U.S. FOOD & DRUG ADMINISTRATION

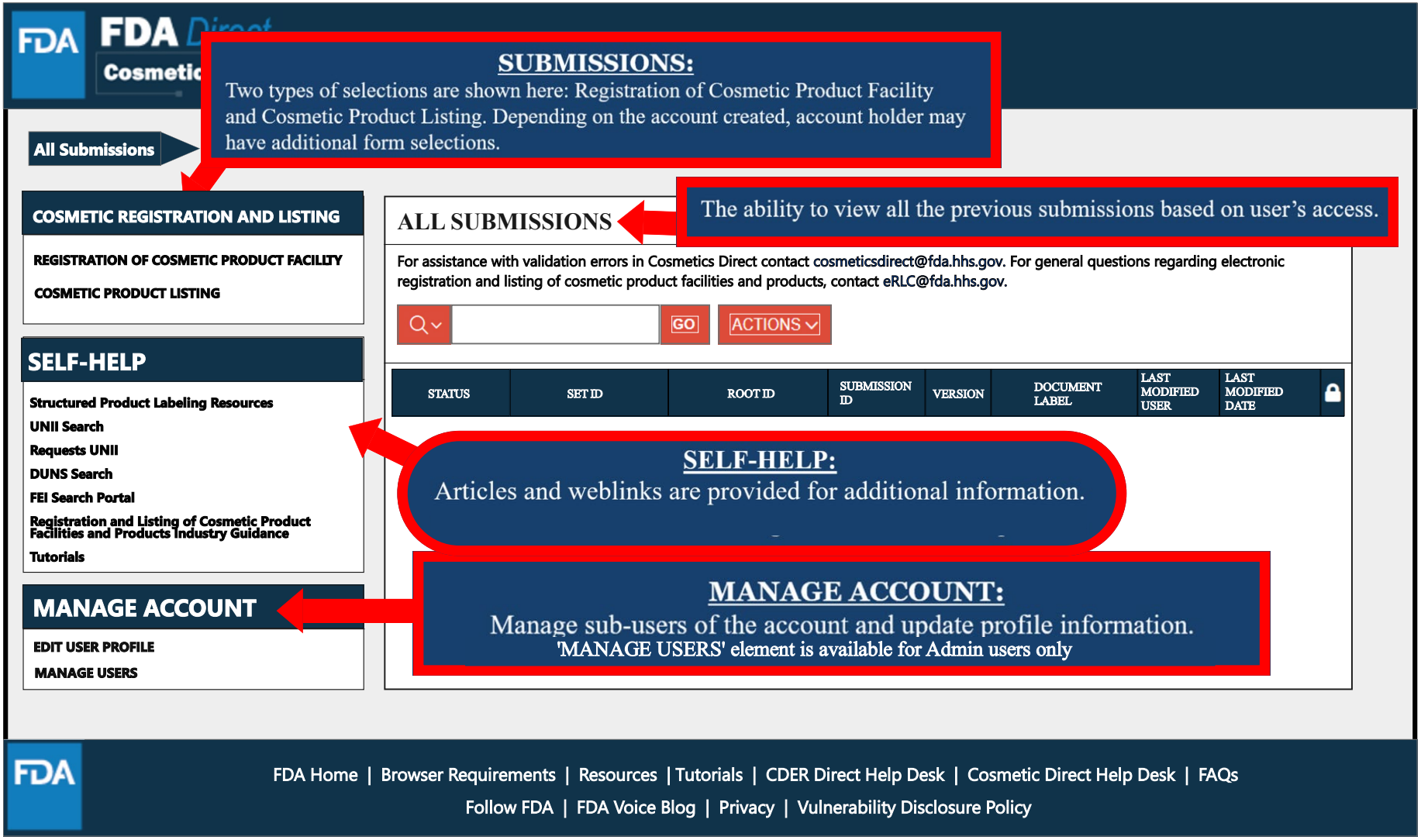
COSMETICS *DIRECT*

FACILITY REGISTRATION
Tutorial

APRIL 2024

Cosmetics Direct Home Page

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



Registration of Cosmetic Product Facility

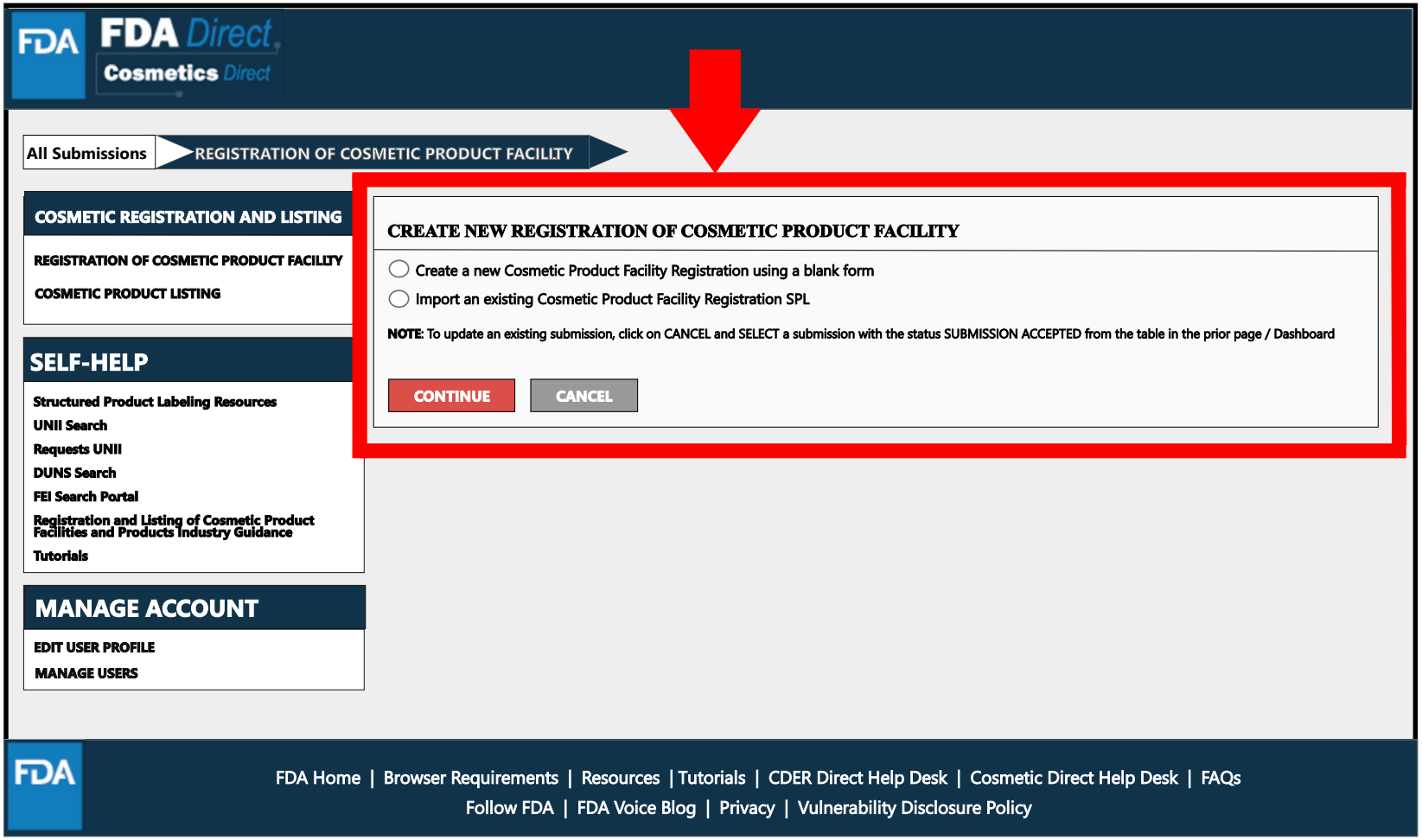
Registration of Cosmetic Product Facility Home Page

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

Create a New Registration or Upload an Existing File

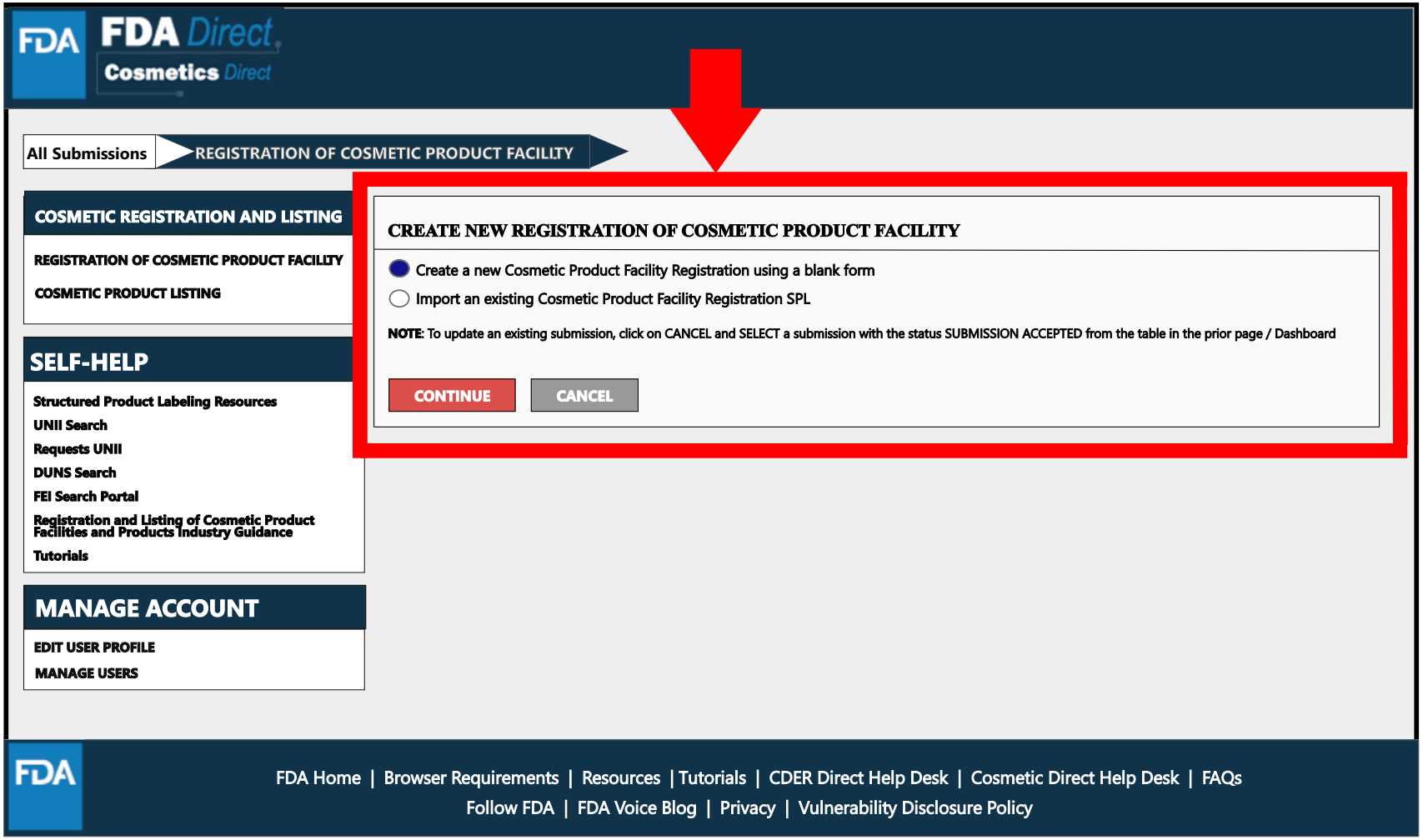
Create a New Registration for Cosmetic Product Facility or Upload an Existing File

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



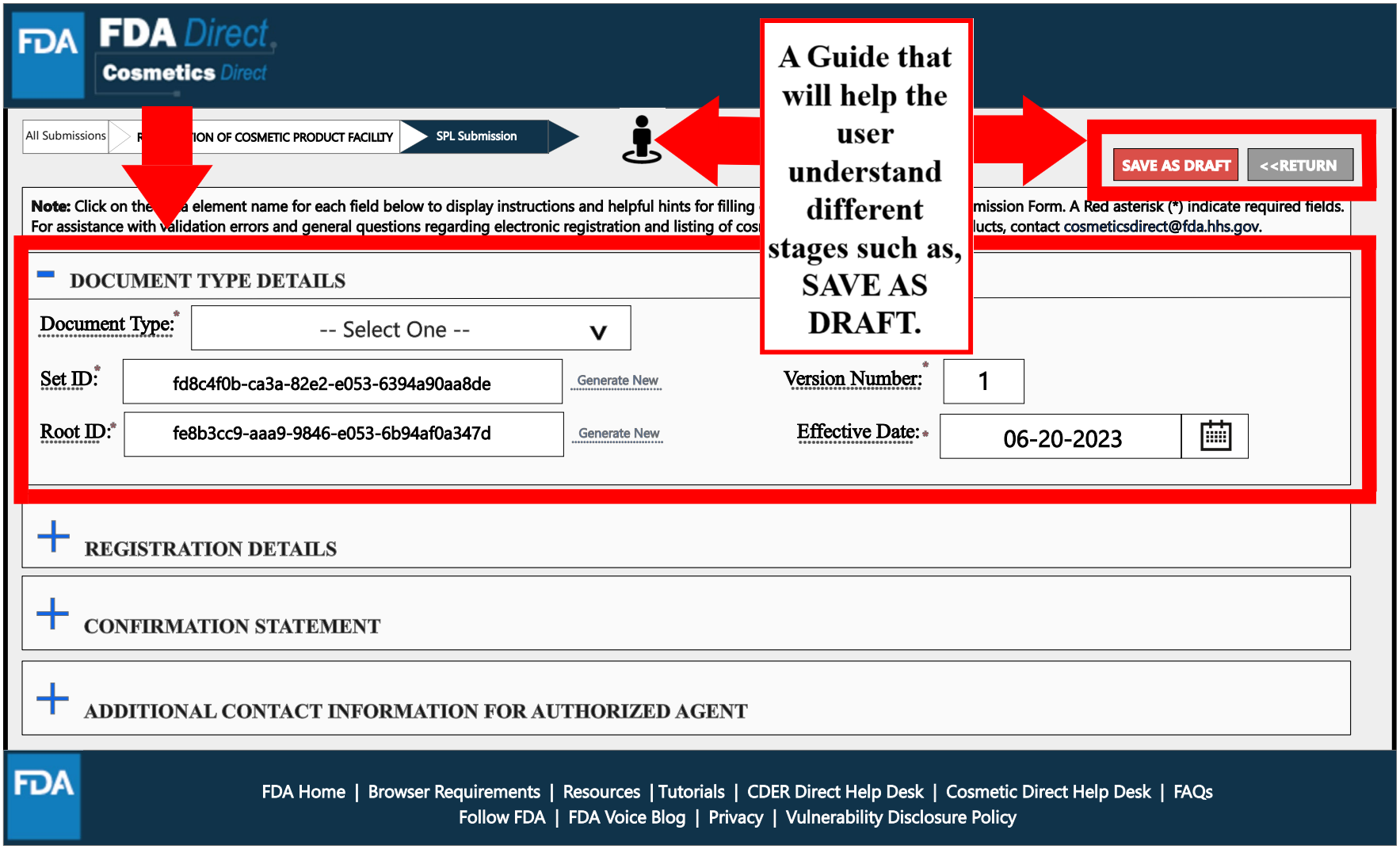
Create a New Product Facility Registration

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

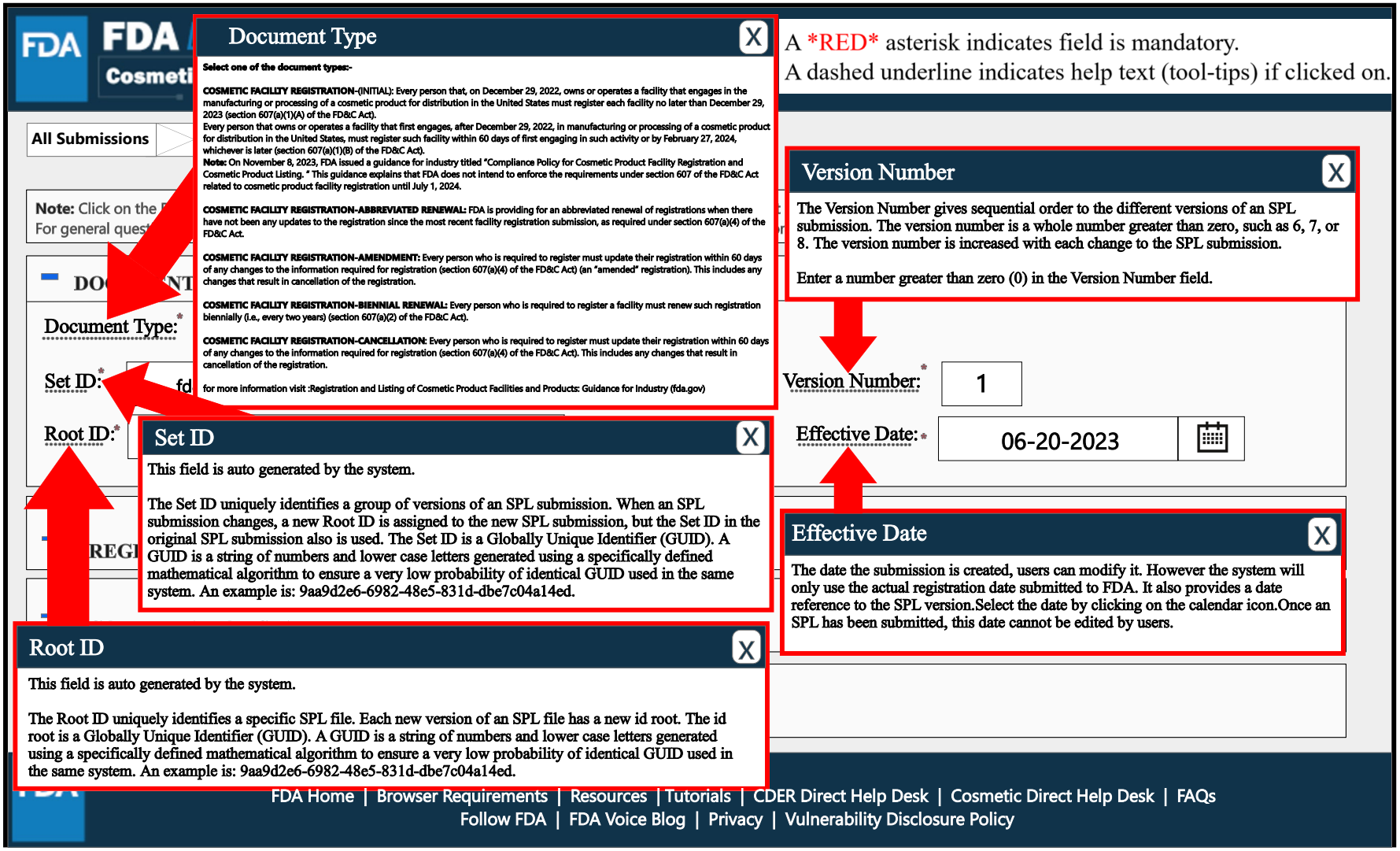


Document Type Details Section

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

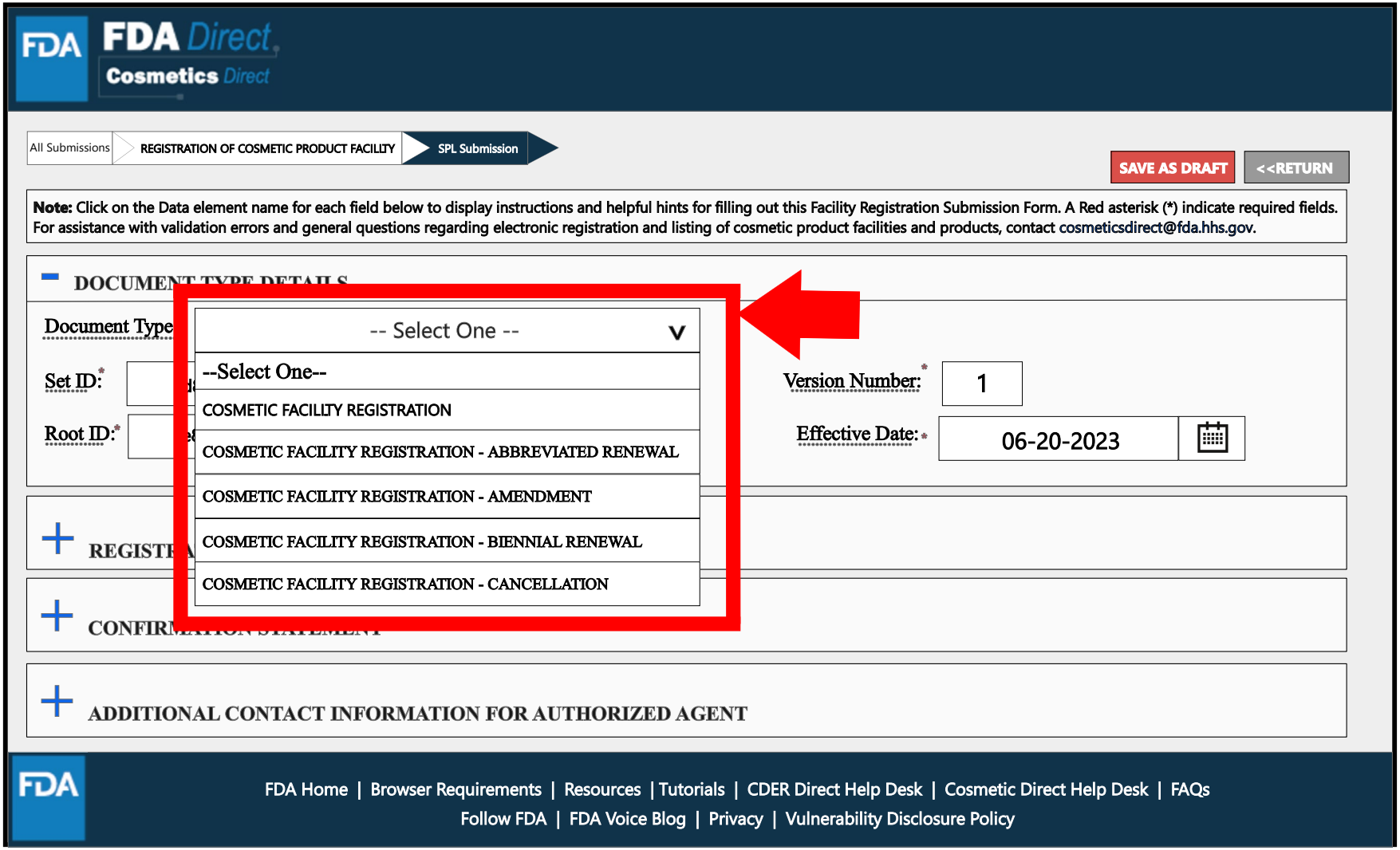


Document Type Tool Tips



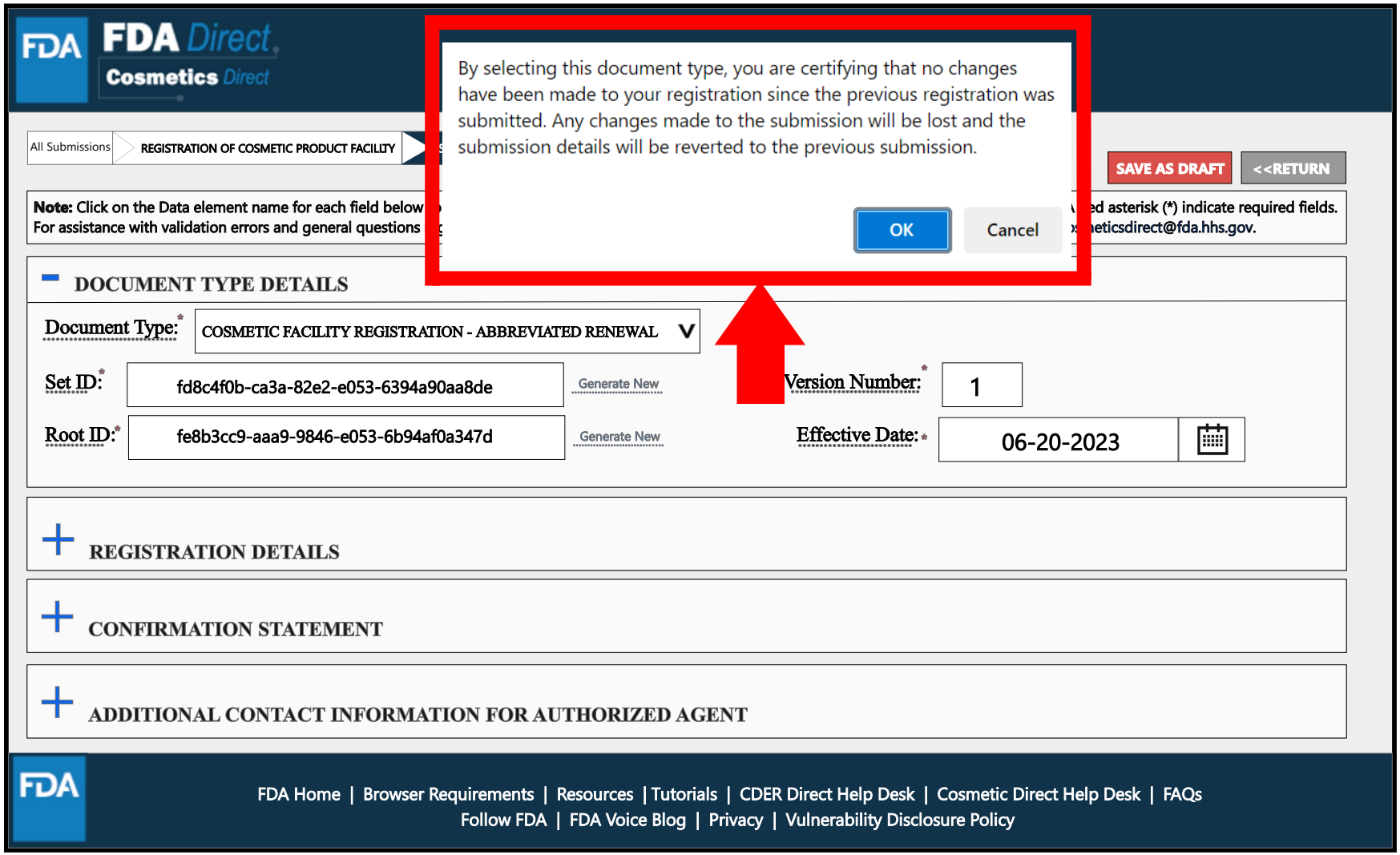
Document Type Details

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



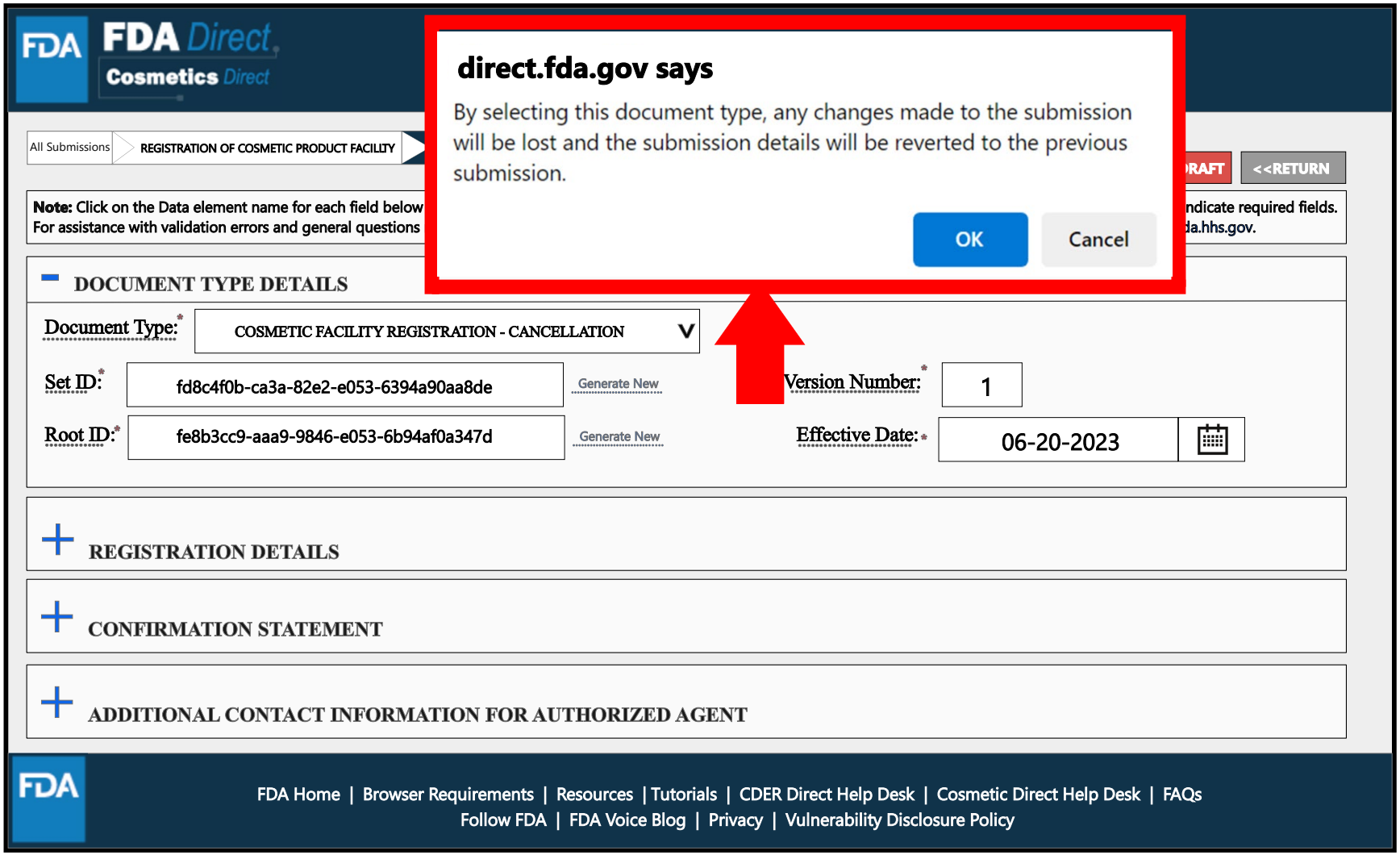
Document Type Details - Abbreviated renewal

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



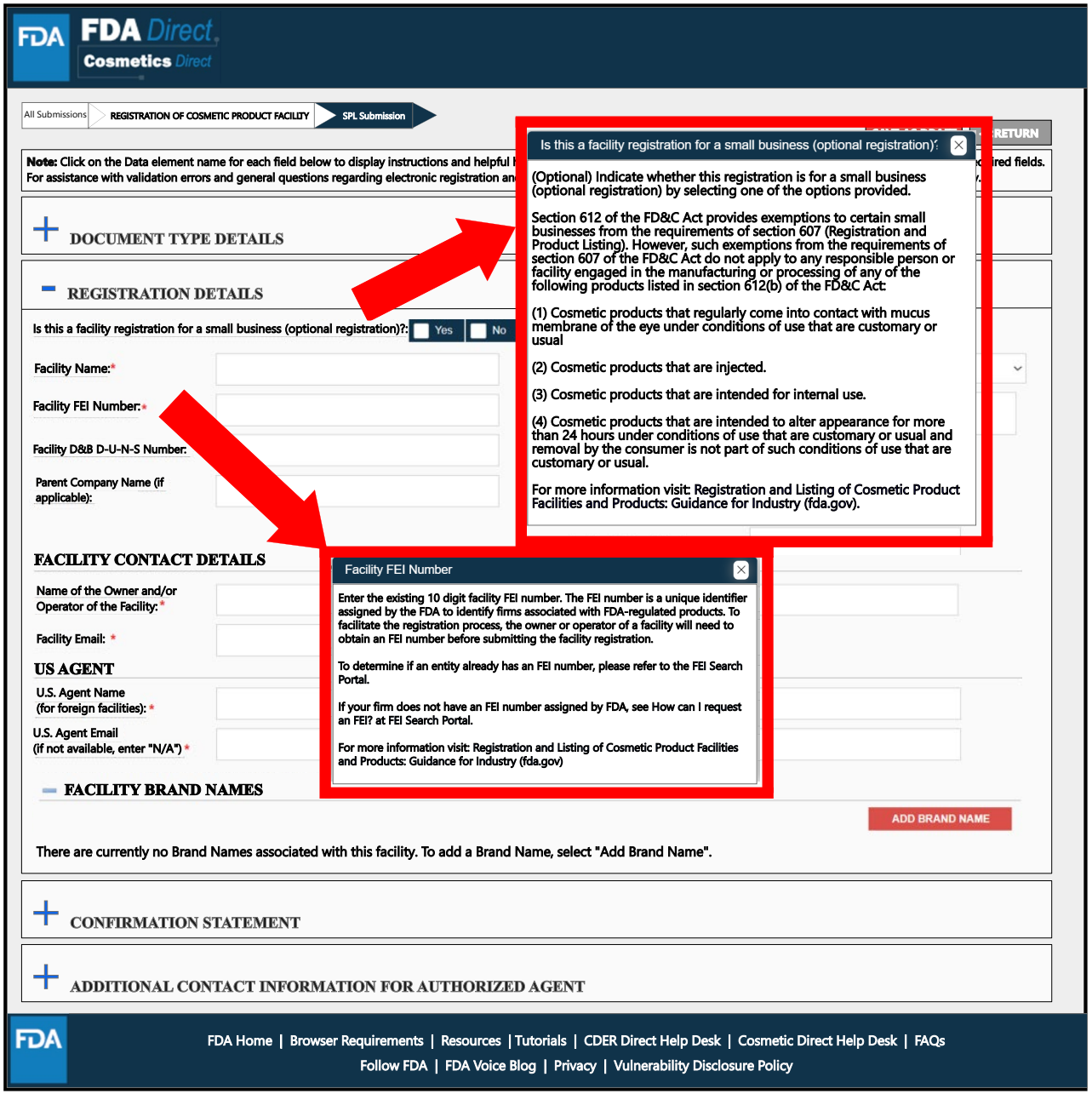
Document Type Details - Cancellation

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



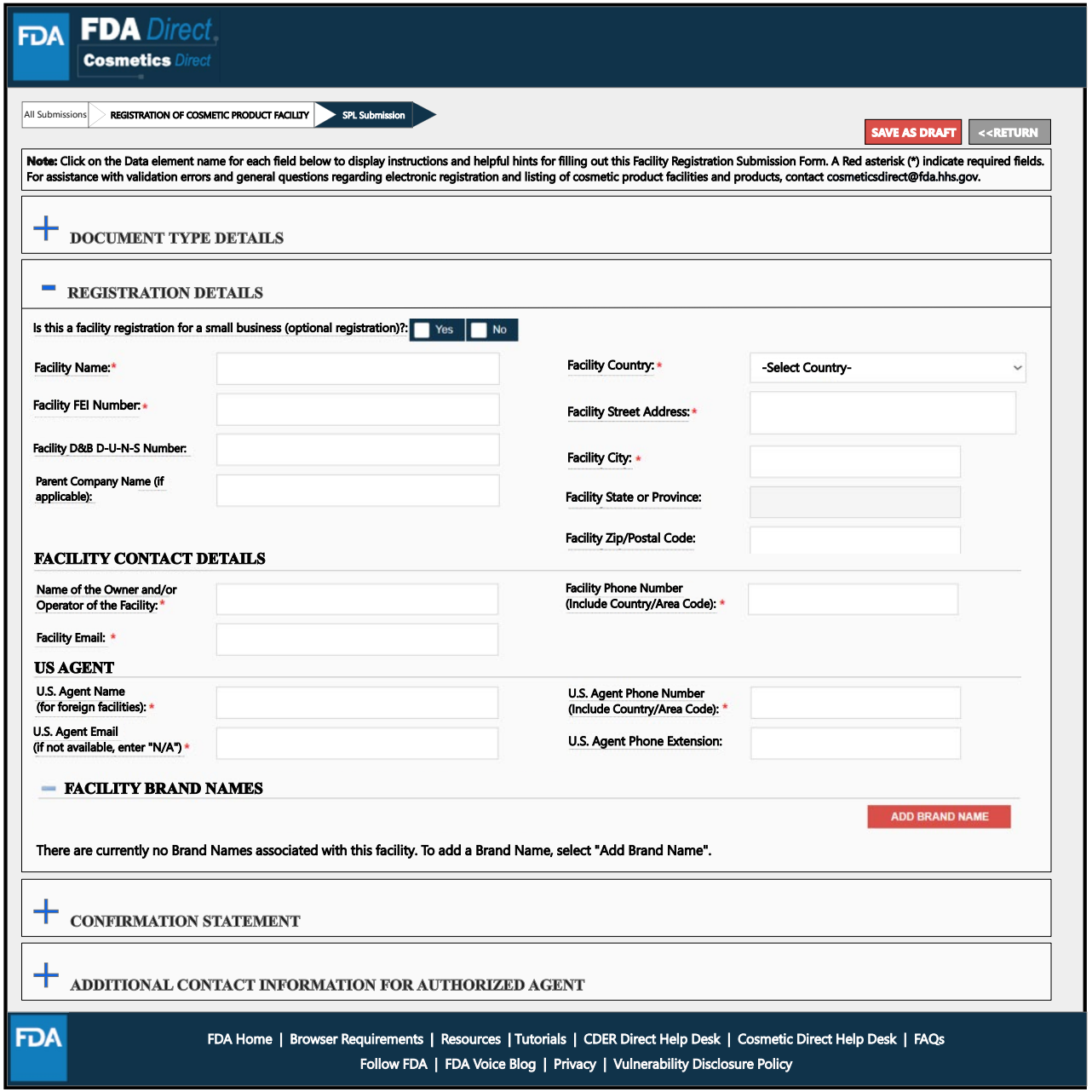
Registration Details Tool-Tips

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



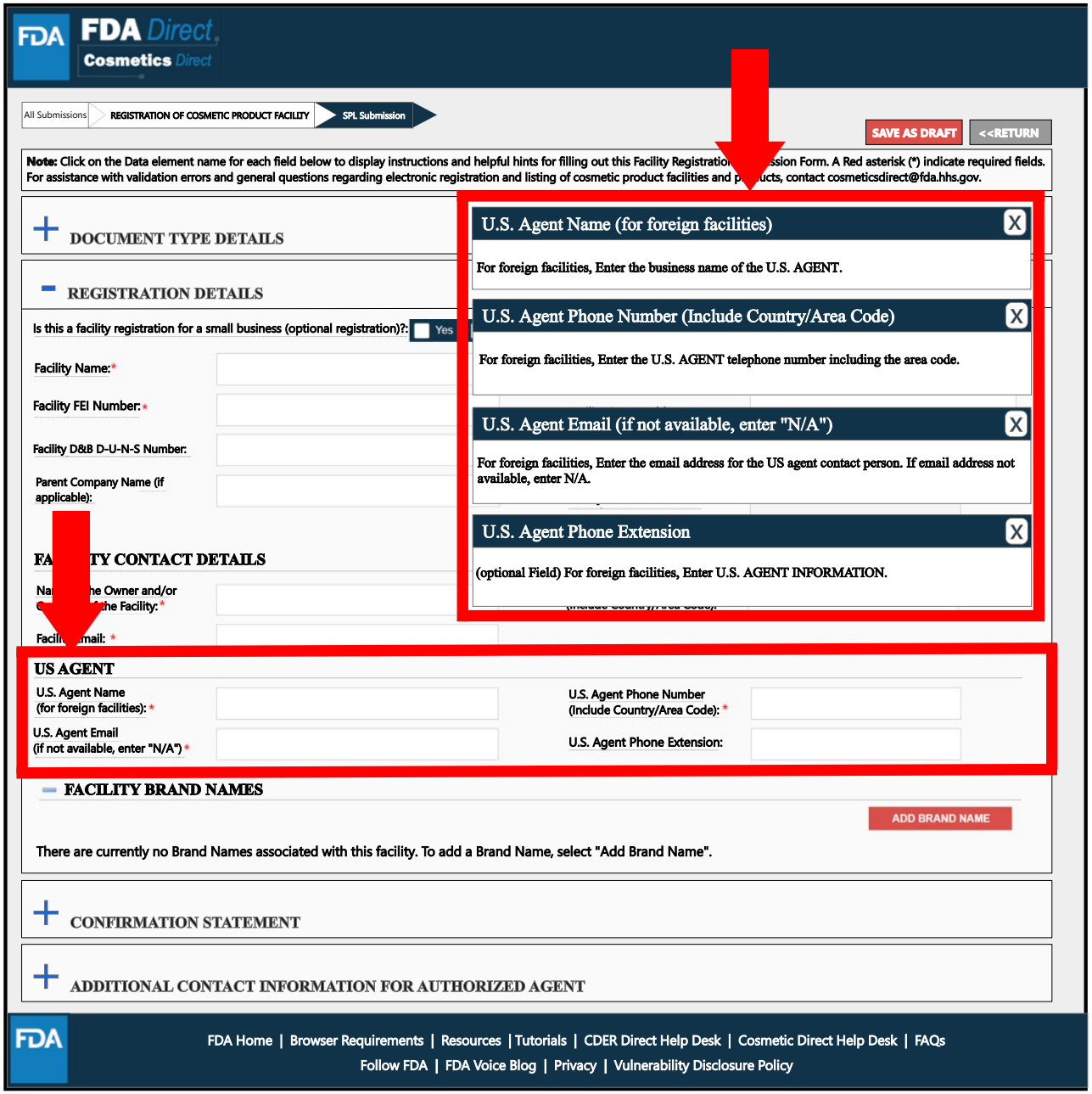
Registration Details

A *RED* asterisk indicates field is mandatory.



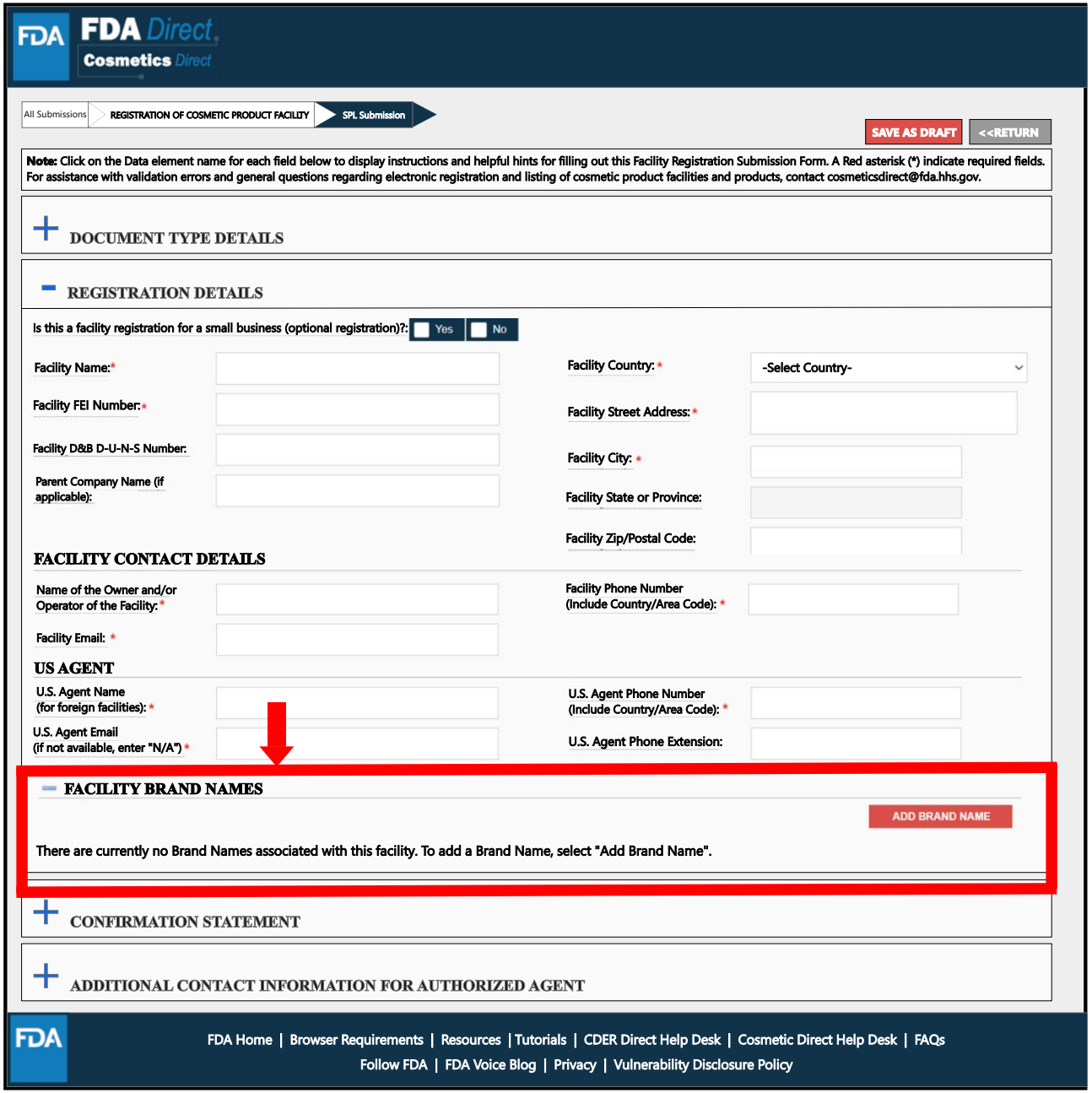
Registration Details - US Agent

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



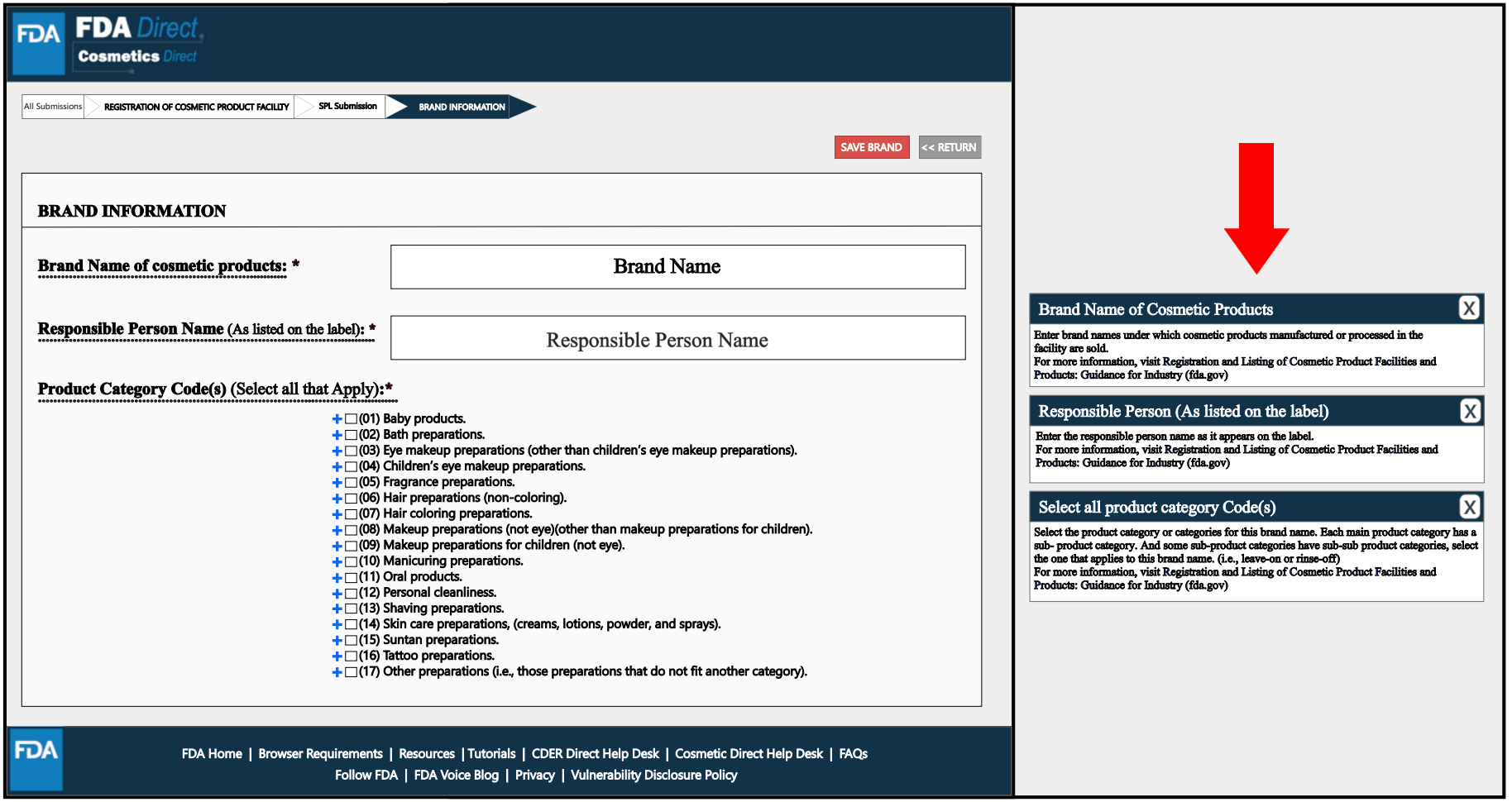
Brand Name

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

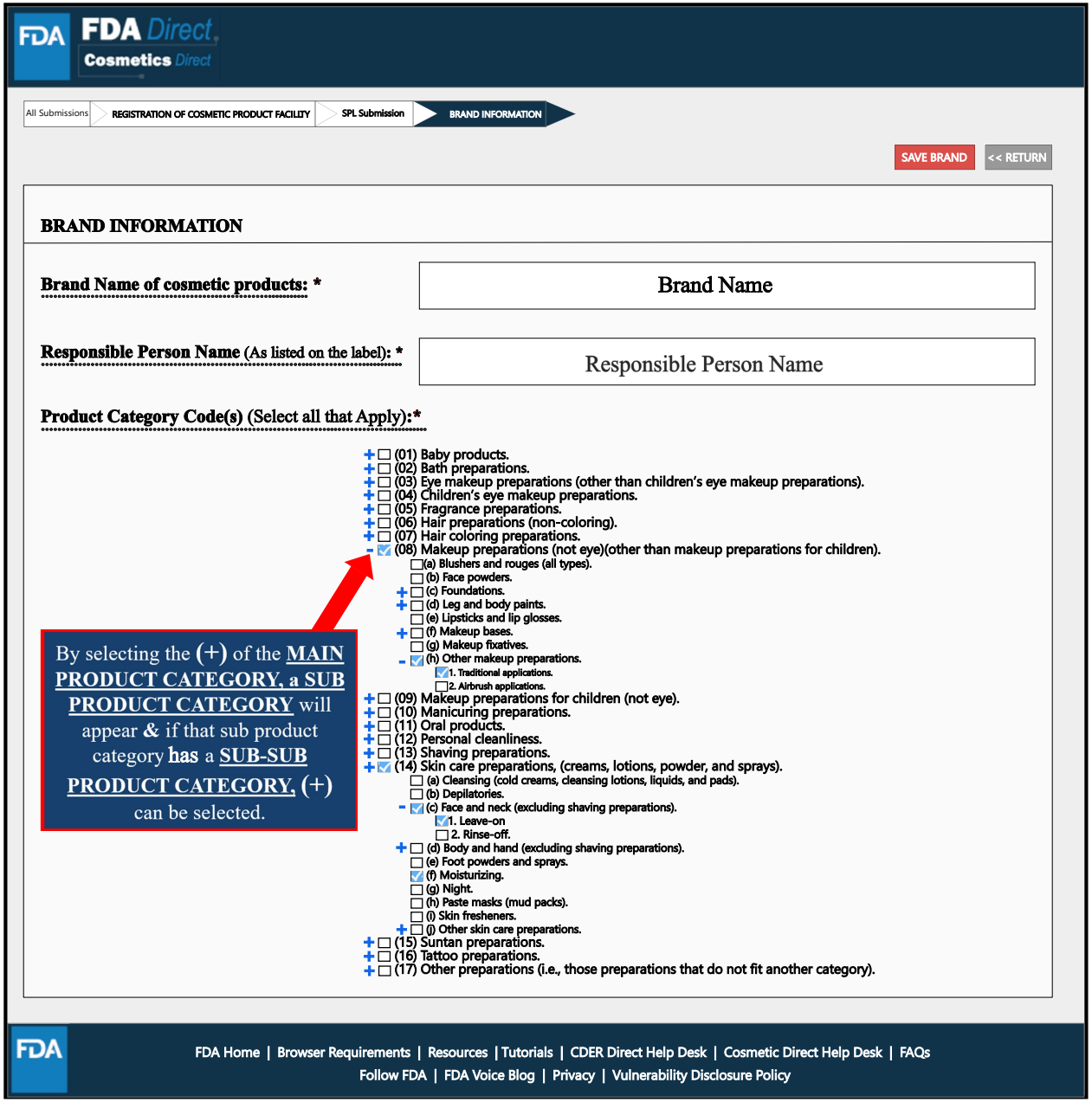


Brand Names of Cosmetic Product(s) Manufactured or Processed in this Facility

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

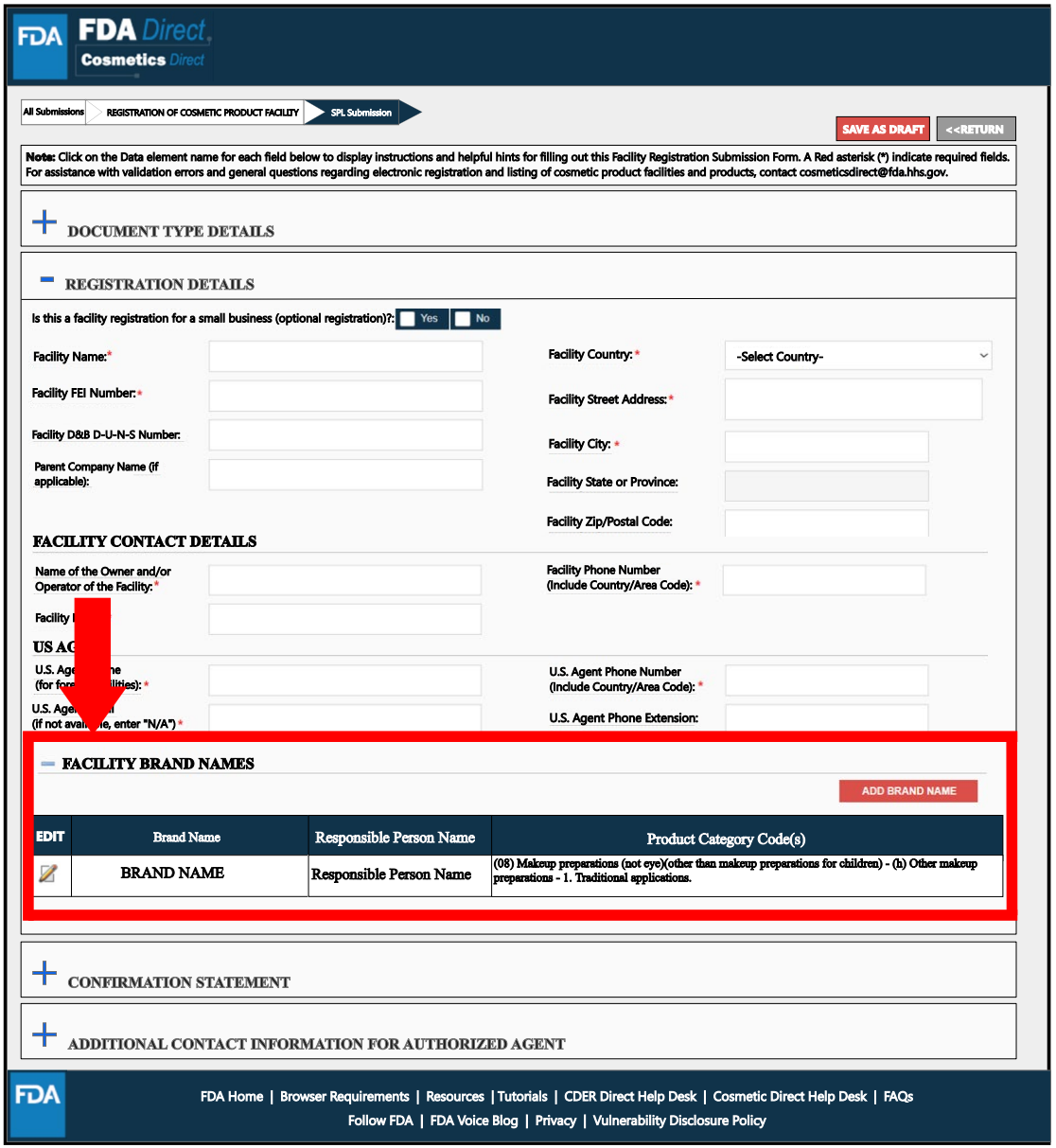


Brand Name of Cosmetic Product(s) Manufactured or Processed in this Facility (Example)



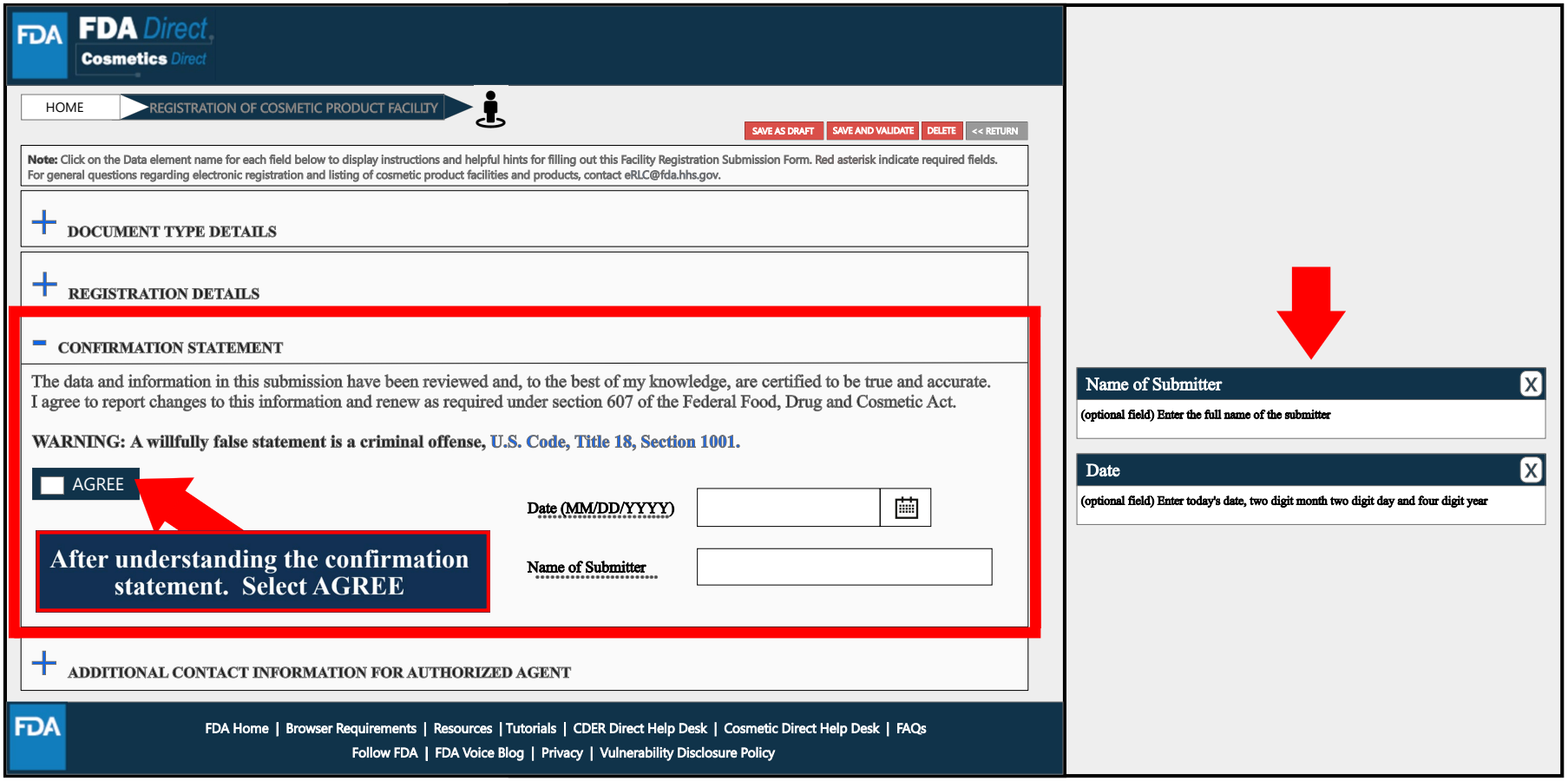
Brand Name of Cosmetic Product Manufactured or Processed in this Facility (Example)

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



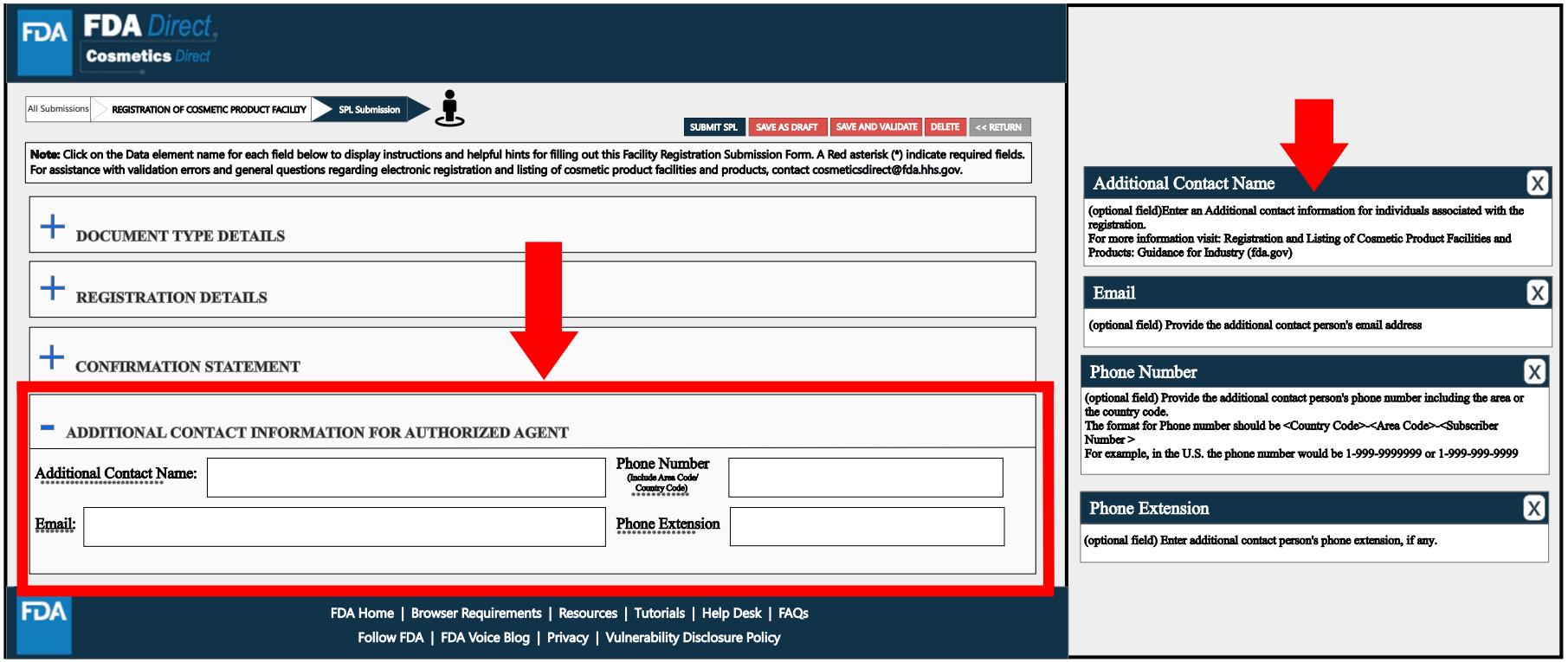
Confirmation Statement

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



Additional Contact Information for Authorized Agent

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

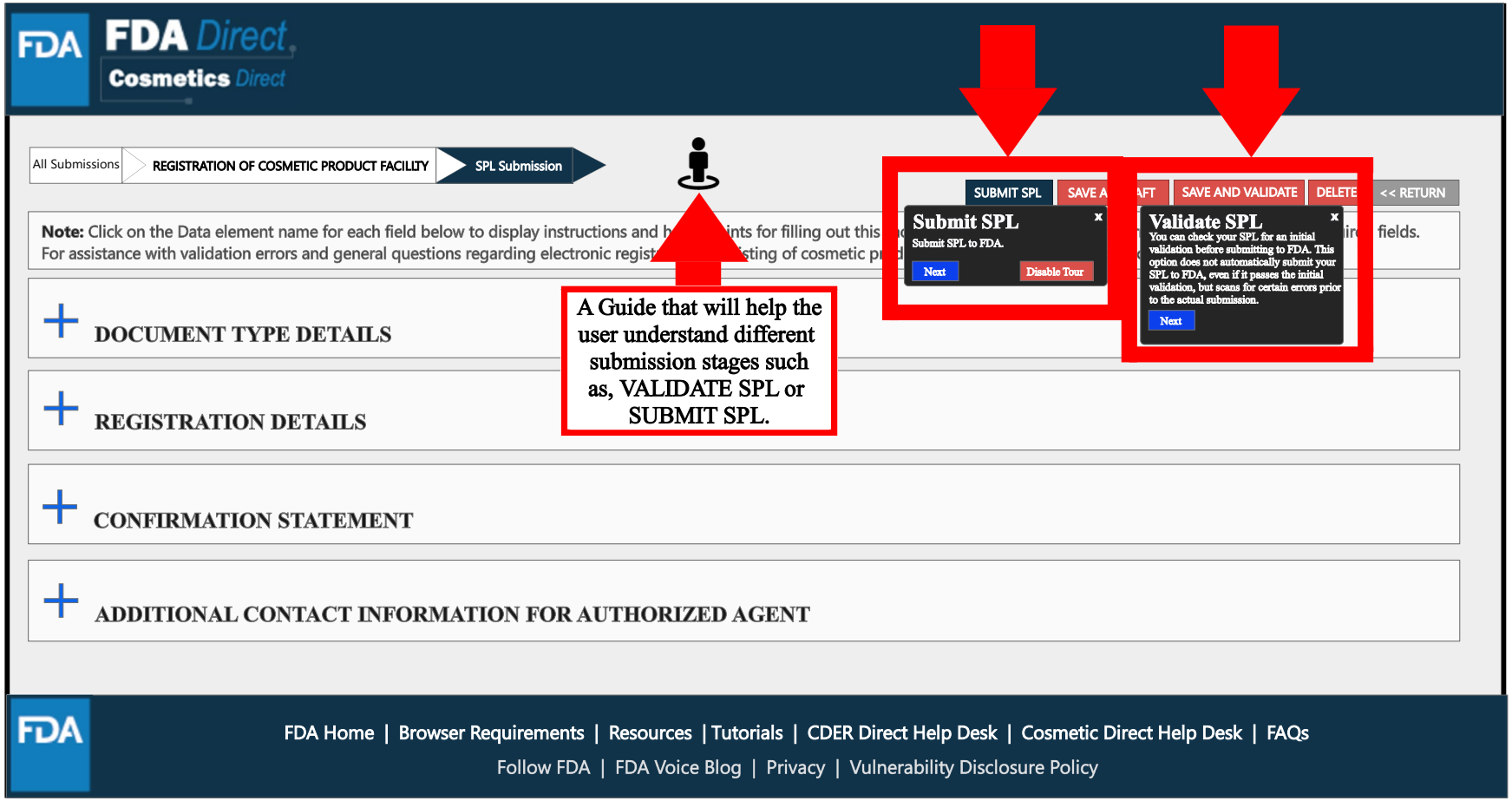


Completed

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

OR

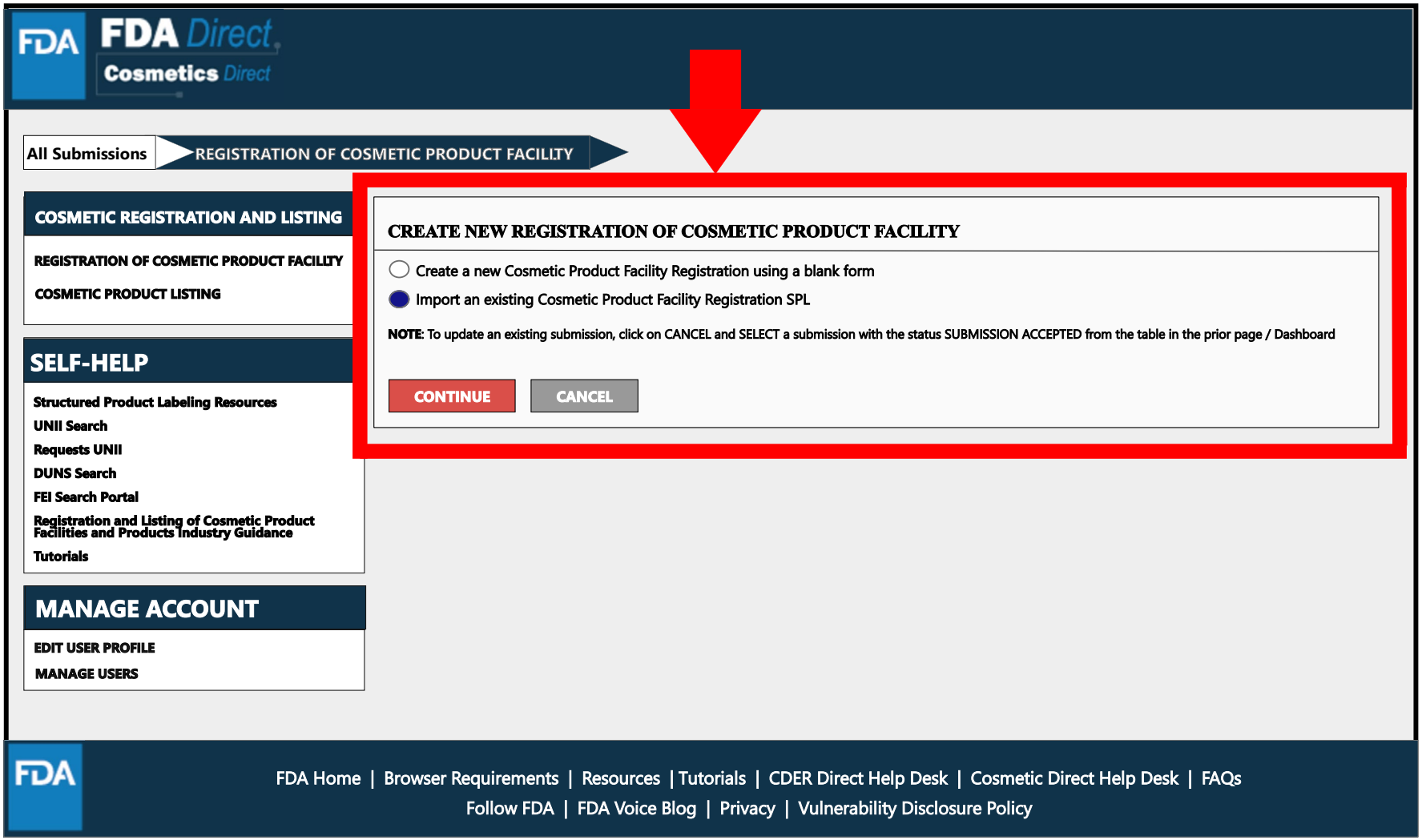
Select **SUBMIT SPL** for the form to be submitted to FDA.



Upload a SPL File

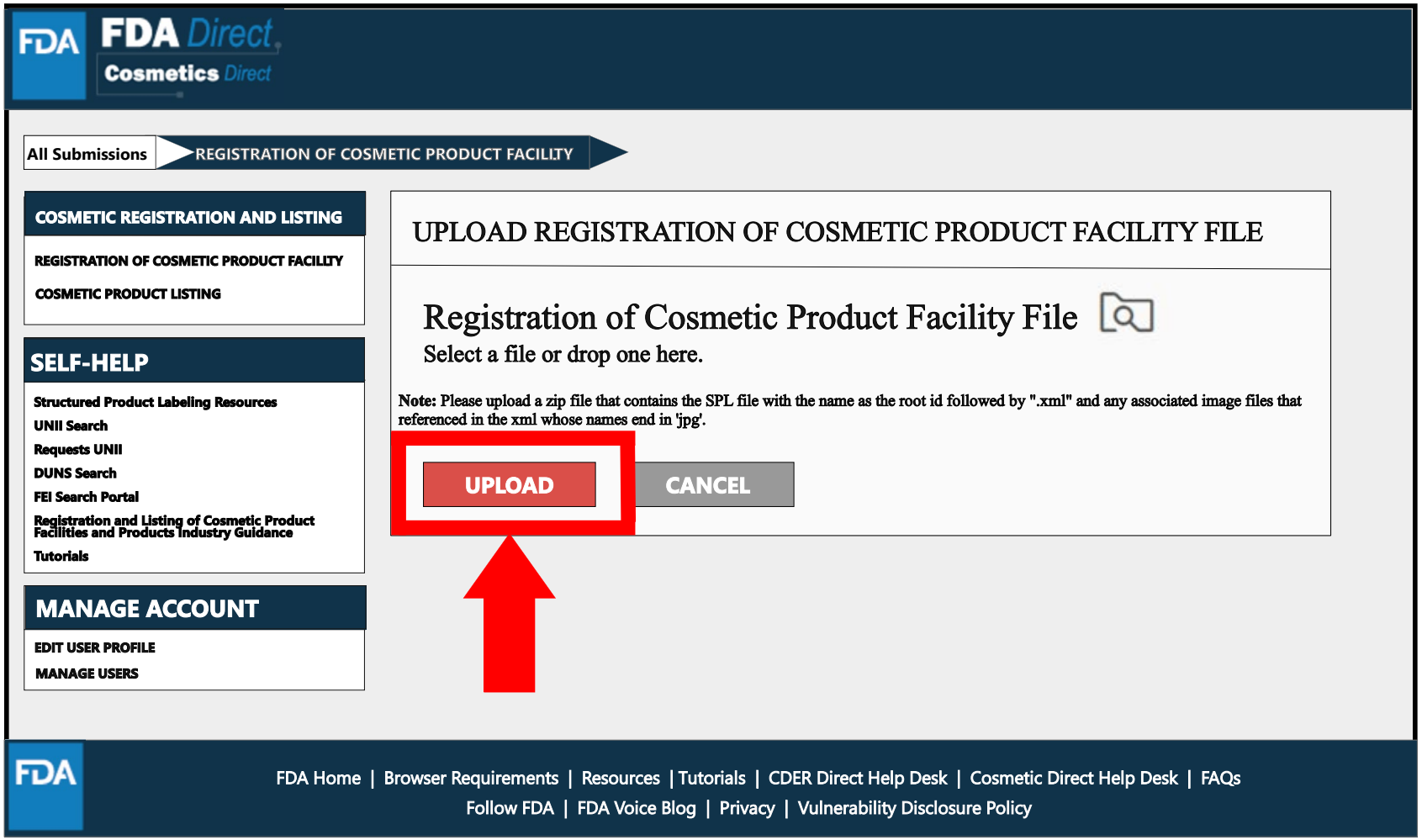
Upload an Existing File

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



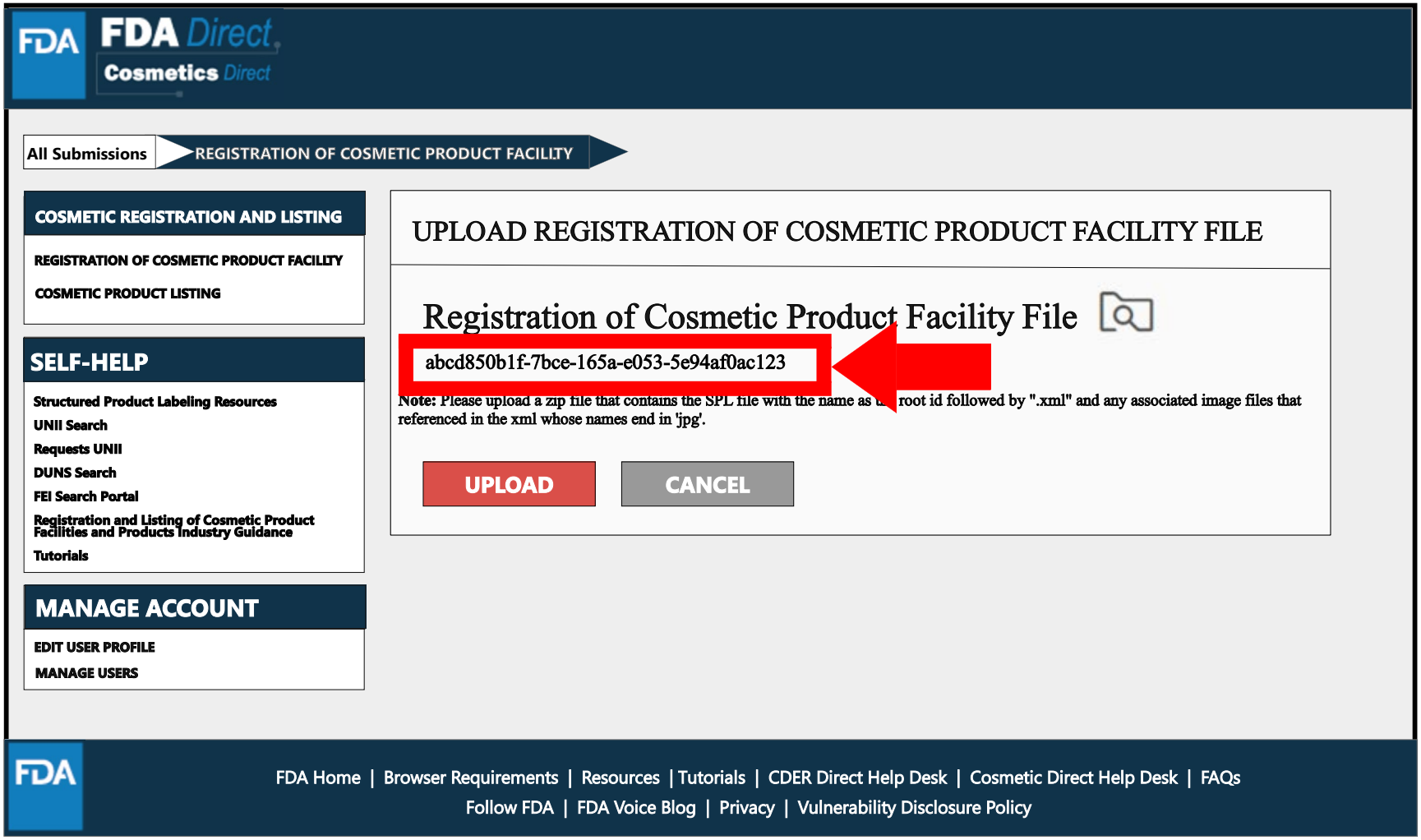
Upload a File

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



Upload a File (Example)

- This is an example of a zip file. Please upload a zip file that contains the SPL file with the name as the root id followed by ".xml"



Zip File (Example)

An example to what an XML format could look like.

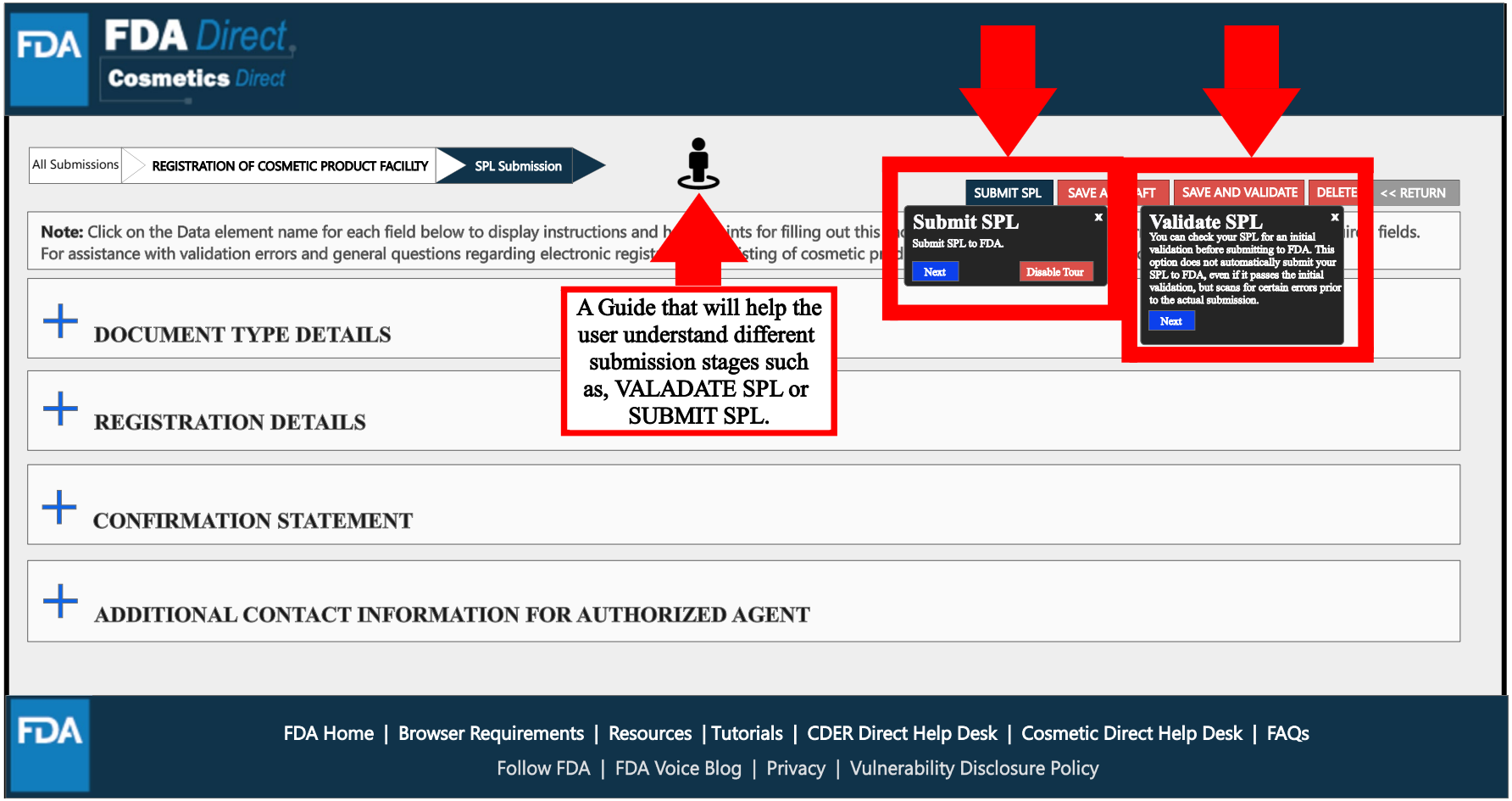
```
<?xml version="1.0" encoding="UTF-8"?>
<?xml-stylesheet href="https://www.accessdata.fda.gov/spl/stylesheet/spl.xsl" type="text/xsl"?>
<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:hl7-org:v3 https://www.accessdata.fda.gov/spl/schema/spl.xsd">
  <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 fields and the form will be ready to **SAVE AND VALIDATE** to check for any errors.

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

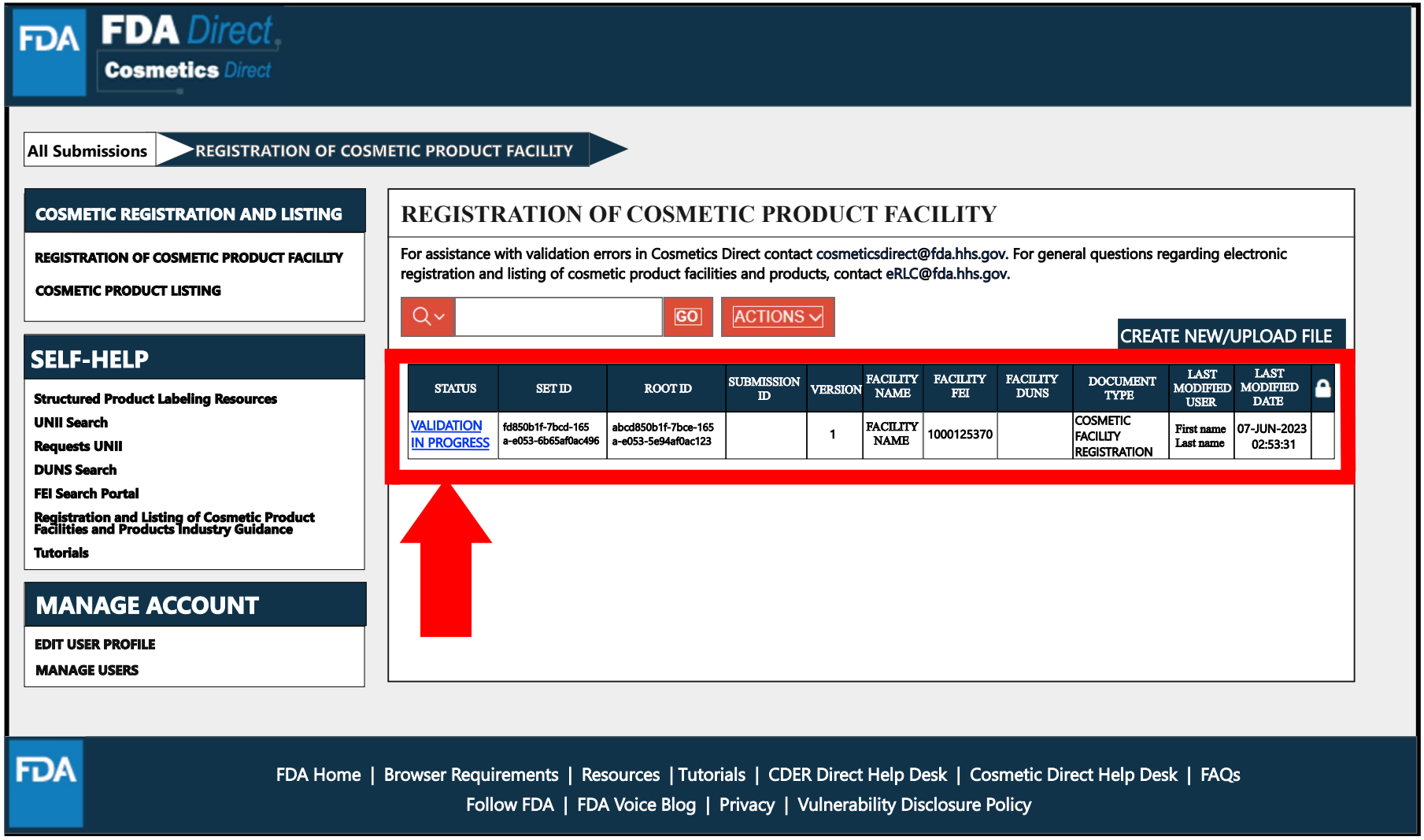
Select SUBMIT SPL for the form to be submitted to FDA. The Submit SPL box is a help tool that can guide a user through the process.



Registration Status Examples

Registration Status: Validation in Progress

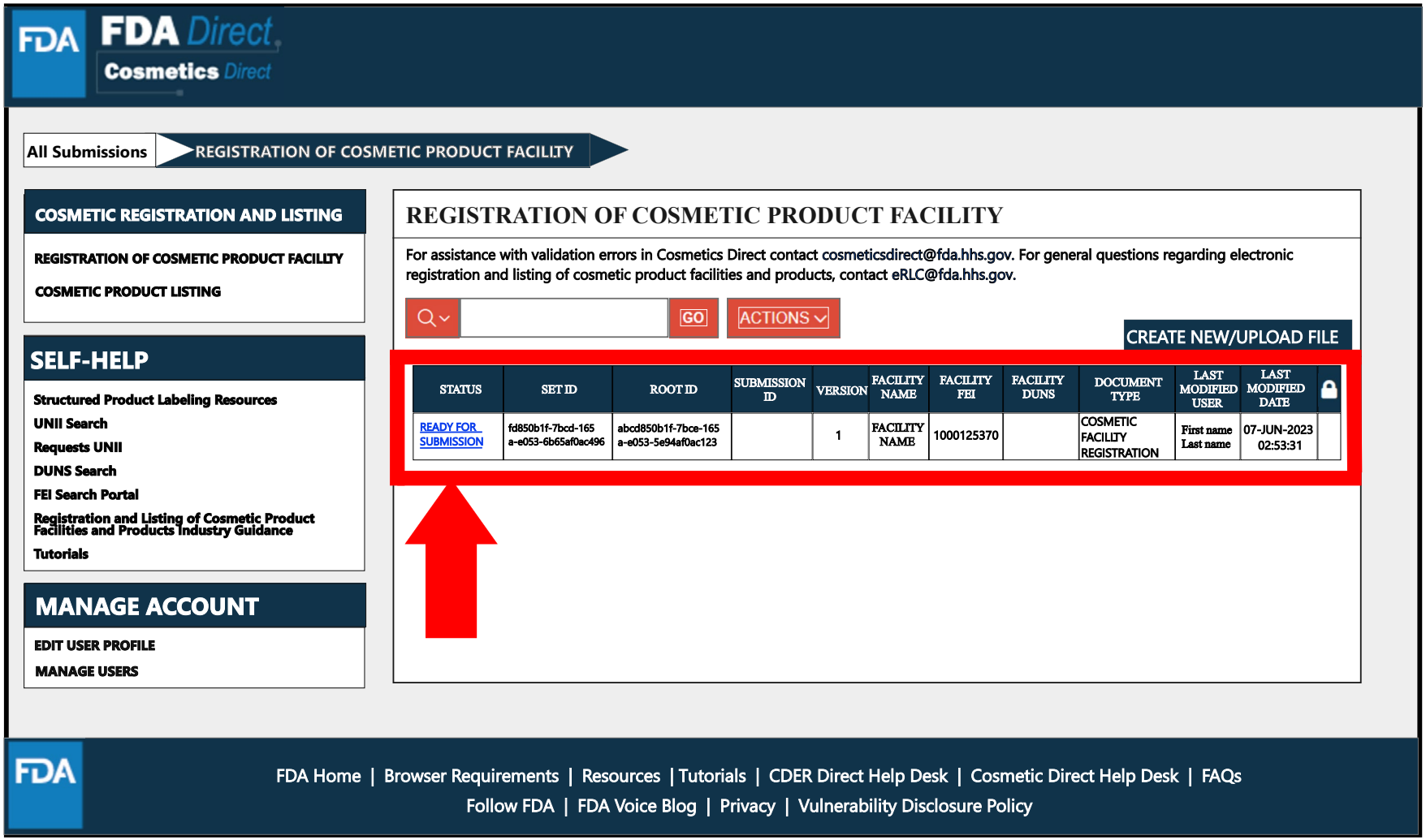
After SAVE AND VALIDATE, the registration of cosmetic product facility home page will have the following details as shown below. The status will be in **VALIDATION IN PROGRESS**.



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.

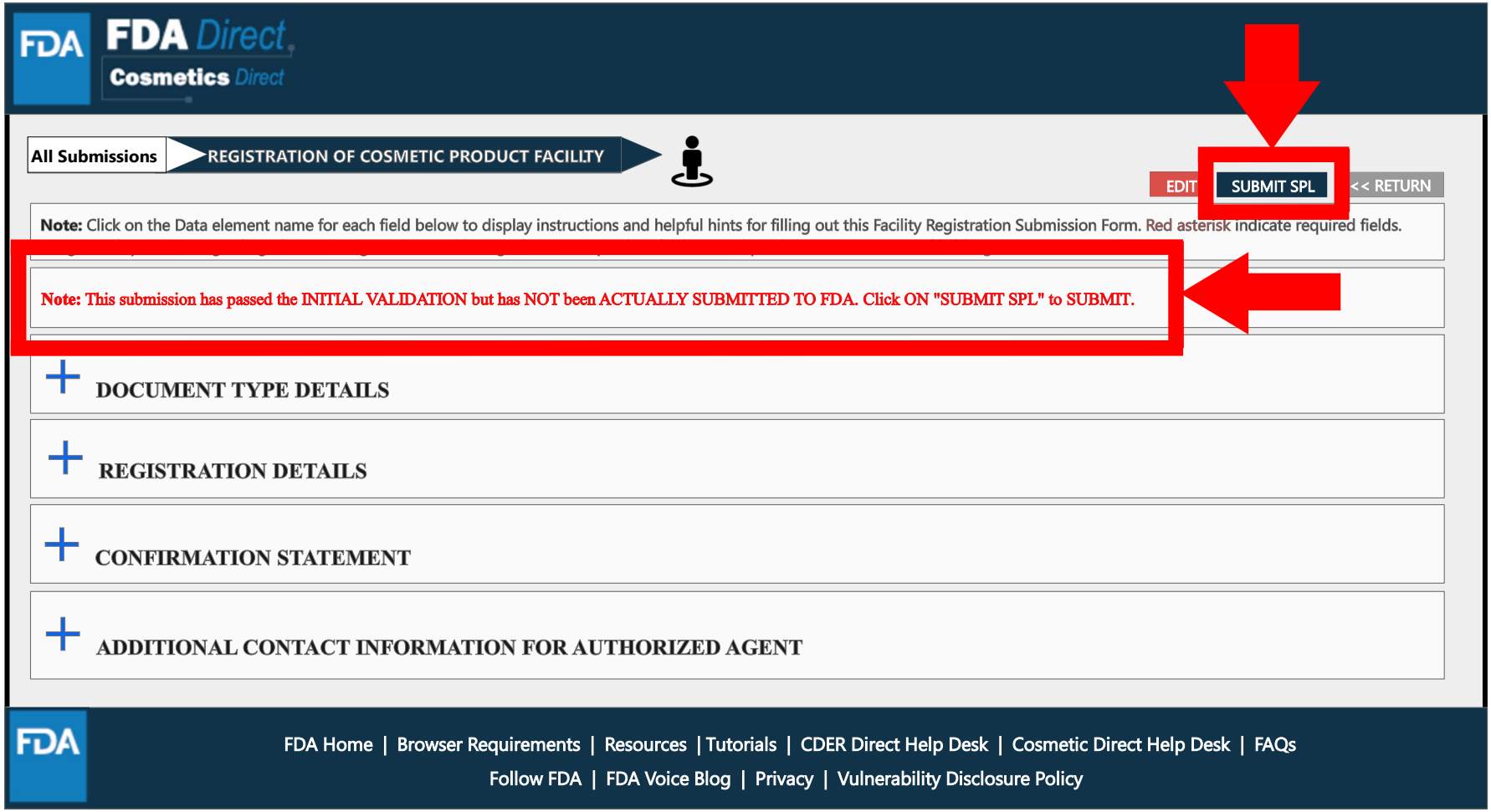
Once the system has completed a quick VALIDATION, the status **VALIDATION IN PROGRESS** will change to **READY FOR SUBMISSION**.



Registration Status: Ready for Submission to Submit SPL

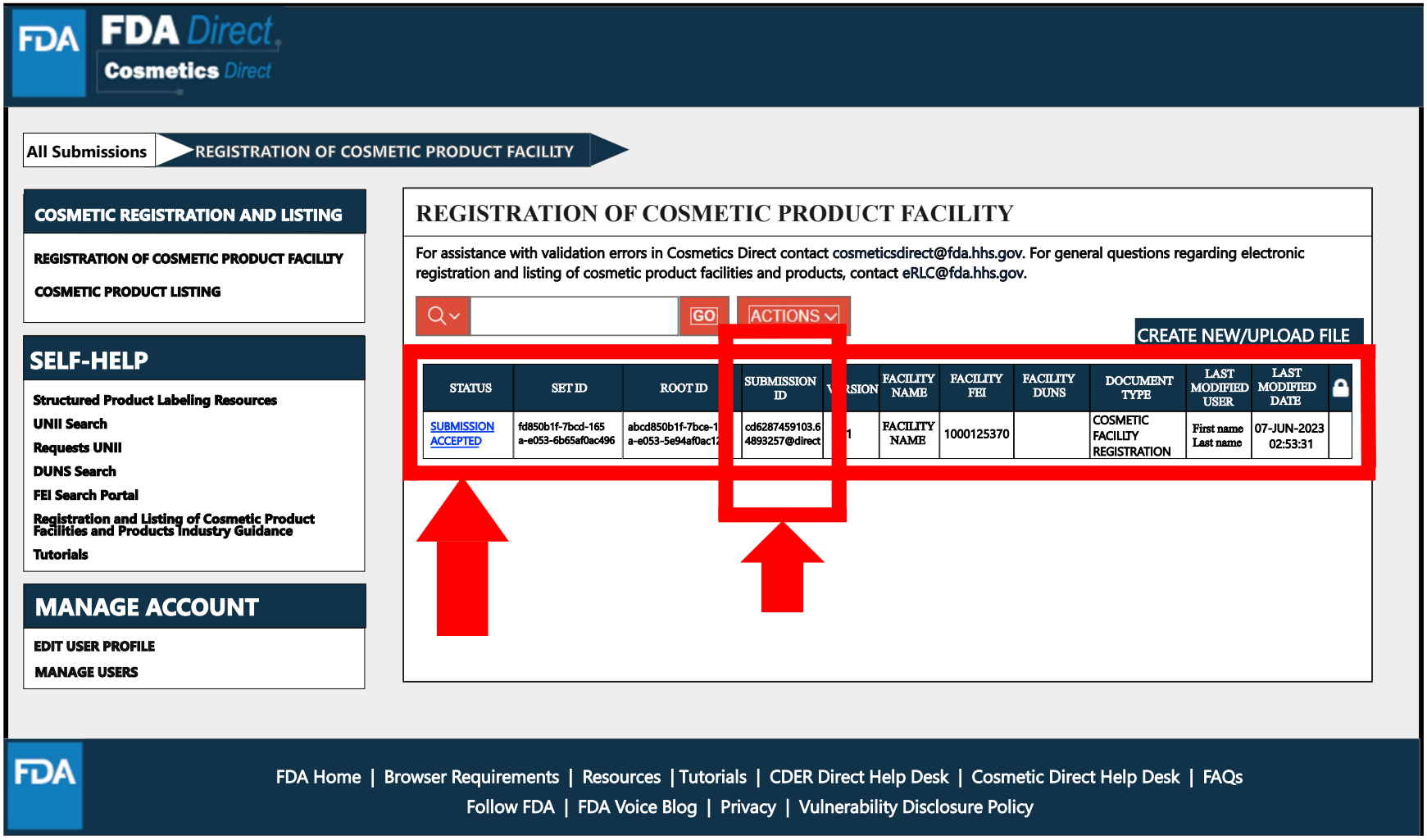
By clicking on the **READY FOR SUBMISSION**, the registration will be ready for **SUBMIT SPL**.

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.*



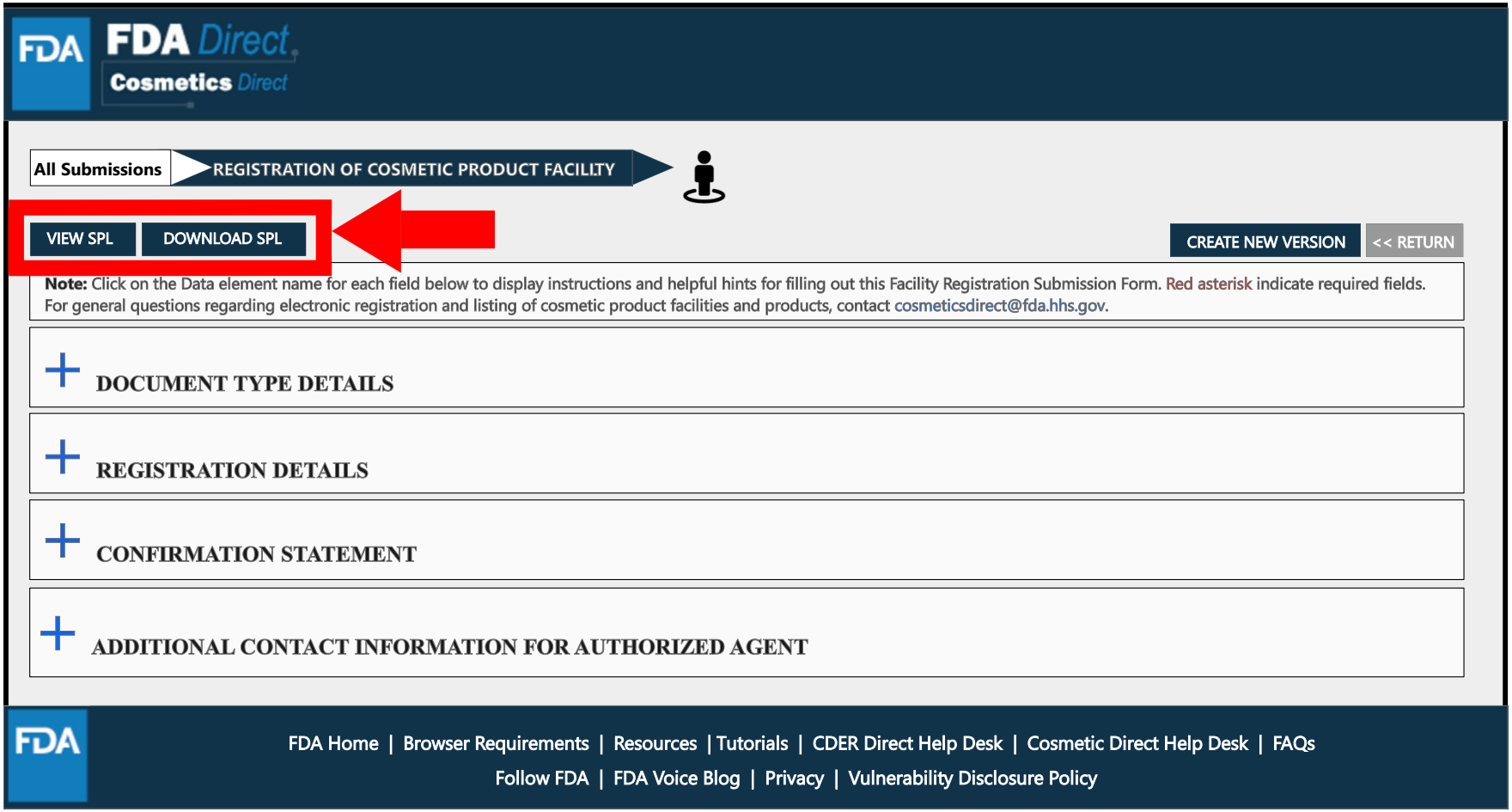
Registration Status: Submit SPL to Submission Accepted

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



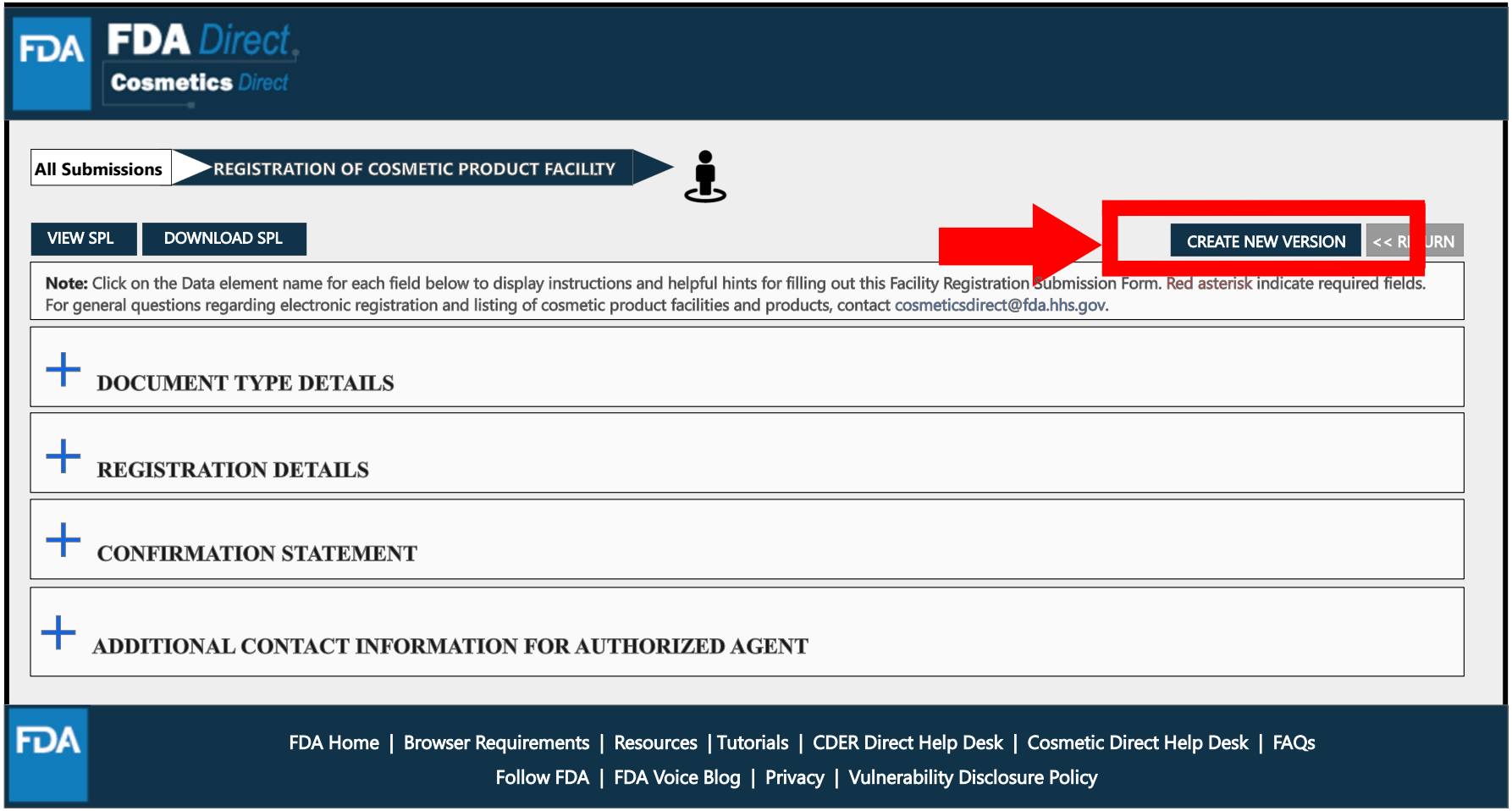
Registration Status: Submission Accepted to View SPL and Download SPL

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



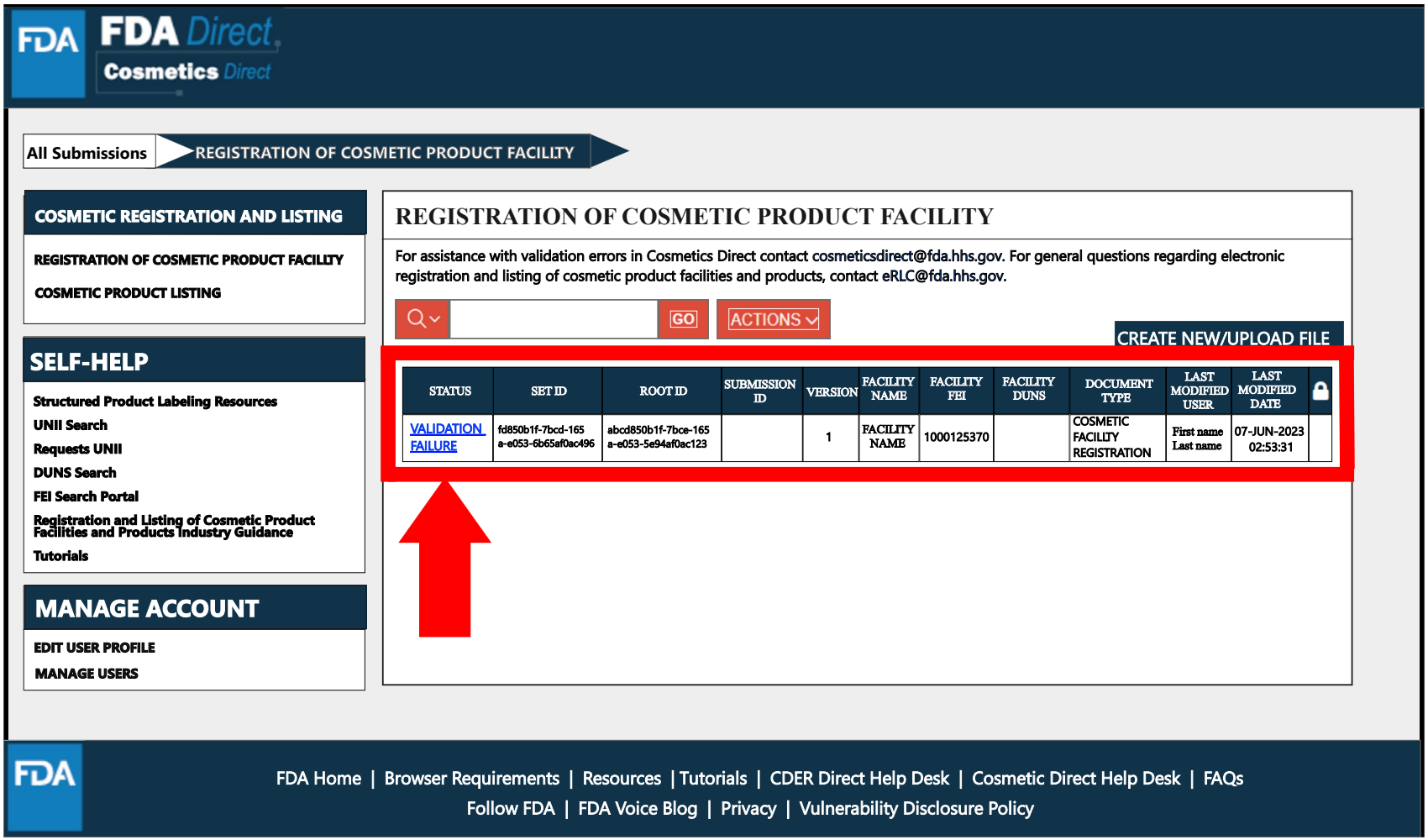
Clone Successfully Submitted SPL

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



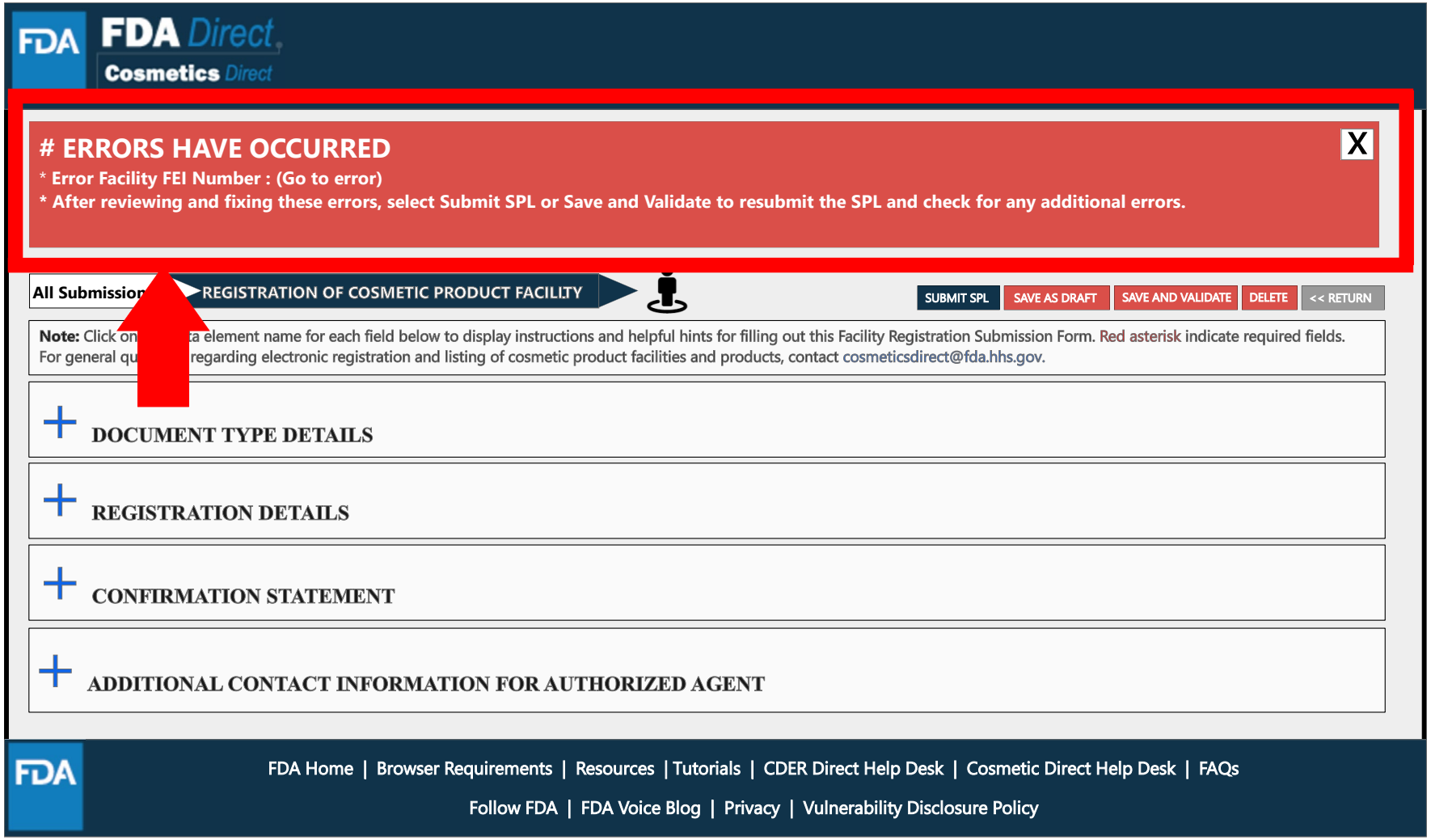
Registration Status: Validation Failure

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



Registration Status: Validation Failure (List of Errors)

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



Registration Status: Save as Draft

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

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**.