COSMETICS DIRECT

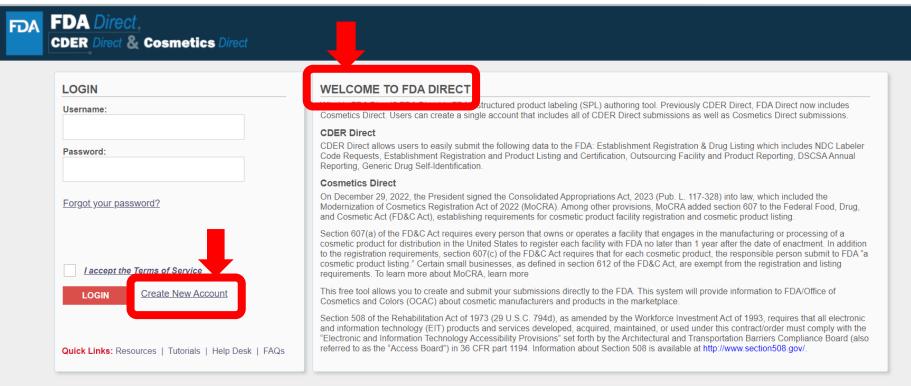
Electronic Submissions Portal

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FDA DIRECT HOME PAGE

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

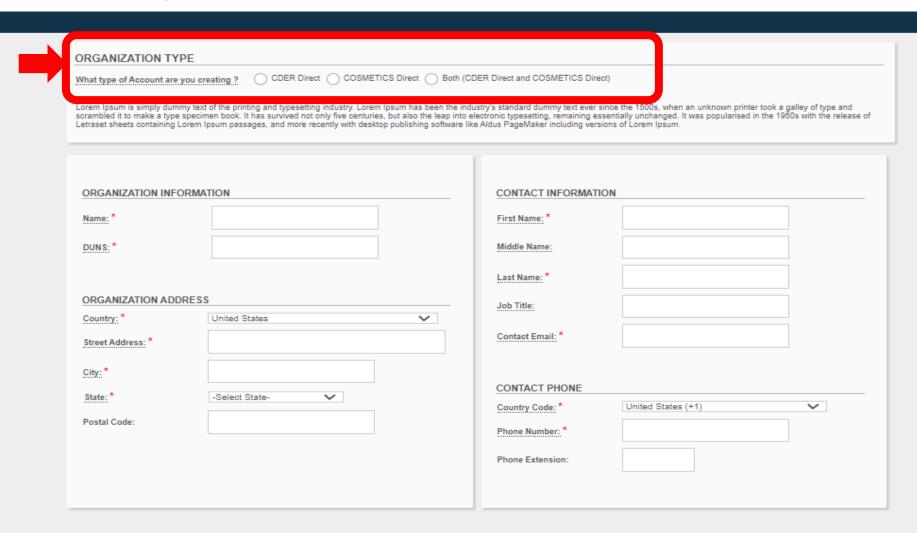


WARNING: This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes all devices/storage media attached to this system. This system is provided for Government authorized use only. Unauthorized or improper use of this system is prohibition and may result in disciplinary action and/or civil and criminal penalties. At any time, and for any lawful Government purpose, the Government may may not active the Government purpose, 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.

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.

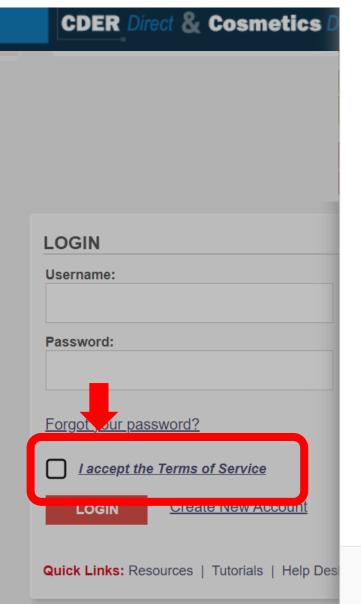
CREATE A NEW ACCOUNT

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.



TERMS OF SERVICE

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



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.

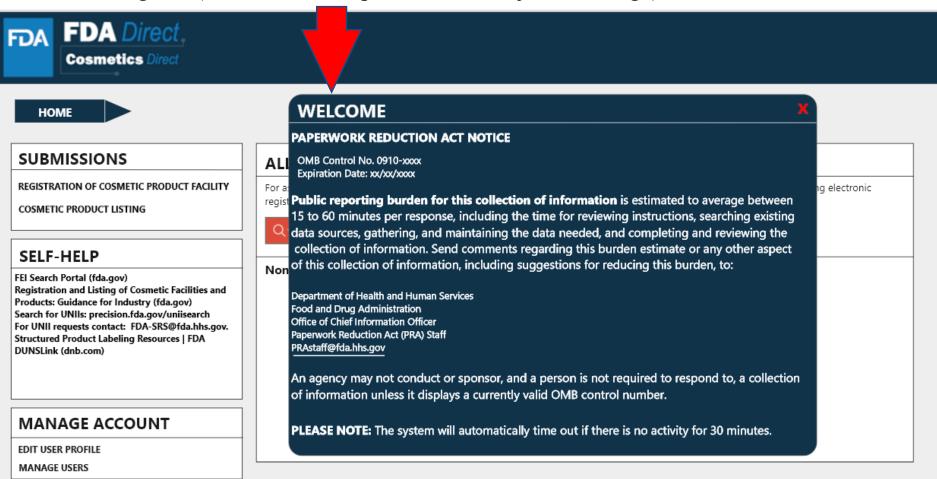
By using this system, you understand and consent to the following: The Government may monitor, record, and audit your system usage, including usage of personal devices and email systems for official duties or to conduct HHS business. Therefore, you have no reasonable expectation of privacy regarding 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)





COSMETICS DIRECT HOME PAGE

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

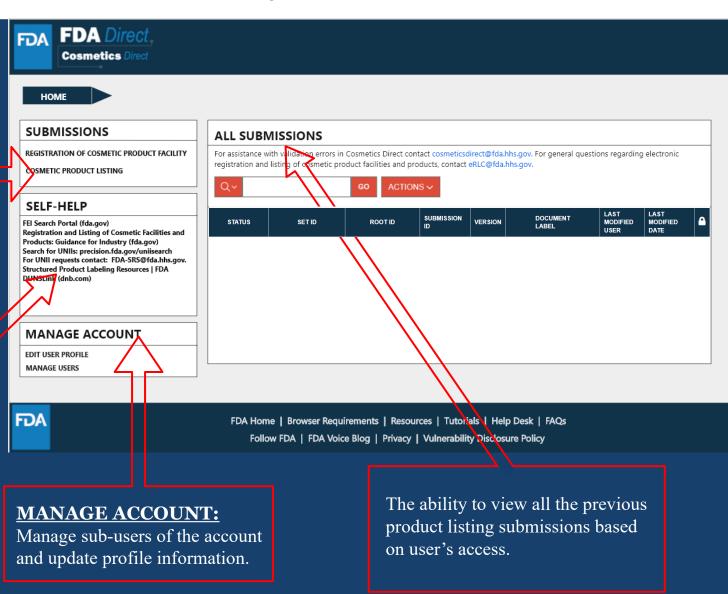
SUBMISSIONS:

Two types of selections are shown here:
Registration of Cosmetic Product Facility and Cosmetic Product Listing.

Depending on the account created, account holder may have additional form selections.

SELF-HELP:

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



REGISTRATION OF COSMETIC PRODUCT FACILITY

| Registration of Cosmetic Product Facility Home Page | 9 |
|--|-----------------|
| Create a New Registration or Upload An Existing File | ¹ 10 |
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HOME PAGE: REGISTRATION OF COSMETIC PRODUCT FACILITY

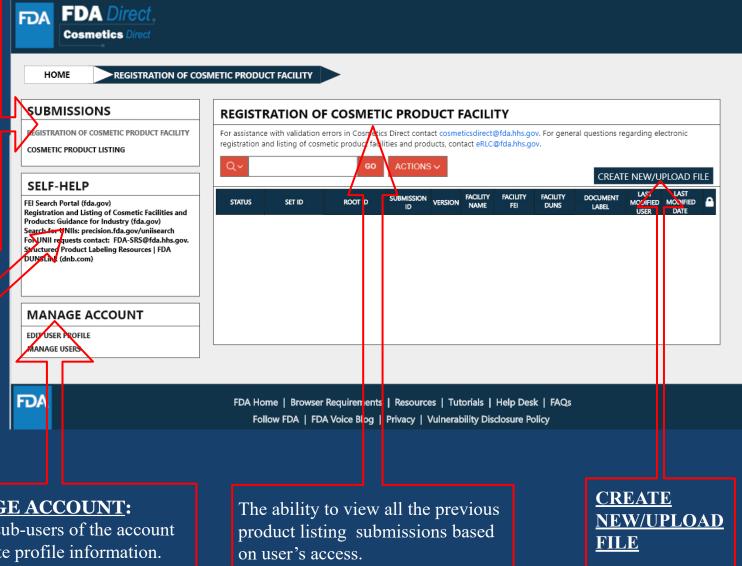
SUBMISSIONS:

Two types of selections are shown here: Registration of Cosmetic Product Facility and Cosmetic Product Listing.

Depending on the account created, account holder may have additional form selections.

SELF-HELP:

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



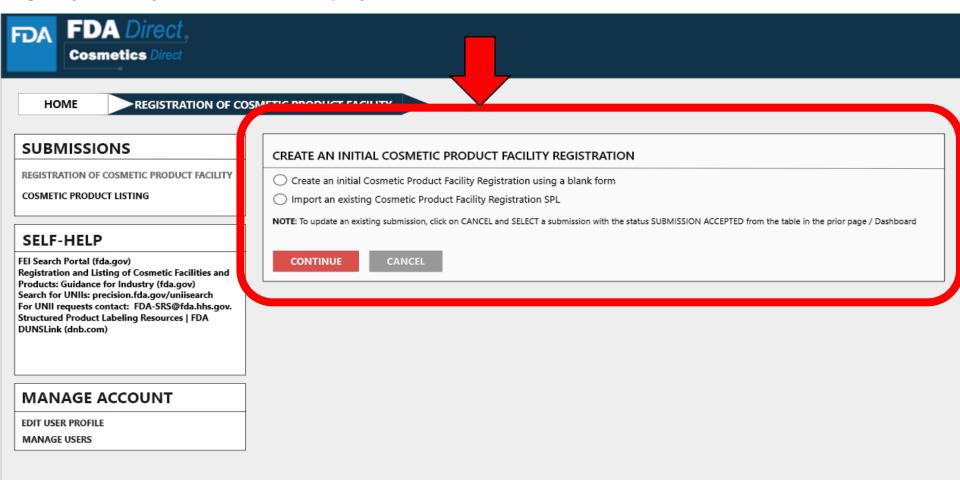
MANAGE ACCOUNT:

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

CREATE A NEW REGISTRATION OR UPLOAD AN EXISTING FILE

CREATE A NEW REGISTRATION OR UPLOAD AN EXISTING FILE

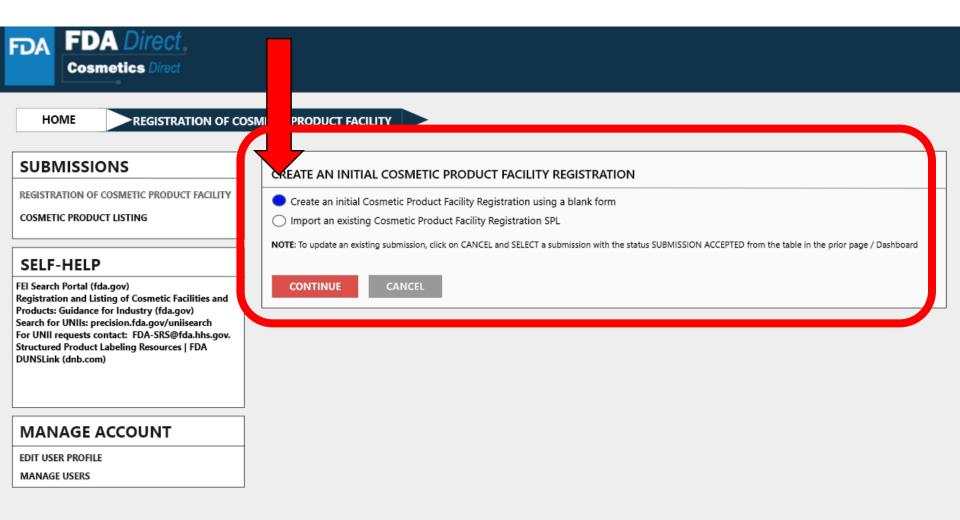
Selecting the <u>CREATE NEW/UPLOAD FILE</u> box, from the <u>Registration of Cosmetic Product Facility home page</u> will direct user to this page with an option of creating an initial Cosmetic Product Facility Registration using a blank form or importing an FDA-accepted SPL stored on your computer in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





CREATE A NEW PRODUCT FACILITY REGISTRATION

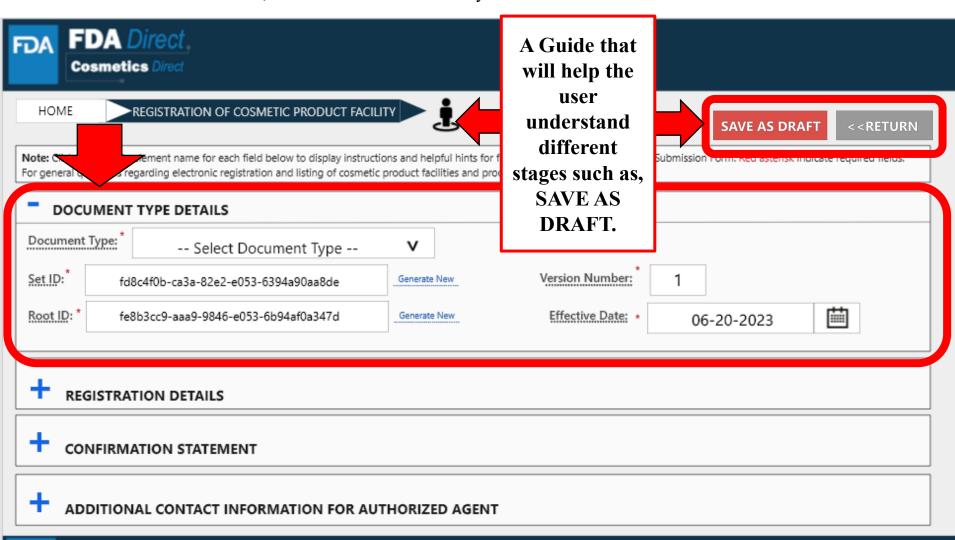
Create an Initial Cosmetic Product Facility Registration using a blank form.





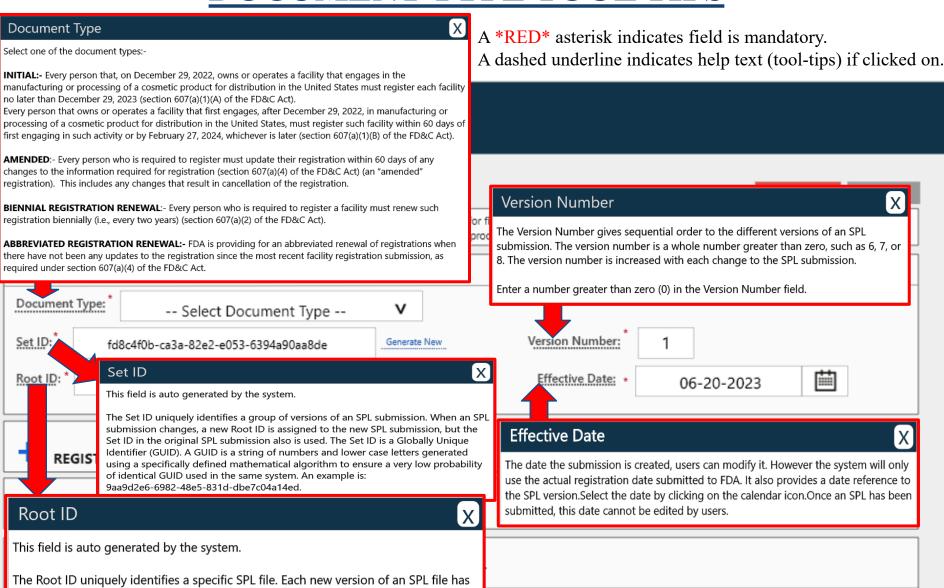
DOCUMENT TYPE DETAILS

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





DOCUMENT TYPE TOOL TIPS



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

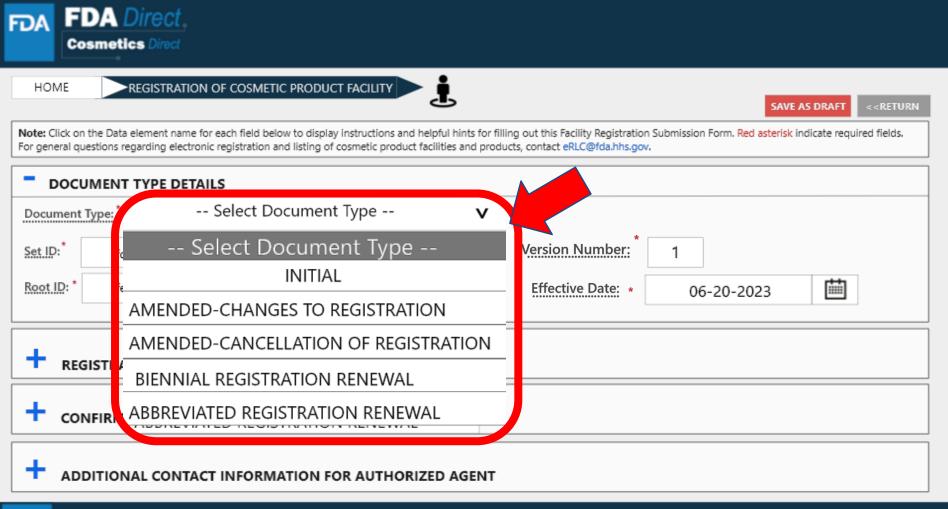
algorithm to ensure a very low probability of identical GUID used in the same

system. An example is: 9aa9d2e6-6982-48e5-831d-dbe7c04a14ed.

Resources | Tutorials | Help Desk | FAQs rivacy | Vulnerability Disclosure Policy

DOCUMENT TYPE DETAILS

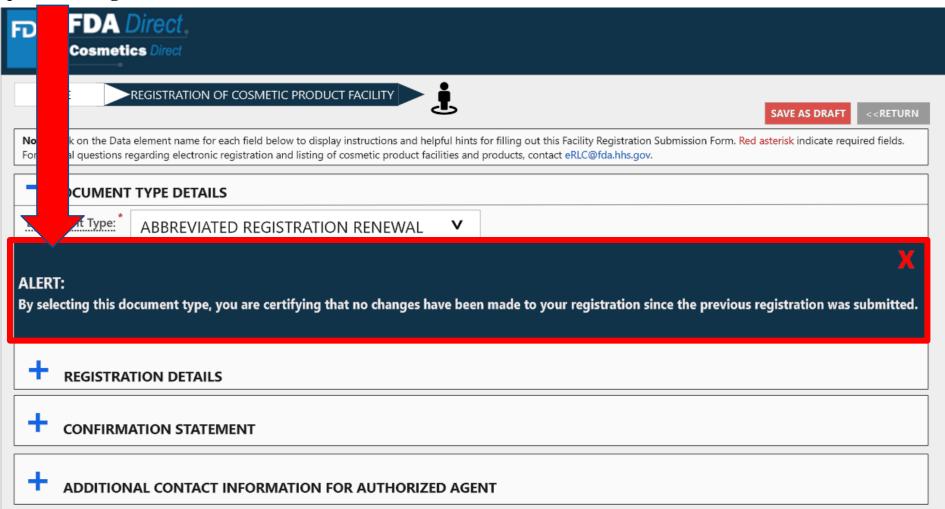
By selecting the drop-down (\mathbf{v}), Five document type options will appear; initial, amended-changes to registration, amended-cancellation of registration, biennial registration renewal, and abbreviated registration renewal. (First time users will only have INITIAL as an option)





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"





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

X

X

Enter the existing facility FEI number. If you need to look-up the FEI number or request https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login

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

Facility DUNS Number

(optional field) The existing 9 digital facility DUNS number.

Obtain a DUNS number: https://www.dnb.com

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

Parent Company Name



(optional field) Provide the parent company's name if available. For more information visit Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)

Facility Country



Provide facility's country name (if the country is other than the USA.) For more information visit Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)

Facility City



Provide the complete name of the city. For more information visit Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)

Facility Street Address



Provide the complete name of the street. For more information visit Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)



Facility State or Province Provide the complete name of the state or province. For more information visit



Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)

Facility Zip/postal Code



Facility Email Provide the facility's email address. For more information visit Registration and Listing

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)

of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)

Facility Owner/Operator

Guidance for Industry (fda.gov)



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:

REGISTRATION DETAILS

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

| Cosmetics Di | | | | | | |
|--|------------------------------------|-------------------------------------|------------------------------|---|---------------------------|--|
| HOME REGIS | TRATION OF COSMETIC PRODUCT FACILE | Y J. | | SAVE AS DRAFT SAVE AND VALIDATE | DELETE << RETURN | |
| Note: Click on the Data eleme | | tions and helpful hints | filling out this | Facility Registration Submission Form. Red asterisk | indicate required fields. | |
| + DOCUMENT T | YPE DETAILS | | | | | |
| = REGISTRATIO | N DETAILS | | | | | |
| IS THIS A FACILITY REGIS | TRATION FOR A SMALL BUSINESS (opt | tional registration)? | ☐ YES | □ NO | | |
| Facility name: | | | | Facility DUNS Number: | | |
| Facility FEI Number: | | Parent Company n (If applicable) | | | | |
| ·FACILITY CONTAC | ·FACILITY CONTACT DETAILS | | | | | |
| Facility Country * | SELECT COUNTRY | V Faci | lity City | | | |
| Facility Street Address* | | Facil | lity State or P | rovince | | |
| Ĺ | | Facil | lity Zip/Posta | code * | | |
| Facility Email | | | ity Phone Nu ude Area/Cou | | | |
| Name of The Owner and/or Operator of the Facility: | | | | | | |
| + U.S. AGENT CONTACT INFORMATION | | | | | | |
| - BRAND NAMES | | | | | | |
| Add FACILITY BRAND NAMES OF COSMETIC PRODUCTS MANUFACTURED OR PROCESSED in this facility. ADD BRAND NAMES | | | | | | |
| | | | | | | |
| ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT | | | | | | |

REGISTRATION **DETAILS**

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

U.S. Agent Name

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

U.S. Agent Phone Number

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

U.S. Agent Email

FDA Direct

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

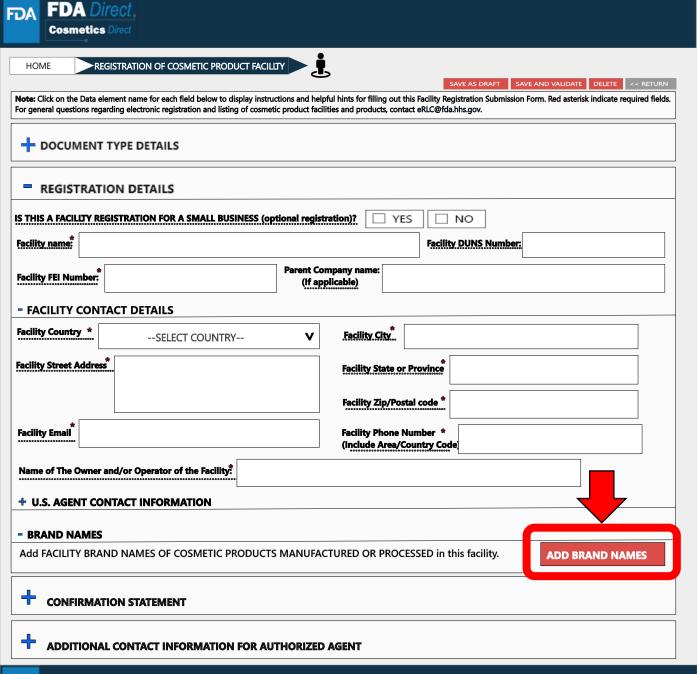
Guidance for Industry (fda.gov)

X (optional Field) For foreign facilities, provide U.S. AGENT INFORMATION. For more information, visit Registration and Listing of Cosmetic Product Facilities and Products:

| Cosmetics Direct | | | | | | | |
|--|---|-------------|-----------------|---|------------------|-----------------------------|------------------|
| HOME REGISTRATI | ION OF COSMETIC PRODUCT FACILL | Y | } | | | | |
| | | | 5 | | SAVE AS DRAFT SA | VE AND VALIDATE DELETE | << RETURN |
| | me for each field below to display instruct ctronic registration and listing of cosmetic | | | | | Form. Red asterisk indicate | required fields. |
| | | | | | | | |
| + DOCUMENT TYP | E DETAILS | | | | | | |
| _ | | | | | | | |
| REGISTRATION I | DETAILS | | | | | | |
| IS THIS A FACILITY REGISTRAT | TION FOR A SMALL BUSINESS (opt | ional regis | tration)? | YES | NO | | |
| Facility name: | | | | Facilit | y DUNS Number: | | |
| Facility FEI Number: | | | ompany name: | | | | |
| *************************************** | | (IT ap | plicable) | | | | |
| - FACILITY CONTACT D | ETAILS | | | - [| | | |
| Facility Country * | SELECT COUNTRY | v | Facility Cit | b x | | | |
| Facility Street Address | | | Facility Sta | te or Province | | | |
| | | | | | | | |
| | | | Facility Zip | /Postal code * | | | |
| y Email * | nail Facility Phone Number * (Include Area/Country Code) | | | | | | |
| of The Owner and/or O | nerator of the Facility* | | * 00000000000 | 0100 ± 0010 000 000 000 5 00000000 | 1 | | |
| | , per a control of the facility. | | | | | | |
| - U.S. AGENT CONTACT I | NFORMATION | | | | | | |
| U.S. Agent Name: * (for foreign facilities) | | | (Include Ar | nt Phone Numbe rea Code) | r* | | |
| U.S. Agent Email * (If not available, enter "N/A") | | | | U.S. Agent Pho | ne Extension | | |
| - BRAND NAMES | | | | | | | |
| Add FACILITY BRAND NAME(S) OF COSMETIC PRODUCTS MANUFACTURED OR PROCESSED in this facility. ADD BRAND NAMES | | | | | | | |
| + CONFIRMATION STATEMENT | | | | | | | |
| ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT | | | | | | | |
| ΕDΑ | EDA Homo I Brow | uror Poquin | omonte Posseu | rces Tutoriale | Holp Dock EAOs | | |



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

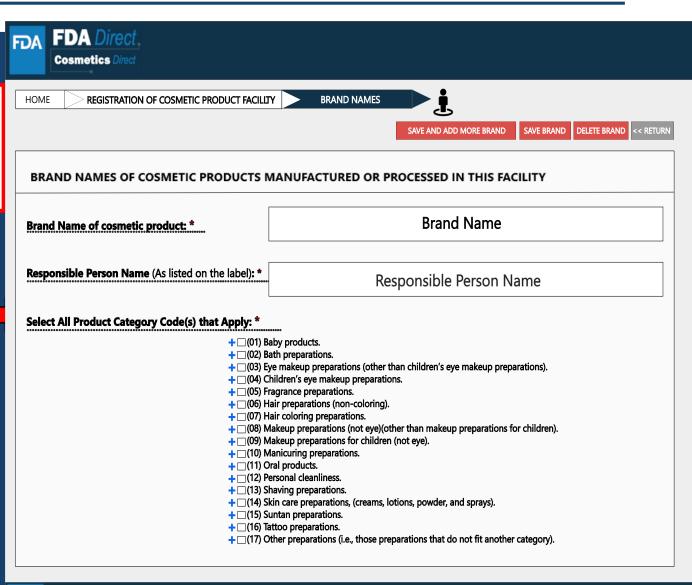




BRAND NAME(S) OF COSMETIC PRODUCT(S) MANUFACTURED OR PROCESSED IN THIS FACILITY

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



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

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



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

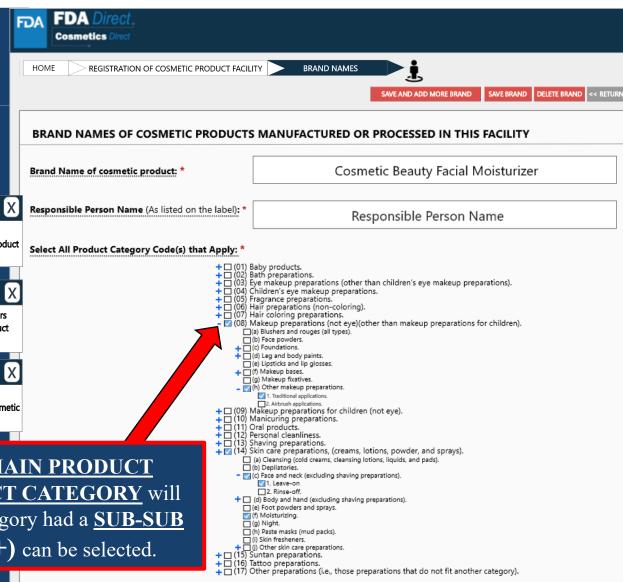
Responsible Person Name

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

Select all product category Code(s)

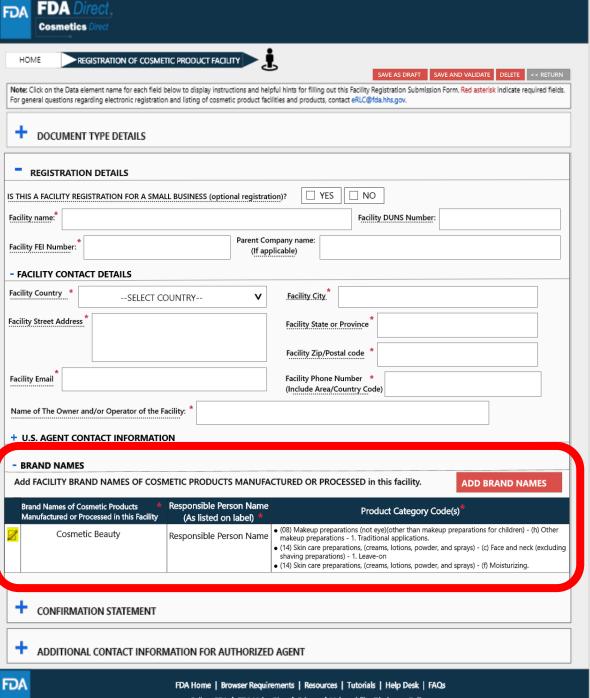
The product category or categories for each cosmetic product manufactured or processed at the facility. For more information, visit Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)

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



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.





CONFIRMATION STATEMENT

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



Signature of Submitter

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

Name of Submitter

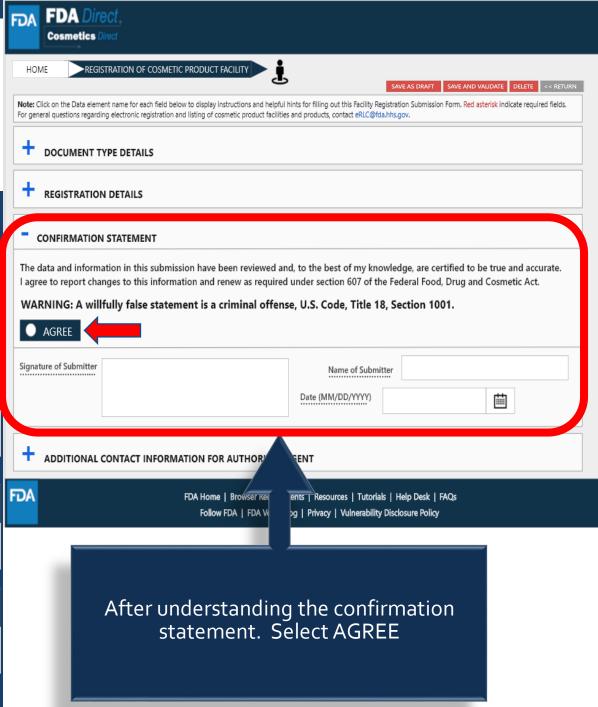
X

(optional field) Enter the full name of the submitter

Date

X

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



ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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

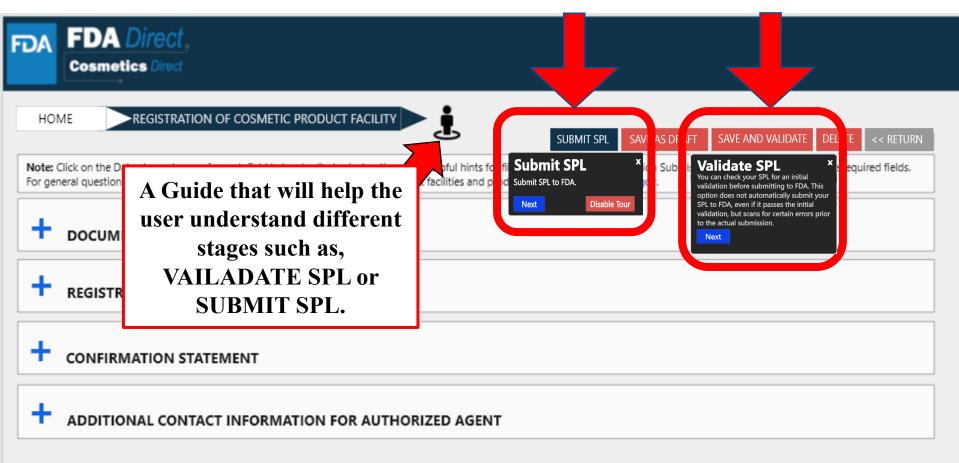


| TOA FDA Direct | | | | | |
|--|--|--|--|--|--|
| Cosmetics Direct | Additional Contact Name | | | | |
| | (optional field) Provide an additional contact name | | | | |
| HOME REGISTRATION OF COSMETIC PRODUCT FACILITY | | | | | |
| Note: Click on the Data element name for each field below to display instructions an | | | | | |
| For general questions regarding electronic registration and listing of cosmetic produc | (optional field) Provide the additional contact person's email address | | | | |
| + DOCUMENT TYPE DETAILS | | | | | |
| | Phone Number X | | | | |
| + REGISTRATION DETAILS | (optional field) Provide the additional contact person's phone number including the area or the country code | | | | |
| + CONFIRMATION STATEMENT | Phone Extension X | | | | |
| | (optional Field) | | | | |
| ADDITIONAL CONTACT INFORMATION FOR AUTHORIZ | ED AGENT | | | | |
| Additional Contact Name: | Phone Number (Include Area Code/ Country Code) | | | | |
| Email: | Phone Extension | | | | |
| | | | | | |

COMPLETED

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

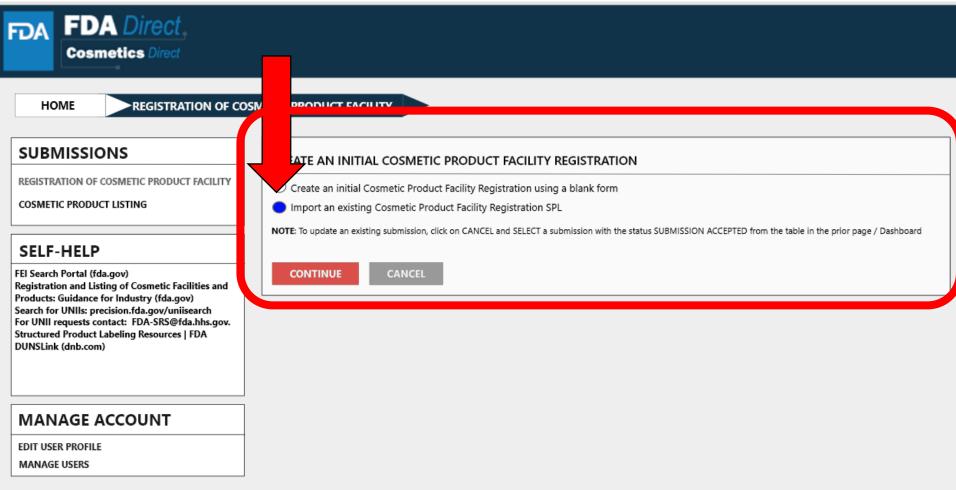
Select submit SPL for the form to be submitted to FDA.





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.





UPLOAD A FILE

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



HOME COSMETIC PRODUCT LISTING

SUBMISSIONS

REGISTRATION OF COSMETIC PRODUCT FACILITY

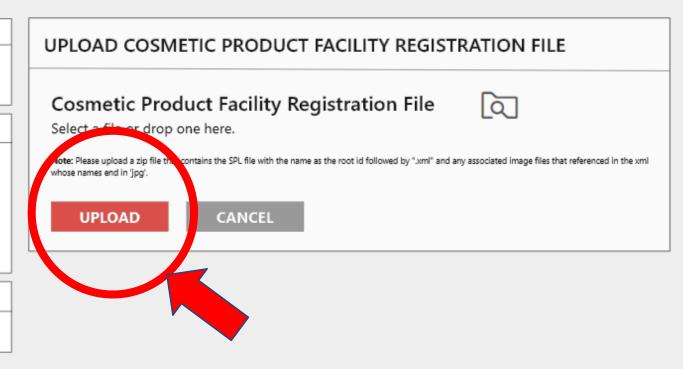
COSMETIC PRODUCT LISTING

SELF-HELP

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

MANAGE ACCOUNT

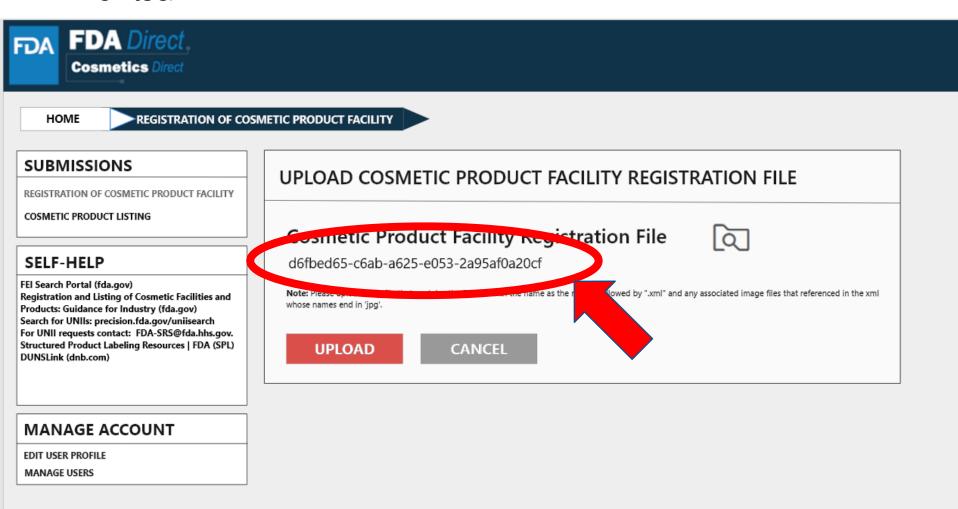
EDIT USER PROFILE MANAGE USERS





UPLOAD 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.





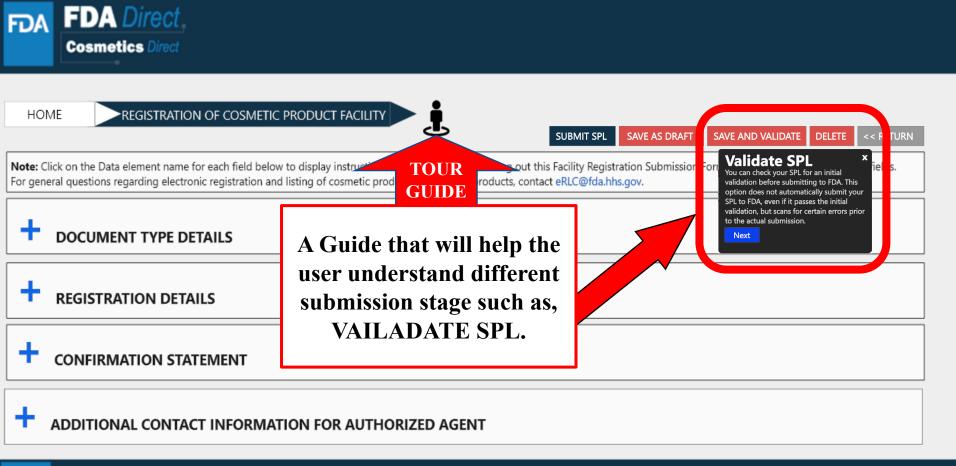
ZIP FILE (EXAMPLE)

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"</p>
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]
         <country>[ENTRY COUNTRY NAME]</country>
        </addr>
        <telecom value="tel:[ENTRY PHONE NUMBER]"/>
        <telecom value="[ENTRY EMAIL ADDRESS]"/>
        <contactPerson>
         <name>[ENTRY FULL NAME]</name>
        </contactPerson>
       </contactParty>
       <assignedEntity>
```

UPLOAD A FILE (EXAMPLE)

After <u>UPLOADING A FILE</u> (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 <u>VALIDATE SPL</u>: "You can check your SPL for an initial validation before submitting to FDA. This option does not automatically submit your SPL to FDA, even if it passes the initial validation, but scans for certain errors prior to the actual submission." SPL(Structured Product Labeling) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information.

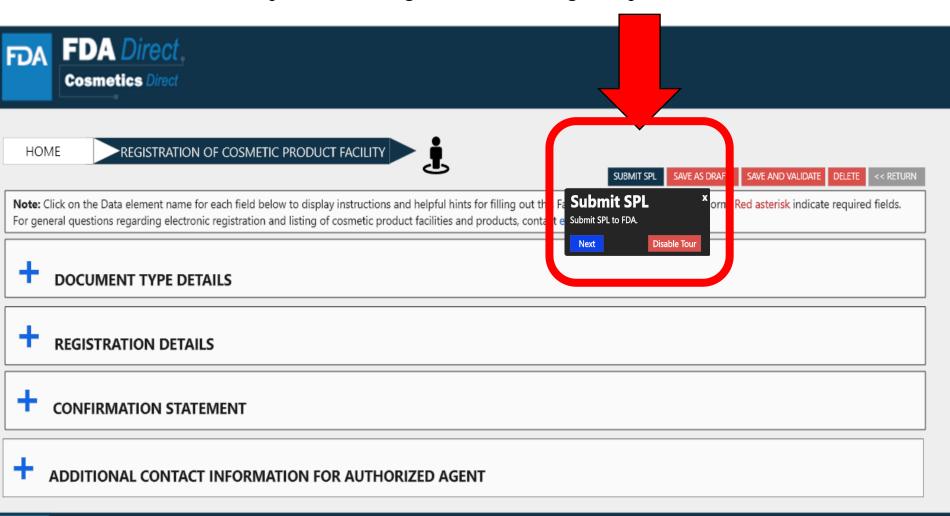




UPLOAD A FILE (EXAMPLE)

Select submit SPL for the form to be submitted to FDA.

The Submit SPL box is a help tool that can guide a user through the process.

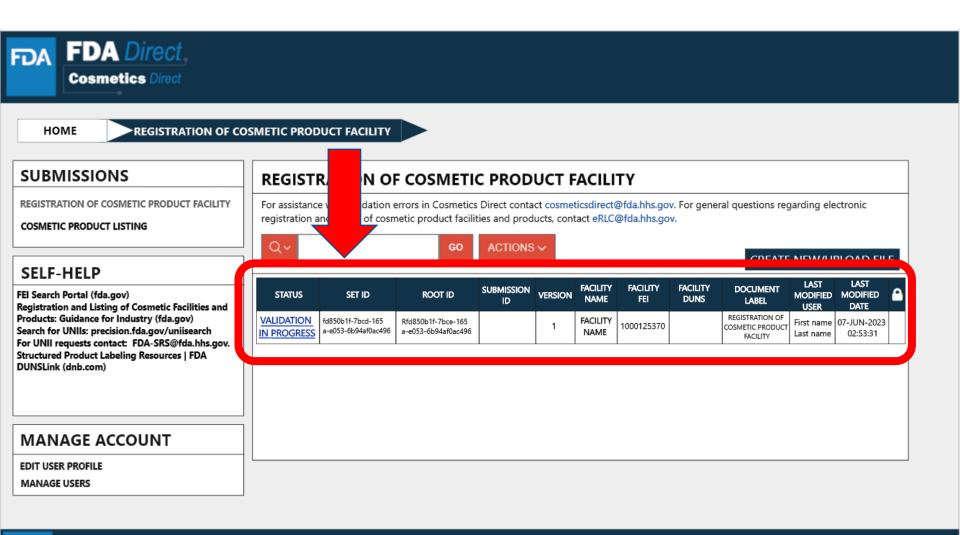




REGISTRATION STATUS EXAMPLES

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 <u>VALIDATION IN PROGRESS</u>.

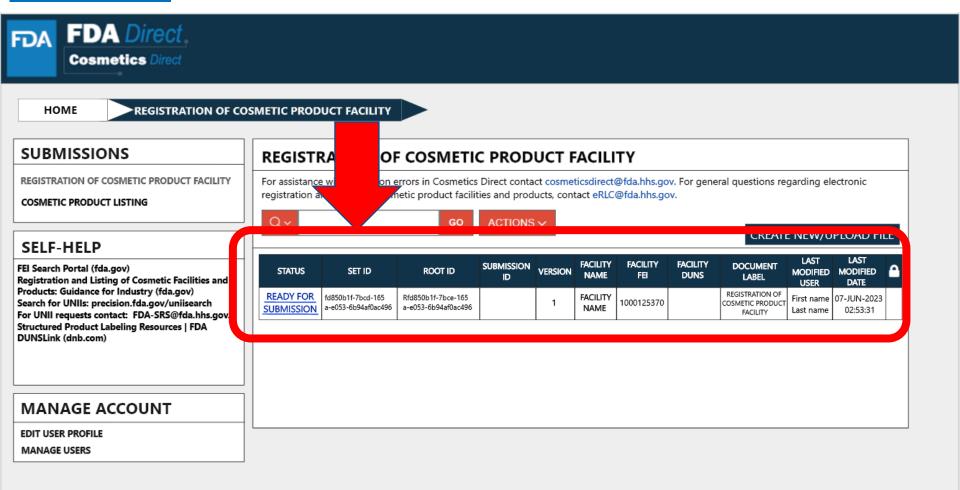




REGISTRATION STATUS: READY FOR SUBMISSION

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.

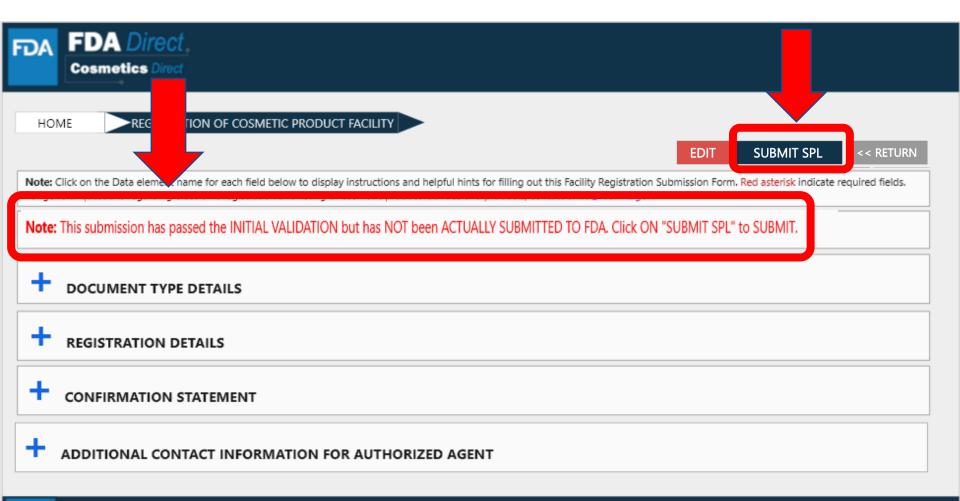
Once the system has completed a quick **VALIDATION**, the status **VALIDATION IN PROGRESS** will change to **READY FOR SUBMISSION**.





REGISTRATION STATUS: READY FOR SUBMISSION to SUBMIT SPL

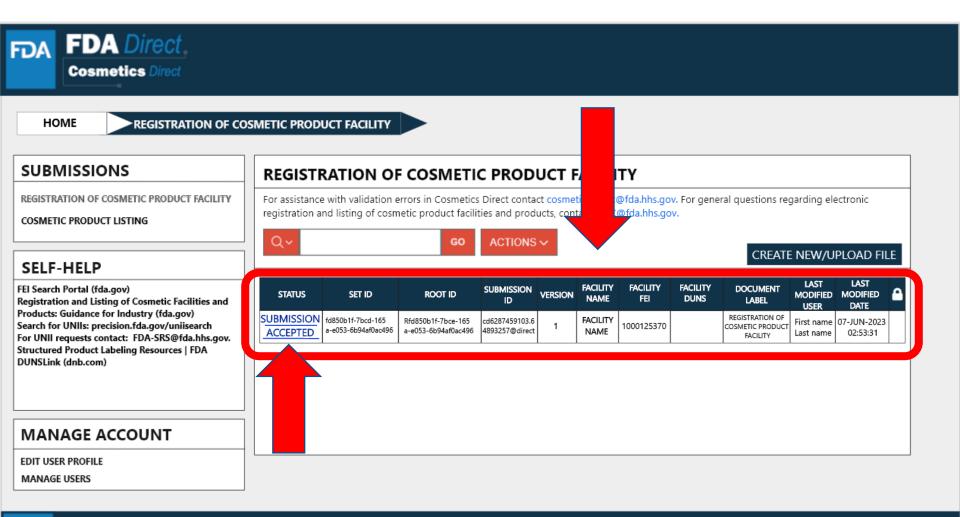
By clicking on the **READY FOR SUBMISSION**, the registration will be ready for **SUBMIT SPL**. The system will generate a message stating that, *This submission has passed the INITIAL VALIDATION but has NOT been ACTUALLY SUBMITTED TO FDA. Click ON "SUBMIT SPL" to SUBMIT.*





REGISTRATION STATUS: SUBMIT SPL to SUBMISSION ACCEPTED

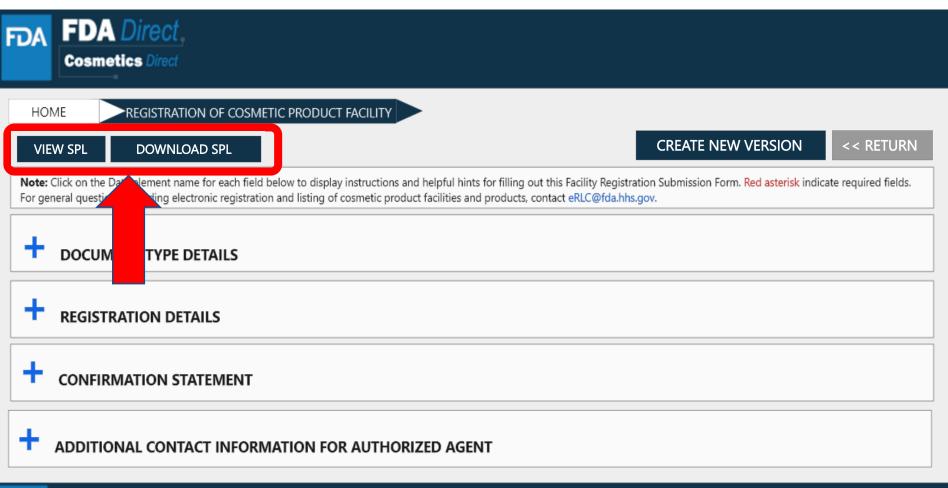
The status will change to **SUBMISSION ACCEPTED** after registration process had been successfully completed. A **SUBMISSION ID** will be given to all **ACCEPTED SUBMISSIONS**.





REGISTRATION STATUS: SUBMISSION ACCEPTED to VIEW SPL and DOWNLOAD SPL

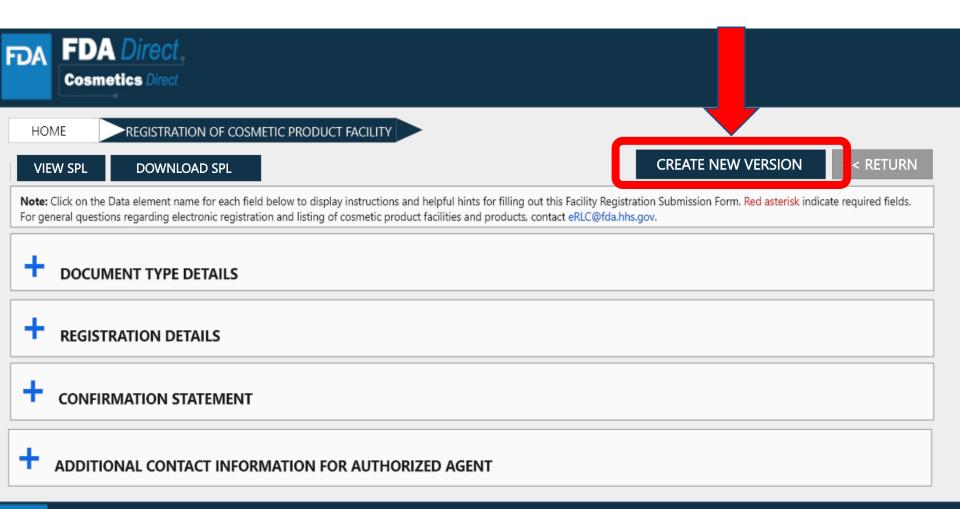
By clicking on the **SUBMISSION ACCEPTED** the system will allow the user to **VIEW SPL** and **DOWNLOAD SPL**.





CREATE A NEW VERSION

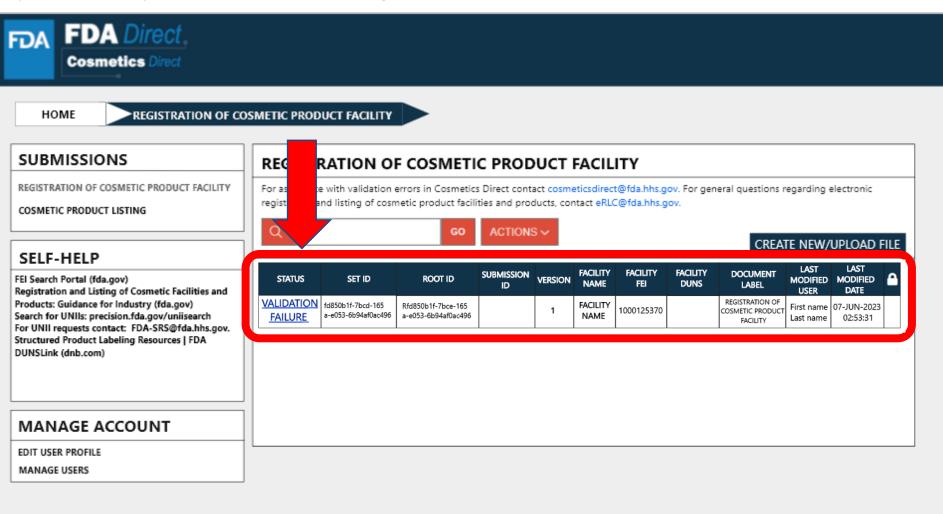
By clicking on the <u>CREATE A NEW VERSION</u>, you can clone a successfully-submitted SPL as a starting point.





REGISTRATION STATUS: VALIDATION FAILURE

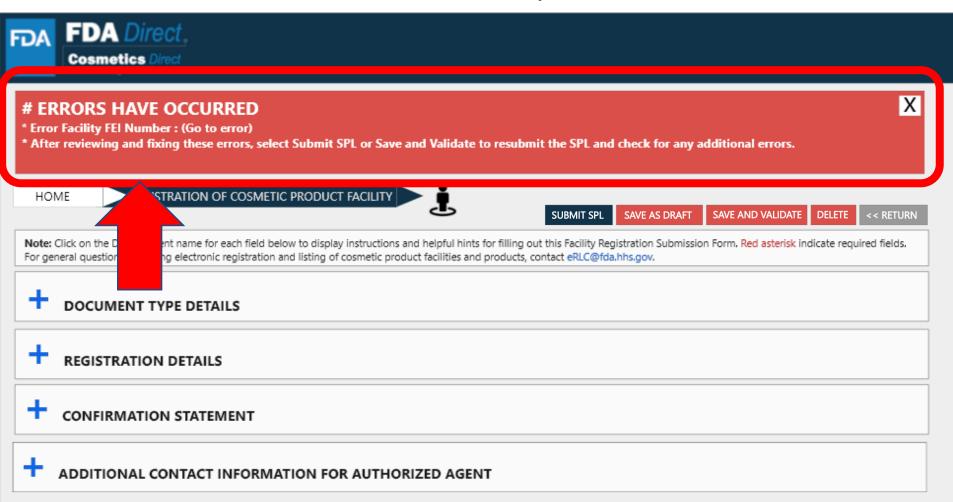
After SAVE AND VALIDATE, the registration of cosmetic product facility home page will have the following details as shown below. The status will be in <u>VALIDATION IN PROGRESS</u>. However, if the system finds any errors the status will change to <u>VALIDATION FAILURE</u>.





REGISTRATION STATUS: VALIDATION FAILURE

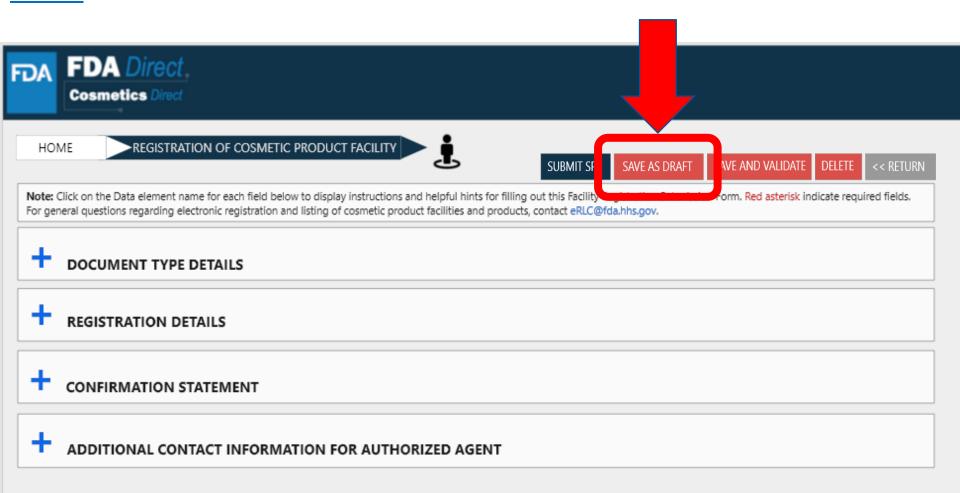
After selecting the <u>VALIDATION FAILURE</u> status, the system will provide a list of errors, that need to be fixed before submitting the SPL. After reviewing and fixing the errors, users can select <u>SUBMIT SPL</u> to resubmit the SPL or <u>SAVE AND VALIDATE</u> to check for any additional errors.





REGISTRATION STATUS: DRAFT

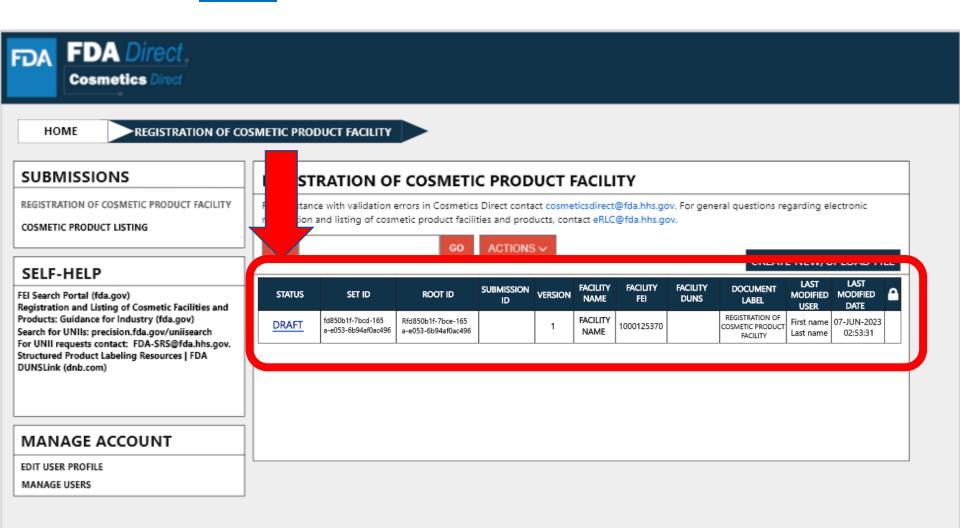
By selecting <u>SAVE AS DRAFT</u>, from any screen during the process of registration of cosmetic product facility, the system saves all information and will bring the user back to the home page. The status will be in **DRAFT**.





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**.





COSMETIC PRODUCT LISTING

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

HOME PAGE: COSMETIC PRODUCT LISTING

SUBMISSIONS:

Two types of selections are shown here:

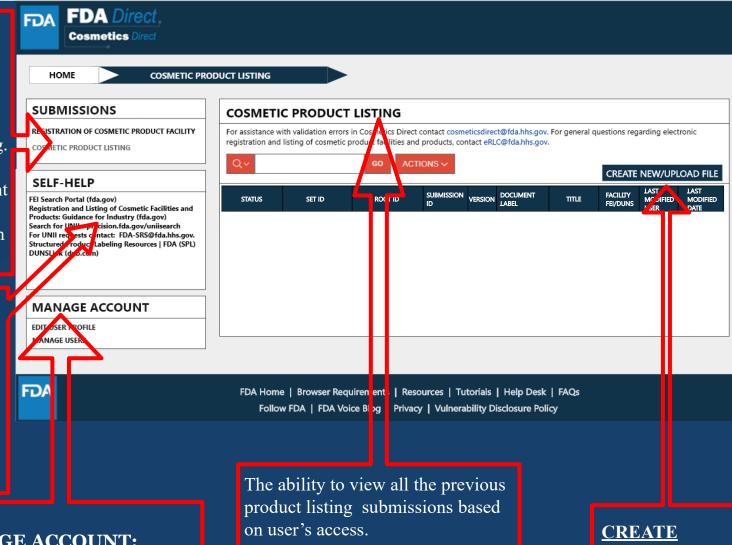
Registration of Cosmetic Product Facility and Cosmetic Product Listing.

REGISTRATION OF COSMETIC COSMETIC PRODUCT LISTING

Depending on the account created, account holder may have additional form selections.

SELF-HELP:

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



NEW/UPLOAD

FILE

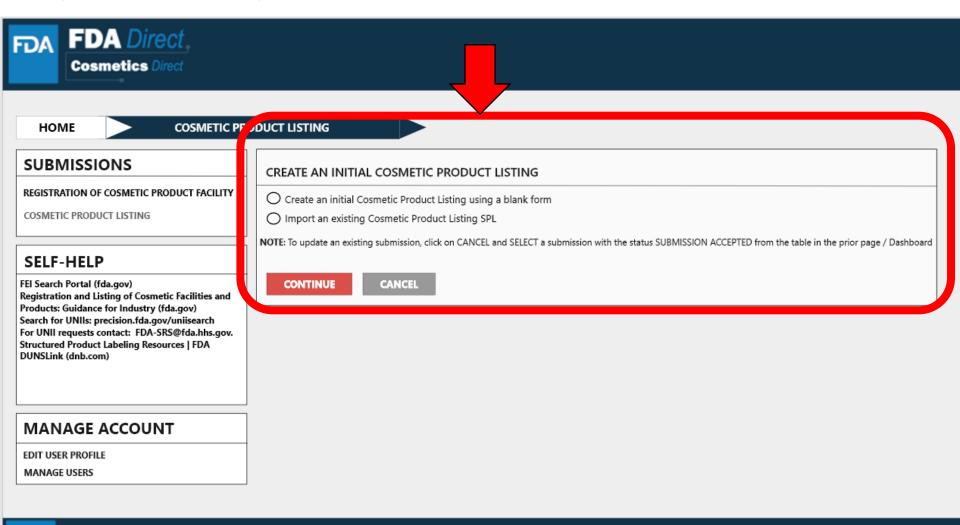
MANAGE ACCOUNT:

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

CREATE A NEW PRODUCT LISTING OR UPLOAD AN EXISTING FILE

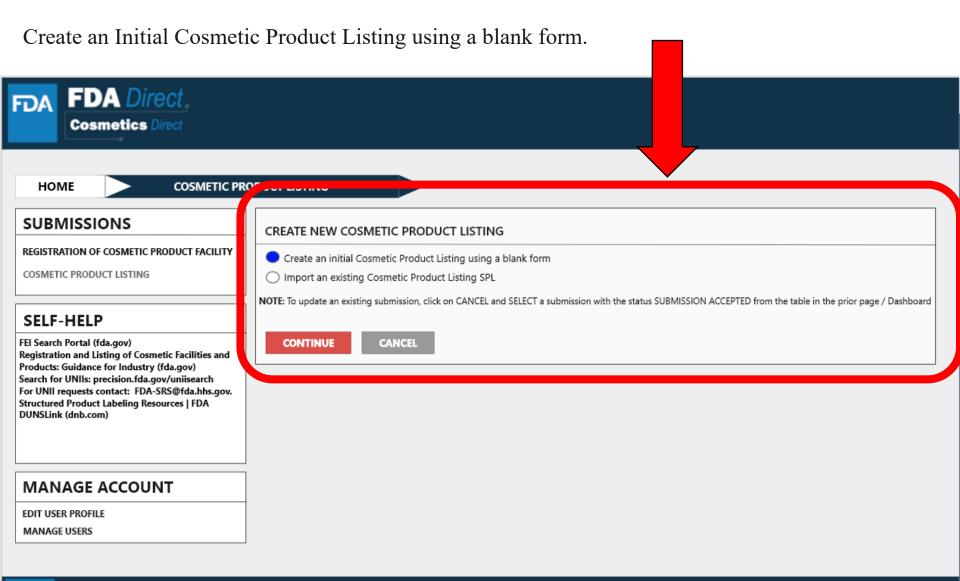
CREATE A NEW PRODUCT LISTING OR UPLOAD AN EXISTING FILE

Selecting the <u>CREATE NEW/UPLOAD FILE</u> box, from the <u>Cosmetic Product listing home page</u> 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



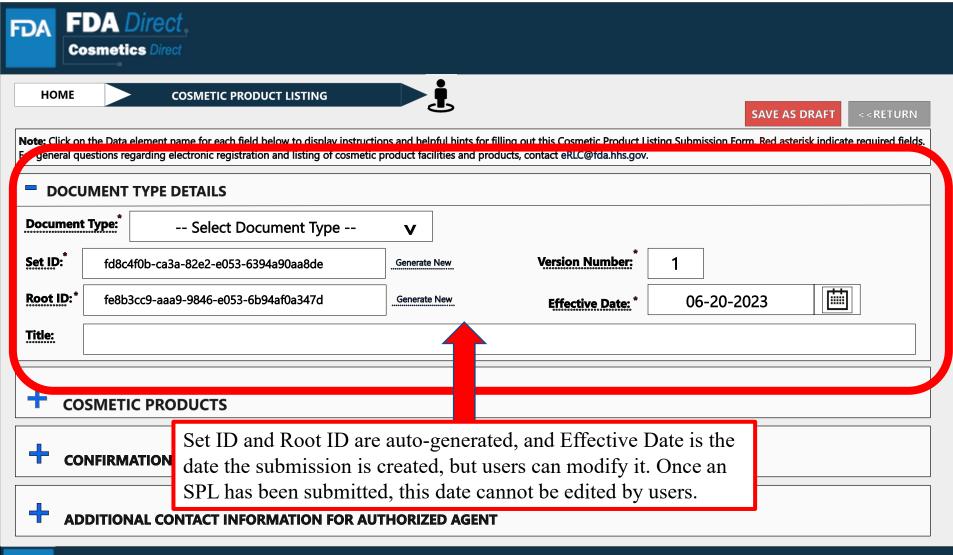


CREATE A NEW COSMETICS PRODUCT LISTING





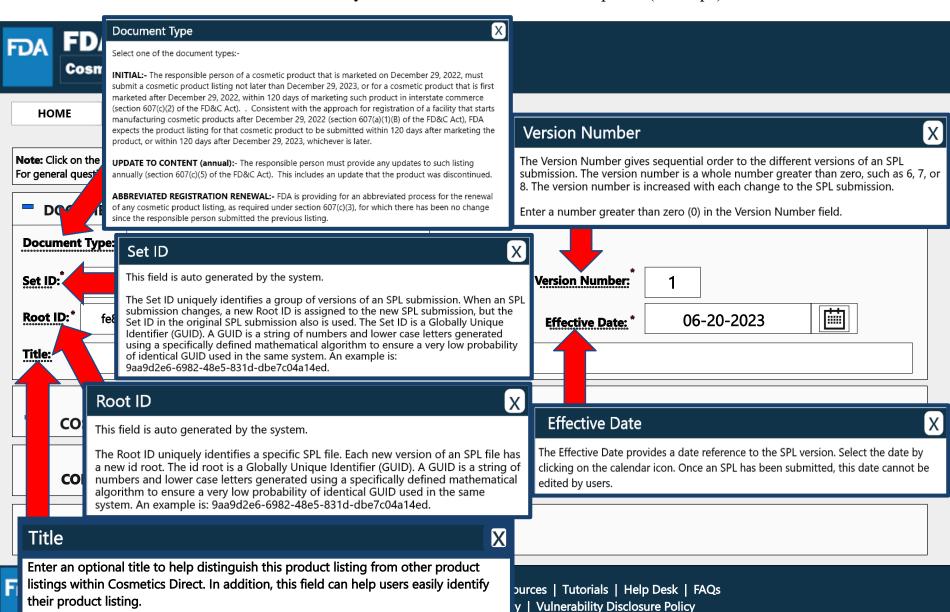
DOCUMENT TYPE DETAILS





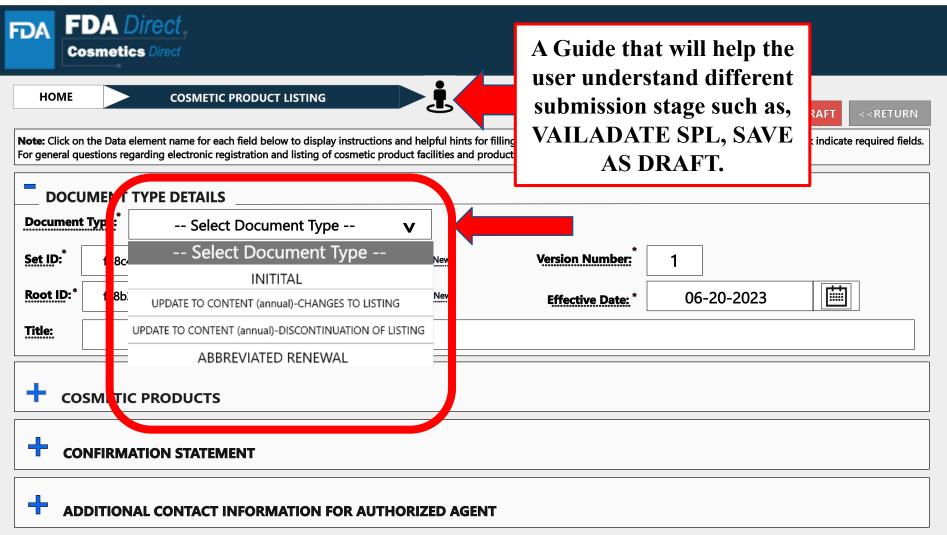
DOCUMENT TYPE TOOL TIPS

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



DOCUMENT TYPE DETAILS

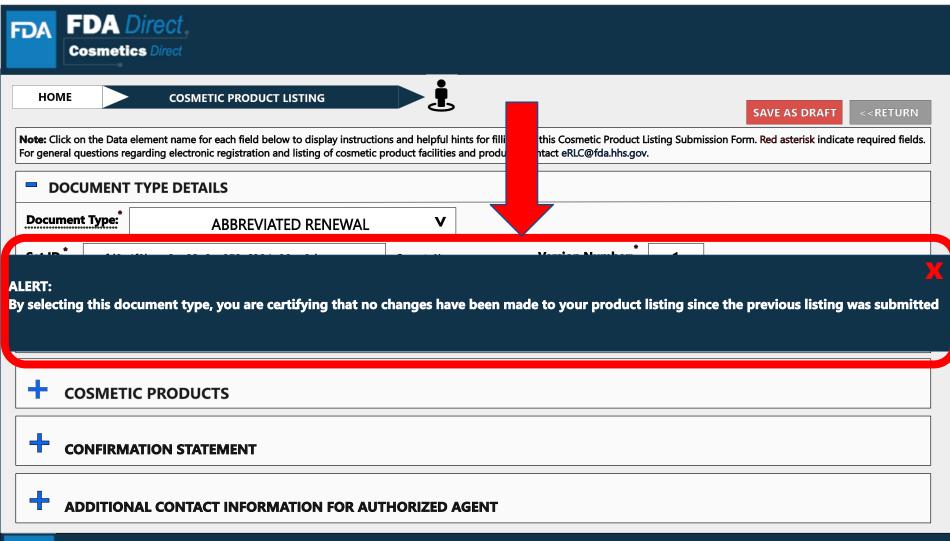
By selecting the drop-down (\mathbf{v}), four document types options will appear; initial, update to content (annual)-(changes to listing), update to content (annual)-(discontinuation of listing), and abbreviated renewal.





DOCUMENT TYPE DETAILS

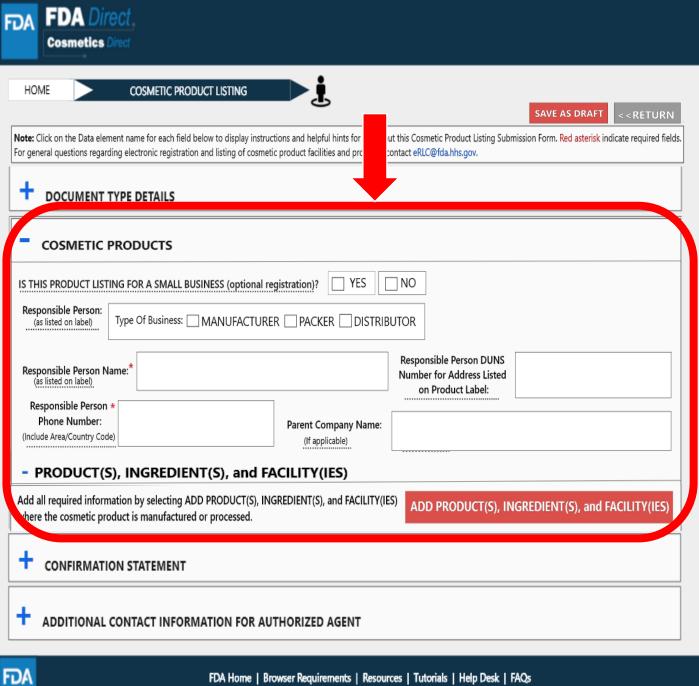
Depending on which document type is selected, an ALERT box will appear, "By selecting this document type, you are certifying that no changes have been made to your product listing since the previous listing was submitted"





COSMETIC **PRODUCTS**

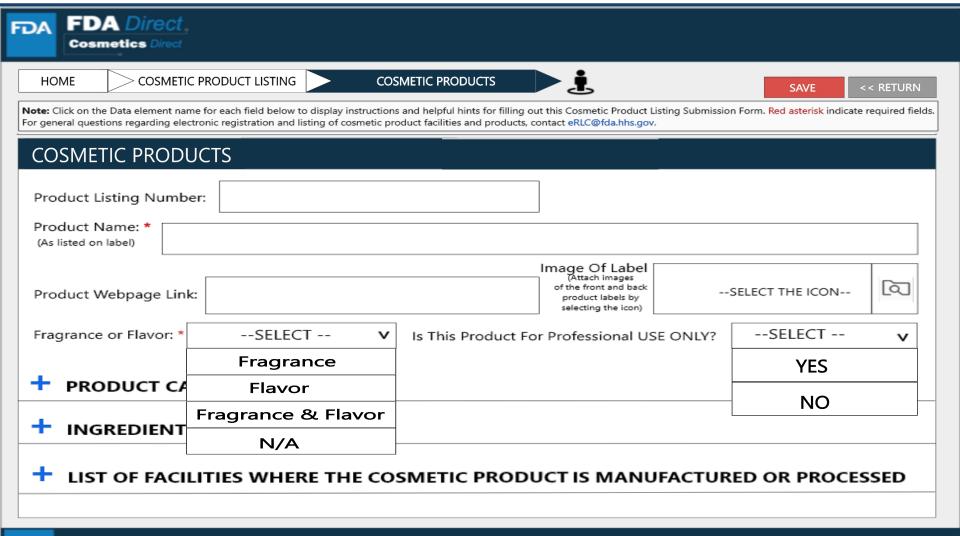
A *RED* asterisk indicates field is mandatory. A dashed underline indicates help text (tool-tips). To list all the PRODUCTS, **INGREDIENTS** and FACILITIES where the cosmetic product is manufactured or processed, SELECT ADD PRODUCT(S), INGREDIENT(S) and FACILITY(IES).



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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.







Fill in all the required fields. PRODUCT LISTING NUMBER is autogenerated for each <u>PRODUCT</u>.

| COSMETIC PROD | DUCTS | |
|---|---|---------------|
| Product Listing Number: | 1234-567-01000 | |
| Product Name: * (As listed on label) Cosm | etic Beauty Aloe Gel -Blue | |
| Product Webpage Link: | (Attach images of the front and back product labels by selecting the icon) | LECT THE ICON |
| Fragrance or Flavor: * | N/A v Is This Product For Professional USE ONLY? | NO v |
| PRODUCT CATEGOR Product Category Code(s): * | RY CODE(s) Select Code(s) v | |
| • (08) Makeup preparation makeup preparation • INGREDIENTS • LIST OF FACILITIES | + _ (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. | - (h) Other |

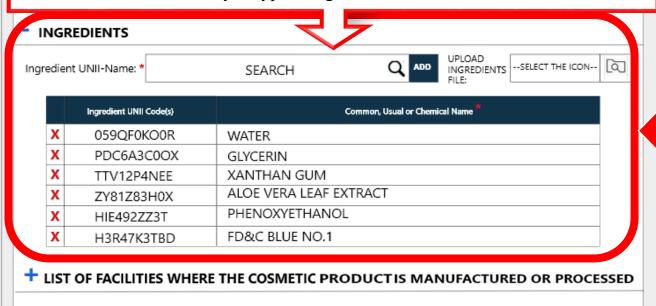
PRODUCT CATEGORY CODE(S)-EXAMPLE

Provide the Product Category
Code(s) by selecting the dropdown 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 (+).





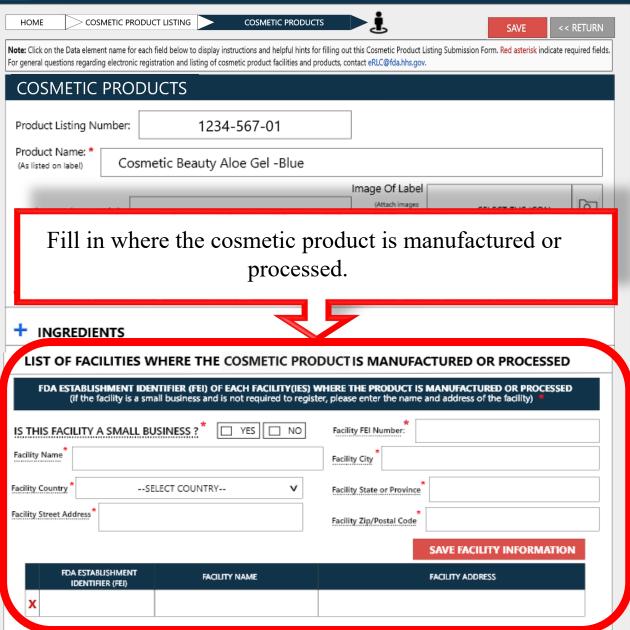
Fill in all the <u>INGREDIENTS</u> that are included in this product listing or upload a prefilled ingredients file. Common, usual or chemical name will auto-populate as you type along with its UNII.



LISTING INGREDIENTS (EXAMPLE)

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





LIST OF FACILITY(IES) (EXAMPLE)

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

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

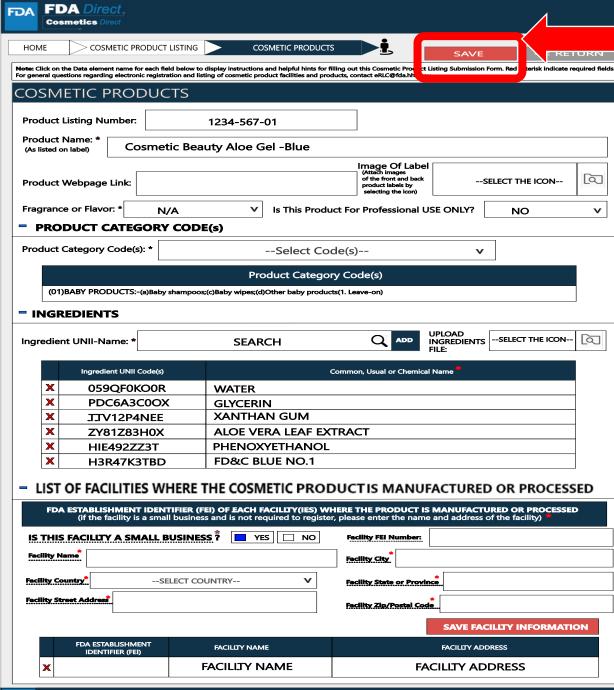
LIST OF FACILITY (EXAMPLE)

| FDA ESTABLISHMENT IDEN (if the facility is a sma | TIFIER (FEI) OF EACH FACILITY(IES) V Il business and is not required to regist | WHERE THE PRODUCT IS MANUFACTURED OR PROCESSED er, please enter the name and address of the facility) |
|---|---|---|
| IS THIS FACILITY A SMALL BUS | SINESS?* YES NO | Facility FEI Number: |
| Facility Name | | Facility City |
| Facility CountrySEL | ECT COUNTRY V | Facility State or Province |
| Facility Street Address | | Facility Zip/Postal Code |
| | | SAVE FACILITY INFORMATION |
| FDA ESTABLISHMENT IDEN (if the facility is a sma | all business and is not required to regist | WHERE THE PRODUCT IS MANUFACTURED OR PROCESSED er, please enter the name and address of the facility) Facility FEI Number: |
| • | | |
| Facility Name | | Facility City * |
| | LECT COUNTRY V | Facility City * Facility State or Province * |
| | ECT COUNTRY V | * |
| Facility Country *SEL | LECT COUNTRY V | Facility State or Province |
| Facility Country *SEL | LECT COUNTRY V | Facility State or Province Facility Zip/Postal Code |

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

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

Once SAVED, the information will appear in this table

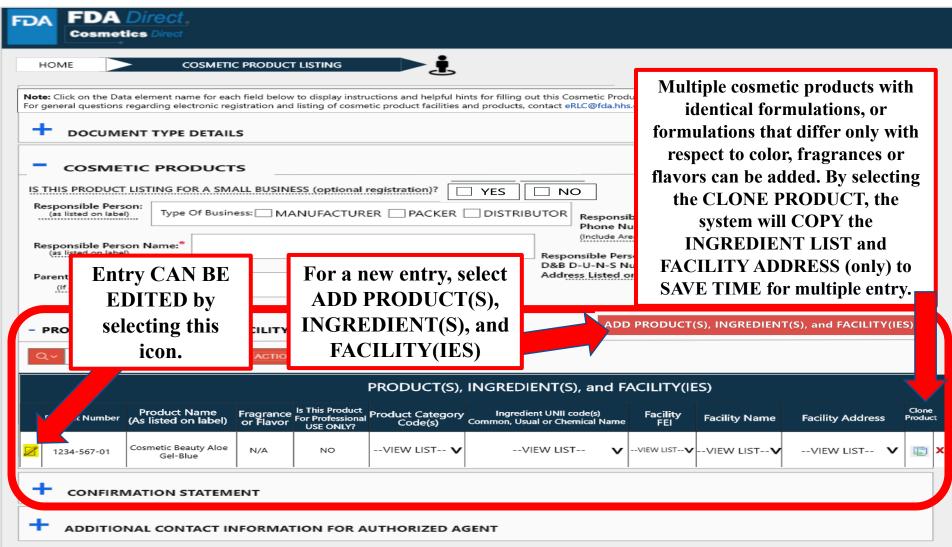


After verifying the entered information is correct, select SAVE

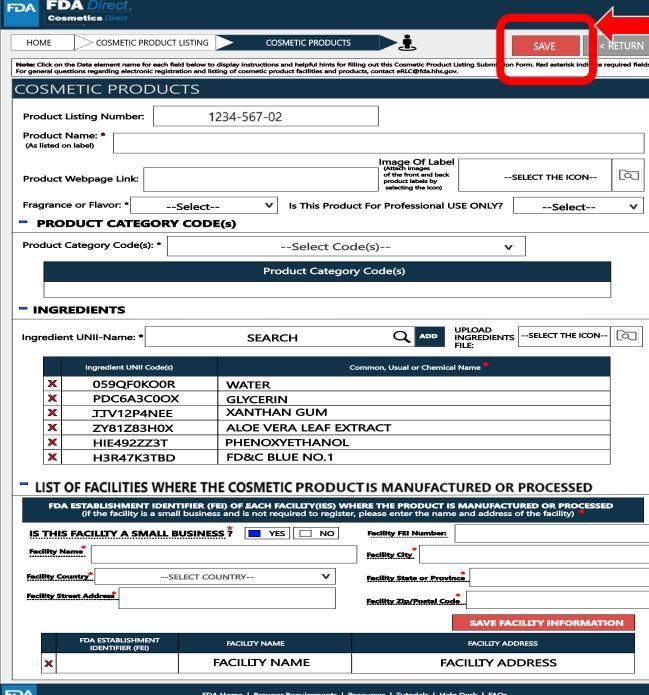
EXAMPLE OF A COMPLETE LISTING (PRODUCTS, INGREDIENTS AND FACILITIES TAB)

PRODUCTS, INGREDIENTS AND FACILITIES

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







After verifying the entered information is correct, select SAVE

EXAMPLE OF A PREFILLED CLONE

Any prefilled information can be edited.

CONFIRMATION STATEMENT

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

Signature of Submitter

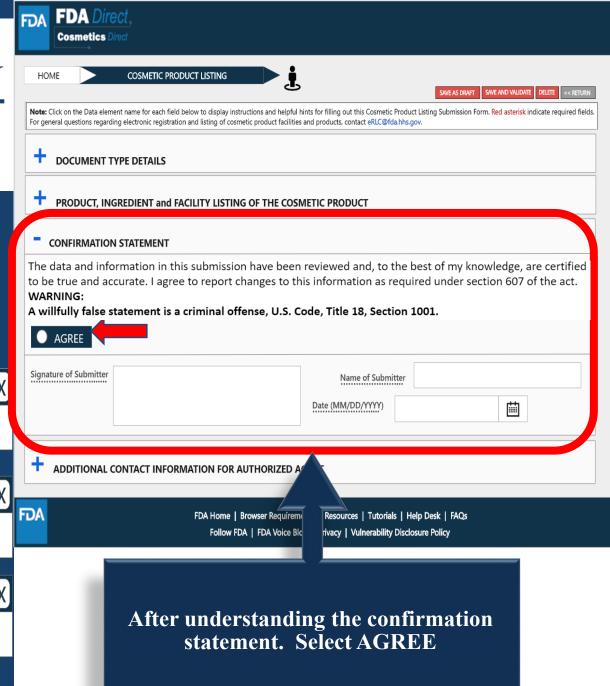
(optional field) Click on the blank signature box to display signature pad

Name of Submitter

(optional field) Enter the full name of the submitter

Date

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



CONFIRMATION STATEMENT SIGNATURE

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

Signature of Submitter

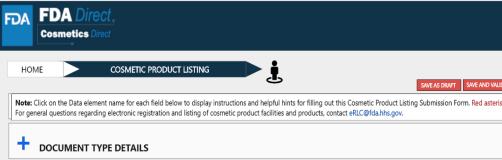
(optional field) Click on the blank signature box to display signature pad

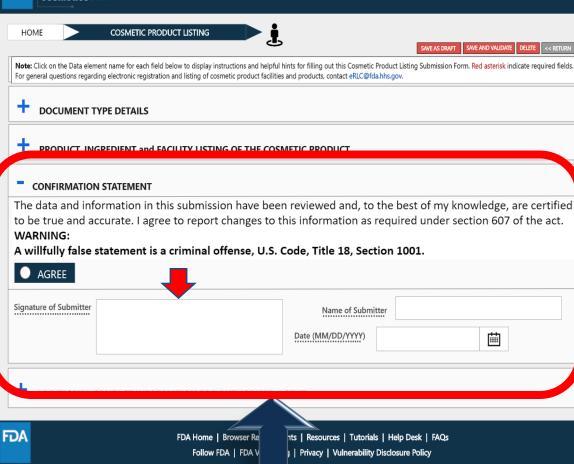
Name of Submitter

(optional field) Enter the full name of the submitter

Date

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





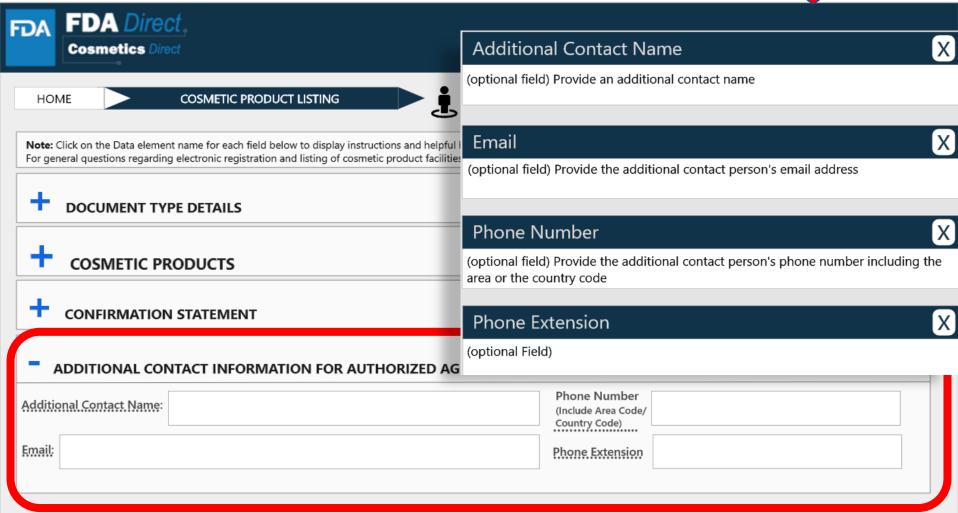
By clicking on the signature of submitter box the USER will be able to provide a

signature

ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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



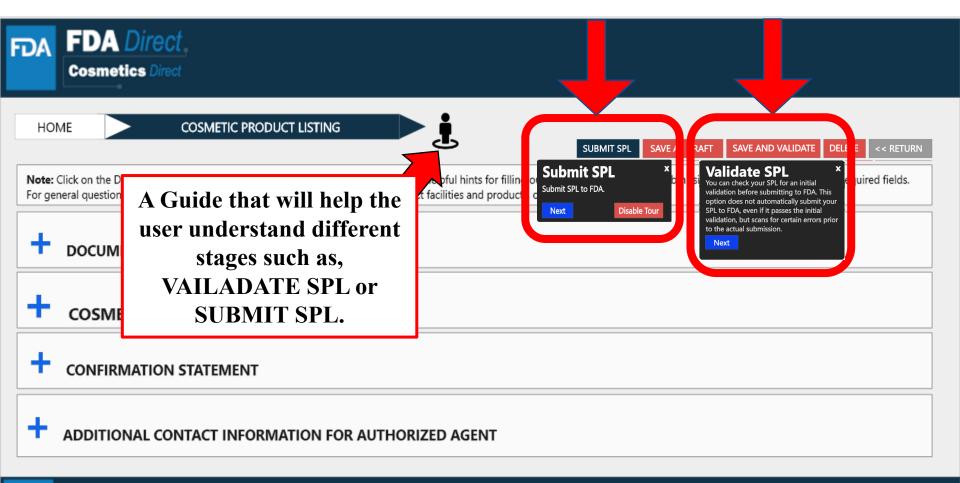




COMPLETED

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

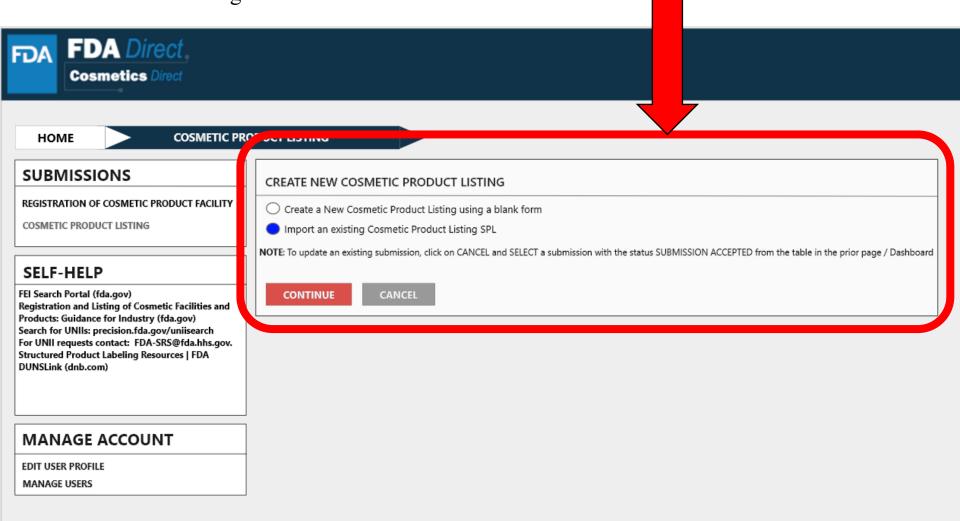
Select submit SPL for the form to be submitted to FDA.





UPLOAD A FILE

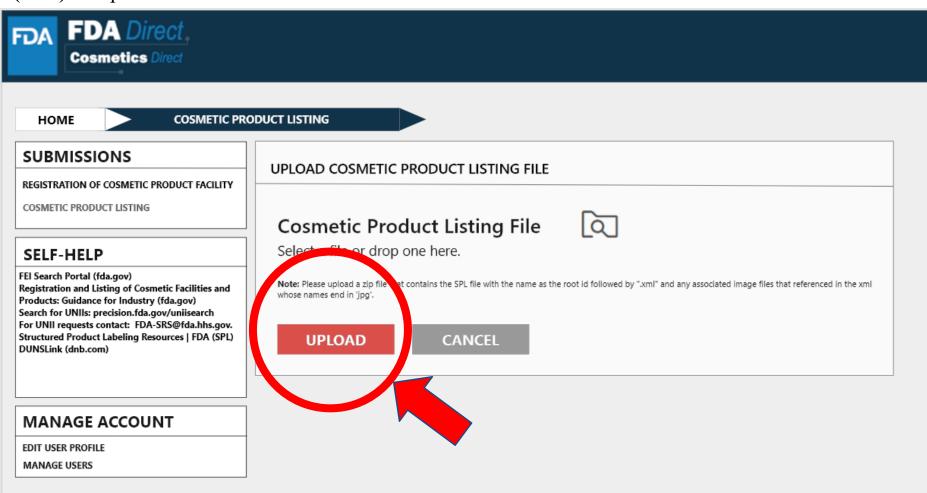
In order to upload a file, select Import an existing Cosmetic Product Listing SPL. Importing an existing Cosmetic Product Listing SPL will be beneficial for bulk submission.





UPLOAD A FILE

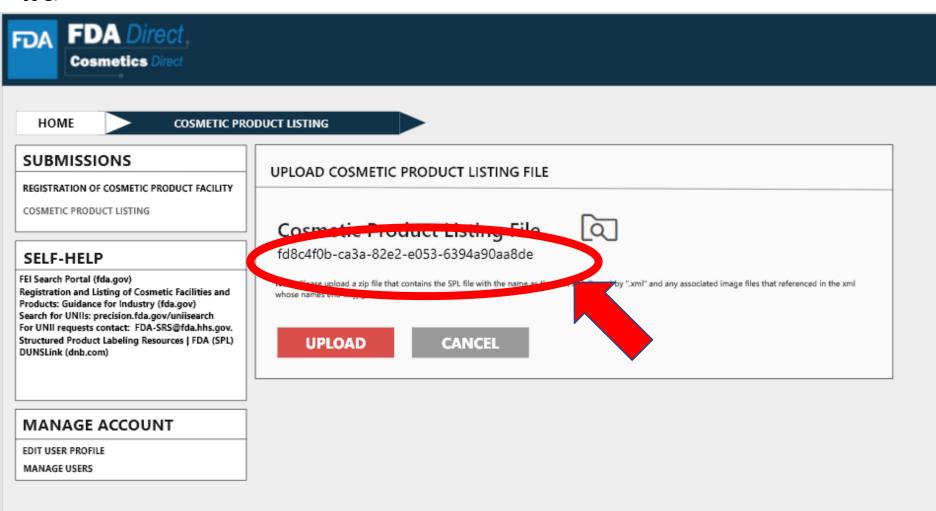
User will be able to upload a pre-existing ZIP FILE, this file may contain both the xml file and image (jpg) files. For more information regarding SPL, utilize the **Structured Product Labeling Resources** | **FDA** (SPL) link provided under **SELF-HELP**





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.





ZIP FILE (EXAMPLE)

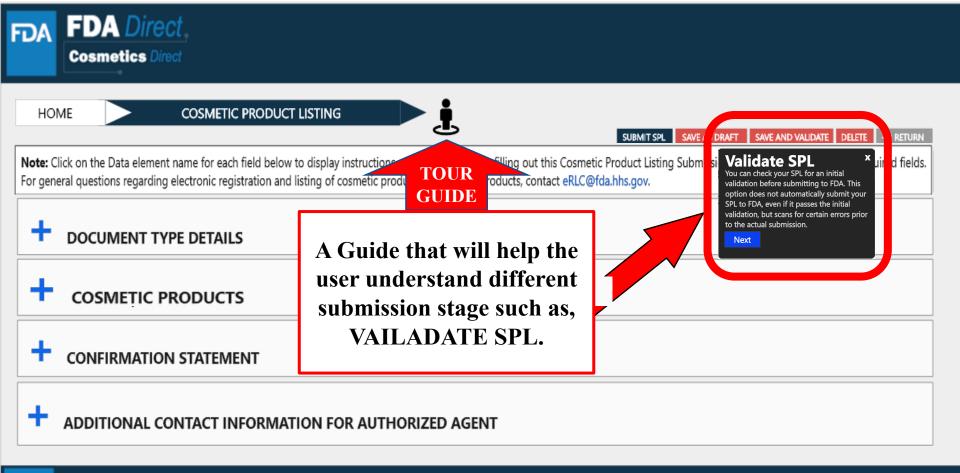
An example to what an XML format could look like

```
<?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"</p>
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 <u>UPLOADING A FILE</u> (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.

<u>VALIDATE SPL</u>: "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."

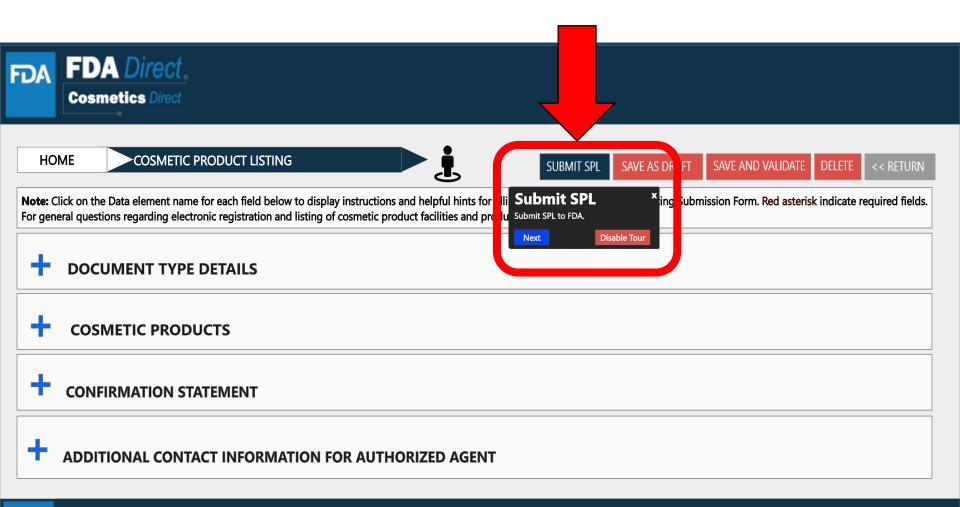




UPLOAD A FILE (EXAMPLE)

Select submit SPL for the form to be submitted to FDA.

The Submit SPL box is a help tool that can guide a user through the process.

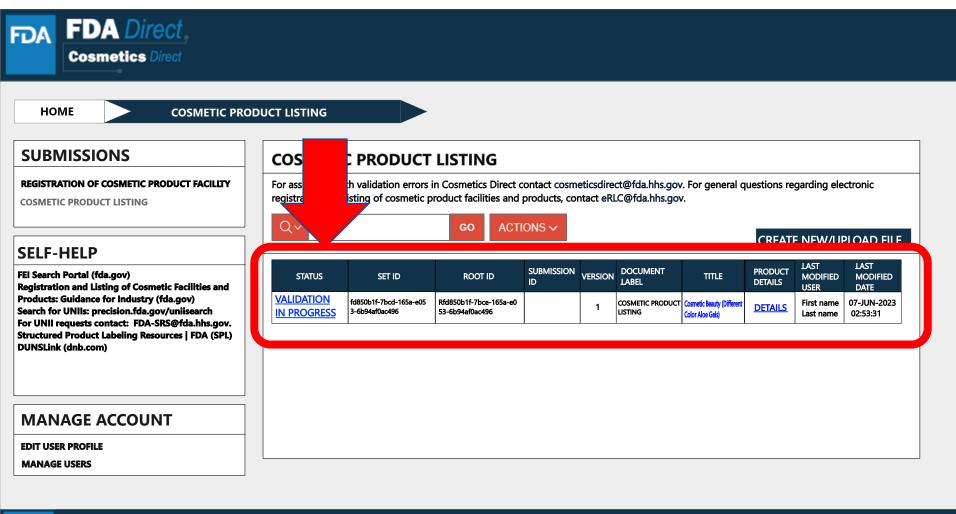




PRODUCT LISTING STATUS EXAMPLES

LISTING STATUS: VALIDATION IN PROGRESS

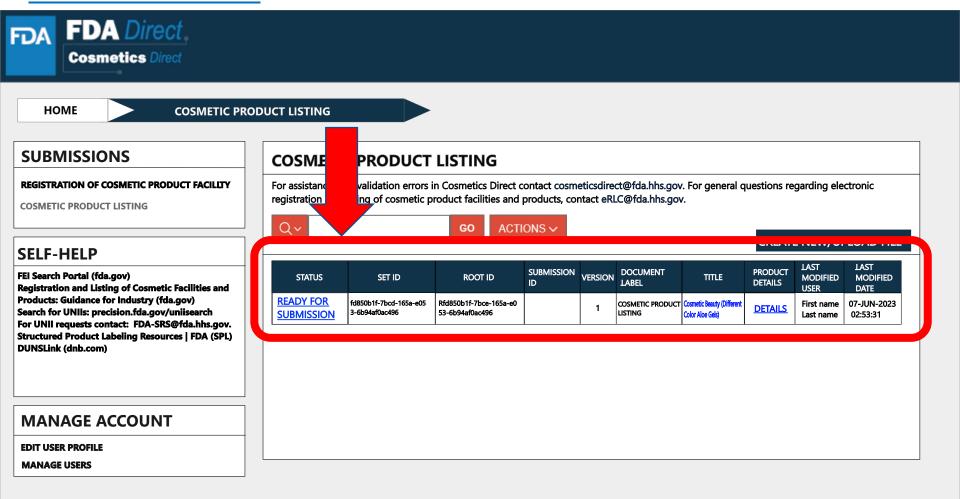
After SAVE AND VALIDATE, the cosmetic product Listing home page will have the following details as shown below. The status will be in <u>VALIDATION IN PROGRESS</u>.





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**.

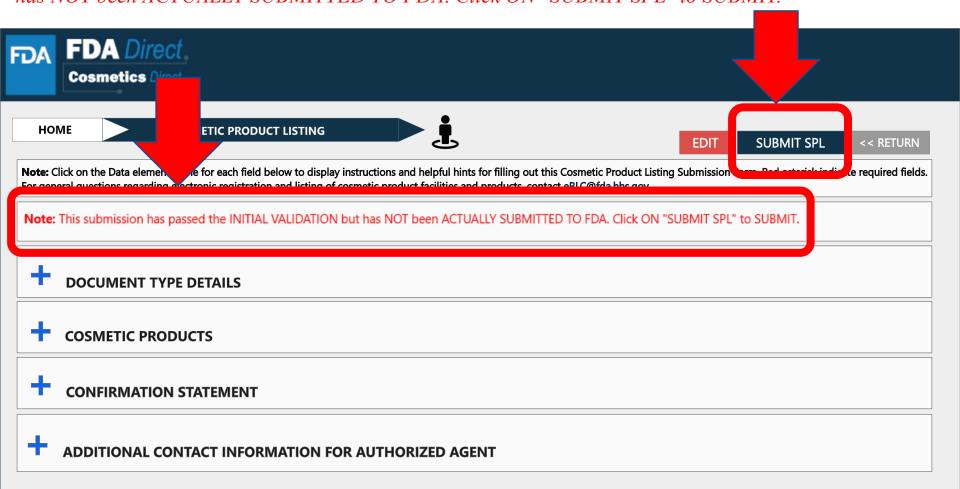




LISTING STATUS: READY FOR SUBMISSION TO SUBMIT SPL

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

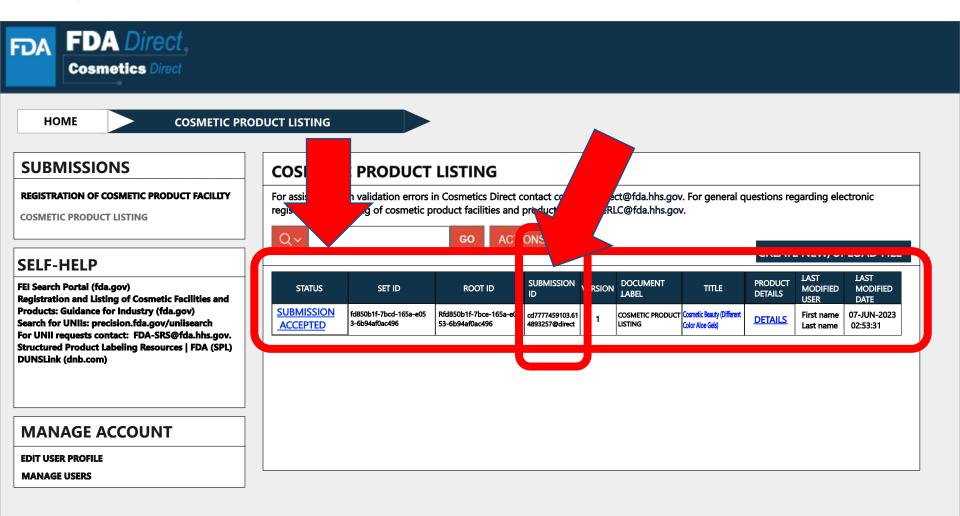
The system will generate a message stating that, *This submission has passed the INITIAL VALIDATION but has NOT been ACTUALLY SUBMITTED TO FDA. Click ON "SUBMIT SPL" to SUBMIT.*





LISTING STATUS: SUBMIT SPL TO SUBMISSION ACCEPTED

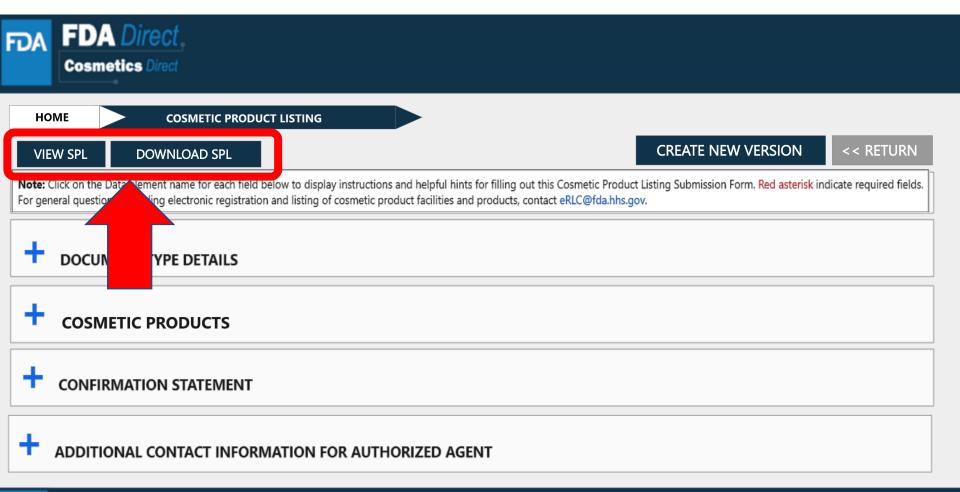
The status will change to **SUBMISSION ACCEPTED** after listing had been successfully completed. A **SUBMISSION ID** will be given to all **ACCEPTED SUBMISSIONS**.





LISTING STATUS: SUBMISSION ACCEPTED to VIEW SPL and DOWNLOAD SPL

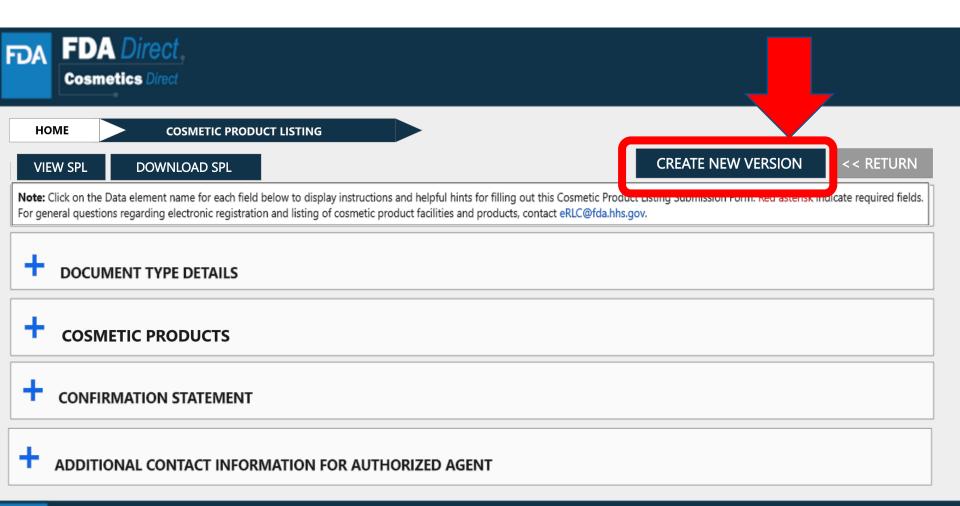
By clicking on the **SUBMISSION ACCEPTED** the system will allow user to **VIEW SPL** and **DOWNLOAD SPL**.





CREATE A NEW VERSION

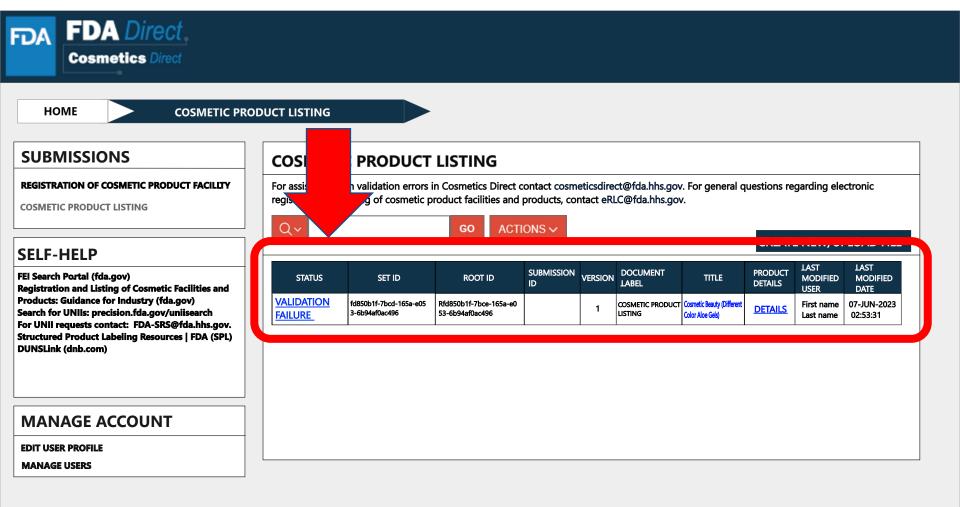
By clicking on the **CREATE A NEW VERSION**, you can clone a successfully-submitted SPL as a starting point.





LISTING STATUS: VALIDATION FAILURE

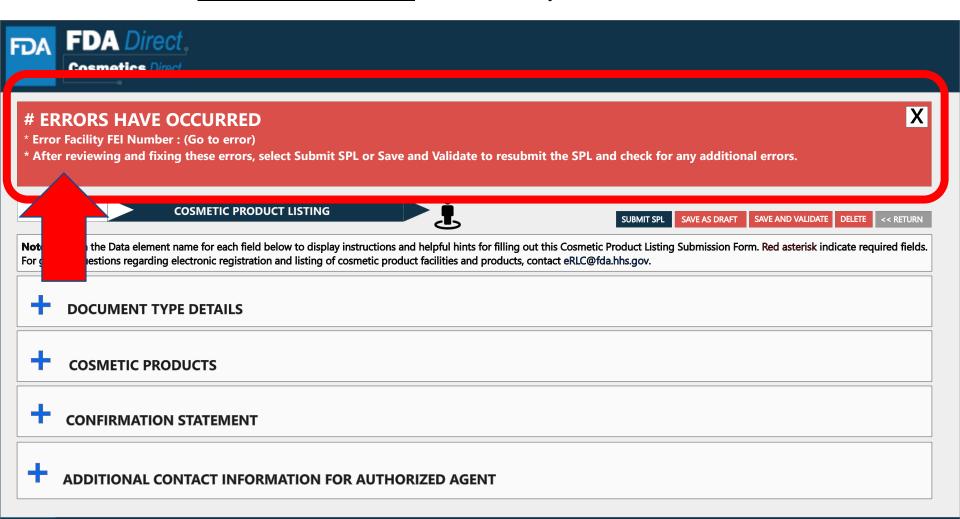
After SAVE AND VALIDATE, the cosmetic product listing home page will have the following details as shown below. The status will be in <u>VALIDATION IN PROGRESS</u>. However, if the system finds any errors the status will change to <u>VALIDATION FAILURE</u>.





LISTING STATUS: VALIDATION FAILURE

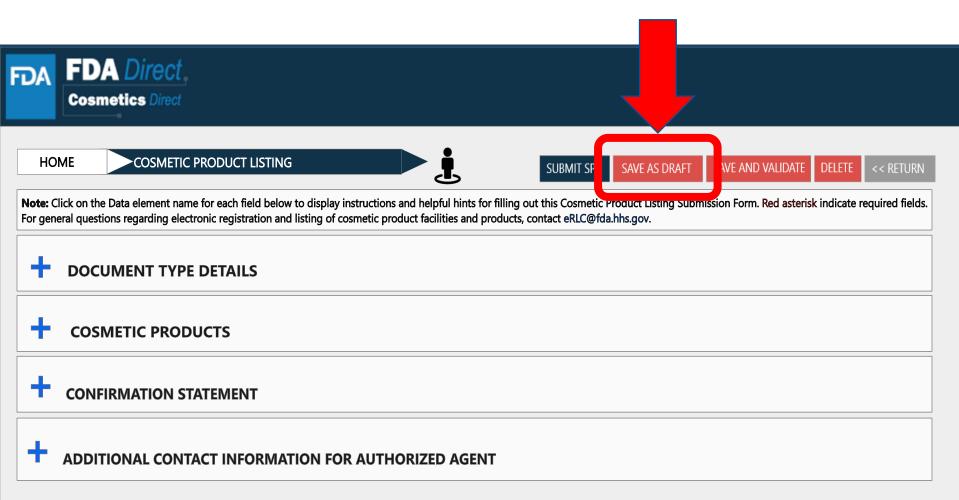
After selecting the <u>VALIDATION FAILURE</u> status, the system will provide a list of errors, that need to be fixed before submitting the SPL. After reviewing and fixing the errors, users can select <u>SUBMIT SPL</u> to resubmit the SPL or <u>SAVE AND VALIDATE</u> to check for any additional errors.





LISTING STATUS: DRAFT

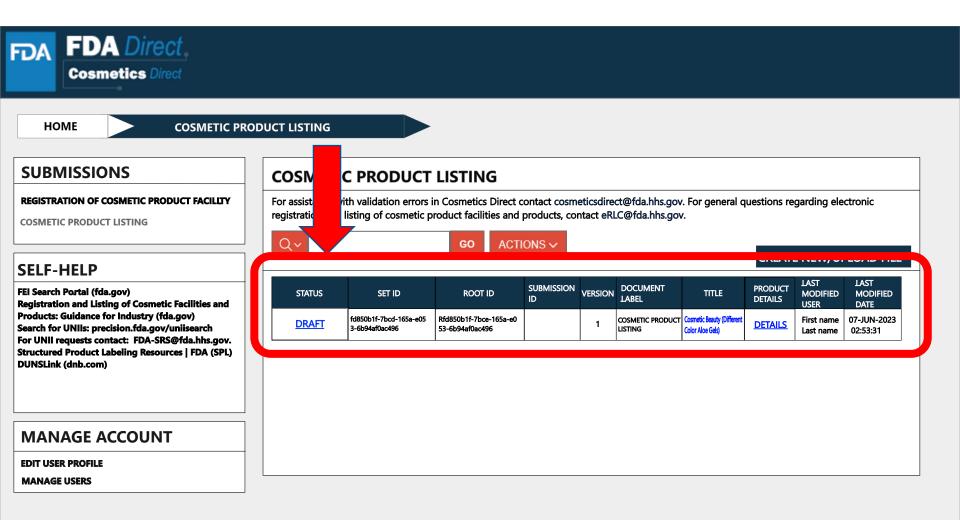
By selecting <u>SAVE AS DRAFT</u>, from any screen during the process of cosmetic product listing, the system will save all information and will bring the user back to the home page. The status will be in <u>DRAFT</u>.





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**.



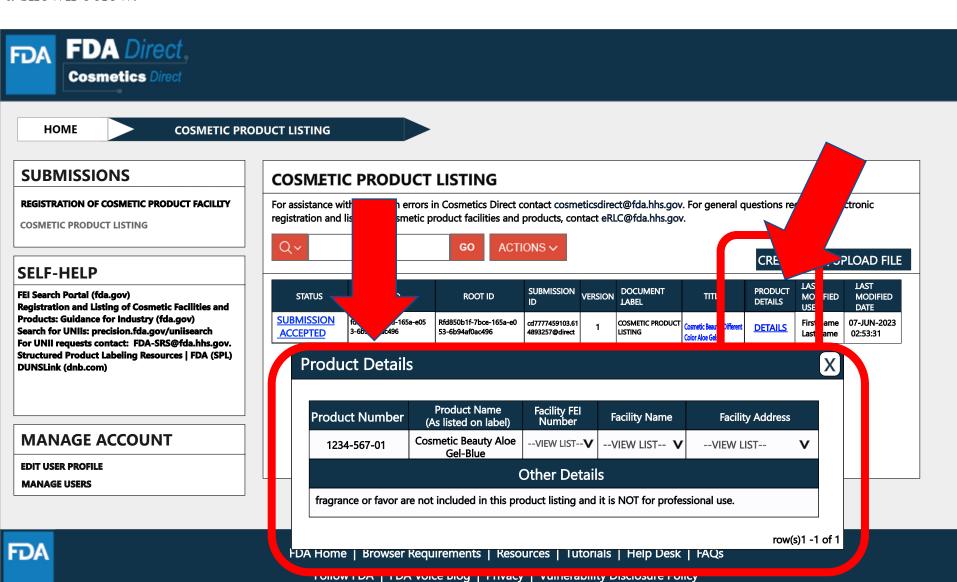


COSMETICS DIRECT HOME PAGE

| Details | 83 |
|----------------|----|
| All submission | 84 |

DETAILS

By clicking on the **<u>DETAILS</u>**, the system will pop-up **<u>PRODUCT LISTING DETAILS</u>** box with information a shown below.



COSMETICS DIRECT HOME PAGE ALL SUBMISSION



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

MANAGE ACCOUNT

EDIT USER PROFILE

MANAGE USERS

