U.S. FOOD & DRUG ADMINISTRATION

COSMETICS *DIRECT*

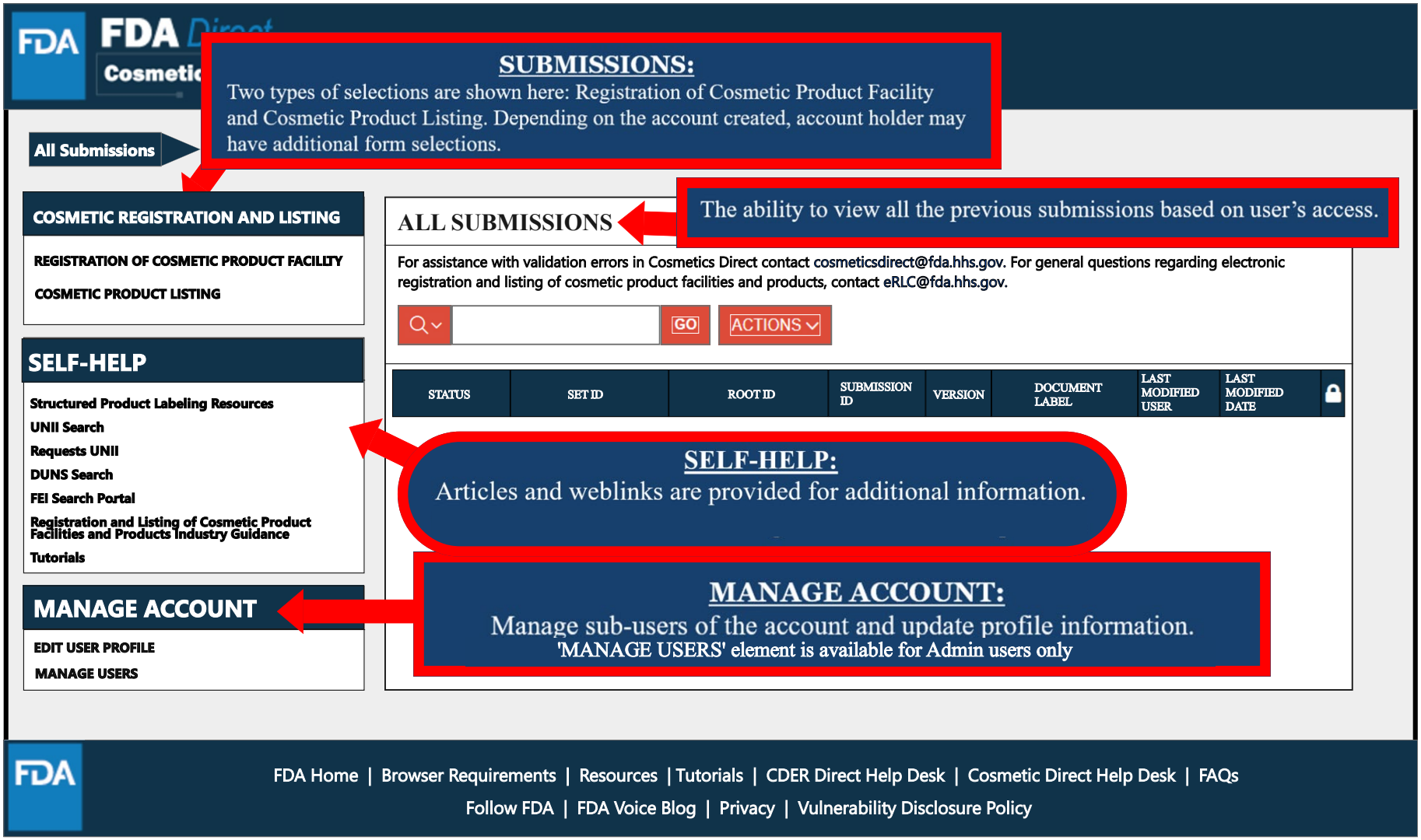
PRODUCT LISTING

Tutorial

APRIL 2024

Cosmetics Direct Home Page

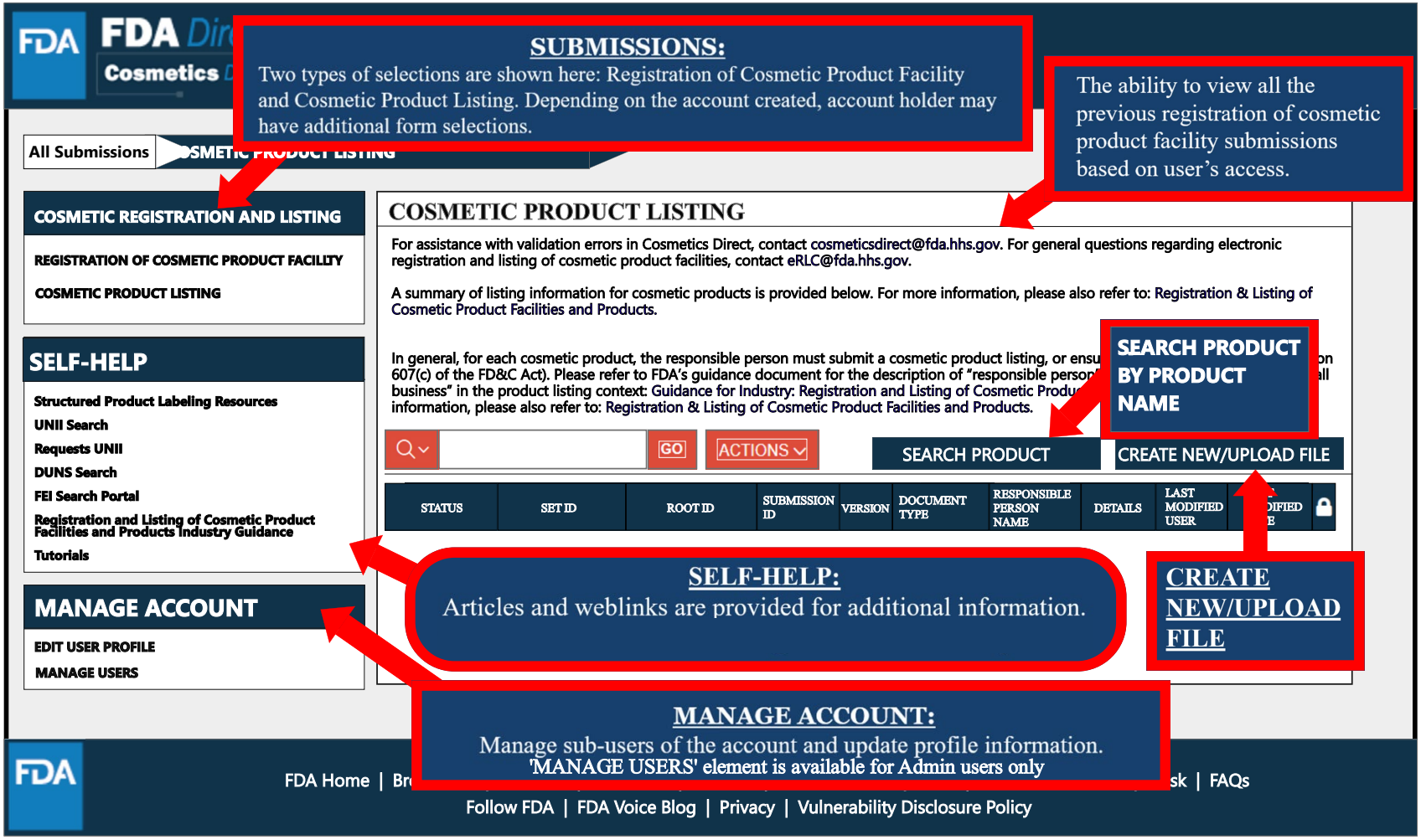
Home page of Cosmetics Direct after creating an account within FDA Direct.



Cosmetic Product Listing

Cosmetic Product Listing Home Page

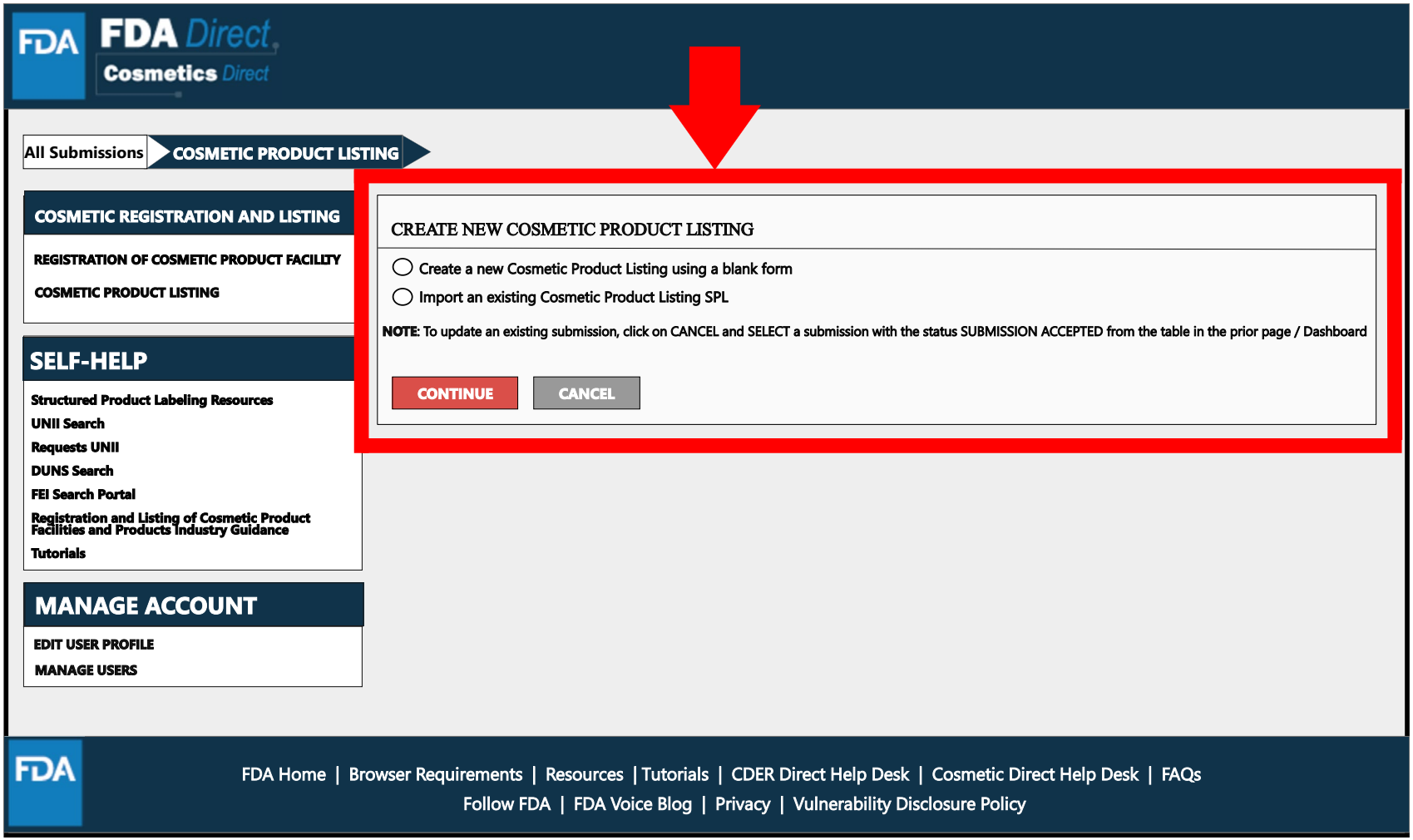
Home page of the Cosmetics Product Listing after logging into FDA Direct and selecting Cosmetic Product Listing under Cosmetic Registration and Listing.



Create a New Product Listing or Upload an Existing File

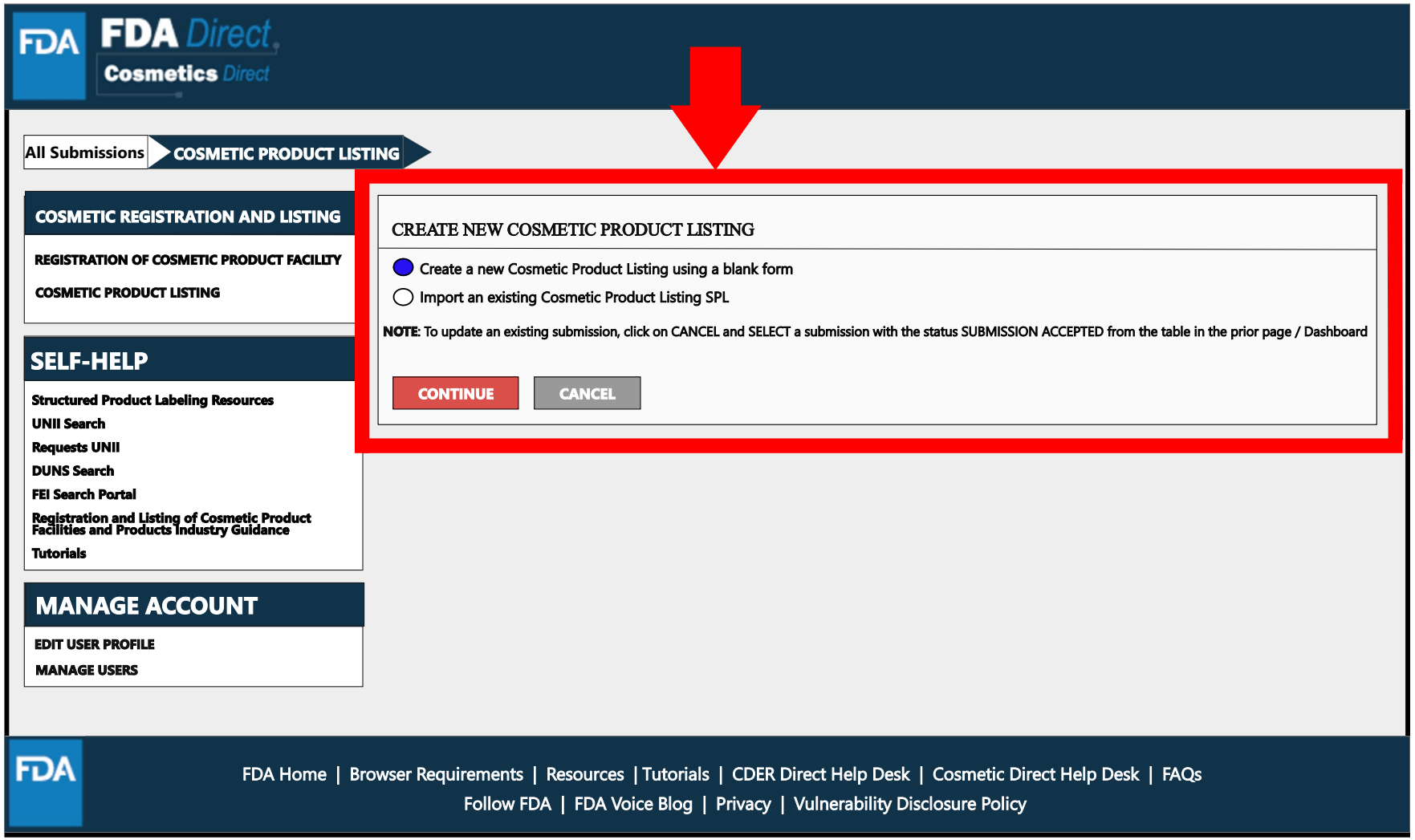
Create a New Cosmetic Product Listing or Upload an Existing File

Selecting the **CREATE NEW/UPLOAD FILE** box from the **Cosmetic Product Listing home page** will direct a user to the option of creating an initial Cosmetic Product Listing 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 Listing SPL is beneficial for bulk submission.



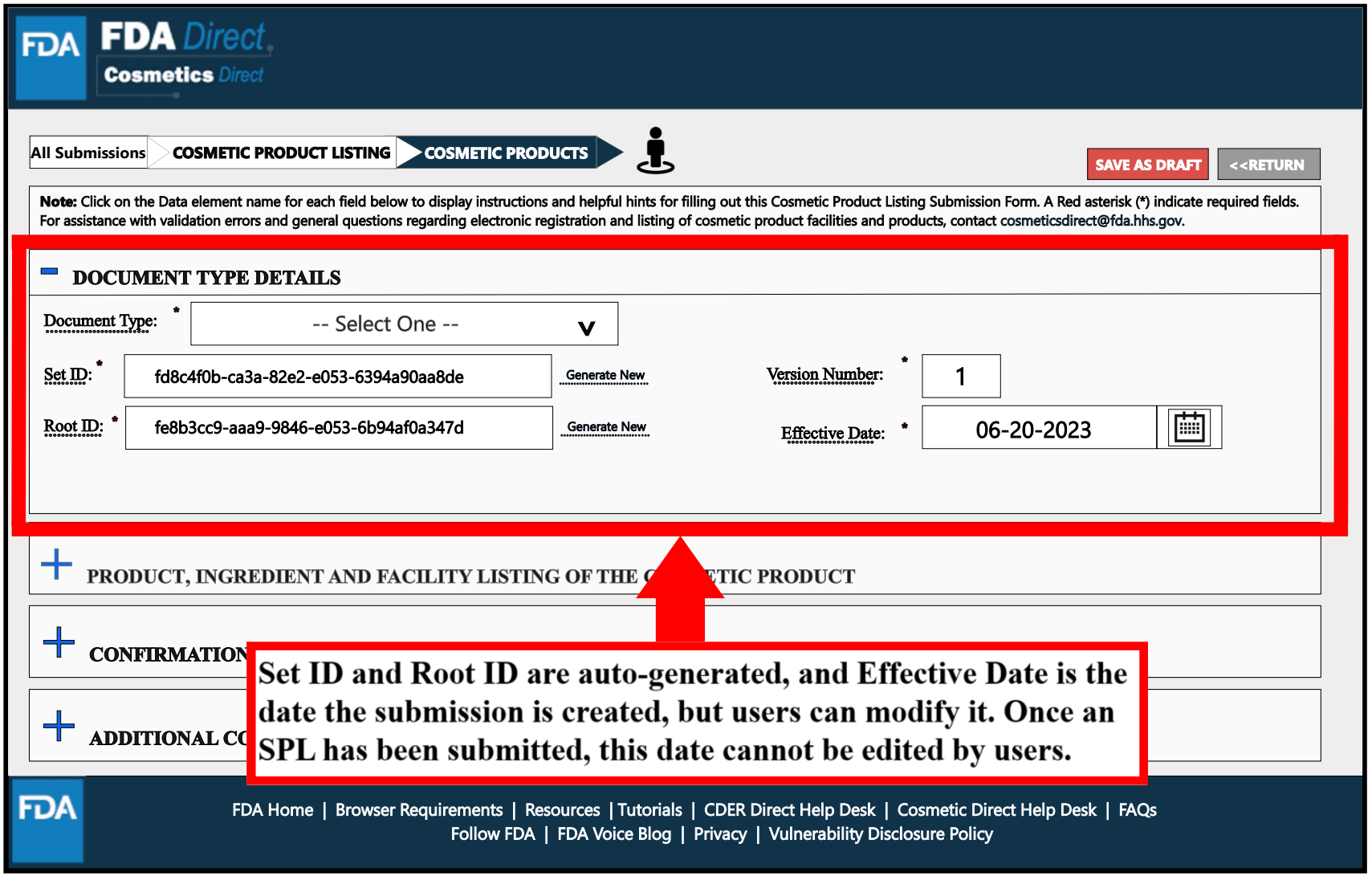
Create a New Cosmetic Product Listing

Create an Initial Cosmetic Product Listing using a blank form.



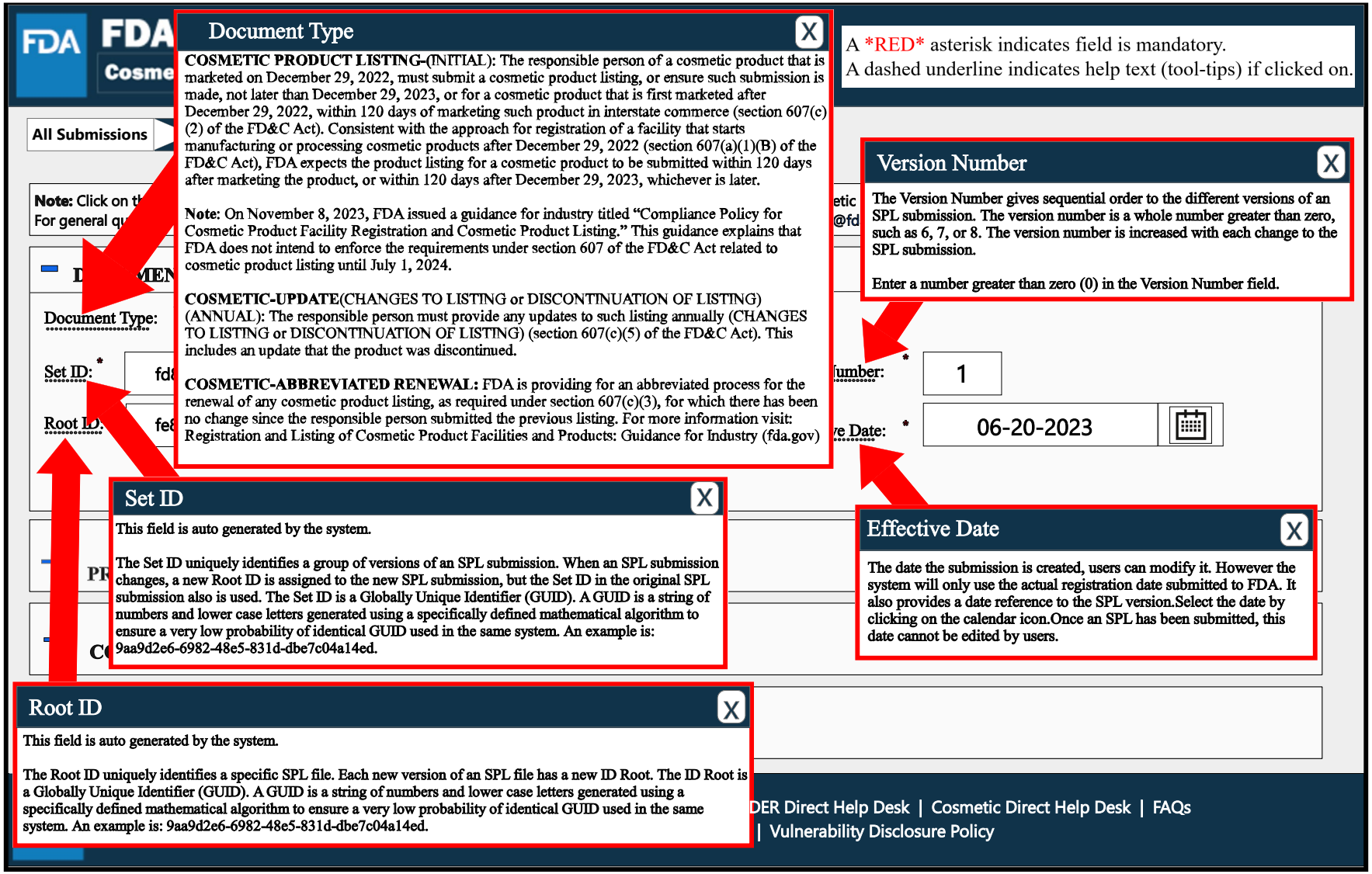
Document Type Details Section

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 changed by users.



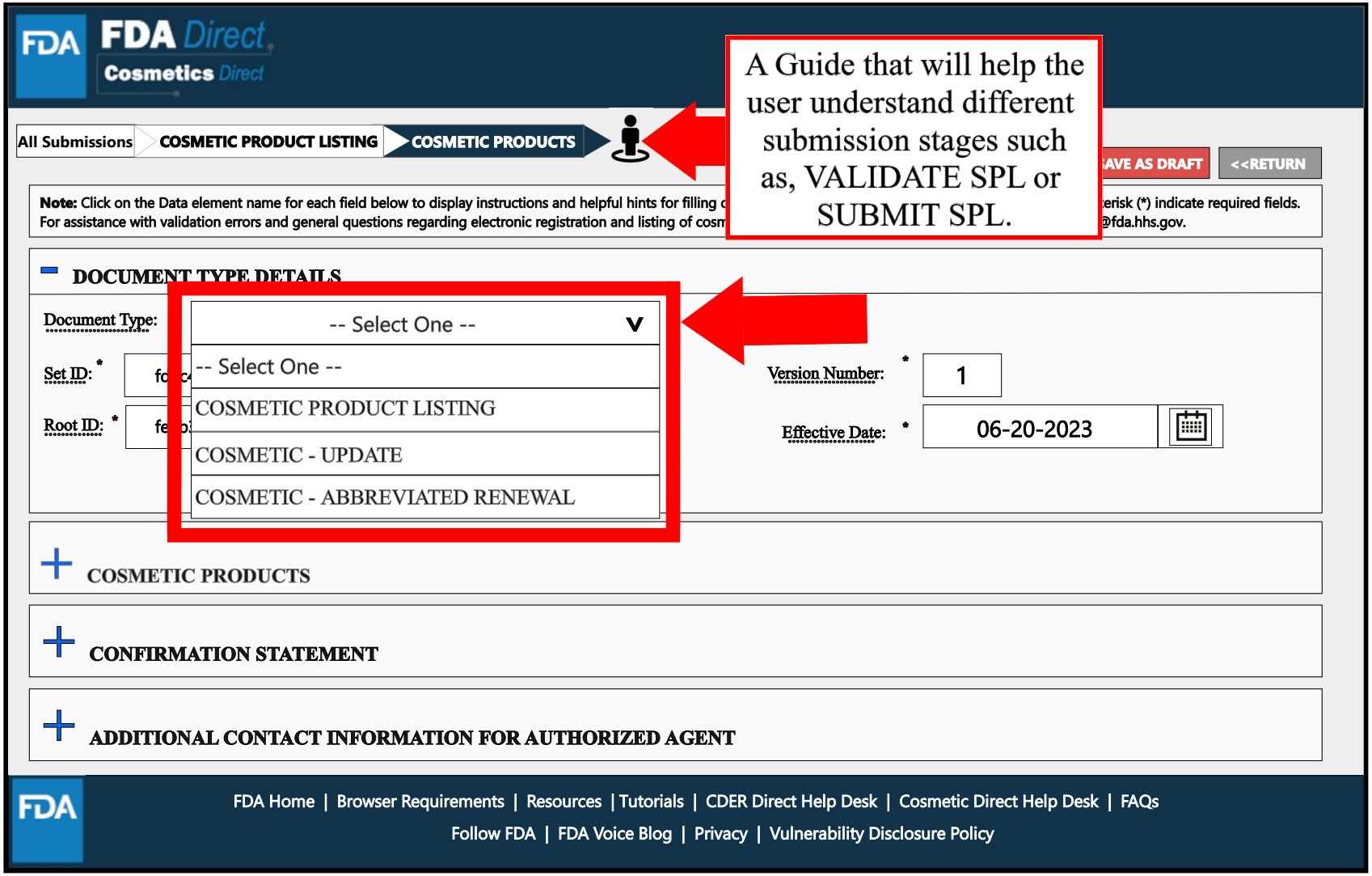
Document Type Tool Tips

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



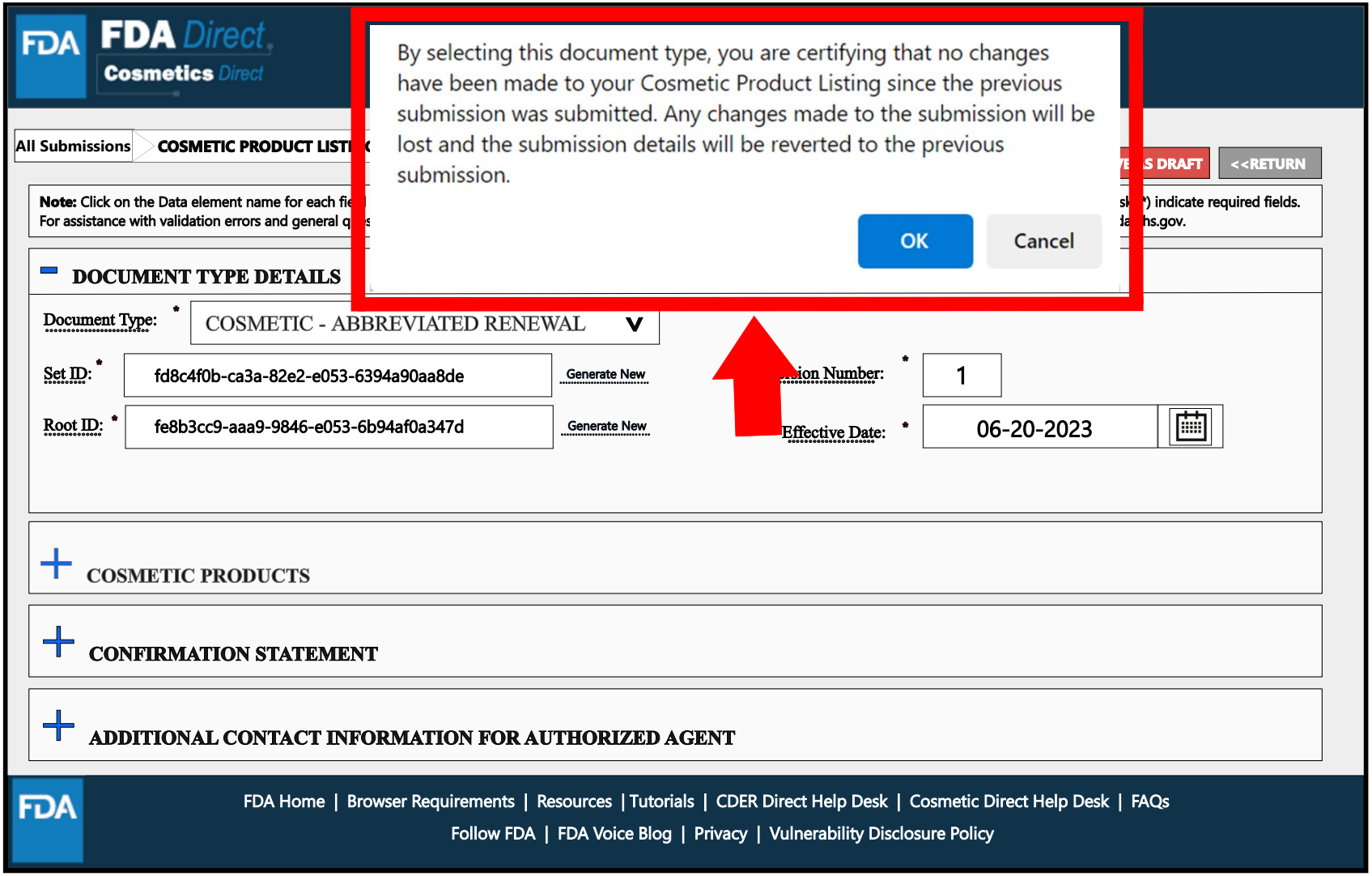
Document Type Details

By selecting the drop-down (v), three document types options will appear: COSMETIC PRODUCT LISTING (initial), COSMETIC – UPDATE, and COSMETIC – ABBREVIATED RENEWAL.



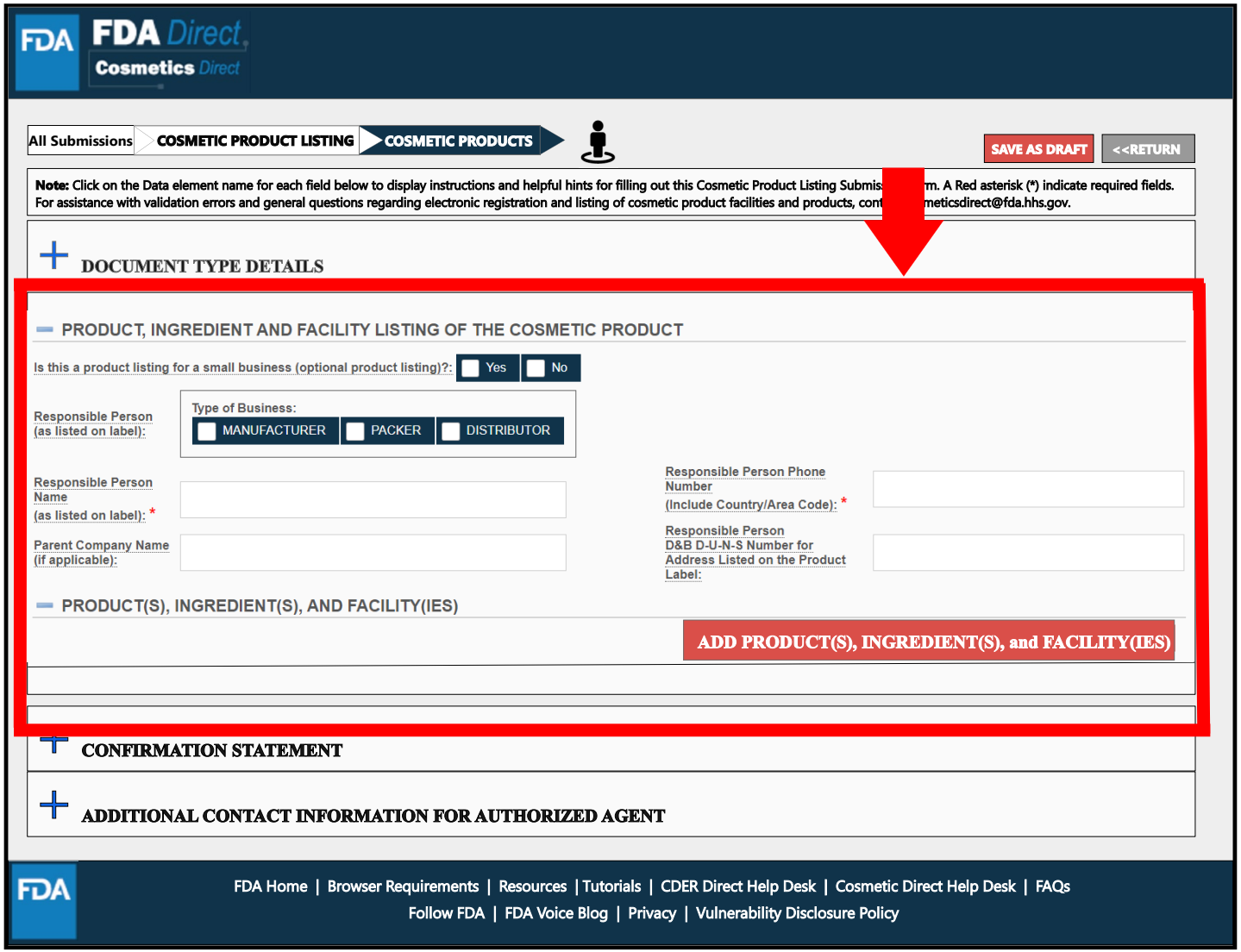
Document Type Details: Abbreviated Renewal

Depending on which document type is selected, an ALERT box will appear as shown below.



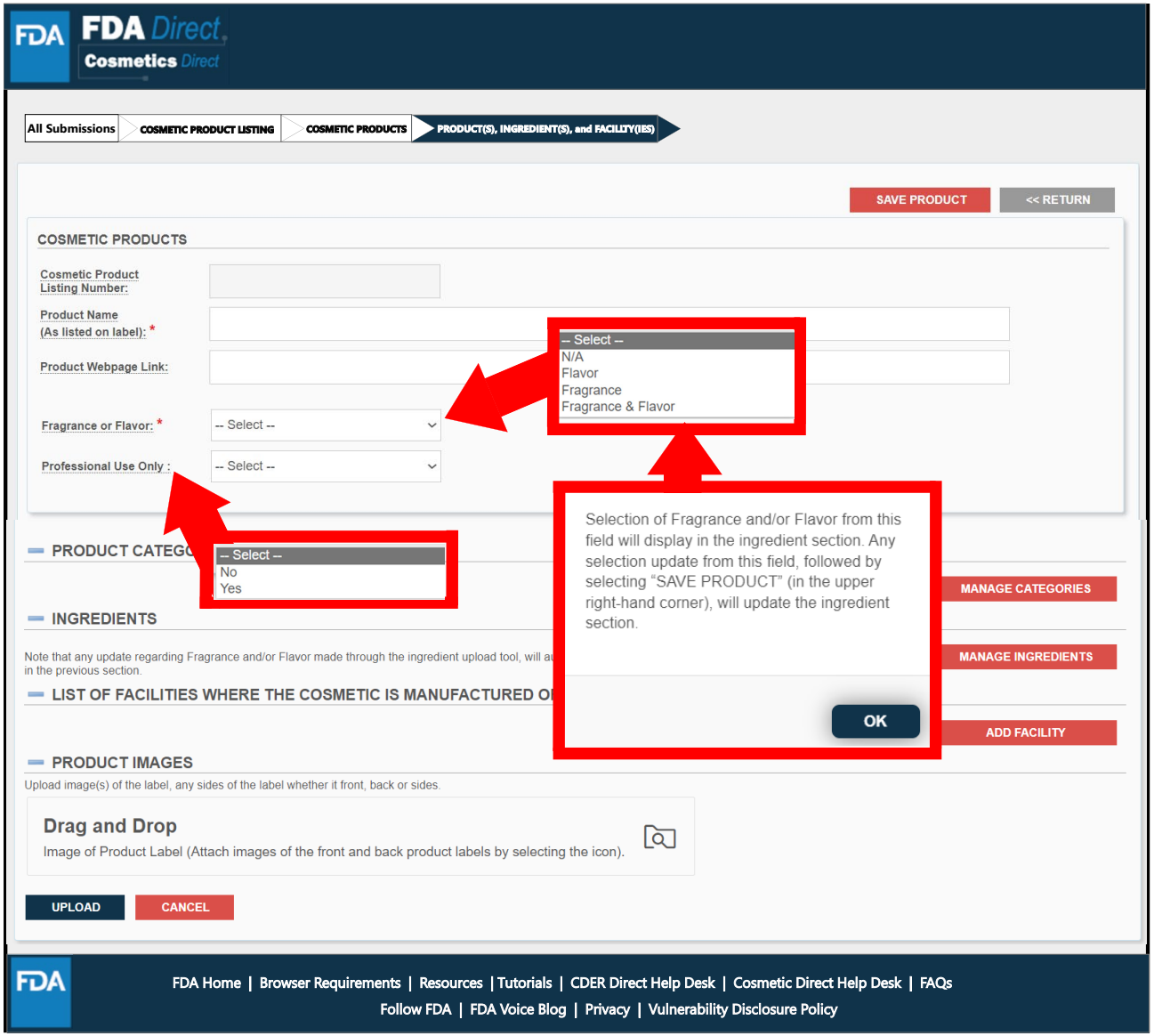
Product, Ingredient, and Facility Listing of The Cosmetic Product Details

- Enter the responsible person as listed on the label information.
- Select “ADD PRODUCT(s), INGREDIENT(s), and FACILITY(ies) to add the product information.



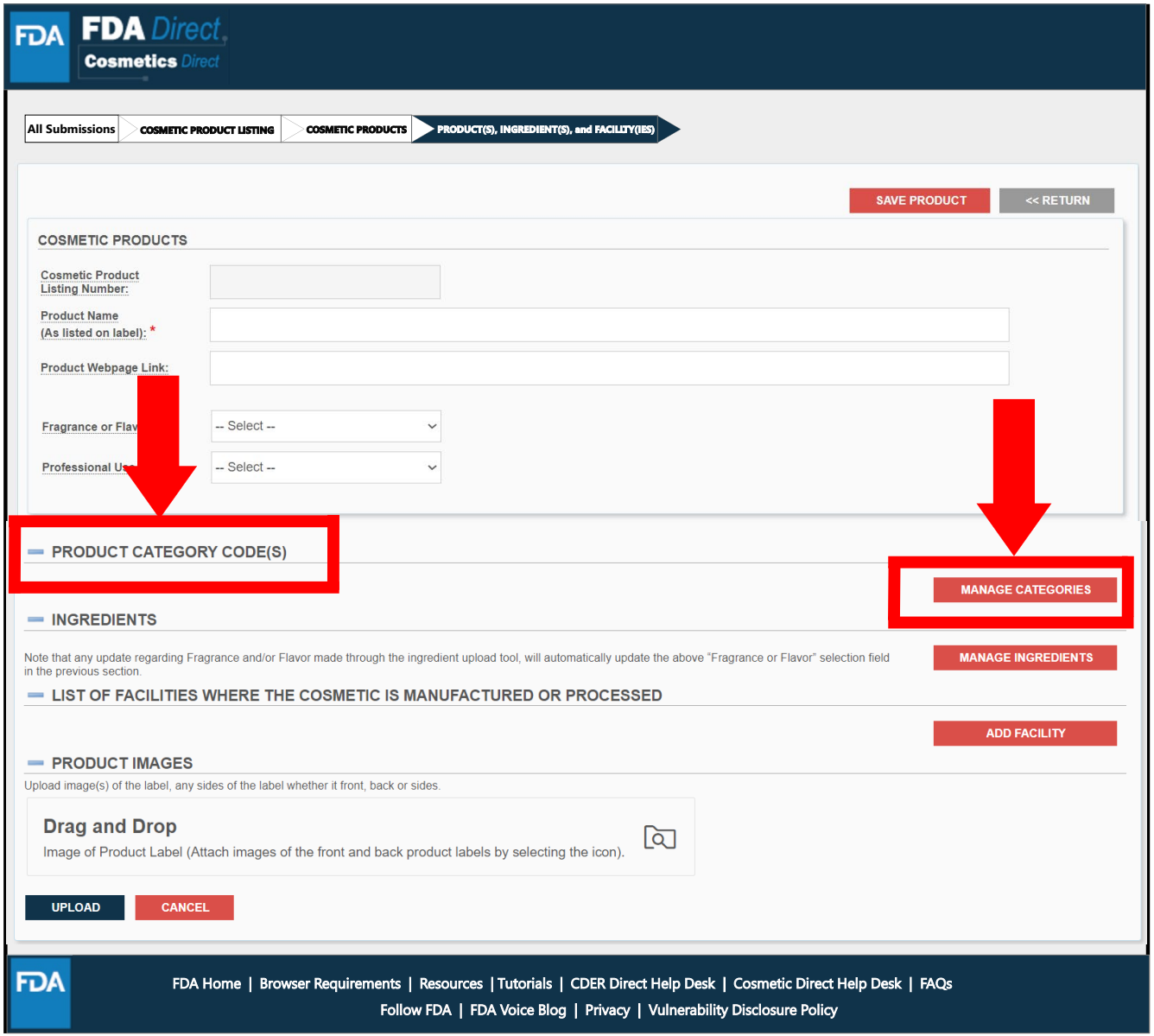
Product(s), Ingredient(s), and Facility(ies)

- A blank template titled *PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)* will display. After clicking the '**ADD PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)**' button from the **PRODUCT, INGREDIENT, AND FACILITY(IES) LISTING OF THE COSMETIC PRODUCT section,** fill in the required fields and select all that apply; a red asterisk (*) indicates a required field.



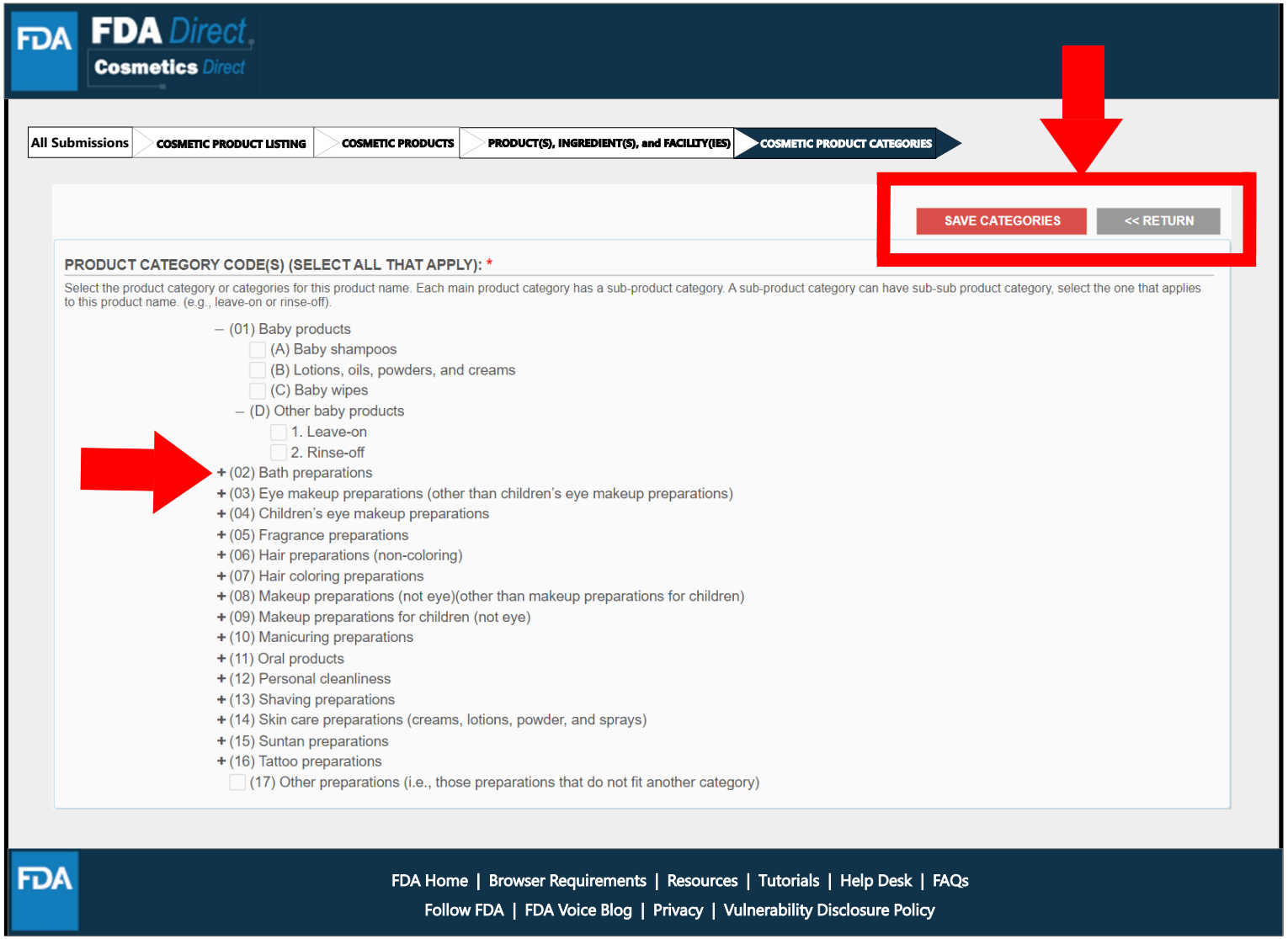
Select Product Category Code(s)

- To add one or multiple **PRODUCT CATEGORY CODE(S),** click the '**MANAGE CATEGORIES**' button in ***Product Category Code(s)*** section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section.



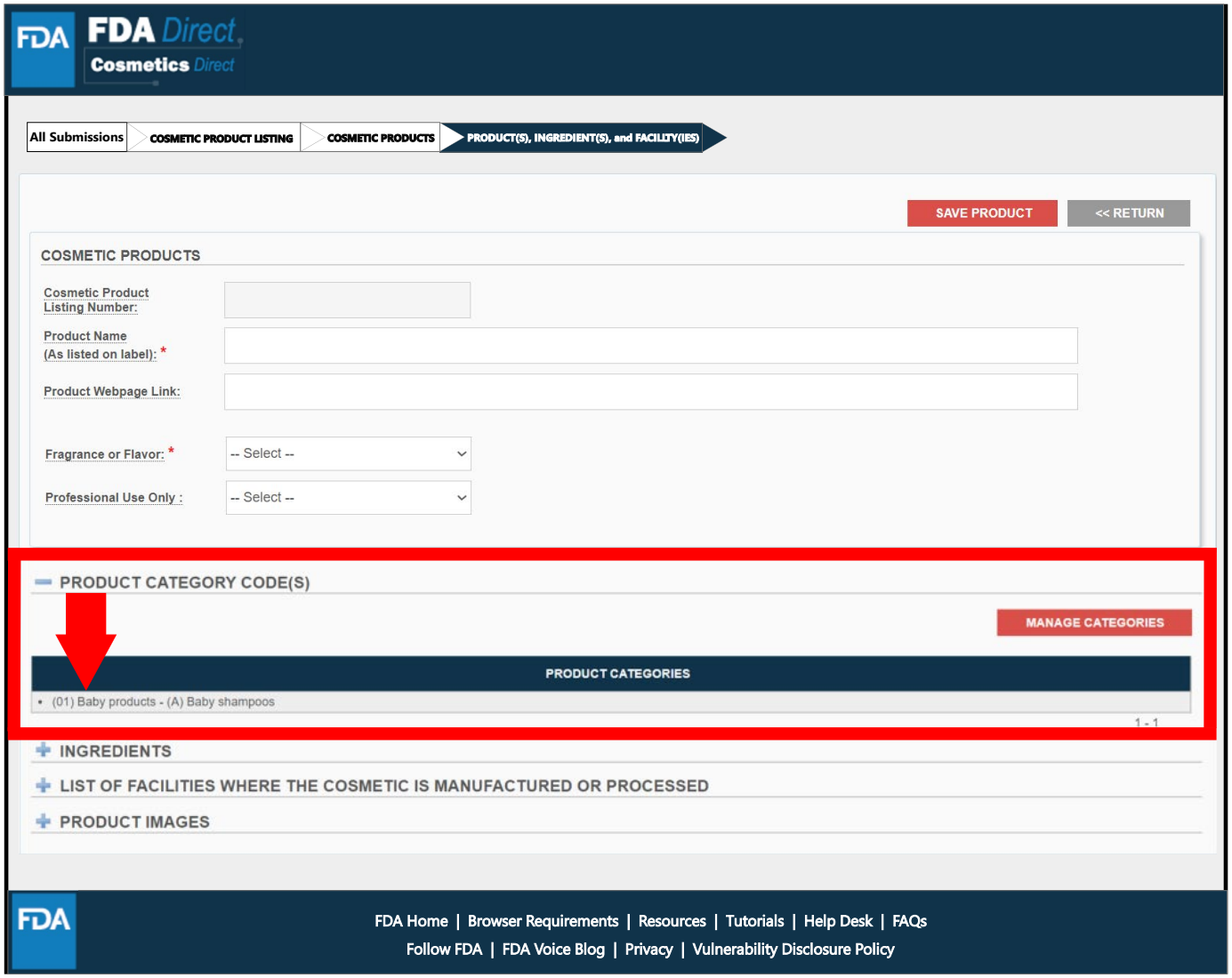
Product Category Code(s) Section

- A selection window titled *COSMETIC PRODUCT CATEGORIES* will display.
- Select all that apply.
- Click on the + icon in front of each category to display additional elements.



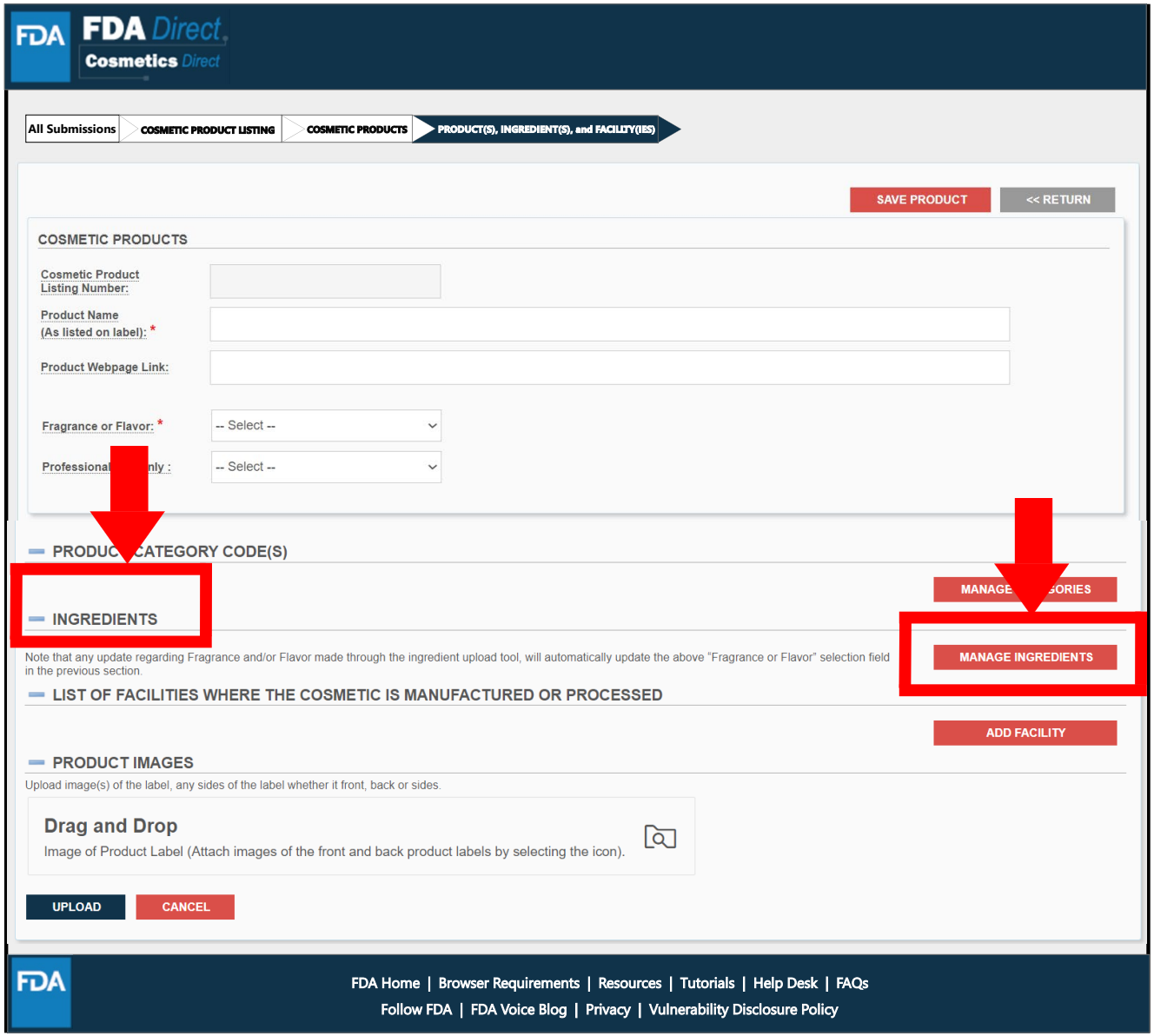
Product Category Code(s)

- After clicking '**SAVE CATEGORIES**', all the selections made on the previous page will be stated under the PRODUCT CATEGORY CODE(S) tab in the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section.



Select Ingredients

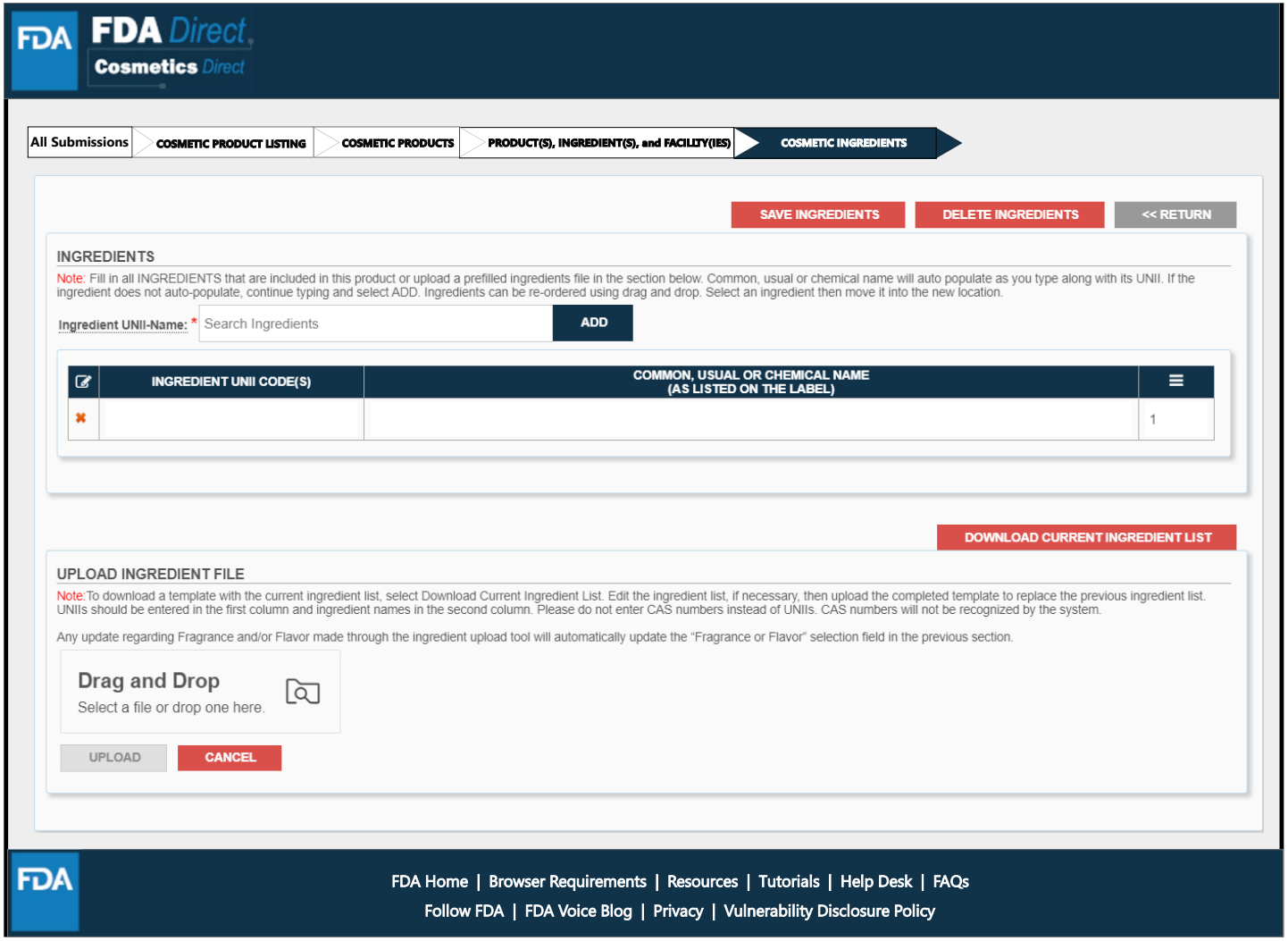
- To add **PRODUCT INGREDIENTS,** click the '**MANAGE INGREDIENTS**' button in ***INGREDIENTS*** section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section.



Cosmetic Ingredients Tab

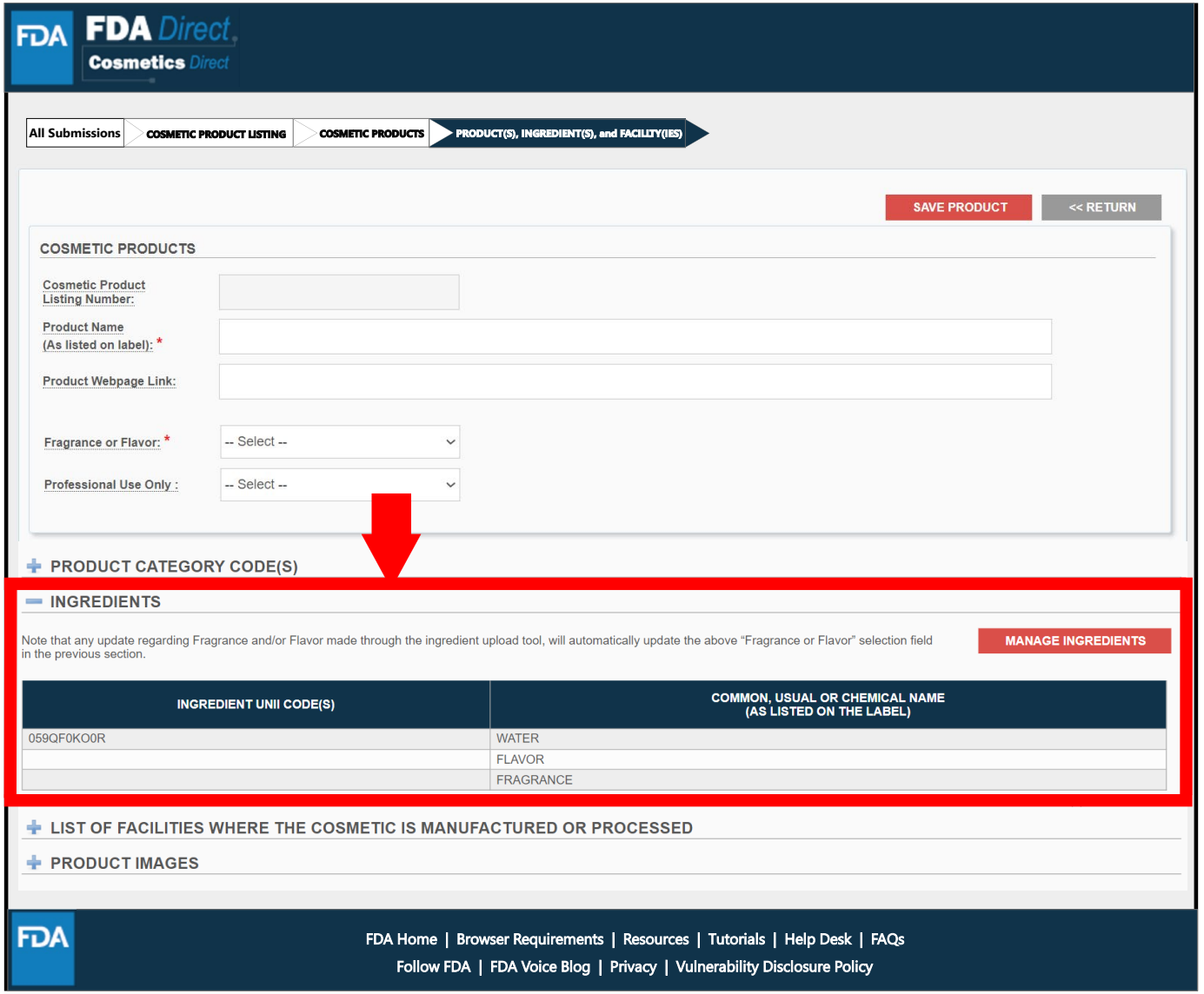
A blank template titled *COSMETIC INGREDIENTS* will display. Ingredients can be searched, added, or uploaded in the **INGREDIENTS** section.

- The ingredient list can be downloaded, edited, re-arranged, deleted, and uploaded.
- Select the UPLOAD button beneath the DRAG AND DROP in the UPLOAD INGREDIENT FILE section to replace the current Ingredient section.



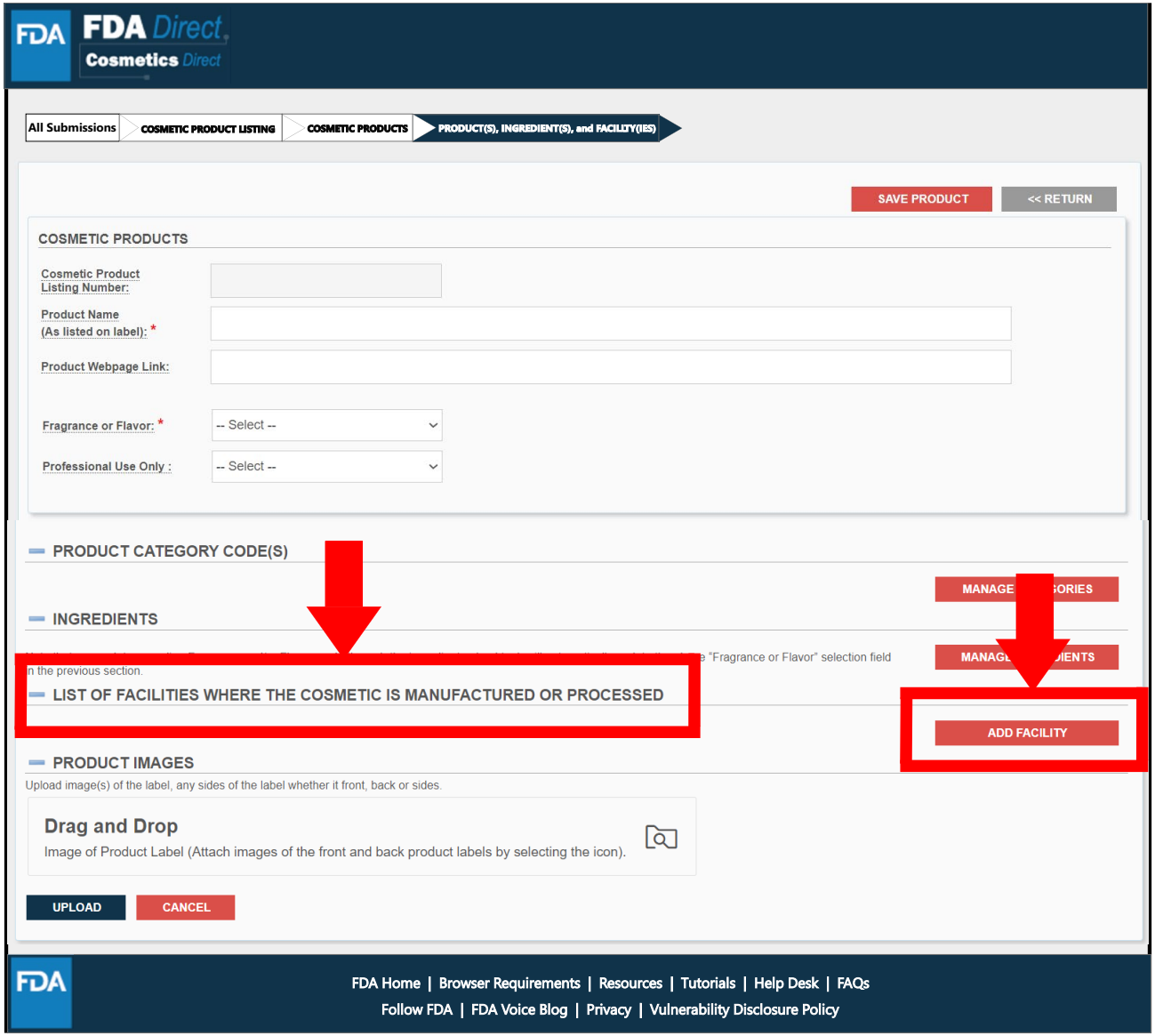
Ingredients

- After clicking **'SAVE INGREDIENTS'**, all the INGREDIENTS that were listed on the previous page will be listed under the ingredients tab in the **PRODUCT(S), INGREDIENT(S) AND FACILITY(IES)** section.



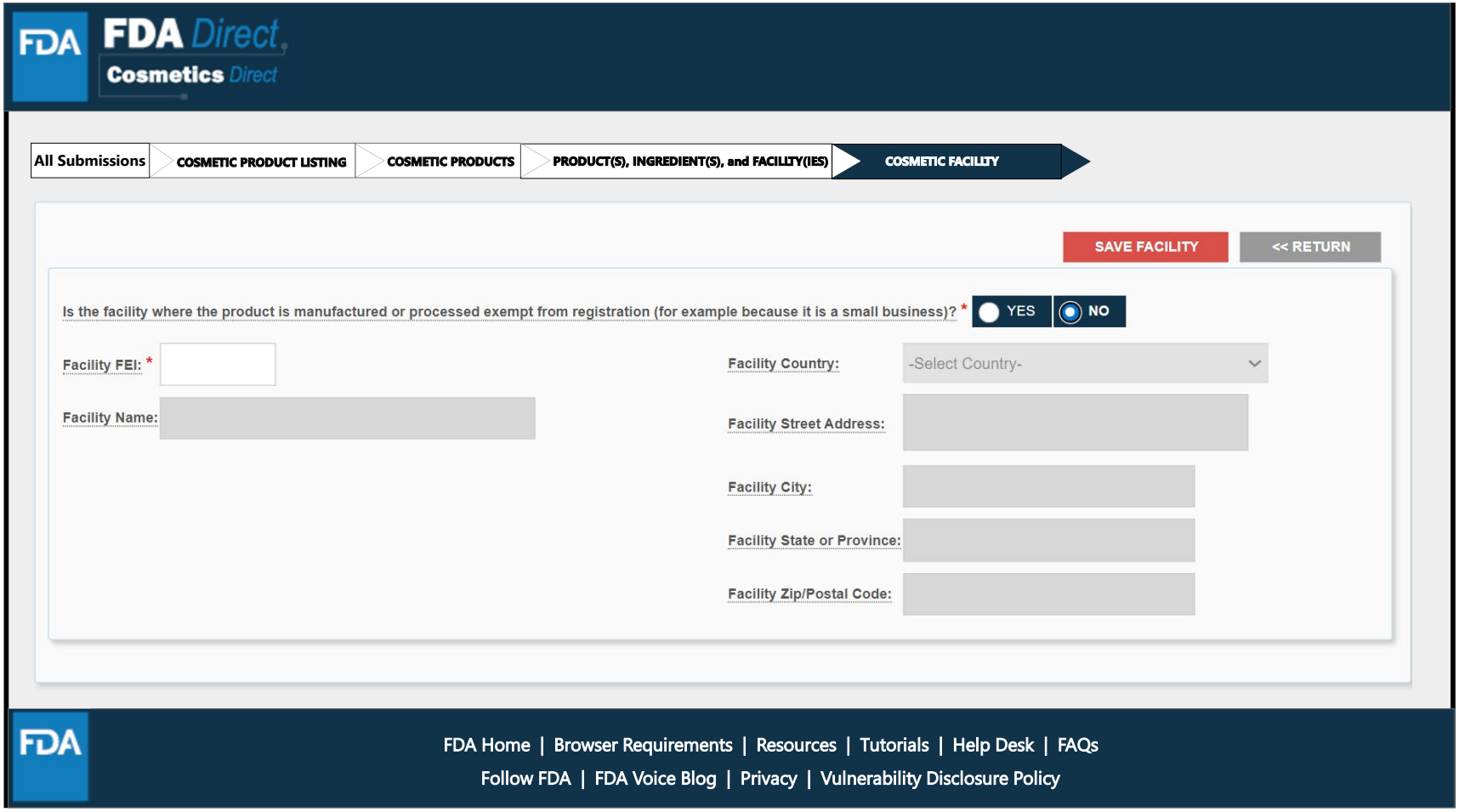
Selecting List of Facilities Where The Cosmetic is Manufactured or Processed

- To add the **LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED,** click the '**ADD FACILITY**' button in ***LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED*** section of the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section.



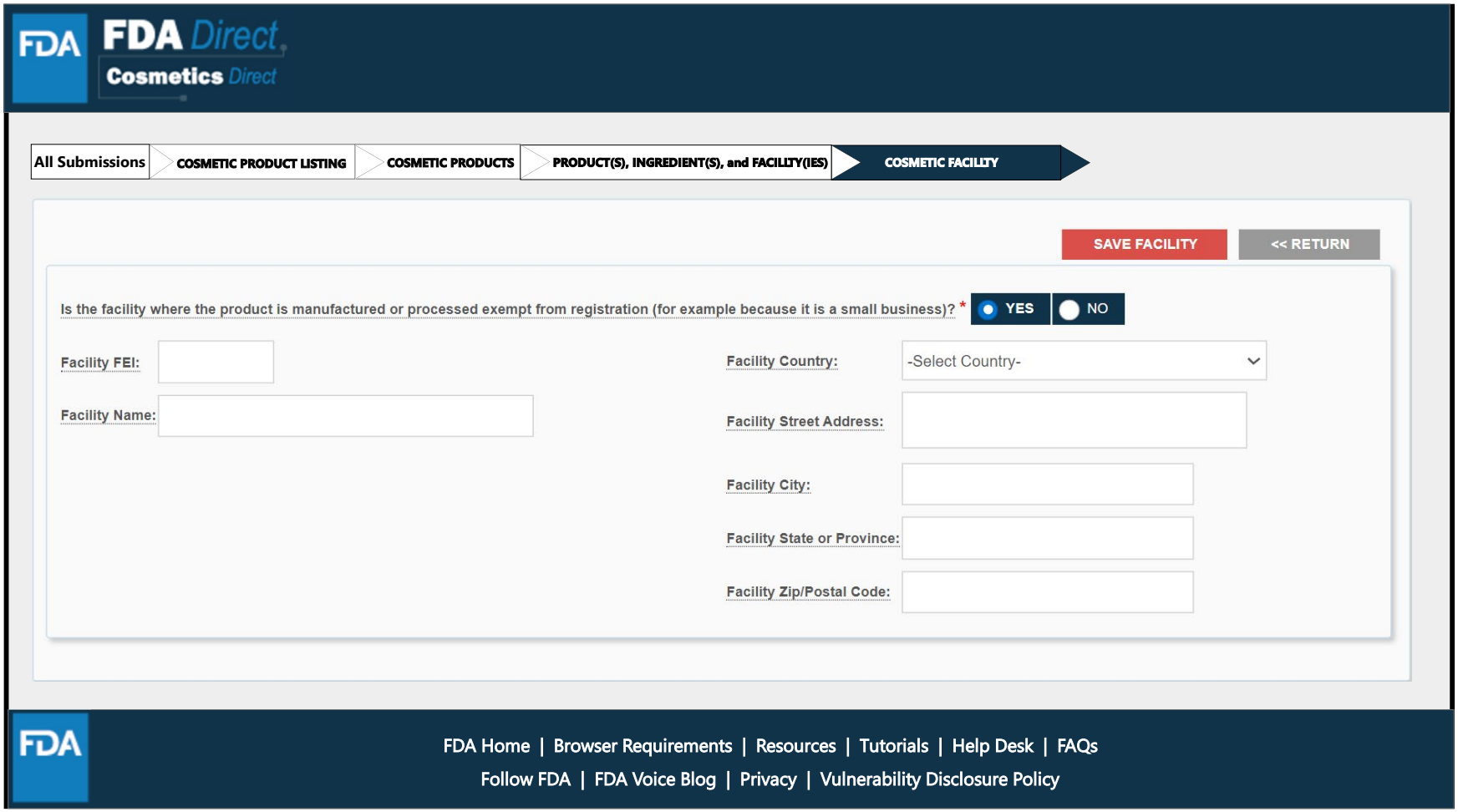
List of Facilities Where The Cosmetic is Manufactured or Processed IS NOT Exempt From Registration

If "**NO**" is selected for, "***Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?***" the FEI (FDA Establishment Identifier) is mandatory, and the name/address is greyed.



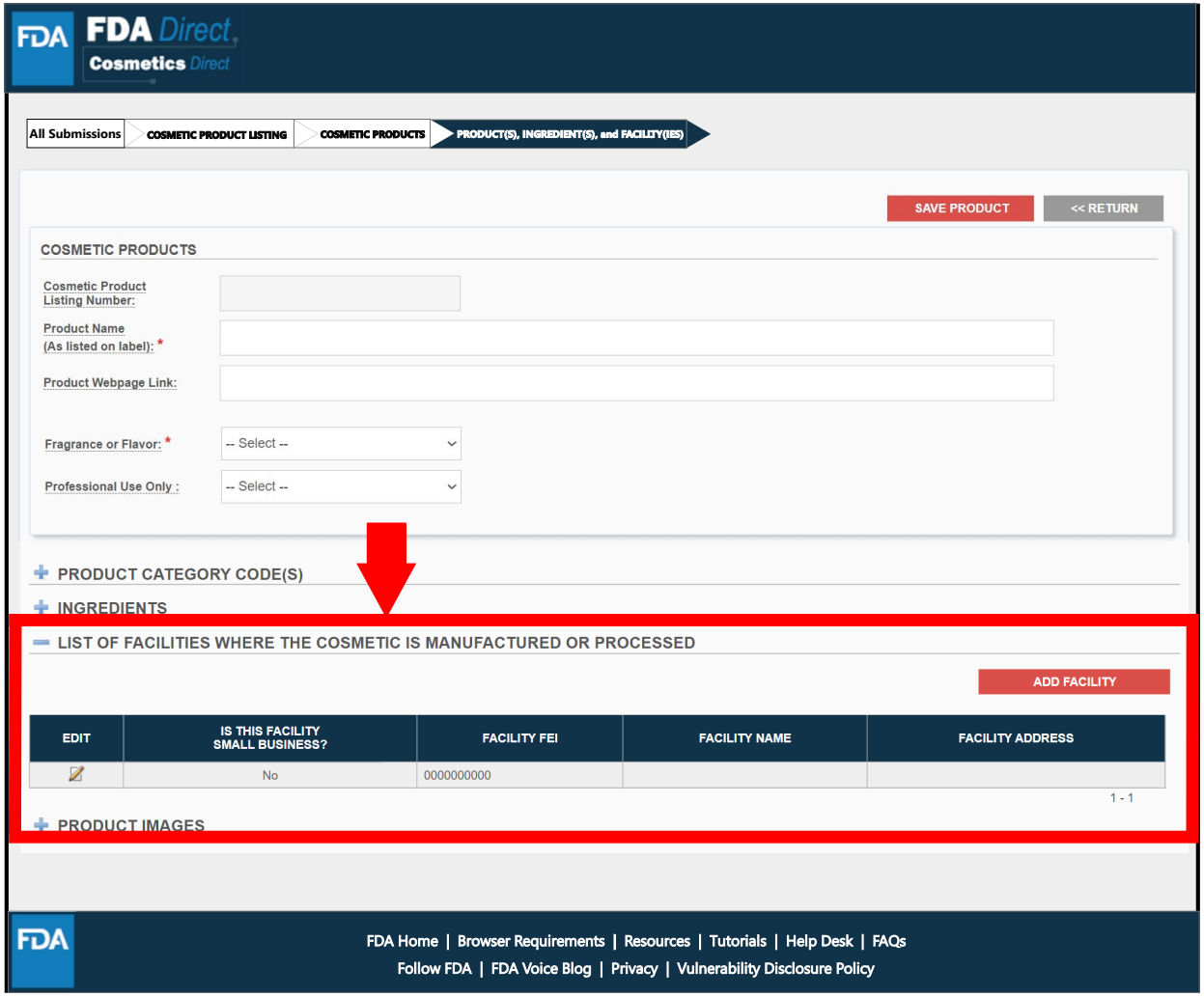
List of Facilities Where The Cosmetic is Manufactured or Processed IS Exempt From Registration

If "**YES**" is selected for, "***Is the facility where the product is manufactured or processed exempt from registration (for example because it is a small business)?"*** all data fields are optional.



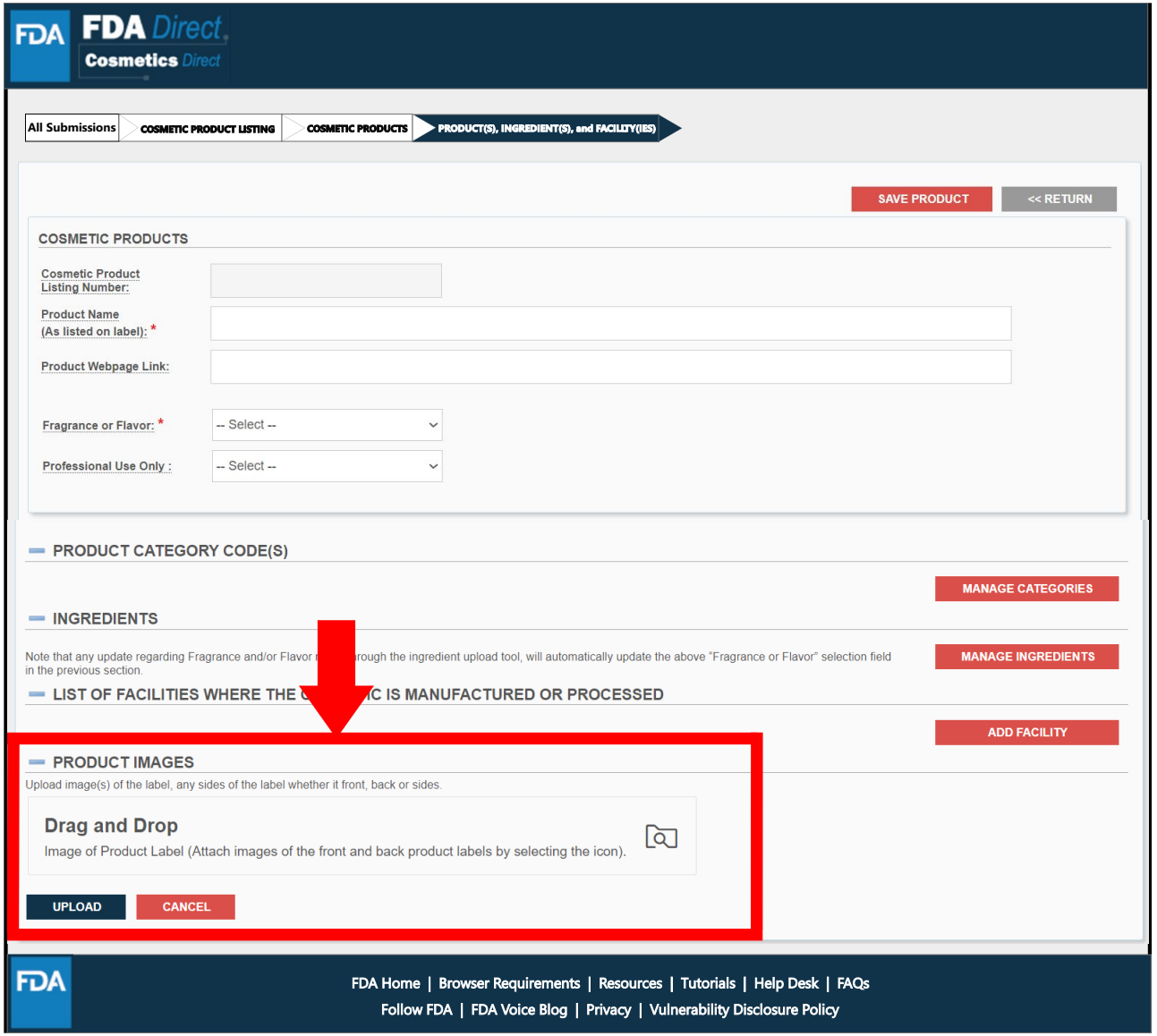
List of Facilities Where The Cosmetic is Manufactured or Processed

- Once complete, click '**SAVE FACILITY**' and the FACILITY will be saved on the previous page under the **LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED** tab in the **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES)** section.



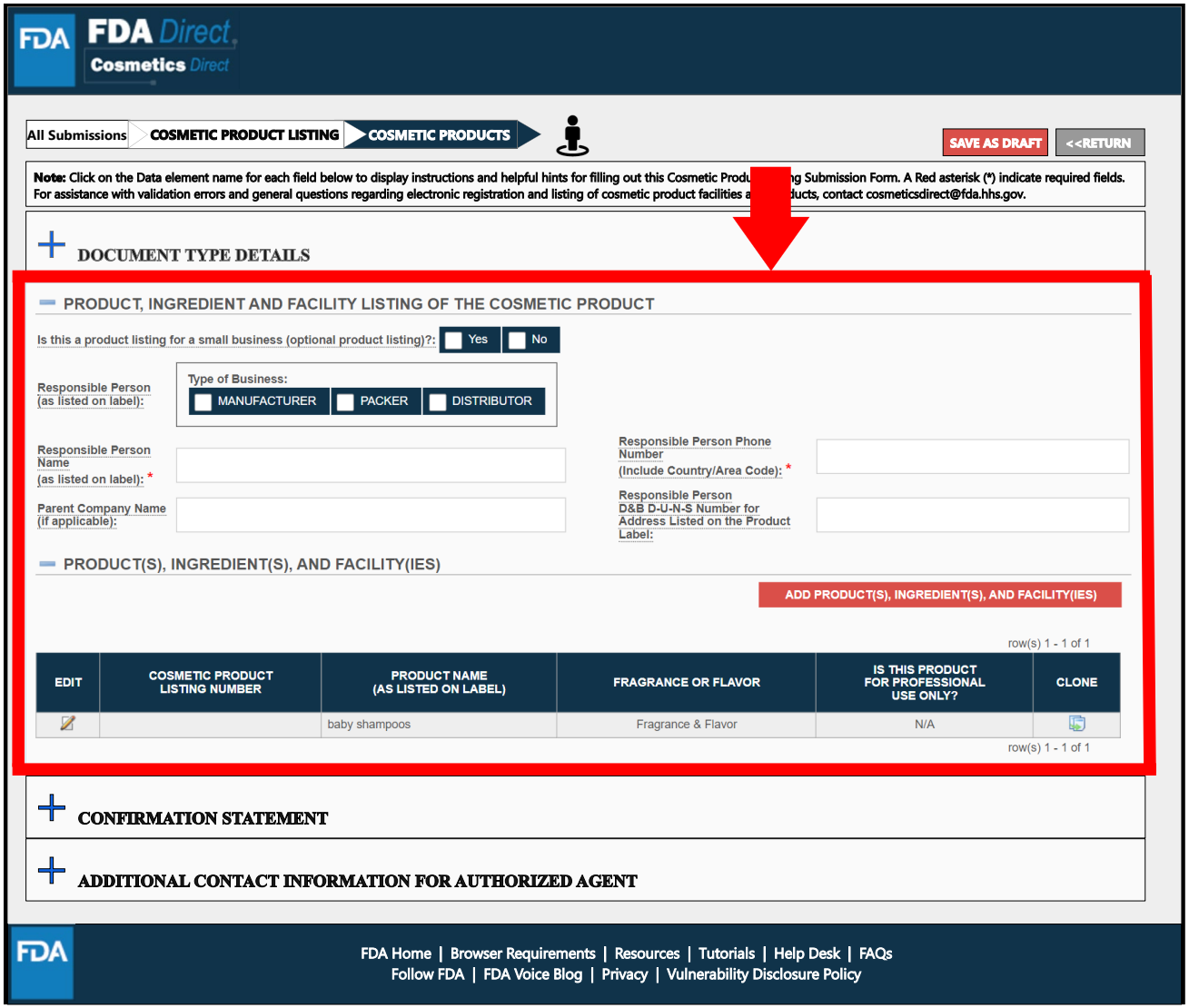
Product Images

- Upload an image of the label on any side of the label, whether it is front, back, or side, by selecting or dragging and dropping the image.
- The image must be in a .jpg format.
- Additionally, if you are uploading more than one image, ensure that the naming convention for each image is different/unique.



Product, Ingredient and Facility Listing of The Cosmetic Product: Product(s), Ingredient(s), and Facility(ies)

- AFTER selecting SAVE PRODUCT, the overall product details will be displayed under **PRODUCT(S), INGREDIENT(S), AND FACILITY(IES).**
- ANY similar PRODUCT with common ingredient(s) can be CLONED by selecting the CLONE icon.
- If any edit needs to be made, select the icon under the EDIT tab.

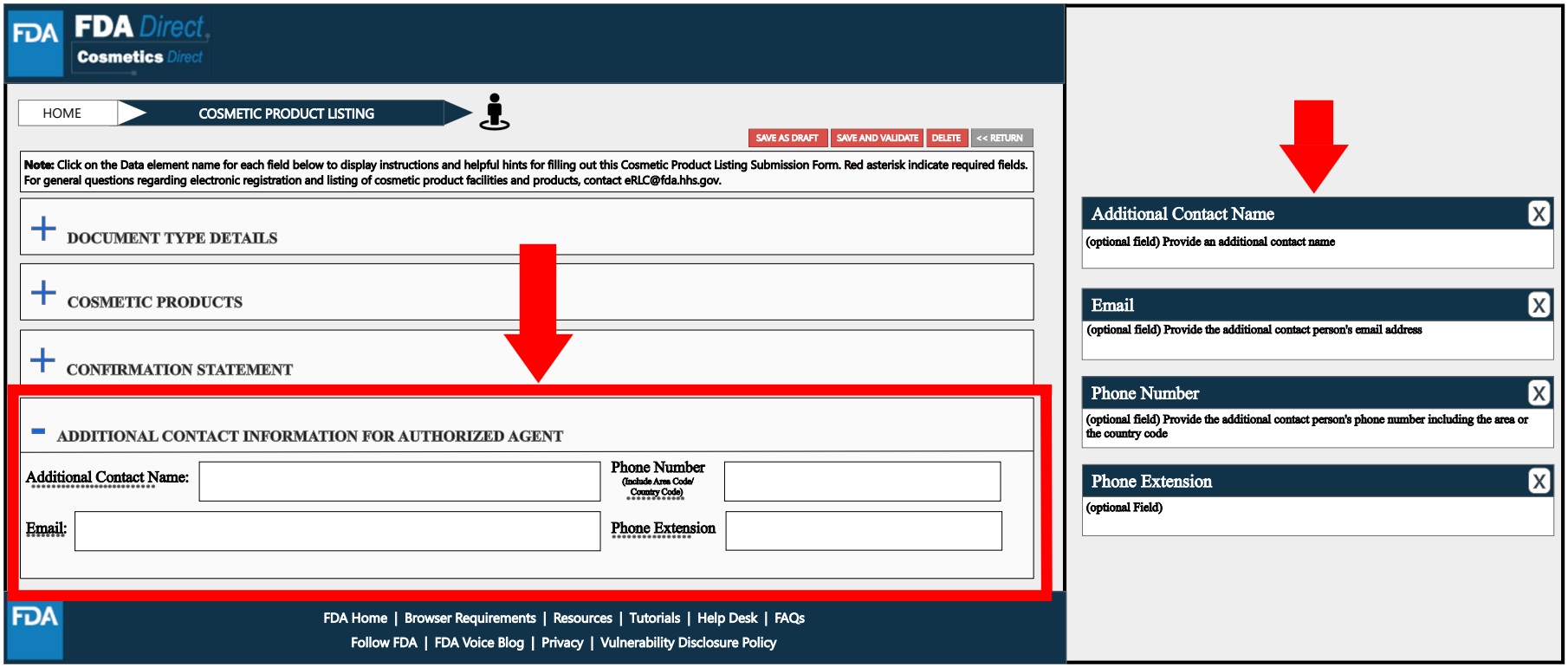


Confirmation Statement

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

Additional Contact Information for Authorized Agent

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

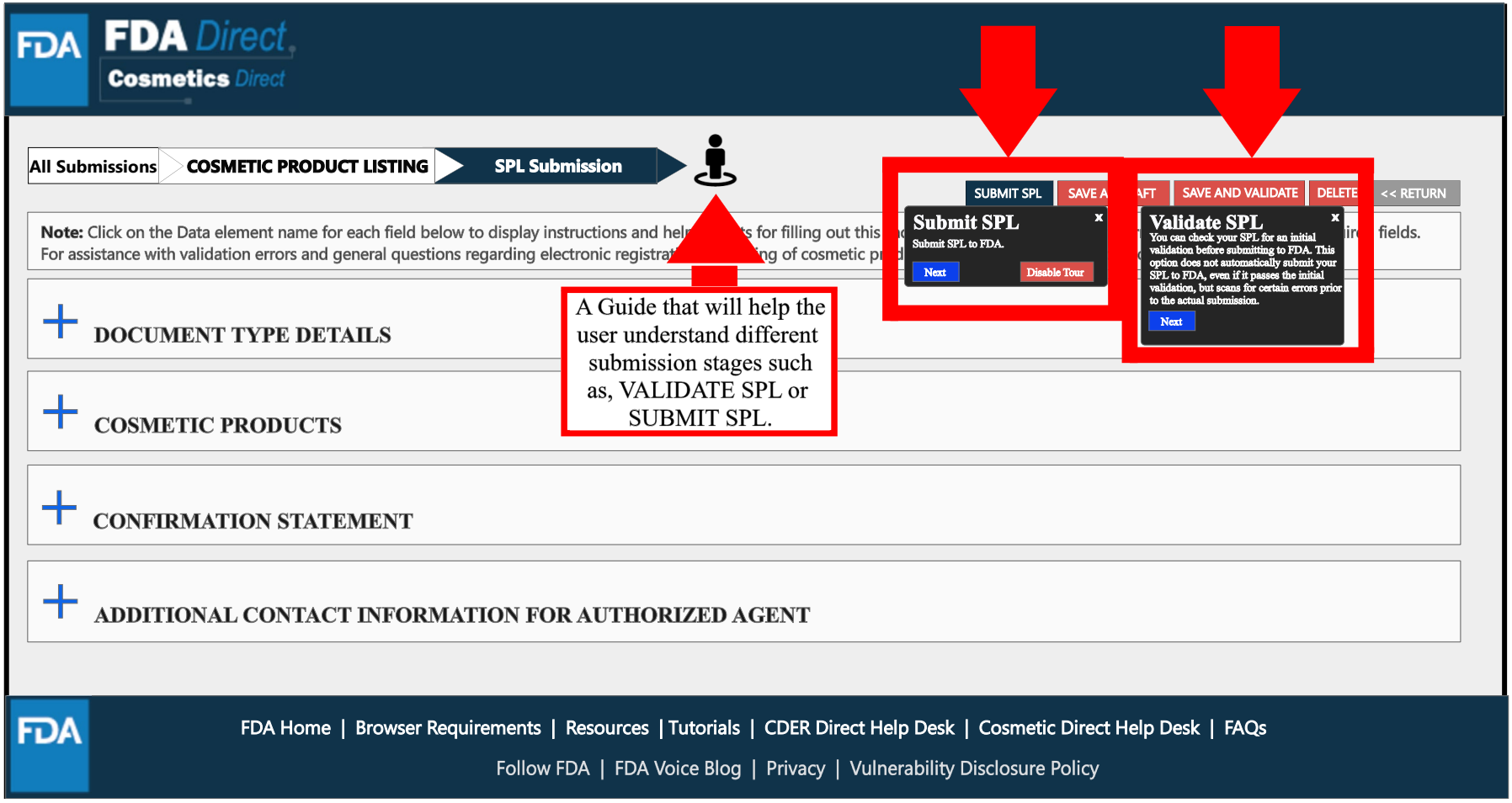


Completed

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

OR

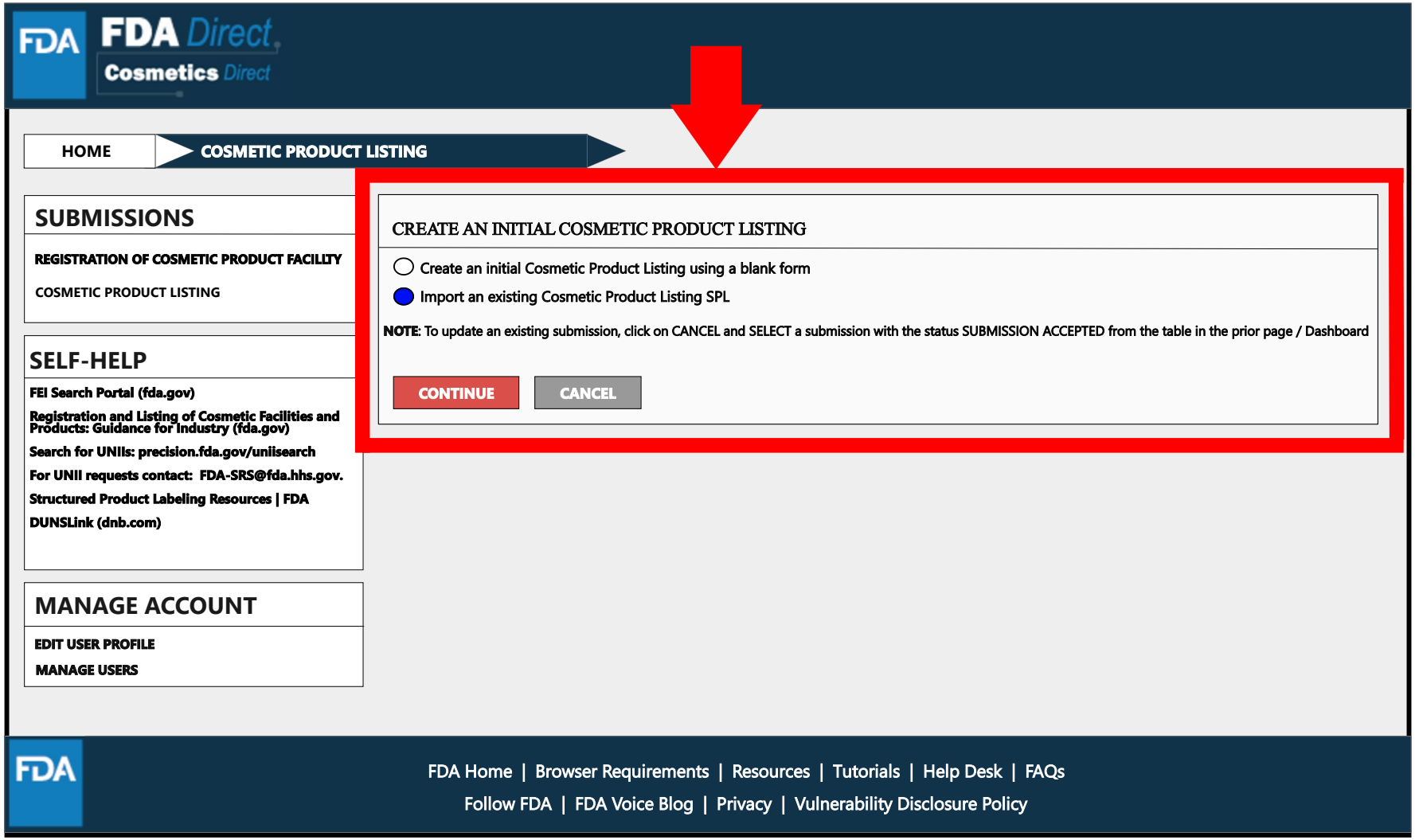
Select **SUBMIT SPL** for the form to be submitted to FDA.



Upload an Existing File

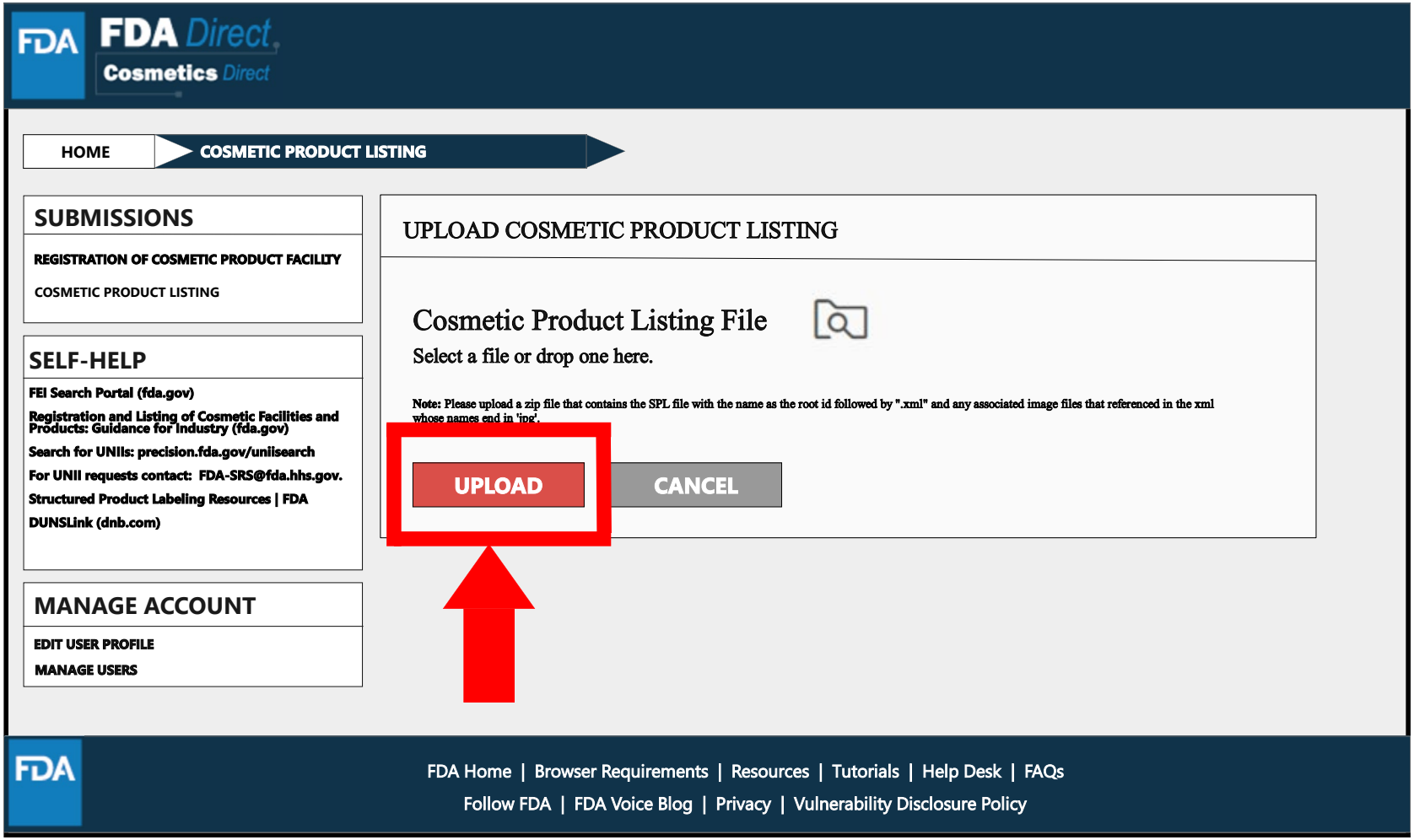
Upload an Existing File

To upload a file, select **Import an existing Cosmetic Product Listing SPL**. Importing an existing Cosmetic Product Listing SPL is beneficial for bulk submission.



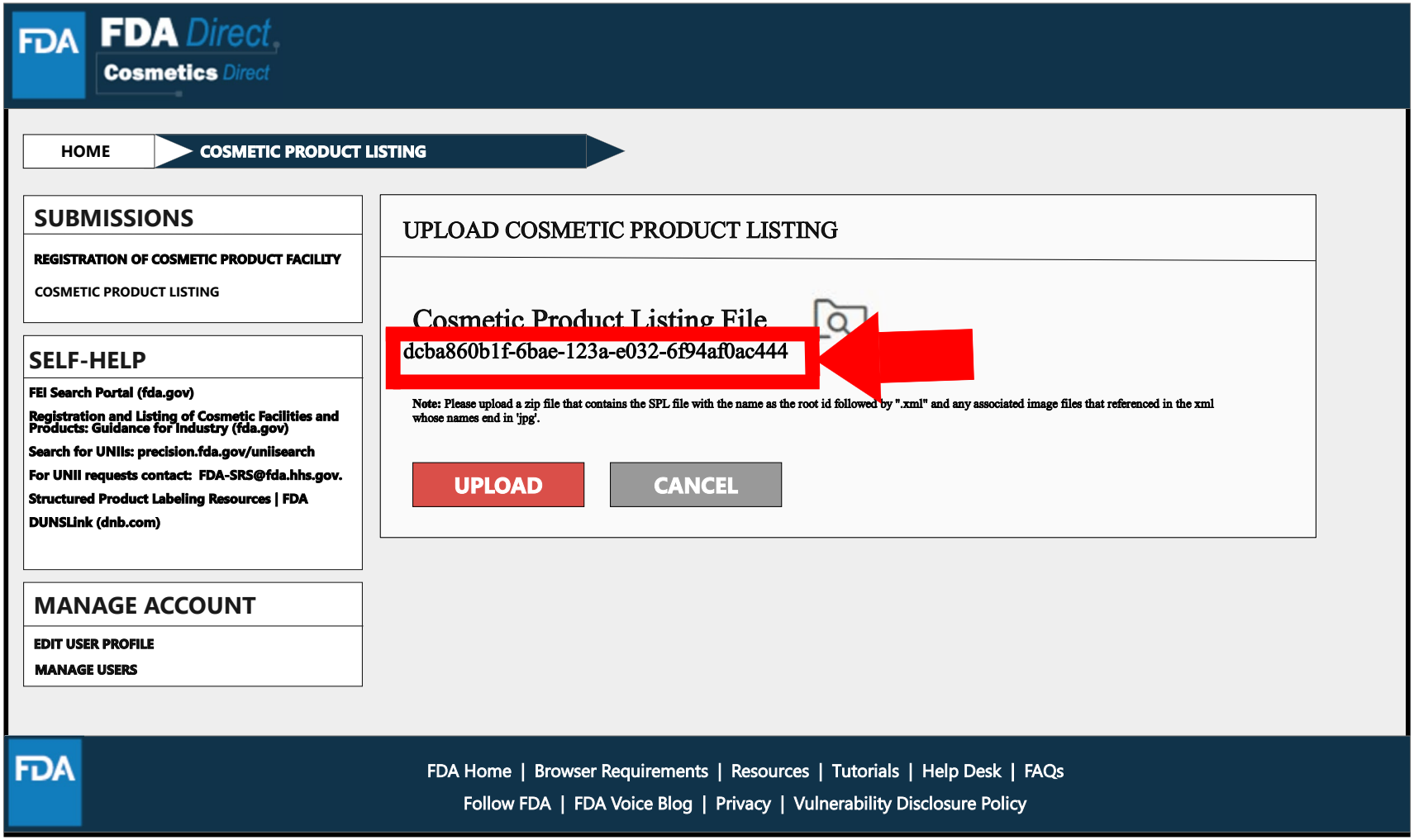
Upload a File

A user can upload a pre-existing ZIP file; this file may contain both the xml file and image (jpg) files. SPL 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 SPL Resources link provided under SELF-HELP.



Upload a File (Example)

The content in the red box is an example of what a zip file could be; it may contain .xml file and image (jpg) files.



Zip File (Example)

An example to what an XML format could look like.

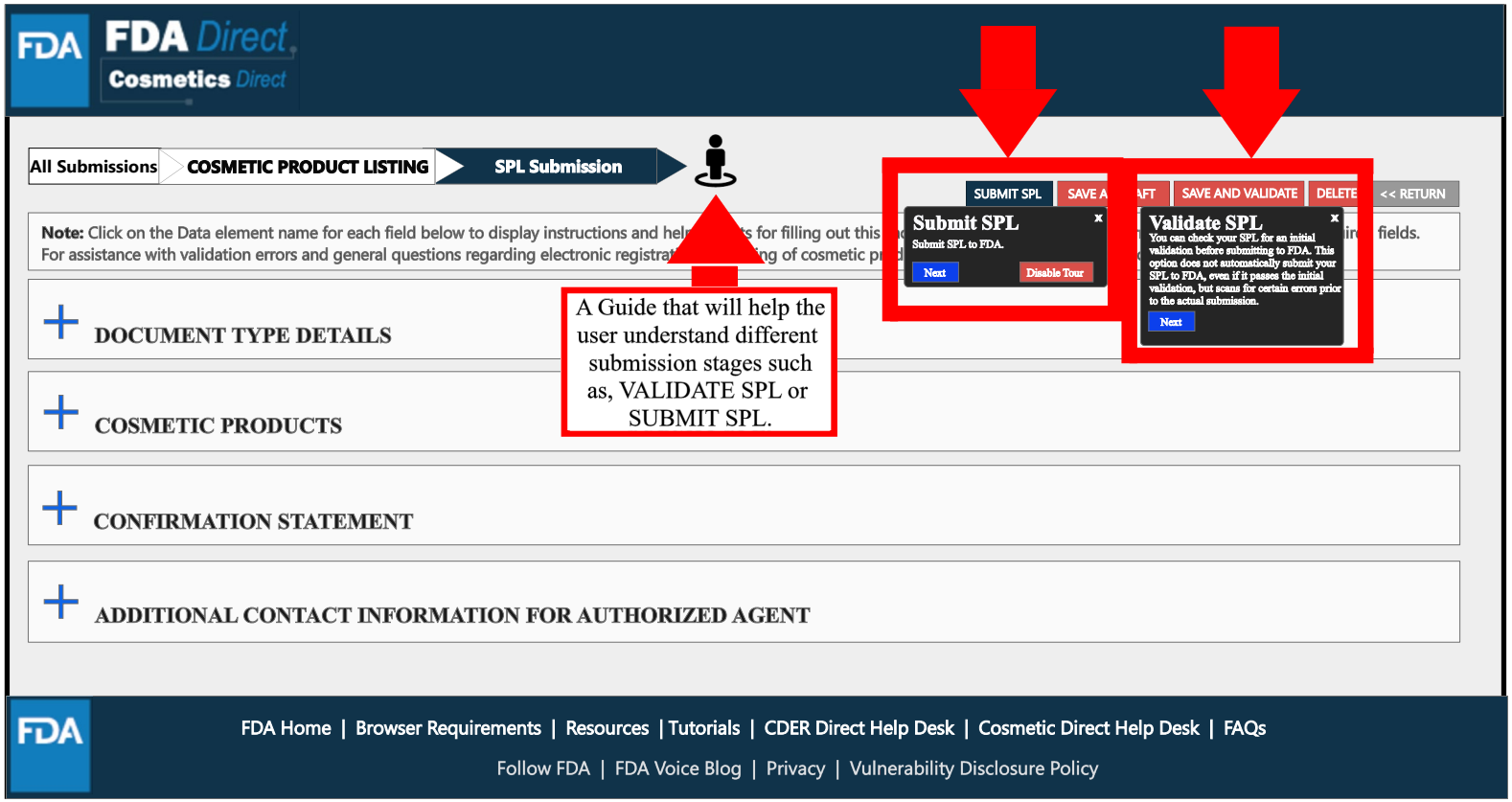
```
<?xml version="1.0" encoding="UTF-8"?>
<?xml-stylesheet href="https://www.accessdata.fda.gov/spl/stylesheet/spl.xsl" type="text/xsl"?>
<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:hl7-org:v3 https://www.accessdata.fda.gov/spl/schema/spl.xsd">
  <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 (Submission)

After **UPLOADING A FILE** (XML ZIP FILE), the system will auto-fill all the data 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: A popup will appear that says, "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."

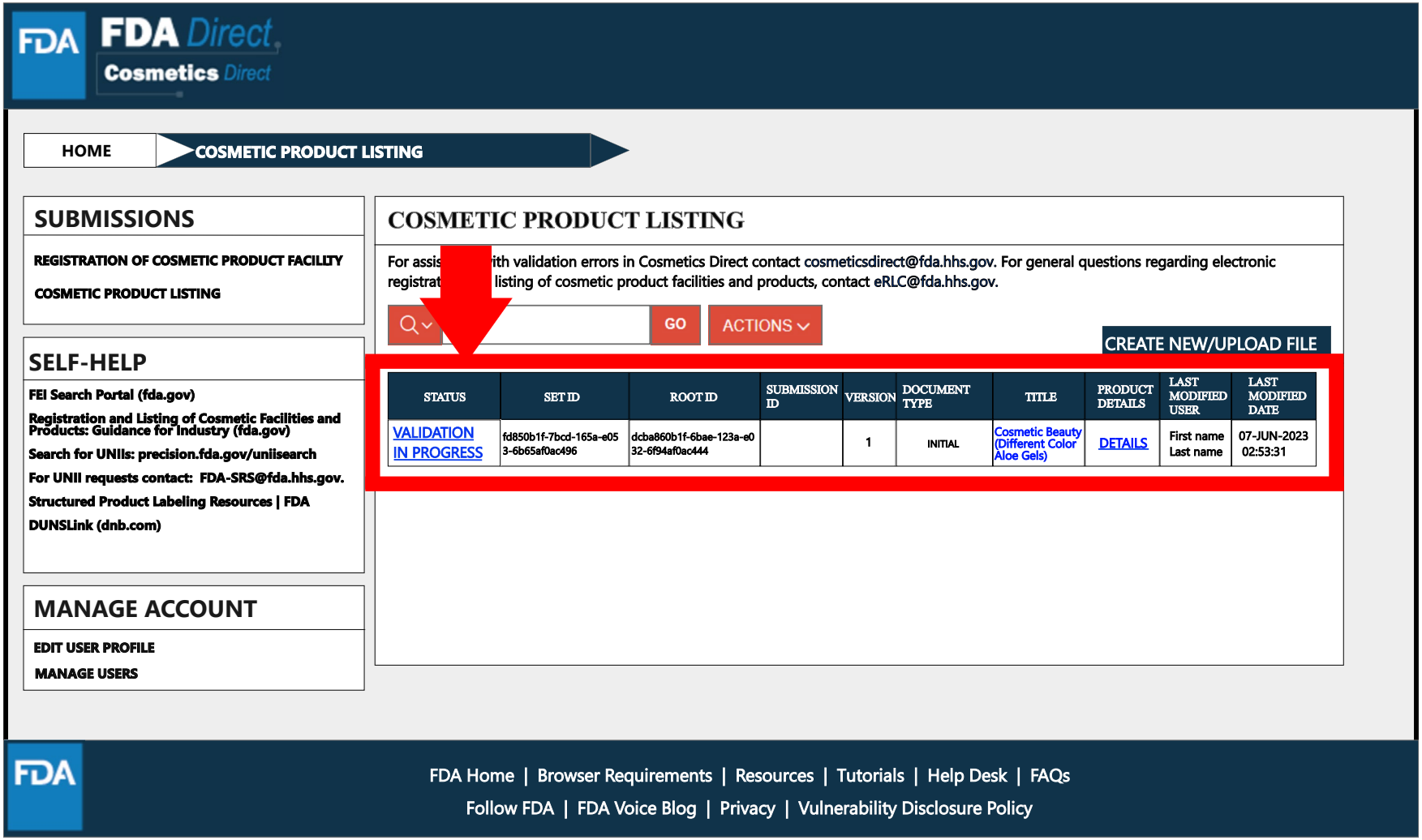
Select **SUBMIT SPL** for the form to be submitted to FDA. The Submit SPL box is a help tool that can guide a user through the process.



Product Listing Status Examples

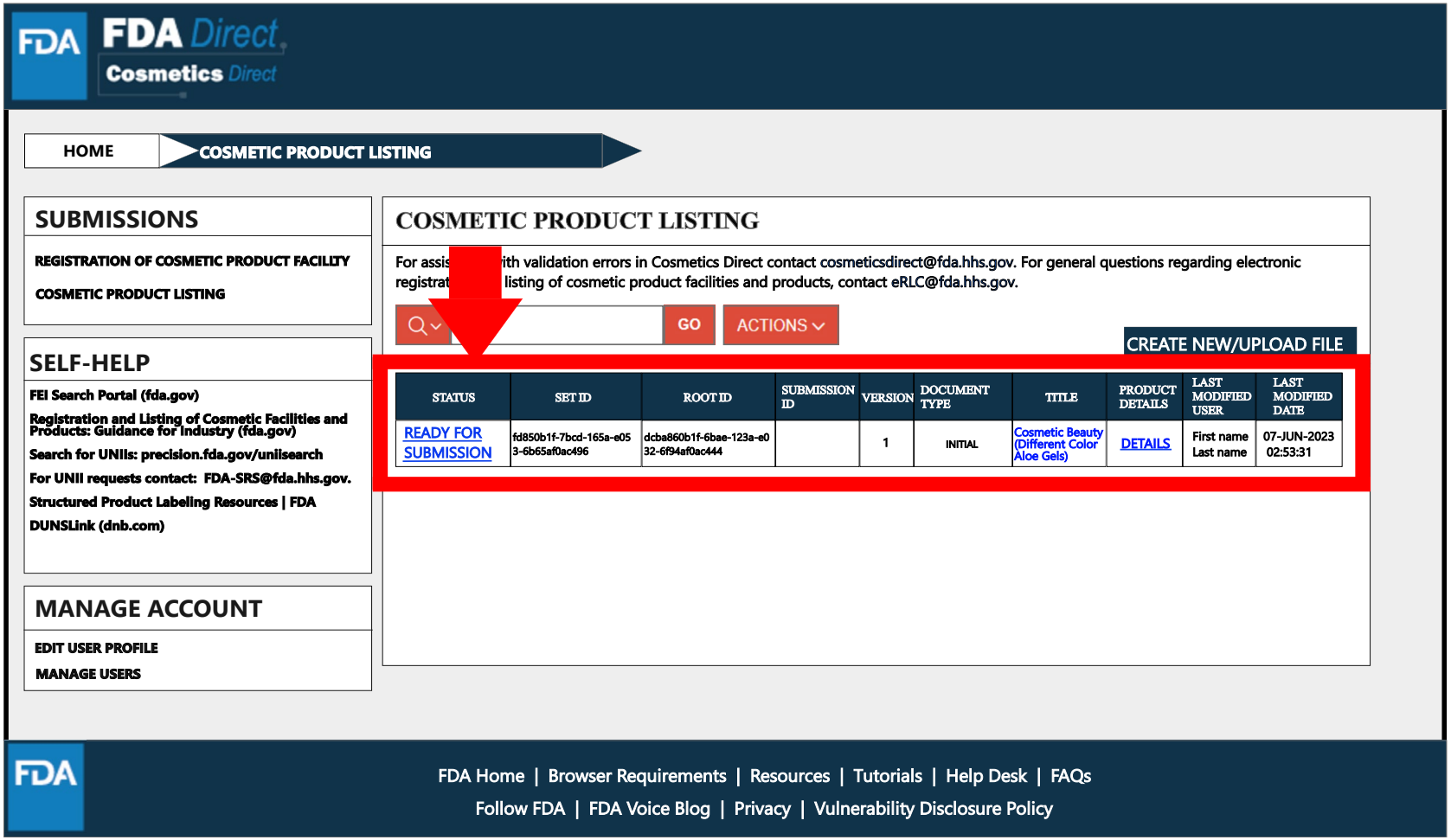
Listing Status: Validation in Progress

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**.



Listing Status: Ready for Submission

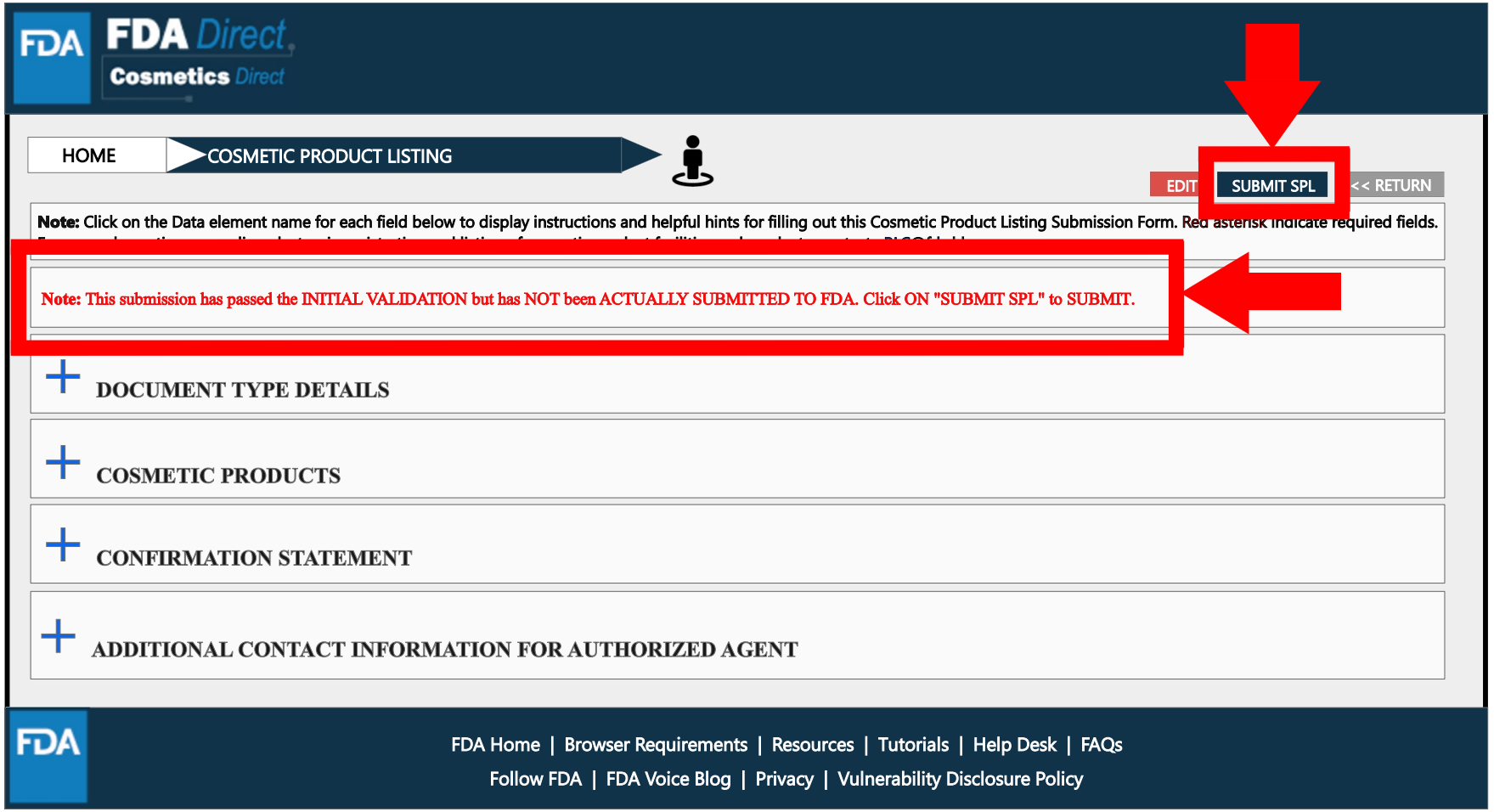
VALIDATE SPL: You can check your SPL for an initial validation before submitting to FDA. This option does not automatically submit your SPL to FDA, even if it passes the initial validation, but scans for certain errors prior to the actual submission. Once the system has completed an INITIAL VALIDATION,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



Listing Status: Ready for Submission to Submit SPL

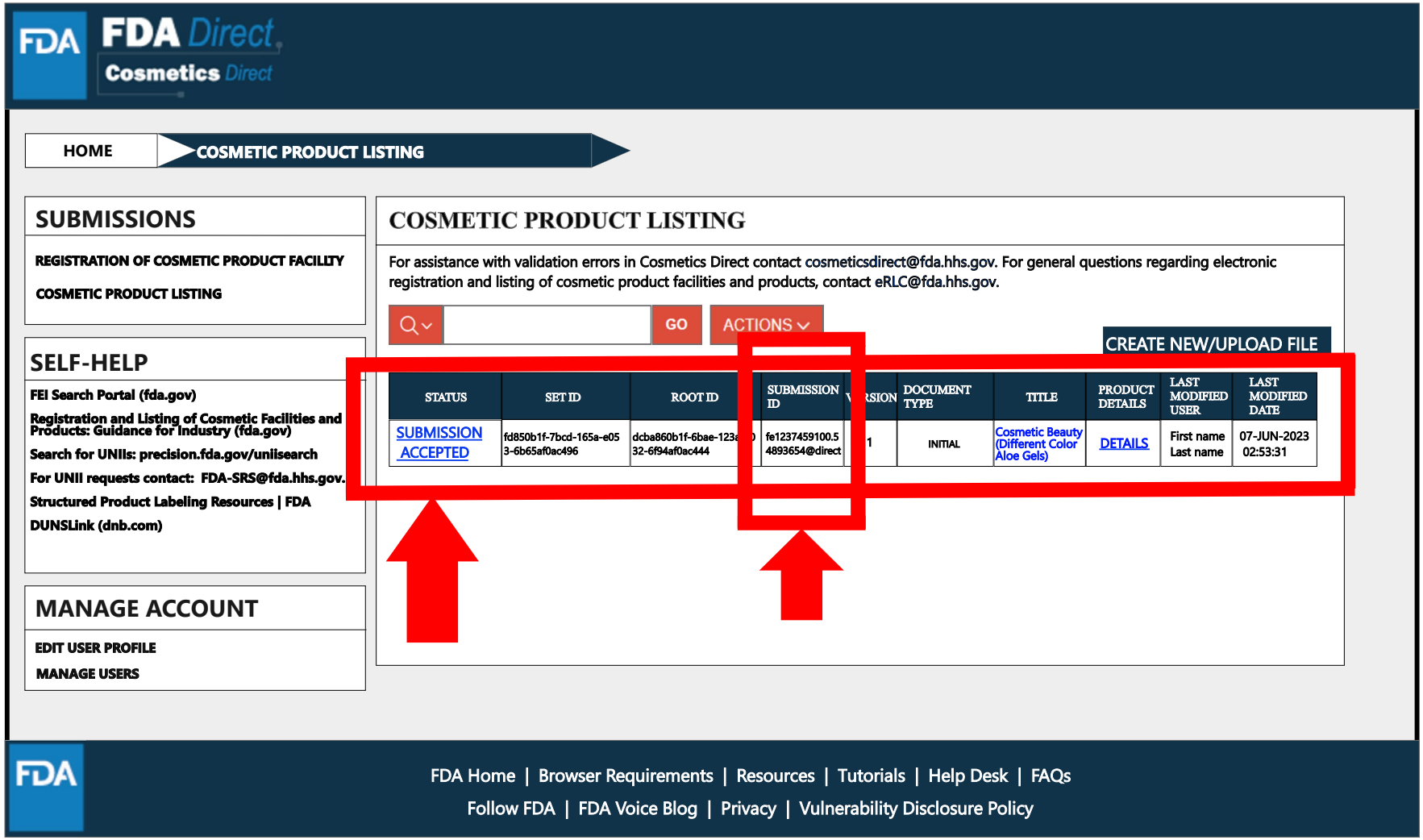
By clicking on the **READY FOR SUBMISSION**, the listing will be ready for **SUBMIT SPL**.

The system will generate a message stating, *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 has been successfully completed. A **SUBMISSION ID** will be given to all **ACCEPTED SUBMISSIONS**.

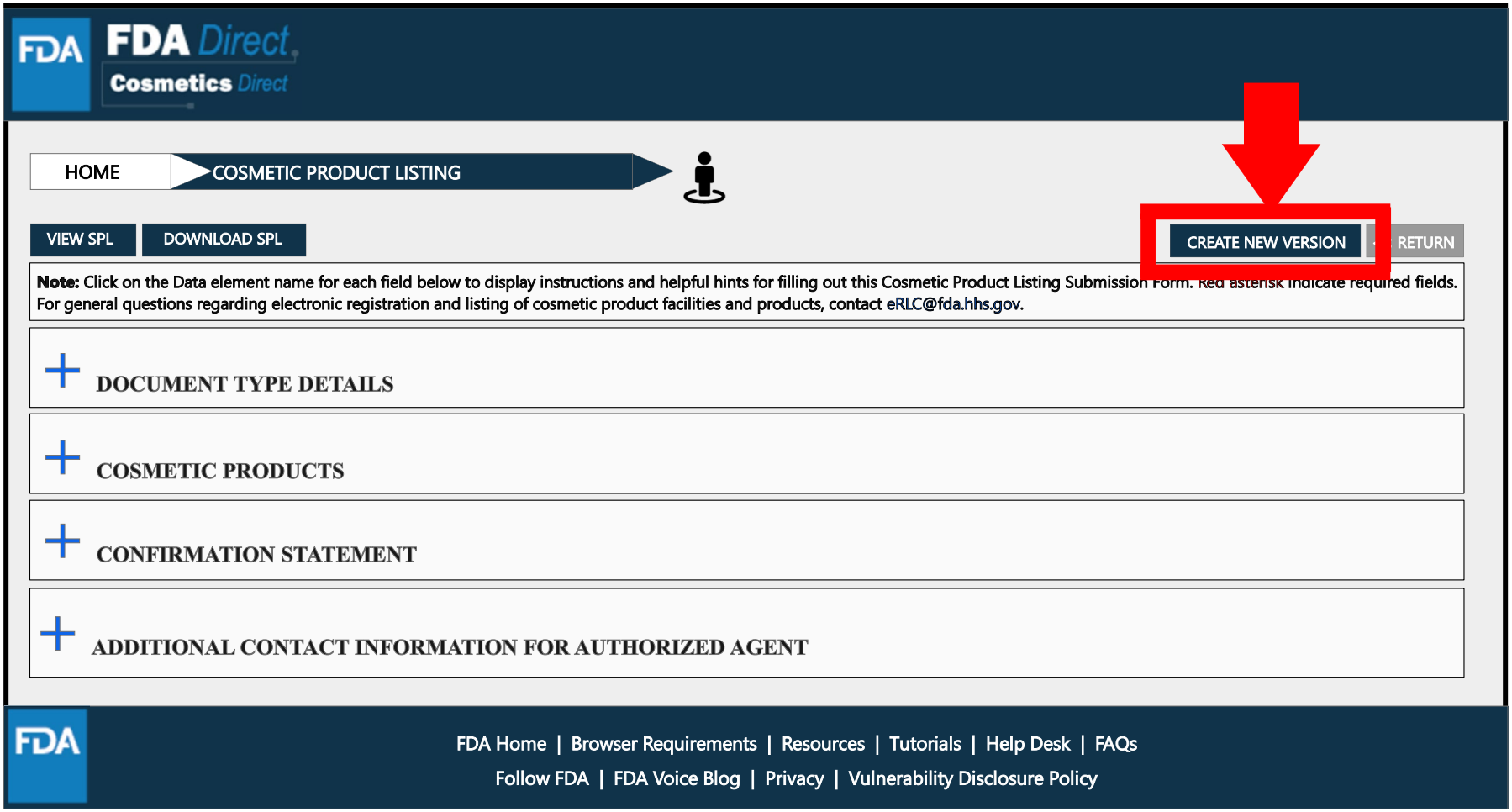


Listing Status: Submission Accepted to View SPL and Download SPL

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

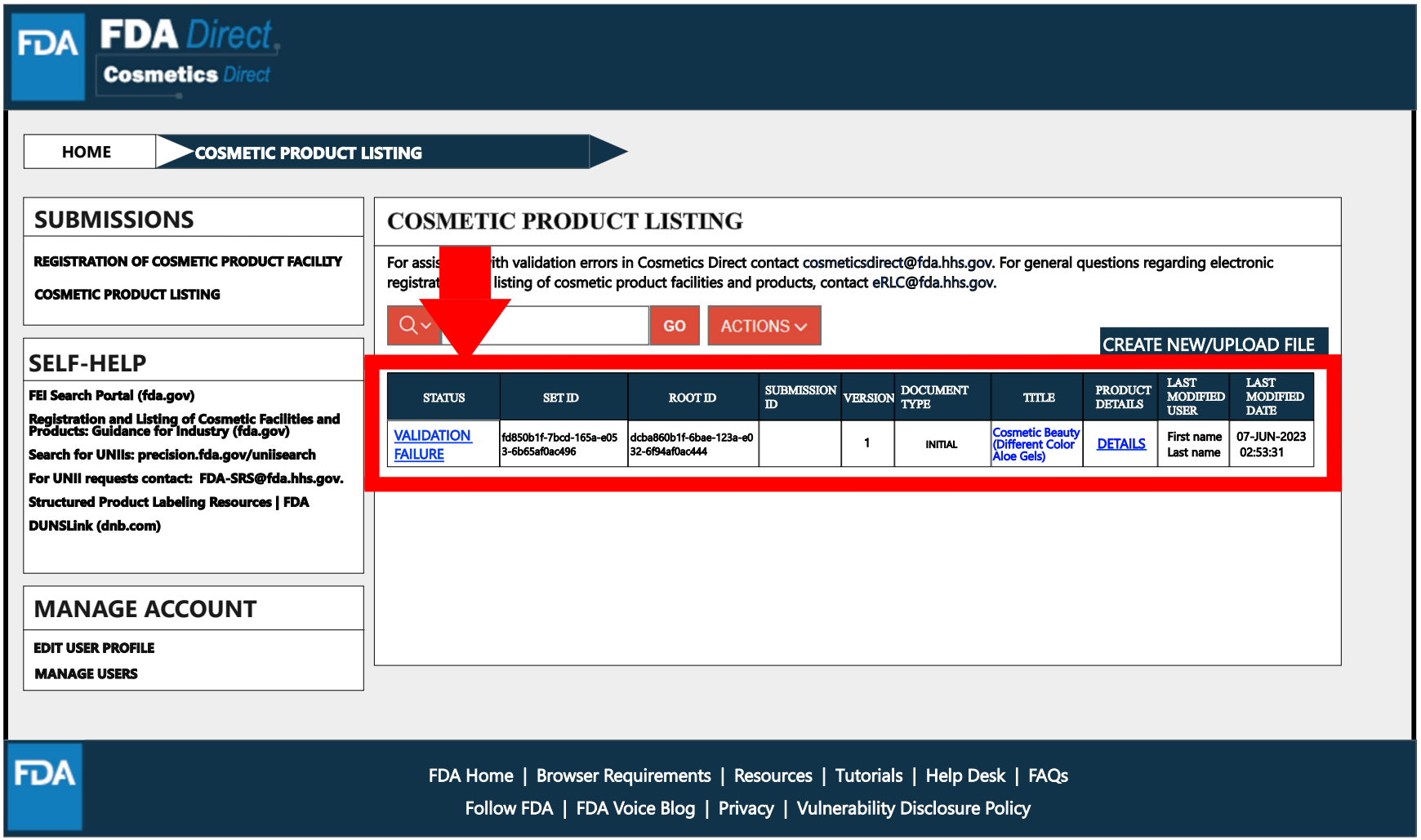
Clone Successfully Submitted SPL

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



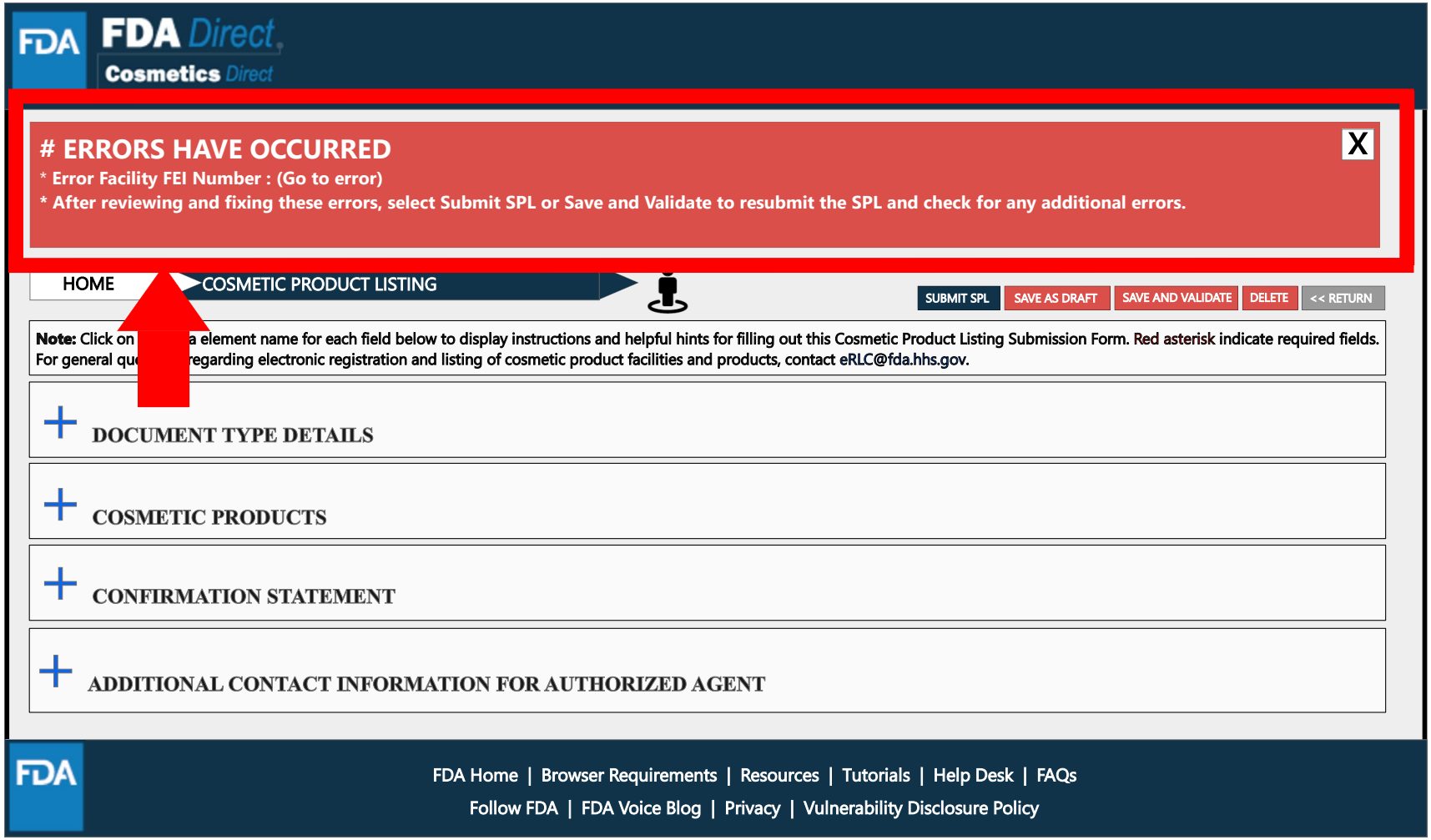
Listing Status: Validation Failure

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



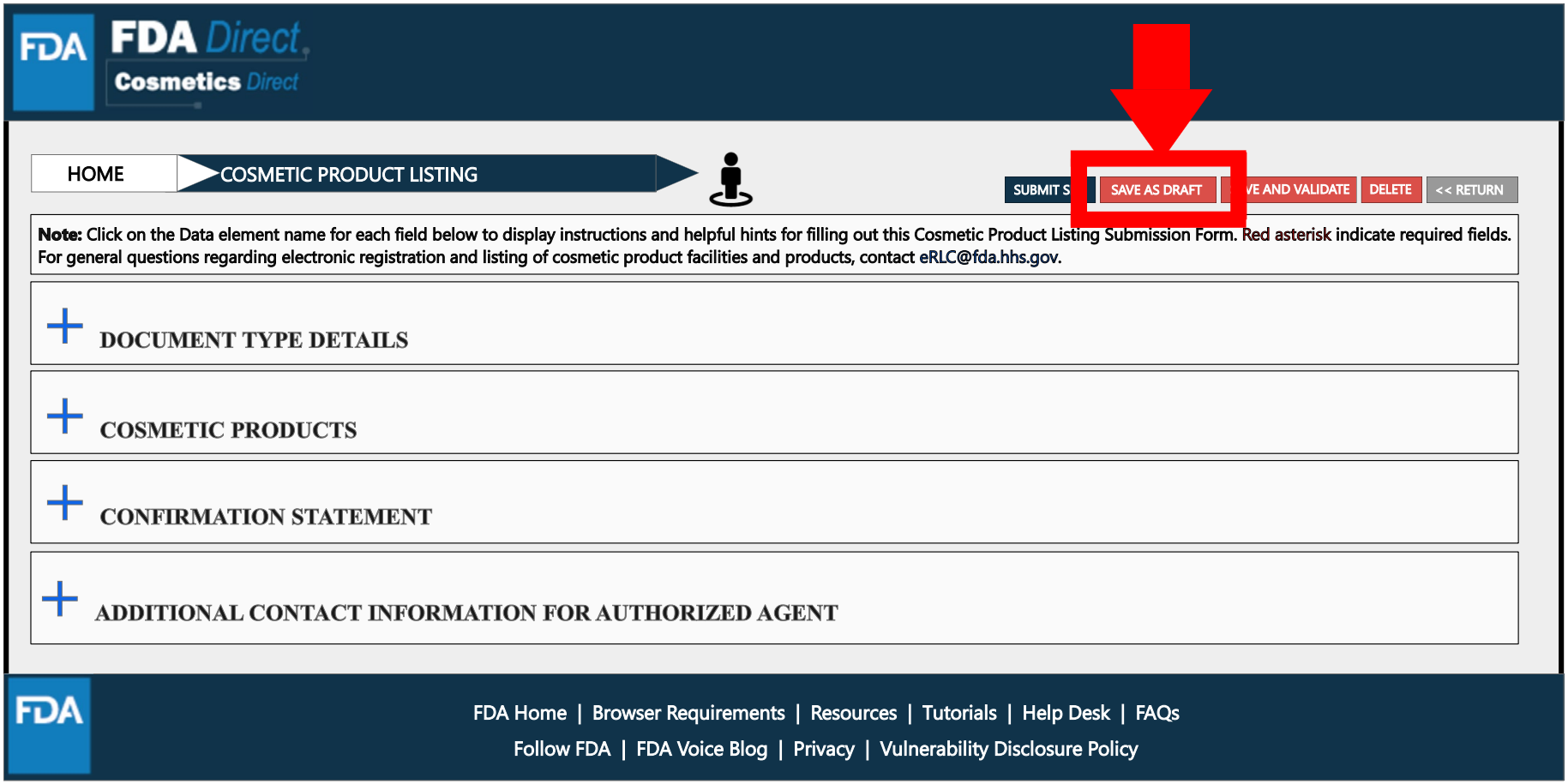
Listing Status: Validation Failure (List of Errors)

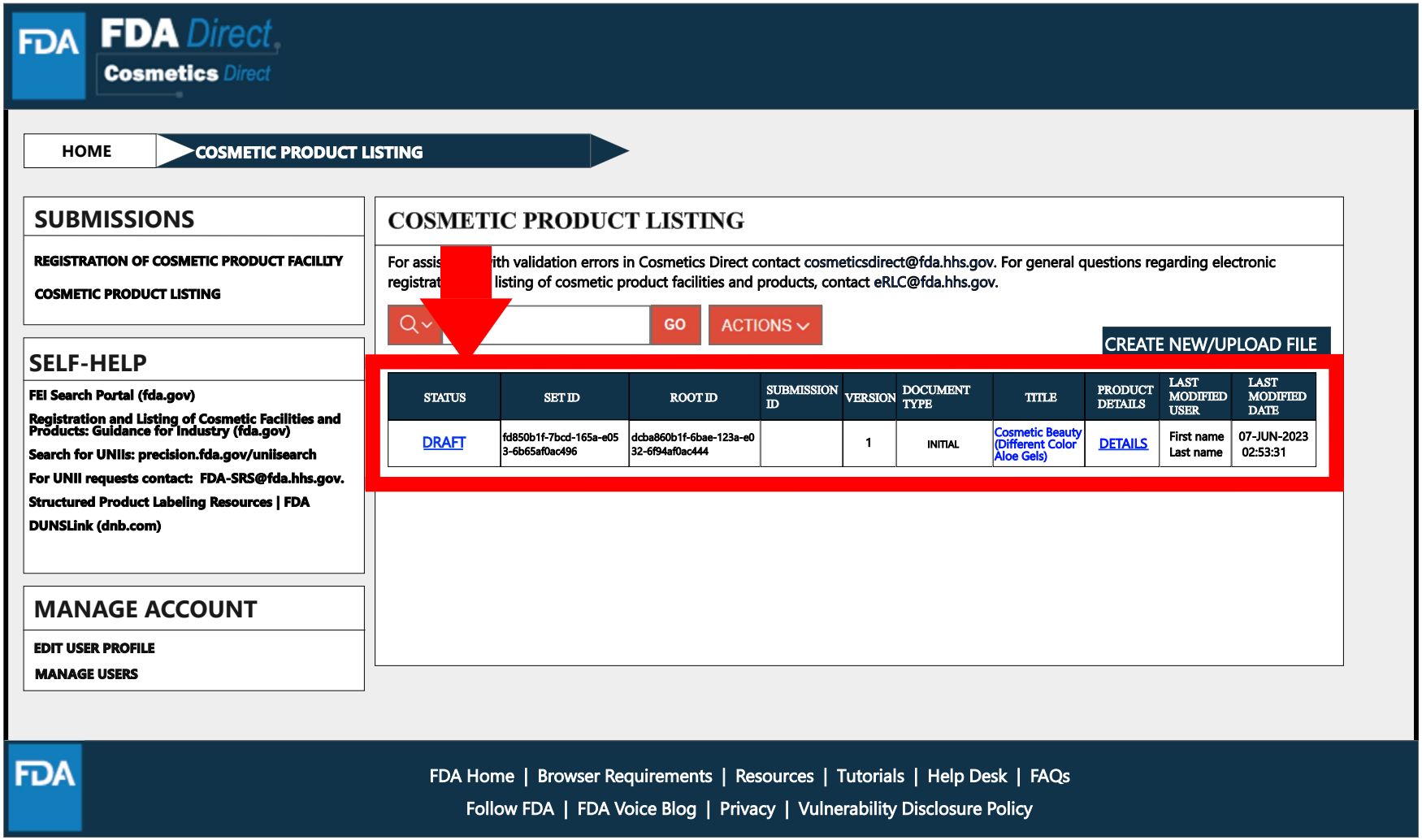
When user selects **VALIDATION FAILURE** status, the system will provide a list of errors that need to be fixed before submitting the SPL. After reviewing and fixing the errors, users can select **SUBMIT SPL** to resubmit the SPL or **SAVE AND VALIDATE** to check for any additional errors.



Listing Status: Save As 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**.



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**.