U.S. FOOD & DRUG ADMINISTRATION

COSMETICS *DIRECT*

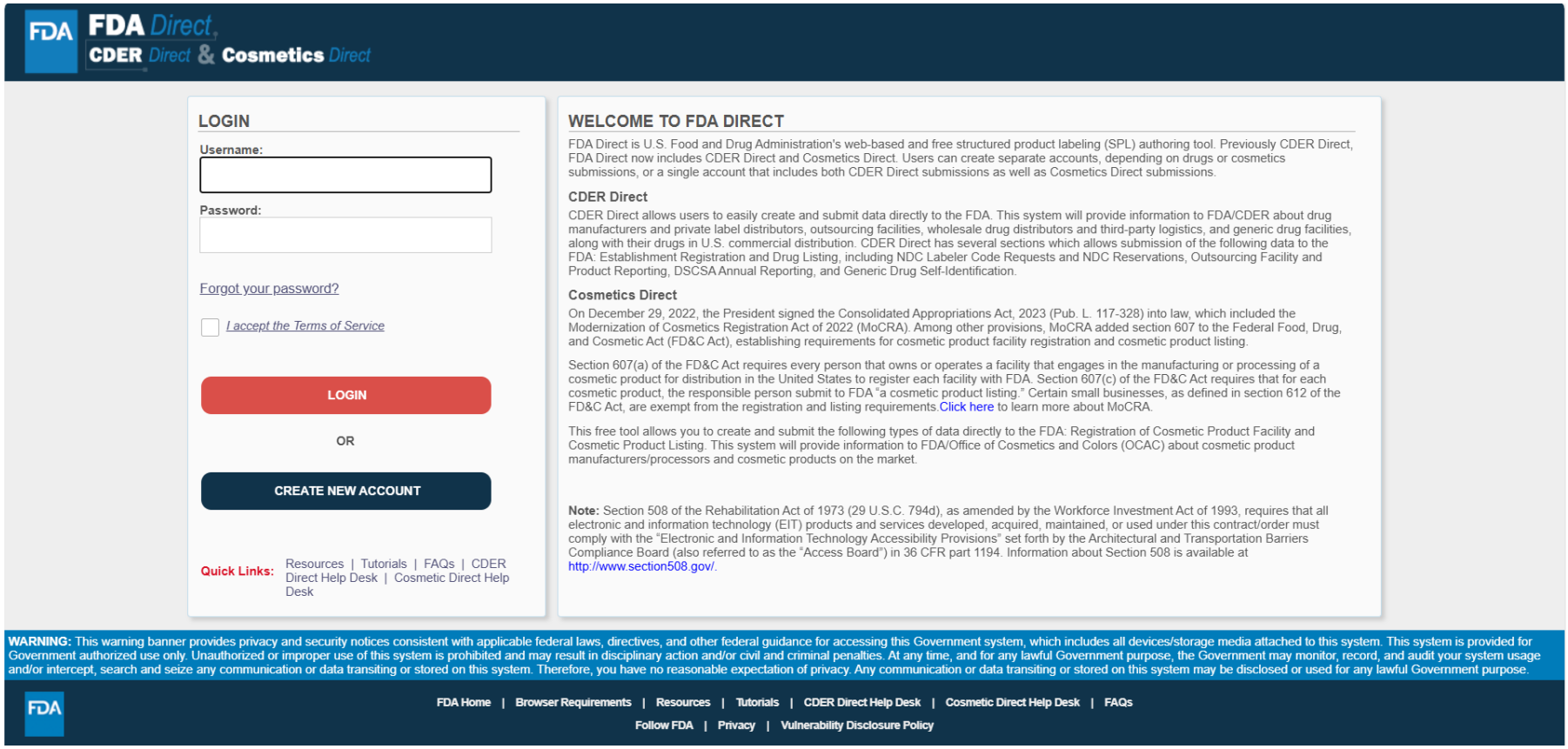
Facility Registration Tutorial

February 2026

Welcome to the Cosmetics Direct Facility Registration Tutorial

This guide provides the essential information you need to register, renew, update and/or cancel a facility registration using Cosmetics Direct.

For technical support, email the eRLC Help Desk at CosmeticsDirect@fda.hhs.gov.



Click here to access the FDA Direct portal.

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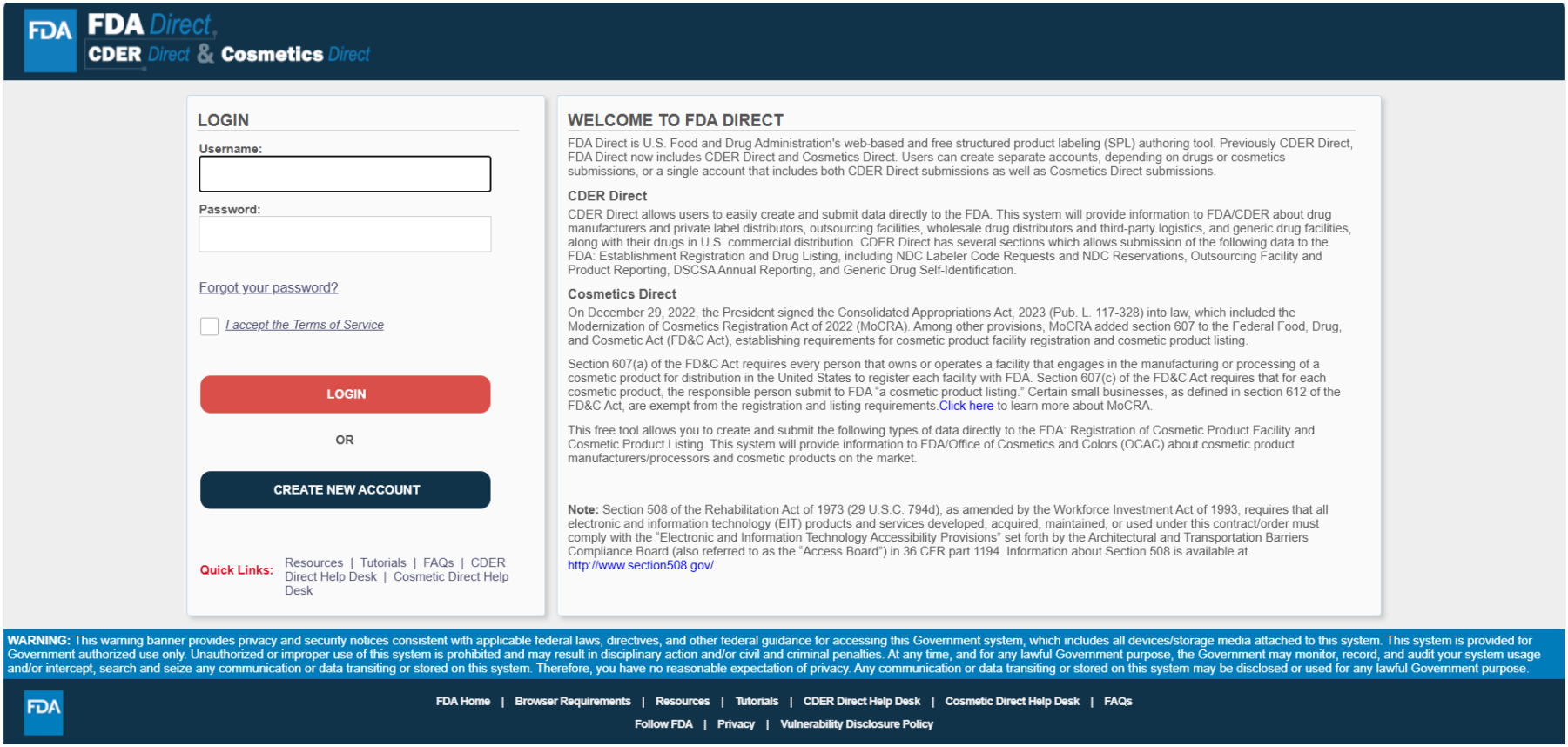
REGISTERING A NEW COSMETIC PRODUCT FACILITY

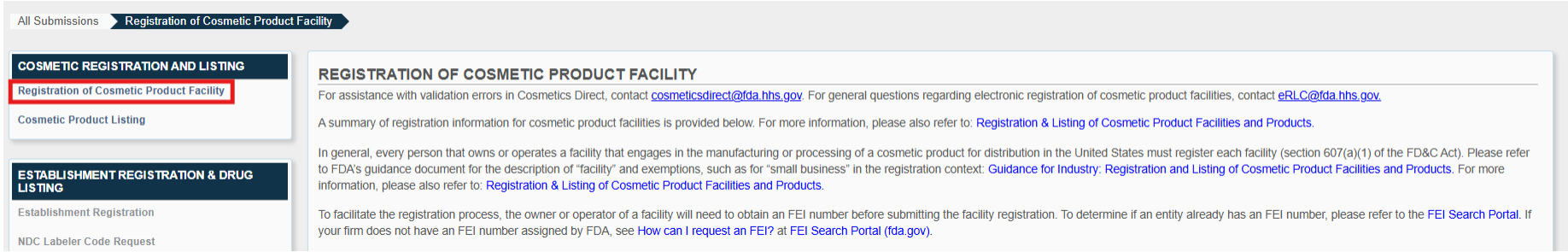
Step 1. Navigate to Cosmetics Direct via https://direct.fda.gov.

Step 2. Enter your log-in credentials, accept the terms of service, and click '**LOGIN**'.

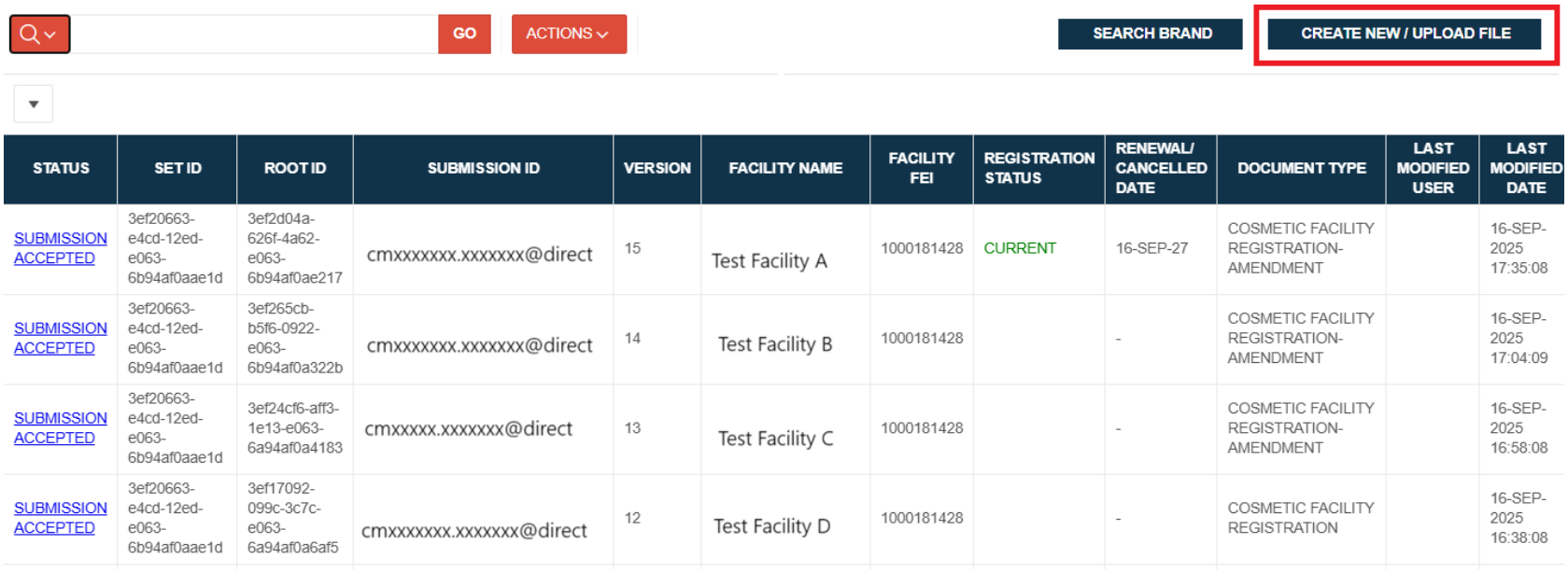


U.S. FOOD & DRUG ADMINISTRATION

Step 3. Select '**Registration of Cosmetic Product Facility**'.



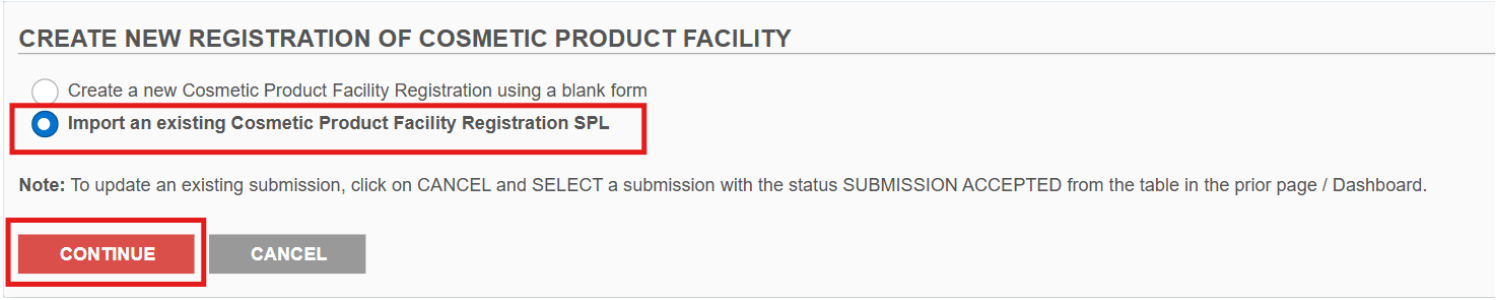
Step 4. Click on '**CREATE NEW/UPLOAD FILE**'.



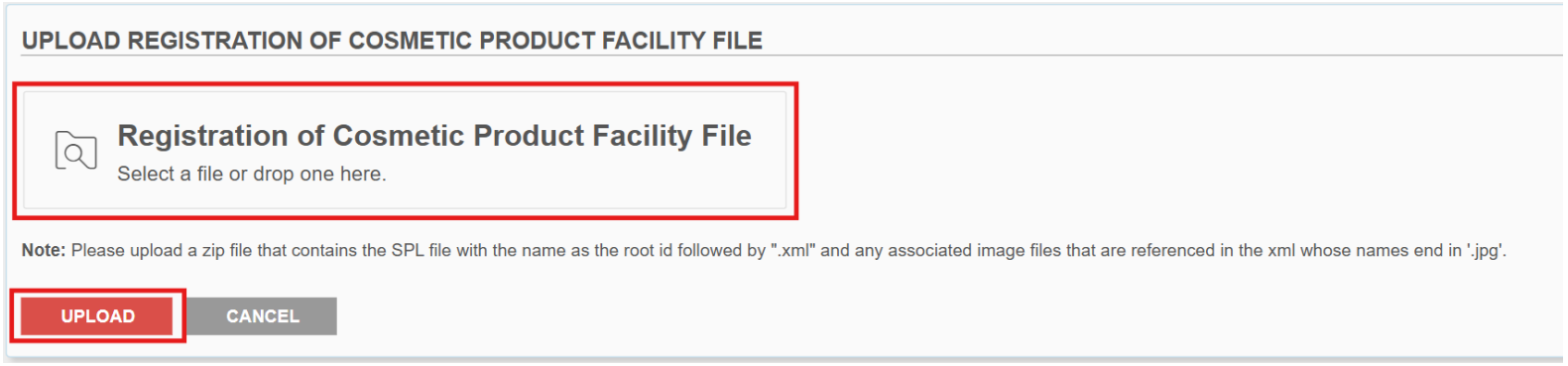
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	REGISTRATION STATUS	RENEWAL/ CANCELLED DATE	DOCUMENT TYPE	LAST MODIFIED USER	LAST MODIFIED DATE
SUBMISSION ACCEPTED	3ef20663-e4cd-12ed-e063-6b94af0aae1d	3ef2d04a-626f-4a62-e063-6b94af0ae217	cmxxxxxxx.xxxxxxx@direct	15	Test Facility A	1000181428	CURRENT	16-SEP-27	COSMETIC FACILITY REGISTRATION-AMENDMENT		16-SEP-2025 17:35:08
SUBMISSION ACCEPTED	3ef20663-e4cd-12ed-e063-6b94af0aae1d	3ef265cb-b5f6-0922-e063-6b94af0a322b	cmxxxxxxx.xxxxxxx@direct	14	Test Facility B	1000181428		-	COSMETIC FACILITY REGISTRATION-AMENDMENT		16-SEP-2025 17:04:09
SUBMISSION ACCEPTED	3ef20663-e4cd-12ed-e063-6b94af0aae1d	3ef24cf6-aff3-1e13-e063-6a94af0a4183	cmxxxxx.xxxxxxx@direct	13	Test Facility C	1000181428		-	COSMETIC FACILITY REGISTRATION-AMENDMENT		16-SEP-2025 16:58:08
SUBMISSION ACCEPTED	3ef20663-e4cd-12ed-e063-6b94af0aae1d	3ef17092-099c-3c7c-e063-6a94af0a6af5	cmxxxxxxx.xxxxxxx@direct	12	Test Facility D	1000181428		-	COSMETIC FACILITY REGISTRATION		16-SEP-2025 16:38:08

Note: A user can upload an existing Cosmetic Product Facility Registration SPL (Structured Product Labeling), a ZIP file that contains the .xml file. 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.

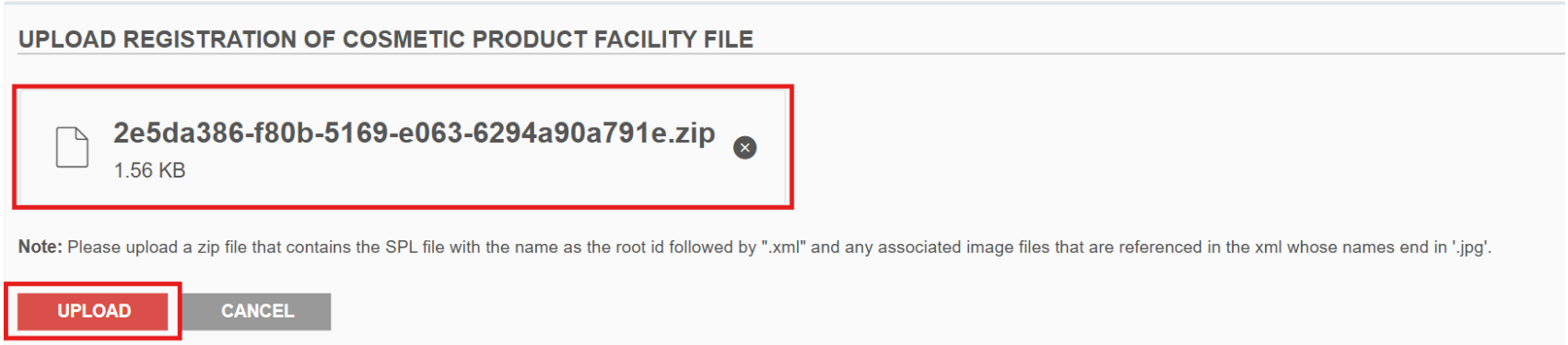
Step 5. To upload a Cosmetic Product Facility Registration SPL File, click on '**Import an existing Cosmetic Product Facility Registration SPL**' and then '**CONTINUE**'.



Step 6. Select '**Registration of Cosmetic Product Facility File**'. Locate and select the Registration of Cosmetic Product Facility File zip file to upload into Cosmetics Direct and click '**UPLOAD**'.



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'.



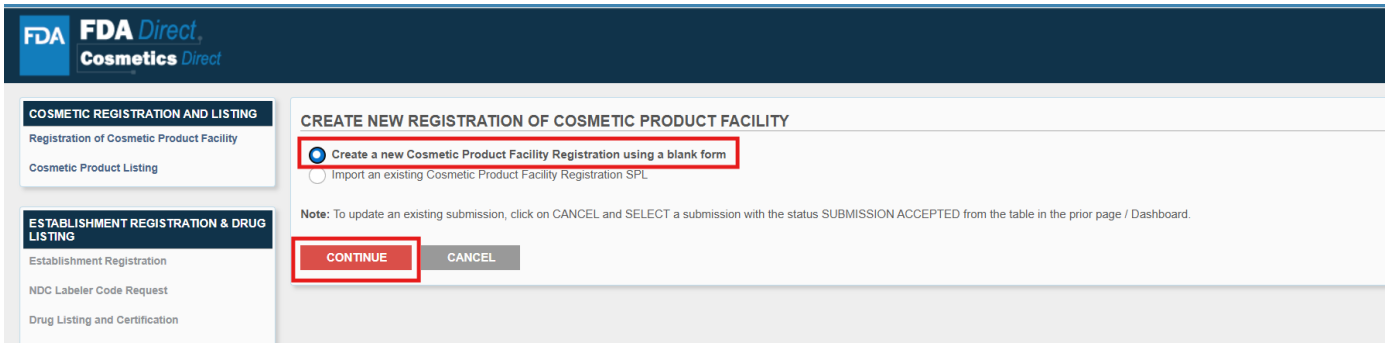
Zip File Example: An example to what an .xml format could look like.

```
<?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>
```

Step 7: Proceed to Slides #11through #16 and update the submission details by following the instructions.

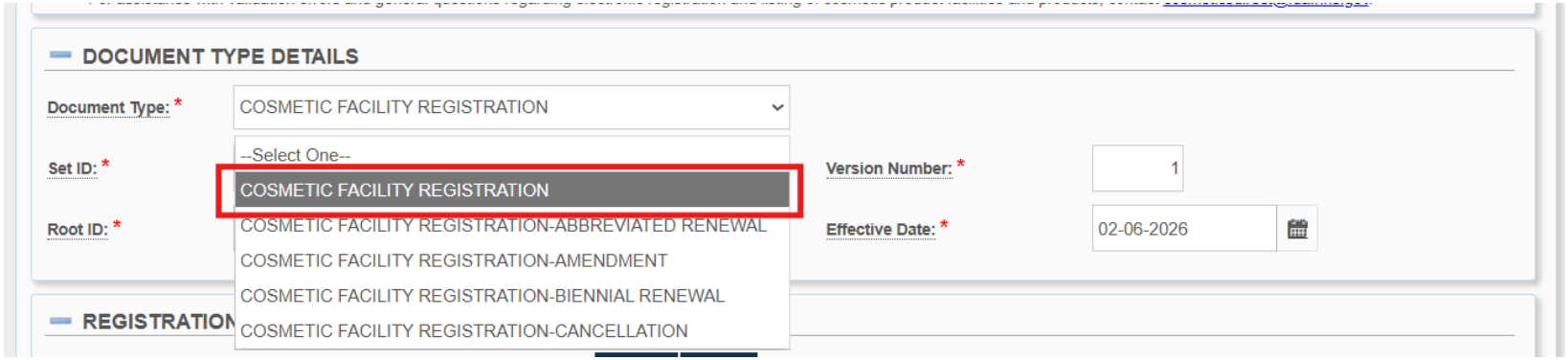
Step 8: Submit the SPL to FDA by following the instructions provided on Slide #17.

Step 9. To '**Create a new Cosmetic Product Facility Registration using a blank form**', select that option and then click '**CONTINUE**'.

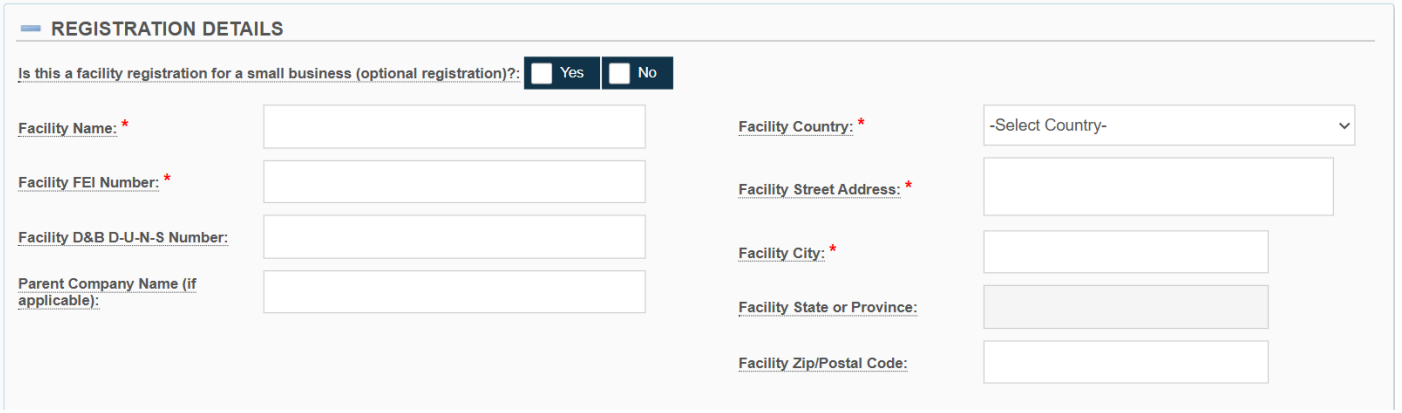


Step 10. The '**DOCUMENT TYPE**' drop-down menu automatically defaults to '**COSMETIC PRODUCT FACILITY REGISTRATION**'. The other information under '**DOCUMENT TYPE DETAILS**' (Set ID, Root ID, Version Number, Effective Date) will automatically populate.

NOTE: The effective date is the date the submission is created, which can be edited by users until the SPL is submitted and accepted by FDA. However, the system will only use the actual registration date accepted by FDA. It also provides a date reference to the SPL version. Select the date by clicking on the calendar icon.

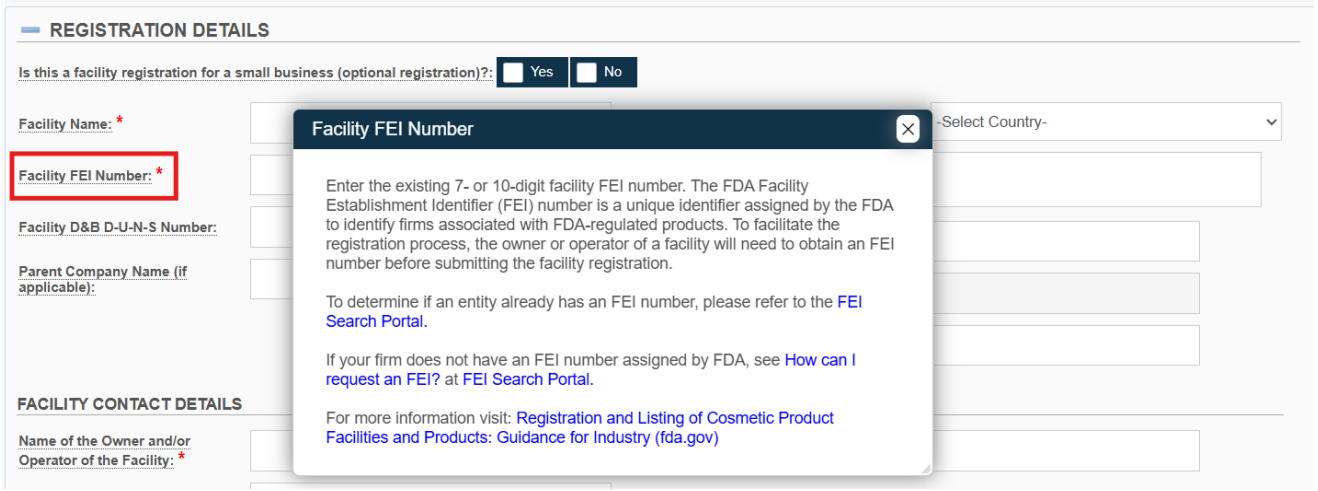


Step 11. Enter the information for '**REGISTRATION DETAILS**'.



Quick Tip! Clicking on a field name that has a dotted underline will bring up 'Help Text' to provide more information.

Fields with the red asterisk (*) are required.

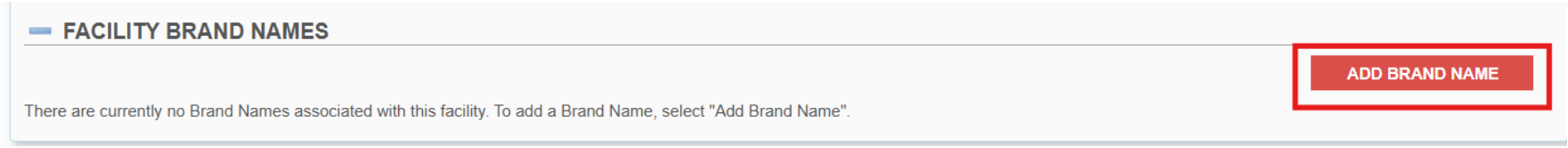


Step 12. Enter the information for '**FACILITY CONTACT DETAILS**'.

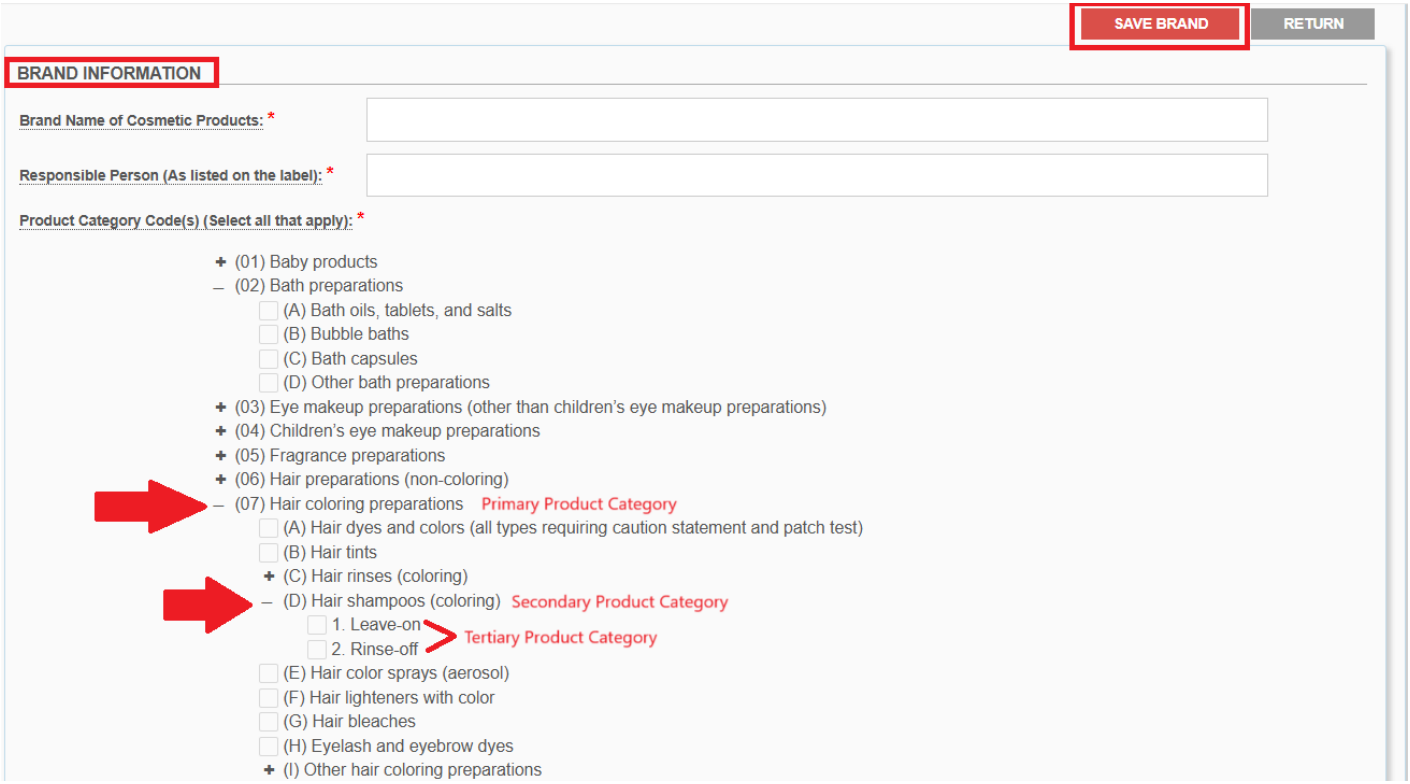
Step 13. Enter the information for '**U.S. AGENT**' (for foreign facilities).

NOTE: The U.S. agent is the person, which includes an individual or business entity, that resides in the U.S. or maintains a U.S. place of business and is physically present in the U.S.

Step 14. To add brand names, click the '**Add Brand Name**' :



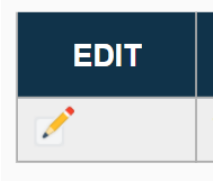
Step 15. Enter the information for **'BRAND INFORMATION'**. Select the applicable product category or categories for this product name. Each primary product category has a secondary product category. A secondary product category can have a tertiary product category (e.g., Leave on or rinse-off). Click on the plus (+) icon in front of each Primary Product Category to display additional Secondary and/or Tertiary Product Categories (when applicable). Click '**SAVE BRAND**', located at the top right of the page:



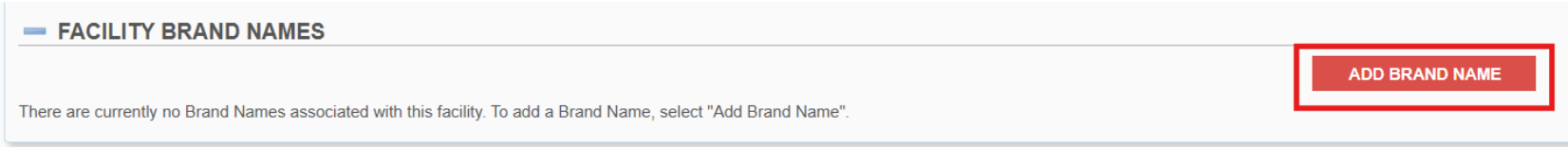
Step 16. The platform will return to the SPL Submission page with the verification banner 'Product brand saved.'

In addition, the entered information will be visible under '**FACILITY BRAND NAMES**'.

To edit the information, select the pencil icon under the 'EDIT' column.



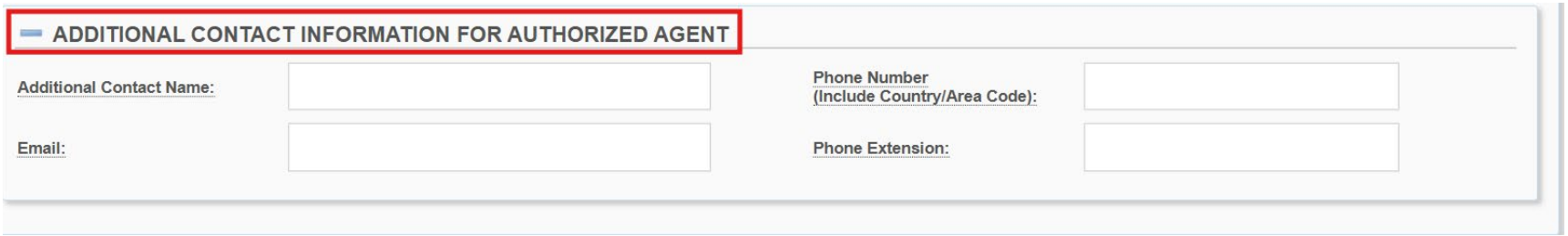
Step 17. If you have more brands to add, click '**ADD BRAND NAME**' and repeat steps 15 – 16.



Step 18. In the '**CONFIRMATION STATEMENT**' section, fill in the following optional blank fields: Click on the calendar icon to select the date. Enter the full '**NAME OF THE SUBMITTER**'. Click '**AGREE**' after reading and understanding the confirmation statement.

PLEASE NOTE: If you enter information into any field in this section, all other fields in the section will also need to be entered.

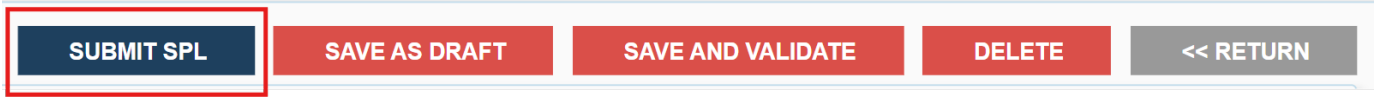
Step 19. If you would like to list additional contact information for an authorized agent, complete the '**ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT**' section.



PLEASE NOTE: If you enter information into any field in this section, all other fields in the section will also need to be entered.

Step 20. Return to the top of the SPL Submission page where you can do the following:

- '**SUBMIT SPL**' button will send the submission to FDA for additional validation and processing.



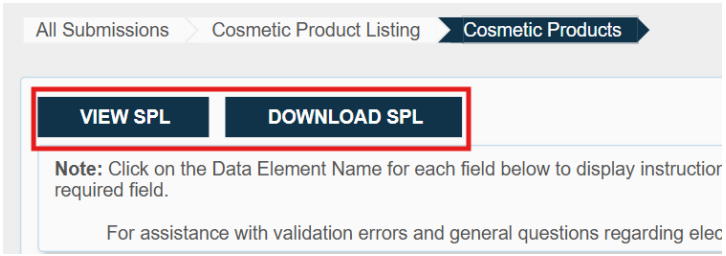
  - After clicking on '**SUBMIT SPL**', the submission undergoes an automated, technical validation indicated by the status of '**AWAITING ACCEPTANCE**'. In addition, a 'SUBMISSION ID' will be generated automatically whenever an SPL is submitted to FDA.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	REGISTRATION STATUS	RENEWAL/ CANCELLED DATE	DOCUMENT TYPE
AWAITING ACCEPTANCE	0c52e442-a982-56fc-e063-6b94af0a8dac	0c52e442-a983-56fc-e063-6b94af0a8dac		1	Test Facility A	XXXXXX		-	COSMETIC FACILITY REGISTRATION

  - If the submission passes technical validation, the status will change to '**SUBMISSION ACCEPTED**'. To view and/or download an accepted submission, click on '**SUBMISSION ACCEPTED**'.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	REGISTRATION STATUS	RENEWAL/ CANCELLED DATE	DOCUMENT TYPE
SUBMISSION ACCEPTED	0c52e442-a982-56fc-e063-6b94af0a8dac	0c52e442-a983-56fc-e063-6b94af0a8dac	cmxxxxx.xxxxxx@direct	1	Test Facility A	xxxxxxx	CURRENT	10-Feb-28	COSMETIC FACILITY REGISTRATION

- Then click on '**VIEW SPL**' and/or '**DOWNLOAD SPL**'.



- If the submission fails technical validation, the status will change to '**SUBMISSION FAILED**'.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	REGISTRATION STATUS
SUBMISSION FAILED	2e5da386-f80a-5169-e063-6294a90a791e	39bdda98-0bf7-2666-e063-6b94af0a7713	cmXXXXXXXX.XXXXXXX @direct	3	Test Facility Name	XXXXXXXX	

- Click on '**SUBMISSION FAILED**' to view and correct the errors identified. Once corrected, click on '**SUBMIT SPL**' to resubmit the SPL or '**SAVE AND VALIDATE**' to recheck for errors.

- ‘**SAVE AS DRAFT**’ button allows you to save your work, preserving your progress without submitting it to the FDA.

- Clicking ‘**SAVE AS DRAFT**’ from any screen during the process of registering the cosmetic product facility process saves all entered information and redirects you to the homepage. The ‘status will display ‘**DRAFT**’.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	REGISTRATION STATUS	RENEWAL/ CANCELLED DATE	DOCUMENT TYPE
DRAFT	4a14ab77-77ae-4456-e063-6b94af0adddd	4a14ab77-77af-4456-e063-6b94af0adddd		1	Test Facility Name	XXXXXXX		-	COSMETIC FACILITY REGISTRATION

- '**SAVE AND VALIDATE**': You can check your SPL for an initial validation before submitting to FDA. This option is only for an initial validation of your SPL before submitting to FDA. It scans for certain errors prior to the actual submission but does not automatically submit your SPL to FDA, even if it passes the initial validation. To submit your data to the FDA, select "Submit SPL".

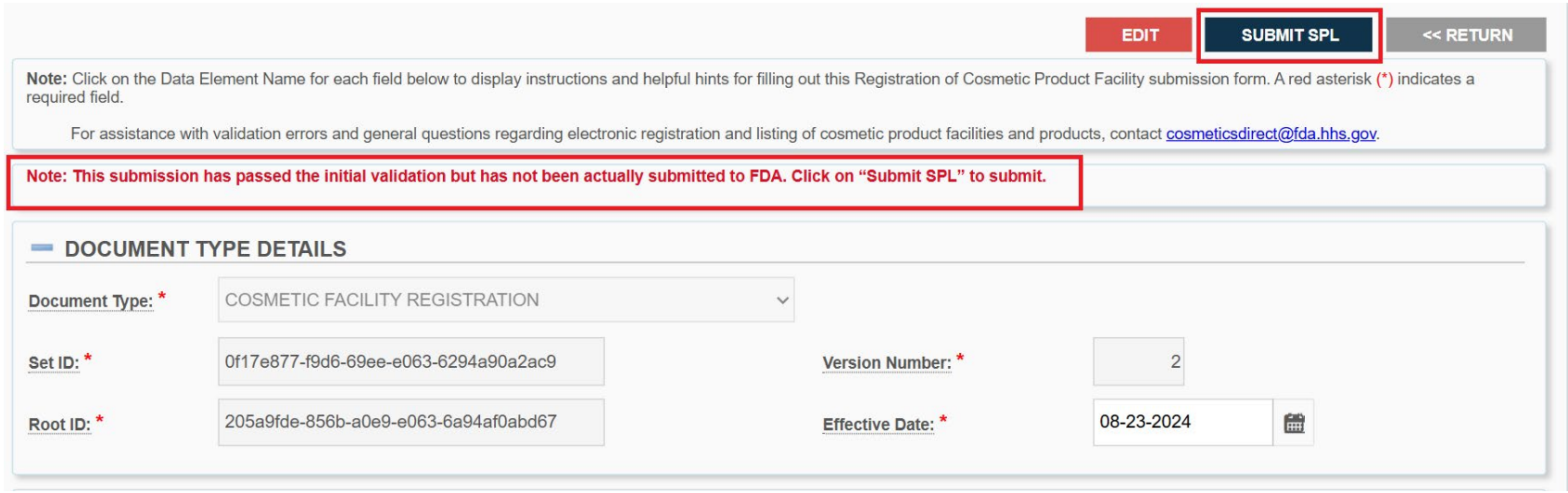
  - Clicking '**SAVE AND VALIDATE**' will automatically change the status to '**VALIDATION IN PROGRESS**'.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	REGISTRATION STATUS	RENEWAL/ CANCELLED DATE	DOCUMENT TYPE
VALIDATION IN PROGRESS	4a14ab77-77ae-4456-e063-6b94af0adddd	4a14ab77-77af-4456-e063-6b94af0adddd		1	Test Facility A	XXXXXX		-	COSMETIC FACILITY REGISTRATION

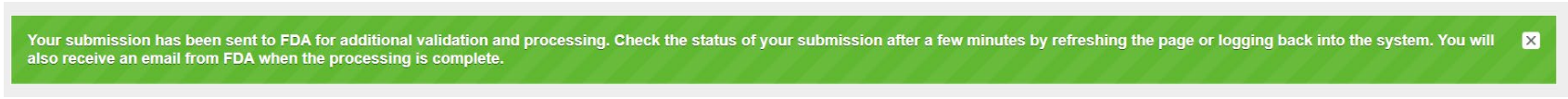
  - Once the system completes the initial validation, the status will change from '**VALIDATION IN PROGRESS**' to '**READY FOR SUBMISSION**'. Click '**READY FOR SUBMISSION**' to proceed.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	REGISTRATION STATUS	RENEWAL/ CANCELLED DATE	DOCUMENT TYPE
READY FOR SUBMISSION	4a14ab77-77ae-4456-e063-6b94af0adddd	4a14ab77-77af-4456-e063-6b94af0adddd		1	Test Facility A	XXXXXX		-	COSMETIC FACILITY REGISTRATION

- This will open the submission. 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.

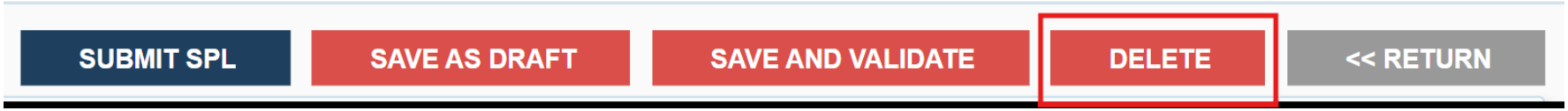


- After clicking '**SUBMIT SPL**' the below message will appear:

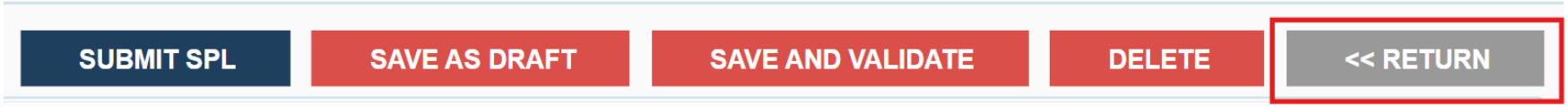


- '**DELETE**': Delete will remove the submission from your account.

  NOTE: Submissions with the status '**SUBMISSION ACCEPTED**' cannot be deleted.



- '**RETURN**': Click '**RETURN**' at any time to return to the Registration of Cosmetic Product Facility main page.

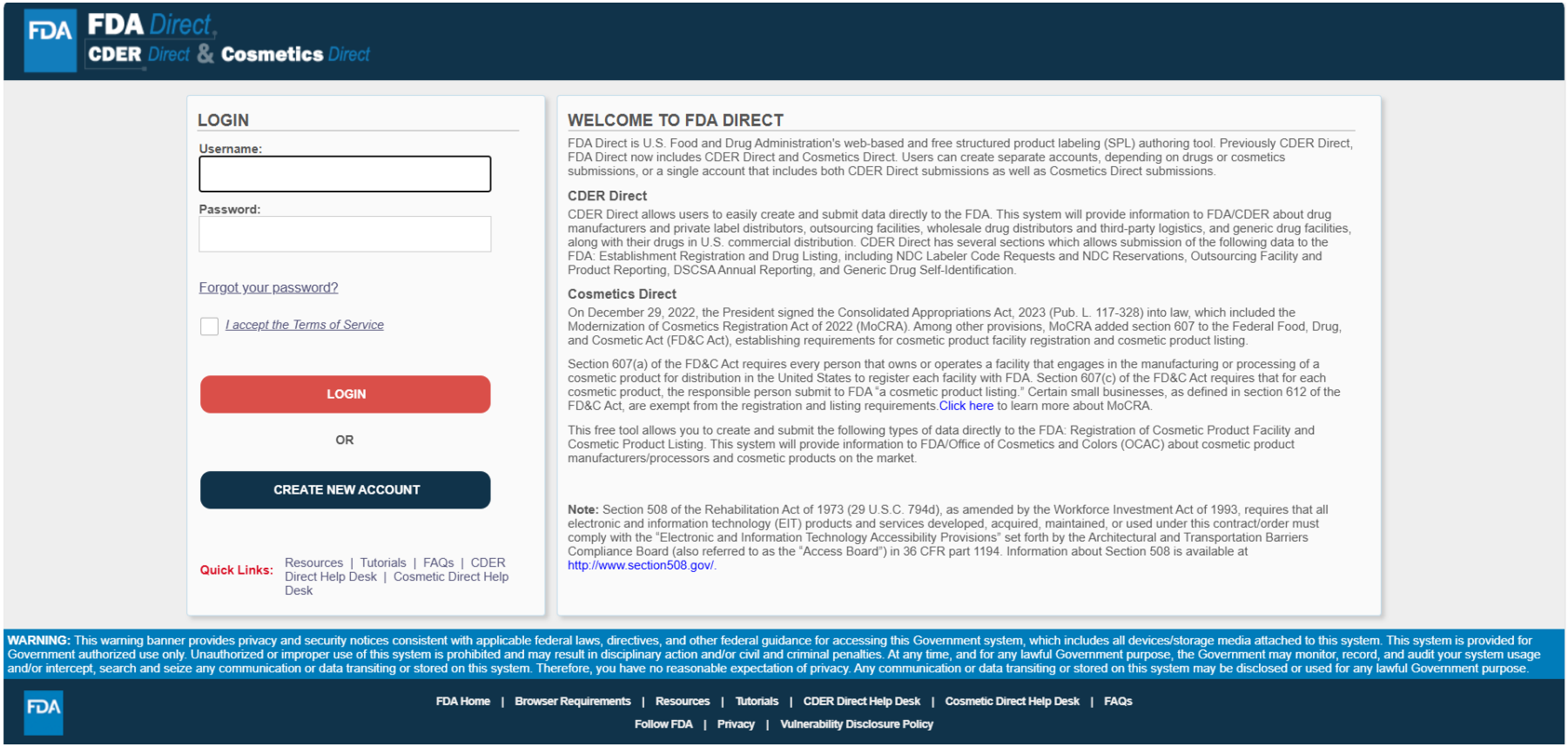


U.S. FOOD & DRUG ADMINISTRATION

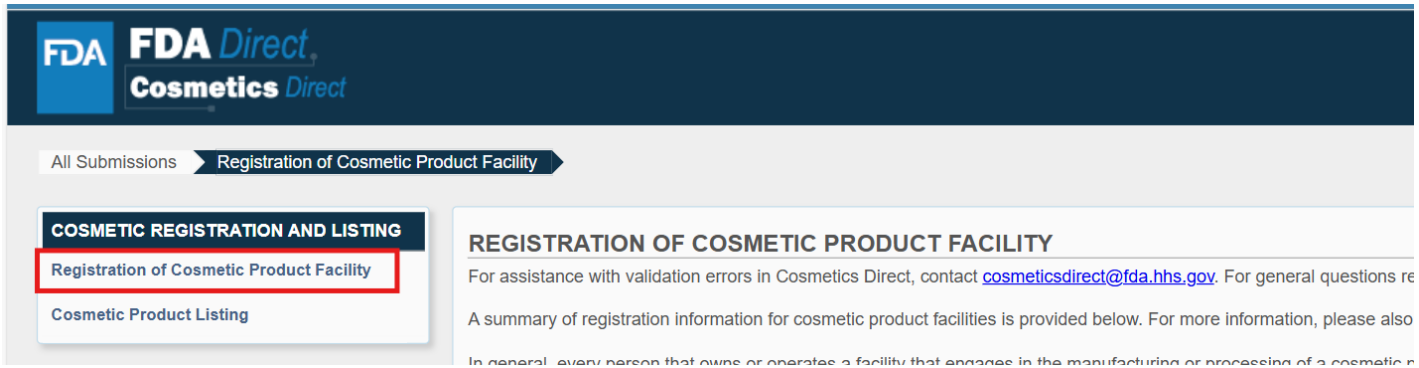
AMENDING A COSMETIC PRODUCT FACILITY REGISTRATION

Step 1. Navigate to Cosmetics Direct via https://direct.fda.gov.

Step 2. Enter your log-in credentials, accept the terms of service, and click '**LOGIN**'.



Step 3. Select '**Registration of Cosmetic Product Facility**'.

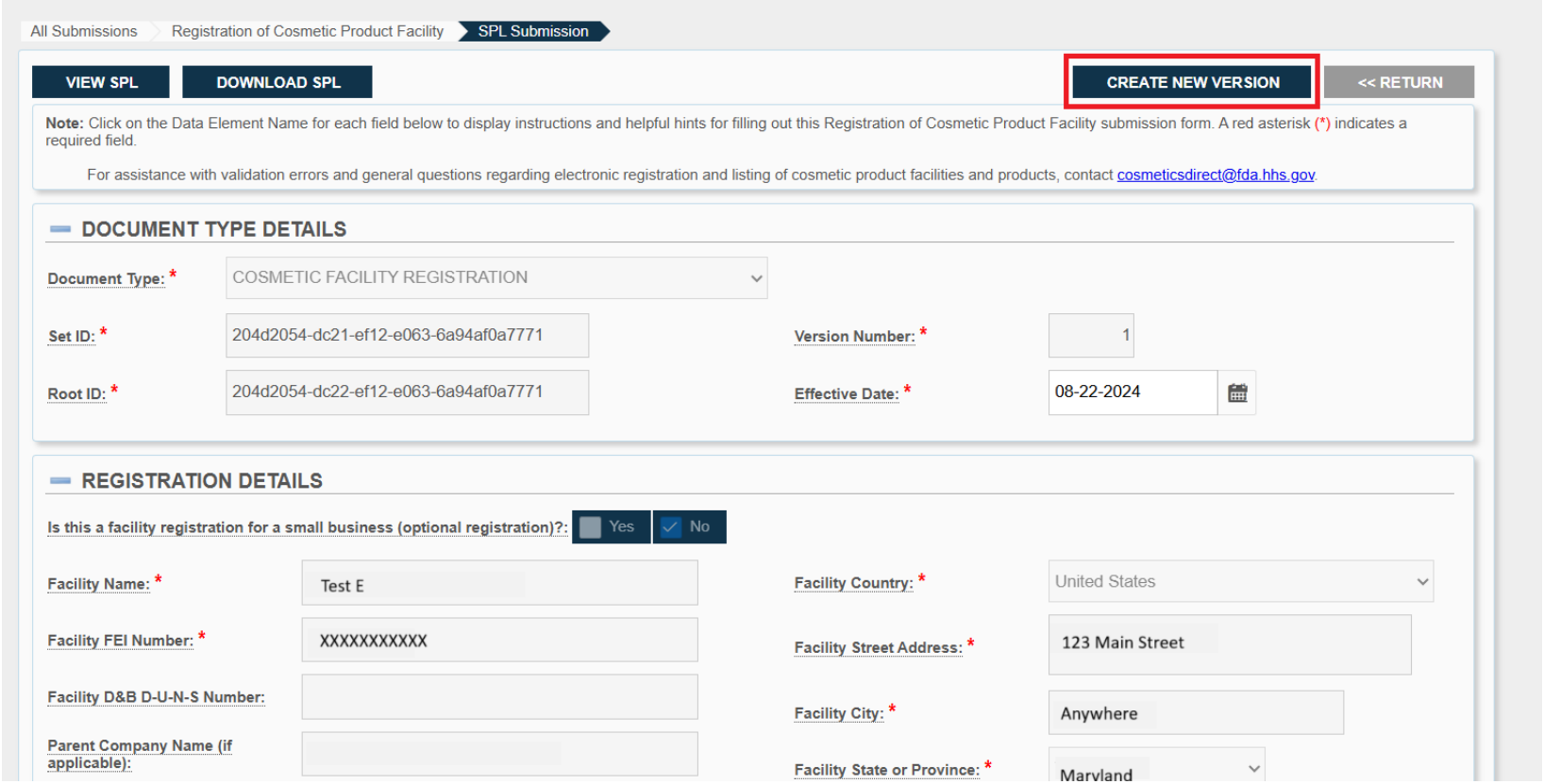


Step 4. Click on '**SUBMISSION ACCEPTED**' on the most recently accepted Cosmetic Product Facility Registration submission that you wish to modify.

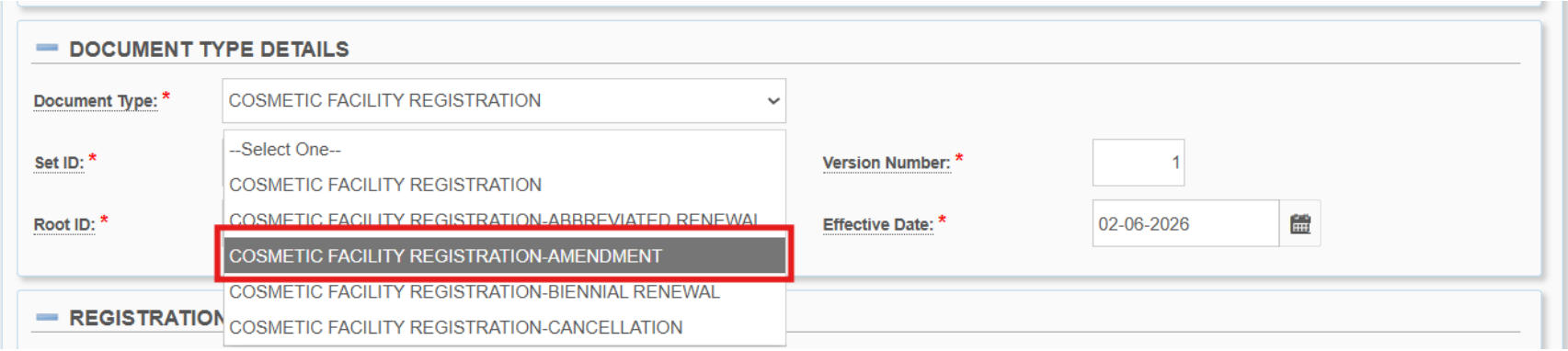
STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	REGISTRATION STATUS	RENEWAL/ CANCELLED DATE	DOCUMENT TYPE	LAST MODIFIED USER	LAST MODIFIED DATE
SUBMISSION ACCEPTED	3ef20663-e4cd-12ed-e063-6b94af0aae1d	3ef2d04a-626f-4a62-e063-6b94af0ae217	cmxxxxxx.xxxxxxx@direct	15	Test Facility A	xxxxxxx	CURRENT	16-SEP-27	COSMETIC FACILITY REGISTRATION-AMENDMENT		16-SEP-2025 17:35:08
SUBMISSION ACCEPTED	3ef20663-e4cd-12ed-e063-6b94af0aae1d	3ef265cb-b5f6-0922-e063-6b94af0a322b	cmxxxxxx.xxxxxxx@direct	14	Test Facility A	xxxxxxx		-	COSMETIC FACILITY REGISTRATION-AMENDMENT		16-SEP-2025 17:04:09
SUBMISSION ACCEPTED	3ef20663-e4cd-12ed-e063-6b94af0aae1d	3ef24cf6-aff3-1e13-e063-6a94af0a4183	cmxxxxxx.xxxxxxx@direct	13	Test Facility A	xxxxxxx		-	COSMETIC FACILITY REGISTRATION-AMENDMENT		16-SEP-2025 16:58:08
SUBMISSION ACCEPTED	3ef20663-e4cd-12ed-e063-6b94af0aae1d	3ef17092-099c-3c7c-e063-6a94af0a6af5	cmxxxxxx.xxxxxxx@direct	12	Test Facility A	xxxxxxx		-	COSMETIC FACILITY REGISTRATION		16-SEP-2025 16:38:08

1 - 4

Step 5. Click on '**CREATE NEW**' to generate an updated version of the SPL to make any necessary changes.



Step 6. Under '**DOCUMENT TYPE**', select '**COSMETIC PRODUCT FACILITY REGISTRATION – AMENDMENT**'.



Step 7: Update the submission details by following the instructions provided in Slides #11 through #16.

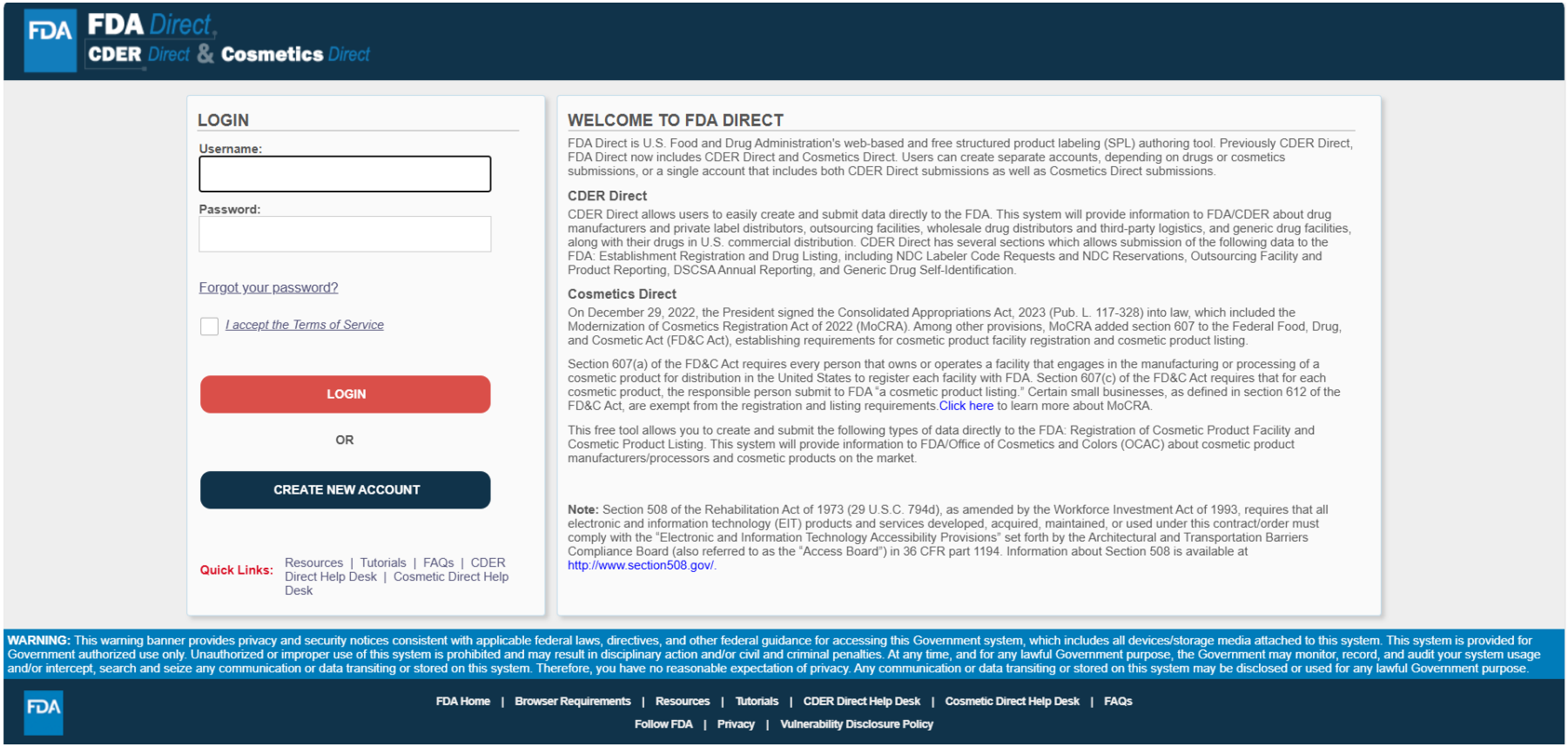
Step 8: Submit the SPL to FDA by following the instructions provided on Slide #17.

U.S. FOOD & DRUG ADMINISTRATION

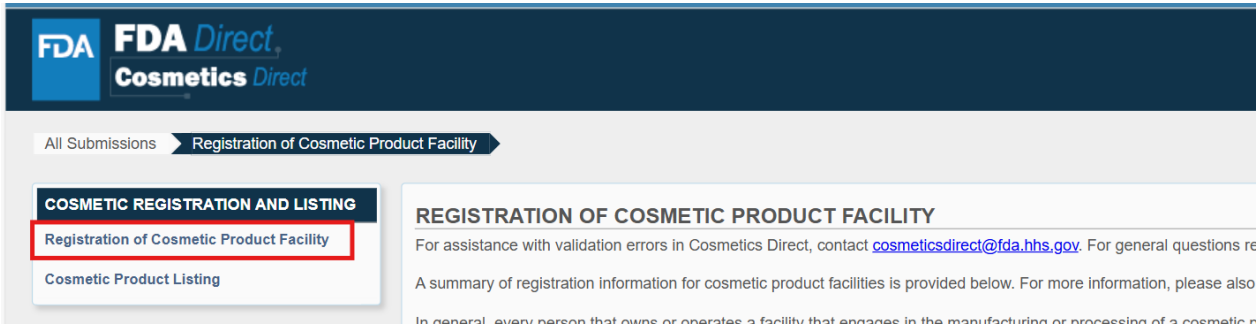
RENEWING A COSMETIC PRODUCT FACILITY REGISTRATION WITHOUT CHANGES (ABBREVIATED RENEWAL)

Step 1. Navigate to Cosmetics Direct via https://direct.fda.gov.

Step 2. Enter your log-in credentials, accept the terms of service, and click '**LOGIN**'.



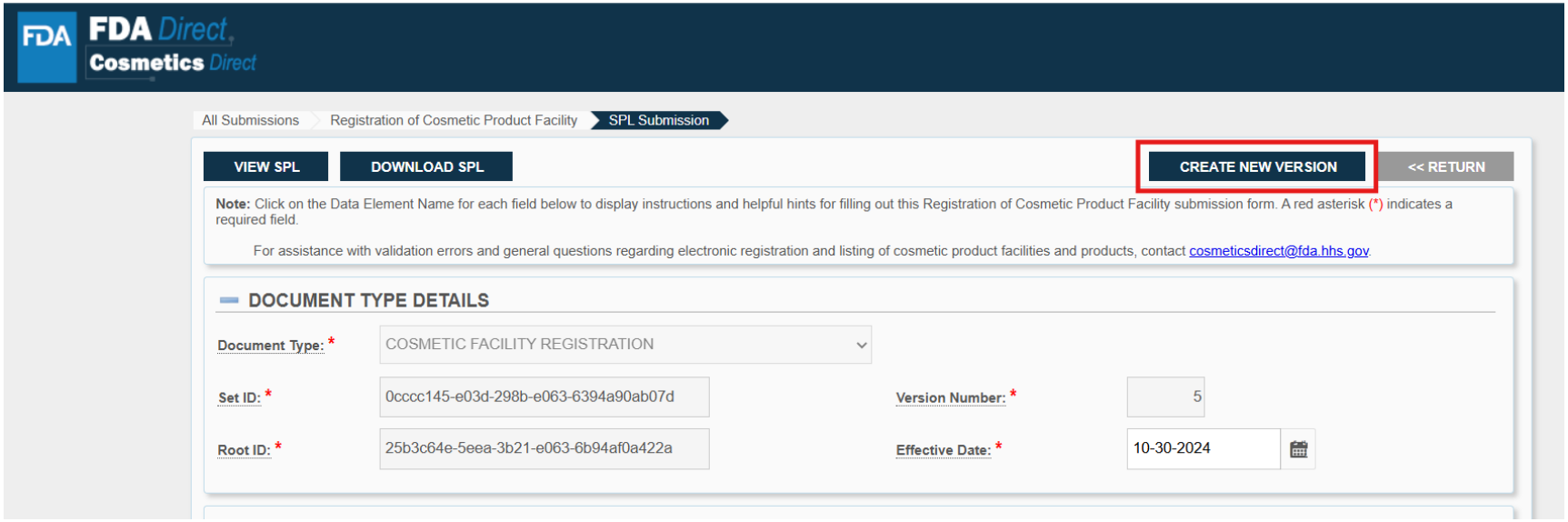
Step 3. Select '**Registration of Cosmetic Product Facility**'.



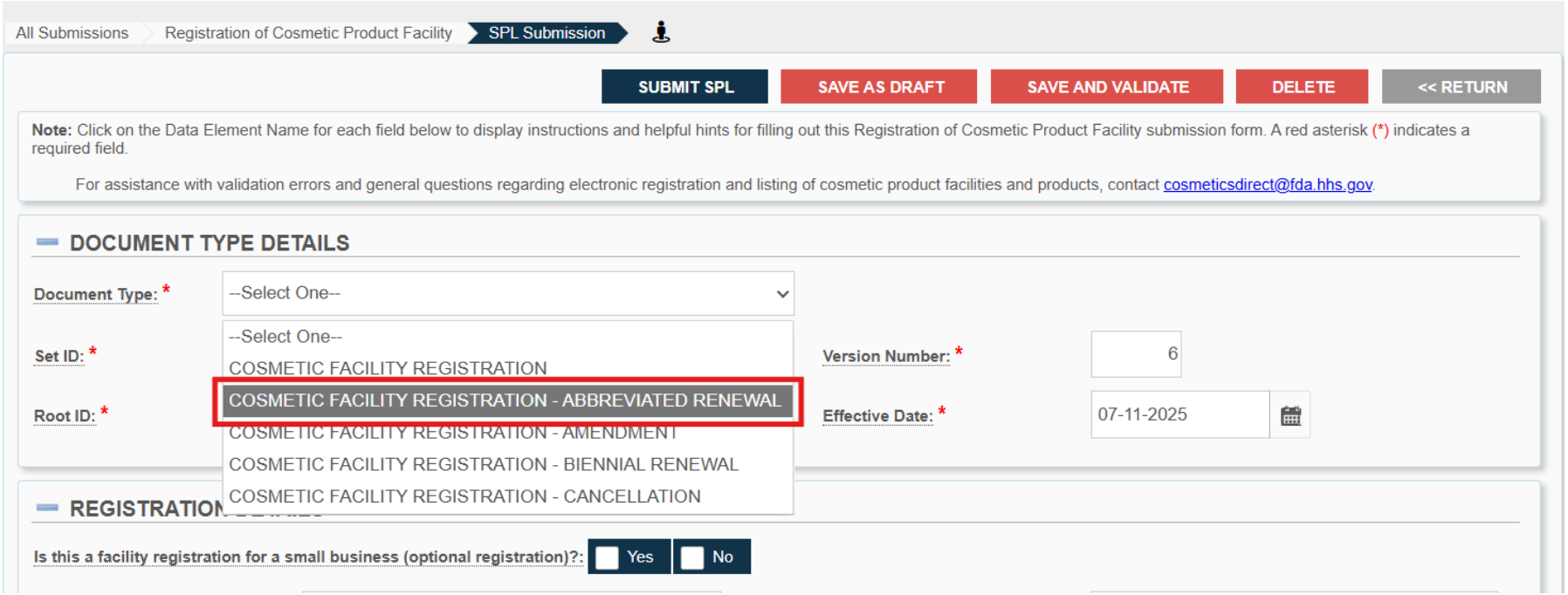
Step 4. Click on '**SUBMISSION ACCEPTED**' on the most recently accepted Cosmetic Product Facility Registration submission that you wish to renew.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	REGISTRATION STATUS	RENEWAL/ CANCELLED DATE	DOCUMENT TYPE	LAST MODIFIED USER	LAST MODIFIED DATE
SUBMISSION ACCEPTED	485e15a0-1d84-091b-e063-6b94af0ae6fd	485e872e-0cd7-4c8a-e063-6b94af0a95b7	cmxxxxx.xxxxxxxx@direct	1	Test Facilty A	xxxxxxx	CURRENT	14-JAN-28	COSMETIC FACILITY REGISTRATION		14-JAN-2026 13:51:08
SUBMISSION ACCEPTED	19362884-60f3-55e1-e063-6394a90a3dfc	485dc624-e4da-e341-e063-6b94af0a06b7	cmxxxxx.xxxxxxxx@direct	6	Test Facility A	xxxxxxx	CANCELLED	14-JAN-26	COSMETIC FACILITY REGISTRATION-CANCELLATION		14-JAN-2026 12:59:08
SUBMISSION ACCEPTED	1be0cbae-8a2a-9b76-e063-6294a90a4fa1	485c0180-cc44-62cb-e063-6a94af0ab1ee	cmxxxxx.xxxxxxxx@direct	8	Test Facility B	xxxxxxx	CURRENT	-	COSMETIC FACILITY REGISTRATION-AMENDMENT		14-JAN-2026 12:55:08
SUBMISSION ACCEPTED	1be0cbae-8a2a-9b76-e063-6294a90a4fa1	3d31d663-dab3-7223-e063-6b94af0aa748	cmxxxxx.xxxxxxxx@direct	7	Test Facility B	xxxxxxx		-	COSMETIC FACILITY REGISTRATION-BIENNIAL RENEWAL		14-JAN-2026 12:39:08

Step 5. Click on '**CREATE NEW VERSION**' to generate an updated version of the SPL for review.



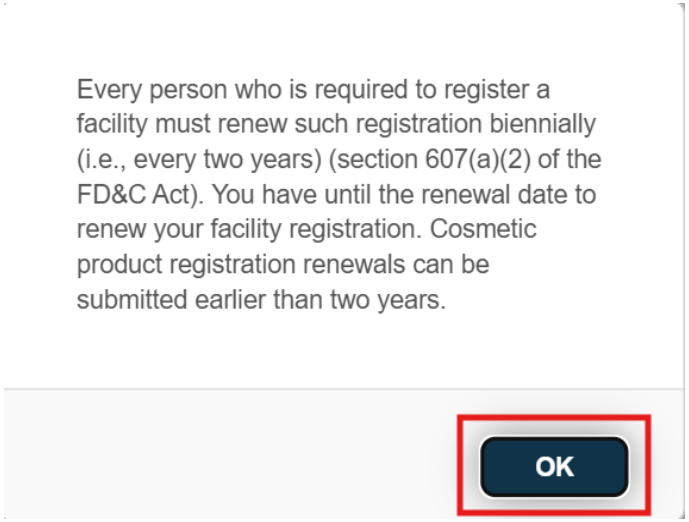
Step 6. Select '**COSMETIC PRODUCT FACILITY REGISTRATION – ABBREVIATED RENEWAL**' under the '**DOCUMENT TYPE**' drop-down menu.



Step 7a. The first of two (2) messages will appear:

"Every person who is required to register a facility must renew such registration biennially (i.e., every two years) (section 607 (a)(2) of FD&C Act). You have until the renewal date to renew your facility registration. Cosmetic product registration renewals can be submitted earlier than two years."

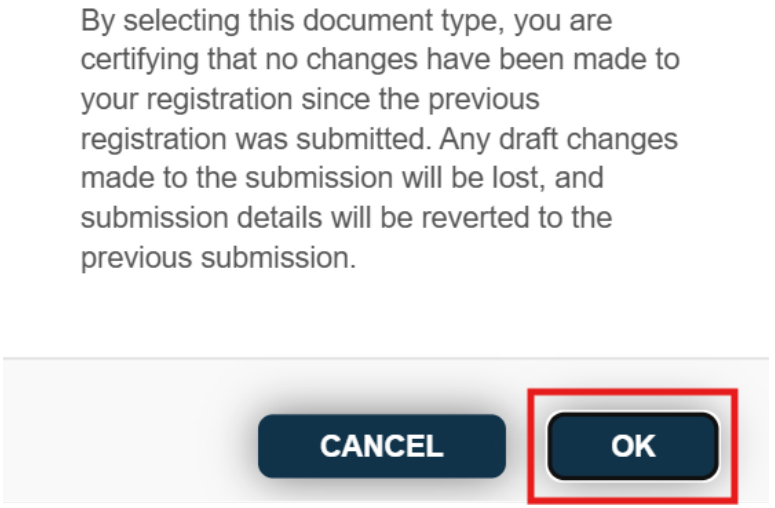
Select, '**OK**' to proceed.



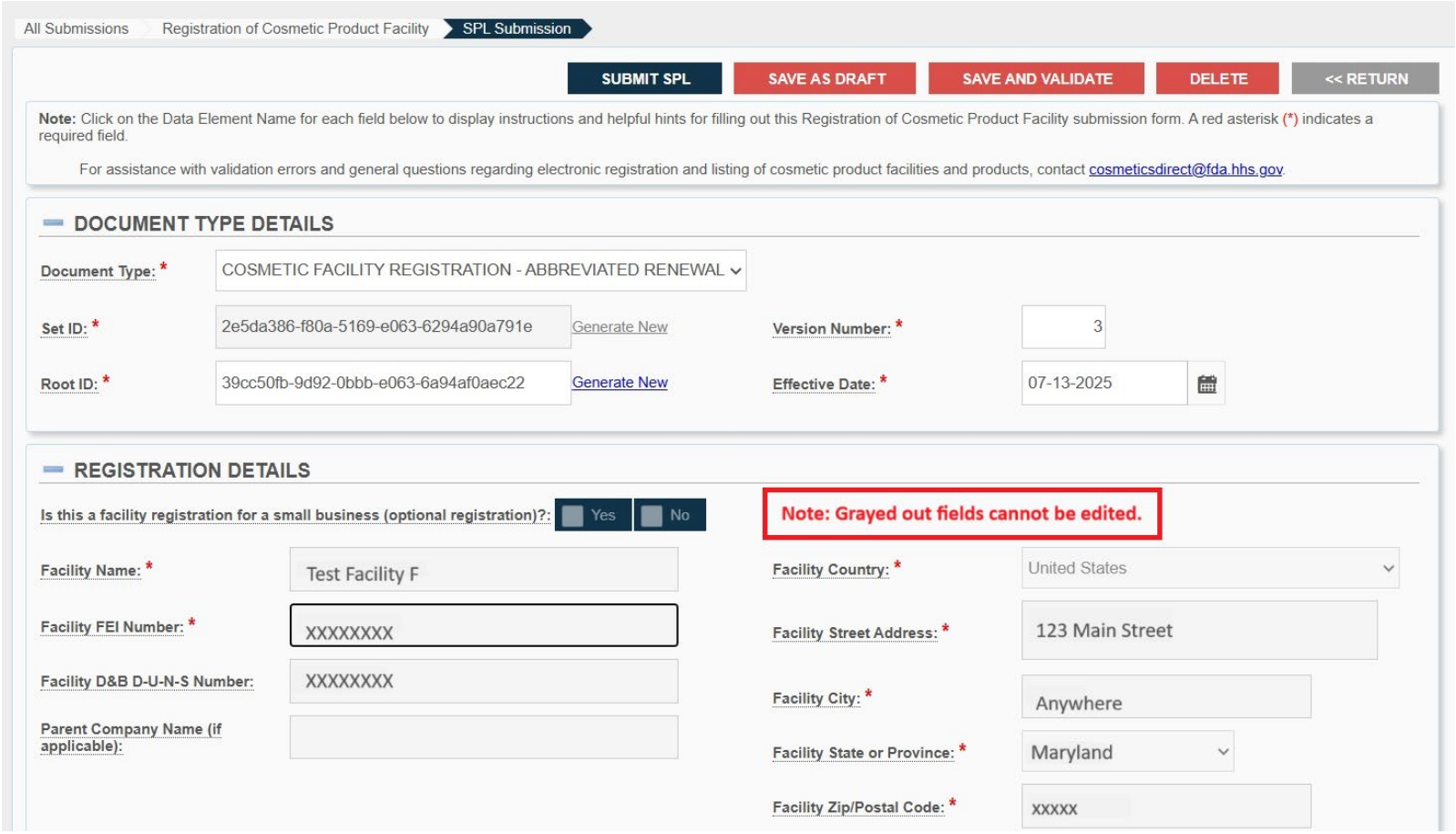
Step 7b. The second of two (2) messages will appear,

"By selecting this document type, you are certifying that no changes have been made to your registration since the previous submission was submitted. Any draft changes made to your submission will be lost, and submission details will be reverted to the previous submission."

Select, '**OK**' to proceed.



Step 8. Review your information to ensure no update is needed and the current information is still accurate.



Step 9. In the '**CONFIRMATION STATEMENT**' section, fill in the following optional blank fields: Click on the calendar icon to select the date. Enter the full '**NAME OF THE SUBMITTER**'. Click '**AGREE**' after reading and understanding the confirmation statement.

PLEASE NOTE: If you enter information into any field in this section, all other fields in the section will also need to be entered.

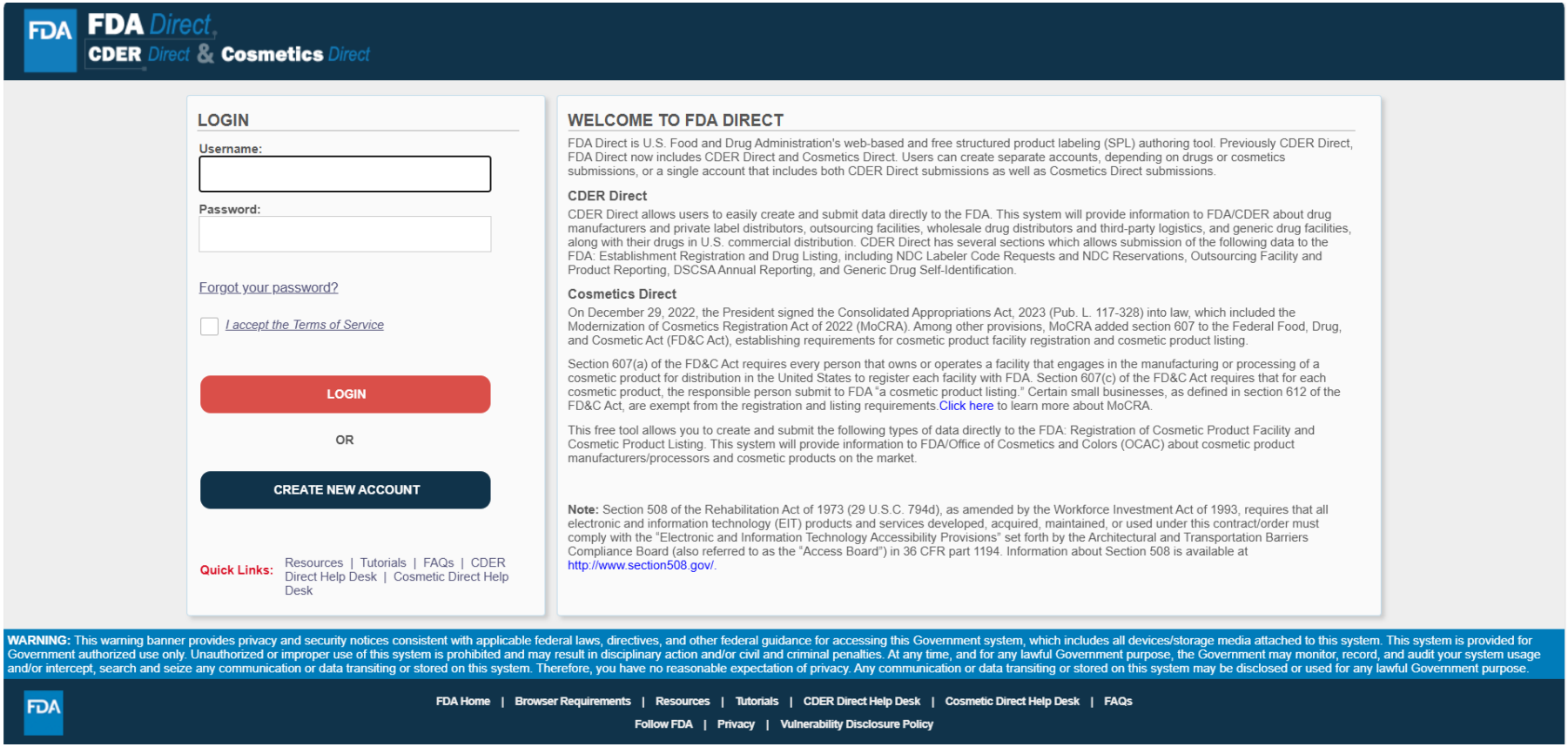
Step 10. Click '**SUBMIT SPL**' to submit your SPL to FDA.

U.S. FOOD & DRUG ADMINISTRATION

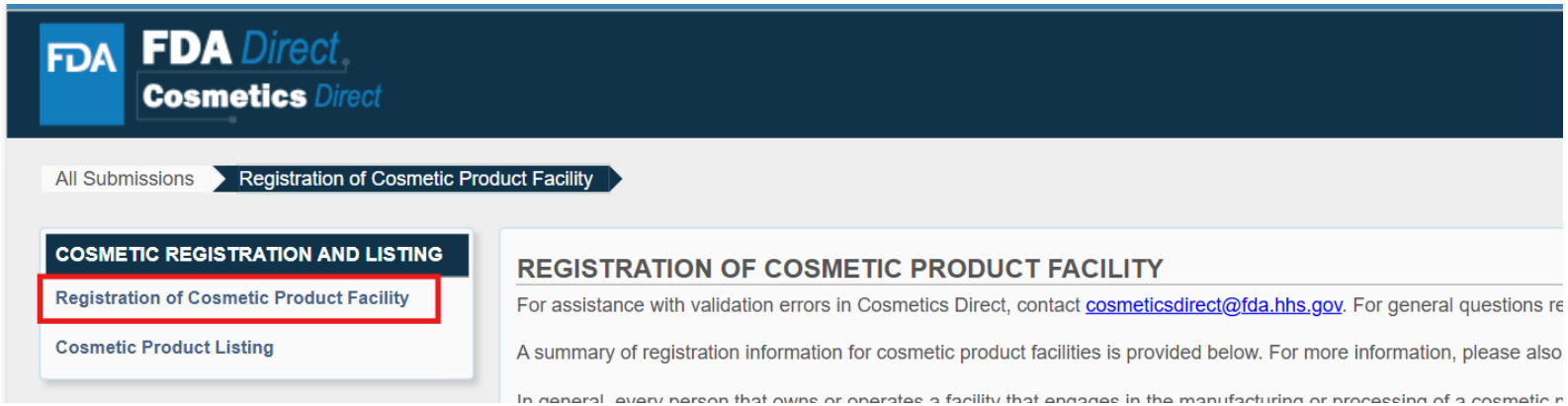
RENEWING A COSMETIC PRODUCT FACILITY REGISTRATION WITH CHANGES

Step 1. Navigate to Cosmetics Direct via https://direct.fda.gov.

Step 2. Enter your log-in credentials, accept the terms of service, and click '**LOGIN**'.



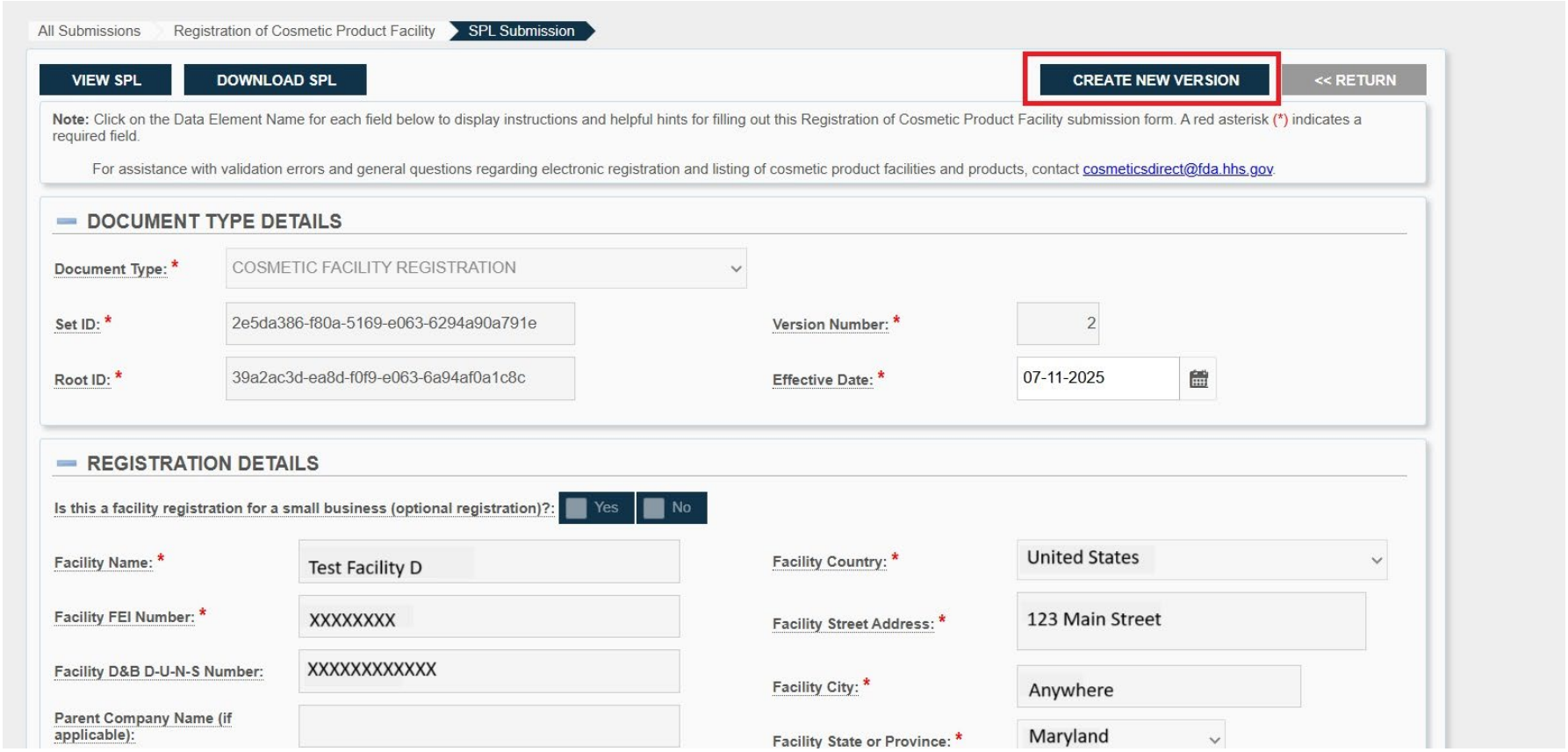
Step 3. Select '**Registration of Cosmetic Product Facility**'.



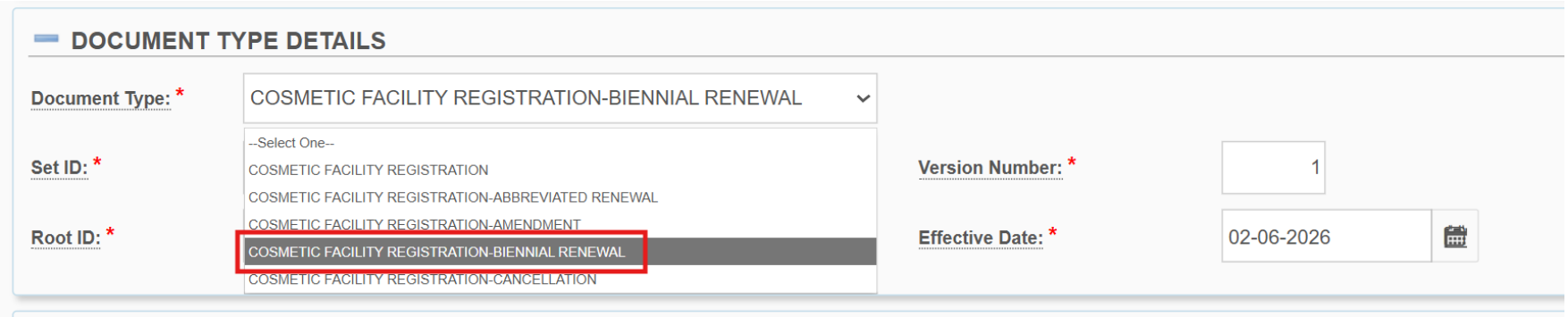
Step 4. Click on '**SUBMISSION ACCEPTED**' on the most recently accepted Cosmetic Product Facility Registration submission that you wish to renew and update.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	REGISTRATION STATUS	RENEWAL/ CANCELLED DATE	DOCUMENT TYPE
SUBMISSION ACCEPTED	0c52e442-a982-56fc-e063-6b94af0a8dac	0c52e442-a983-56fc-e063-6b94af0a8dac	cmxxxxx.xxxxxx@direct	1	Test Facility A	xxxxxxx	CURRENT	15-Feb-26	COSMETIC FACILITY REGISTRATION

Step 5. Click on '**CREATE NEW VERSION**' to generate an updated version of the SPL to make any necessary changes.



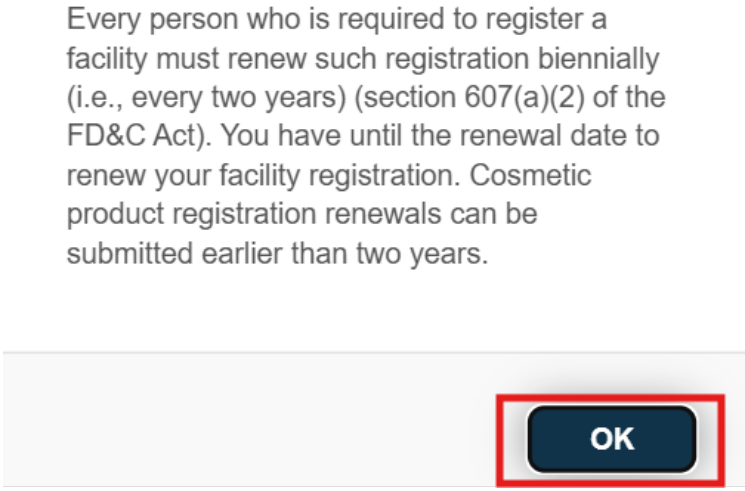
Step 6. Under '**DOCUMENT TYPE**', select '**COSMETIC PRODUCT FACILITY REGISTRATION – BIENNIAL RENEWAL**'.



Step 7. A message will appear,

"Every person who is required to register a facility must renew such registration biennially (i.e., every two years) (section 607 (a)(2) of FD&C Act). You have until the renewal date to renew your facility registration. Cosmetic product registration renewals can be submitted earlier than two years."

Select, '**OK**' to proceed.



Step 8: Update the submission details by following the instructions provided in Slides #11 through #16.

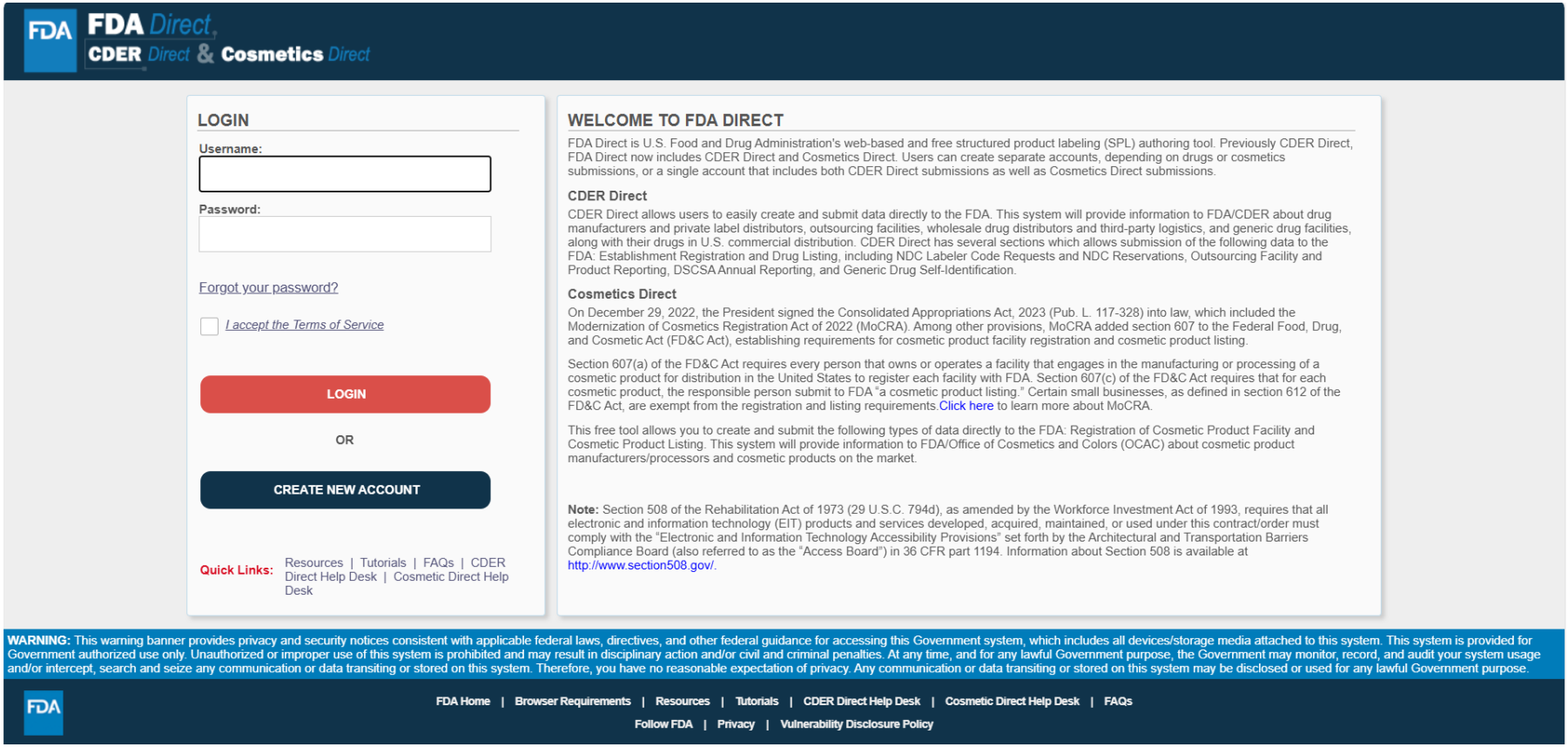
Step 9: Submit the SPL to FDA by following the instructions provided on Slide #17.

U.S. FOOD & DRUG ADMINISTRATION

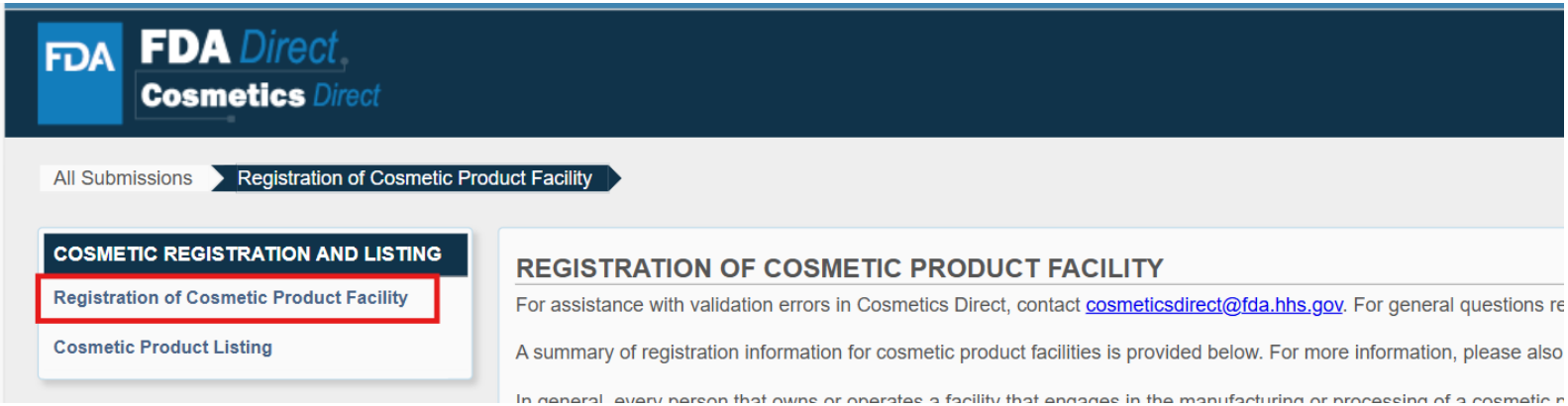
CANCELING A COSMETIC PRODUCT FACILITY REGISTRATION

Step 1. Navigate to Cosmetics Direct via https://direct.fda.gov.

Step 2. Enter your log-in credentials, accept the terms of service, and click '**LOGIN**'.



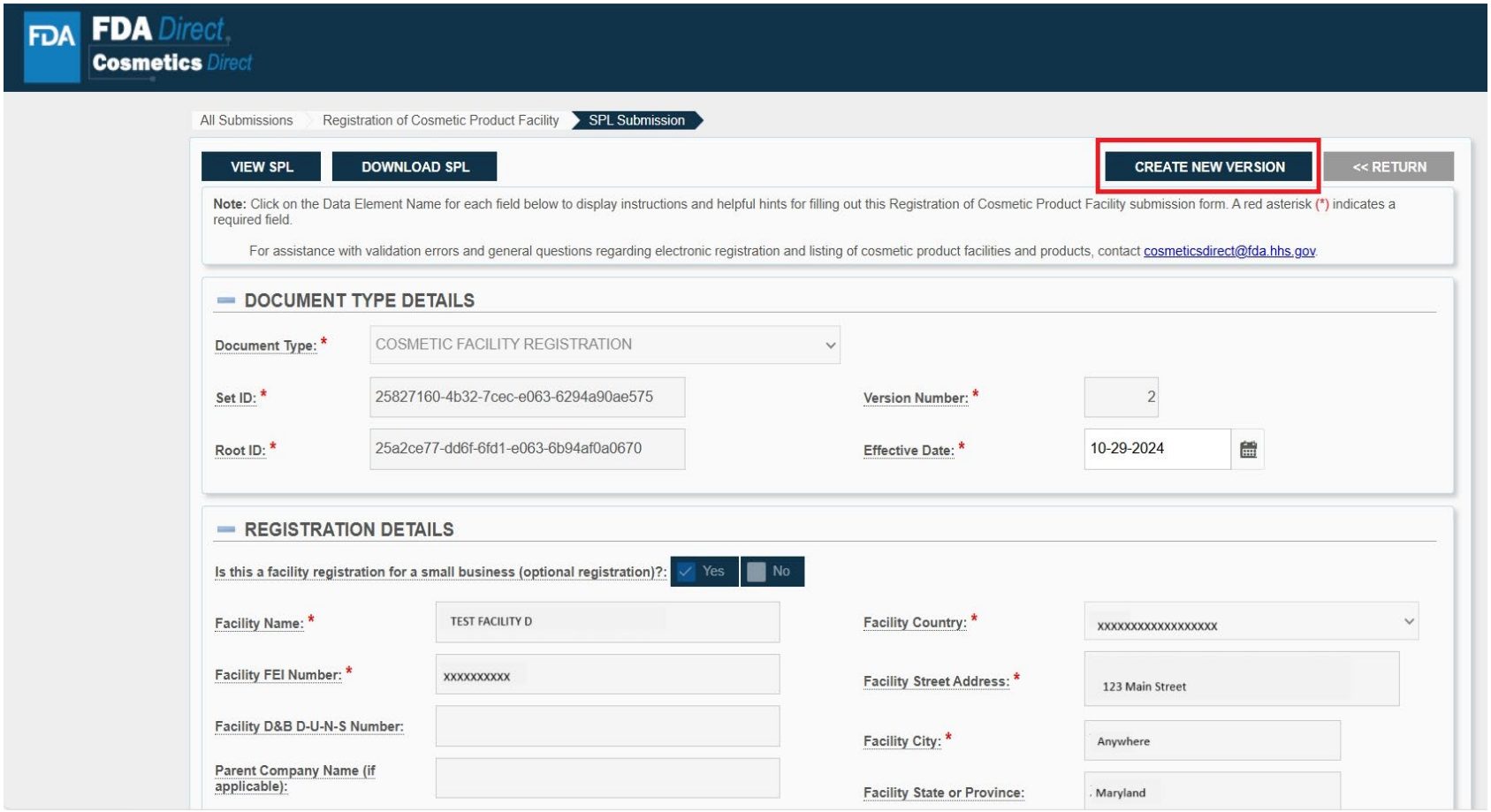
Step 3. Select '**Registration of Cosmetic Product Facility**'.



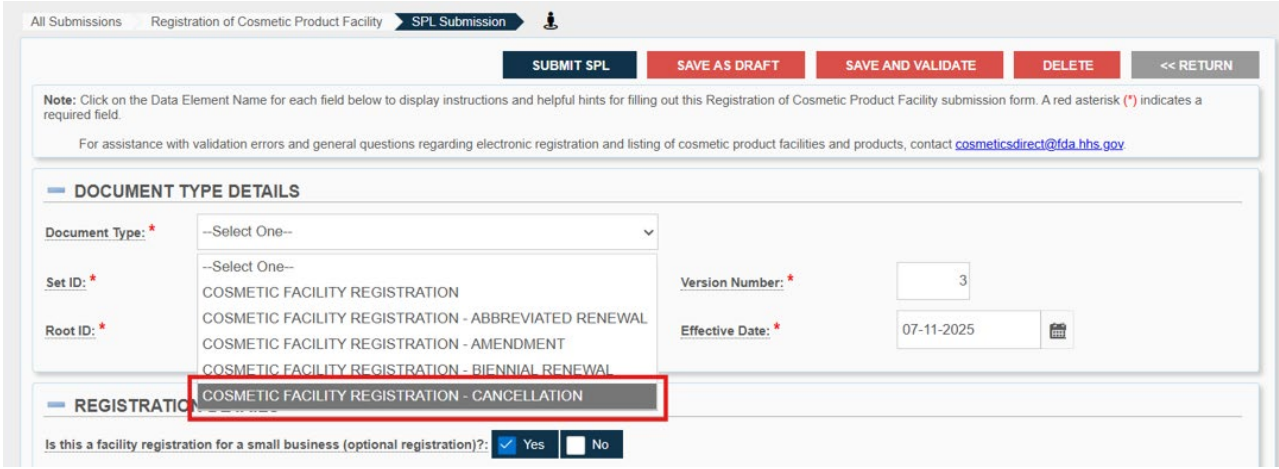
Step 4. Click on '**SUBMISSION ACCEPTED**' on the most recently accepted Cosmetic Product Facility Registration submission that you wish to cancel.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	FACILITY NAME	FACILITY FEI	REGISTRATION STATUS	RENEWAL/ CANCELLED DATE	DOCUMENT TYPE	LAST MODIFIED USER	LAST MODIFIED DATE
SUBMISSION ACCEPTED	485e15a0-1d84-091b-e063-6b94af0ae6fd	485e872e-0cd7-4c8a-e063-6b94af0a95b7	cmxxxxx.xxxxxxxx@direct	1	Test Facilty A	xxxxxxx	CURRENT	14-JAN-28	COSMETIC FACILITY REGISTRATION		14-JAN-2026 13:51:08

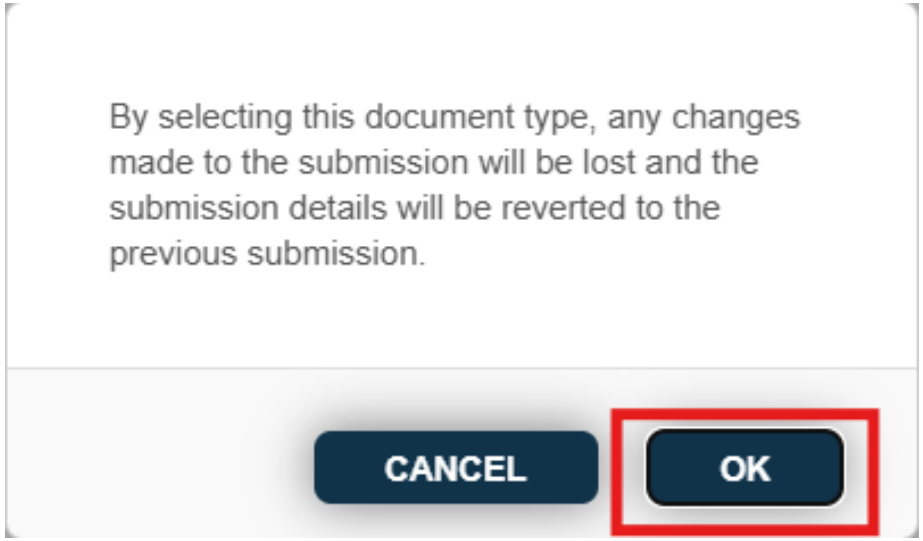
Step 5. Click on '**CREATE NEW VERSION**' to generate an updated version of the SPL for review.



Step 6. Under '**DOCUMENT TYPE**', select '**COSMETIC PRODUCT FACILITY REGISTRATION – CANCELLATION**'.



Step 7. The following message will appear, "By selecting this document type, any changes made to the submission will be lost and the submission details will be reverted to the previous submission." Select '**OK**'.



Step 8. In the '**CONFIRMATION STATEMENT**' section, fill in the following optional blank fields: Click on the calendar icon to select the date. Enter the full '**NAME OF THE SUBMITTER**'. Click '**AGREE**' after reading and understanding the confirmation statement.

PLEASE NOTE: If you enter information into any field in this section, all other fields in the section will also need to be entered.

Step 9. Click '**SUBMIT SPL**' to submit your SPL to FDA.

FDA U.S. FOOD & DRUG ADMINISTRATION

ASSISTANCE WITH VALIDATION ERRORS

U.S. FOOD & DRUG ADMINISTRATION

For assistance with validation errors received in Cosmetics Direct, contact **CosmeticsDirect@fda.hhs.gov**.