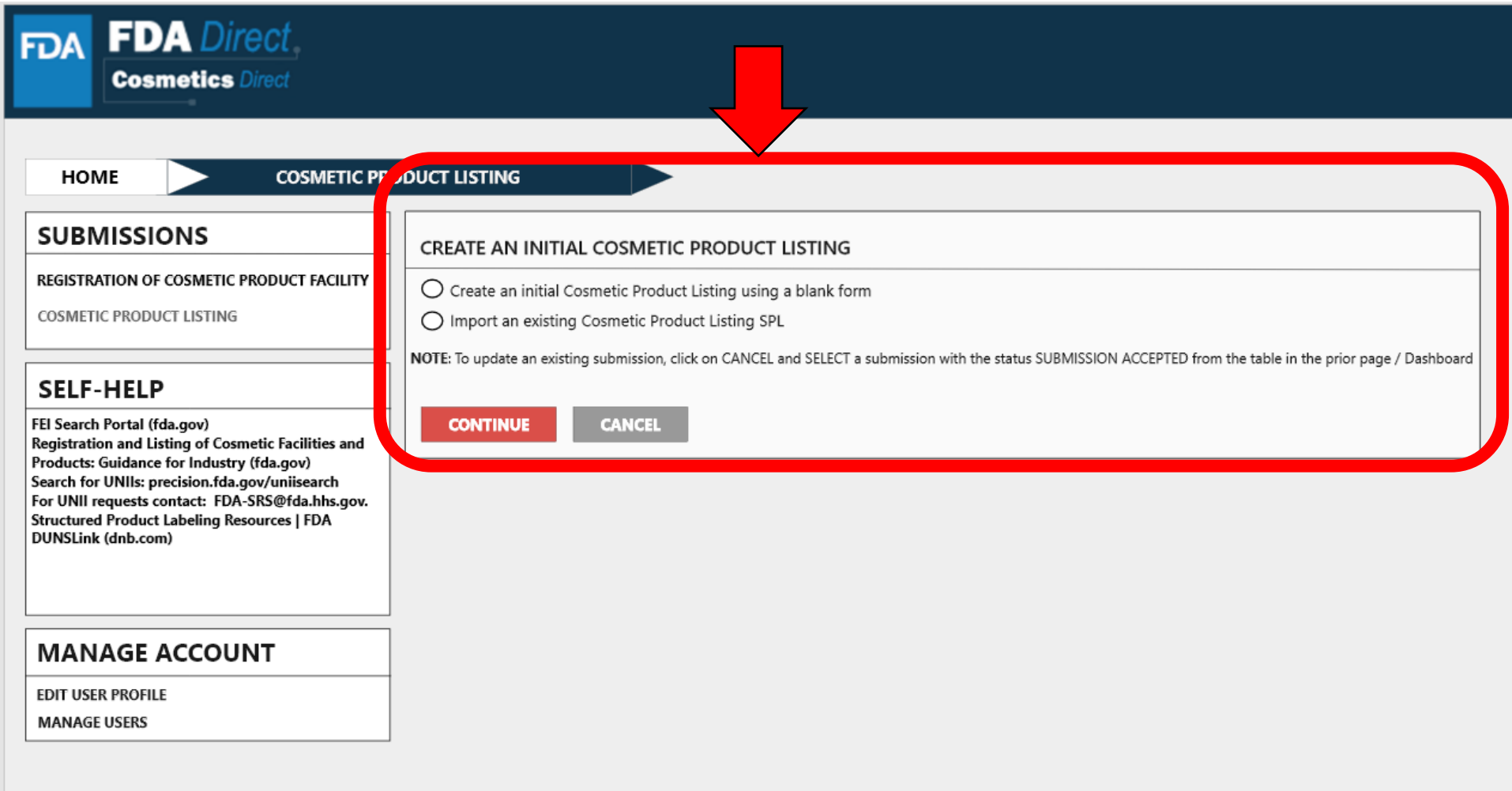
CREATE
NEW/UPLOAD
FILE

The screenshot displays the FDA Direct Cosmetics Direct homepage. At the top, the navigation bar includes 'HOME' and 'COSMETIC PRODUCT LISTING'. The main content area is divided into three sections: 'SUBMISSIONS', 'SELF-HELP', and 'MANAGE ACCOUNT'. The 'SUBMISSIONS' section contains links for 'REGISTRATION OF COSMETIC PRODUCT FACILITY' and 'COSMETIC PRODUCT LISTING'. The 'SELF-HELP' section provides links to the FEI Search Portal, registration and listing guidance, UNIL search, and UNIL requests. The 'MANAGE ACCOUNT' section includes links for 'EDIT USER PROFILE' and 'MANAGE USER'. On the right side, the 'COSMETIC PRODUCT LISTING' section features a search bar with a 'GO' button and an 'ACTIONS' dropdown menu. Below this is a table with columns for 'STATUS', 'SET ID', 'ROW ID', 'SUBMISSION ID', 'VERSION', 'DOCUMENT LABEL', 'TITLE', 'FACILITY FEI/DUNS', 'LAST MODIFIED USER', and 'LAST MODIFIED DATE'. A 'CREATE NEW/UPLOAD FILE' button is located to the right of the table. The footer contains links for 'FDA Home', 'Browser Requirements', 'Resources', 'Tutorials', 'Help Desk', 'FAQs', 'Follow FDA', 'FDA Voice Blog', 'Privacy', and 'Vulnerability Disclosure Policy'.

CREATE A NEW PRODUCT
LISTING OR UPLOAD AN
EXISTING FILE

CREATE A NEW PRODUCT LISTING OR UPLOAD AN EXISTING FILE

Selecting the [CREATE NEW/UPLOAD FILE](#) box, from the [Cosmetic Product listing home page](#) will direct user to this page with an option of creating an initial Cosmetic Product Listing using a blank form or import 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 will be beneficial for bulk submission



The screenshot shows the FDA Direct Cosmetics Direct interface. A red arrow points to the 'CREATE AN INITIAL COSMETIC PRODUCT LISTING' section, which is highlighted with a red rounded rectangle. The interface includes a navigation bar with 'HOME' and 'COSMETIC PRODUCT LISTING' tabs. The left sidebar contains sections for 'SUBMISSIONS' (with links for 'REGISTRATION OF COSMETIC PRODUCT FACILITY' and 'COSMETIC PRODUCT LISTING') and 'SELF-HELP' (with links for 'FEI Search Portal (fda.gov)', 'Registration and Listing of Cosmetic Facilities and Products: Guidance for Industry (fda.gov)', 'Search for UNILs: precision.fda.gov/uniisearch', 'For UNIL requests contact: FDA-SRS@fda.hhs.gov', 'Structured Product Labeling Resources | FDA DUNSLink (dnb.com)', 'MANAGE ACCOUNT', 'EDIT USER PROFILE', and 'MANAGE USERS'). The main content area displays the 'CREATE AN INITIAL COSMETIC PRODUCT LISTING' options: 'Create an initial 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 'CONTINUE' and 'CANCEL' buttons.

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/uniisearch
- 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**

CREATE A NEW COSMETICS PRODUCT LISTING

Create an Initial Cosmetic Product Listing using a blank form.



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/uniisearch
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 NEW 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

DOCUMENT TYPE DETAILS

HOME

COSMETIC PRODUCT LISTING



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. 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

Document Type: *

Set ID: * [Generate New](#)

Version Number: *

Root ID: * [Generate New](#)

Effective Date: *

Title:

+ COSMETIC PRODUCTS

+ CONFIRMATION

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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.

DOCUMENT TYPE TOOL TIPS

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

The screenshot shows the FDA Cosmetics Direct interface. On the left, there is a navigation menu with 'HOME' and 'DOCUMENTS'. The main area displays a 'Document Type' dropdown menu. Several fields are visible: 'Set ID*', 'Root ID*', 'Title', 'Version Number*', and 'Effective Date*'. Red arrows point from the tool tips to these fields. The tool tips provide detailed information about each field, including their purpose and how they are generated.

Document Type

Select one of the document types:-

INITIAL- The responsible person of a cosmetic product that is marketed on December 29, 2022, must submit a cosmetic product listing 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 cosmetic products after December 29, 2022 (section 607(a)(1)(B) of the FD&C Act), FDA expects the product listing for that cosmetic product to be submitted within 120 days after marketing the product, or within 120 days after December 29, 2023, whichever is later.

UPDATE TO CONTENT (annual)- The responsible person must provide any updates to such listing annually (section 607(c)(5) of the FD&C Act). This includes an update that the product was discontinued.

ABBREVIATED REGISTRATION 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.

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.

Title

Enter an optional title to help distinguish this product listing from other product listings within Cosmetics Direct. In addition, this field can help users easily identify their product listing.

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 Effective Date 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.

Version Number: 1

Effective Date: 06-20-2023

DOCUMENT TYPE DETAILS

By selecting the drop-down (▼), four document types options will appear; initial, update to content (annual)-(changes to listing), update to content (annual)-(discontinuation of listing), and abbreviated renewal.

A Guide that will help the user understand different submission stage such as, VAILADATE SPL, SAVE AS DRAFT.

HOME COSMETIC PRODUCT LISTING

Note: Click on the Data element name for each field below to display instructions and helpful hints for filling. For general questions regarding electronic registration and listing of cosmetic product facilities and products, click on the Data element name.

DOCUMENT TYPE DETAILS

Document Type: * -- Select Document Type -- ▼

- Select Document Type --
- INITIAL
- UPDATE TO CONTENT (annual)-CHANGES TO LISTING
- UPDATE TO CONTENT (annual)-DISCONTINUATION OF LISTING
- ABBREVIATED RENEWAL

Set ID: * 18c **Version Number:** * 1

Root ID: * 18b **Effective Date:** * 06-20-2023

Title: * UPDATE TO CONTENT (annual)-DISCONTINUATION OF LISTING

+ COSMETIC PRODUCTS


+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

DOCUMENT TYPE DETAILS

Depending on which document type is selected, an ALERT box will appear, “By selecting this document type, you are certifying that no changes have been made to your product listing since the previous listing was submitted”

FDA **FDA Direct**
Cosmetics Direct

HOME > COSMETIC PRODUCT LISTING 

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. 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

Document Type*: ABBREVIATED RENEWAL v

ALERT:
By selecting this document type, you are certifying that no changes have been made to your product listing since the previous listing was submitted

+ COSMETIC PRODUCTS

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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



Note: Click on the Data element name for each field below to display instructions and helpful hints for completing 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, please contact eRLC@fda.hhs.gov.

+ DOCUMENT TYPE DETAILS

- COSMETIC PRODUCTS

IS THIS PRODUCT LISTING FOR A SMALL BUSINESS (optional registration)? YES NO

Responsible Person:
(as listed on label)

Type Of Business: MANUFACTURER PACKER DISTRIBUTOR

Responsible Person Name: *
(as listed on label)

Responsible Person DUNS
Number for Address Listed
on Product Label:

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

Parent Company Name:
(If applicable)

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

Add all required information by selecting ADD PRODUCT(S), INGREDIENT(S), and FACILITY(IES) where the cosmetic product is manufactured or processed.

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

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT


COSMETIC PRODUCTS

A ***RED*** asterisk indicates field is mandatory. A dashed underline indicates help text (tool-tips). To list all the **PRODUCTS**, **INGREDIENTS** and **FACILITIES** where the cosmetic product is manufactured or processed, **SELECT ADD PRODUCT(S), INGREDIENT(S) and FACILITY(IES)**.

PRODUCTS, INGREDIENTS AND FACILITIES

Provide all the information required for PRODUCT(S), INGREDIENT(S) and FACILITY(IES) where the cosmetic product is manufactured or processed.

**FDA Direct**
Cosmetics Direct

[HOME](#) > [COSMETIC PRODUCT LISTING](#) > **COSMETIC PRODUCTS** 

[SAVE](#) [<< 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.

COSMETIC PRODUCTS

Product Listing Number:

Product Name: *
(As listed on label)

Product Webpage Link: Image Of Label 
(Attach images of the front and back product labels by selecting the icon)

Fragrance or Flavor: *

--SELECT --	▼
Fragrance	
Flavor	
Fragrance & Flavor	
N/A	

 Is This Product For Professional USE ONLY?

--SELECT --	▼
YES	
NO	

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

Fill in all the required fields. PRODUCT LISTING NUMBER is autogenerated for each PRODUCT.

COSMETIC PRODUCTS

Product Listing Number:

Product Name: *
(As listed on label)

Product Webpage Link: Image Of Label 
(Attach images of the front and back product labels by selecting the icon)

Fragrance or Flavor: * Is This Product For Professional USE ONLY?

PRODUCT CATEGORY CODE(S)- EXAMPLE

- PRODUCT CATEGORY CODE(s)

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).

(08) Makeup preparations (not eye)(other than makeup preparations for children).

(h) Other

+ INGREDIENTS

+ LIST OF FACILITIES

ESSED

Provide the Product Category Code(s) by selecting the drop-down icon. After selecting the drop-down icon, SELECT ALL PRODUCT CATEGORY CODE(s) that apply to this submission. The list can be minimized/maximized with the (-) or (+).

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.

COSMETIC PRODUCTS

Product Listing Number:

Product Name: *
(As listed on label)

Product Webpage Link: Image Of Label 
(Attach images of the front and back)

Fill in all the INGREDIENTS that are included in this product listing or upload a prefilled ingredients file. Common, usual or chemical name will auto-populate as you type along with its UNII.

INGREDIENTS

Ingredient UNII-Name: *  ADD UPLOAD INGREDIENTS FILE: 

	Ingredient UNII Code(s)	Common, Usual or Chemical Name *
X	059QF0KO0R	WATER
X	PDC6A3C0OX	GLYCERIN
X	TTV12P4NEE	XANTHAN GUM
X	ZY81Z83H0X	ALOE VERA LEAF EXTRACT
X	HIE492ZZ3T	PHENOXYETHANOL
X	H3R47K3TBD	FD&C BLUE NO.1

LISTING INGREDIENTS (EXAMPLE)

List of the complete ingredients list will appear with UNII (if available)

+ LIST OF FACILITIES WHERE THE COSMETIC PRODUCT IS MANUFACTURED OR PROCESSED

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.

COSMETIC PRODUCTS

Product Listing Number:

Product Name: *
(As listed on label)

Image Of Label
(Attach images)

Fill in where the cosmetic product is manufactured or processed.

+ INGREDIENTS

LIST OF FACILITIES WHERE THE COSMETIC PRODUCT IS MANUFACTURED OR PROCESSED

FDA ESTABLISHMENT IDENTIFIER (FEI) OF EACH FACILITY(IES) WHERE THE PRODUCT IS MANUFACTURED OR PROCESSED
(if the facility is a small business and is not required to register, please enter the name and address of the facility) *

IS THIS FACILITY A SMALL BUSINESS? * YES NO

Facility Name *

Facility Country *

Facility Street Address *

Facility FEI Number: *

Facility City *

Facility State or Province *

Facility Zip/Postal Code *

SAVE FACILITY INFORMATION

FDA ESTABLISHMENT IDENTIFIER (FEI)	FACILITY NAME	FACILITY ADDRESS
X		

LIST OF FACILITY(IES) (EXAMPLE)

If the business is a NOT a small business, then FEI is REQUIRED.

If the facility is a small business and is not required to register, then FEI IS NOT REQUIRED, but will need to provide the name and address of the facility.

LIST OF FACILITY (EXAMPLE)

FDA ESTABLISHMENT IDENTIFIER (FEI) OF EACH FACILITY(IES) WHERE THE PRODUCT IS MANUFACTURED OR PROCESSED
(if the facility is a small business and is not required to register, please enter the name and address of the facility) *

IS THIS FACILITY A SMALL BUSINESS ? *

YES NO

Facility FEI Number: *

Facility Name

Facility City

Facility Country

--SELECT COUNTRY-- ▼

Facility State or Province

Facility Street Address

Facility Zip/Postal Code

SAVE FACILITY INFORMATION

FDA ESTABLISHMENT IDENTIFIER (FEI) OF EACH FACILITY(IES) WHERE THE PRODUCT IS MANUFACTURED OR PROCESSED
(if the facility is a small business and is not required to register, please enter the name and address of the facility) *

IS THIS FACILITY A SMALL BUSINESS ? *

YES NO

Facility FEI Number:

Facility Name *

Facility City *

Facility Country *

--SELECT COUNTRY-- ▼

Facility State or Province *

Facility Street Address *

Facility Zip/Postal Code *

SAVE FACILITY INFORMATION

	FDA ESTABLISHMENT IDENTIFIER (FEI)	FACILITY NAME	FACILITY ADDRESS
X			

If the business is a NOT a small business, then FEI is REQUIRED

If the facility is a small business and is not required to register, then FEI IS NOT REQUIRED, but will need to provide the name and address of the facility.

Once SAVED, the information will appear in this table



After verifying the entered information is correct, select **SAVE**

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

COSMETIC PRODUCTS

Product Listing Number:

Product Name: *
(As listed on label)

Product Webpage Link: Image Of Label (Attach images of the front and back product labels by selecting the icon)

Fragrance or Flavor: * Is This Product For Professional USE ONLY?

PRODUCT CATEGORY CODE(S)

Product Category Code(s): *

Product Category Code(s)
(01)BABY PRODUCTS:-(a)Baby shampoos;(c)Baby wipes;(d)Other baby products(1. Leave-on)

INGREDIENTS

Ingredient UNII-Name: *

	Ingredient UNII Code(s)	Common, Usual or Chemical Name *
X	059QF0K00R	WATER
X	PDC6A3C00X	GLYCERIN
X	JTV12P4NEE	XANTHAN GUM
X	ZY81Z83H0X	ALOE VERA LEAF EXTRACT
X	HIE492ZZ3T	PHENOXYETHANOL
X	H3R47K3TBD	FD&C BLUE NO.1

LIST OF FACILITIES WHERE THE COSMETIC PRODUCT IS MANUFACTURED OR PROCESSED

FDA ESTABLISHMENT IDENTIFIER (FEI) OF EACH FACILITY(IES) WHERE THE PRODUCT IS MANUFACTURED OR PROCESSED
(if the facility is a small business and is not required to register, please enter the name and address of the facility) *

IS THIS FACILITY A SMALL BUSINESS ? YES NO **Facility FEI Number:**

Facility Name: **Facility City:**

Facility Country: **Facility State or Province:**

Facility Street Address: **Facility Zip/Postal Code:**

SAVE FACILITY INFORMATION

	FDA ESTABLISHMENT IDENTIFIER (FEI)	FACILITY NAME	FACILITY ADDRESS
X		FACILITY NAME	FACILITY ADDRESS

EXAMPLE OF A COMPLETE LISTING (PRODUCTS, INGREDIENTS AND FACILITIES TAB)

PRODUCTS, INGREDIENTS AND FACILITIES

The information that was provided in the pop-up will appear under PRODUCT(S),
INGREDIENT(S) and FACILITY(IES).

Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out this Cosmetic Product Listing. For general questions regarding electronic registration and listing of cosmetic product facilities and products, contact eRLC@fda.hhs.gov.

+ DOCUMENT TYPE DETAILS

- COSMETIC PRODUCTS

IS THIS PRODUCT LISTING FOR A SMALL BUSINESS (optional registration)? YES NO

Responsible Person: (as listed on label) Type Of Business: MANUFACTURER PACKER DISTRIBUTOR

Responsible Person Name: * (as listed on label)

Parent Facility (if applicable)

Multiple cosmetic products with identical formulations, or formulations that differ only with respect to color, fragrances or flavors can be added. By selecting the CLONE PRODUCT, the system will COPY the INGREDIENT LIST and FACILITY ADDRESS (only) to SAVE TIME for multiple entry.

Entry CAN BE EDITED by selecting this icon.

For a new entry, select ADD PRODUCT(S), INGREDIENT(S), and FACILITY(IES)

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

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

Product Number	Product Name (As listed on label)	Fragrance or Flavor	Is This Product For Professional USE ONLY?	Product Category Code(s)	Ingredient UNII code(s) Common, Usual or Chemical Name	Facility FEI	Facility Name	Facility Address	Clone Product
<input checked="" type="checkbox"/> 1234-567-01	Cosmetic Beauty Aloe Gel-Blue	N/A	NO	--VIEW LIST--	--VIEW LIST--	--VIEW LIST--	--VIEW LIST--	--VIEW LIST--	X

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

COSMETIC PRODUCTS

Product Listing Number:

Product Name: *

(As listed on label)

Product Webpage Link:

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

Fragrance or Flavor: * Is This Product For Professional USE ONLY?

PRODUCT CATEGORY CODE(S)

Product Category Code(s): *

INGREDIENTS

Ingredient UNII-Name: * SEARCH

UPLOAD INGREDIENTS FILE:

	Ingredient UNII Code(s)	Common, Usual or Chemical Name *
X	059QF0KO0R	WATER
X	PDC6A3C0OX	GLYCERIN
X	JTV12P4NEE	XANTHAN GUM
X	ZY81Z83H0X	ALOE VERA LEAF EXTRACT
X	HIE492ZZ3T	PHENOXYETHANOL
X	H3R47K3TBD	FD&C BLUE NO.1

LIST OF FACILITIES WHERE THE COSMETIC PRODUCT IS MANUFACTURED OR PROCESSED

FDA ESTABLISHMENT IDENTIFIER (FEI) OF EACH FACILITY(IES) WHERE THE PRODUCT IS MANUFACTURED OR PROCESSED
(if the facility is a small business and is not required to register, please enter the name and address of the facility) *

IS THIS FACILITY A SMALL BUSINESS ? YES NO **Facility FEI Number:**

Facility Name: **Facility City:**

Facility Country: **Facility State or Province:**

Facility Street Address: **Facility Zip/Postal Code:**

SAVE FACILITY INFORMATION

	FDA ESTABLISHMENT IDENTIFIER (FEI)	FACILITY NAME	FACILITY ADDRESS
X		FACILITY NAME	FACILITY ADDRESS

After verifying the entered information is correct, select **SAVE**

EXAMPLE OF A PREFILLED CLONE

Any prefilled information can be edited.

CONFIRMATION STATEMENT

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



Signature of Submitter



(optional field) Click on the blank signature box to display signature pad

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

FDA **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

+ PRODUCT, INGREDIENT and FACILITY LISTING OF THE COSMETIC PRODUCT

- **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 act.

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

AGREE

Signature of Submitter Name of Submitter

Date (MM/DD/YYYY)

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED A...

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

After understanding the confirmation statement. Select **AGREE**



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

+ PRODUCT INGREDIENT and FACILITY LISTING OF THE COSMETIC PRODUCT

- 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 act.

WARNING:

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

AGREE



Signature of Submitter

Name of Submitter

Date (MM/DD/YYYY)



By clicking on the signature of submitter box the USER will be able to provide a signature

CONFIRMATION STATEMENT SIGNATURE

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



Signature of Submitter



(optional field) Click on the blank signature box to display signature pad

Name of Submitter



(optional field) Enter the full name of the submitter

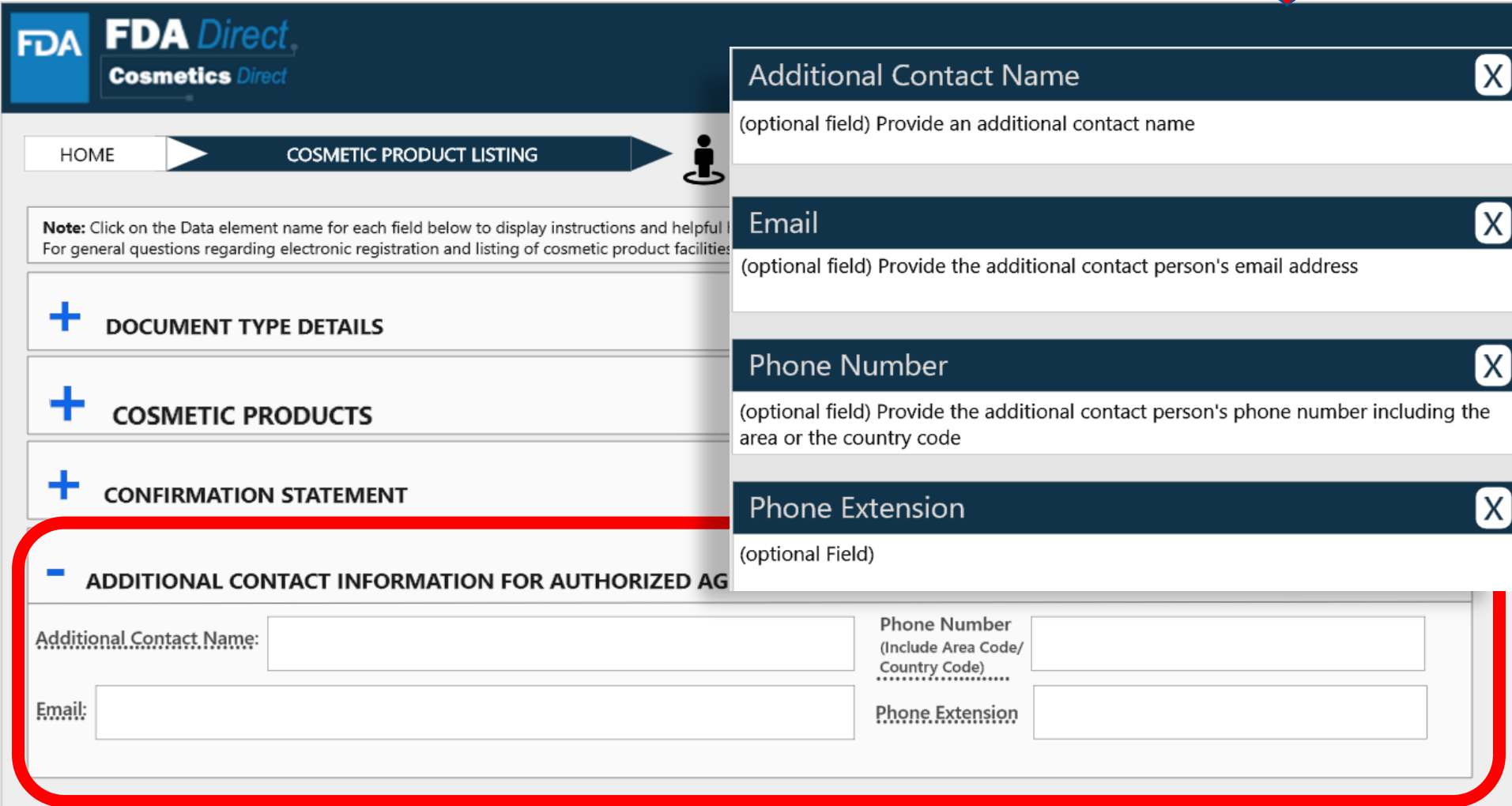
Date



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

ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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



FDA Direct
Cosmetics Direct

HOME | COSMETIC PRODUCT LISTING

Note: Click on the Data element name for each field below to display instructions and helpful information. For general questions regarding electronic registration and listing of cosmetic product facilities, click on the Help icon.

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

ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

Additional Contact Name:

Email:

Phone Number (Include Area Code/Country Code):

Phone Extension:

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)

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.

FDA Direct
Cosmetics Direct

HOME > COSMETIC PRODUCT LISTING

Note: Click on the D...
For general question...

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

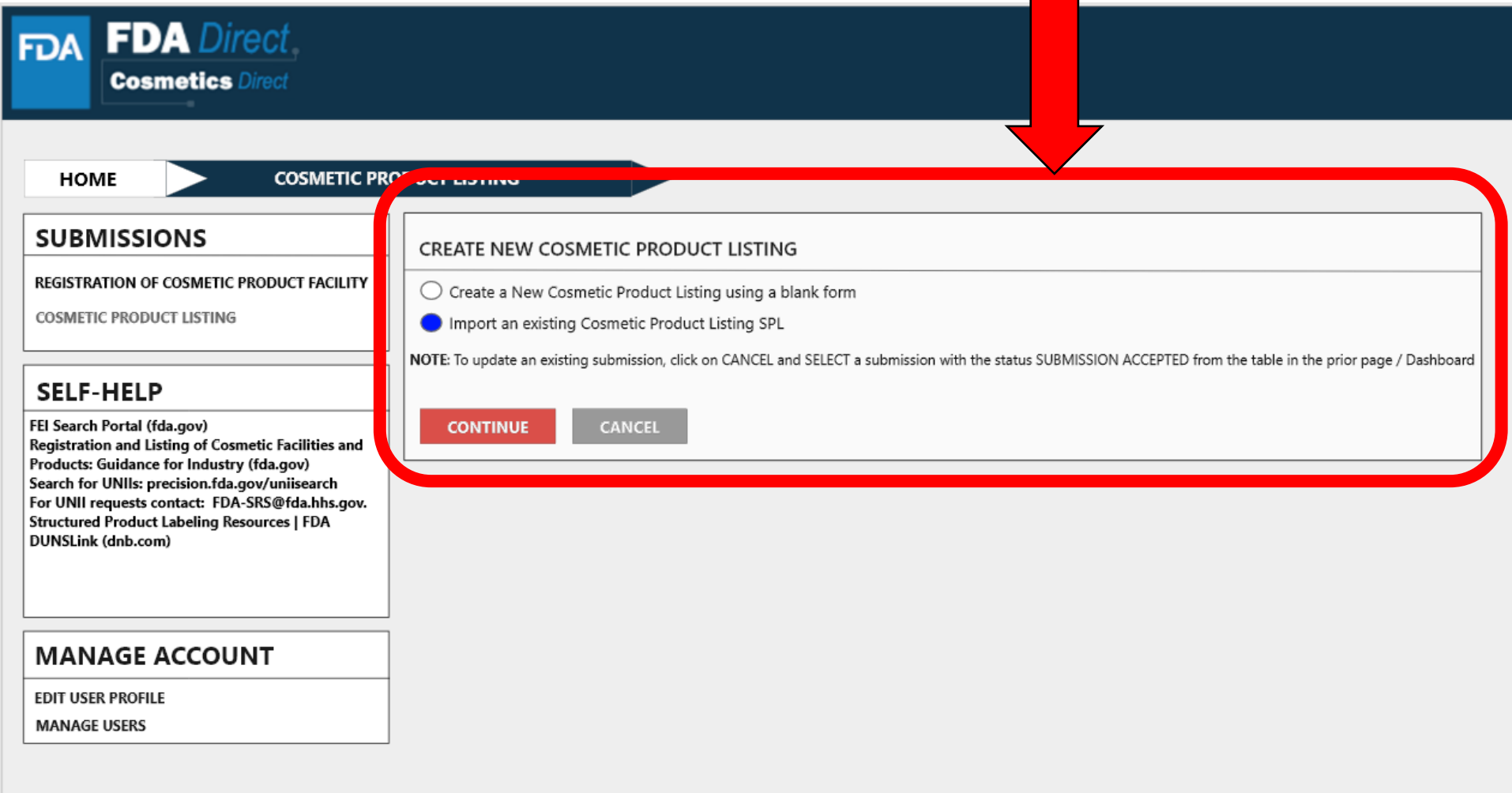
Submit SPL
Submit SPL to FDA.
Next Disable Tour

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

+ DOCUMENT...
+ COSME...
+ CONFIRMATION STATEMENT
+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

UPLOAD A FILE

In order to upload a file, select Import an existing Cosmetic Product Listing SPL. Importing an existing Cosmetic Product Listing SPL will be beneficial for bulk submission.



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/uniisearch
For UNIL requests contact: FDA-SRS@fda.hhs.gov.
Structured Product Labeling Resources | FDA
[DUNSLink \(dnb.com\)](http://DUNSLink.com)

MANAGE ACCOUNT

- EDIT USER PROFILE
- MANAGE USERS

CREATE NEW COSMETIC PRODUCT LISTING

- Create a New Cosmetic Product Listing using a blank form
- Import an existing Cosmetic Product Listing SPL

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

CONTINUE **CANCEL**

UPLOAD A FILE

User will be able to upload a pre-existing ZIP FILE, this file may contain both the xml file and image (jpg) files. For more information regarding SPL, utilize the **Structured Product Labeling Resources | FDA (SPL)** link provided under **SELF-HELP**

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/uniisearch

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

Structured Product Labeling Resources | FDA (SPL)

DUNSLink (dnb.com)

MANAGE ACCOUNT

EDIT USER PROFILE

MANAGE USERS

UPLOAD COSMETIC PRODUCT LISTING FILE

Cosmetic Product Listing File

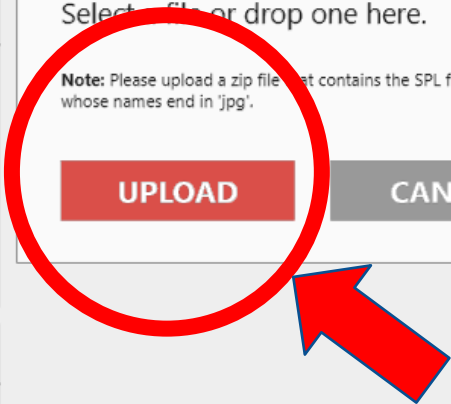


Select a file or drop one here.

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

UPLOAD

CANCEL



UPLOAD A FILE (EXAMPLE)

The content in the red circle is an example to what a zip file could be, may contain .xml file and image (jpg) files.

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 UNII: precision.fda.gov/uniisearch
For UNII requests contact: FDA-SRS@fda.hhs.gov.
Structured Product Labeling Resources | FDA (SPL)
DUNSLink (dnb.com)

MANAGE ACCOUNT
EDIT USER PROFILE
MANAGE USERS

UPLOAD COSMETIC PRODUCT LISTING FILE

Cosmetic Product Listing File 
fd8c4f0b-ca3a-82e2-e053-6394a90aa8de

Please upload a zip file that contains the SPL file with the name as "Cosmetic Product Listing File" by ".xml" and any associated image files that referenced in the xml whose names end in ".jpg".

UPLOAD **CANCEL**

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 (EXAMPLE)

After [UPLOADING A FILE](#) (XML ZIP FILE), the system will auto-fill all the required fields 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: “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. ”

The screenshot shows the FDA Direct Cosmetics Direct interface. At the top left is the FDA Direct logo. Below it is a navigation bar with 'HOME' and 'COSMETIC PRODUCT LISTING'. A user icon is in the center. On the right, there are buttons for 'SUBMIT SPL', 'SAVE', 'DRAFT', 'SAVE AND VALIDATE', 'DELETE', and 'RETURN'. A 'Validate SPL' modal is open, displaying 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.' A 'Next' button is at the bottom of the modal. A red callout box labeled 'TOUR GUIDE' points to the 'Validate SPL' modal and contains the text: 'A Guide that will help the user understand different submission stage such as, VAILADATE SPL.' The left sidebar has a list of sections: 'DOCUMENT TYPE DETAILS', 'COSMETIC PRODUCTS', 'CONFIRMATION STATEMENT', and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'.

**TOUR
GUIDE**

A Guide that will help the user understand different submission stage such as, VAILADATE SPL.

Validate SPL

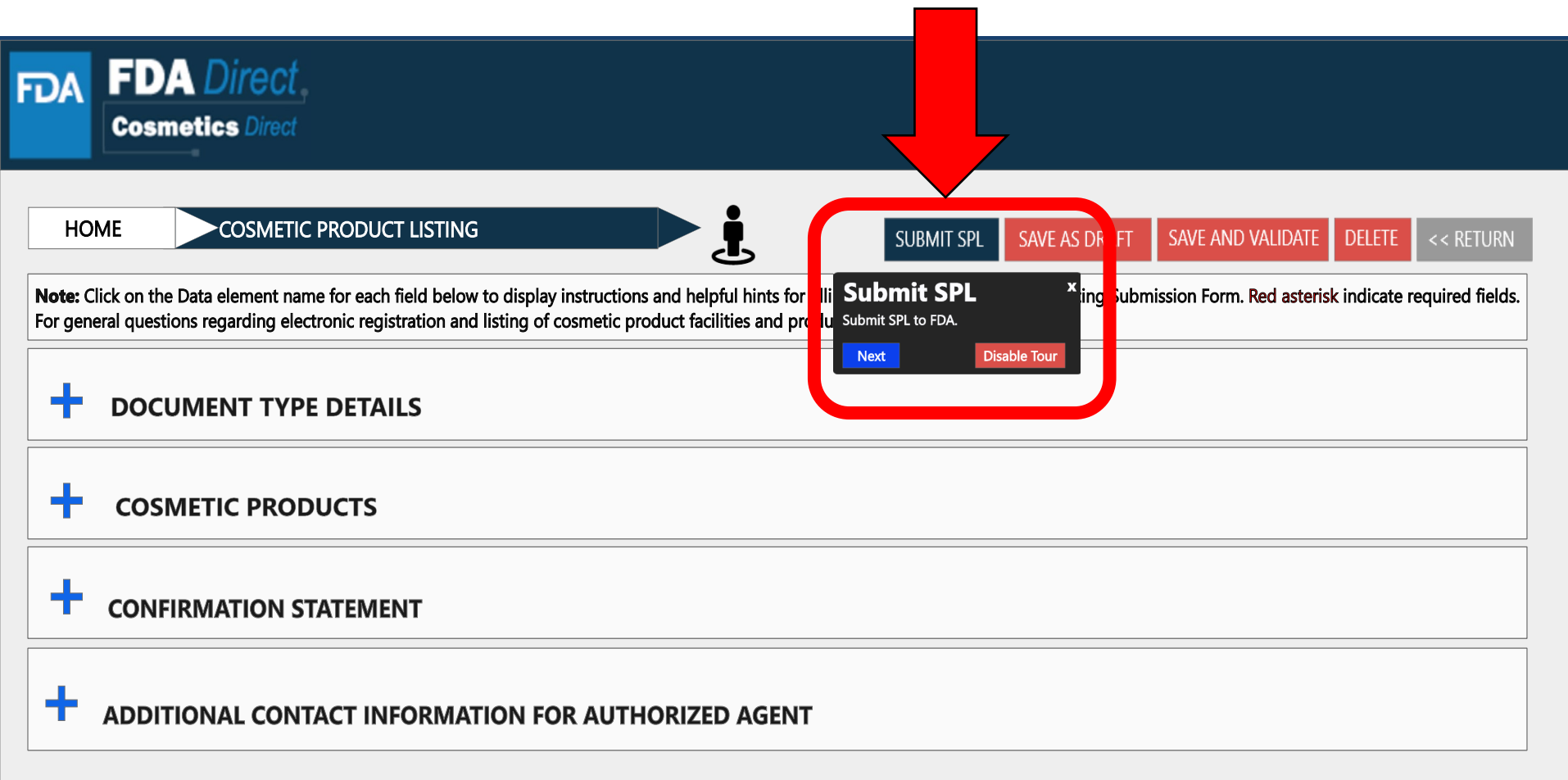
You can check your SPL for an initial validation before submitting to FDA. This option does not automatically submit your SPL to FDA, even if it passes the initial validation, but scans for certain errors prior to the actual submission.

[Next](#)

UPLOAD A FILE (EXAMPLE)

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 left, the logo for FDA Direct Cosmetics Direct is visible. The main navigation bar includes a breadcrumb trail: HOME > COSMETIC PRODUCT LISTING, followed by a user icon. To the right of the user icon, a row of action buttons is present: SUBMIT SPL (highlighted with a red arrow and a red box), SAVE AS DRAFT, 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 the Submission Form. Red asterisk indicate required fields. For general questions regarding electronic registration and listing of cosmetic product facilities and products, please contact the FDA." Below the note, there are four expandable sections, each with a plus sign icon: DOCUMENT TYPE DETAILS, COSMETIC PRODUCTS, CONFIRMATION STATEMENT, and ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT. A 'Submit SPL' tooltip is overlaid on the 'SUBMIT SPL' button, containing the text 'Submit SPL' and 'Submit SPL to FDA.', along with 'Next' and 'Disable Tour' buttons.

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](#).

The screenshot displays the FDA Direct Cosmetics Direct interface. At the top, the navigation bar includes 'HOME' and 'COSMETIC PRODUCT LISTING'. 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, a table lists submissions. The first submission is highlighted with a red box and has a status of 'VALIDATION IN PROGRESS'. The table columns are: STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, DOCUMENT LABEL, TITLE, PRODUCT DETAILS, LAST MODIFIED USER, and LAST MODIFIED DATE. The 'PRODUCT DETAILS' column for the highlighted submission contains a 'DETAILS' link. The 'LAST MODIFIED DATE' is '07-JUN-2023 02:53:31'.

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/uniisearch
For UNIL requests contact: FDA-SRS@fda.hhs.gov.
Structured Product Labeling Resources | FDA (SPL)
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

CREATE NEW/UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
VALIDATION IN PROGRESS	fd850b1f-7bcd-165a-e053-6b94af0ac496	Rfd850b1f-7bce-165a-e053-6b94af0ac496		1	COSMETIC PRODUCT LISTING	Cosmetic Beauty (Different Color Aloe Gels)	DETAILS	First name Last name	07-JUN-2023 02:53:31

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 a quick **VALIDATION**, the status [VALIDATION IN PROGRESS](#) will change to [READY FOR SUBMISSION](#).



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 (SPL)
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.

Q GO ACTIONS

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
READY FOR SUBMISSION	fd850b1f-7bcd-165a-e053-6b94af0ac496	Rfd850b1f-7bce-165a-e053-6b94af0ac496		1	COSMETIC PRODUCT LISTING	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 that, *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'. Below this is a navigation bar with 'HOME', 'ETIC PRODUCT LISTING', and a user icon. On the right side of the navigation bar are buttons for 'EDIT', 'SUBMIT SPL', and '<< RETURN'. A large red arrow points down to the 'SUBMIT SPL' button. Below the navigation bar is a note: 'Note: Click on the Data element 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 ePLC@fda.hhs.gov'. A second large red arrow points down to this note. Below the note is a red-bordered box containing the text: 'Note: This submission has passed the INITIAL VALIDATION but has NOT been ACTUALLY SUBMITTED TO FDA. Click ON "SUBMIT SPL" to SUBMIT.'. Below this box are four expandable sections: '+ DOCUMENT TYPE DETAILS', '+ COSMETIC PRODUCTS', '+ CONFIRMATION STATEMENT', and '+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'.

LISTING STATUS: SUBMIT SPL TO SUBMISSION ACCEPTED

The status will change to [SUBMISSION ACCEPTED](#) after listing had been successfully completed. A SUBMISSION ID will be given to all ACCEPTED SUBMISSIONS.

The screenshot shows the FDA Direct Cosmetics Direct interface. At the top, there is a navigation bar with 'HOME' and 'COSMETIC PRODUCT LISTING'. Below this, there are three main sections: 'SUBMISSIONS', 'SELF-HELP', and 'MANAGE ACCOUNT'. The 'SUBMISSIONS' section contains a table of product listings. One listing is highlighted with a red box and a red arrow pointing to its status, which is 'SUBMISSION ACCEPTED'. The 'SELF-HELP' section provides links to various resources, and the 'MANAGE ACCOUNT' section offers options to edit the user profile or manage users. The bottom of the page features a footer with links to FDA Home, Browser Requirements, Resources, Tutorials, Help Desk, FAQs, and other resources.

FDA Direct Cosmetics Direct

HOME COSMETIC PRODUCT LISTING

SUBMISSIONS

REGISTRATION OF COSMETIC PRODUCT FACILITY
COSMETIC PRODUCT LISTING

SELF-HELP

FEI Search Portal (fda.gov)
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For UNIL requests contact: FDA-SRS@fda.hhs.gov.
Structured Product Labeling Resources | FDA (SPL)
DUNSLink (dnb.com)

MANAGE ACCOUNT

EDIT USER PROFILE
MANAGE USERS

COSMETIC PRODUCT LISTING

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

SEARCH GO ACTIONS

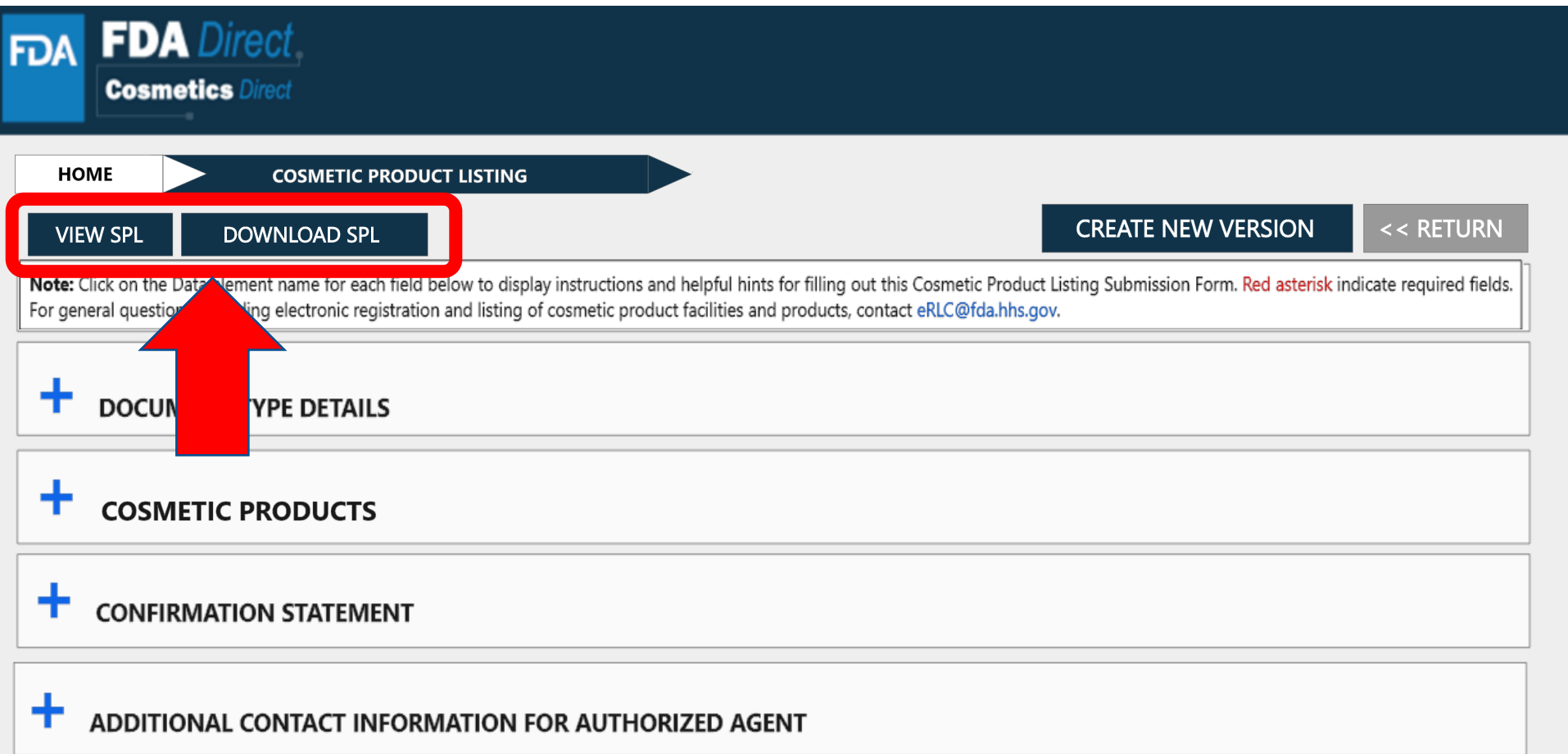
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
SUBMISSION ACCEPTED	fd850b1f-7bcd-165a-e053-6b94af0ac496	Rfd850b1f-7bce-165a-e053-6b94af0ac496	cd7777459103.614893257@direct	1	COSMETIC PRODUCT LISTING	Cosmetic Beauty (Different Color Aloe Gels)	DETAILS	First name Last name	07-JUN-2023 02:53:31

SEARCH REVIEW / UPLOAD FILE

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

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. In the center of the navigation bar, there are two buttons: 'VIEW SPL' and 'DOWNLOAD SPL', both of which are highlighted with a red rectangular box. To the right of these buttons are 'CREATE NEW VERSION' and '<< RETURN' buttons. Below the navigation bar, 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 is a list of sections, each with a blue plus sign icon: 'DOCUMENT TYPE DETAILS', 'COSMETIC PRODUCTS', 'CONFIRMATION STATEMENT', and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. A large red arrow points upwards from the bottom of the 'DOCUMENT TYPE DETAILS' section towards the 'VIEW SPL' and 'DOWNLOAD SPL' buttons.

CREATE A NEW VERSION

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

HOME

COSMETIC PRODUCT LISTING

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 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.

+ DOCUMENT TYPE DETAILS

+ COSMETIC PRODUCTS

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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 in VALIDATION IN PROGRESS. However, if the system finds any errors the status will change to VALIDATION FAILURE.

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/uniisearch
For UNIL requests contact: FDA-SRS@fda.hhs.gov.
Structured Product Labeling Resources | FDA (SPL)
DUNSLink (dnb.com)

MANAGE ACCOUNT

EDIT USER PROFILE
MANAGE USERS

COSMETIC PRODUCT LISTING

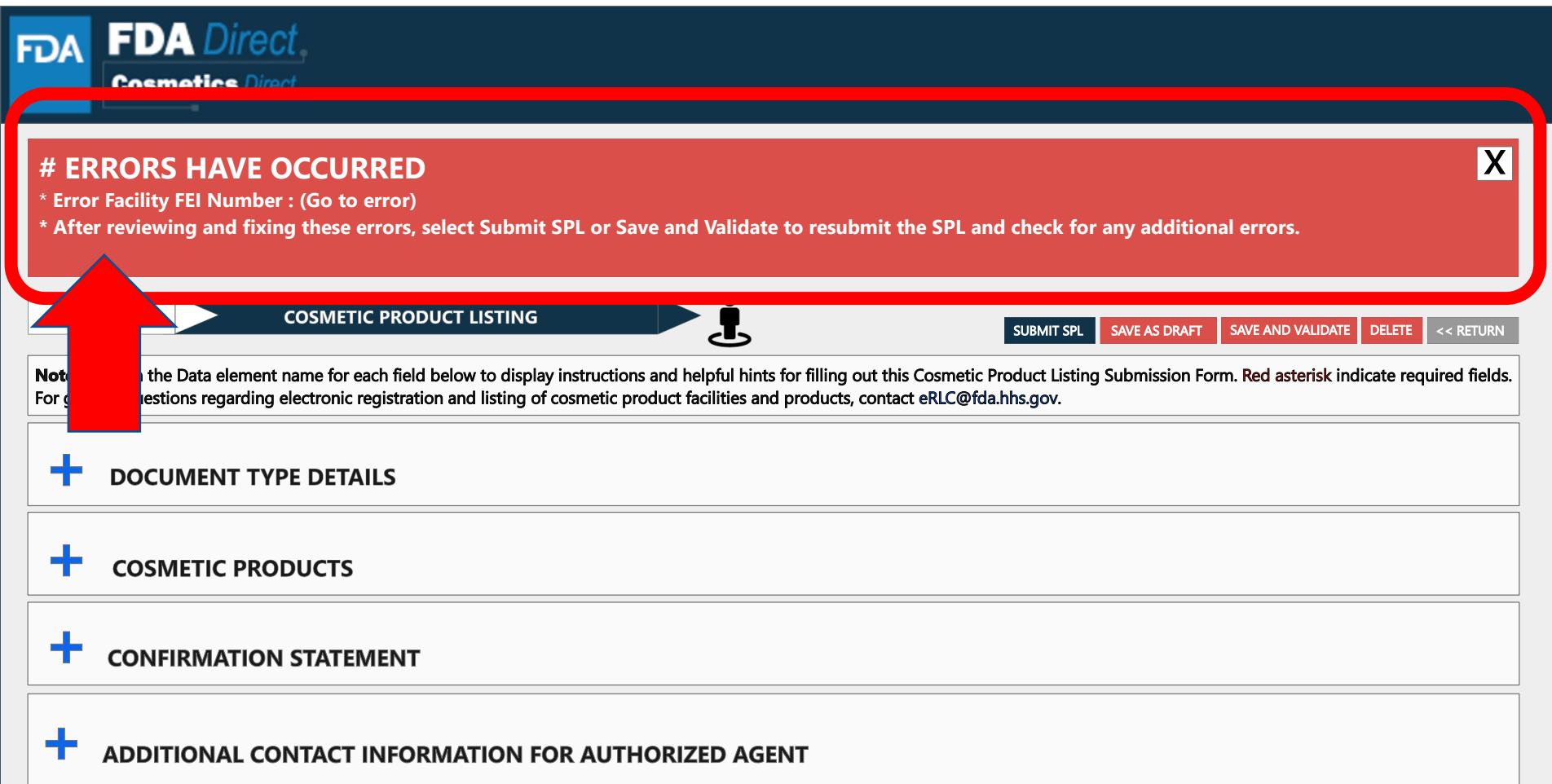
For assistance with validation errors in Cosmetics Direct contact cosmeticsdirect@fda.hhs.gov. For general questions regarding electronic registration of cosmetic product facilities and products, contact eRLC@fda.hhs.gov.

GO ACTIONS

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
VALIDATION FAILURE	fd850b1f-7bcd-165a-e053-6b94af0ac496	Rfd850b1f-7bce-165a-e053-6b94af0ac496		1	COSMETIC PRODUCT LISTING	Cosmetic Beauty (Different Color Aloe Gels)	DETAILS	First name Last name	07-JUN-2023 02:53:31

LISTING STATUS: VALIDATION FAILURE

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 visible. A red-bordered notification box at the top contains the following text:

ERRORS HAVE OCCURRED X

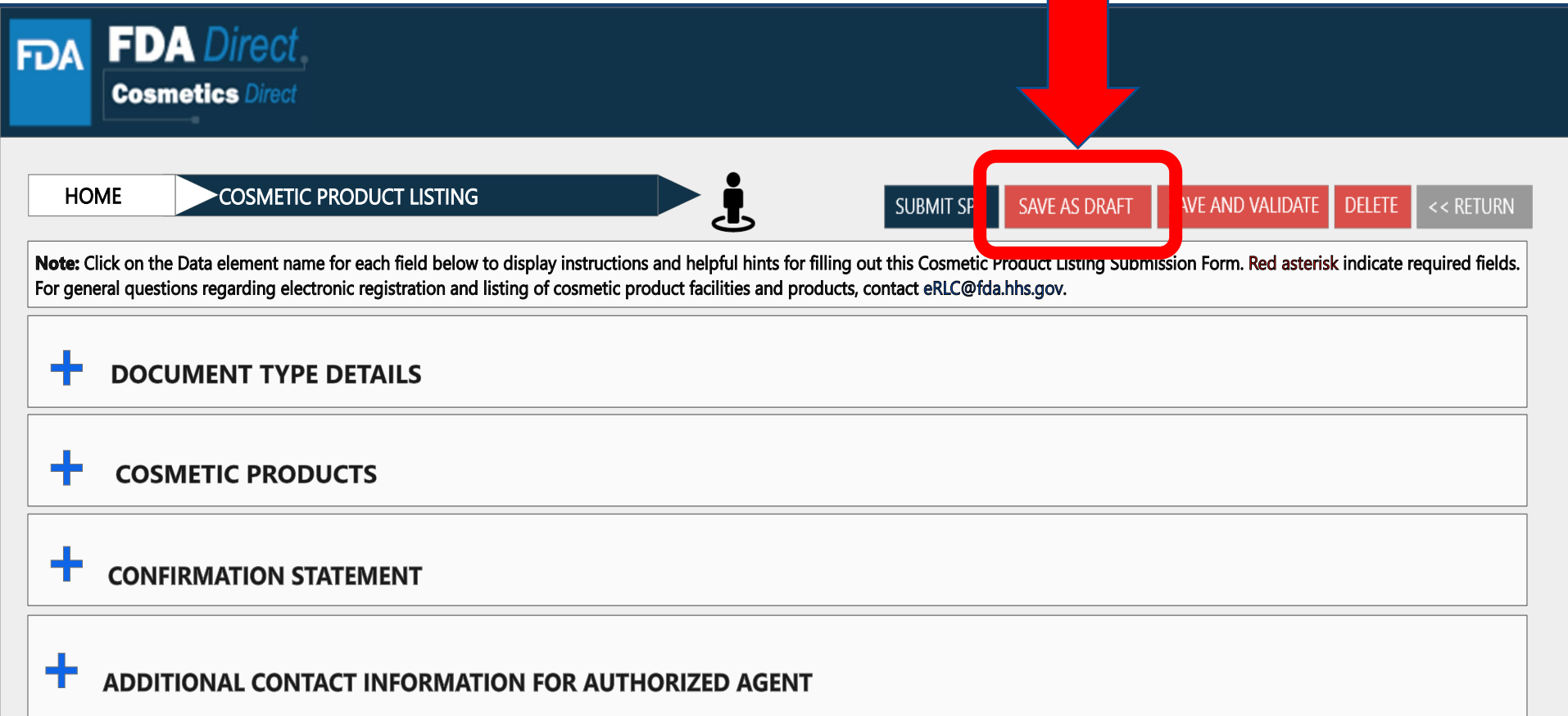
- * Error Facility FEI Number : (Go to error)
- * After reviewing and fixing these errors, select Submit SPL or Save and Validate to resubmit the SPL and check for any additional errors.

A red arrow points from the notification box to the "COSMETIC PRODUCT LISTING" section header. Below the header is a navigation bar with buttons: SUBMIT SPL, SAVE AS DRAFT, SAVE AND VALIDATE, DELETE, and << RETURN. A note below the navigation bar reads: "Note: Review 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 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 plus sign icon:

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

LISTING STATUS: 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 is the FDA logo and 'FDA Direct Cosmetics Direct'. 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 series of buttons: 'SUBMIT SP...', 'SAVE AS DRAFT' (highlighted with a red box and a red arrow), 'SAVE AND VALIDATE', 'DELETE', and '<< RETURN'. 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 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'.

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.

The screenshot displays the FDA Direct Cosmetics Direct web application. The top navigation bar includes 'HOME' and 'COSMETIC PRODUCT LISTING'. The main content area is titled 'COSMETIC PRODUCT LISTING' and contains a table of listings. A red arrow points to the 'DRAFT' status in the first row of the table. A red box highlights the entire table area.

SUBMISSIONS

REGISTRATION OF COSMETIC PRODUCT FACILITY
COSMETIC PRODUCT LISTING

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DUNSLink (dnb.com)

MANAGE ACCOUNT

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COSMETIC PRODUCT LISTING

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GO ACTIONS

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
DRAFT	fd850b1f-7bcd-165a-e053-6b94af0ac496	Rfd850b1f-7bce-165a-e053-6b94af0ac496		1	COSMETIC PRODUCT LISTING	Cosmetic Beauty (Different Color Aloe Gels)	DETAILS	First name Last name	07-JUN-2023 02:53:31

COSMETICS DIRECT HOME PAGE

Details.....	83
All submission	84

DETAILS

By clicking on the [DETAILS](#), the system will pop-up [PRODUCT LISTING DETAILS](#) box with information as shown below.

FDA Direct Cosmetics Direct

HOME | COSMETIC PRODUCT LISTING

SUBMISSIONS

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COSMETIC PRODUCT LISTING

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DUNSLink (dnb.com)

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COSMETIC PRODUCT LISTING

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SEARCH [] GO ACTIONS ▾

STATUS	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	TITLE	PRODUCT DETAILS	LAST MODIFIED	LAST MODIFIED DATE
SUBMISSION ACCEPTED	Rfd850b1f-7bce-165a-e053-6b94af0ac496	Rfd850b1f-7bce-165a-e053-6b94af0ac496	1	COSMETIC PRODUCT LISTING	Cosmetic Beauty Different Color Aloe Gel	DETAILS	First Name Last Name	07-JUN-2023 02:53:31

Product Details

Product Number	Product Name (As listed on label)	Facility FEI Number	Facility Name	Facility Address
1234-567-01	Cosmetic Beauty Aloe Gel-Blue	--VIEW LIST-- ▾	--VIEW LIST-- ▾	--VIEW LIST-- ▾

Other Details

fragrance or favor are not included in this product listing and it is NOT for professional use.

row(s)1 -1 of 1

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COSMETICS DIRECT HOME PAGE

ALL SUBMISSION



HOME

SUBMISSIONS

REGISTRATION OF COSMETIC PRODUCT FACILITY
COSMETIC PRODUCT LISTING

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For UNIL requests contact: FDA-SRS@fda.hhs.gov.
Structured Product Labeling Resources | FDA (SPL)
[DUNSLink \(dnb.com\)](https://dunslink.com)

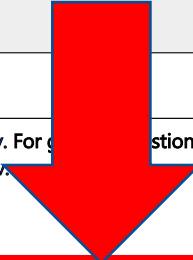
MANAGE ACCOUNT

EDIT USER PROFILE
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ALL SUBMISSIONS

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Qv GO ACTIONS v



STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
SUBMISSION ACCEPTED	fd123451f-7bcd-165a-e053-6b94af0ac496	Rfd850b1f-7bce-165a-e053-6b94af0ac496	cd6287459103.614893257@direct	1	REGISTRATION OF COSMETIC PRODUCT FACILITY	First name Last name	07-JUN-2023 02:53:31	
SUBMISSION ACCEPTED	fd8765451f-7nrg-143n-p075-6b94af0ac123	Rfd850b1f-7ecd-172a-f176-7d34af0bg554	cd6587346913.546893257@direct	1	COSMETIC PRODUCT LISTING	First name Last name	07-JUN-2023 02:53:31	

