

COSMETICS *DIRECT*

Electronic Submissions Portal
Screenshots for Commenting
September 2023

<https://www.fda.gov/cosmetics/registration-listing-cosmetic-product-facilities-and-products>



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FDA DIRECT Home Page

FDA

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**. The FDA warning banner is also provided on the FDA home page.

FDA **FDA Direct**
Cosmetics Direct

LOGIN

Username:

Password:

[Forgot Your Password?](#)

[I Accept The Terms Of Service](#)

LOGIN **Create New Account**

WELCOME TO FDA DIRECT

What is FDA Direct? FDA Direct is FDA's 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.](#)

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/>.

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

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.

FDA **FDA Direct**
Cosmetics Direct

ORGANIZATION TYPE

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

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 INFORMATION

Name: *

DUNS: *

ORGANIZATION ADDRESS

Country: *

Street Address: *

City: *

State: *

Postal Code:

CONTACT INFORMATION

First Name: *

Middle Name:

Last Name: *

Job Title:

Contact Email: *

CONTACT PHONE

Country Code: *

Phone Number: *

Phone Extension:

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Terms of Service



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

The screenshot shows the FDA Direct login interface. On the left is a login form with fields for Username and Password, and a link for 'Forgot Your Password?'. Below the form are 'LOGIN' and 'Create New Account' buttons. A red box highlights the checkbox labeled 'I Accept The Terms Of Service' with a red arrow pointing to it. At the bottom left of the page is a 'WARNING' banner. The main content area is a white pop-up window with a blue information icon. It contains several paragraphs of text regarding system security, unauthorized use, and social media restrictions. A red box highlights the 'I AGREE' button at the bottom right of the pop-up with a red arrow pointing to it. The background shows parts of the login page, including the 'FDA Direct' and 'Cosmetics Direct' logos and a 'Quick Links' section.

FDA **FDA Direct**
Cosmetics Direct

LOGIN

Username:

Password:

[Forgot Your Password?](#)

I Accept The Terms Of Service

LOGIN [Create New Account](#)

Quick Links: [Resources](#) | [Tutorials](#) | [Help](#)

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 (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)

The screenshot shows the FDA Direct Cosmetics Direct home page. A dark blue pop-up window is centered on the page, titled "WELCOME" with a red "X" in the top right corner. The pop-up contains the following text:

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
PRAsstaff@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.

The background of the screenshot shows the FDA Direct Cosmetics Direct logo at the top left, a "HOME" button, and several 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/unilsearch", "For UNIL requests contact: FDA-SRS@fda.hhs.gov", "Structured Product Labeling Resources | FDA", and "DUNSLink (dnb.com)"), and "MANAGE ACCOUNT" (with links for "EDIT USER PROFILE" and "MANAGE USERS"). A search bar and a "LAST MODIFIED DATE" field are also visible.

Cosmetics Direct Home Page

FDA

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

FDA **FDA Direct**
Cosmetic

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 \(dnb.com\)](http://DUNSLink.com)

MANAGE ACCOUNT

- EDIT USER PROFILE
- MANAGE USERS

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

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

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	LAST MODIFIED USER	LAST MODIFIED DATE	🔒
--------	--------	---------	---------------	---------	----------------	--------------------	--------------------	---

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.

FDA

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Registration of Cosmetic Product Facility

Registration of Cosmetic Product Facility Home Page



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

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

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
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.

Qv GO ACTIONS v

CREATE NEW/UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT TYPE	LAST MODIFIED USER	LAST MODIFIED DATE	
--------	--------	---------	---------------	---------	---------------	--------------	---------------	---------------	--------------------	--------------------	--

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

CREATE NEW/UPLOAD FILE

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

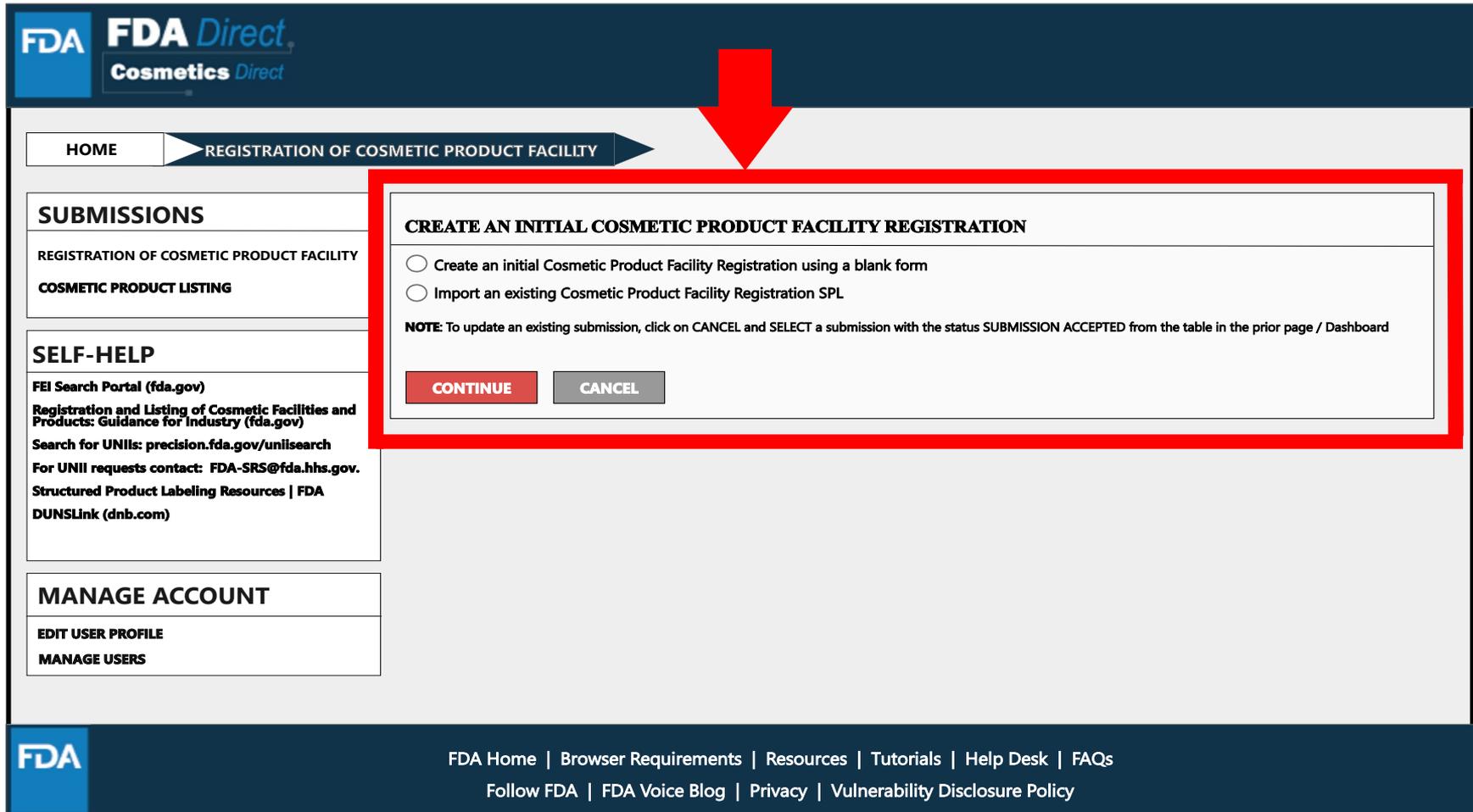
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Create a New Registration or Upload an Existing File

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.



The screenshot shows the FDA Direct Cosmetics Direct website interface. A red arrow points to the 'CREATE AN INITIAL COSMETIC PRODUCT FACILITY REGISTRATION' section, which is highlighted with a red border. The page includes a navigation bar with 'HOME' and 'REGISTRATION OF COSMETIC PRODUCT FACILITY'. 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 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/unilsearch', and 'For UNIL requests contact: FDA-SRS@fda.hhs.gov'. The 'MANAGE ACCOUNT' section includes links for 'EDIT USER PROFILE' and 'MANAGE USERS'. The 'CREATE AN INITIAL COSMETIC PRODUCT FACILITY REGISTRATION' section offers two options: 'Create an initial Cosmetic Product Facility Registration using a blank form' and 'Import an existing Cosmetic Product Facility Registration SPL'. A note 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'. Below the options are 'CONTINUE' and 'CANCEL' buttons.

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

MANAGE ACCOUNT

EDIT USER PROFILE
MANAGE USERS

CREATE AN INITIAL COSMETIC PRODUCT 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

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Create a New Product Facility Registration



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

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/unilsearch
For UNII 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**

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Document Type Details

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

FDA Direct
Cosmetics Direct

HOME REGISTRATION OF COSMETIC PRODUCT FACILITY

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

DOCUMENT TYPE DETAILS

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

Set ID: * fd8c4f0b-ca3a-82e2-e053-6394a90aa8de Generate New

Root ID: * fe8b3cc9-aaa9-9846-e053-6b94af0a347d Generate New

Version Number: * 1

Effective Date: * 06-20-2023

SAVE AS DRAFT <<RETURN

+ REGISTRATION DETAILS

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

Document Type Tool Tips

Document Type

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.

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.

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

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.

Version Number: *

Effective Date: *

Effective Date

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

HOME

Note: Click on the...
For general ques...

Document Type: *

Set ID: *

Root ID: *

REGI...

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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)

The screenshot shows the 'REGISTRATION OF COSMETIC PRODUCT FACILITY' form in the FDA Direct Cosmetics Direct system. A red box highlights the 'Document Type' dropdown menu, which is currently open and showing five options: 'INITIAL', 'AMENDED-CHANGES TO REGISTRATION', 'AMENDED-CANCELLATION OF REGISTRATION', 'BIENNIAL REGISTRATION RENEWAL', and 'ABBREVIATED REGISTRATION RENEWAL'. A red arrow points to the dropdown arrow icon. The form also includes fields for 'Set ID', 'Root ID', 'Version Number' (set to 1), and 'Effective Date' (set to 06-20-2023). Navigation buttons for 'HOME', 'SAVE AS DRAFT', and '<<RETURN' are visible. The footer contains links for FDA Home, Browser Requirements, Resources, Tutorials, Help Desk, FAQs, Follow FDA, FDA Voice Blog, Privacy, and Vulnerability Disclosure Policy.

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”.

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

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

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Registration Details



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

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

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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/cplportal/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 digit 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)

Registration Details



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

FDA **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 * -SELECT COUNTRY- Facility City: *

Facility Street Address * Facility State or Province: *

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

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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U.S. Agent Name X
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 X
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 X
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 X
(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)

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

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

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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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. 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 > 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).
- + (09) Makeup preparations for children (not eye).
- + (10) Manicuring preparations.
- + (11) Oral products.
- + (12) Personal cleanliness.
- + (13) Shaving preparations.
- + (14) Skin care preparations, (creams, lotions, powder, and sprays).
- + (15) Suntan preparations.
- + (16) Tattoo preparations.
- + (17) Other preparations (i.e., those preparations that do not fit another category).

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Brand Name of Cosmetic Product X

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 X

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) X

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 \(fda.gov\)](#)

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



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: *
Cosmetic Beauty Facial Moisturizer

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).
 - (a) Blushers and rouges (all types).
 - (b) Face powders.
 - (c) Foundations.
 - (d) Leg and body paints.
 - (e) Lipsticks and lip glosses.
 - (f) Makeup bases.
 - (g) Makeup fixatives.
 - (h) Other makeup preparations.
 - 1. Traditional applications.
 - 2. Airbrush applications.
- (09) Makeup preparations for children (not eye).
- (10) Manicuring preparations.
- (11) Oral products.
- (12) Personal cleanliness.
- (13) Shaving preparations.
- (14) Skin care preparations, (creams, lotions, powder, and sprays).
 - (a) Cleansing (cold creams, cleansing lotions, liquids, and pads).
 - (b) Depilatories.
 - (c) Face and neck (excluding shaving preparations).
 - 1. Leave-on.
 - 2. Rinse-off.
 - (d) Body and hand (excluding shaving preparations).
 - (e) Foot powders and sprays.
 - (f) Moisturizing.
 - (g) Night.
 - (h) Paste masks (mud packs).
 - (i) Skin fresheners.
 - (j) Other skin care preparations.
- (15) Suntan preparations.
- (16) Tattoo preparations.
- (17) Other preparations (i.e., those preparations that do not fit another category).

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

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



The information that was provided in the BRAND NAME TAB will appear under 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 * --SELECT COUNTRY-- Facility City * *

Facility Street Address * Facility State or Province * *

Facility Zip/Postal code * *

Facility Email * Facility Phone Number * (Include Area/County 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 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) - (e) 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

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Confirmation Statement

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

FDA Direct Cosmetics Direct

HOME > REGISTRATION OF COSMETIC PRODUCT FACILITY

SAVE AS DRAFT SAVE AND VALIDATE DELETE << RETURN

Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out this Facility Registration Submission Form. Red asterisk indicate required fields. For general questions regarding electronic registration and listing of cosmetic product facilities and products, contact eRLC@fda.hhs.gov.

+ DOCUMENT TYPE DETAILS

+ REGISTRATION DETAILS

- CONFIRMATION STATEMENT

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

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

AGREE

After understanding the confirmation statement. Select AGREE

Signature of Submitter

Name of Submitter

Date (MM/DD/YYYY)

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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

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

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Additional Contact Information for Authorized Agent



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

The screenshot shows the FDA Direct Cosmetics Direct interface. The main navigation bar includes 'HOME', 'REGISTRATION OF COSMETIC PRODUCT FACILITY', and a user icon. Below the navigation bar are buttons for 'SAVE AS DRAFT', 'SAVE AND VALIDATE', 'DELETE', and '<< RETURN'. A note states: 'Click on the Data element name for each field below to display instructions and helpful hints for filling out this 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 has four expandable sections:

- DOCUMENT TYPE DETAILS
- REGISTRATION DETAILS
- CONFIRMATION STATEMENT
- ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT** (highlighted with a red box)

The expanded view of the 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT' section shows the following fields:

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

The footer contains links: FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs | Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy.

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 Data element name for each field below to display instructions and help hints for filling out this form. For general questions regarding electronic registration and listing of cosmetic products and products, contact [redacted].

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

Submit SPL
Submit SPL to FDA.
Next Disable Tour

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

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

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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.

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 'REGISTRATION OF COSMETIC PRODUCT FACILITY'. The main content area is divided into three sections: 'SUBMISSIONS', 'SELF-HELP', and 'MANAGE ACCOUNT'. The 'SUBMISSIONS' section contains 'REGISTRATION OF COSMETIC PRODUCT FACILITY' and 'COSMETIC PRODUCT LISTING'. The 'SELF-HELP' section contains links for 'FEI Search Portal (fda.gov)', 'Registration and Listing of Cosmetic Facilities and Products: Guidance for Industry (fda.gov)', 'Search for UNII: precision.fda.gov/unilsearch', 'For UNII requests contact: FDA-SRS@fda.hhs.gov', 'Structured Product Labeling Resources | FDA', and 'DUNSLink (dnb.com)'. The 'MANAGE ACCOUNT' section contains 'EDIT USER PROFILE' and 'MANAGE USERS'. The 'CREATE AN INITIAL COSMETIC PRODUCT FACILITY REGISTRATION' section is highlighted with a red border and contains two radio button options: 'Create an initial Cosmetic Product Facility Registration using a blank form' (unselected) and 'Import an existing Cosmetic Product Facility Registration SPL' (selected). Below these options is a note: 'NOTE: To update an existing submission, click on CANCEL and SELECT a submission with the status SUBMISSION ACCEPTED from the table in the prior page / Dashboard'. At the bottom of this section are two buttons: 'CONTINUE' (red) and 'CANCEL' (grey). A red arrow points to the 'Import an existing Cosmetic Product Facility Registration SPL' option.

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. SPL(Structured Product Labeling) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information. For more information regarding SPL, utilize the **Structured Product Labeling Resources (SPL)** link provided under **SELF-HELP**.

The screenshot displays the FDA Direct Cosmetics Direct interface. At the top, 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, the text reads 'Cosmetic Product Facility Registration File' with a folder icon, followed by 'Select a file or drop one here.' A note specifies: 'Note: Please upload a zip file that contains the SPL file with the name as the root id followed by ".xml" and any associated image files that referenced in the xml whose names end in 'jpg'.' Two buttons are visible: 'UPLOAD' (highlighted with a red box and a red arrow pointing to it) and 'CANCEL'. The left sidebar contains sections for 'SUBMISSIONS', 'SELF-HELP', and 'MANAGE ACCOUNT'.

Upload a File (Example)

An example to what a zip file could be, may contain .xml file and image (jpg) files.

The screenshot shows the FDA Direct Cosmetics Direct interface. At the top, there is a navigation bar with '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 file icon. A red box highlights the root ID 'abcd850b1f-7bce-165a-e053-5e94af0ac123', with a red arrow pointing to it. Below the root ID, there is a note: 'Note: Please upload a zip file that contains the SPL file with the name as the root id followed by ".xml" and any associated image files that referenced in the xml whose names end in ".jpg"'. At the bottom of the upload area, there are two buttons: 'UPLOAD' and 'CANCEL'. On the left side, there are three main 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/unilsearch', 'For UNIL requests contact: FDA-SRS@fda.hhs.gov.', 'Structured Product Labeling Resources | FDA', 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.xsl" type="text/xsl"?>
<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:hl7-org:v3 https://www.accessdata.fda.gov/spl/schema/spl.xsd">
  <id root="fd8c4f0b-ca3b-82e2-e053-6394a90aa8de"/>
  <code code="51725-0" codeSystem="2.16.840.1.113883.6.1" displayName=" FACILITY
REGISTRATION"/>
  <effectiveTime value="[DATE]"/>
  <setId root="fd8c4f0b-ca3a-82e2-e053-6394a90aa8de"/>
  <versionNumber value="1"/>
  <author>
  <time/>
  <assignedEntity>
    <representedOrganization>
      <assignedEntity>
        <assignedOrganization>
          <id root="1.3.6.1.4.1.519.1" extension="314988747"/>
          <name>[COMPANY'S NAME]</name>
          <contactParty>
            <addr>
              <streetAddressLine>[ENTRY THE STREET ADDRESS]</streetAddressLine>
              <city>[ENTRY CITY NAME]</city>
              <postalCode>[ENTRY POSTAL CODE]</postalCode>
              <country>[ENTRY COUNTRY NAME]</country>
            </addr>
            <telecom value="tel:[ENTRY PHONE NUMBER]"/>
            <telecom value="[ENTRY EMAIL ADDRESS]"/>
            <contactPerson>
              <name>[ENTRY FULL NAME]</name>
            </contactPerson>
          </contactParty>
        </assignedEntity>
```

Upload 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.”

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

The screenshot displays the FDA Direct Cosmetics Direct interface. At the top, the navigation bar includes the FDA logo and the text 'FDA Direct Cosmetics Direct'. Below this, a breadcrumb trail shows 'HOME' followed by 'REGISTRATION OF COSMETIC PRODUCT FACILITY'. A user icon is positioned above the main content area. A note provides instructions on clicking data element names for field details and contacting support for general questions. The main content area features four expandable sections: 'DOCUMENT TYPE DETAILS', 'REGISTRATION DETAILS', 'CONFIRMATION STATEMENT', and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. Two modal boxes are overlaid on the right side: 'Submit SPL' and 'Validate SPL'. The 'Submit SPL' modal contains the text 'Submit SPL to FDA.' and buttons for 'Next' and 'Disable Tour'. The 'Validate SPL' modal contains the text 'You can check your SPL for an initial validation before submitting to FDA. This option does not automatically submit your SPL to FDA, even if it passes the initial validation, but scans for certain errors prior to the actual submission.' and a 'Next' button. A red-bordered text box with an arrow pointing to the user icon contains the text: 'A Guide that will help the user understand different stages such as, VAILADATE SPL or SUBMIT SPL.' Two large red arrows point down to the modal boxes. The footer contains the FDA logo and a list of links: 'FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs' and 'Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy'.

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**.

The screenshot displays the 'REGISTRATION OF COSMETIC PRODUCT FACILITY' page. The status is 'VALIDATION IN PROGRESS', highlighted with a red box and a red arrow. The page includes a navigation bar, a sidebar with links to 'SUBMISSIONS', 'SELF-HELP', and 'MANAGE ACCOUNT', and a main content area with a search bar and a table of registration details.

REGISTRATION OF COSMETIC PRODUCT FACILITY

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

Q GO ACTIONS

CREATE NEW/UPLOAD FILE

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

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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**.

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/unisearch
For UNII requests contact: FDA-SRS@fda.hhs.gov.
Structured Product Labeling Resources | FDA
[DUNSLink \(dnb.com\)](https://dunslink.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 TYPE	LAST MODIFIED USER	LAST MODIFIED DATE	
READY FOR SUBMISSION	fd850b1f-7bcd-165 a-e053-6b65af0ac496	abcd850b1f-7bce-165 a-e053-5e94af0ac123		1	FACILITY NAME	1000125370		INITIAL	First name Last name	07-JUN-2023 02:53:31	

Registration Status: Ready for Submission to Submit SPL



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

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

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

Registration Status: Submit SPL to Submission Accepted



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

The screenshot displays the FDA Direct Cosmetics Direct interface. The main content area is titled "REGISTRATION OF COSMETIC PRODUCT FACILITY". It includes a search bar, a "GO" button, and an "ACTIONS" dropdown menu. A table lists registration details, with the "SUBMISSION ID" column highlighted by a red box and a red arrow pointing to it. The "STATUS" column shows "SUBMISSION ACCEPTED" with a red arrow pointing to it. The table also includes columns for SET ID, ROOT ID, FACILITY NAME, FACILITY FEI, FACILITY DUNS, DOCUMENT TYPE, LAST MODIFIED USER, and LAST MODIFIED DATE.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT TYPE	LAST MODIFIED USER	LAST MODIFIED DATE	
SUBMISSION ACCEPTED	fd850b1f-7bcd-165a-e053-6b65af0ac496	abcd850b1f-7bce-1a-e053-5e94af0ac12	cd6287459103.64893257@direct	1	FACILITY NAME	1000125370		INITIAL	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**.

The screenshot displays the FDA Direct Cosmetics Direct interface. At the top left, the logo reads "FDA Direct Cosmetics Direct". A breadcrumb trail shows "HOME" followed by "REGISTRATION OF COSMETIC PRODUCT FACILITY" with a right-pointing arrow. To the right of the breadcrumb is a user icon. Below the breadcrumb, there are two buttons: "VIEW SPL" and "DOWNLOAD SPL", both of which are highlighted with a red rectangular box and a red arrow pointing to them from the right. To the right of these buttons are two more buttons: "CREATE NEW VERSION" and "<< RETURN". Below the buttons is a note: "Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out this 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." Below the note are four expandable sections, each with a plus sign icon and a title: "DOCUMENT TYPE DETAILS", "REGISTRATION DETAILS", "CONFIRMATION STATEMENT", and "ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT". At the bottom of the page, there is a footer with the FDA logo on the left and a list of links: "FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs" and "Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy".

Clone Successfully Submitted SPL

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

The screenshot shows the FDA Direct Cosmetics Direct interface. At the top left is the FDA logo and 'FDA Direct Cosmetics Direct'. Below this is a navigation bar with 'HOME' and 'REGISTRATION OF COSMETIC PRODUCT FACILITY' (the latter is highlighted with a blue arrow). To the right of the navigation bar is a user icon. Below the navigation bar are two buttons: 'VIEW SPL' and 'DOWNLOAD SPL'. To the right of these is a red arrow pointing to a button labeled 'CREATE NEW VERSION', which is highlighted with a red rectangular box. To the right of the 'CREATE NEW VERSION' button is a '< RETURN' button. Below the navigation and buttons is a note: 'Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out this 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.' Below the note are four expandable sections, each with a plus sign icon and a title: 'DOCUMENT TYPE DETAILS', 'REGISTRATION DETAILS', 'CONFIRMATION STATEMENT', and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. At the bottom of the page is a footer with the FDA logo and a list of links: 'FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs | Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy'.

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 heading is "REGISTRATION OF COSMETIC PRODUCT FACILITY". Below this, there is a search bar with a "GO" button and an "ACTIONS" dropdown. A "CREATE NEW/UPLOAD FILE" button is also visible. A table displays registration details, with the status "VALIDATION FAILURE" highlighted in blue and a red arrow pointing to it. The table has columns for STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, FACILITY NAME, FACILITY FEI, FACILITY DUNS, DOCUMENT TYPE, LAST MODIFIED USER, and LAST MODIFIED DATE. A lock icon is present in the final column.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	FACILITY DUNS	DOCUMENT TYPE	LAST MODIFIED USER	LAST MODIFIED DATE	
VALIDATION FAILURE	fd850b1f-7bcd-165a-e053-6b65af0ac496	abcd850b1f-7bce-165a-e053-5e94af0ac123		1	FACILITY NAME	1000125370		INITIAL	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 reads "FDA FDA Direct Cosmetics Direct". A prominent red banner at the top contains the message: "# ERRORS HAVE OCCURRED" with a close button (X) in the top right corner. Below this banner, two error messages are listed: "* Error Facility FEI Number : (Go to error)" and "* After reviewing and fixing these errors, select Submit SPL or Save and Validate to resubmit the SPL and check for any additional errors." The main navigation bar includes "HOME", "REGISTRATION OF COSMETIC PRODUCT FACILITY" (with a person icon), and buttons for "SUBMIT SPL", "SAVE AS DRAFT", "SAVE AND VALIDATE", "DELETE", and "<< RETURN". A red arrow points to the "HOME" link. Below the navigation bar, a note states: "Note: Click on the data element name for each field below to display instructions and helpful hints for filling out this 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 is divided into four expandable sections, each with a plus sign icon: "DOCUMENT TYPE DETAILS", "REGISTRATION DETAILS", "CONFIRMATION STATEMENT", and "ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT". The footer contains the FDA logo and navigation links: "FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs" and "Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy".

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**.

The screenshot shows the FDA Direct Cosmetics Direct interface. At the top left is the FDA logo and 'FDA Direct Cosmetics Direct' text. Below this is a navigation bar with 'HOME' and 'REGISTRATION OF COSMETIC PRODUCT FACILITY' buttons, a user icon, and a set of action buttons: 'SUBMIT S...', 'SAVE AS DRAFT', 'SAVE AND VALIDATE', 'DELETE', and '<< RETURN'. A red arrow points to the 'SAVE AS DRAFT' button, which is also highlighted with a red box. Below the navigation bar is a note: 'Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out this Facility Registration Submission Form. Red asterisk indicate required fields. For general questions regarding electronic registration and listing of cosmetic product facilities and products, contact eRLC@fda.hhs.gov.' The main content area contains four expandable sections, each with a plus sign icon and a title: 'DOCUMENT TYPE DETAILS', 'REGISTRATION DETAILS', 'CONFIRMATION STATEMENT', and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. At the bottom is a footer with the FDA logo and a list of links: 'FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs | Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy'.

Registration Status: Draft

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

The screenshot shows the FDA Direct Cosmetics Direct interface. The main content area is titled "REGISTRATION OF COSMETIC PRODUCT FACILITY". It includes a search bar, a "GO" button, and an "ACTIONS" dropdown menu. A table lists registration details, with the status "DRAFT" highlighted in blue. A red arrow points to the "DRAFT" status in the table. The table has columns for STATUS, SET ID, ROOT ID, SUBMISSION ID, VERSION, FACILITY NAME, FACILITY FEI, FACILITY DUNS, DOCUMENT TYPE, LAST MODIFIED USER, and LAST MODIFIED DATE. The first row shows a registration with a status of "DRAFT", a set ID of "fd850b1f-7bcd-165 a-e053-6b65af0ac496", a root ID of "abcd850b1f-7bce-165 a-e053-5e94af0ac123", a submission ID, a version of "1", a facility name, a facility FEI of "1000125370", a document type of "INITIAL", a last modified user of "First name Last name", and a last modified date of "07-JUN-2023 02:53:31".

SUBMISSIONS

REGISTRATION OF COSMETIC PRODUCT FACILITY
COSMETIC PRODUCT LISTING

SELF-HELP

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

MANAGE ACCOUNT

EDIT USER PROFILE
MANAGE USERS

REGISTRATION OF COSMETIC PRODUCT FACILITY

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

Q GO ACTIONS

CREATE NEW/UPLOAD FILE

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



Cosmetic Product Listing

Cosmetic Product Listing Home Page

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

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

SUBMISSIONS
REGISTRATION OF COSMETIC PRODUCT FACILITY
COSMETIC PRODUCT LISTING

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

MANAGE ACCOUNT
EDIT USER PROFILE
MANAGE USERS

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

Q v GO ACTIONS v

CREATE NEW/UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT TYPE	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
--------	--------	---------	---------------	---------	---------------	-------	-----------------	--------------------	--------------------

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

CREATE NEW/UPLOAD FILE

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

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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. At the top, there is a navigation bar with 'HOME' and 'COSMETIC PRODUCT LISTING'. A red arrow points to the 'COSMETIC PRODUCT LISTING' tab. Below the navigation bar, there are three main sections: 'SUBMISSIONS', 'SELF-HELP', and 'MANAGE ACCOUNT'. The 'SUBMISSIONS' section includes 'REGISTRATION OF COSMETIC PRODUCT FACILITY' and 'COSMETIC PRODUCT LISTING'. The 'SELF-HELP' section includes 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/unilsearch', 'For UNIL requests contact: FDA-SRS@fda.hhs.gov.', 'Structured Product Labeling Resources | FDA', and 'DUNSLink (dnb.com)'. The 'MANAGE ACCOUNT' section includes 'EDIT USER PROFILE' and 'MANAGE USERS'. The main content area is titled 'CREATE AN INITIAL COSMETIC PRODUCT LISTING' and contains two radio button options: 'Create an initial Cosmetic Product Listing using a blank form' and 'Import an existing Cosmetic Product Listing SPL'. Below these options is a note: 'NOTE: To update an existing submission, click on CANCEL and SELECT a submission with the status SUBMISSION ACCEPTED from the table in the prior page / Dashboard'. At the bottom of this section are two buttons: 'CONTINUE' and 'CANCEL'. The footer of the page includes the FDA logo and links for 'FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs' and 'Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy'.

Create a New Cosmetics Product Listing



Create an Initial Cosmetic Product Listing using a blank form.

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/unii/search
- 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 LISTING

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

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

CONTINUE **CANCEL**

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Document Type Details



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: * **v**

Set ID: * **Generate New**

Version Number: *

Root ID: * **Generate New**

Effective Date: *

Title:

+ COSMETIC PRODUCTS

+ CONFIRMATION

+ ADDITIONAL CO

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

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Document Type Tool Tips

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

The screenshot shows the 'Document Type' selection interface. A dropdown menu is open, showing options: INITIAL, UPDATE TO CONTENT (annual), and ABBREVIATED REGISTRATION RENEWAL. Below the dropdown are fields for Set ID, Root ID, Title, Version Number, and Effective Date. Red arrows point from tool tip boxes to these fields. The tool tips provide detailed instructions and examples for each field.

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.

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 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.

Legend:

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

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Document Type Details



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

FDA Direct
Cosmetics Direct

HOME > COSMETIC PRODUCT LISTING

Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out the form. An asterisk indicates required fields.

DOCUMENT TYPE DETAILS

Document Type: -- Select Document Type -- v

Set ID: * [field] [field]

Root ID: * [field] [field]

Title: [field]

Version Number: * [1]

Effective Date: * [06-20-2023] [calendar icon]

SAVE AS DRAFT <<RETURN

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

-- Select Document Type --

-- Select Document Type --

INITIAL

UPDATE TO CONTENT (annual)-CHANGES TO LISTING

UPDATE TO CONTENT (annual)-DISCONTINUATION OF LISTING

ABBREVIATED RENEWAL

+ COSMETIC PRODUCTS

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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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: * **v**

Set ID: * **Version Number:** *

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

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Cosmetic Products

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

- 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: * (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

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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 **FDA Direct**
Cosmetics Direct

HOME > COSMETIC PRODUCT LISTING > COSMETIC PRODUCTS 

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

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

<input type="list" value="Fragrance"/>	<input type="list" value="YES"/>
<input type="list" value="Flavor"/>	<input type="list" value="NO"/>
<input type="list" value="Fragrance & Flavor"/>	
<input type="list" value="N/A"/>	

Product Webpage Link:

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

+ PRODUCT C

+ INGREDIENTS

+ LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

FDA

FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs
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Product Category Code(s) (Example)



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: 53-00000-00000

Product Name: *
(As listed on label) Cosmetic Beauty Aloe Gel -Blue

Fragrance or Flavor: * N/A

Is This Product For Professional USE ONLY? NO

Product Webpage Link:

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

--SELECT THE ICON--

PRODUCT CATEGORY CODE(S)

Product Category Code(s): * --Select 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).

INGREDIENTS

LIST OF FACILITIES

ROCE

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

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 (+).

FDA **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: 53-00000-00000

Product Name: *

Product For

Product Category Co

(14) Skin care preparations, (creams, lotions, ointments, and sprays) - (c) Face and neck (excluding shaving preparations) - 1
 (14) Skin care preparations, (creams, lotions, ointments, and sprays) - (f) Moisturizing

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. If ingredient does not auto-populate continue typing and select ADD.

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

INGREDIENTS

Ingredient UNII-Name: * SEARCH

UPLOAD INGREDIENTS FILE:

	Ingredient UNII Code(s)	Common, Usual or Chemical Name * (As listed on the Label)
X	059QF0K00R	WATER
X	PDC6A3C00X	GLYCERIN
X	TTV12P4NEE	XANTHAN GUM
X	ZY81Z83H0X	ALOE VERA LEAF EXTRACT
X	HIE492ZZ3T	PHENOXYETHANOL
X	H3R47K3TBD	FD&C BLUE NO.1

LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED

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Listing Ingredients (Example)

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

COSMETIC PRODUCTS

Product Listing Number:

Product Name: *
(As listed on label)

Fragrance or Flavor: * Is This Product For Professional Use?

Product Website Link: Image Of Label
(Attach images of the product label)

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.

Fill in where the cosmetic product is manufactured or processed.

+ INGREDIENTS

- LIST OF FACILITIES WHERE THE COSMETIC 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		

List of Facility(ies)
(Example)

List of Facility (Example)

- LIST OF FACILITIES WHERE THE COSMETIC 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: --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.

- LIST OF FACILITIES WHERE THE COSMETIC 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: --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		

Once SAVED, the information will appear in this table

FDA **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. Asterisks 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: 53-0000-00000

Product Name: * Cosmetic Beauty Aloe Gel -Blue
(As listed on label)

Fragrance or Flavor: * N/A Is This Product For P...

Product Webpage Link: Im...

- PRODUCT CATEGORY CODE(S)

Product Category Code(s): * --Select Cod...

Product Category Code(s) *

- (14) Skin care preparations, (creams, lotions, powder, and sprays) - (3) Face and neck (excluding shaving preparations) - 1. Leave-on
- (14) Skin care preparations, (creams, lotions, powder, and sprays) - (3) Moisturizing.

- INGREDIENTS

Ingredient UNII-Name: * SEARCH --SELECT THE ICON-

	Ingredient UNII Code(s)	Common, Usual or Chemical Name * <small>(As listed on the Label)</small>
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

- LIST OF FACILITIES WHERE THE COSMETIC 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 * --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		FACILITY NAME	FACILITY ADDRESS

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

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).**

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

- COSMETIC PRODUCTS

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

Business: MANUFACTURER PACKER

Entry CAN BE EDITED by selecting this icon.

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

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.

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--	

+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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Example of a Prefilled Clone

FDA Direct Cosmetics Direct

HOME > COSMETIC PRODUCT LISTING > COSMETIC PRODUCTS

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

COSMETIC PRODUCTS

Product Listing Number: 53-00000-00000

Product Name: *

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

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

PRODUCT CATEGORY CODE(S)

Product Category Code(s): * --Select Code(s)--

INGREDIENTS

Ingredient UNII-Name: * SEARCH ADD UPLOAD INGREDIENTS FILE: --SELECT THE ICON--

	Ingredient UNII Code(s)	Common, Usual or Chemical Name (As listed on the Label)
X	059QF0K00R	WATER
X	PDC6A3C00X	GLYCERIN
X	TTV12P4NEB	XANTHAN GUM
X	ZY81Z83H0X	ALOE VERA LEAF EXTRACT
X	HIE492ZZ3T	PHENOXYETHANOL
X	H3R47K3TBD	FD&C BLUE NO.1

LIST OF FACILITIES WHERE THE COSMETIC 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: * --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		FACILITY NAME	FACILITY ADDRESS

After verifying the entered information is correct, select SAVE

Any prefilled information can be edited.



Confirmation Statement



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

FDA Direct Cosmetics Direct

HOME COSMETIC PRODUCT LISTING

SAVE AS DRAFT SAVE AND VALIDATE DELETE << RETURN

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

+ DOCUMENT TYPE DETAILS

+ COSMETIC PRODUCTS

- CONFIRMATION STATEMENT

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

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

AGREE

Signature of Submitter Name of Submitter

Date (MM/DD/YYYY)

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

After understanding the confirmation statement. Select AGREE

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

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

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Additional Contact Information for Authorized Agent



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

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

The main content area has three expandable sections: 'DOCUMENT TYPE DETAILS', 'COSMETIC PRODUCTS', and 'CONFIRMATION STATEMENT'. The 'CONFIRMATION STATEMENT' section is expanded, showing 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. This section contains four fields: 'Additional Contact Name', 'Phone Number', 'Email', and 'Phone Extension'. The 'Additional Contact Name' field is highlighted with a red box and a red arrow pointing to a detailed view on the right.

The detailed view on the right shows the following fields:

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

The footer of the interface includes the FDA logo and the following text: 'FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs' and 'Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy'.

Completed

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

OR

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

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, a note provides instructions on how to use the data elements. The main content area is divided into sections: 'DOCUMENT TYPE DETAILS', 'COSMETIC PRODUCTS', 'CONFIRMATION STATEMENT', and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. A red arrow points to a user icon, and another red arrow points to a 'SUBMIT SPL' button. A third red arrow points to a 'VALIDATE SPL' button. A red box highlights the 'SUBMIT SPL' button, and another red box highlights the 'VALIDATE SPL' button. A red box also highlights a text box that reads: 'A Guide that will help the user understand different stages such as, VAILADATE SPL or SUBMIT SPL.' The bottom of the page features a footer with links to FDA Home, Browser Requirements, Resources, Tutorials, Help Desk, FAQs, Follow FDA, FDA Voice Blog, Privacy, and Vulnerability Disclosure Policy.

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.

The screenshot shows the FDA Direct Cosmetics Direct interface. The top navigation bar includes 'HOME' and 'COSMETIC PRODUCT LISTING'. The main content area is titled 'CREATE AN INITIAL COSMETIC PRODUCT LISTING' and contains two radio button options: 'Create an initial Cosmetic Product Listing using a blank form' and 'Import an existing Cosmetic Product Listing SPL'. The second option is selected. A red box highlights this option, and a red arrow points to it from the top. Below the options is a note: 'NOTE: To update an existing submission, click on CANCEL and SELECT a submission with the status SUBMISSION ACCEPTED from the table in the prior page / Dashboard'. At the bottom of the main content area are two buttons: 'CONTINUE' and 'CANCEL'. The left sidebar contains sections for 'SUBMISSIONS', 'SELF-HELP', and 'MANAGE ACCOUNT'.

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/unisearch
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 LISTING

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

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

CONTINUE **CANCEL**

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Upload a File

User will be able to upload a pre-existing ZIP FILE, this file may contain both the xml file and image (jpg) files. SPL(Structured Product Labeling) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information. For more information regarding SPL, utilize the **Structured Product Labeling Resources (SPL)** link provided under **SELF-HELP**.

The screenshot 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 includes 'REGISTRATION OF COSMETIC PRODUCT FACILITY' and 'COSMETIC PRODUCT LISTING'. The 'SELF-HELP' section includes 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/unilsearch', 'For UNIL requests contact: FDA-SRS@fda.hhs.gov', 'Structured Product Labeling Resources | FDA', and 'DUNSLink (dnb.com)'. The 'MANAGE ACCOUNT' section includes 'EDIT USER PROFILE' and 'MANAGE USERS'. The main content area is titled 'UPLOAD COSMETIC PRODUCT LISTING' and contains a file upload interface. It says 'Cosmetic Product Listing File' and 'Select a file or drop one here.' Below this, there is a note: 'Note: Please upload a zip file that contains the SPL file with the name as the root id followed by ".xml" and any associated image files that referenced in the xml whose names end in ".jpg".' At the bottom of the upload area, there are two buttons: 'UPLOAD' and 'CANCEL'. The 'UPLOAD' button is highlighted with a red box, and a red arrow points to it from below.

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 the FDA logo and the text "FDA Direct Cosmetics Direct". Below this, a breadcrumb trail shows "HOME" and "COSMETIC PRODUCT LISTING". The main content area is divided into a left sidebar and a central panel. The sidebar contains sections for "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 "DUNSLink (dnb.com)"), and "MANAGE ACCOUNT" (with links for "EDIT USER PROFILE" and "MANAGE USERS"). The central panel is titled "UPLOAD COSMETIC PRODUCT LISTING" and features a file upload area. The file name "Cosmetic Product Listing File" is displayed above a text input field containing the alphanumeric string "dcba860b1f-6bae-123a-e032-6f94af0ac444". A red circle highlights this string, and a red arrow points to it from the right. Below the input field is a note: "Note: Please upload a zip file that contains the SPL file with the name as the root id followed by '.xml' and any associated image files that referenced in the xml whose names end in '.jpg'." At the bottom of the upload area are two buttons: "UPLOAD" (in red) and "CANCEL" (in grey). The footer of the page contains the FDA logo and a list of links: "FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs" and "Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy".

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="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.”

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 shows the FDA Direct Cosmetics Direct interface. The top navigation bar includes 'HOME' and 'COSMETIC PRODUCT LISTING'. Below this, there is a note about clicking on data element names for instructions. The main content area has several expandable sections: 'DOCUMENT TYPE DETAILS', 'COSMETIC PRODUCTS', 'CONFIRMATION STATEMENT', and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. A red box highlights the 'SUBMIT SPL' and 'VALIDATE SPL' options, with arrows pointing to them. A text box explains that a guide will help users understand these stages.

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



Product Listing Status Examples

Listing Status: Validation in Progress



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

FDA FDA Direct
Cosmetics Direct

HOME ▶ COSMETIC PRODUCT LISTING

SUBMISSIONS

[REGISTRATION OF COSMETIC PRODUCT FACILITY](#)

[COSMETIC PRODUCT LISTING](#)

COSMETIC PRODUCT LISTING

For assistance with validation errors in Cosmetics Direct contact cosmeticsdirect@fda.hhs.gov. For general questions regarding electronic registration 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	DOCUMENT TYPE	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
VALIDATION IN PROGRESS	fd850b1f-7bcd-165a-e053-6b65af0ac496	dcb860b1f-6bae-123a-e032-6f94af0ac444		1	INITIAL	Cosmetic Beauty (Different Color Aloe Gels)	DETAILS	First name Last name	07-JUN-2023 02:53:31

SELF-HELP

[FEI Search Portal \(fda.gov\)](#)

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

[Search for UNILs: precision.fda.gov/unilsearch](#)

[For UNIL requests contact: FDA-SRS@fda.hhs.gov.](#)

[Structured Product Labeling Resources | FDA](#)

[DUNSLink \(dnb.com\)](#)

MANAGE ACCOUNT

[EDIT USER PROFILE](#)

[MANAGE USERS](#)

FDA
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Listing Status: Ready for Submission

VALIDATE SPL: You can check your SPL for an initial validation before submitting to FDA. This option does not automatically submit your SPL to FDA, even if it passes the initial validation, but scans for certain errors prior to the actual submission. Once the system has completed a quick **VALIDATION**, the status **VALIDATION IN PROGRESS** will change to **READY FOR SUBMISSION**.

FDA Direct Cosmetics Direct

HOME **COSMETIC PRODUCT LISTING**

SUBMISSIONS

- REGISTRATION OF COSMETIC PRODUCT FACILITY
- COSMETIC PRODUCT LISTING

SELF-HELP

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

MANAGE ACCOUNT

- EDIT USER PROFILE
- MANAGE USERS

COSMETIC PRODUCT LISTING

For assistance with validation errors in Cosmetics Direct contact cosmeticsdirect@fda.hhs.gov. For general questions regarding electronic registration 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 TYPE	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
READY FOR SUBMISSION	fd850b1f-7bcd-165a-e053-6b65af0ac496	dcba860b1f-6bae-123a-e032-6f94af0ac444		1	INITIAL	Cosmetic Beauty (Different Color Aloe Gels)	DETAILS	First name Last name	07-JUN-2023 02:53:31

FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs
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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 displays the FDA Direct Cosmetics Direct interface. At the top left, the logo reads "FDA Direct Cosmetics Direct". The navigation bar includes "HOME" and "COSMETIC PRODUCT LISTING" with a user icon. On the right, there are buttons for "EDIT", "SUBMIT SPL", and "<< RETURN". A red box highlights the "SUBMIT SPL" button, with a red arrow pointing down to it from above. Below the navigation, a note states: "Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out this Cosmetic Product Listing Submission Form. Red asterisk indicate required fields." A larger red box highlights a message: "Note: This submission has passed the INITIAL VALIDATION but has NOT been ACTUALLY SUBMITTED TO FDA. Click ON 'SUBMIT SPL' to SUBMIT." A red arrow points left to this message from the right. Below the message are four expandable sections: "+ DOCUMENT TYPE DETAILS", "+ COSMETIC PRODUCTS", "+ CONFIRMATION STATEMENT", and "+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT". The footer contains the FDA logo and a list of links: "FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs | Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy".

Listing Status:

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. The main heading is "COSMETIC PRODUCT LISTING". Below this, there is a search bar with a "GO" button and an "ACTIONS" dropdown. A "CREATE NEW/UPLOAD FILE" button is also visible. A table lists submissions, with one entry highlighted in red. This entry has a status of "SUBMISSION ACCEPTED" and a submission ID of "fe1237459100.54893654@direct". Two red arrows point to the "SUBMISSION ACCEPTED" status and the submission ID.

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

Listing Status:



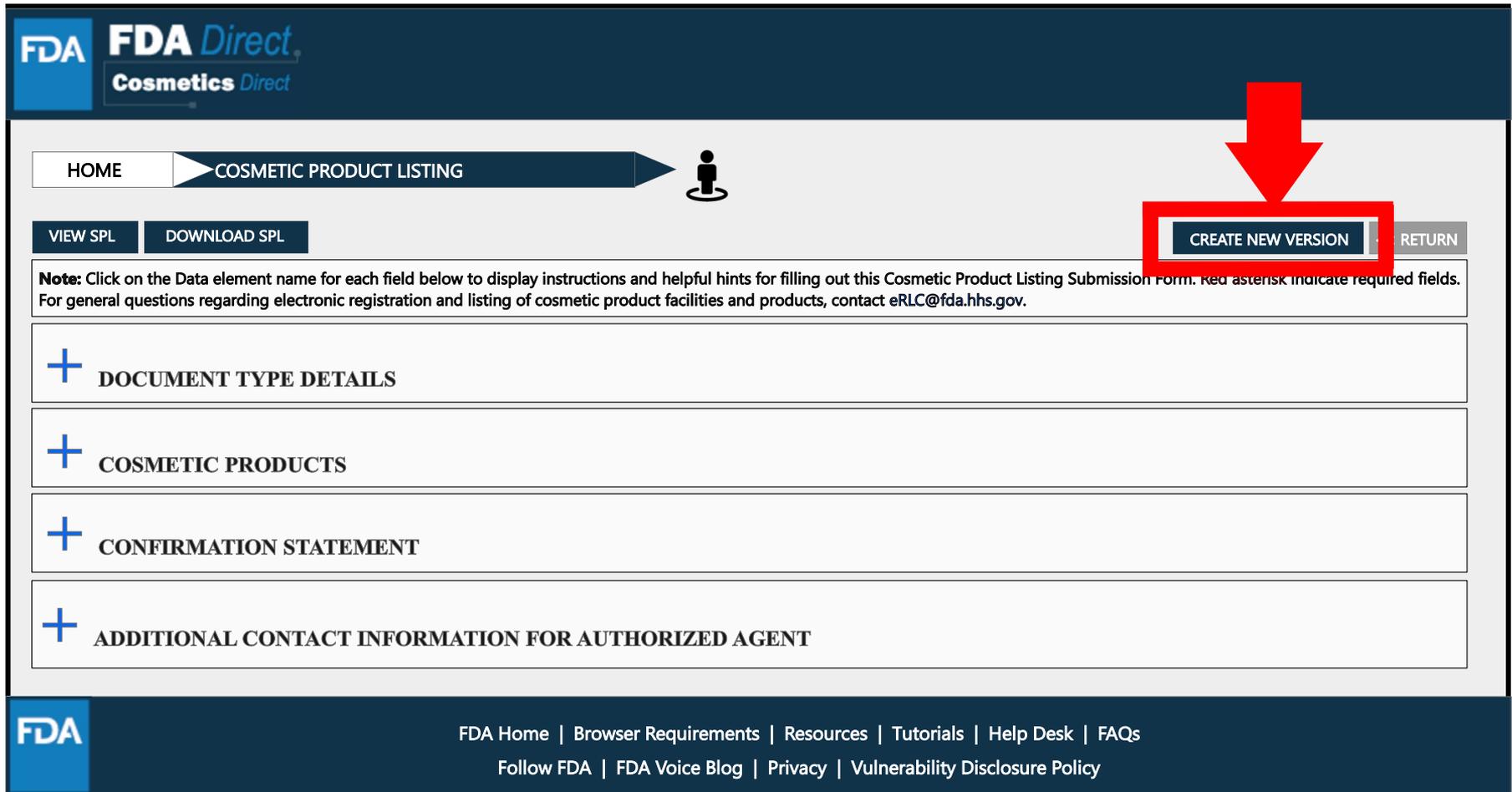
Submission Accepted to View SPL and Download SPL

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

The screenshot shows the FDA Direct Cosmetics Direct interface. At the top left is the FDA logo and the text '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. Below the navigation bar are two buttons: 'VIEW SPL' and 'DOWNLOAD SPL', both of which are enclosed in a red rectangular box. A large red arrow points from the right towards these buttons. To the right of these buttons are two more buttons: 'CREATE NEW VERSION' and '<< RETURN'. Below the buttons is a note: 'Note: Click on the Data element name for each field below to display instructions and helpful hints for filling out this Cosmetic Product Listing Submission Form. Red 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 and a title: 'DOCUMENT TYPE DETAILS', 'COSMETIC PRODUCTS', 'CONFIRMATION STATEMENT', and 'ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. At the bottom of the page is a dark blue footer with the FDA logo on the left and a list of links: 'FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs | Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy'.

Clone Successfully Submitted SPL

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



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

Listing Status: Validation Failure



After SAVE AND VALIDATE, the cosmetic product listing home page will have the following details as shown below. The status will be 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 heading is "COSMETIC PRODUCT LISTING". A red arrow points to a search bar containing the text "VALIDATION FAILURE". Below the search bar is a table with the following data:

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



Listing Status: Validation Failure

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 reads "FDA Direct Cosmetics Direct". A prominent red banner at the top contains the message: "# ERRORS HAVE OCCURRED" with a close button (X) in the top right corner. Below this banner, two lines of text provide instructions: "* Error Facility FEI Number : (Go to error)" and "* After reviewing and fixing these errors, select Submit SPL or Save and Validate to resubmit the SPL and check for any additional errors." Below the banner is a navigation bar with "HOME" and "COSMETIC PRODUCT LISTING" (the latter is highlighted with a blue arrow). To the right of the navigation bar are buttons for "SUBMIT SPL", "SAVE AS DRAFT", "SAVE AND VALIDATE", "DELETE", and "<< RETURN". Below the navigation bar is a note: "Note: Click on [red asterisk] 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". At the bottom of the page is a footer with the FDA logo on the left and a list of links: "FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs | Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy".

Listing Status: Draft

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' text. Below this is a navigation bar with 'HOME' and 'COSMETIC PRODUCT LISTING' (the latter is highlighted with a dark blue arrow). To the right of the navigation bar is a user icon and a set of buttons: 'SUBMIT S...', 'SAVE AS DRAFT', 'VE AND VALIDATE', 'DELETE', and '<< RETURN'. The 'SAVE AS DRAFT' button is highlighted with a red box, and a large red arrow points down to it from above. 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 plus sign icon and a title: '+ DOCUMENT TYPE DETAILS', '+ COSMETIC PRODUCTS', '+ CONFIRMATION STATEMENT', and '+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT'. At the bottom of the page is a dark blue footer with the FDA logo on the left and a list of links: 'FDA Home | Browser Requirements | Resources | Tutorials | Help Desk | FAQs | Follow FDA | FDA Voice Blog | Privacy | Vulnerability Disclosure Policy'.

Listing Status: Draft



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

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

MANAGE ACCOUNT

EDIT USER PROFILE
MANAGE USERS

COSMETIC PRODUCT LISTING

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

Q GO ACTIONS

CREATE NEW/UPLOAD FILE

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





Cosmetics Direct Home Page

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

- REGISTRATION OF COSMETIC PRODUCT FACILITY
- COSMETIC PRODUCT LISTING

SELF-HELP

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

MANAGE ACCOUNT

- EDIT USER PROFILE
- MANAGE USERS

COSMETIC PRODUCT LISTING

For assistance with validation errors in Cosmetics Direct contact cosmeticsdirect@fda.hhs.gov. For general questions regarding electronic registration 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	DOCUMENT TYPE	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE
SUBMISSION ACCEPTED	fd850b1f-7bcd-1655-3-6b65af0ac496	fa860b1f-6bae-123a-e02-6f94af0ac444	fe1237459100.54893654@direct	1	INITIAL	Cosmetic Beauty (Different Color Aloe Gels)	DETAILS	First name Last name	07-JUN-2023 02:53:31

Product Details [X]

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 Submissions

FDA

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 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

ALL SUBMISSIONS

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	LAST MODIFIED USER	LAST MODIFIED DATE	
SUBMISSION ACCEPTED	fd850b1f-7bcd-165a-e053-6b65af0ac496	abcd850b1f-7bce-165a-e053-5e94af0ac123	cd6287459103.64893257@direct	1	REGISTRATION OF COSMETIC PRODUCT FACILITY	First name Last name	07-JUN-2023 02:53:31	
SUBMISSION ACCEPTED	fd850b1f-7bcd-165a-e053-6b65af0ac496	dcb860b1f-6bae-123a-e032-6f94af0ac444	fe1237459100.54893654@direct	1	COSMETIC PRODUCT LISTING	First name Last name	07-JUN-2023 02:53:31	



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