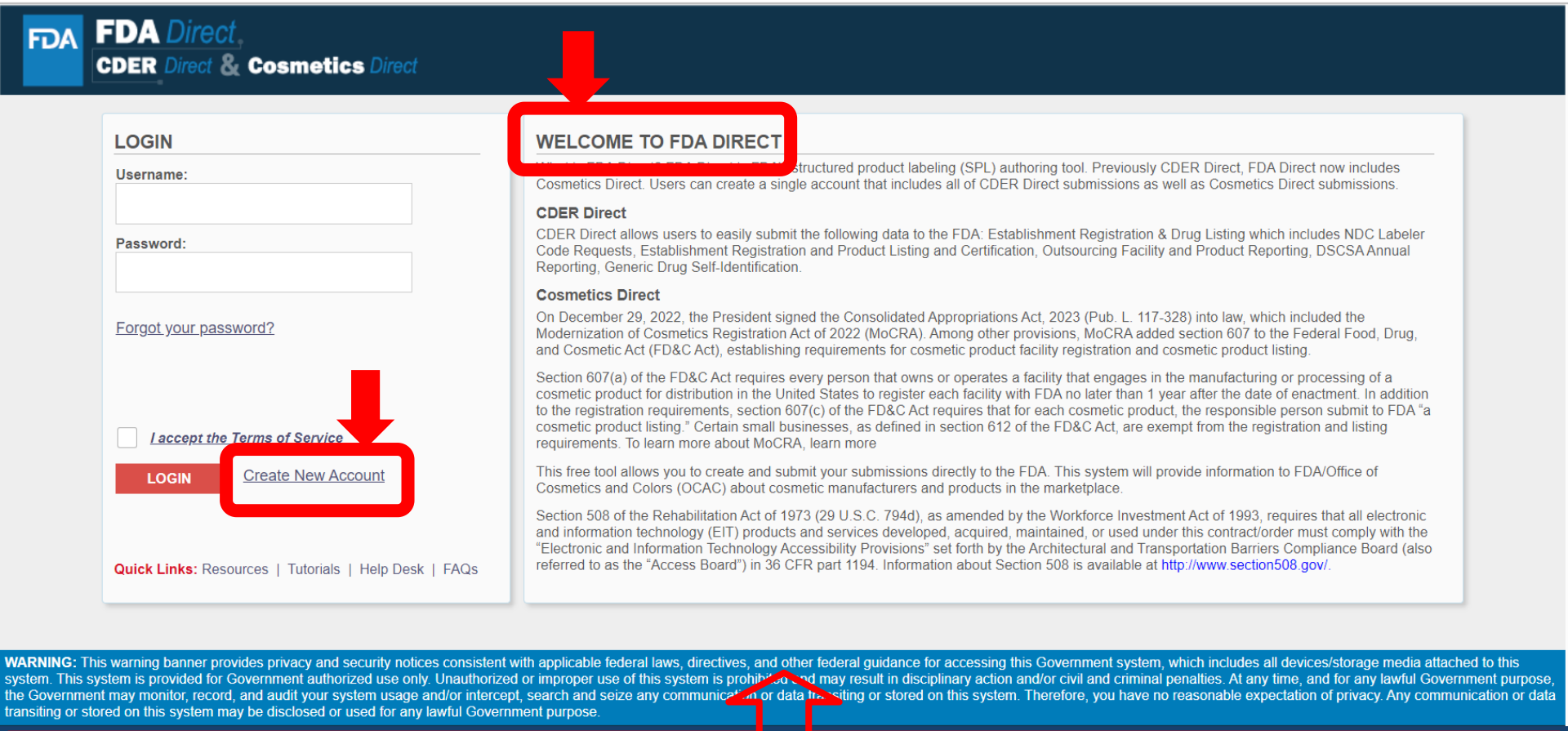
COSMETICS *DIRECT*

Electronic Submissions Portal

TABLE OF CONTENTS

FDA DIRECT HOME PAGE

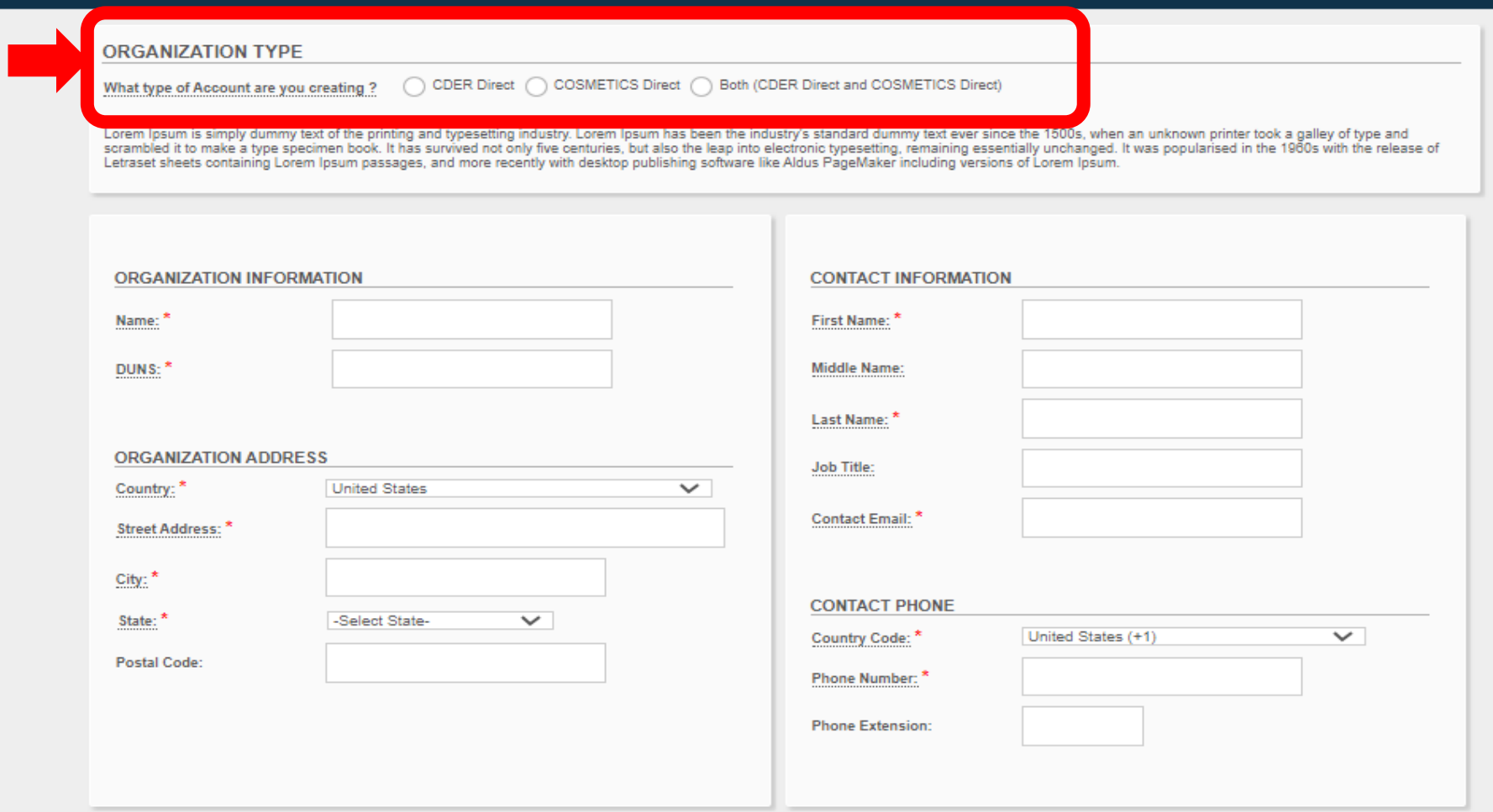
The WELCOME TO FDA DIRECT provides short background info about each (CDER Direct and Cosmetics Direct). First time user can create a new account by selecting the Create New Account.



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.

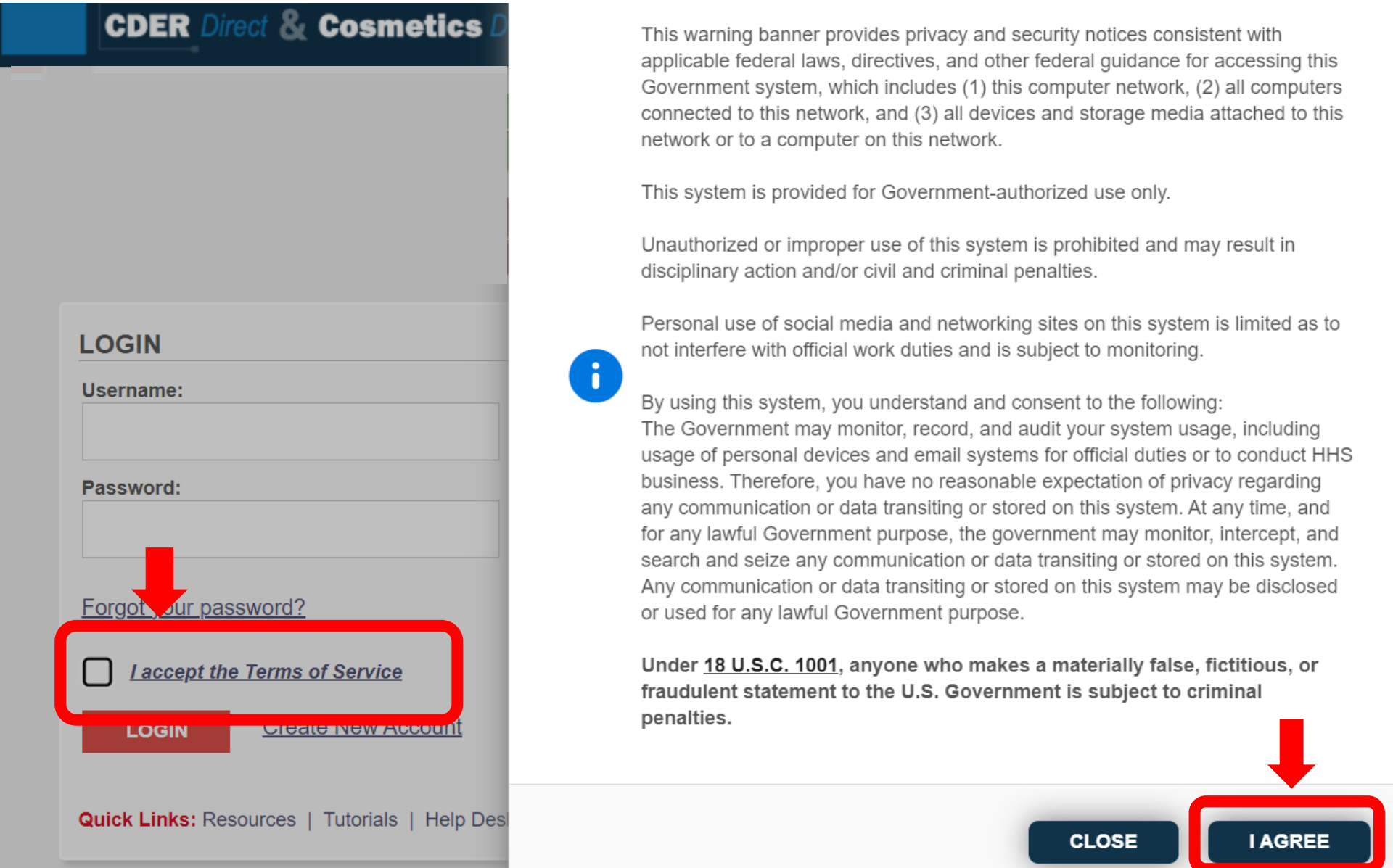
CREATE A NEW ACCOUNT

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.



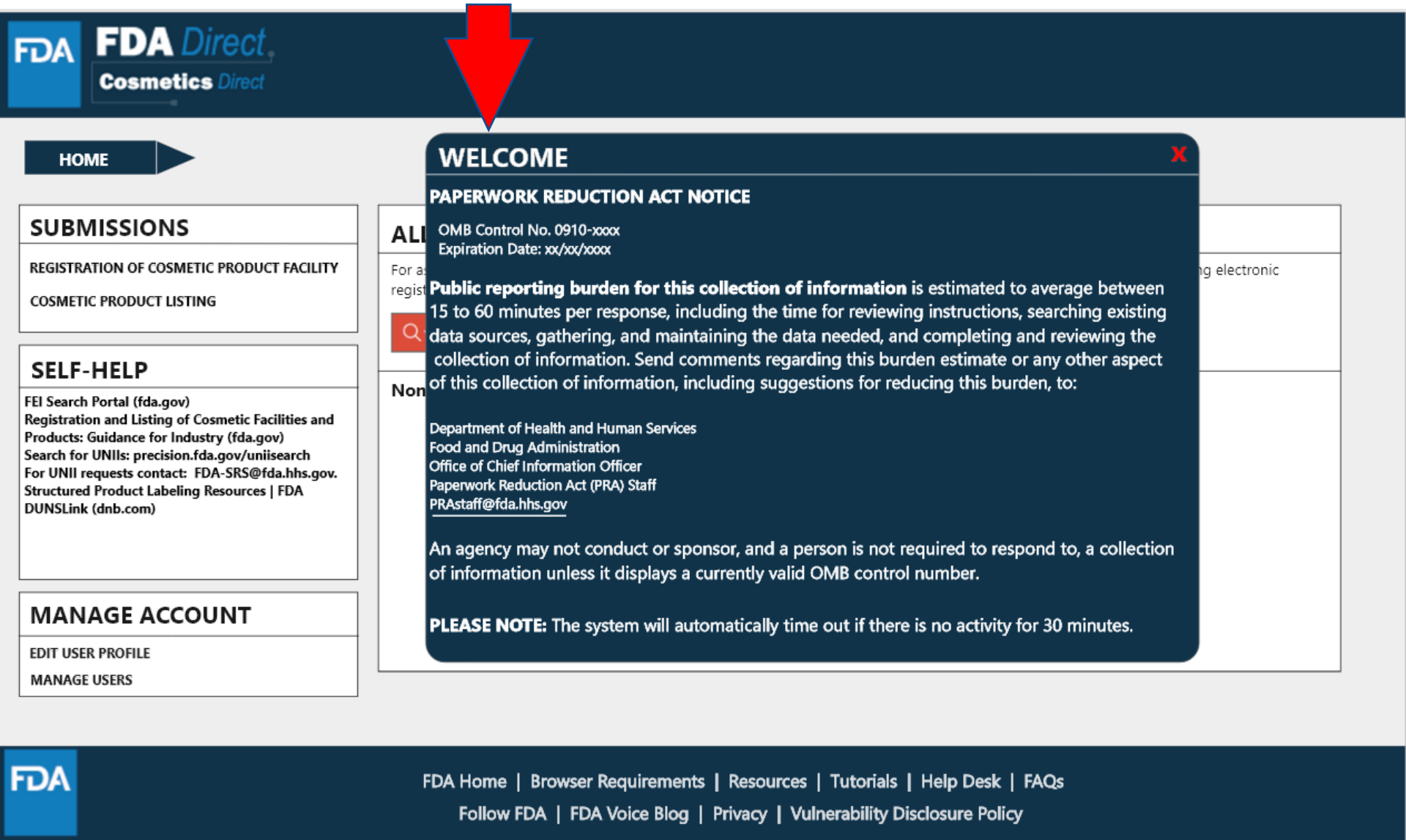
TERMS OF SERVICE

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*



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)



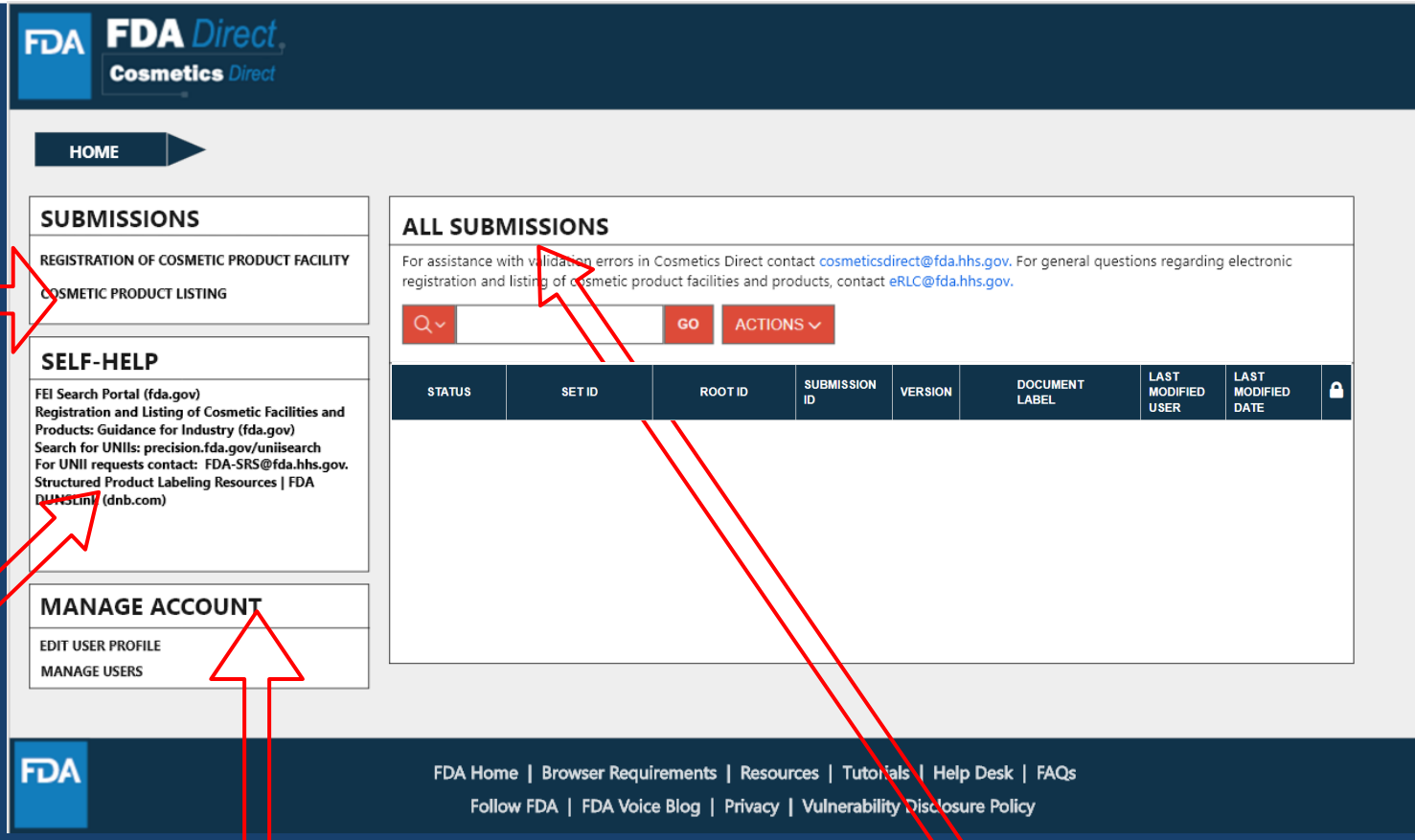
COSMETICS DIRECT HOME PAGE

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.



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

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

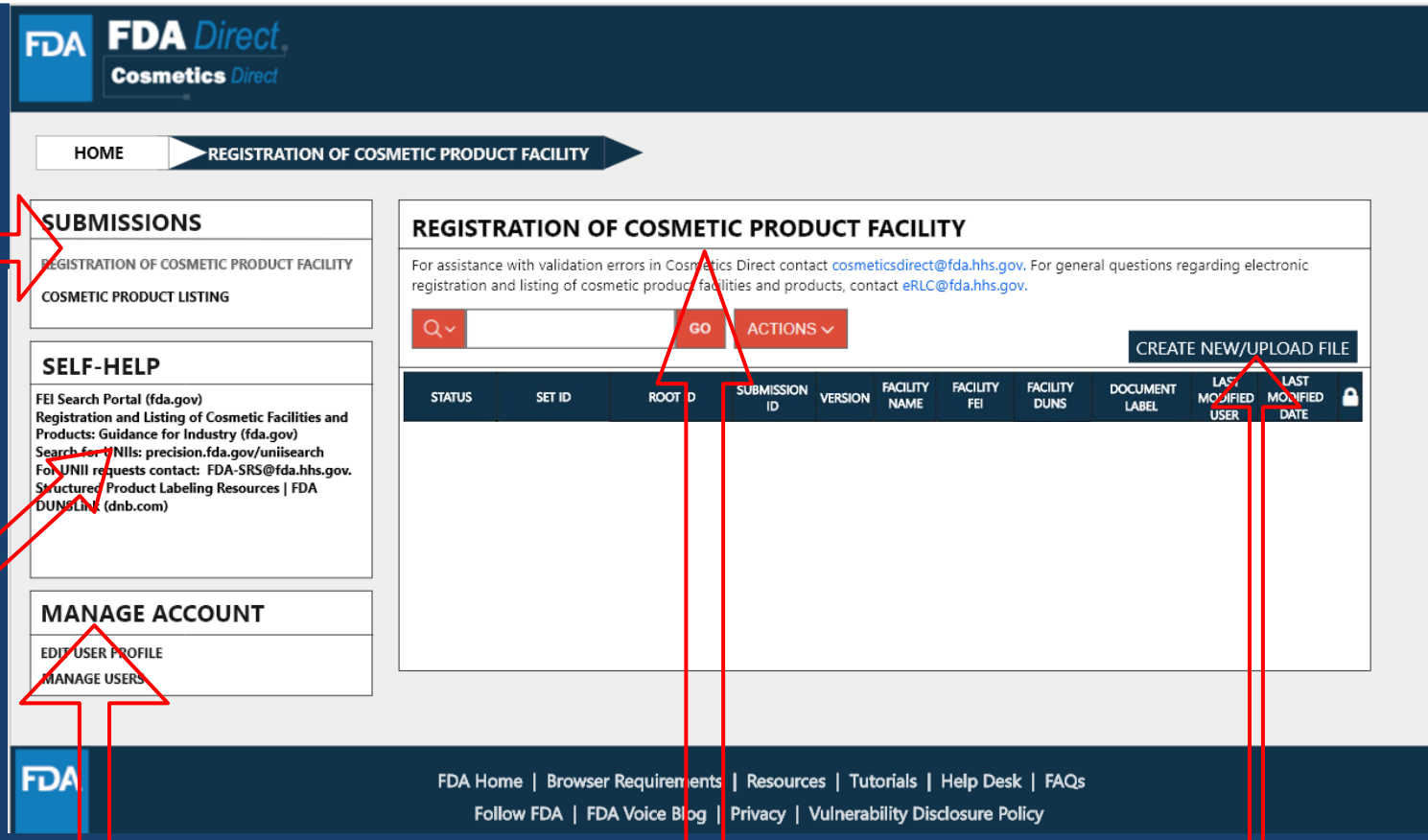
REGISTRATION OF COSMETIC PRODUCT FACILITY

HOME PAGE: REGISTRATION OF COSMETIC PRODUCT FACILITY

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

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

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



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

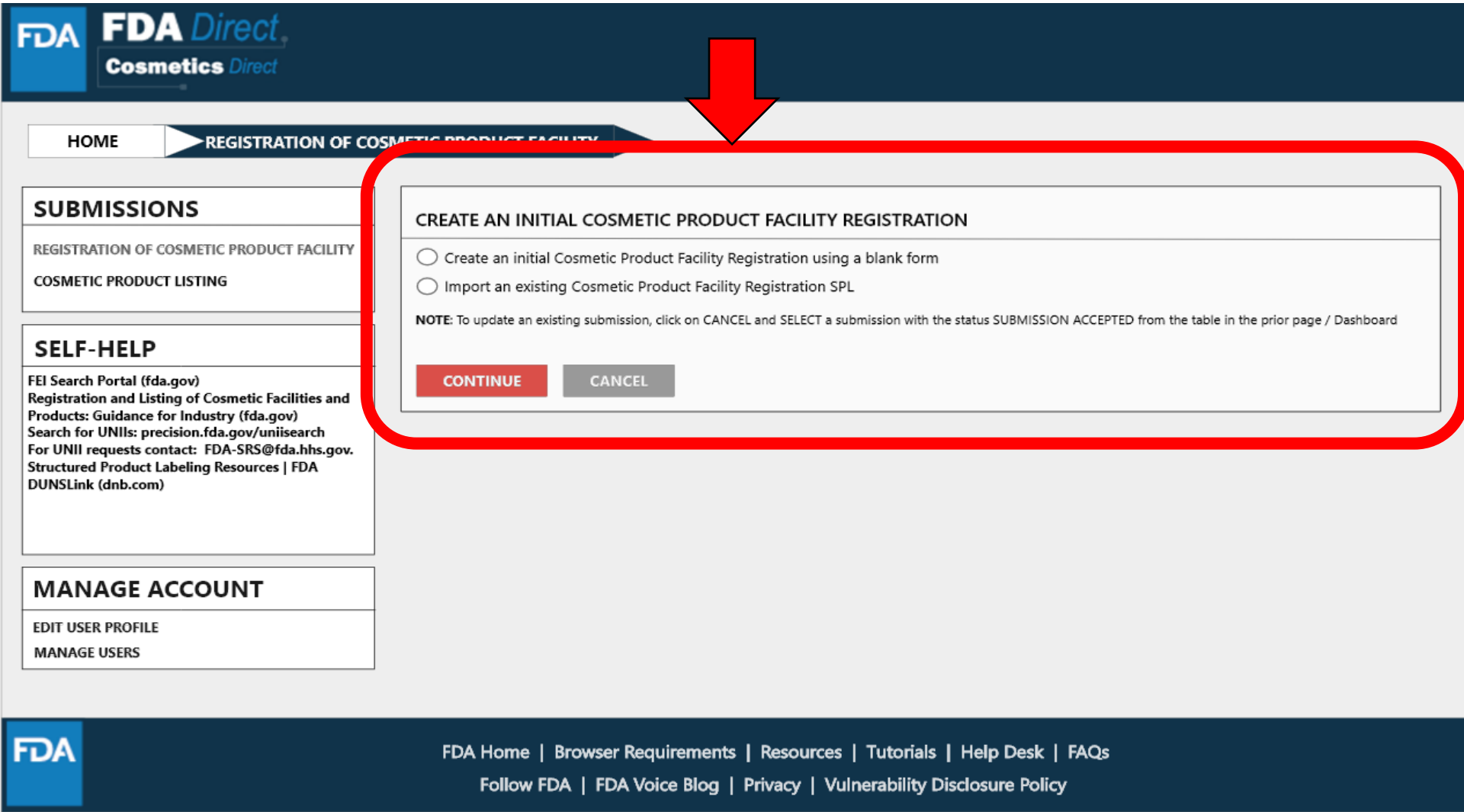
The ability to view all the previous product listing submissions based on user's access.

CREATE NEW/UPLOAD FILE

CREATE A NEW REGISTRATION OR UPLOAD AN EXISTING FILE

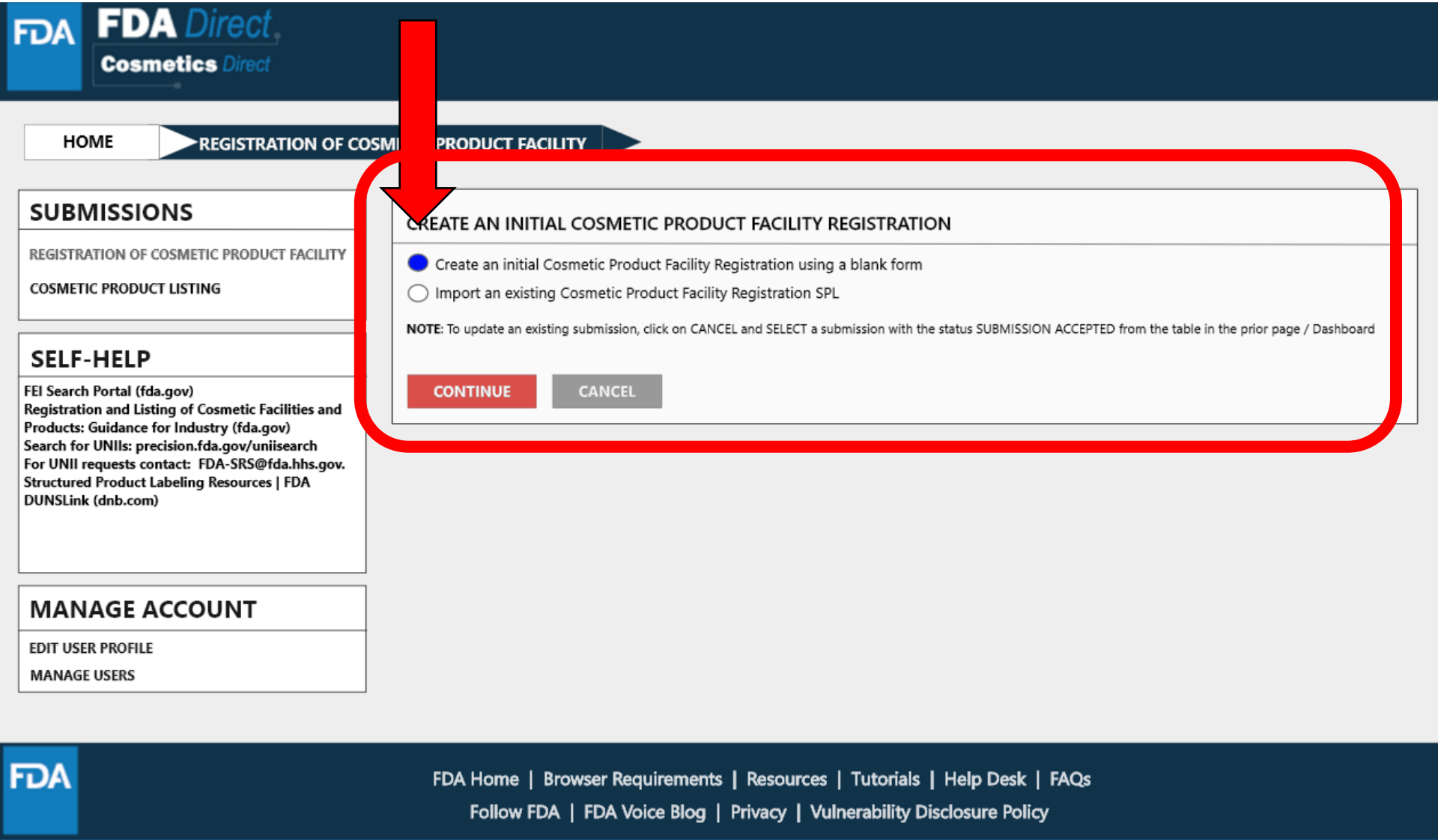
CREATE A NEW REGISTRATION OR UPLOAD AN EXISTING FILE

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



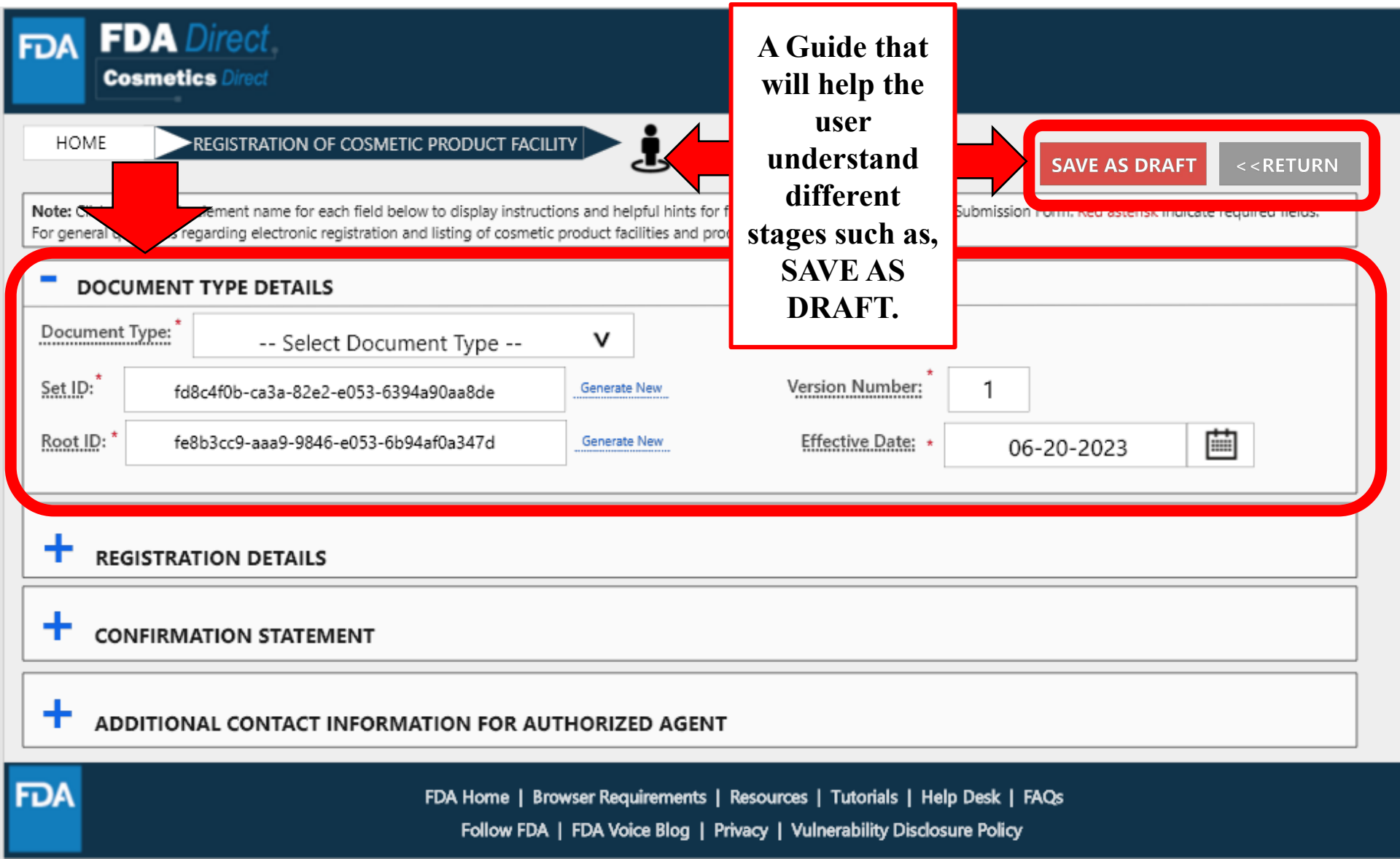
CREATE A NEW PRODUCT FACILITY REGISTRATION

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



DOCUMENT TYPE DETAILS

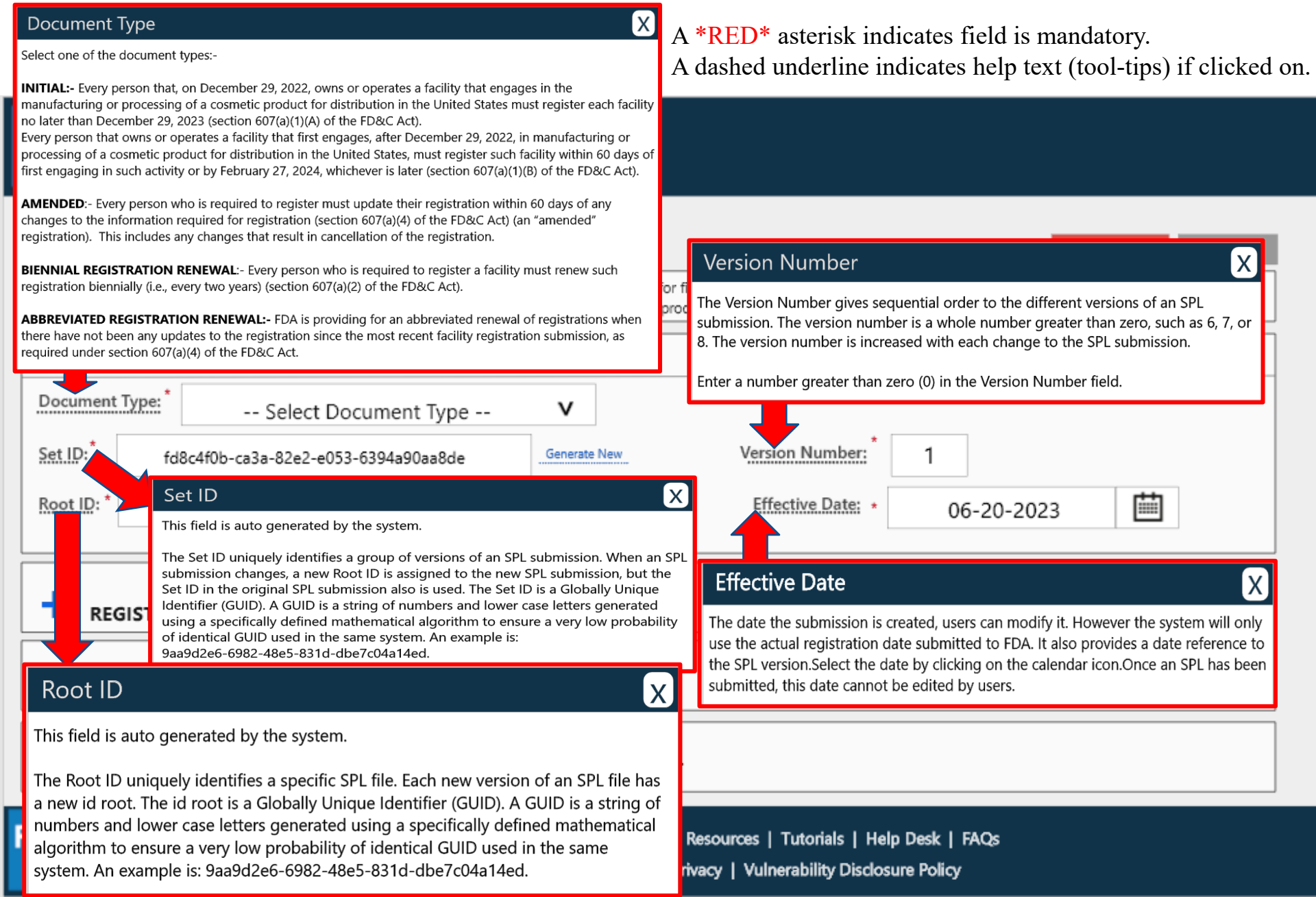
Set ID and Root ID are auto-generated, and the Effective Dates is the date the submission is created, but users can modify it. Once an SPL has been submitted, this date cannot be edited by users.



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

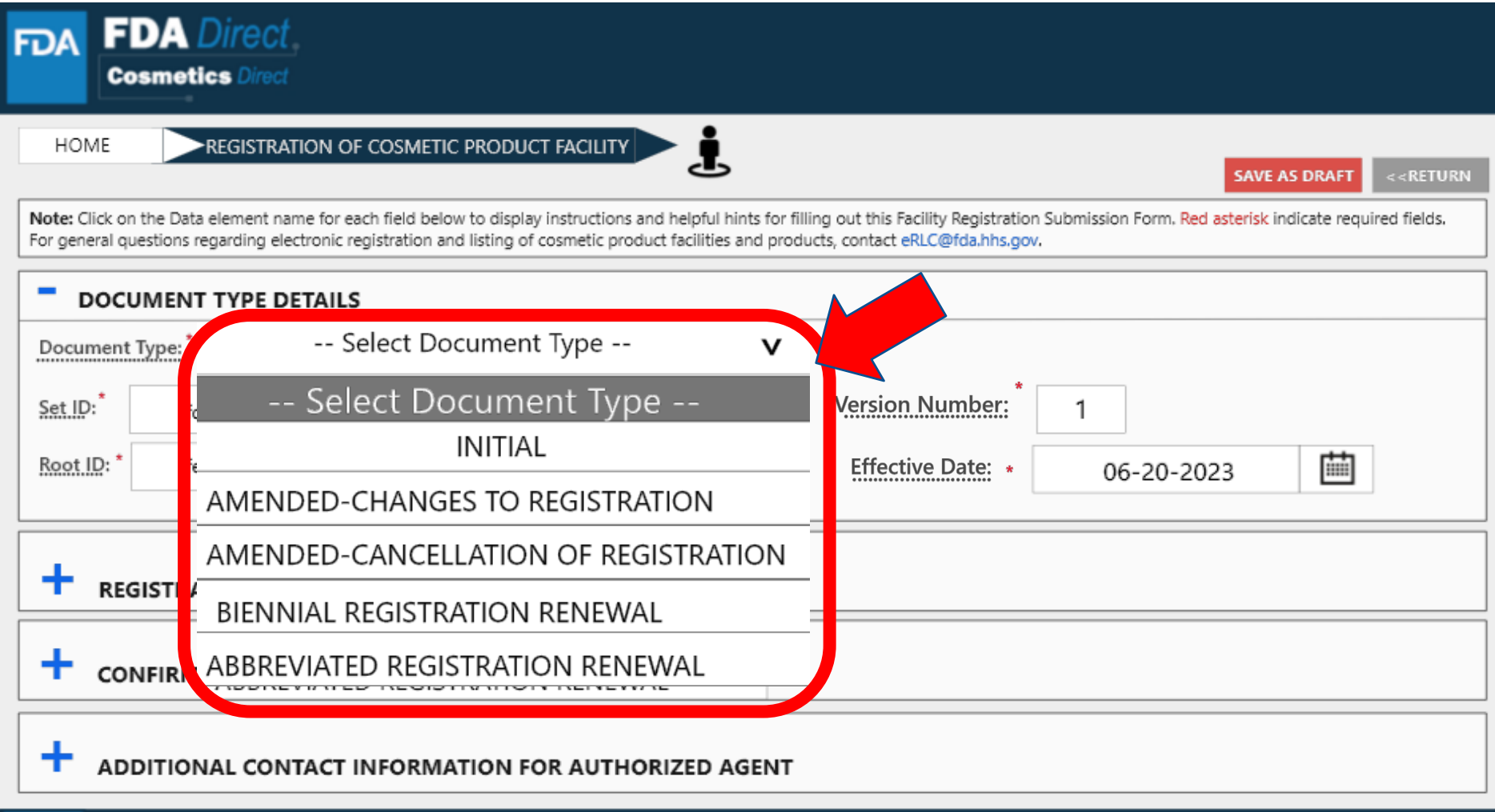
DOCUMENT TYPE TOOL TIPS

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



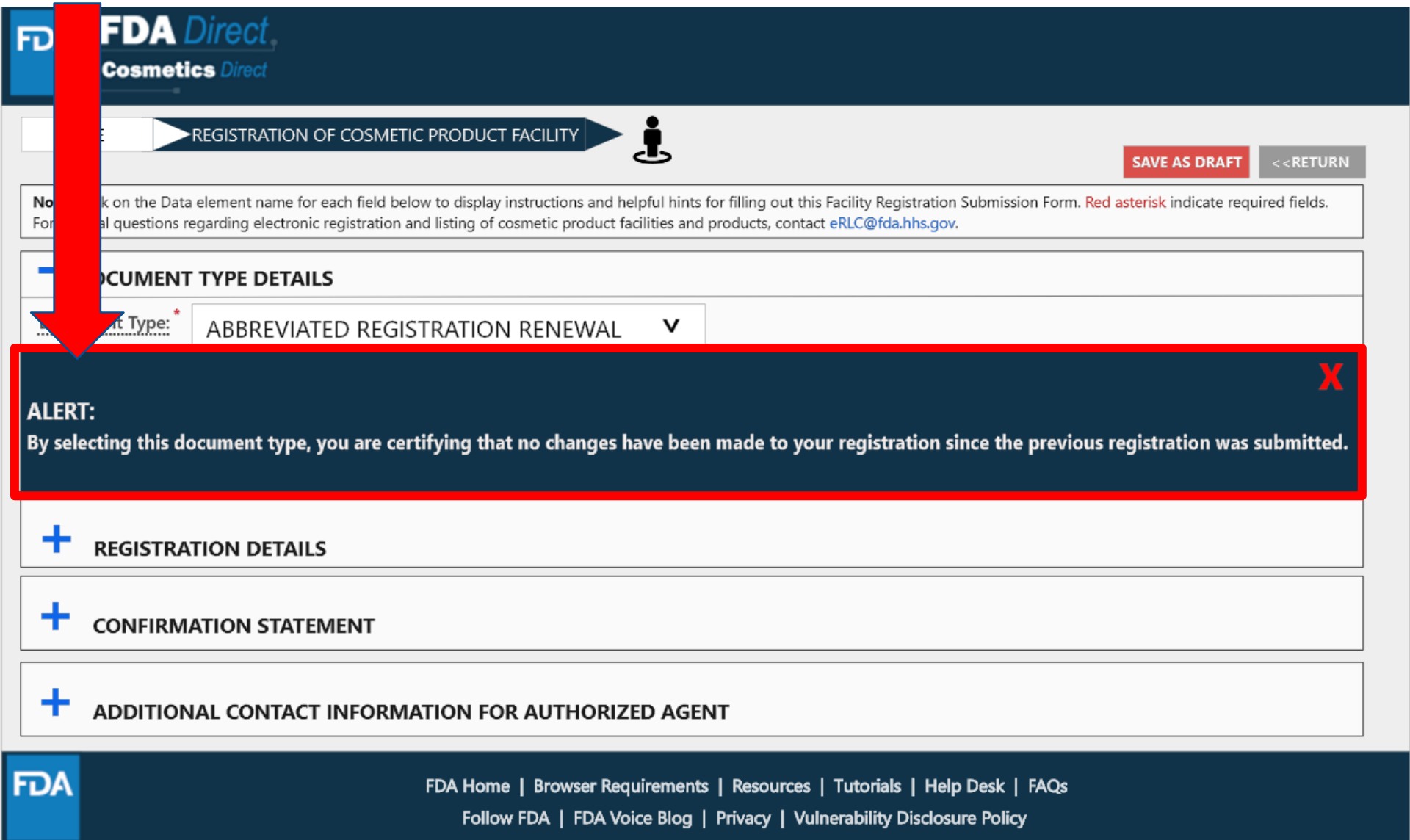
DOCUMENT TYPE DETAILS

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)



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*"



REGISTRATION DETAILS

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

Small Business

(optional field) Indicate whether your business is a small business by selecting one of the options provided. For more information visit Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)

Facility Name

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

Facility FEI Number

Enter the existing facility FEI number. If you need to look-up the FEI number or request an FEI number:
https://www.accessdata.fda.gov/scripts/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

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

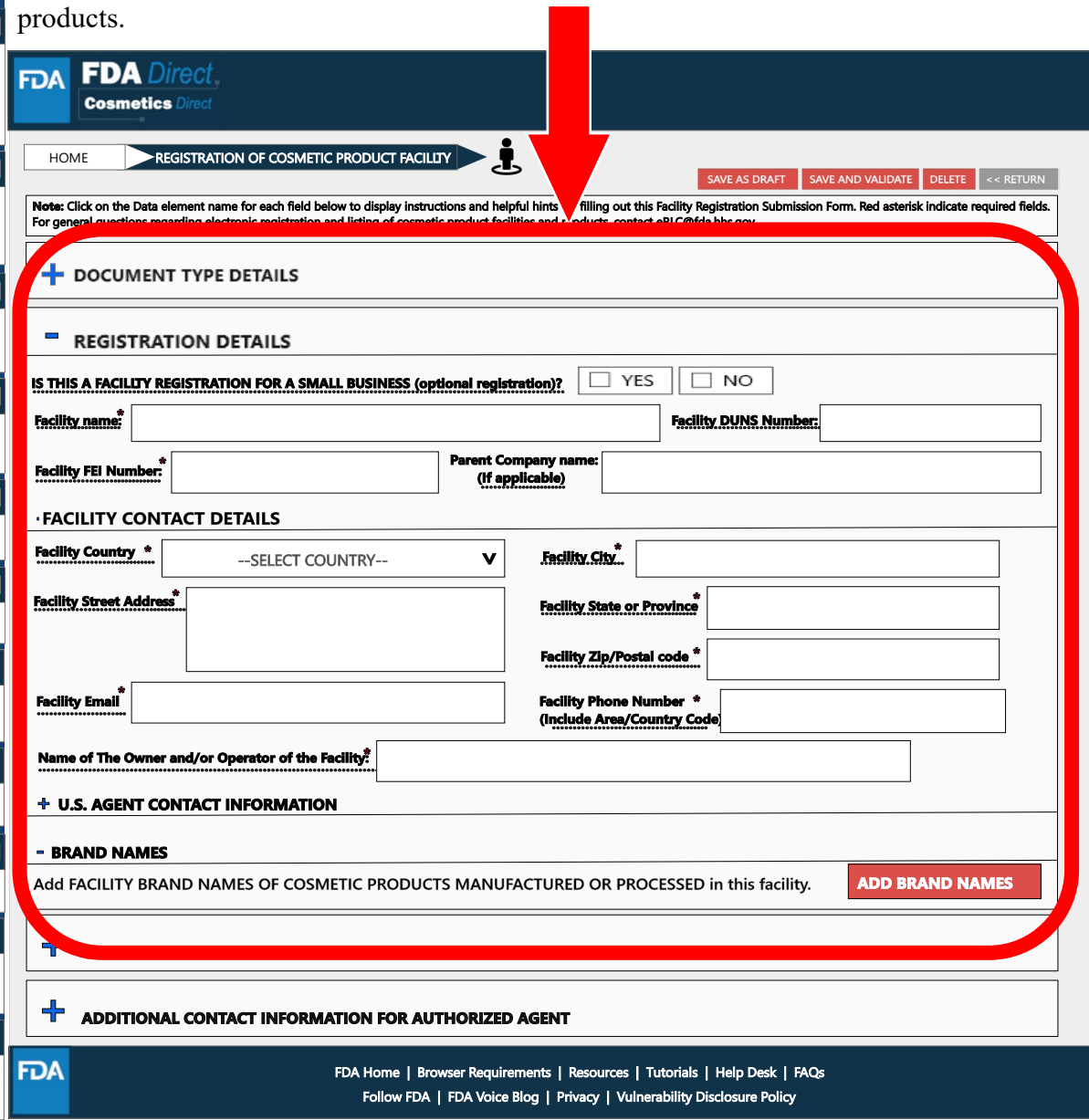
Provide the facility's email address. For more information visit Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)

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 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 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)

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 *

y Email * | Facility Phone Number * (Include Area/Country Code)

s of The Owner and/or Operator of the Facility:*

- U.S. AGENT CONTACT INFORMATION

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

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

- BRAND NAMES

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

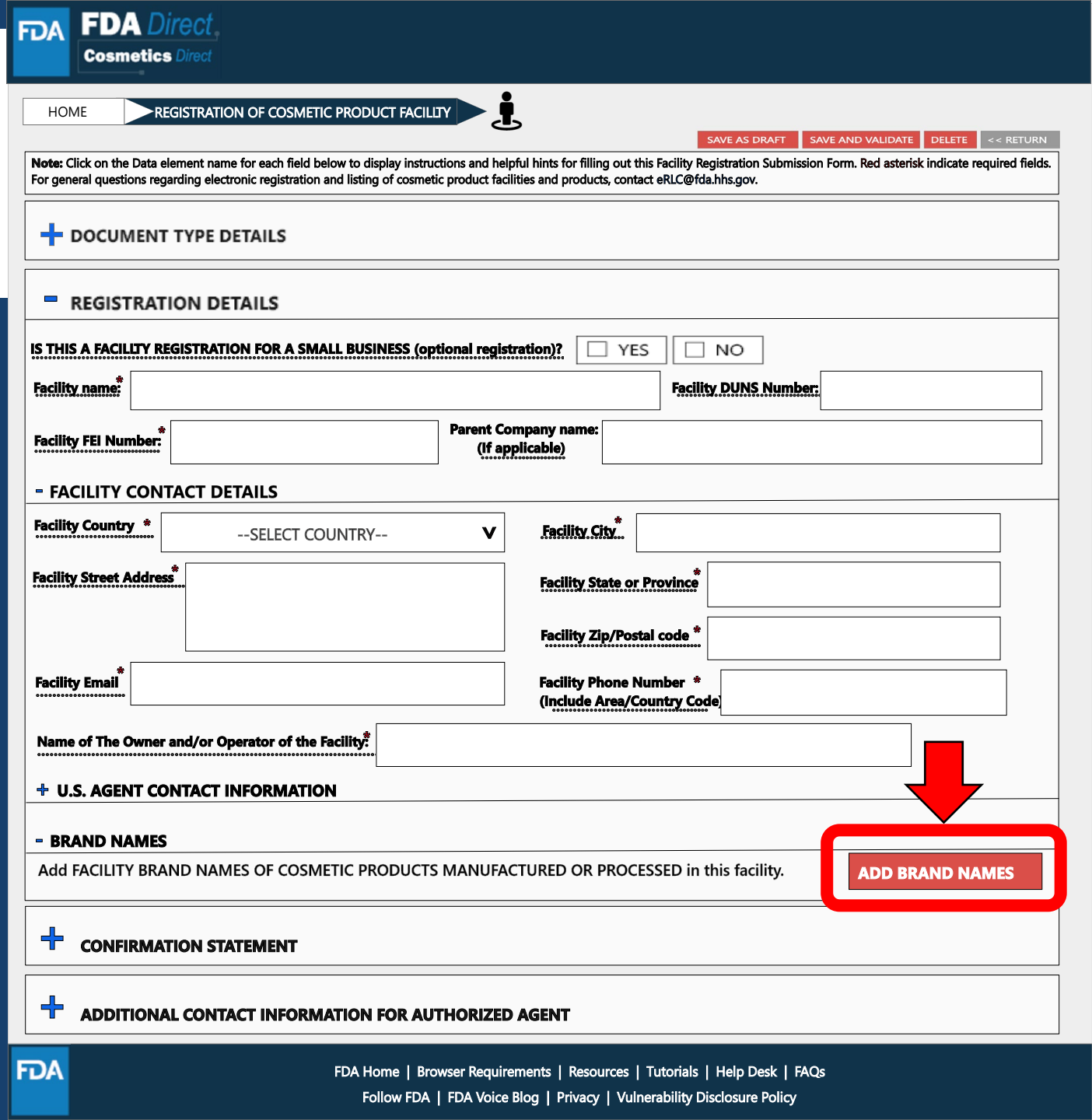
+ CONFIRMATION STATEMENT

+ ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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

BRAND NAME(S)

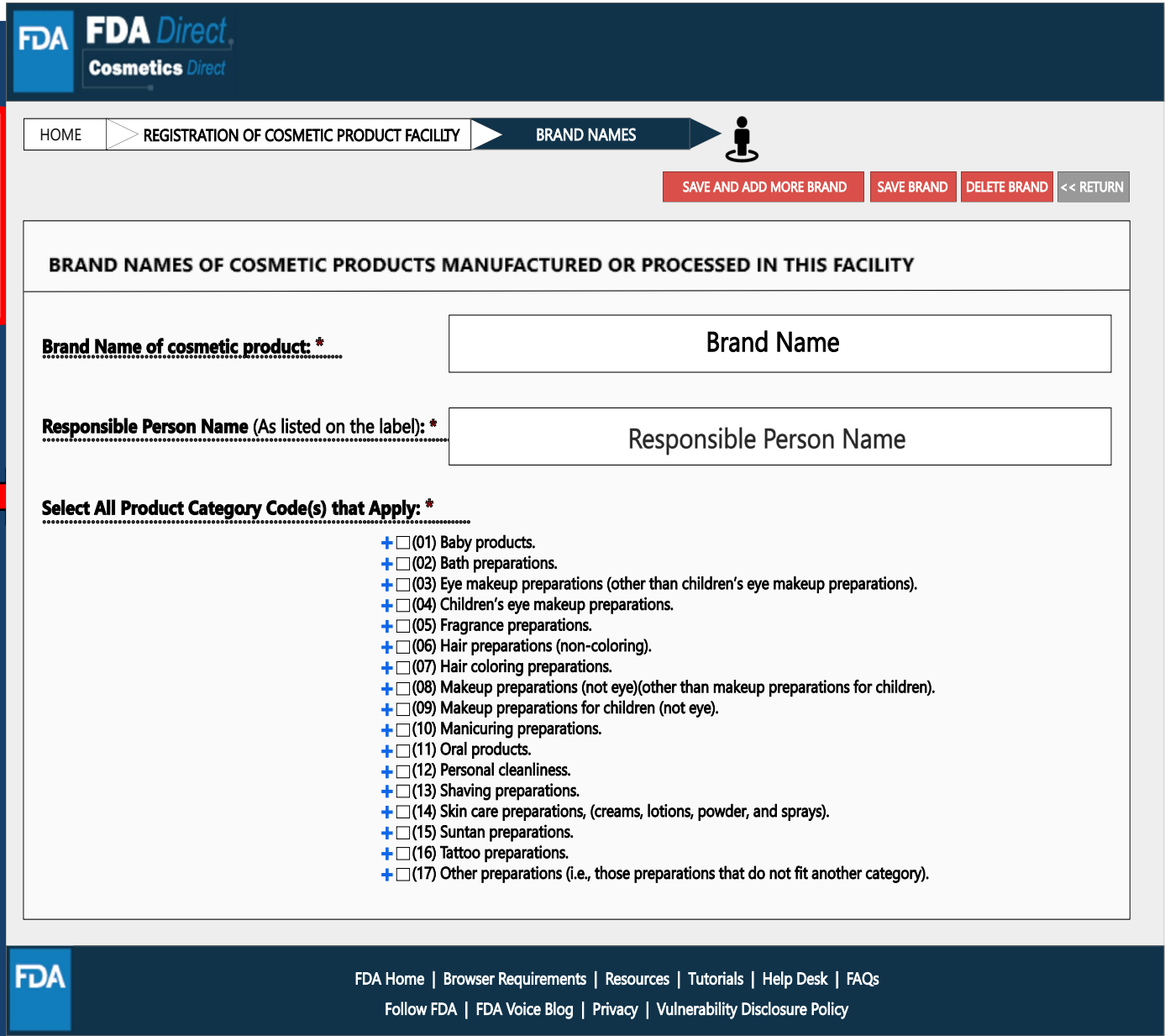
Add Brand Names of cosmetic products manufactured or processed at this facility by selecting ADD BRAND NAMES



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.

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)

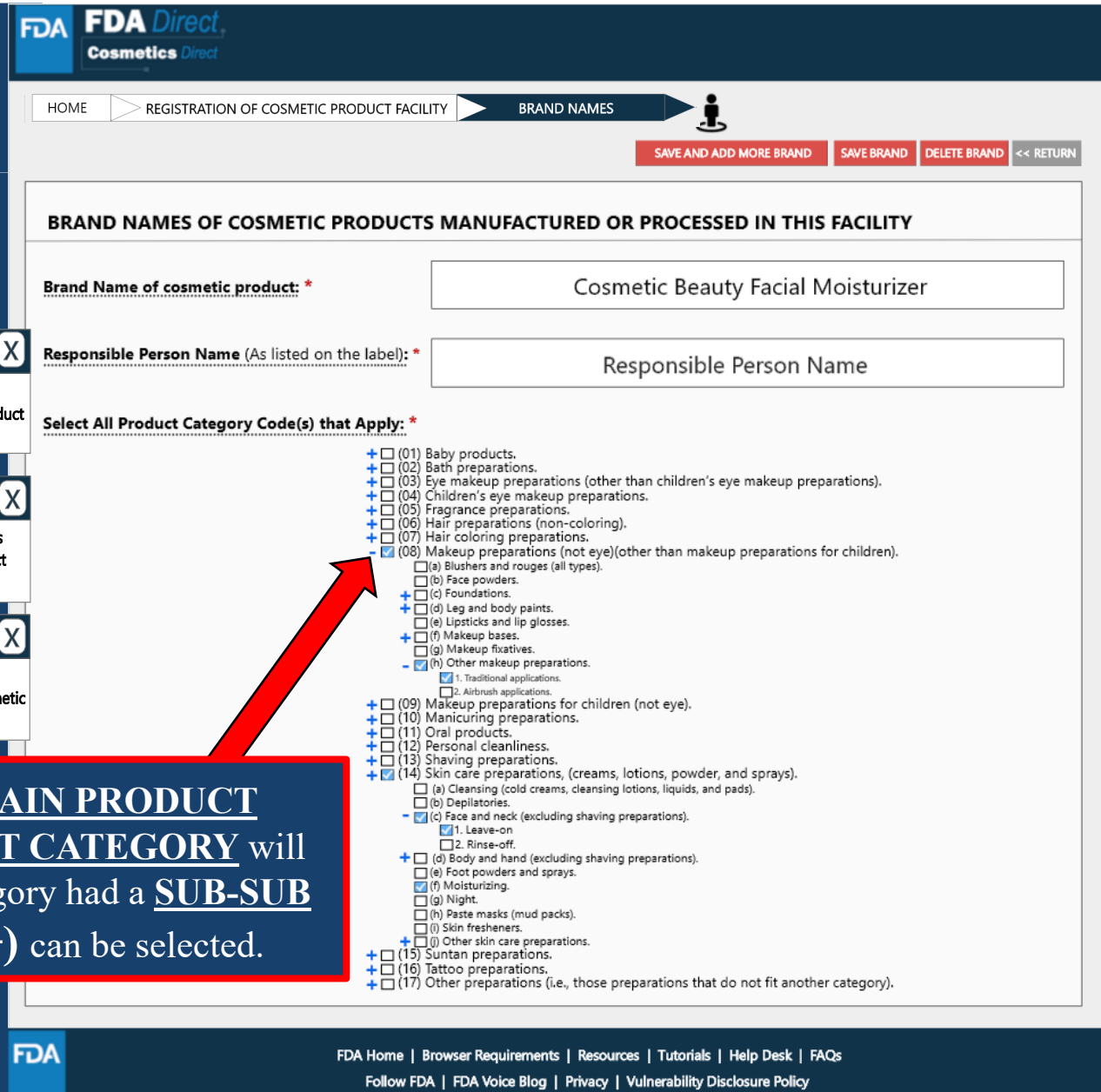
Responsible Person Name X

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

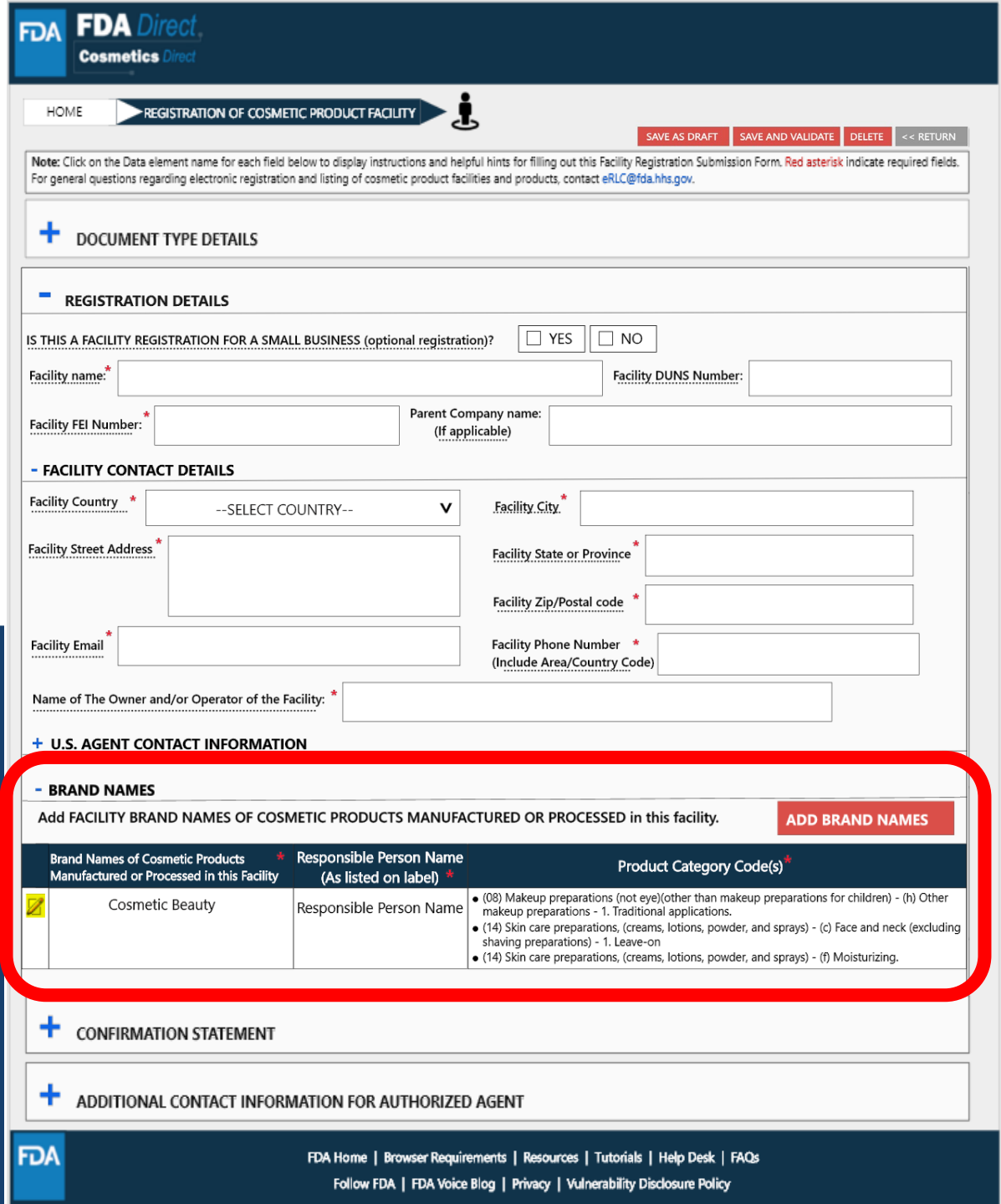
The product category or categories for each cosmetic product manufactured or processed at the facility. For more information, visit Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry (fda.gov)

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

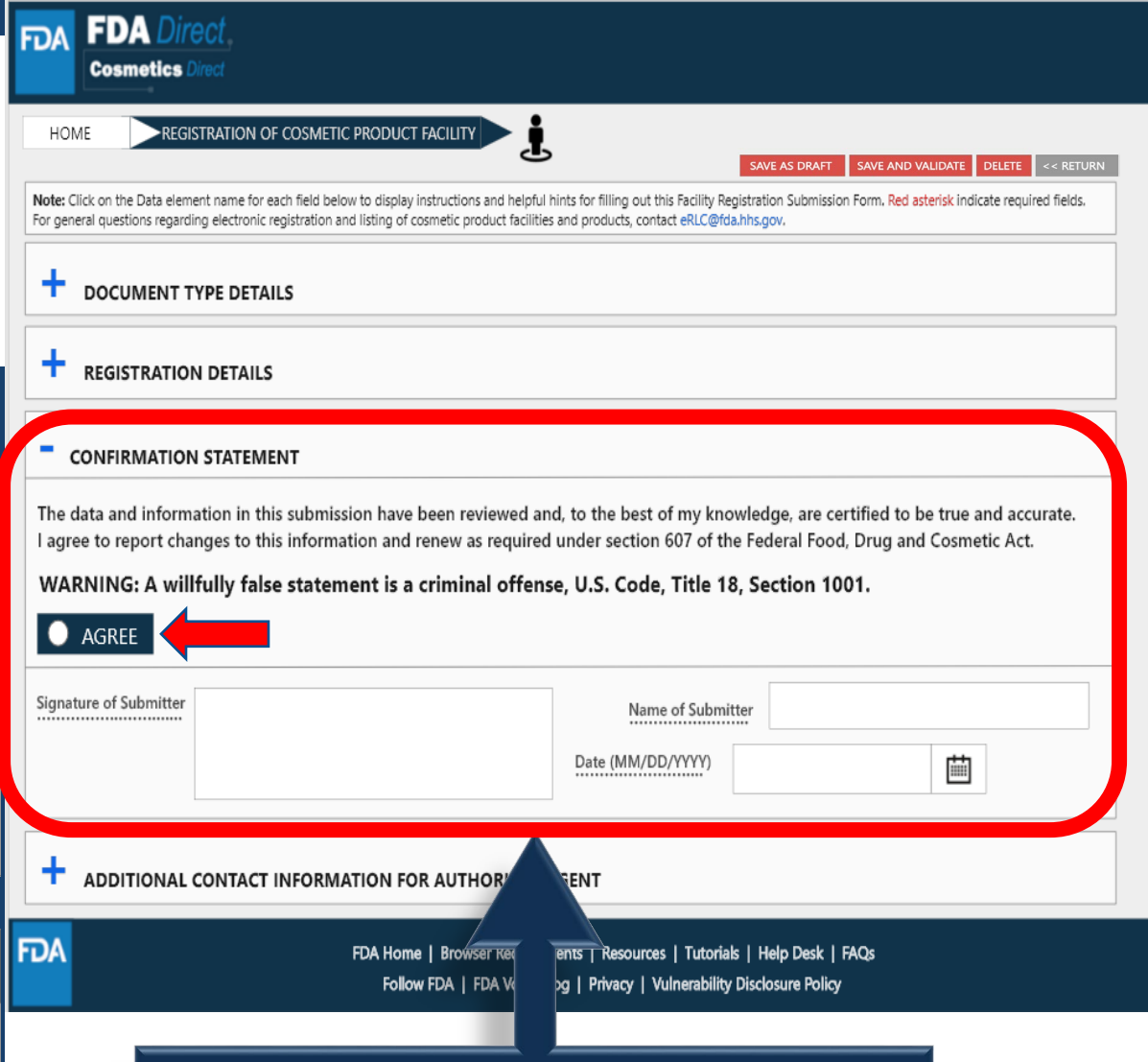
(optional field) Use the blank space to provide a signature of the Submitter.

Name of Submitter

(optional field) Enter the full name of the submitter

Date

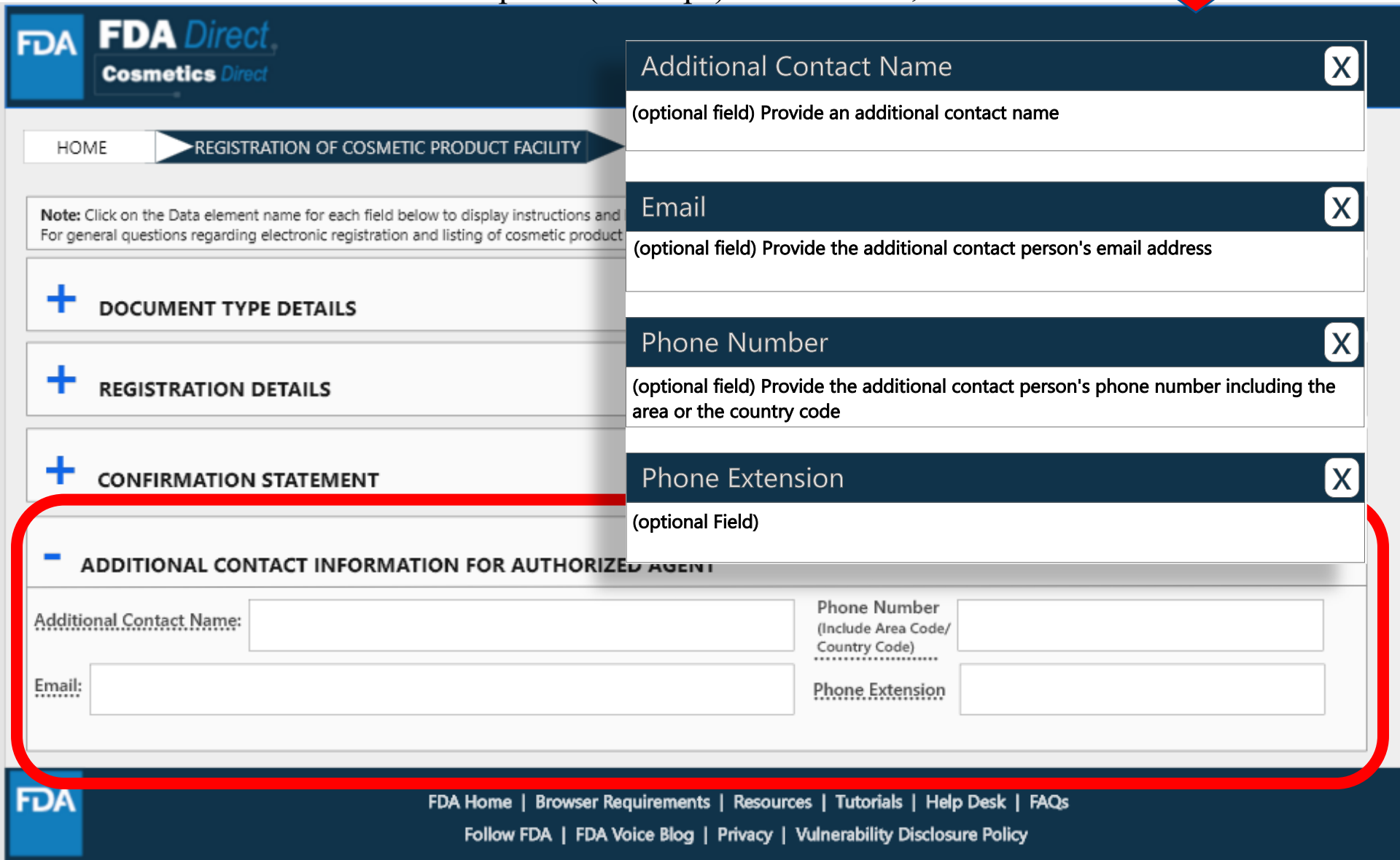
(optional field) Enter today's date, two digit month two digit day and four digit year



After understanding the confirmation statement. Select AGREE

ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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



COMPLETED

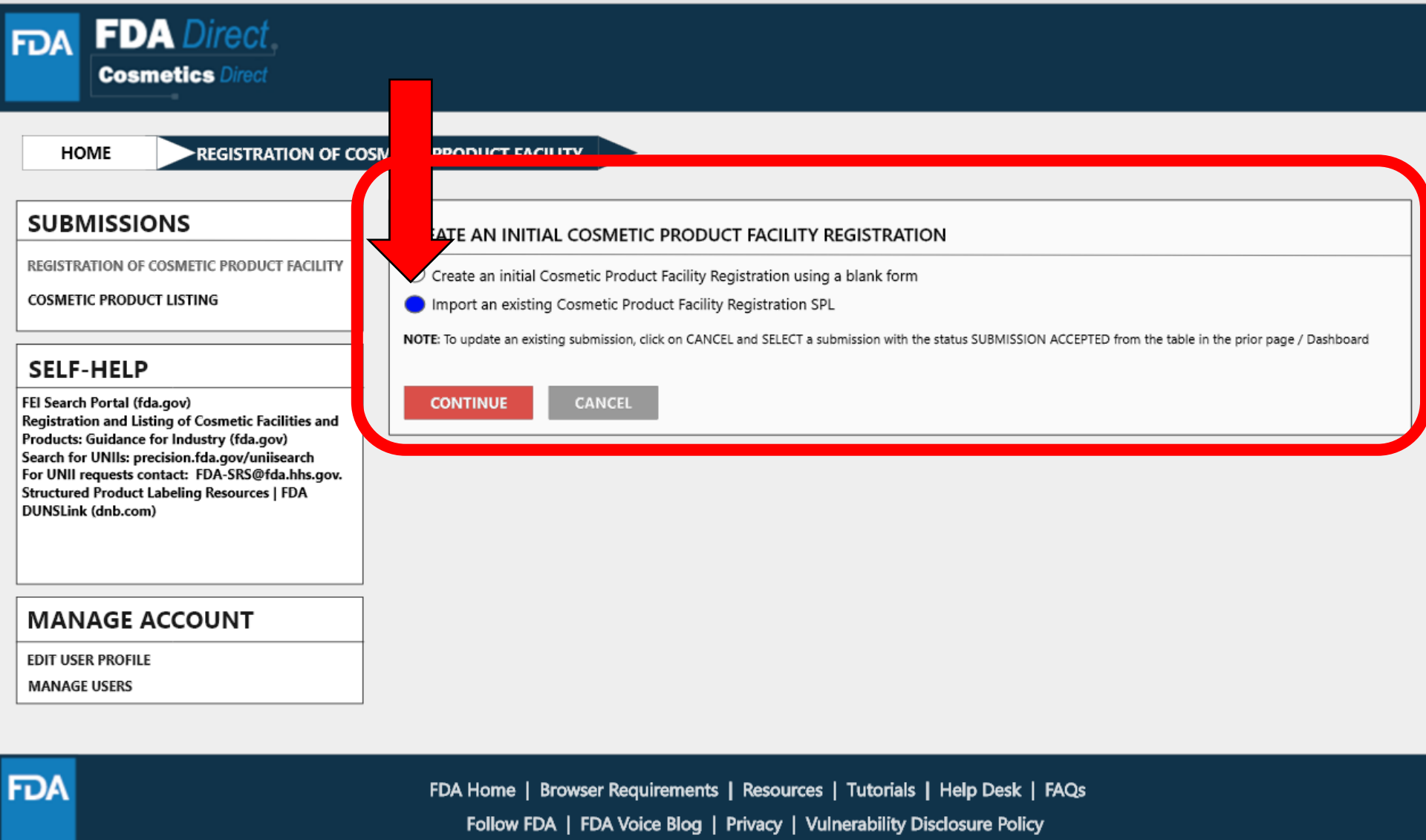
After filling in all the required information, SAVE AND VALIDATE, to identify any errors.

OR

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

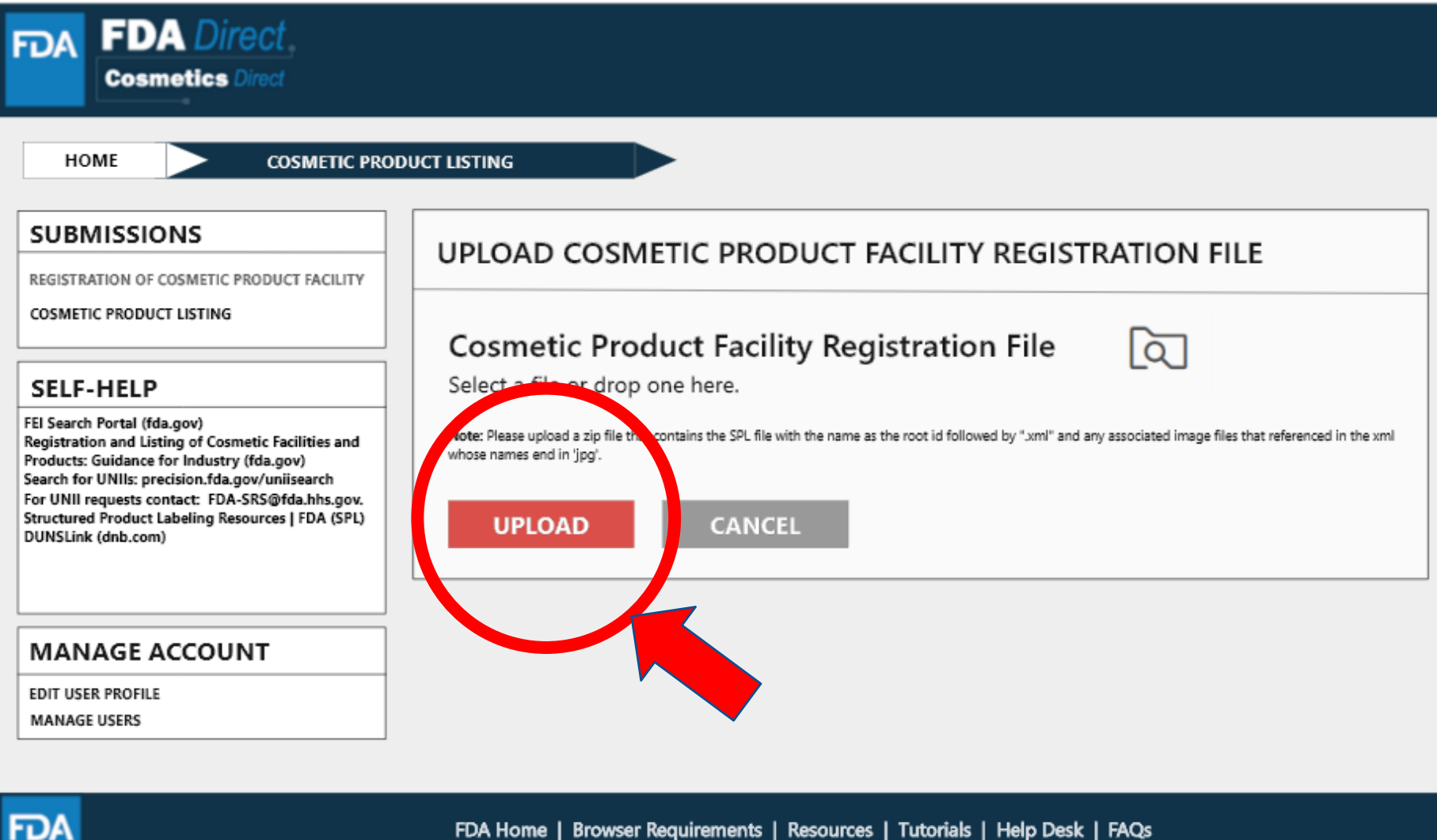
UPLOAD A FILE

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.



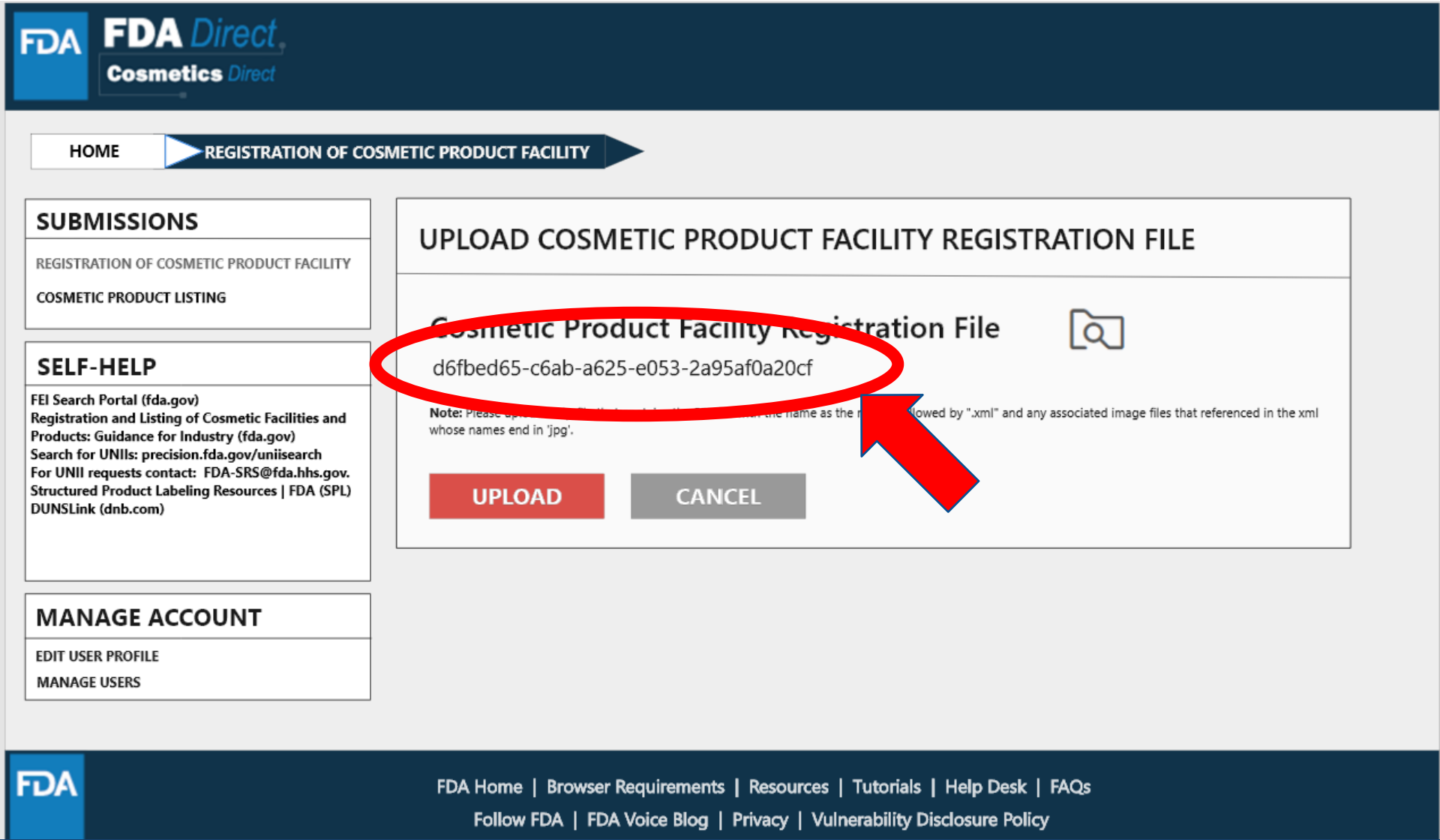
UPLOAD A FILE

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**



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

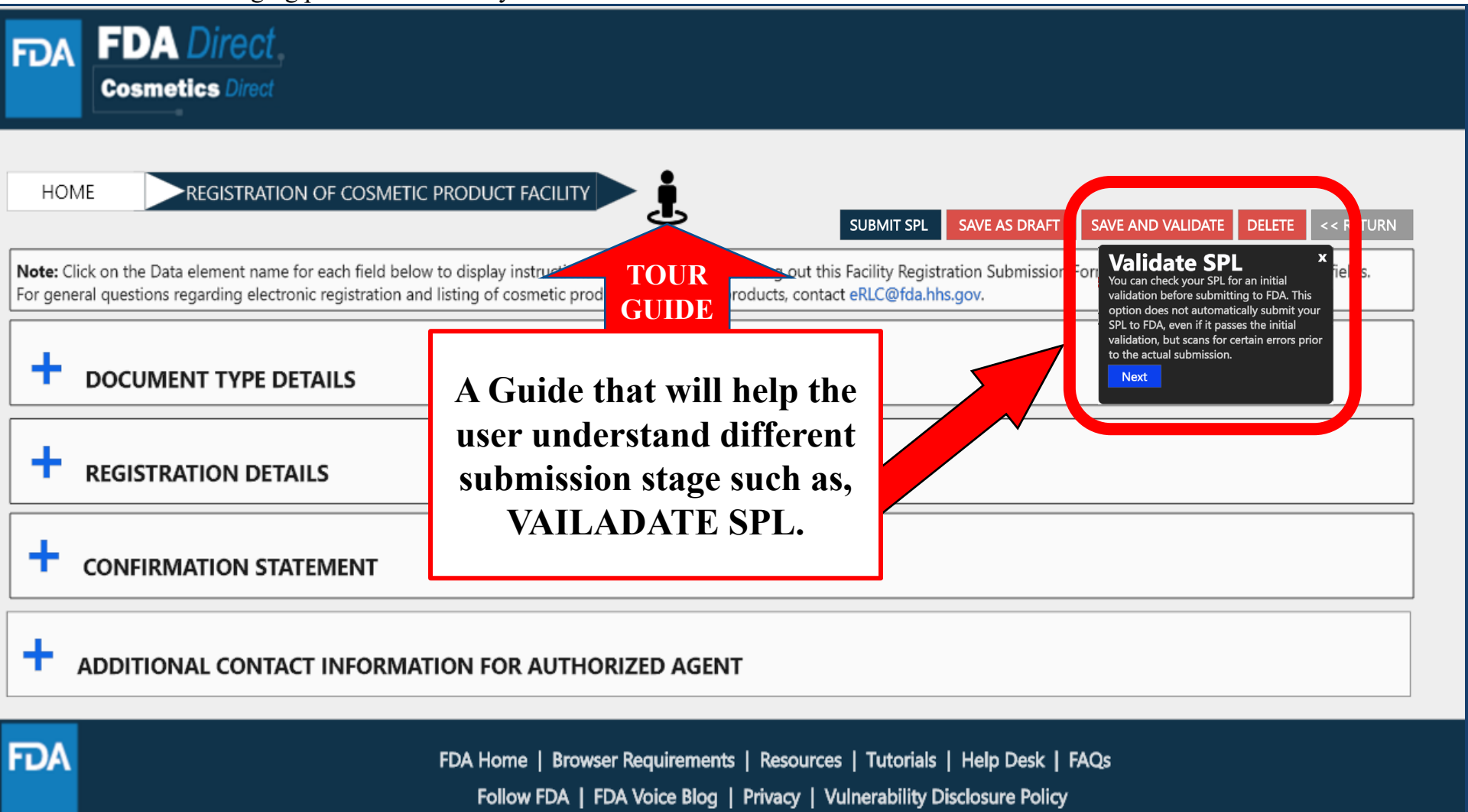
```
<?xml version="1.0" encoding="UTF-8"?>
<?xml-stylesheet href="https://www.accessdata.fda.gov/spl/stylesheet/spl.xsl" type="text/xsl"?>
<document xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
xsi:schemaLocation="urn:hl7-org:v3 https://www.accessdata.fda.gov/spl/schema/spl.xsd">
  <id root="fd8c4f0b-ca3b-82e2-e053-6394a90aa8de"/>
  <code code="51725-0" codeSystem="2.16.840.1.113883.6.1" displayName=" FACILITY
REGISTRATION"/>
  <effectiveTime value="[DATE]"/>
  <setId root="fd8c4f0b-ca3a-82e2-e053-6394a90aa8de"/>
  <versionNumber value="1"/>
  <author>
   <time/>
   <assignedEntity>
    <representedOrganization>
     <assignedEntity>
      <assignedOrganization>
       <id root="1.3.6.1.4.1.519.1" extension="314988747"/>
       <name>[COMPANY'S NAME]</name>
       <contactParty>
        <addr>
         <streetAddressLine>[ENTRY THE STREET ADDRESS]</streetAddressLine>
         <city>[ENTRY CITY NAME]</city>
         <postalCode>[ENTRY POSTAL CODE]</postalCode>
         <country>[ENTRY COUNTRY NAME]</country>
        </addr>
        <telecom value="tel:[ENTRY PHONE NUMBER]"/>
        <telecom value="[ENTRY EMAIL ADDRESS]"/>
        <contactPerson>
         <name>[ENTRY FULL NAME]</name>
        </contactPerson>
       </contactParty>
       <assignedEntity>
```

UPLOAD A FILE (EXAMPLE)

After **UPLOADING A FILE** (XML ZIP FILE), the system will auto-fill all the required fields and the form will be ready to save and validate to check for any errors. This is an easy way to submit multiple Cosmetic Product Facility Registrations under one submission ID.

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

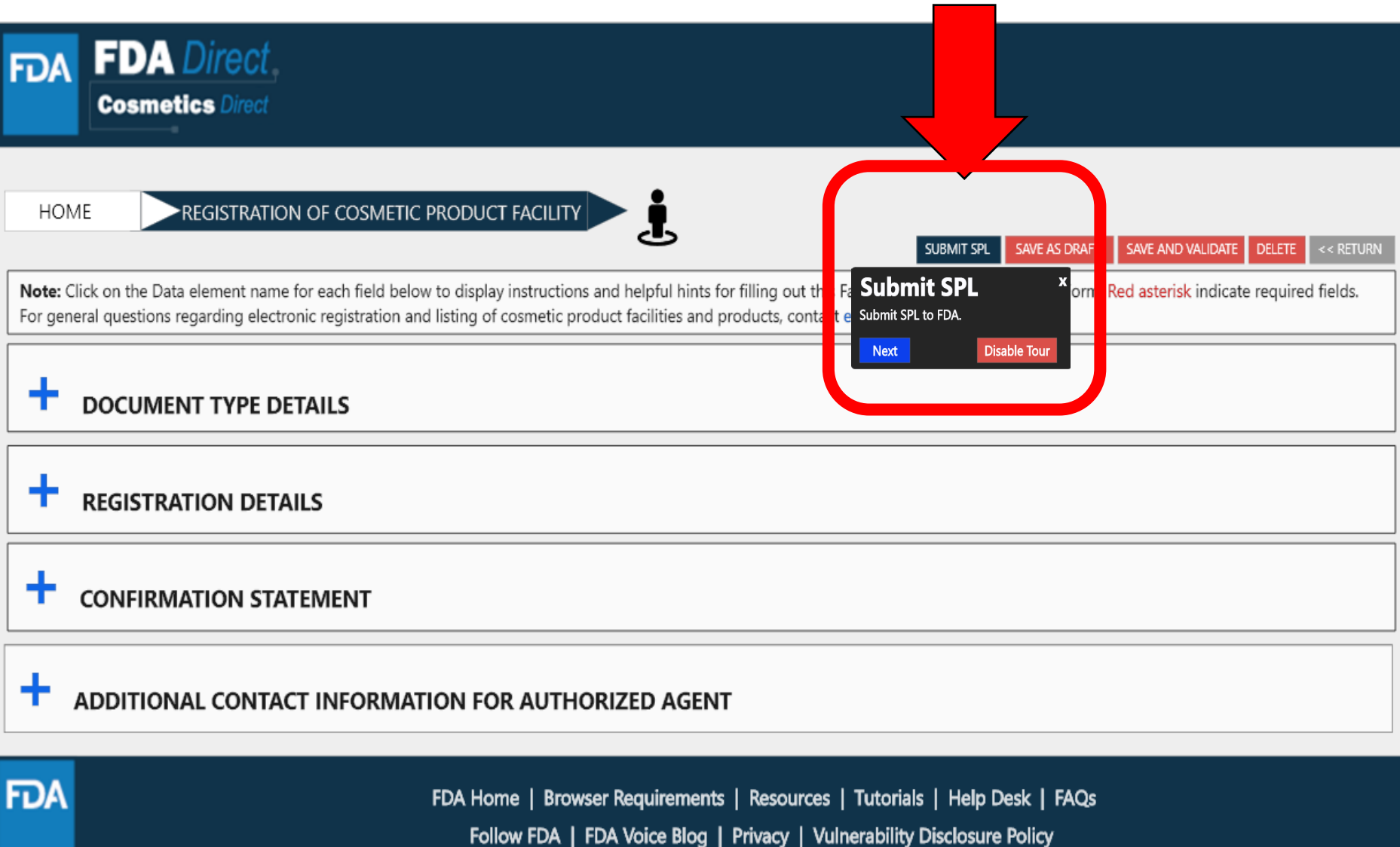
SPL(Structured Product Labeling) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product and facility information.



UPLOAD A FILE (EXAMPLE)

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

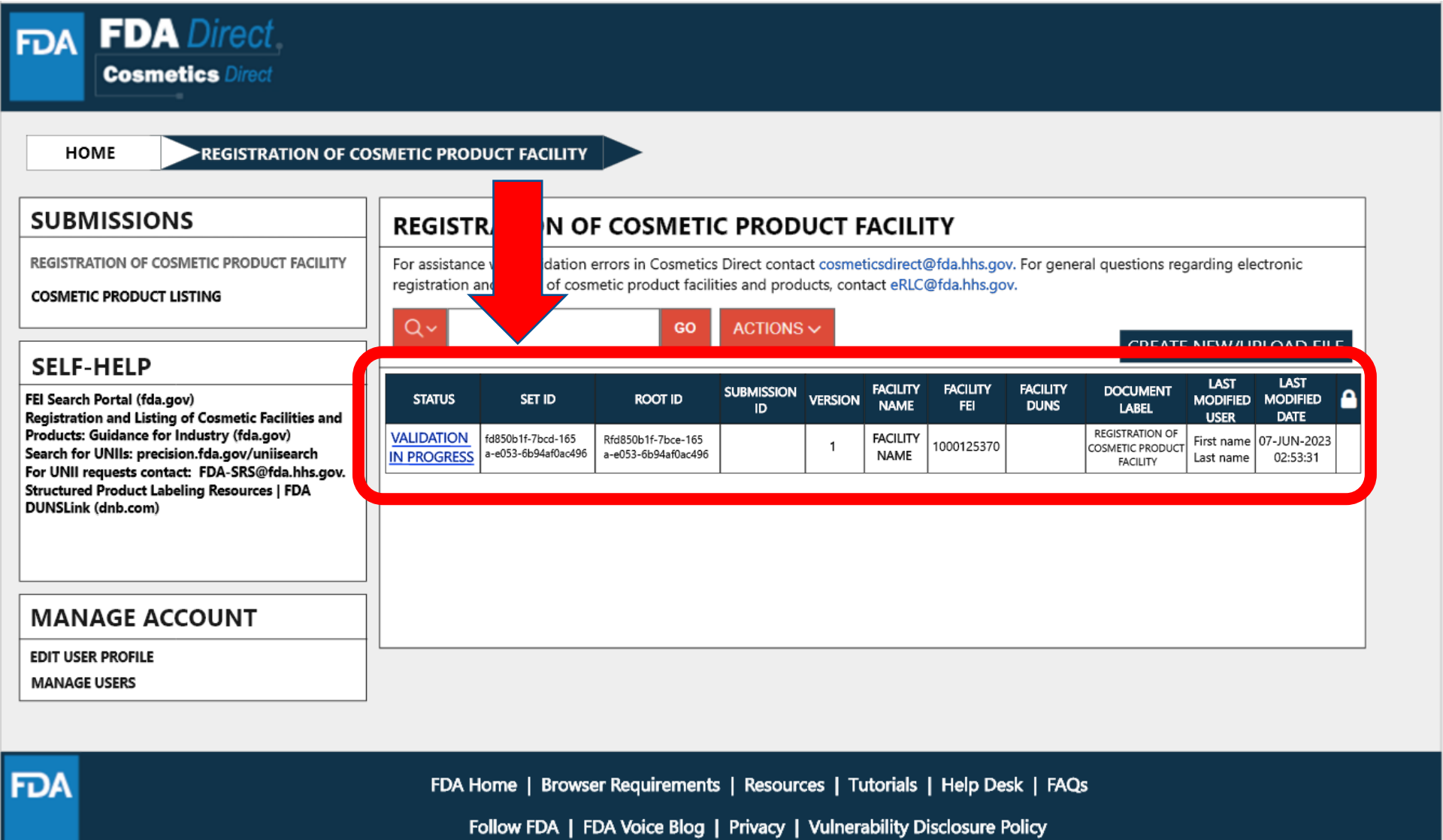
The Submit SPL box is a help tool that can guide a user through the process.



REGISTRATION STATUS EXAMPLES

REGISTRATION STATUS: VALIDATION IN PROGRESS

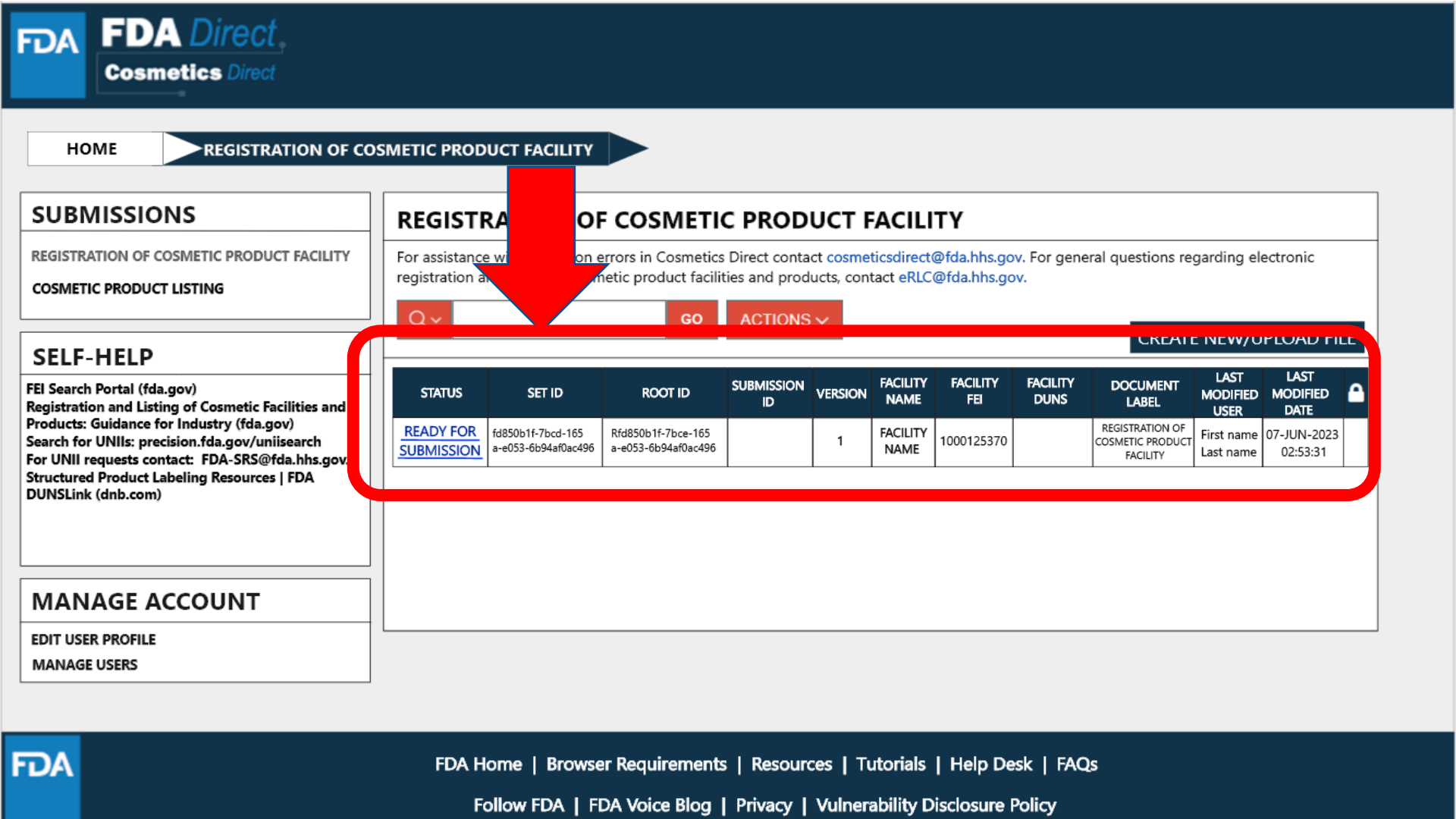
After SAVE AND VALIDATE, the registration of cosmetic product facility home page will have the following details as shown below. The status will be in **VALIDATION IN PROGRESS**.



REGISTRATION STATUS: READY FOR SUBMISSION

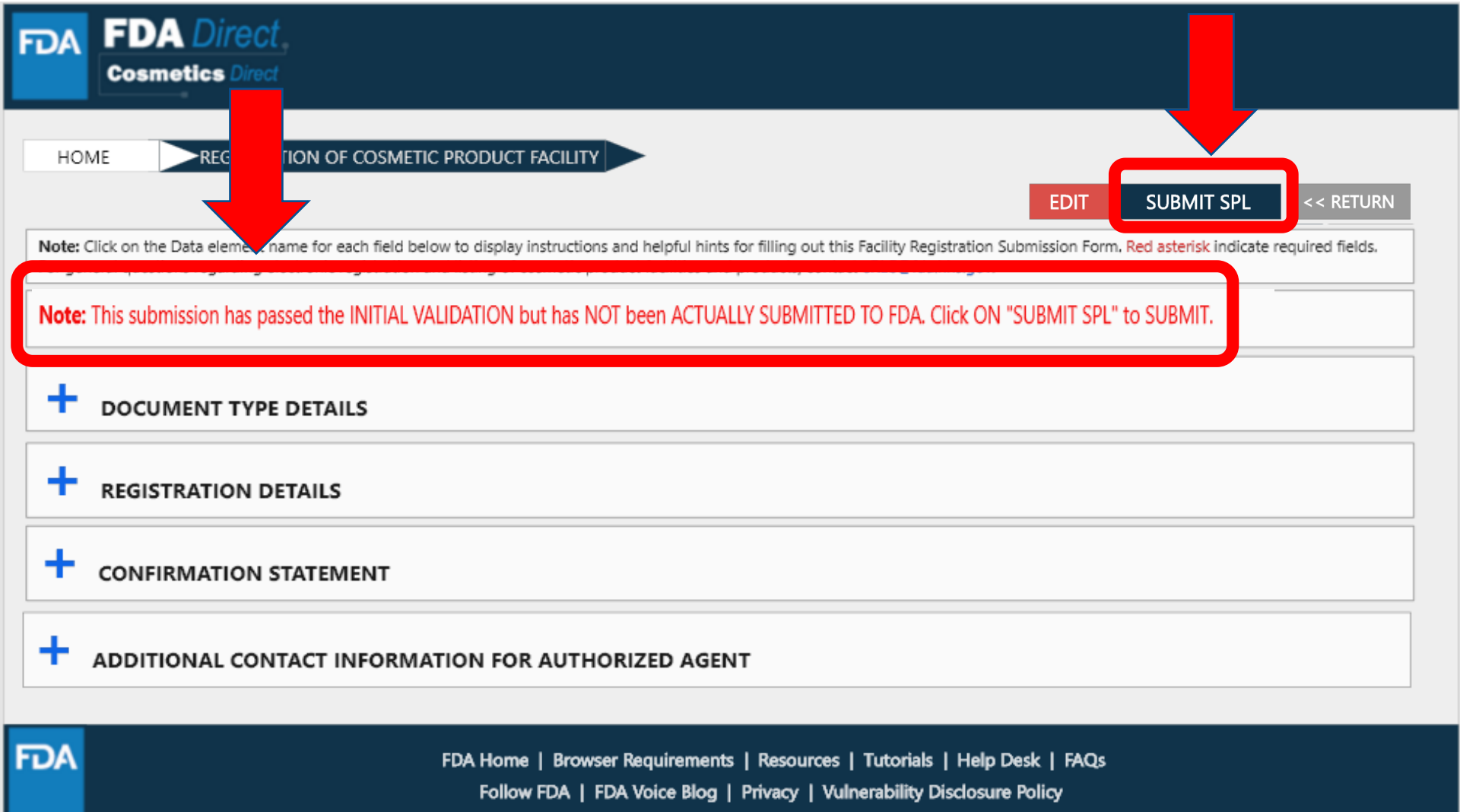
VALIDATE SPL: You can check your SPL for an initial validation before submitting to FDA. This option does not automatically submit your SPL to FDA, even if it passes the initial validation, but scans for certain errors prior to the actual submission.

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



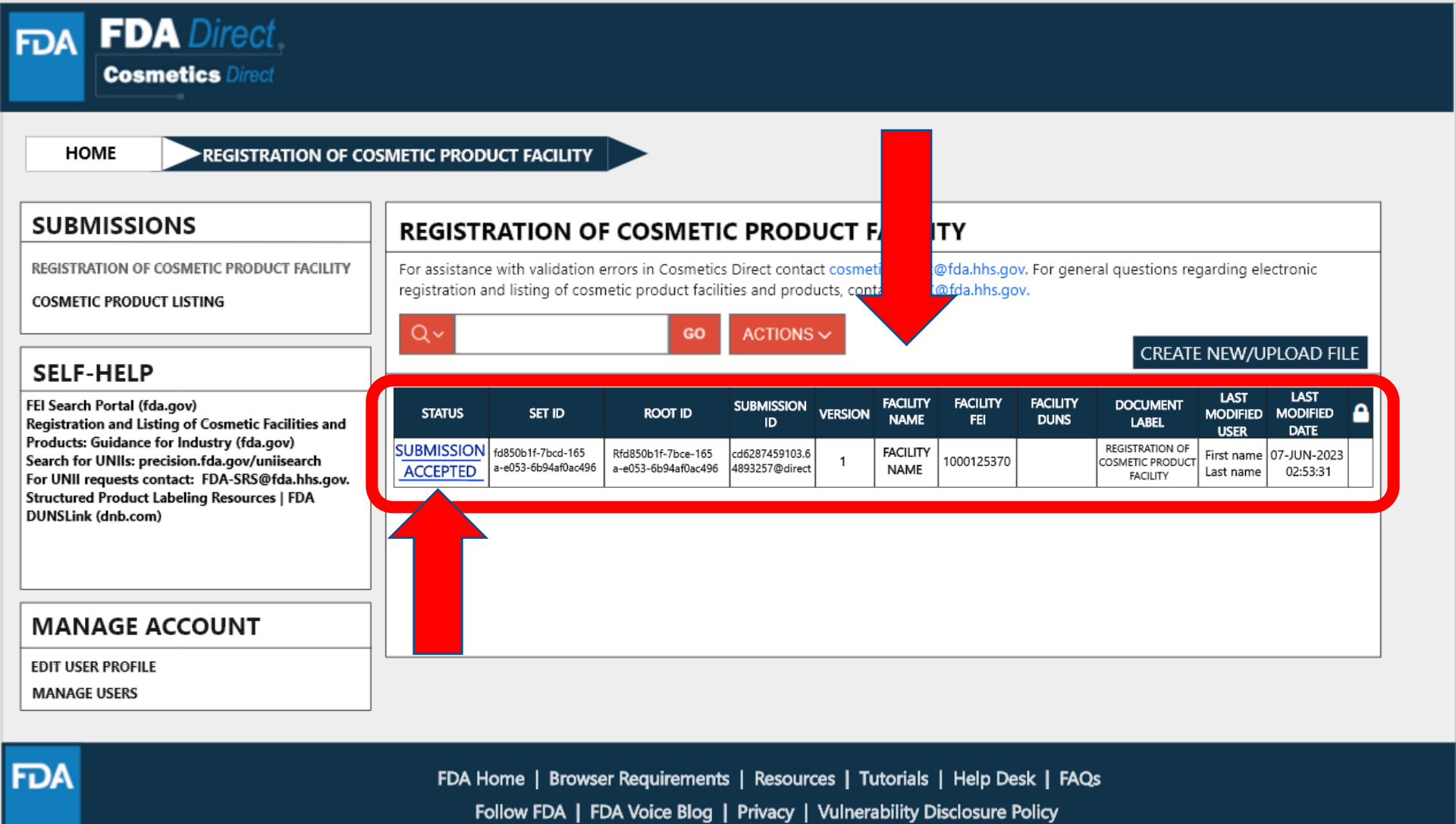
REGISTRATION STATUS: READY FOR SUBMISSION to SUBMIT SPL

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.*



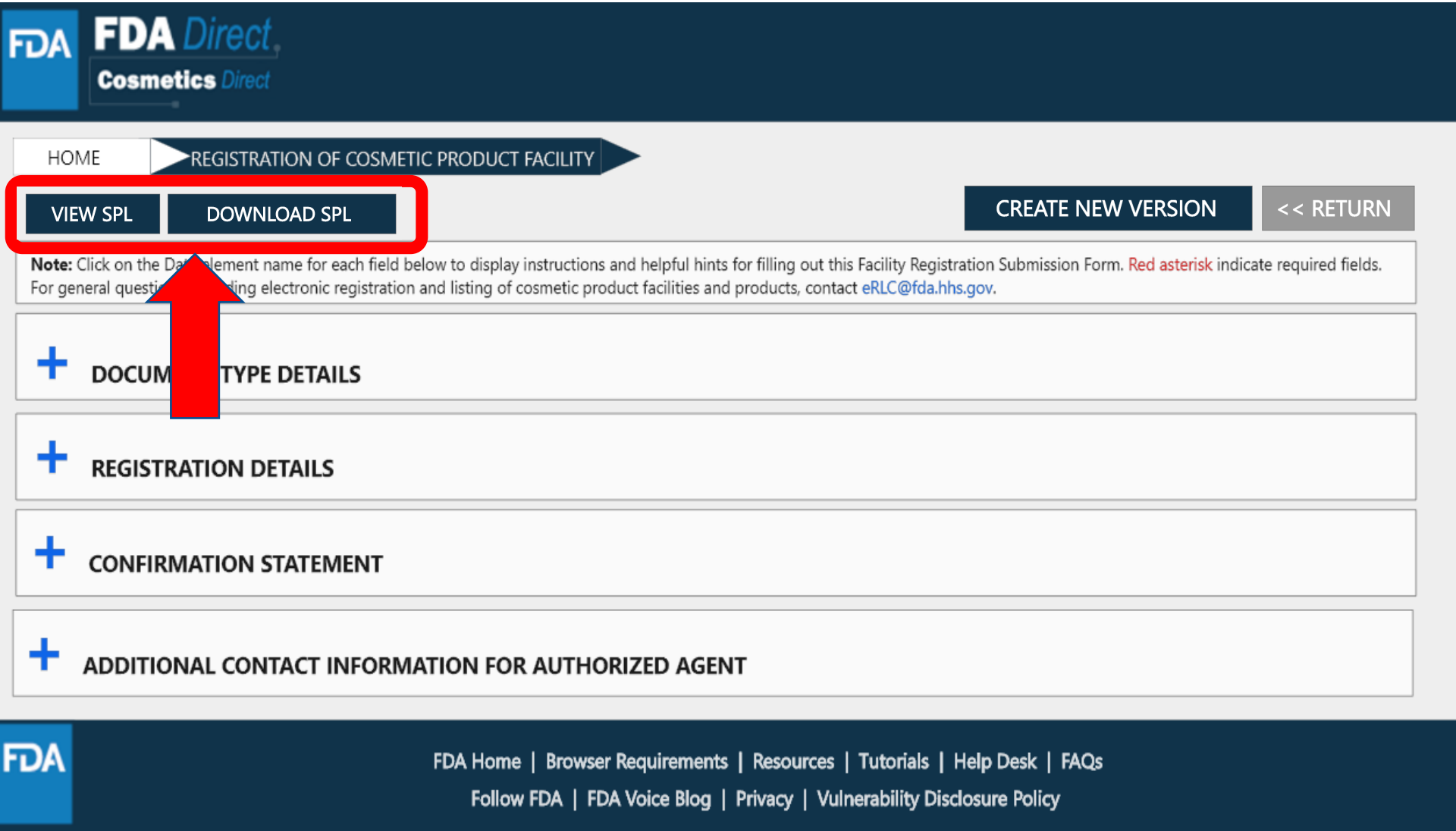
REGISTRATION STATUS: SUBMIT SPL to SUBMISSION ACCEPTED

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



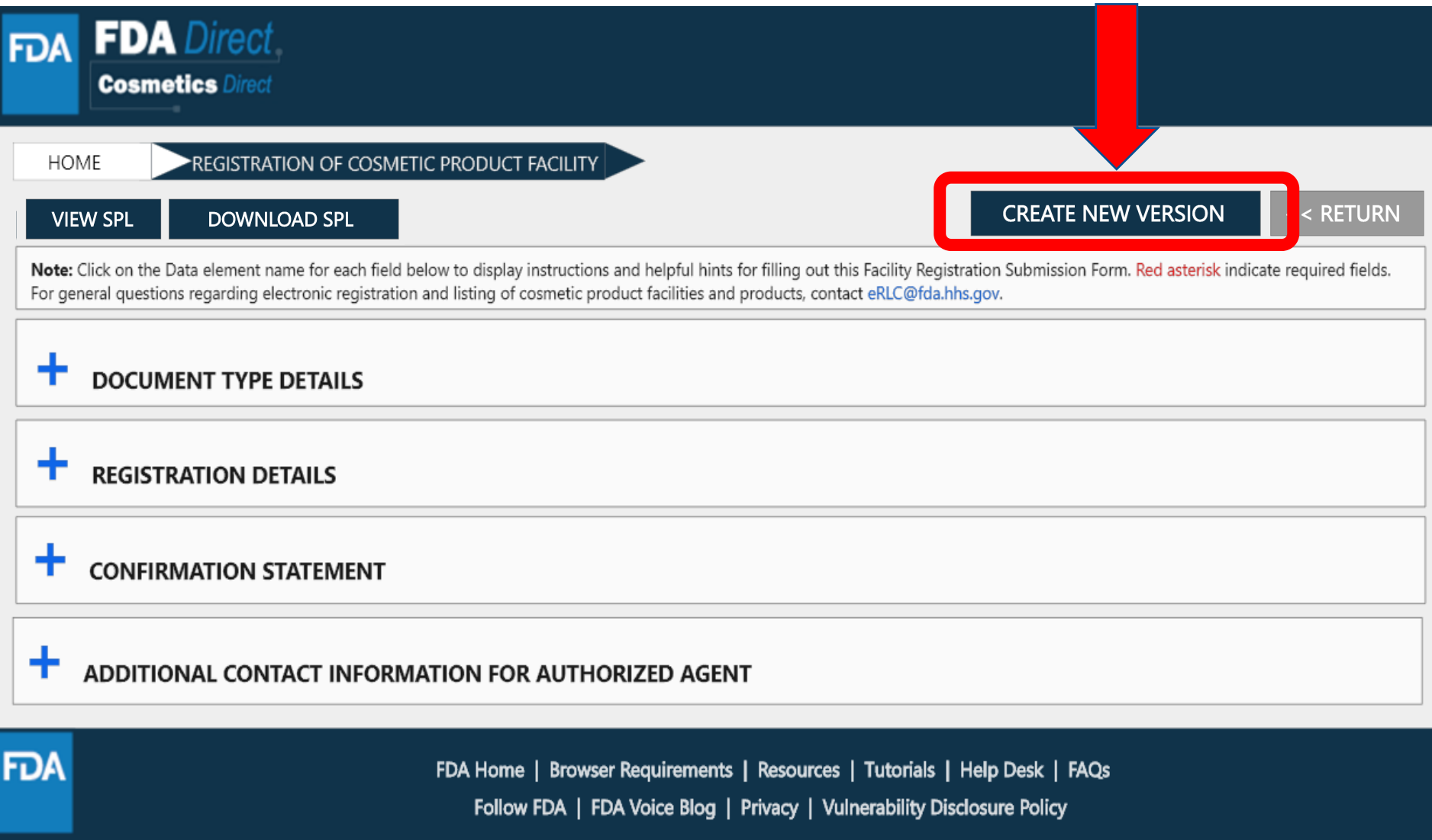
REGISTRATION STATUS: SUBMISSION ACCEPTED to VIEW SPL and DOWNLOAD SPL

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



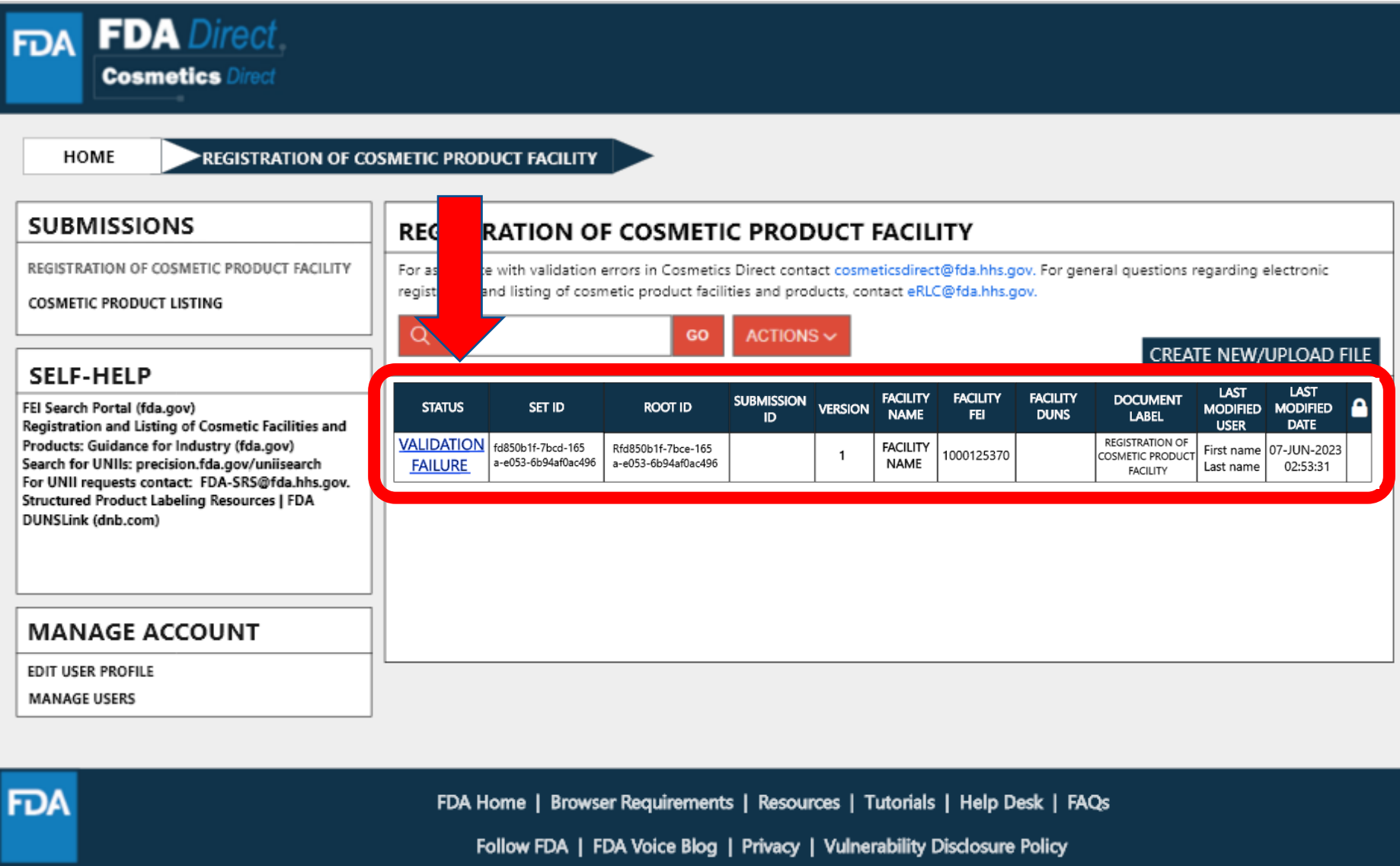
CREATE A NEW VERSION

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



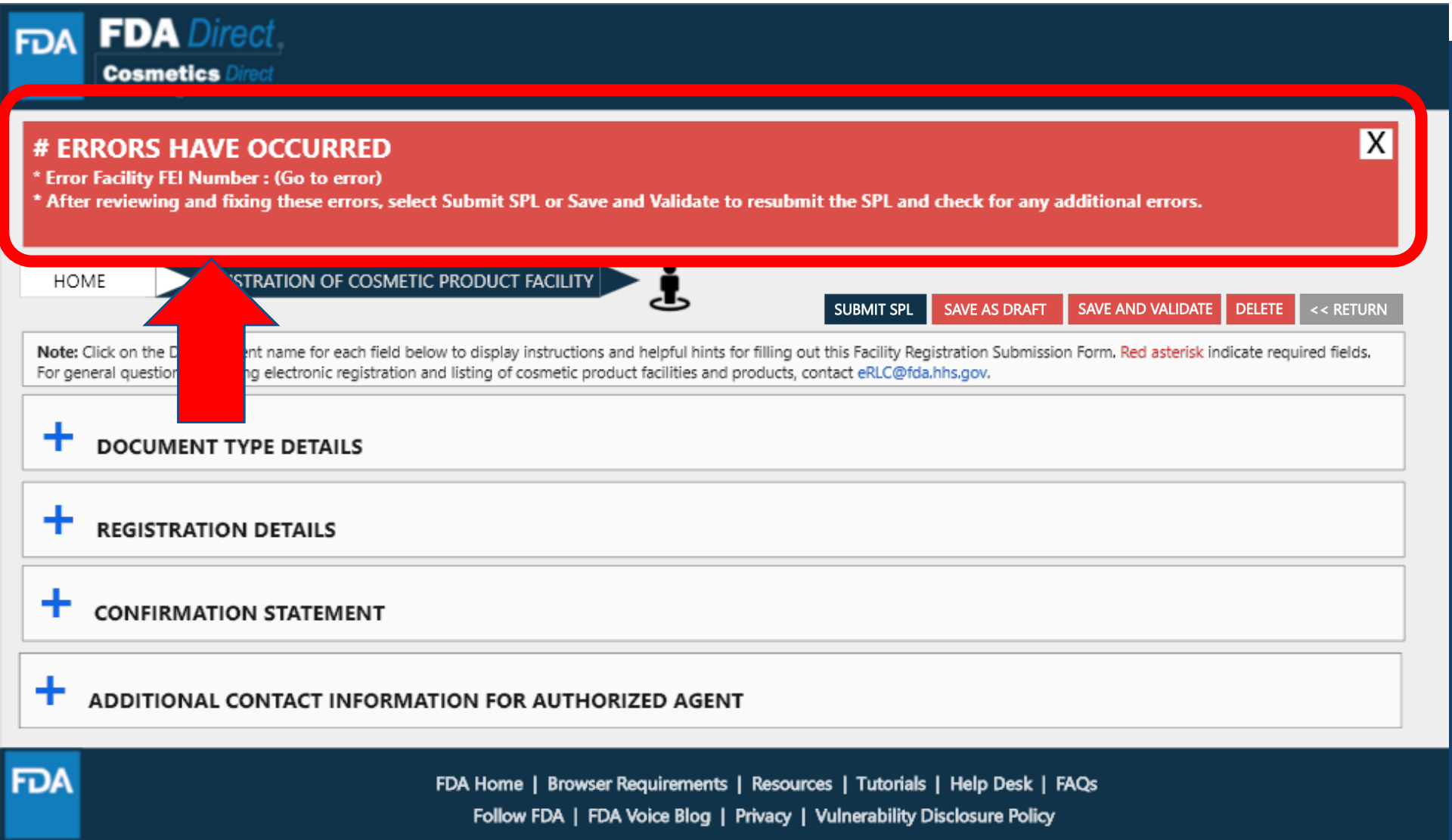
REGISTRATION STATUS: VALIDATION FAILURE

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**.



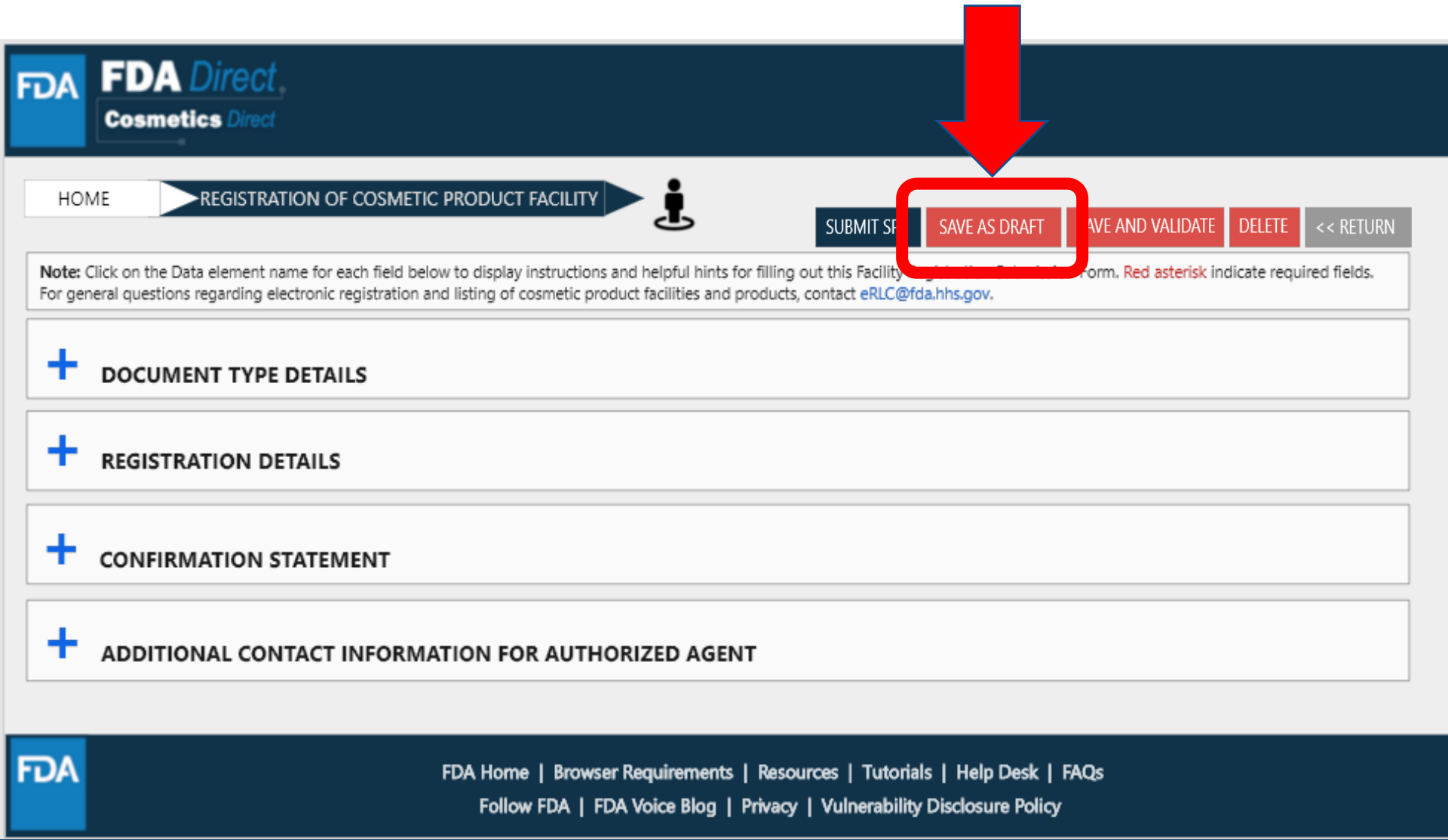
REGISTRATION STATUS: VALIDATION FAILURE

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.



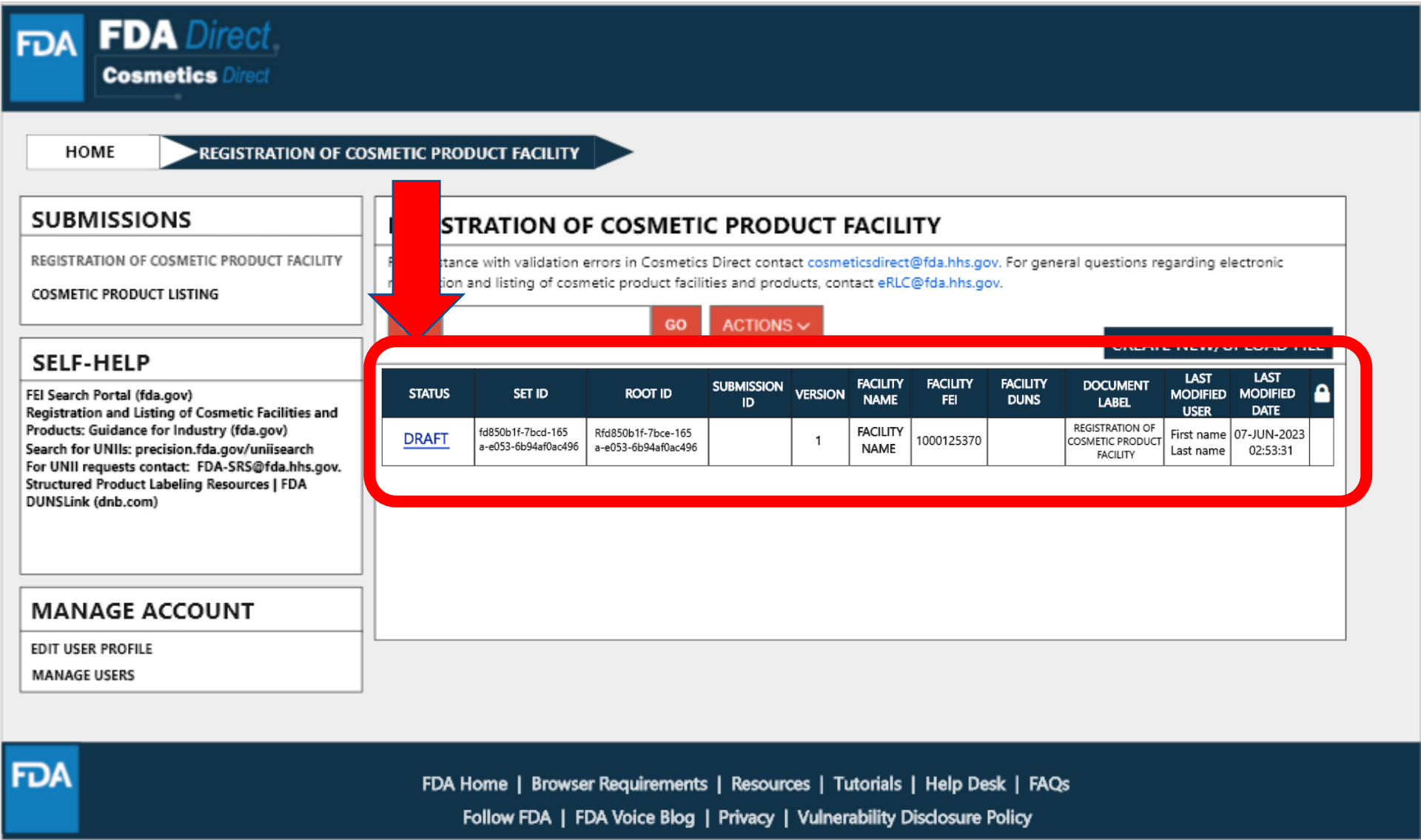
REGISTRATION STATUS: DRAFT

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**.



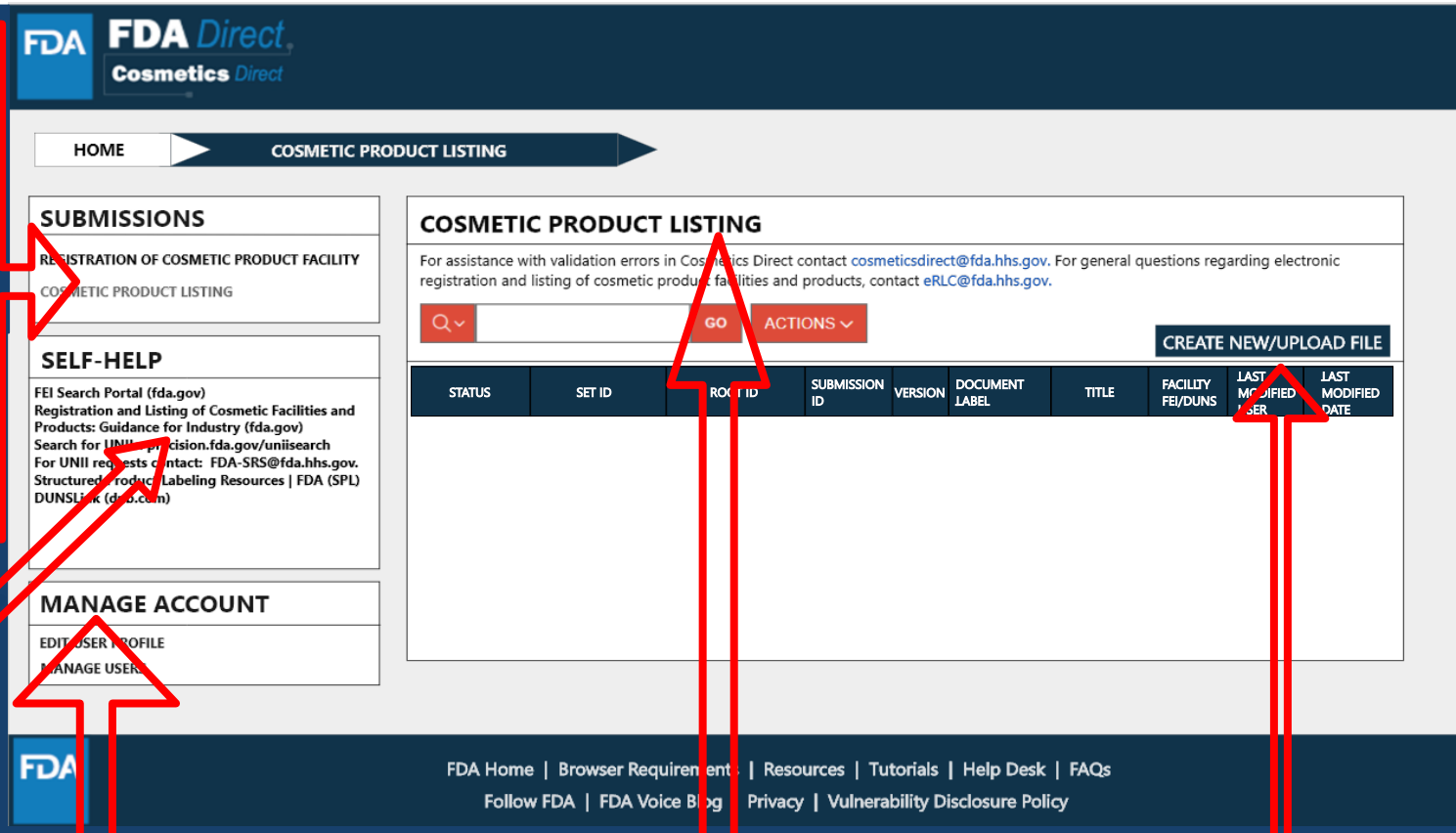
COSMETIC PRODUCT LISTING

HOME PAGE: COSMETIC PRODUCT LISTING

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

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

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



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

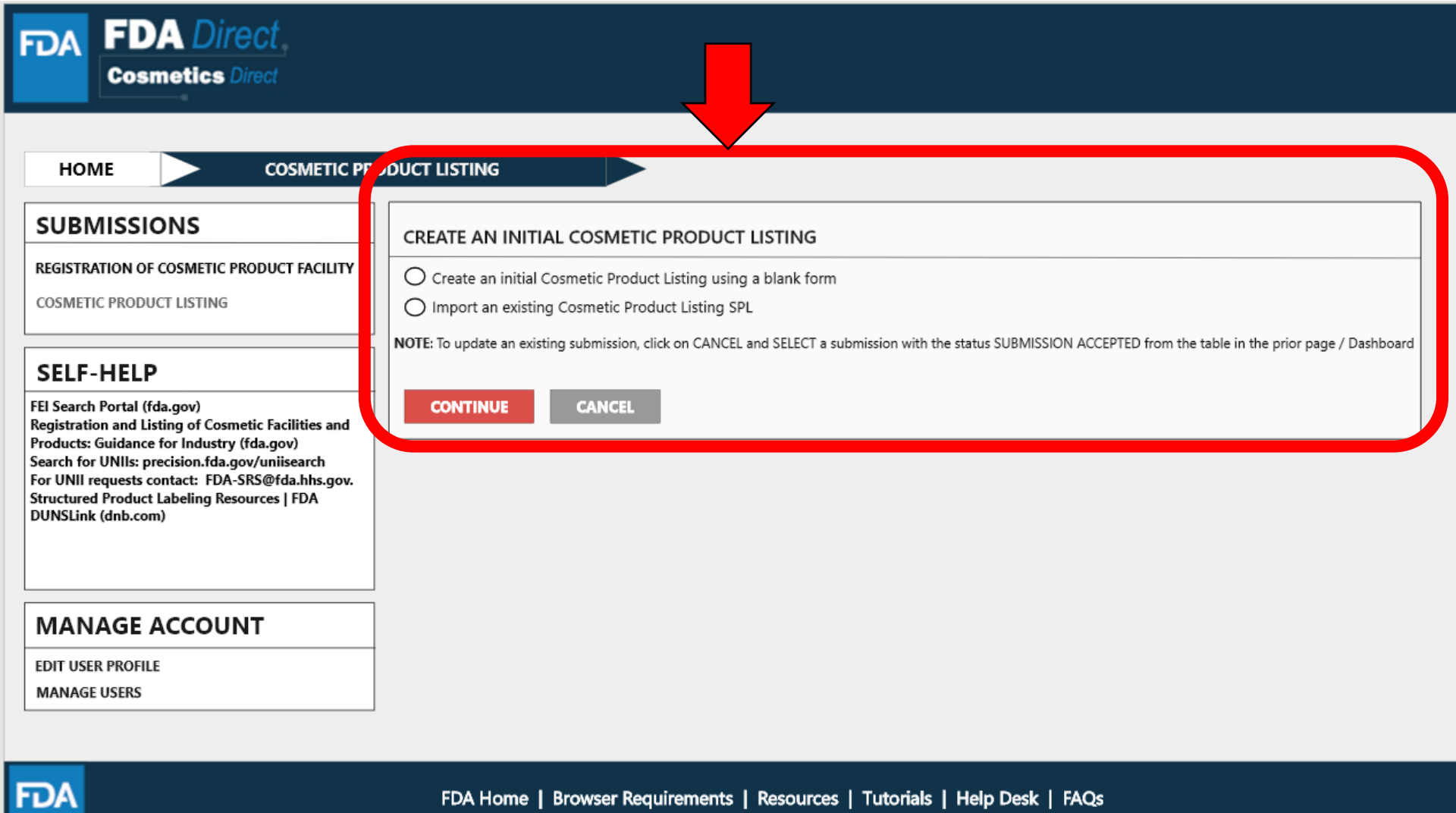
The ability to view all the previous product listing submissions based on user's access.

CREATE NEW/UPLOAD FILE

CREATE A NEW PRODUCT LISTING OR UPLOAD AN EXISTING FILE

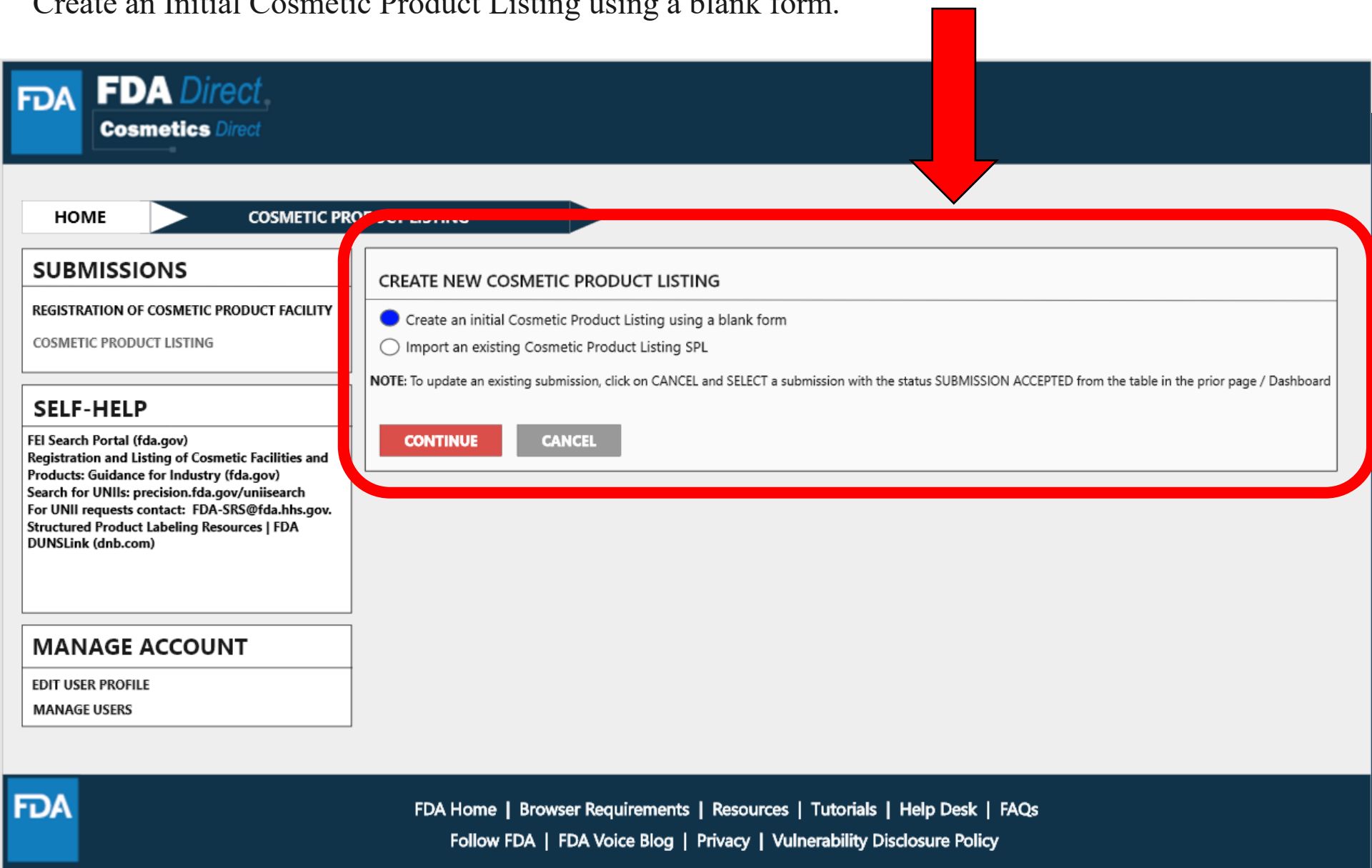
CREATE A NEW PRODUCT LISTING OR UPLOAD AN EXISTING FILE

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

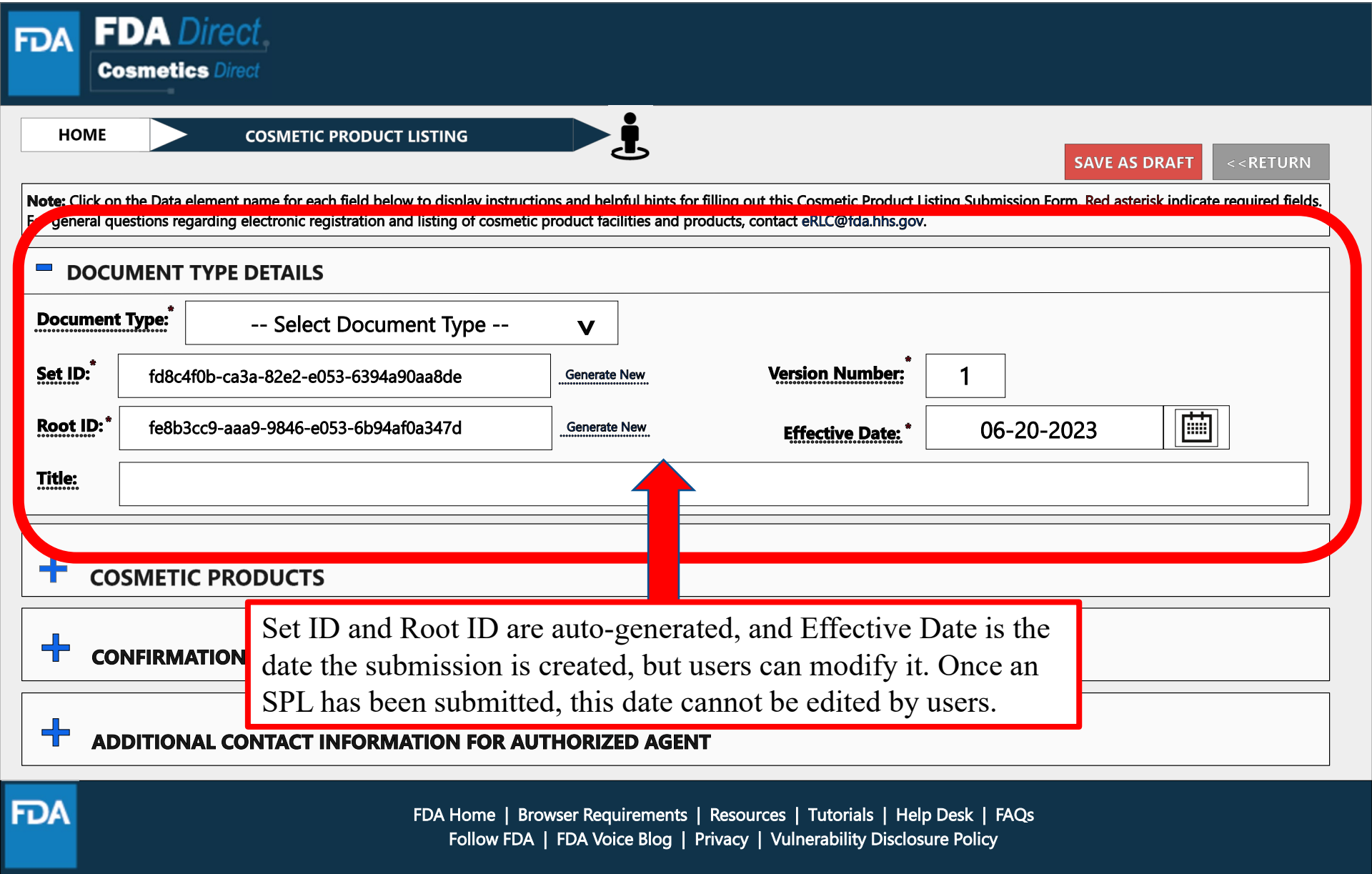


CREATE A NEW COSMETICS PRODUCT LISTING

Create an Initial Cosmetic Product Listing using a blank form.



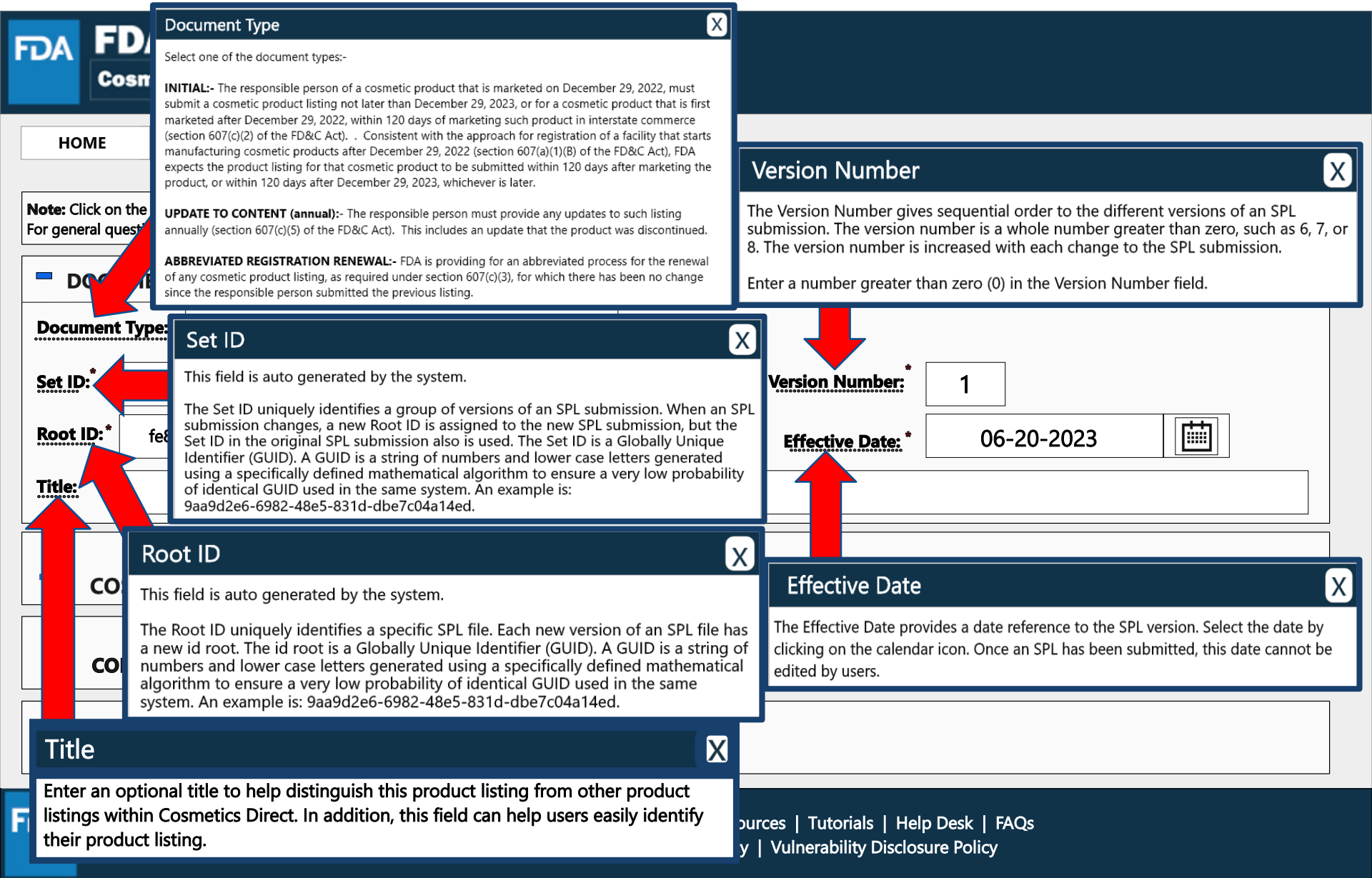
DOCUMENT TYPE DETAILS



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

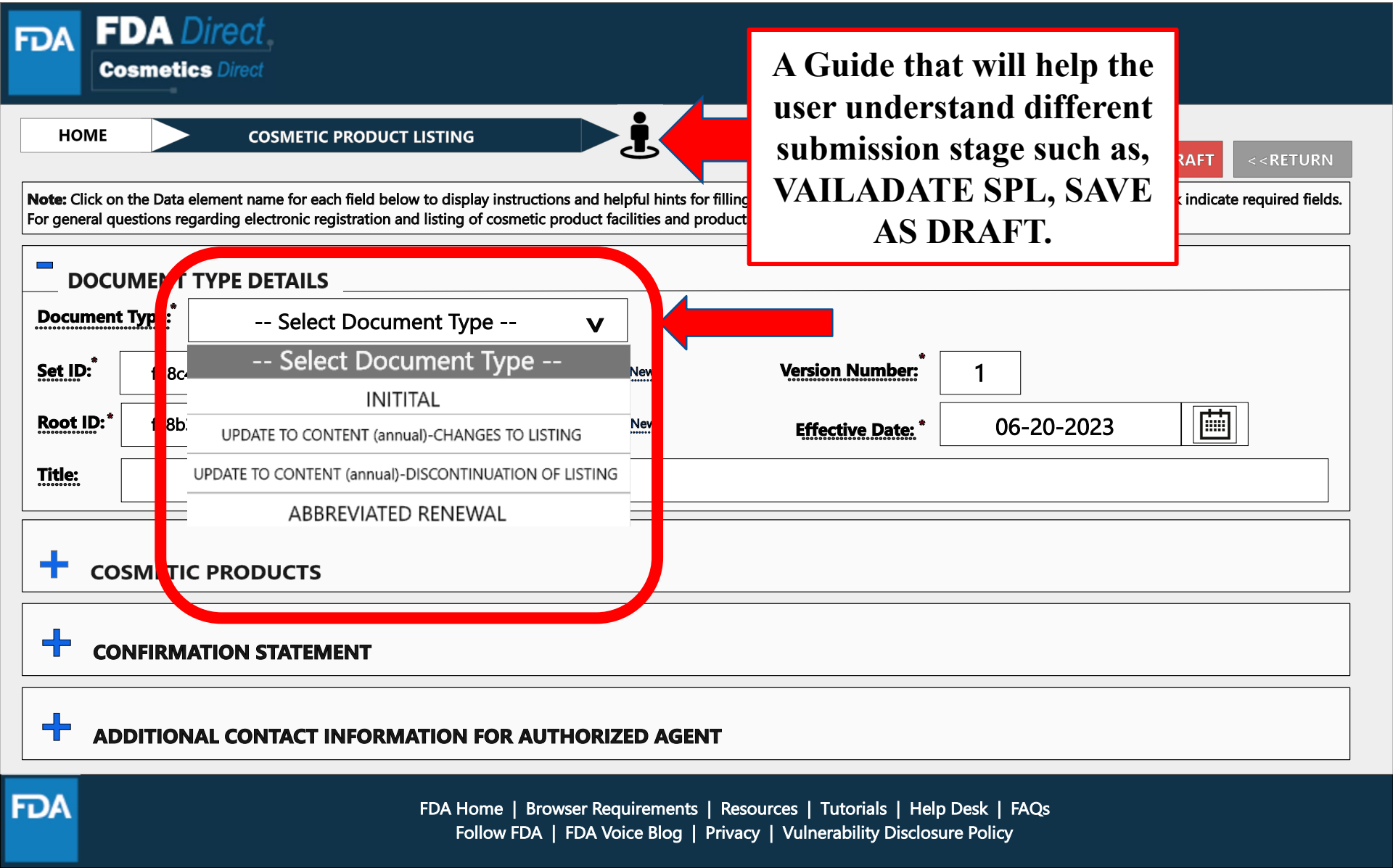
DOCUMENT TYPE TOOL TIPS

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



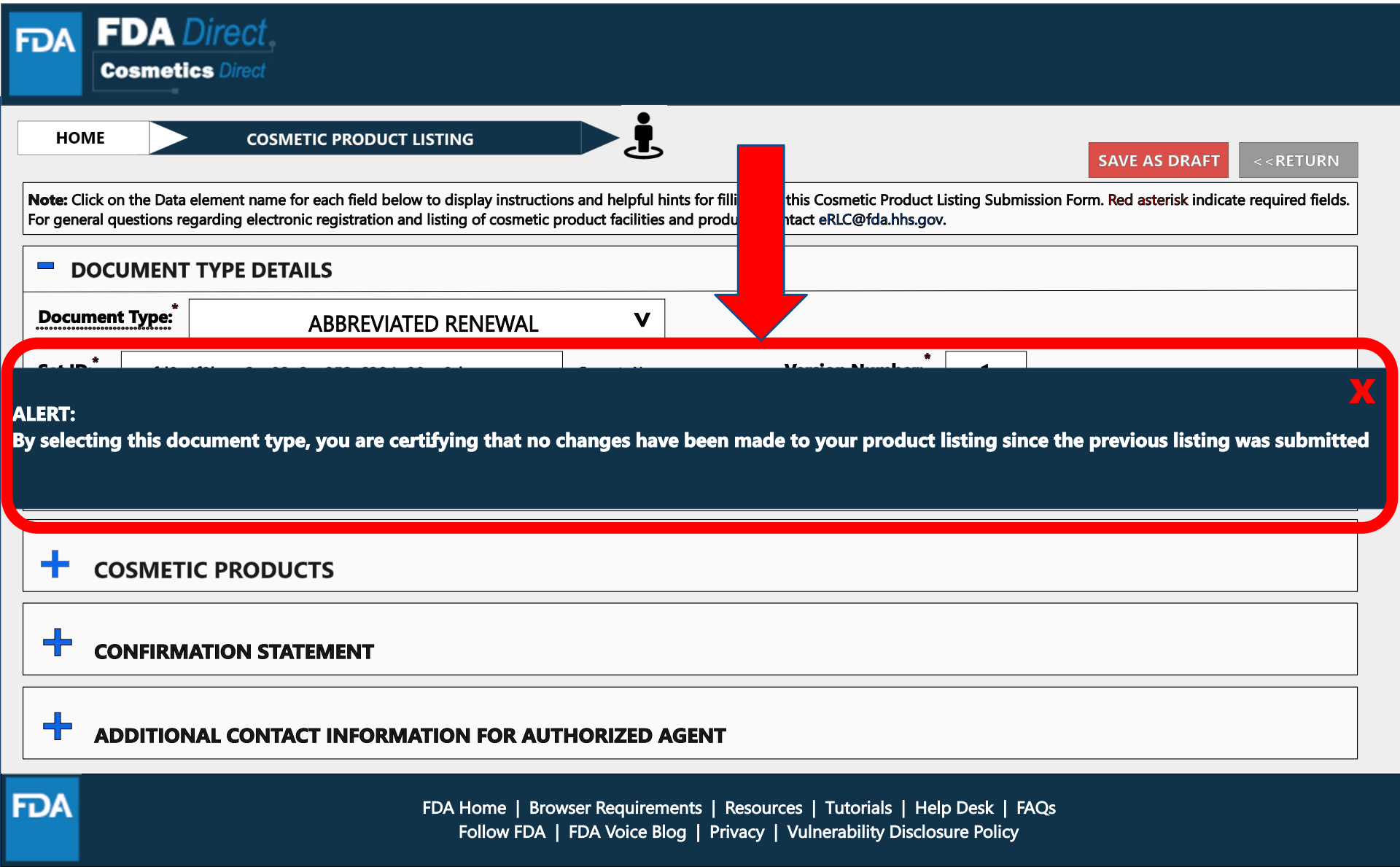
DOCUMENT TYPE DETAILS

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.



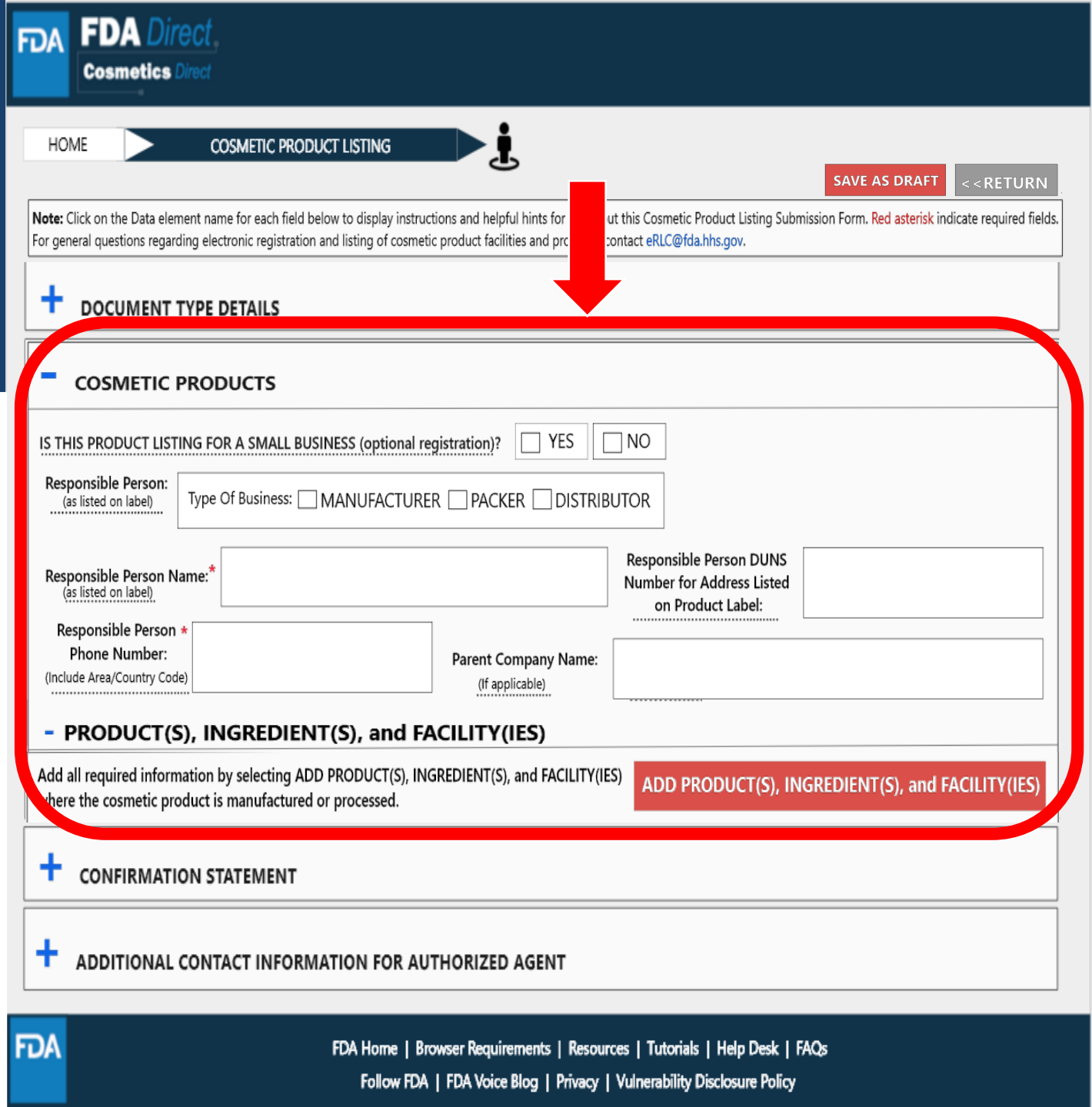
DOCUMENT TYPE DETAILS

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*"



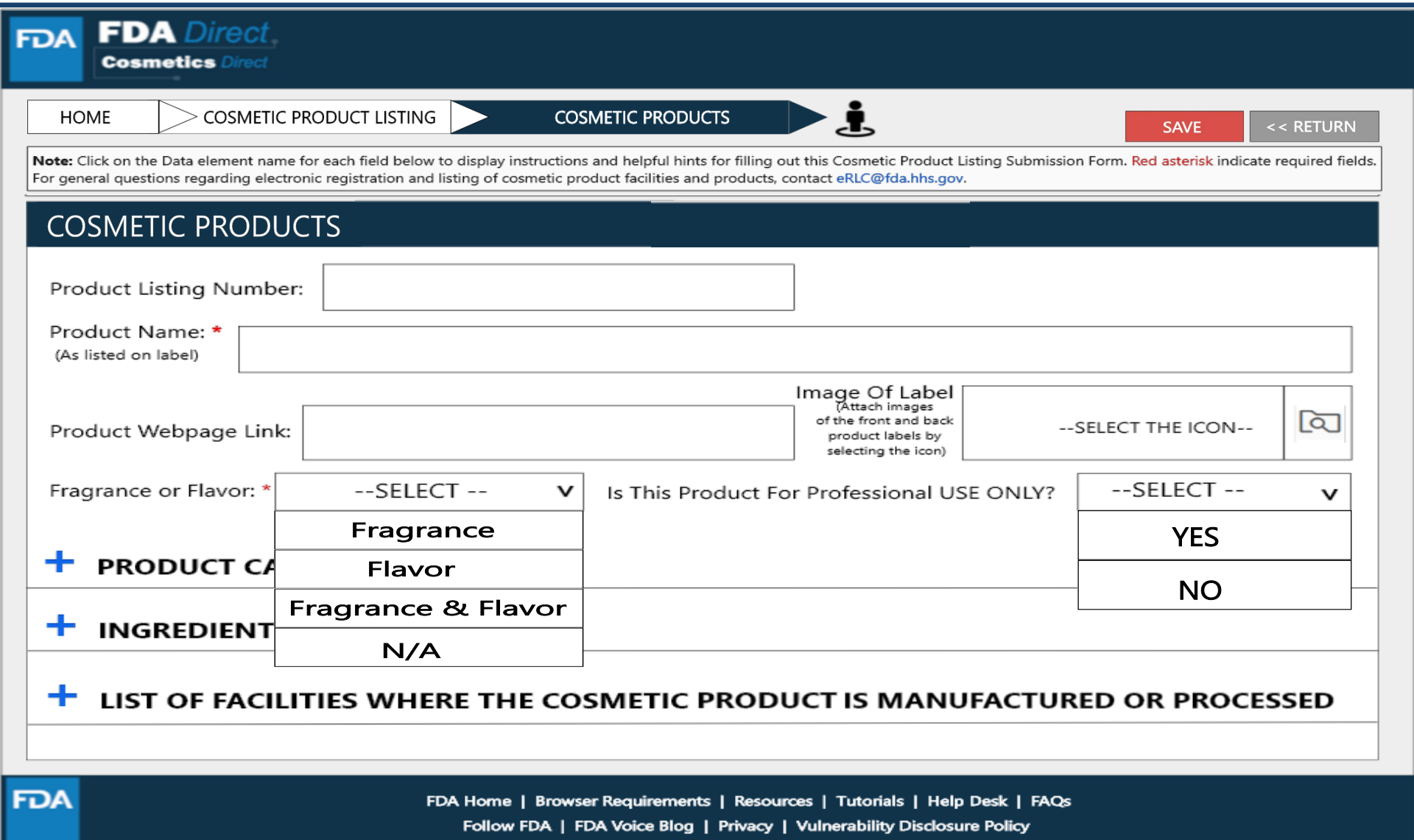
COSMETIC PRODUCTS

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).



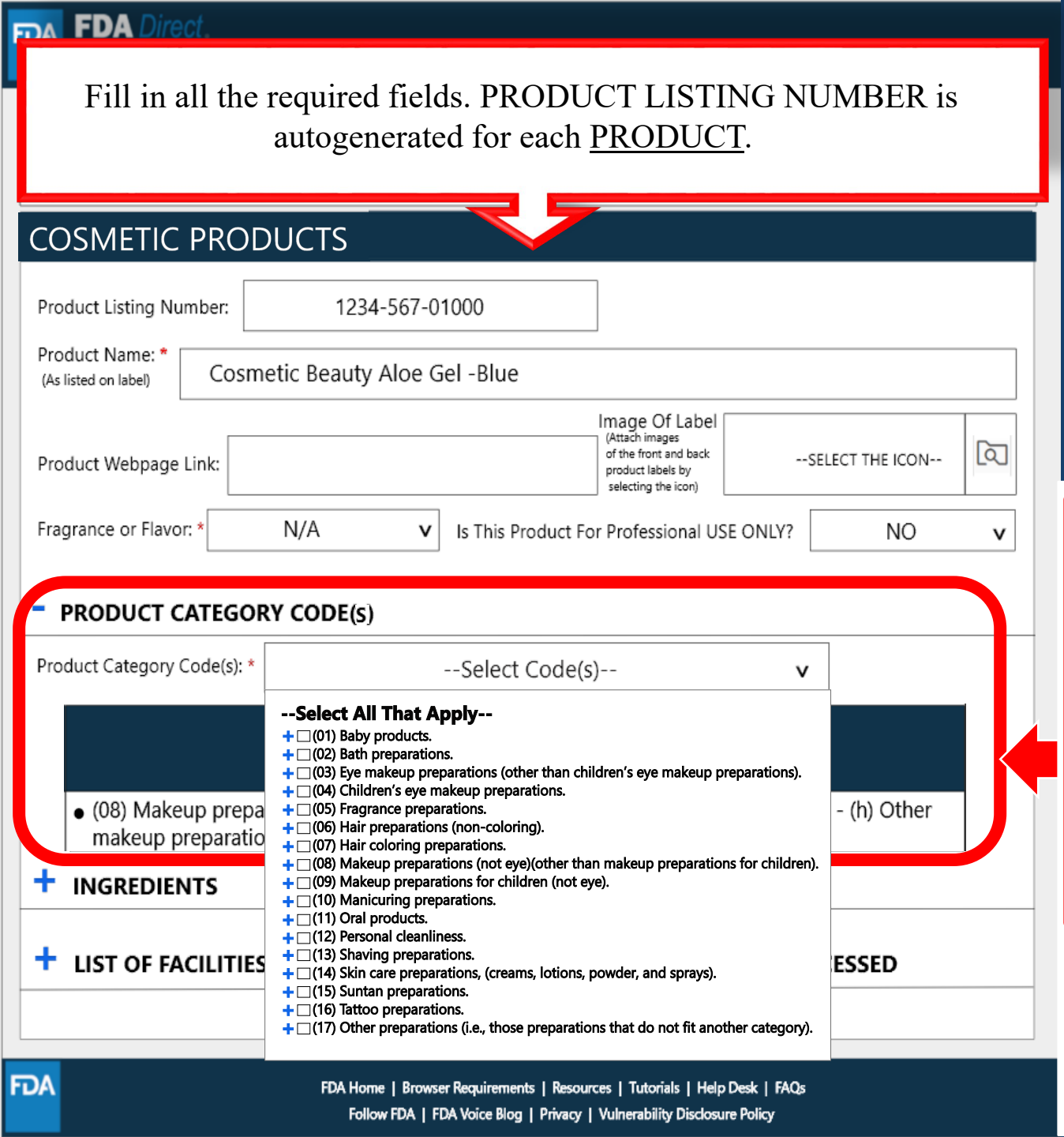
PRODUCTS, INGREDIENTS AND FACILITIES

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



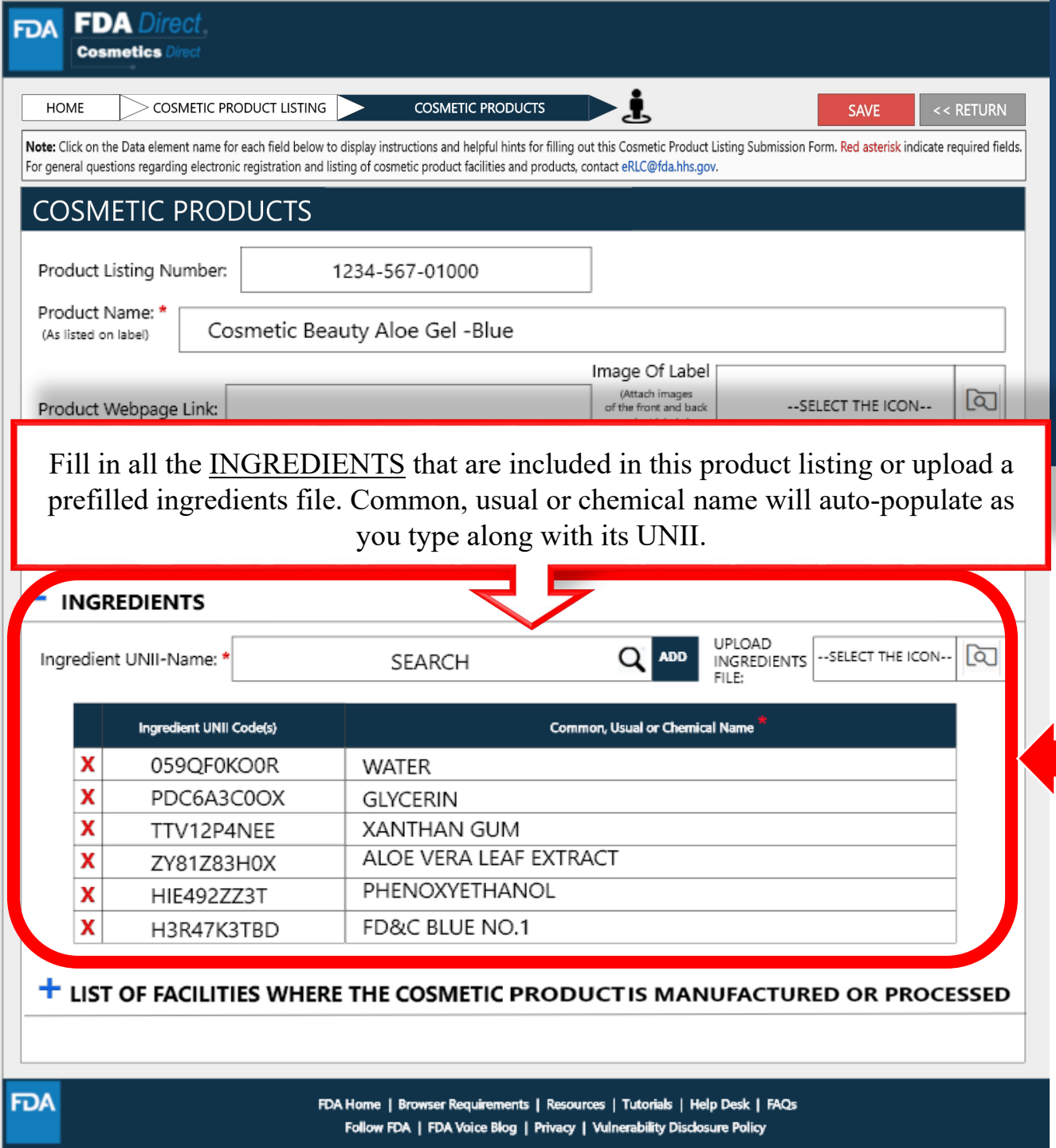
PRODUCT CATEGORY CODE(S)- EXAMPLE

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

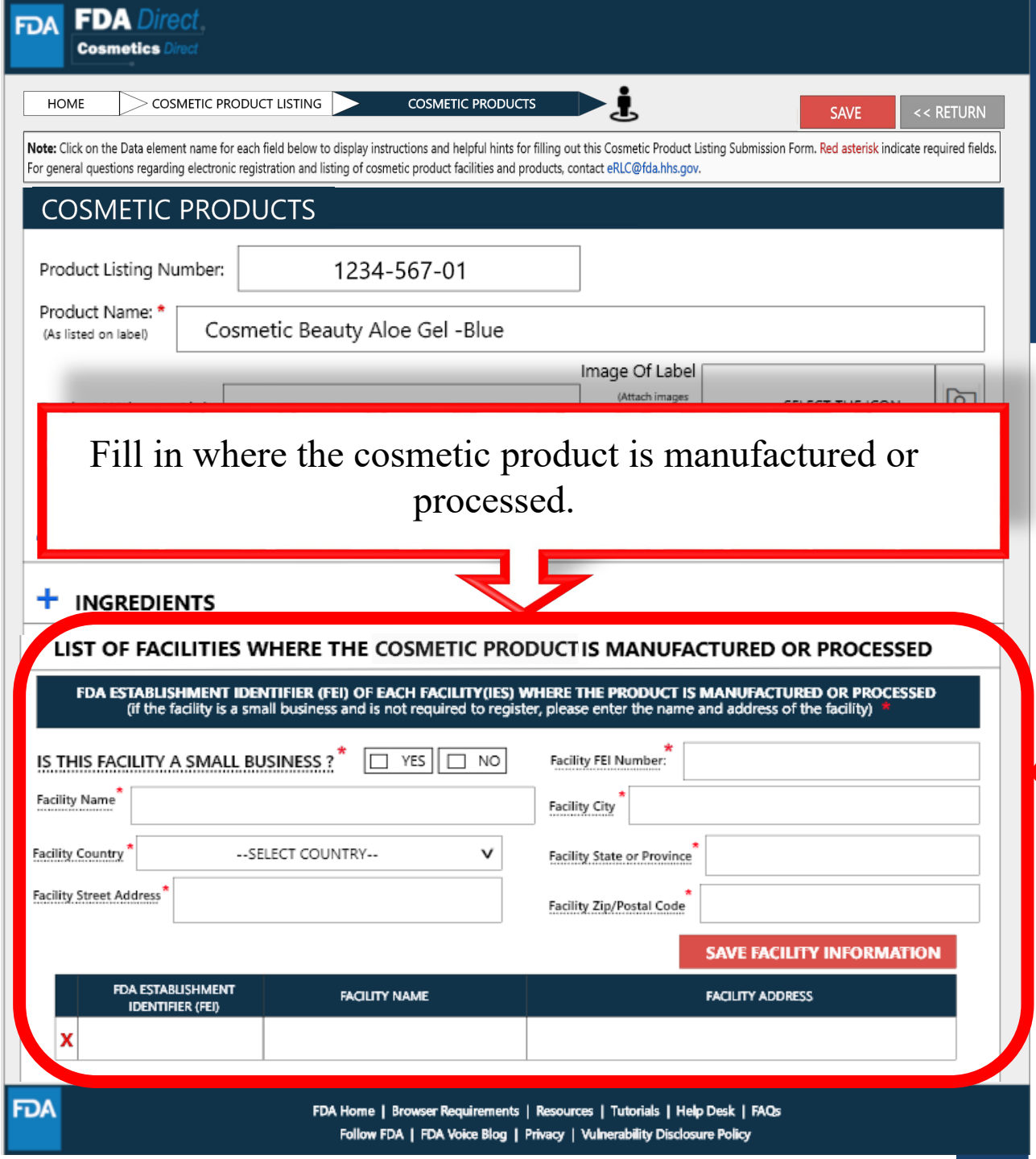


Provide the Product Category Code(s) by selecting the drop-down icon. After selecting the drop-down icon, SELECT ALL PRODUCT CATEGORY CODE(s) that apply to this submission. The list can be minimized/maximized with the (-) or (+).

LISTING INGREDIENTS (EXAMPLE)



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

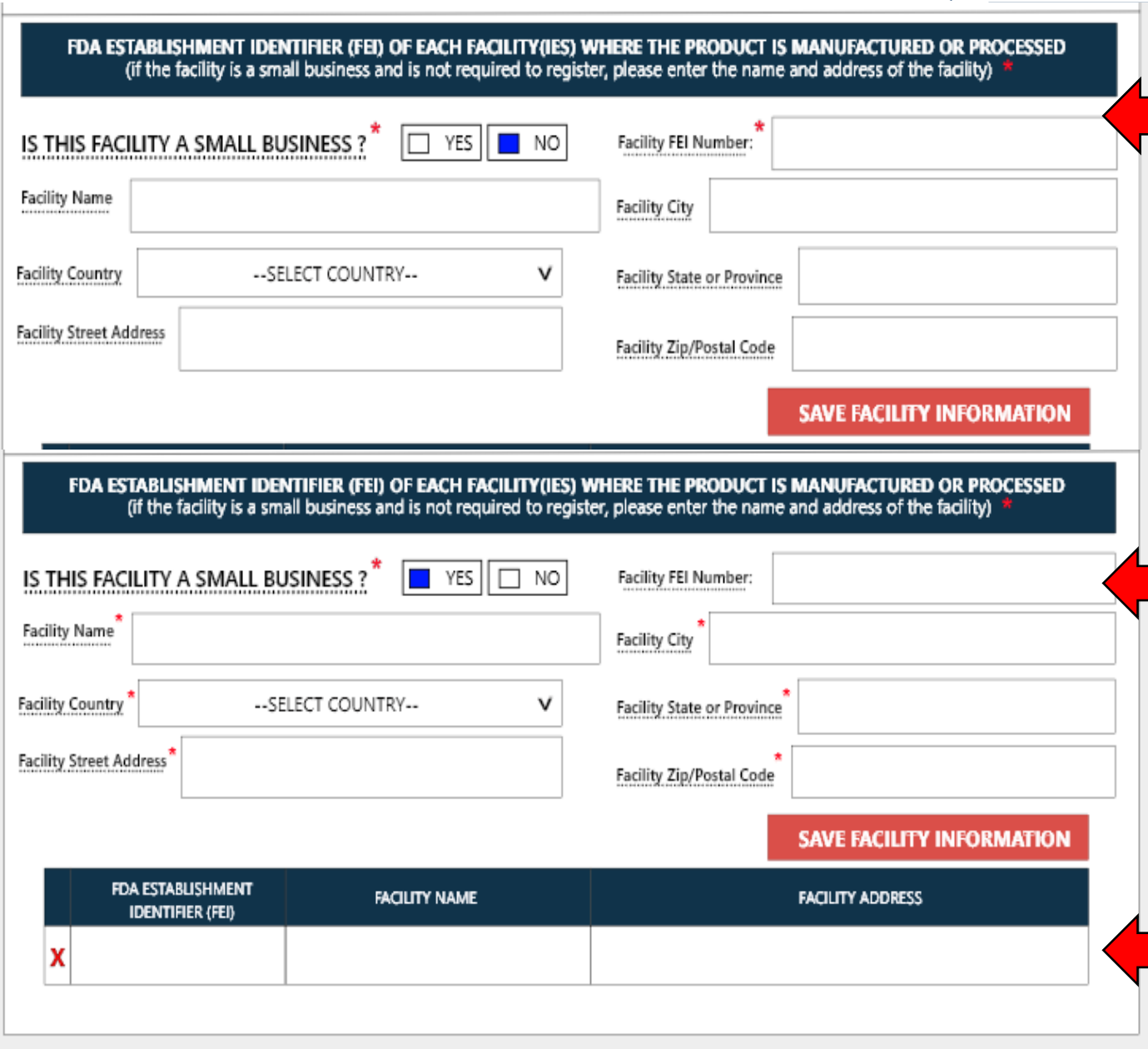


LIST OF FACILITY(IES) (EXAMPLE)

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.

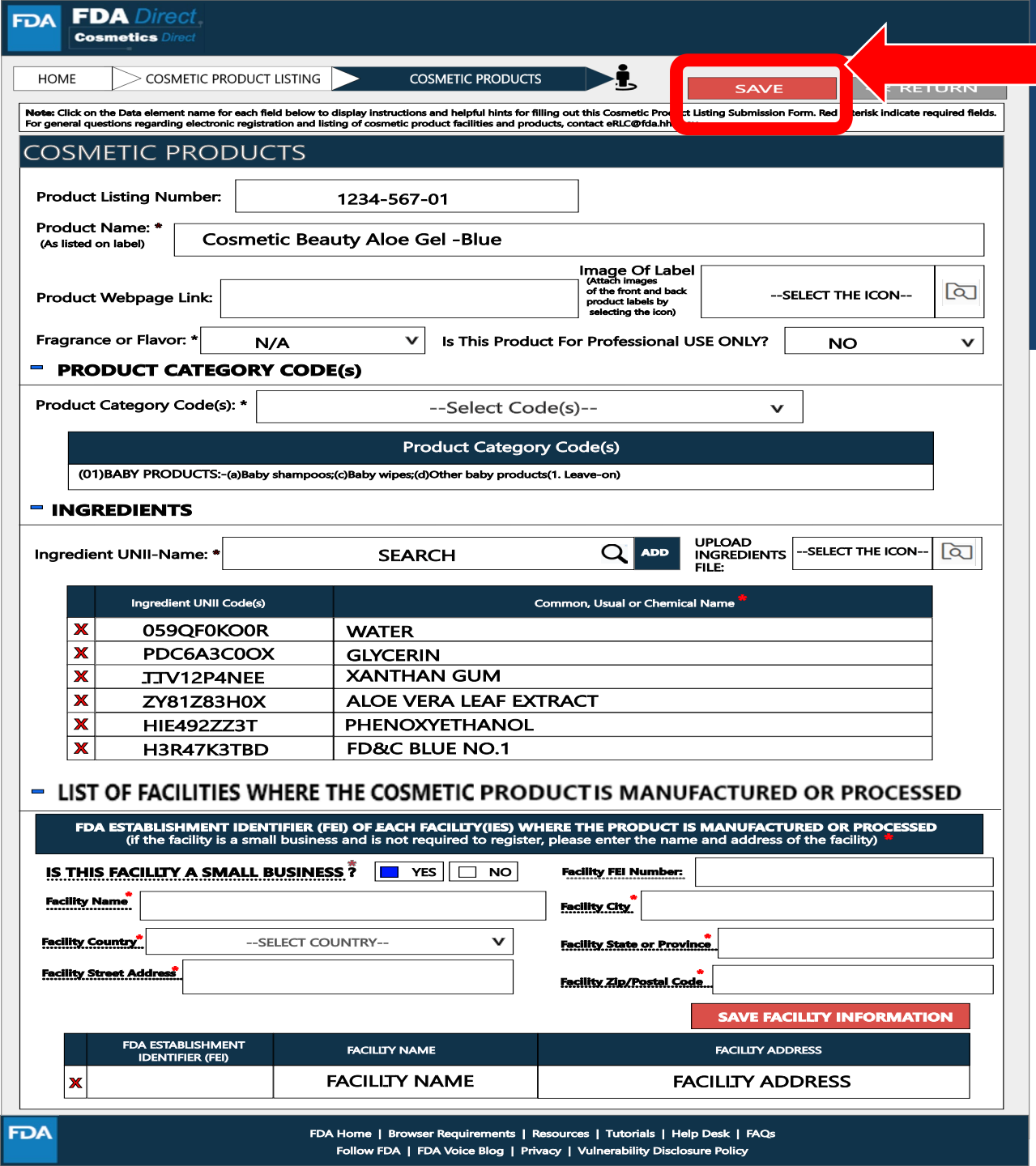
LIST OF FACILITY (EXAMPLE)



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

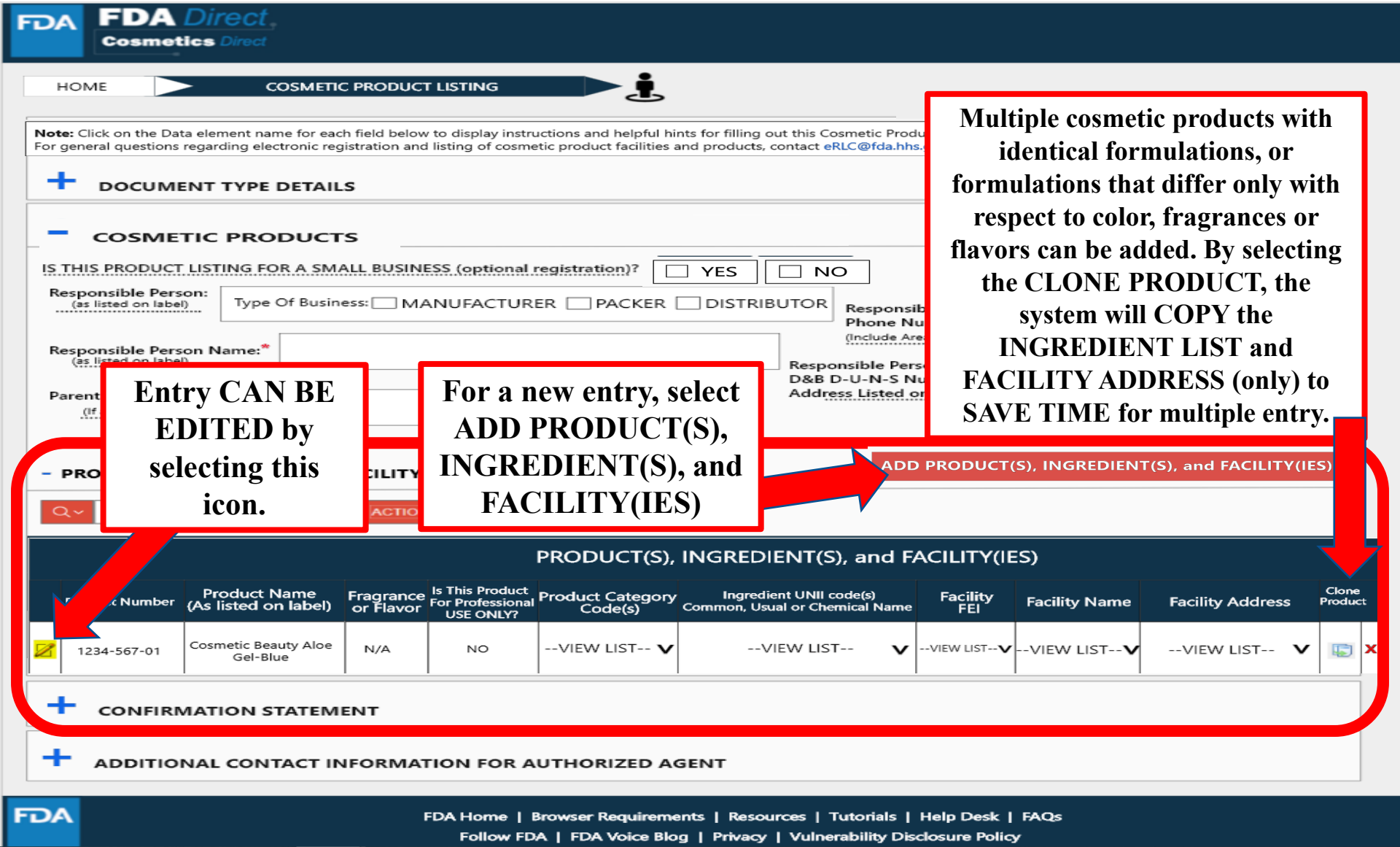


After verifying the entered information is correct, select SAVE

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).



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 indicates required fields.
For general questions regarding electronic registration and listing of cosmetic product facilities and products, contact eRLC@fda.hhs.gov.

COSMETIC PRODUCTS

Product Listing Number: 1234-567-02

Product Name: * (As listed on label)

Product Webpage Link:

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

Fragrance or Flavor: * --Select--

Is This Product For Professional USE ONLY? --Select--

PRODUCT CATEGORY CODE(s)

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

Product Category Code(s)

INGREDIENTS

Ingredient UNII-Name: * SEARCH ADD

UPLOAD INGREDIENTS FILE: --SELECT THE ICON--

	Ingredient UNII Code(s)	Common, Usual or Chemical Name *
X	059QF0KO0R	WATER
X	PDC6A3C0OX	GLYCERIN
X	...TV12P4NEE	XANTHAN GUM
X	ZY81Z83H0X	ALOE VERA LEAF EXTRACT
X	HIE492ZZ3T	PHENOXYETHANOL
X	H3R47K3TBD	FD&C BLUE NO.1

LIST OF FACILITIES WHERE THE COSMETIC PRODUCT IS MANUFACTURED OR PROCESSED

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

IS THIS FACILITY A SMALL BUSINESS? * YES NO

Facility FEI Number:

Facility Name *

Facility City *

Facility Country * --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

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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 X

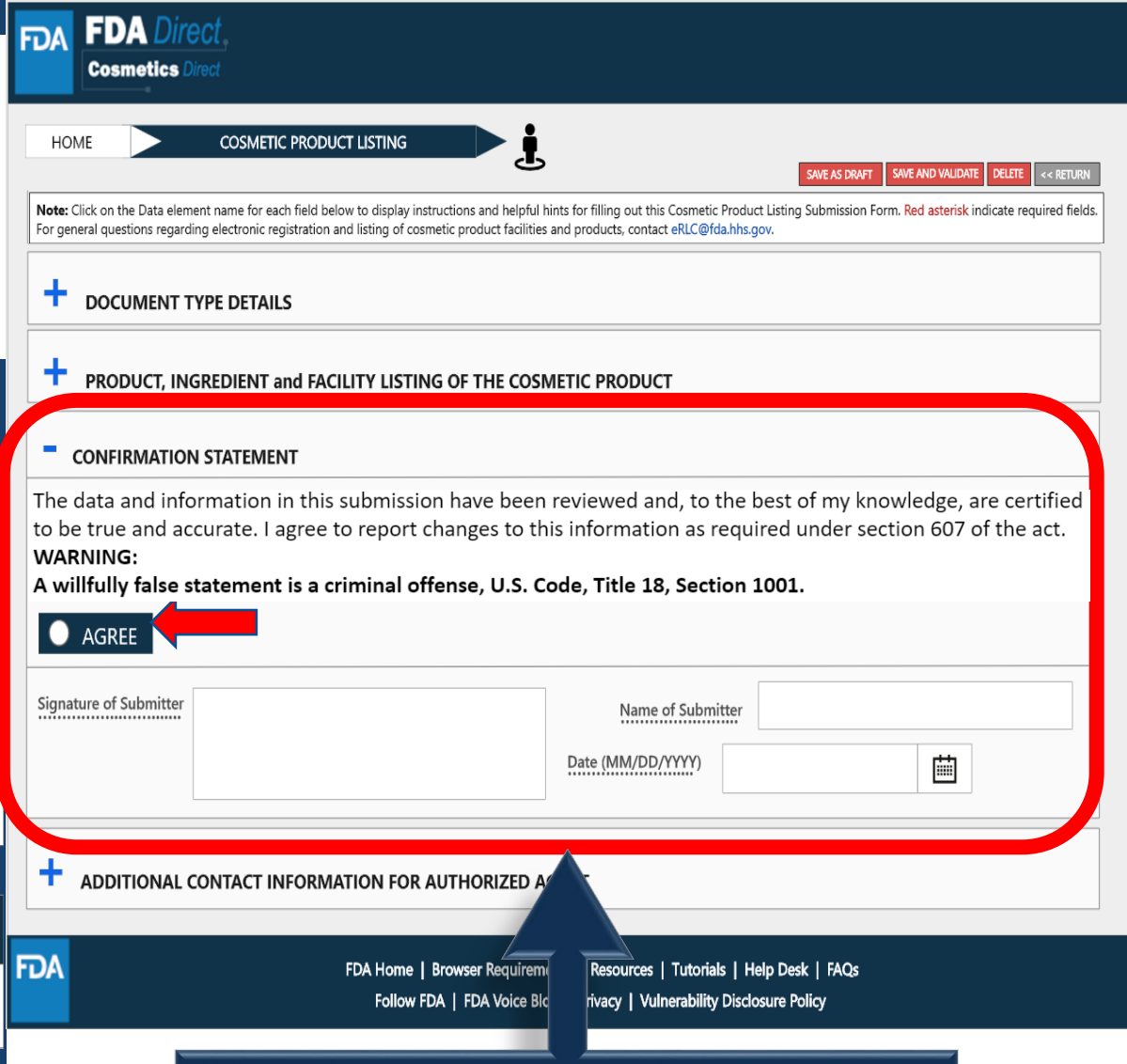
(optional field) Click on the blank signature box to display signature pad

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



After understanding the confirmation statement. Select AGREE

CONFIRMATION STATEMENT SIGNATURE

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

Signature of Submitter X

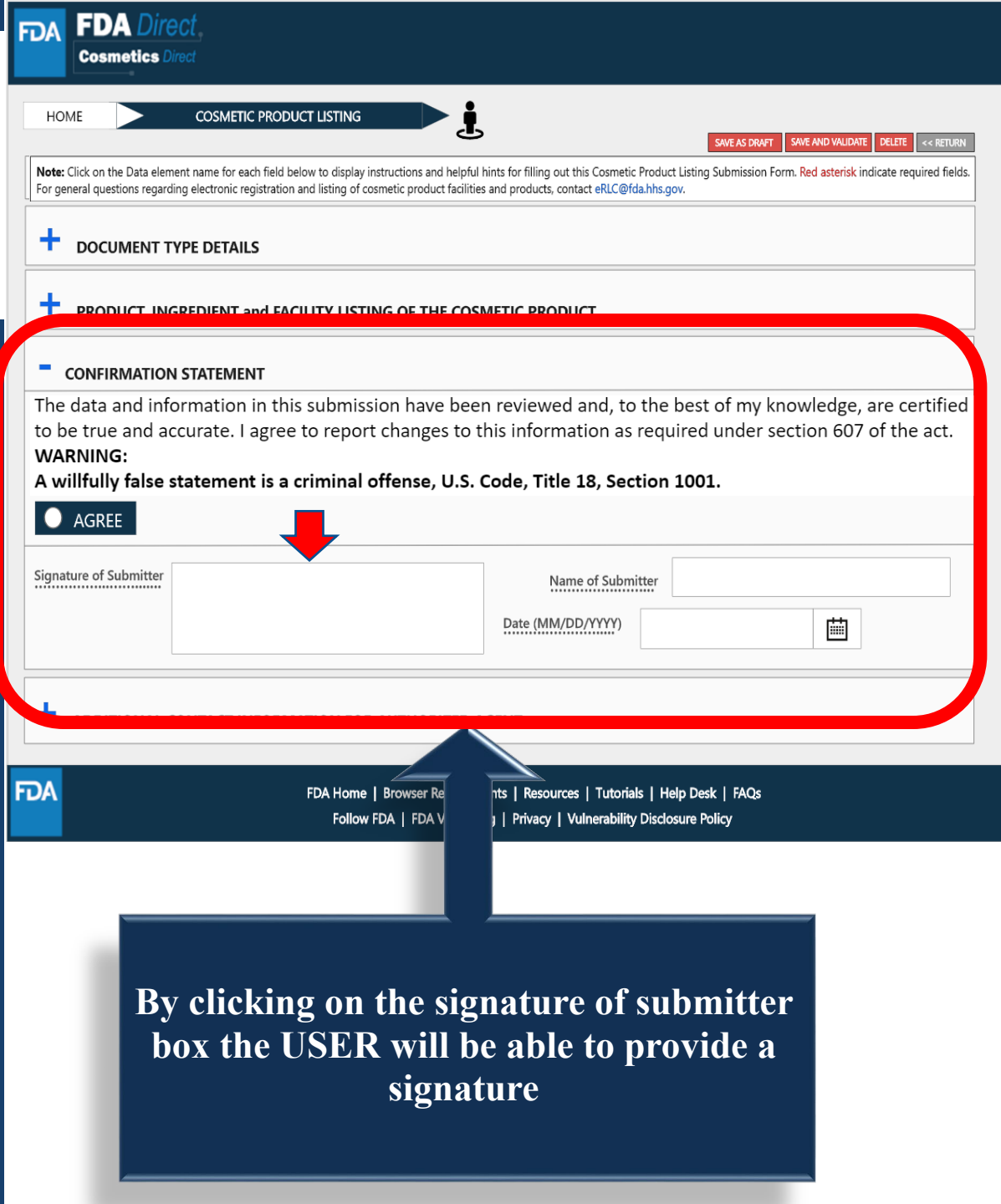
(optional field) Click on the blank signature box to display signature pad

Name of Submitter X

(optional field) Enter the full name of the submitter

Date X

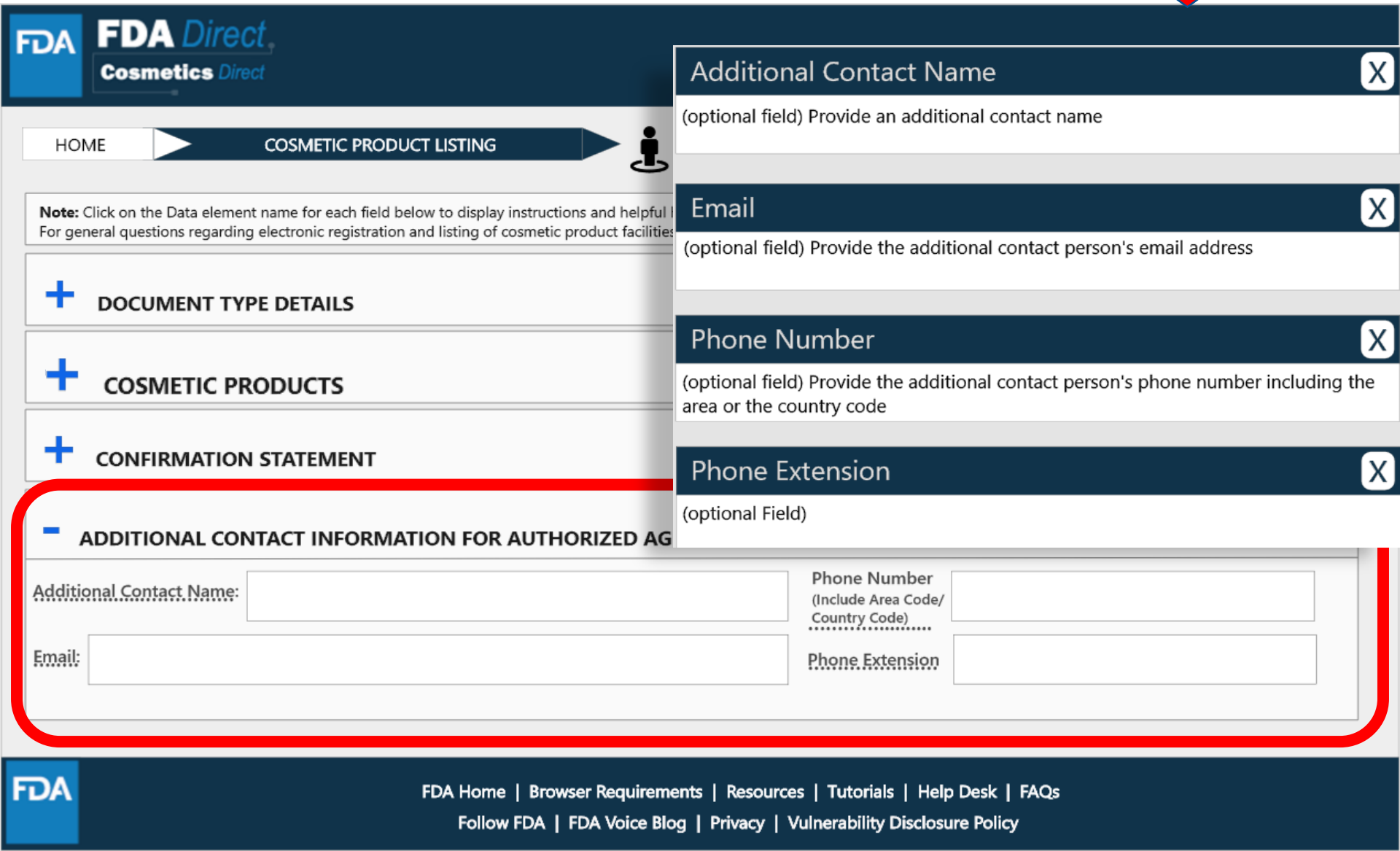
(optional field) Enter today's date, two digit month two digit day and four digit year



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

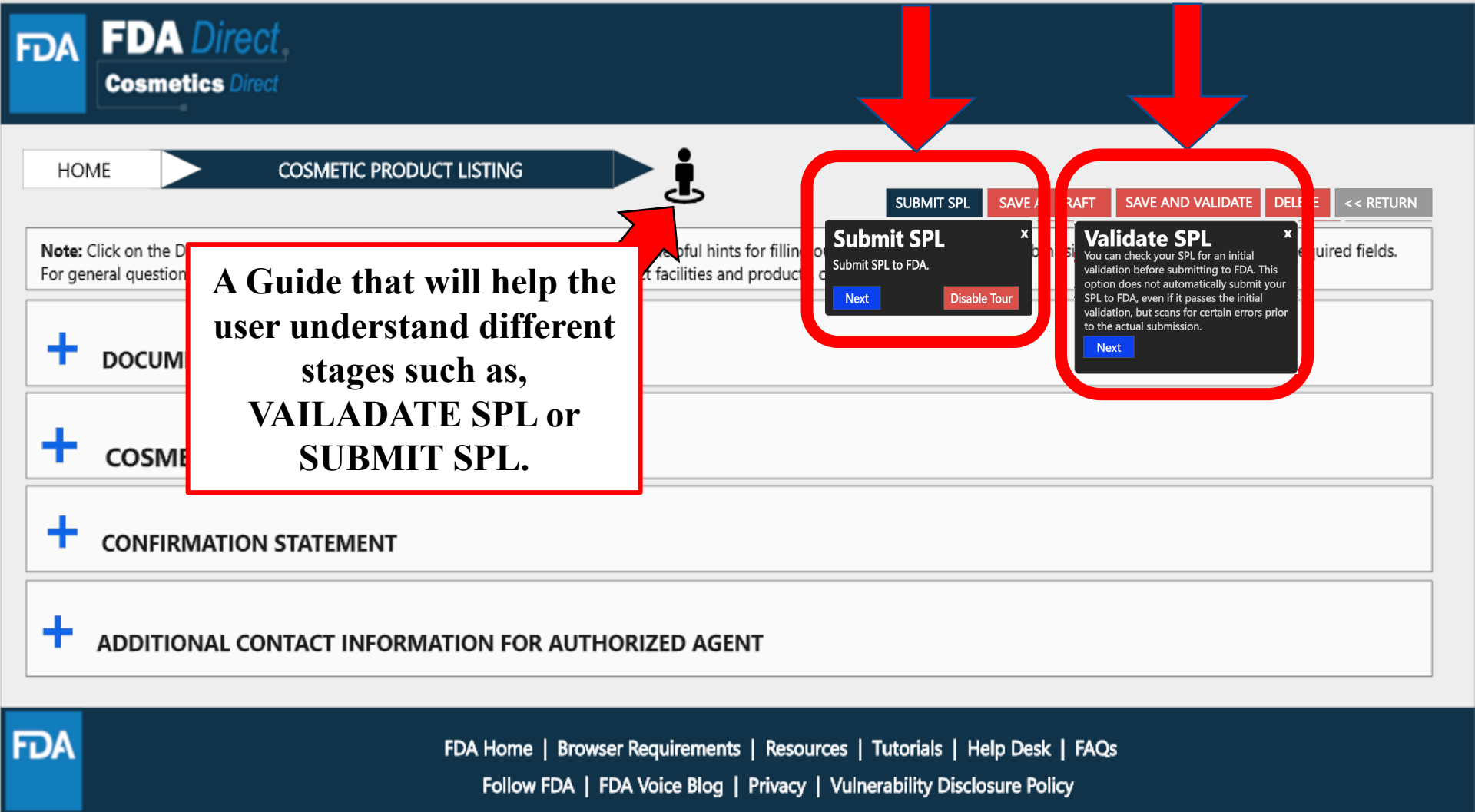
ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT

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



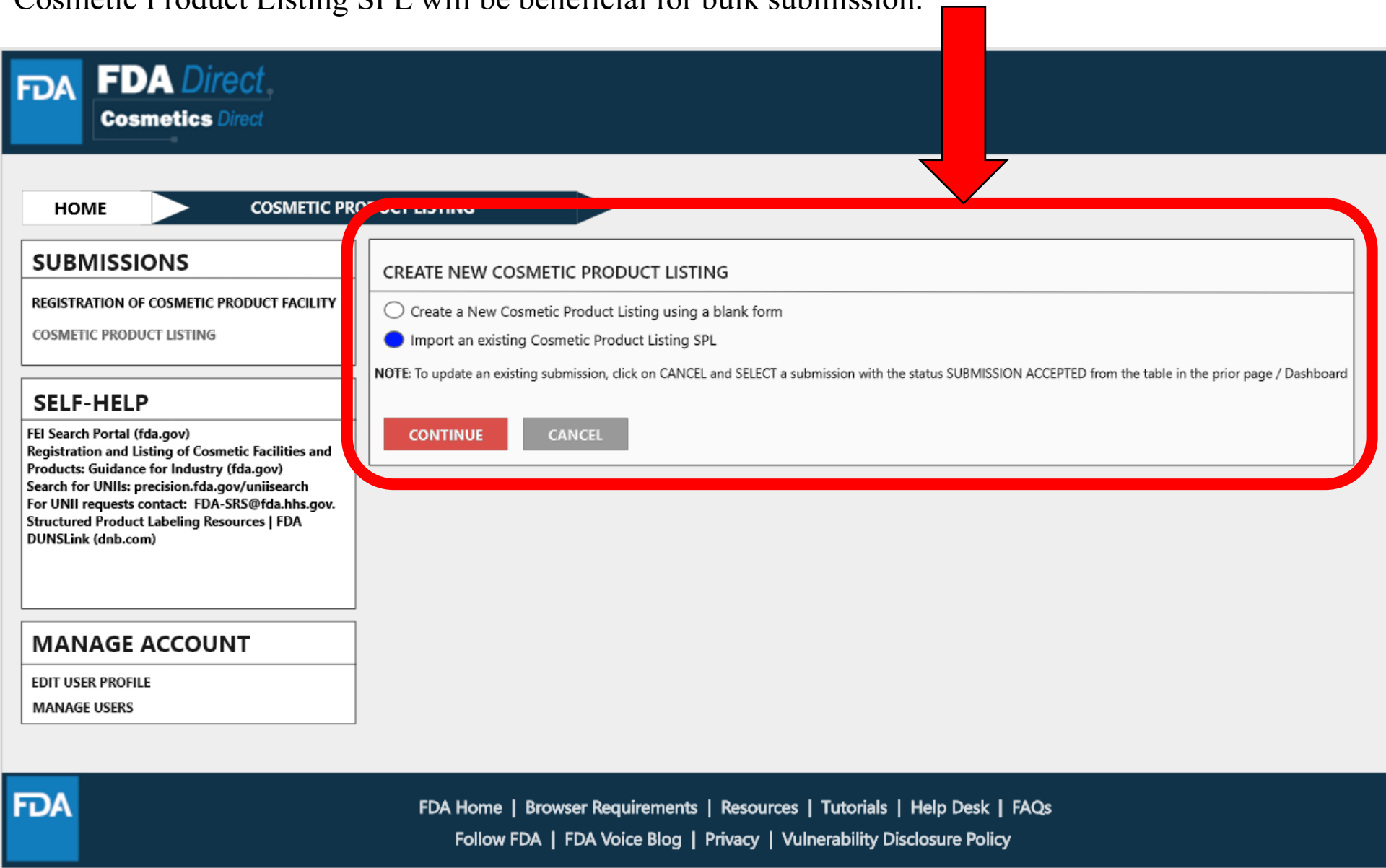
COMPLETED

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.



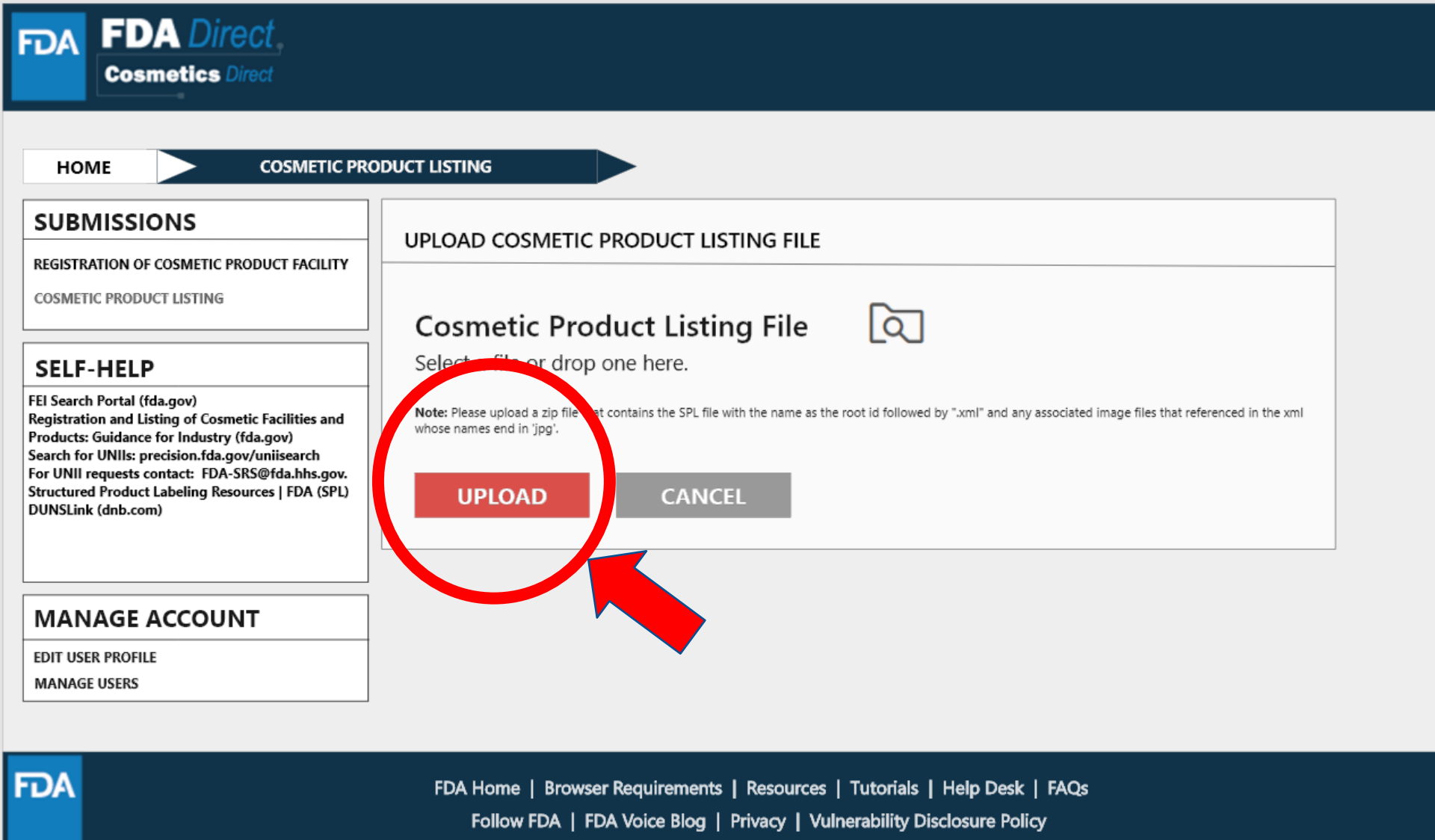
UPLOAD A FILE

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.



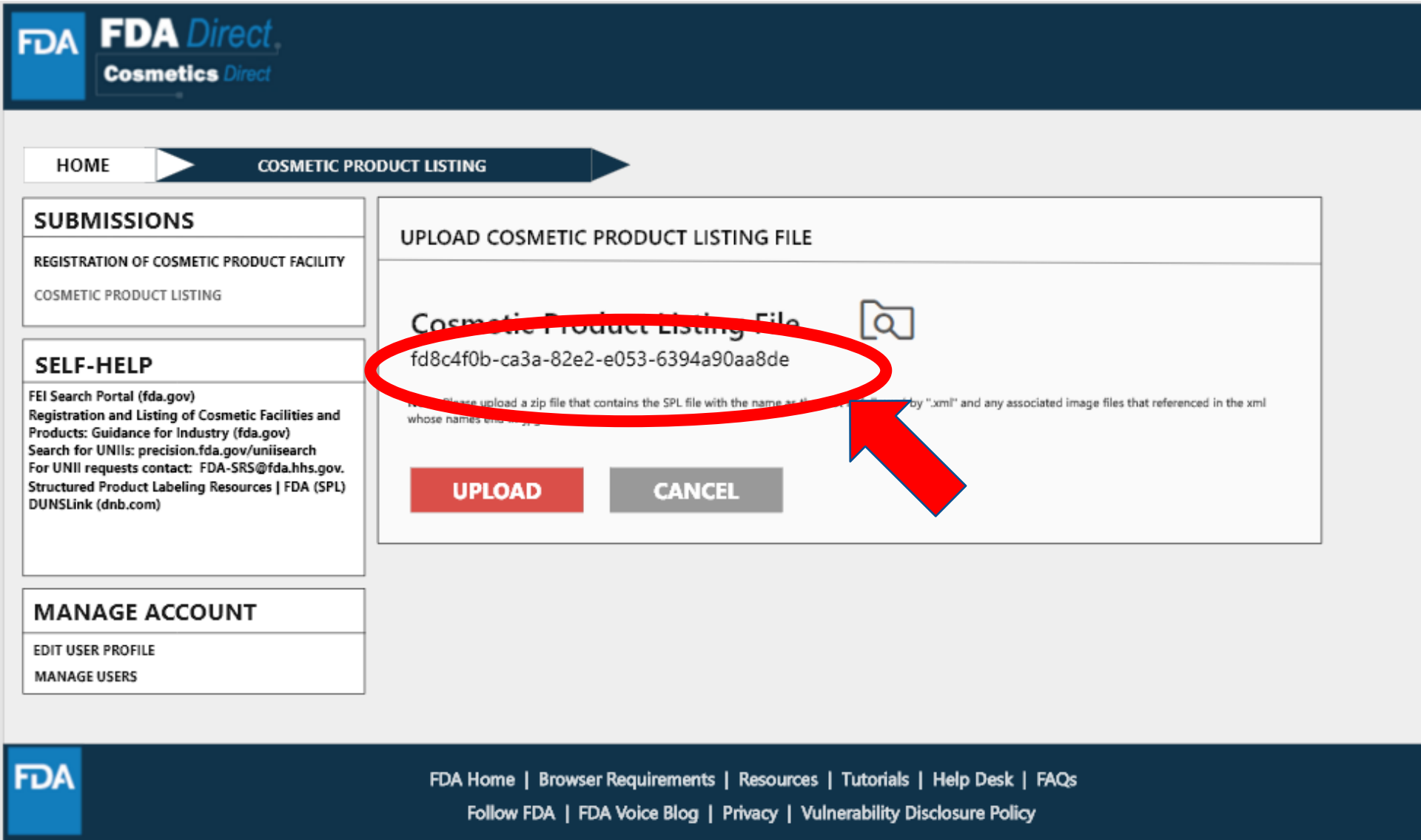
UPLOAD A FILE

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)

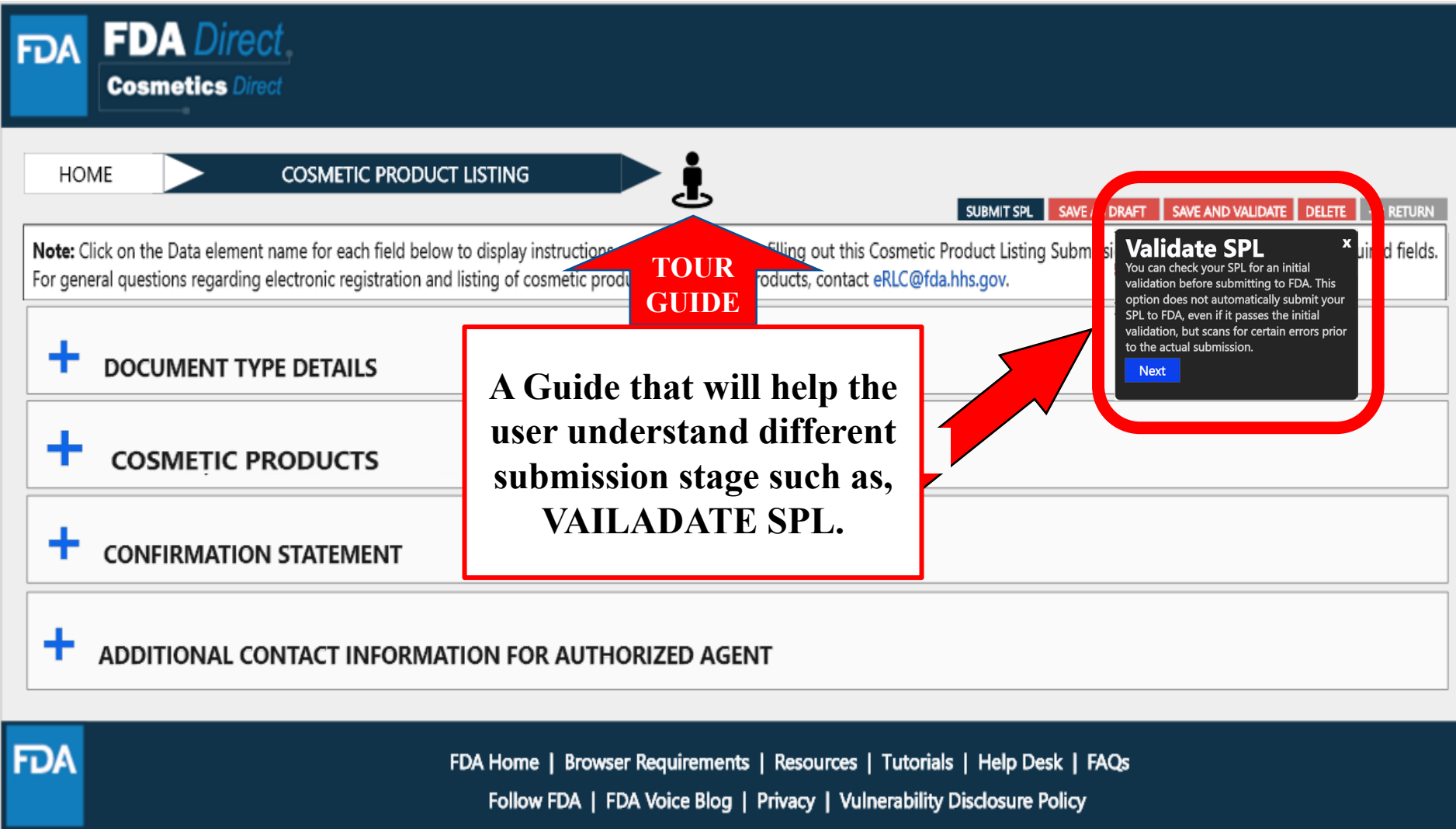
An example to what an XML format could look like

```
<?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"
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.

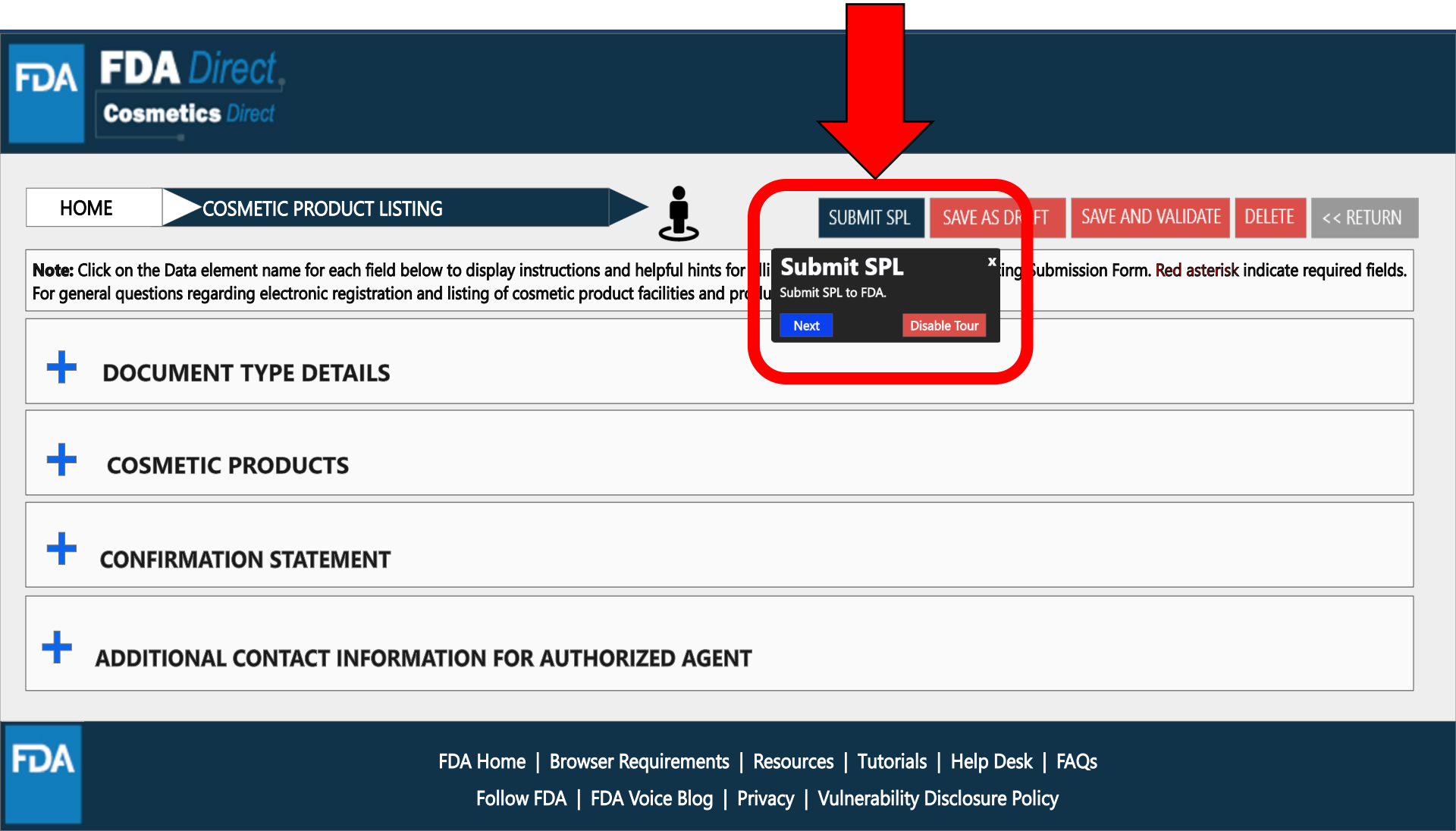
VALIDATE SPL: "*You can check your SPL for an initial validation before submitting to FDA. This option does not automatically submit your SPL to FDA, even if it passes the initial validation, but scans for certain errors prior to the actual submission.* "



UPLOAD A FILE (EXAMPLE)

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

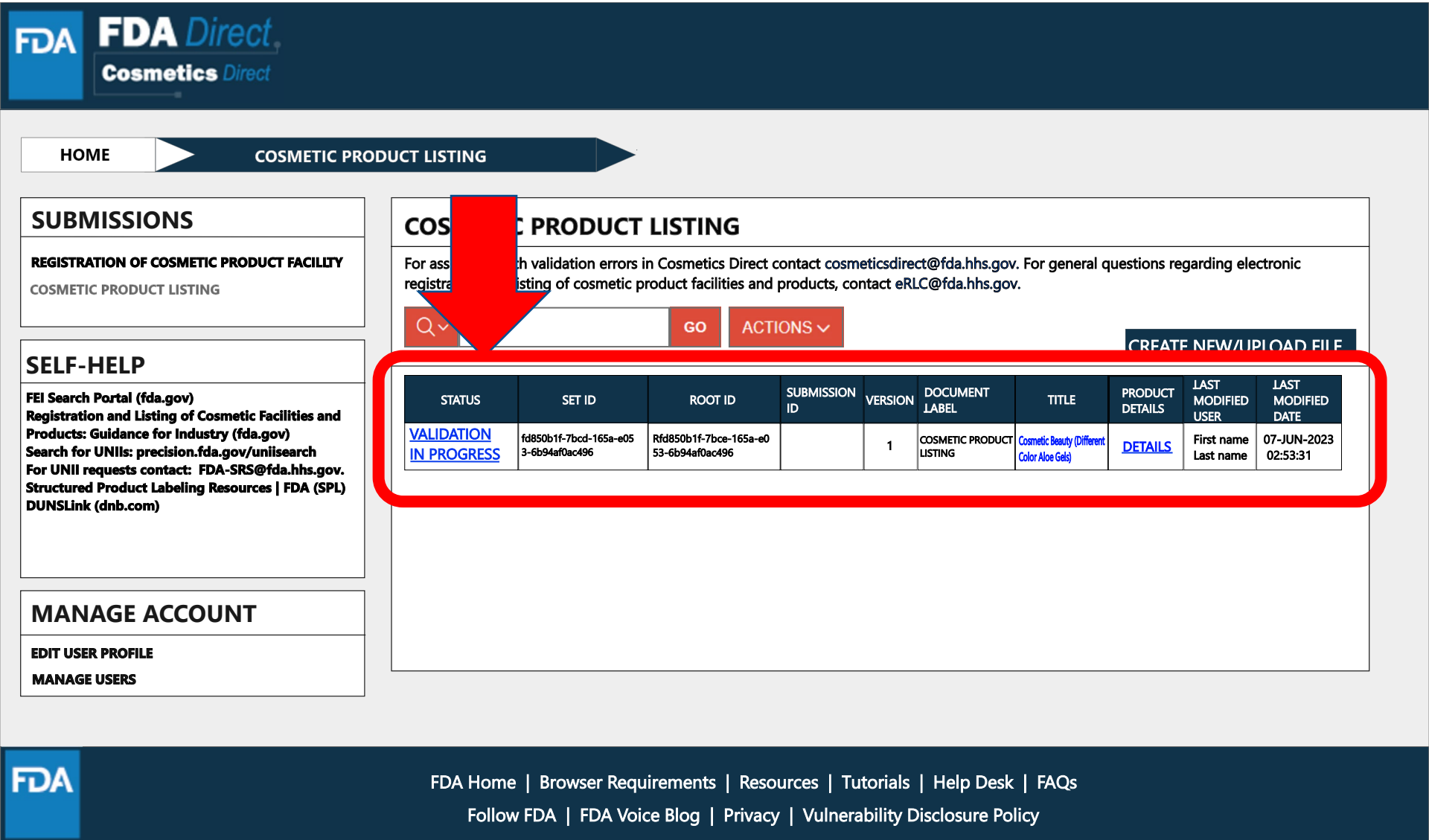
The Submit SPL box is a help tool that can guide a user through the process.



PRODUCT LISTING STATUS EXAMPLES

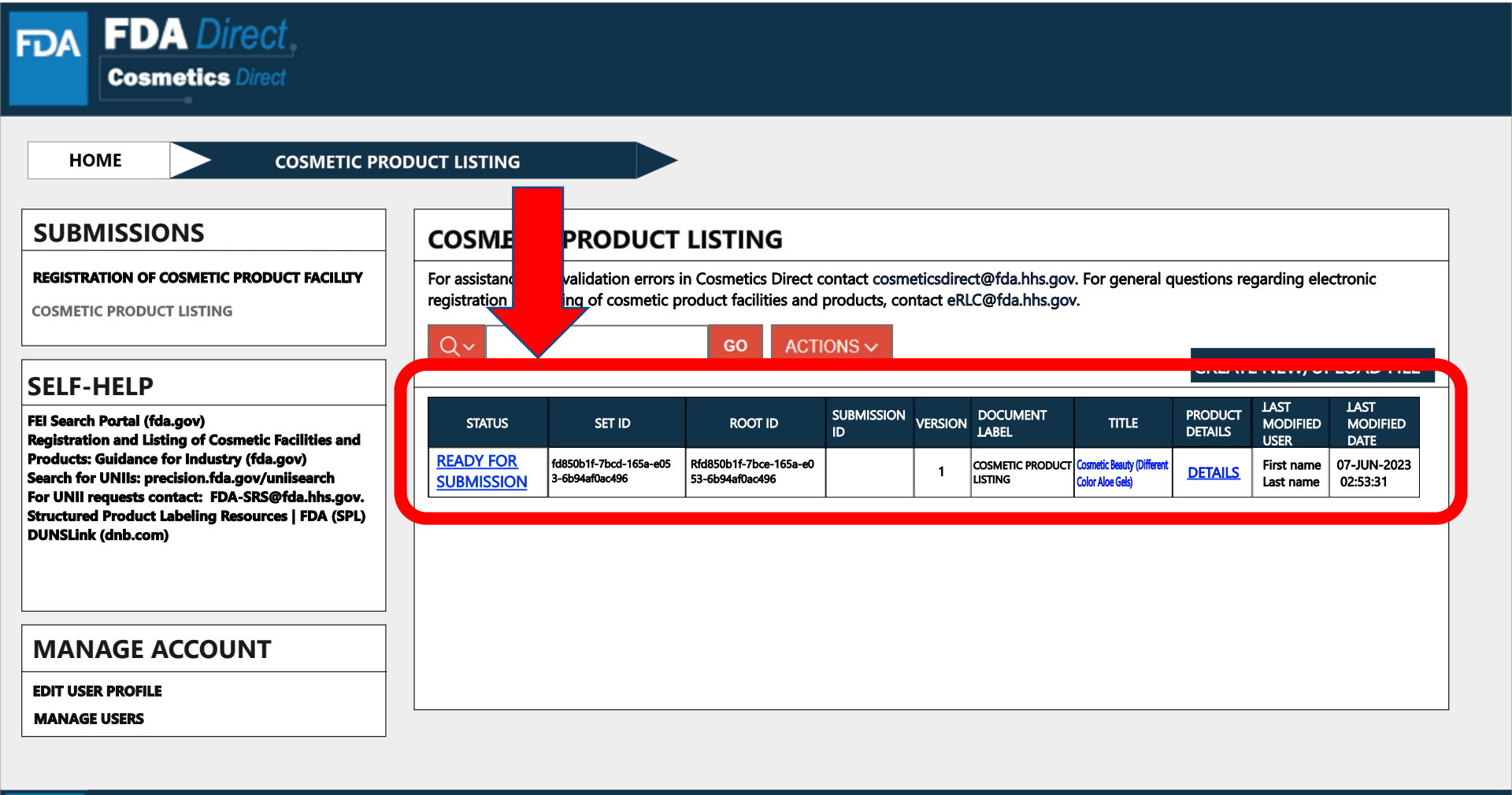
LISTING STATUS: VALIDATION IN PROGRESS

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



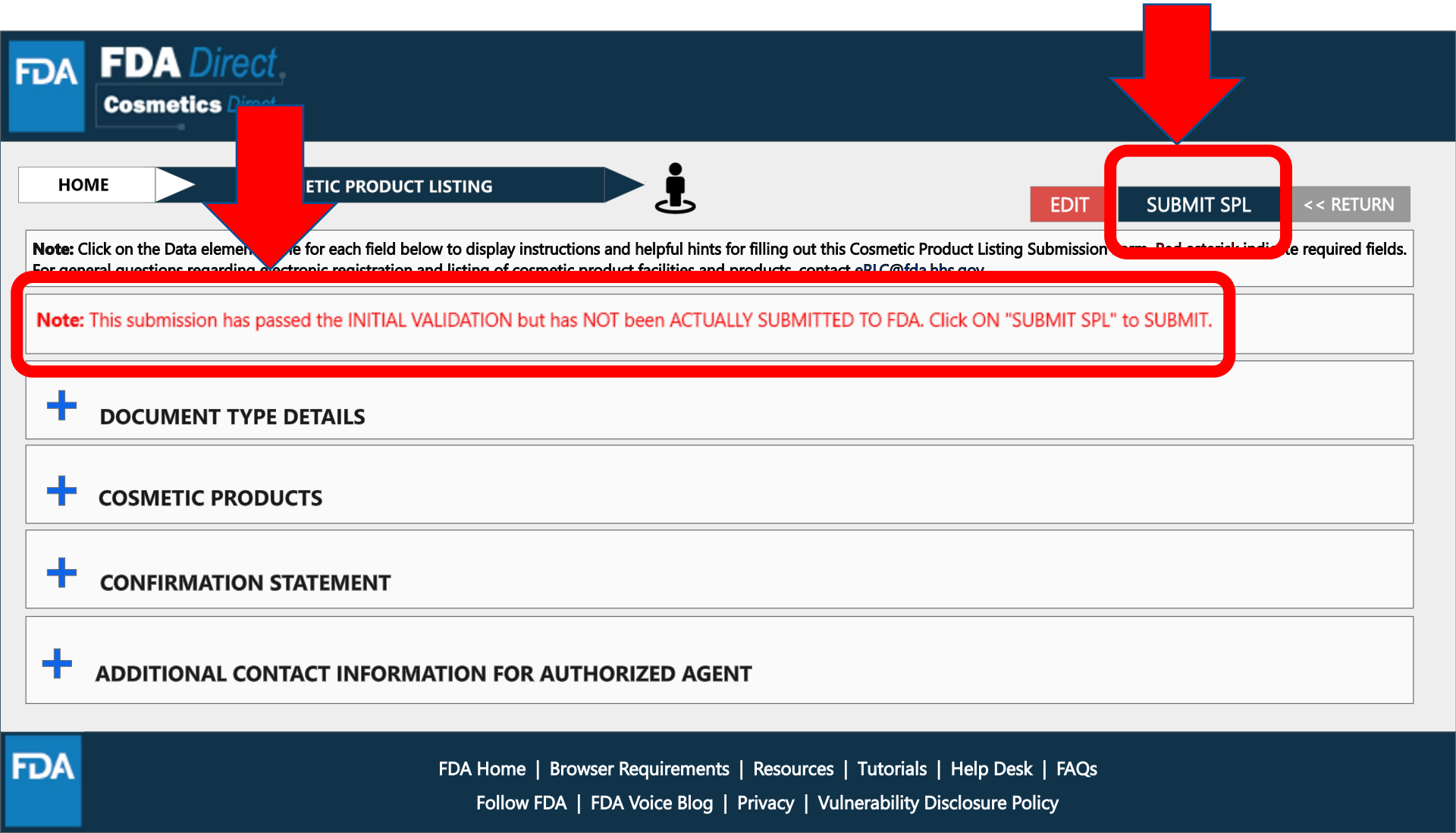
LISTING STATUS: READY FOR SUBMISSION

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



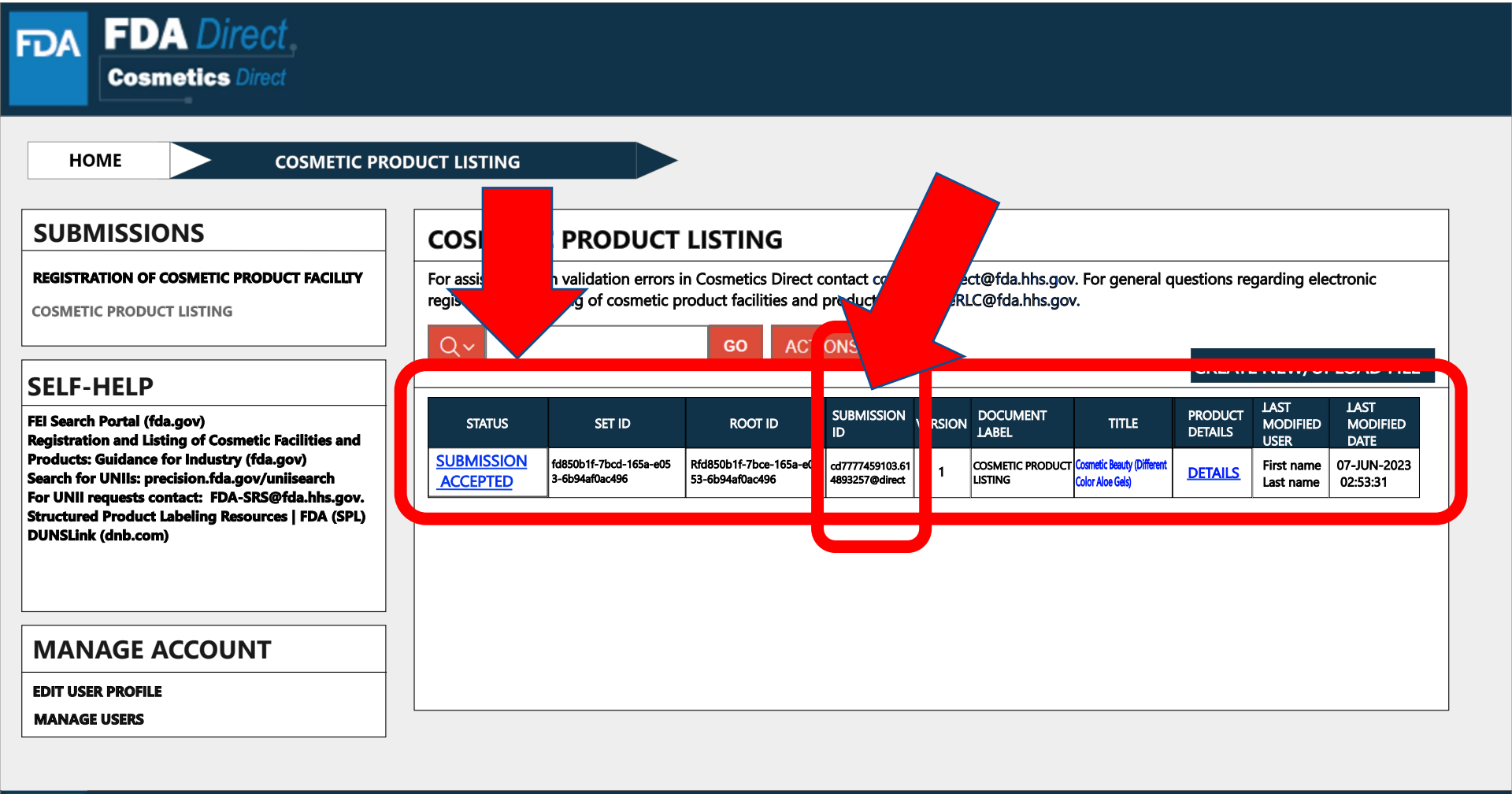
LISTING STATUS: READY FOR SUBMISSION TO SUBMIT SPL

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.*



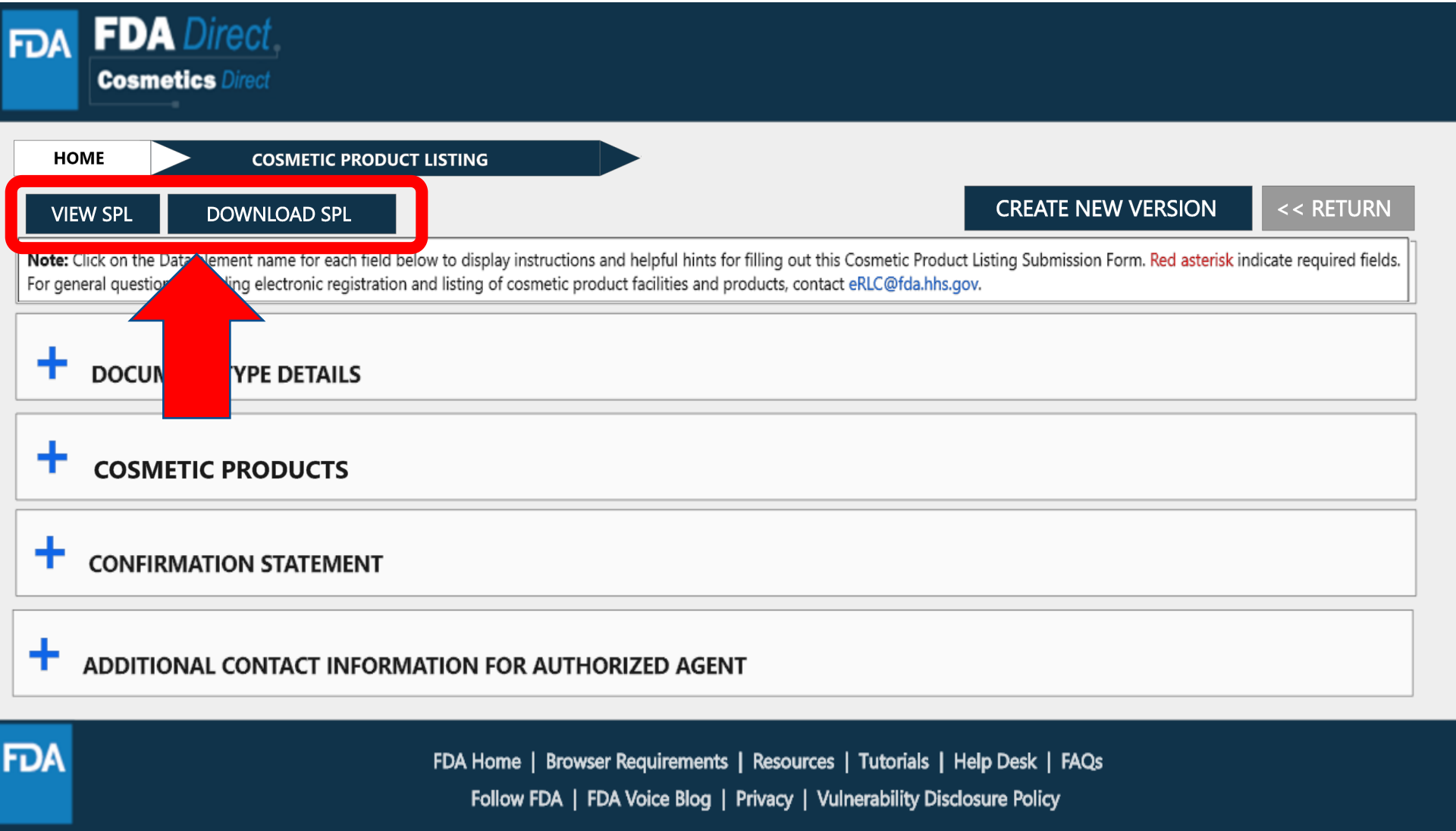
LISTING STATUS: SUBMIT SPL TO SUBMISSION ACCEPTED

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



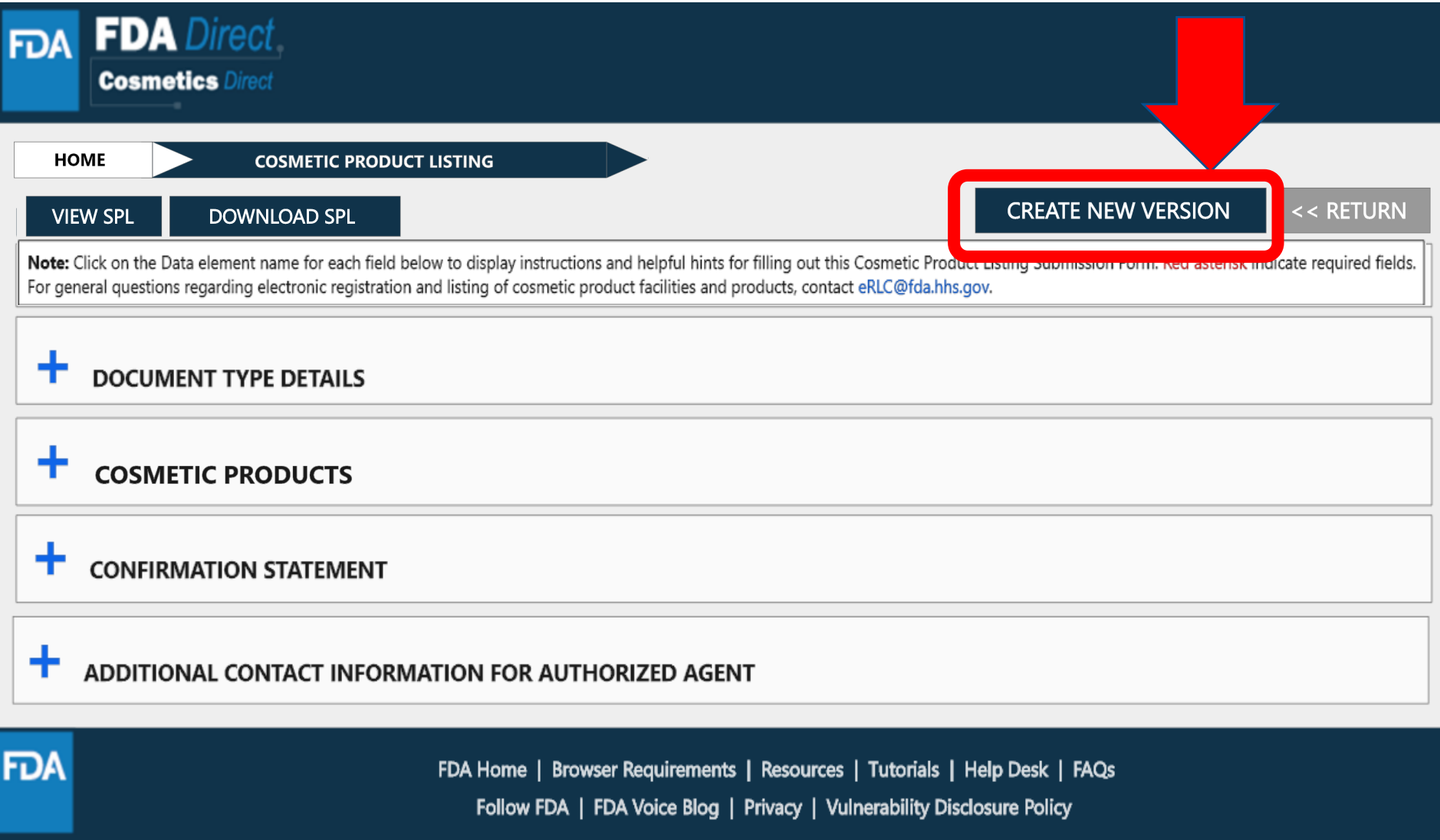
LISTING STATUS: SUBMISSION ACCEPTED to VIEW SPL and DOWNLOAD SPL

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



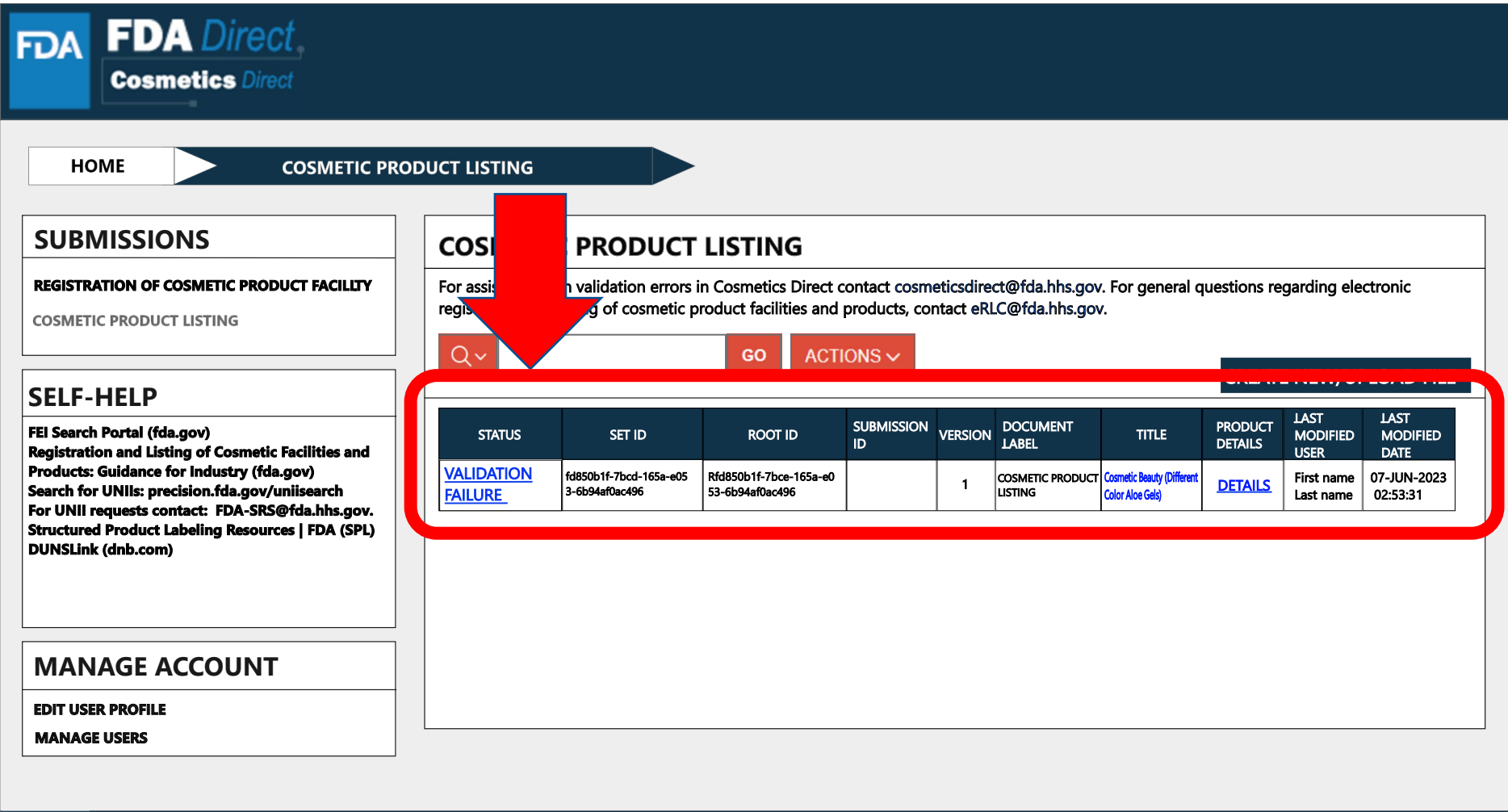
CREATE A NEW VERSION

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



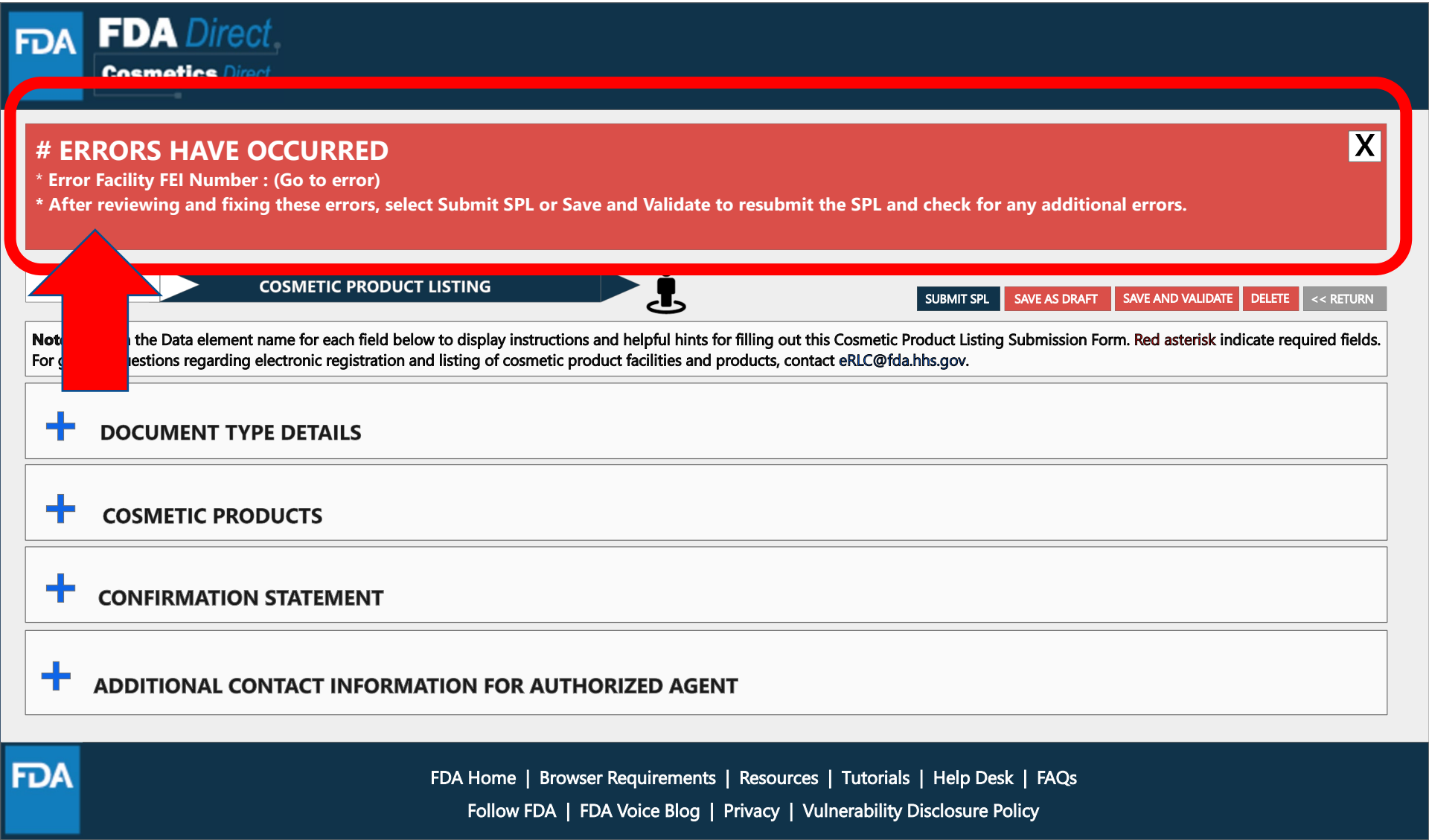
LISTING STATUS: VALIDATION FAILURE

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



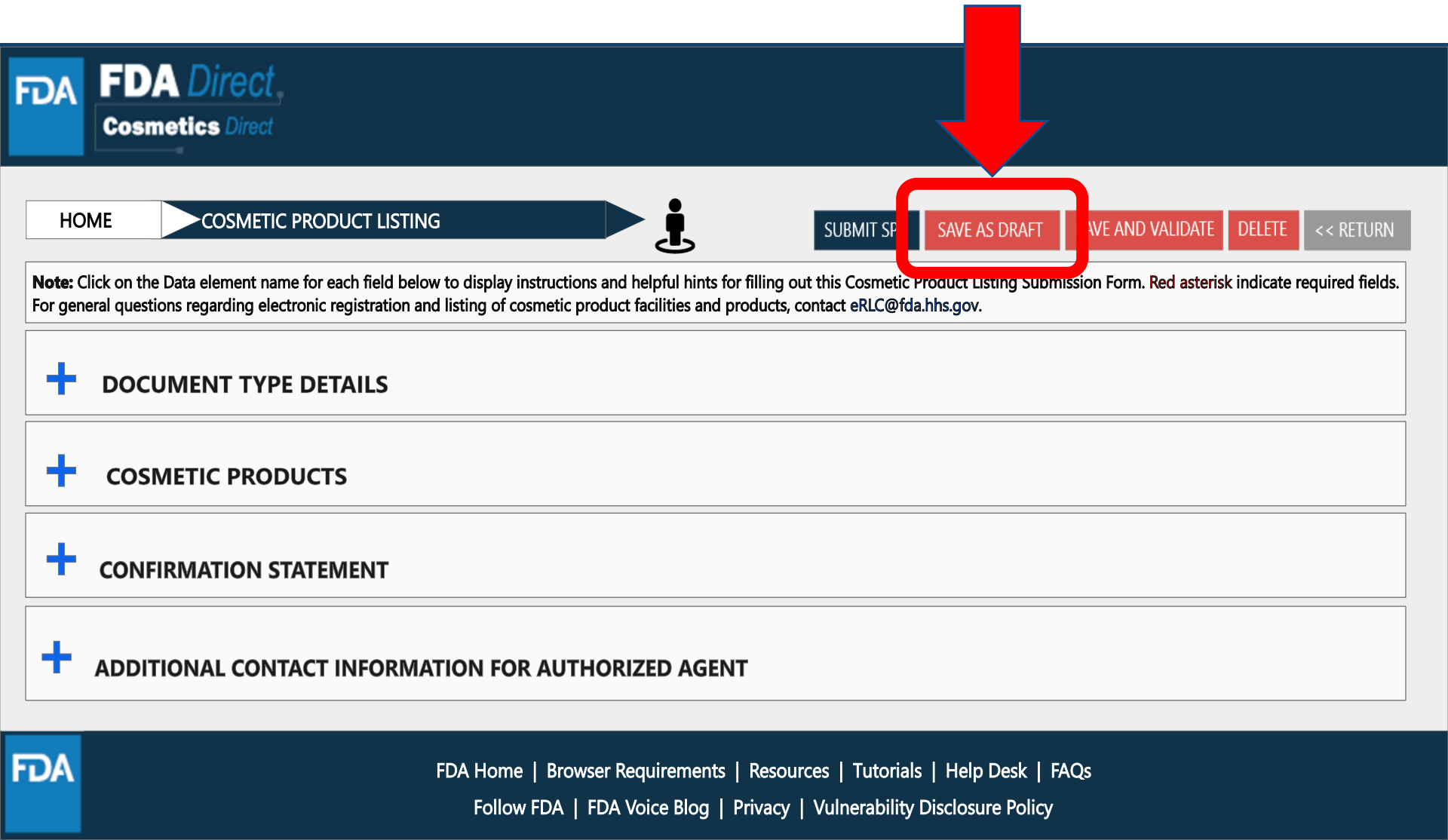
LISTING STATUS: VALIDATION FAILURE

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.



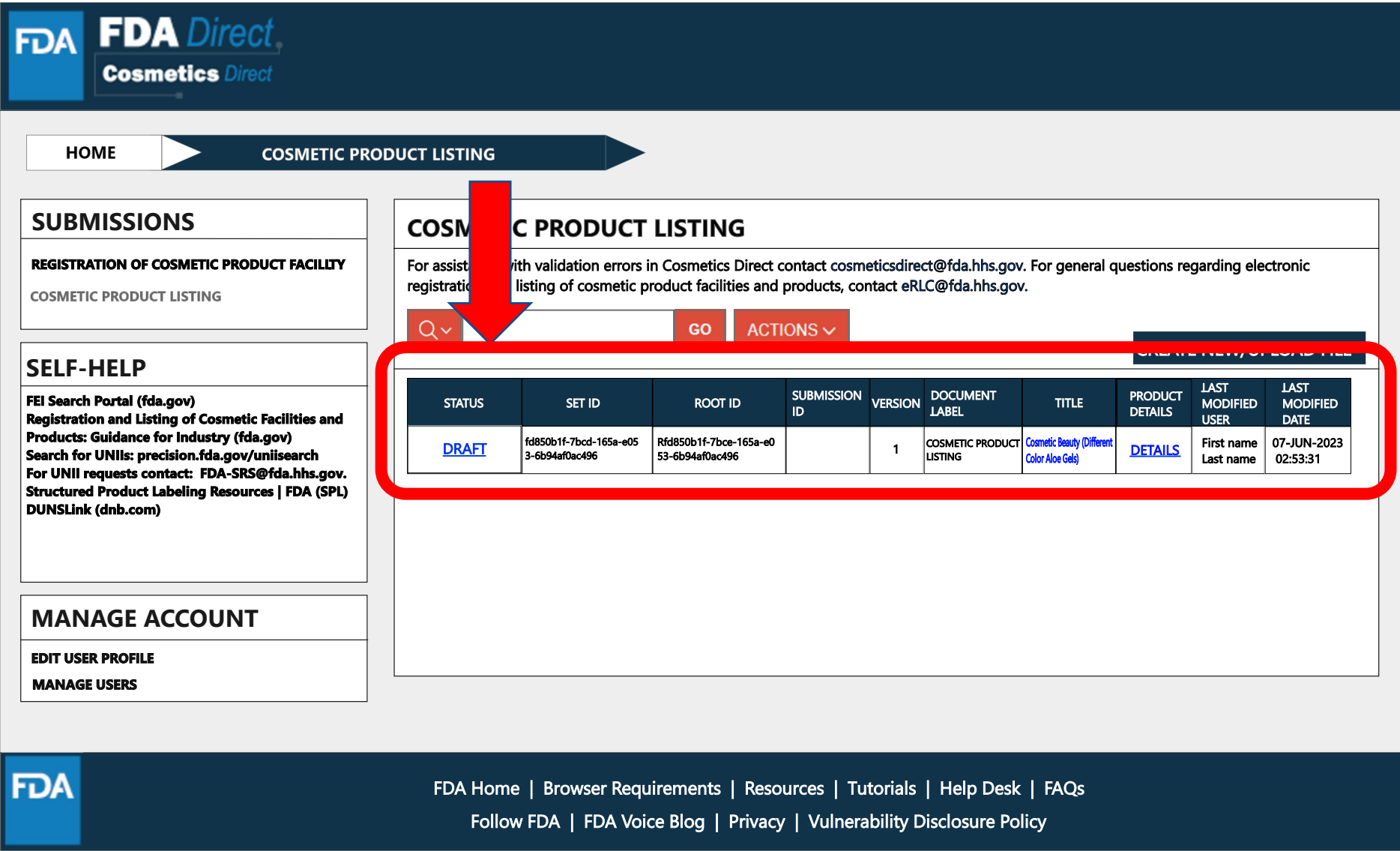
LISTING STATUS: DRAFT

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**.



LISTING STATUS: DRAFT

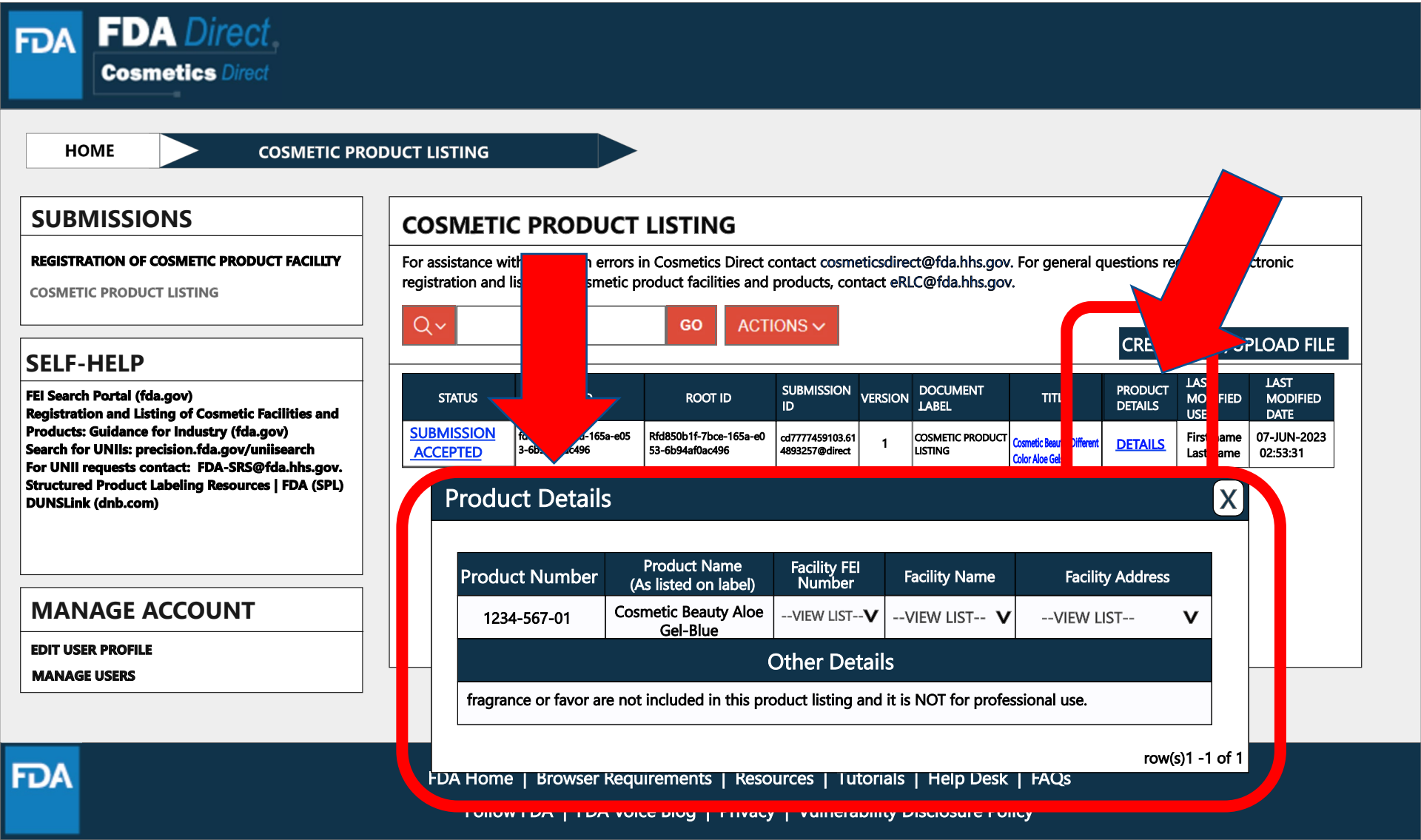
The registration of cosmetic product facility home page will have the following details as shown below. The status will be in **DRAFT**.



COSMETICS DIRECT HOME PAGE

DETAILS

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



COSMETICS DIRECT HOME PAGE
ALL SUBMISSION