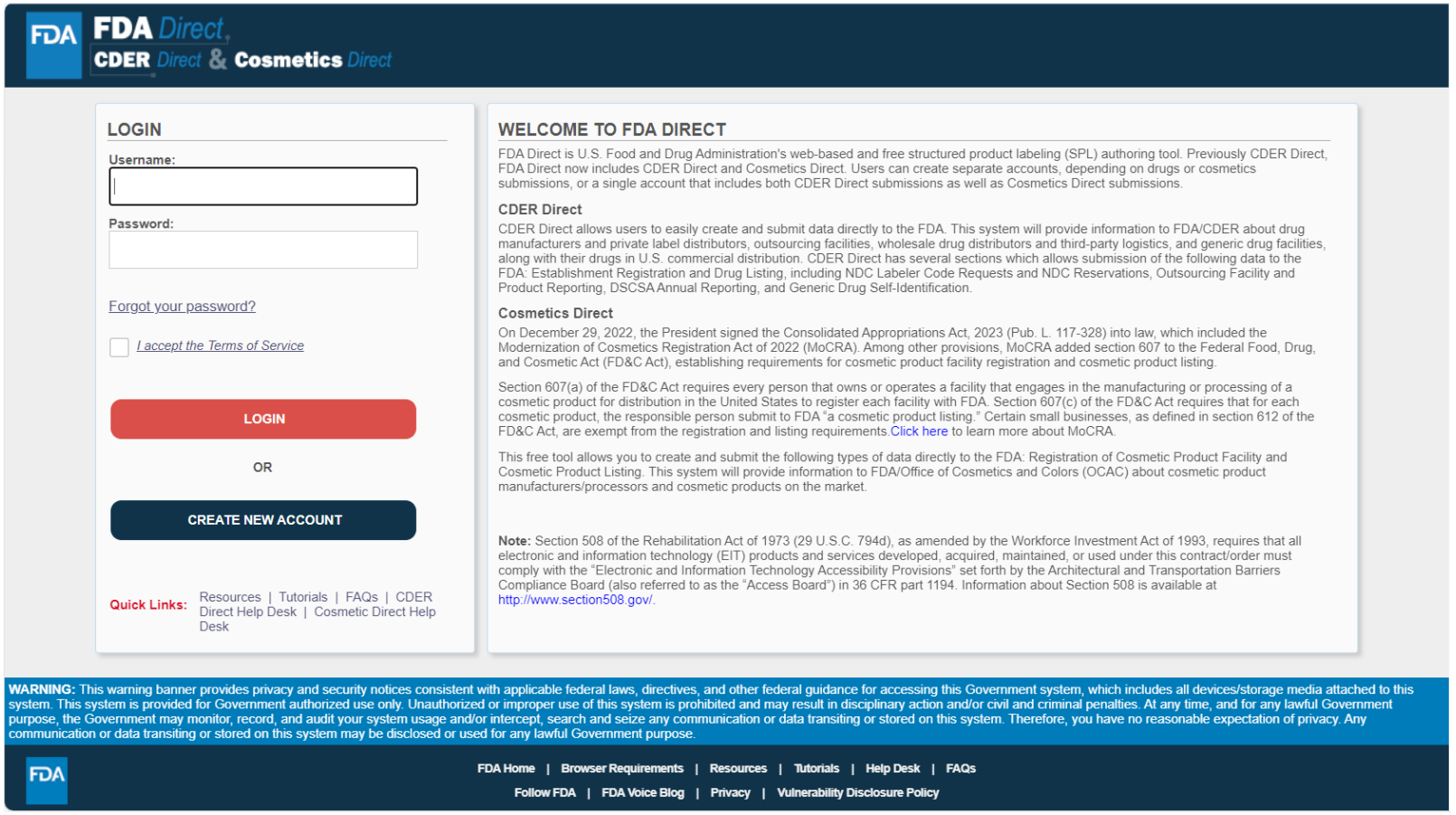
Reference Guide:
Human Drug Product Listing

Welcome to Human Drug Product Listing in the FDA Direct Portal

This guide provides the essential information you need to list a human drug product or upload a drug product listing SPL file into FDA Direct.

For technical support, email the eDRLS Help Desk at CDERdirect@fda.hhs.gov.



Click here to access the FDA Direct Portal

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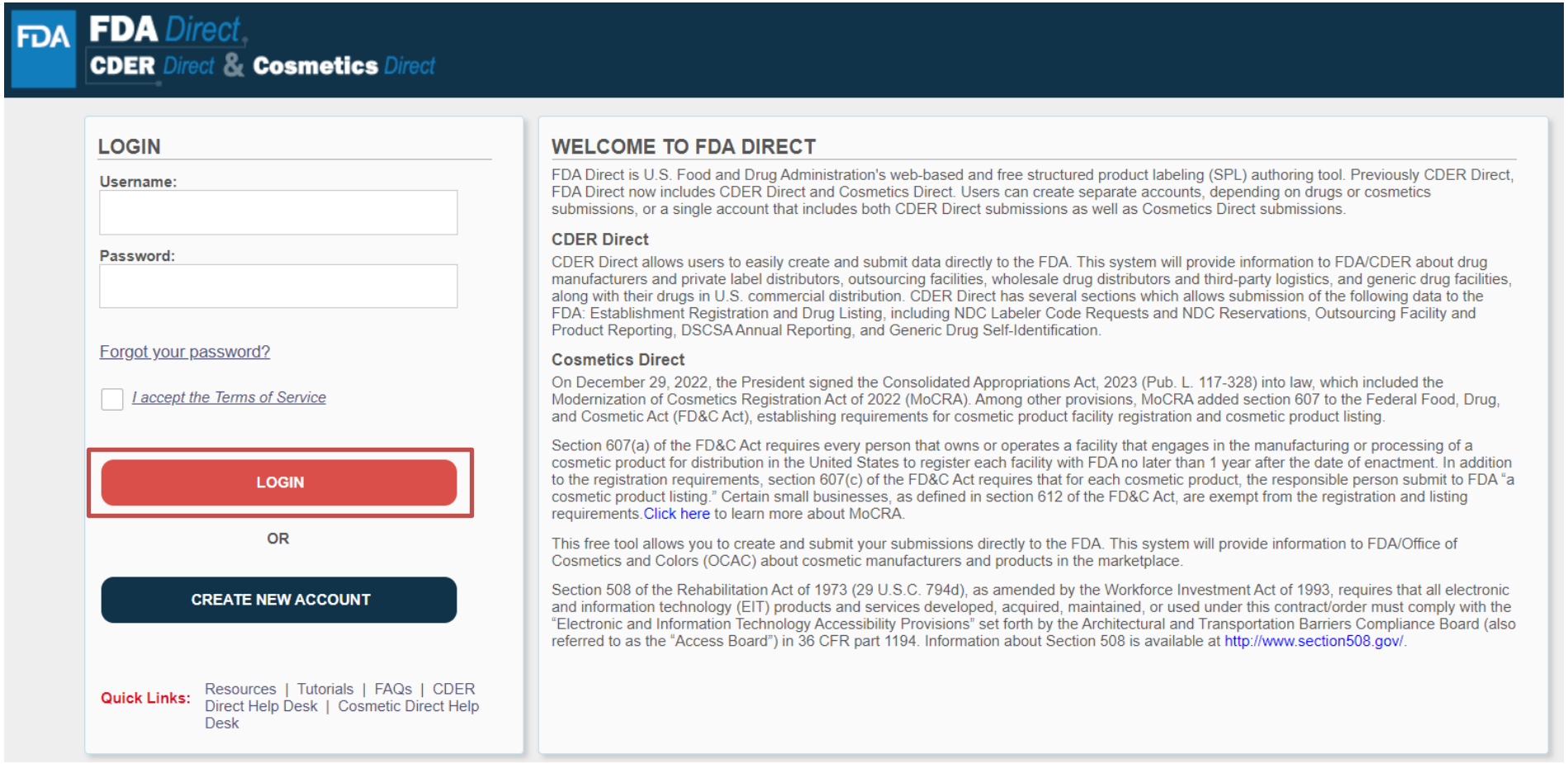
Listing a Human Drug Product

Step 1 Navigate to FDA Direct by accessing: https://direct.fda.gov

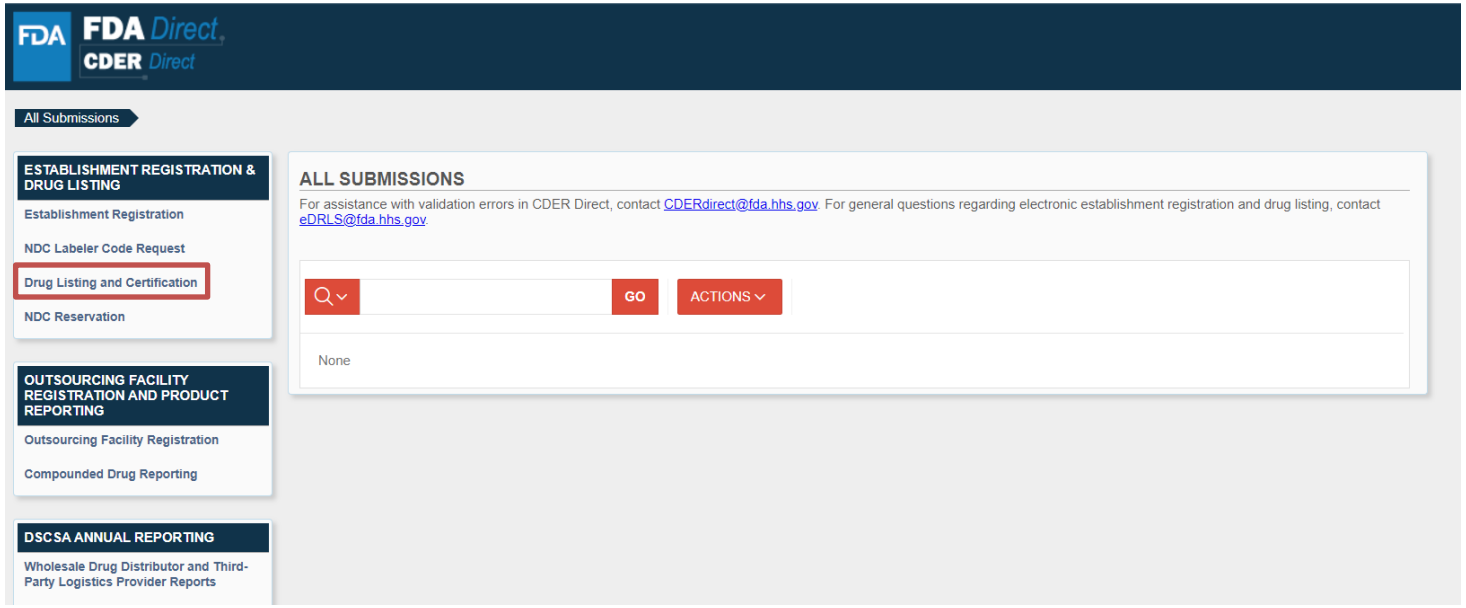
Step 2 Enter your login credentials, accept the terms of service, and click **Login**



Listing a Human Drug Product

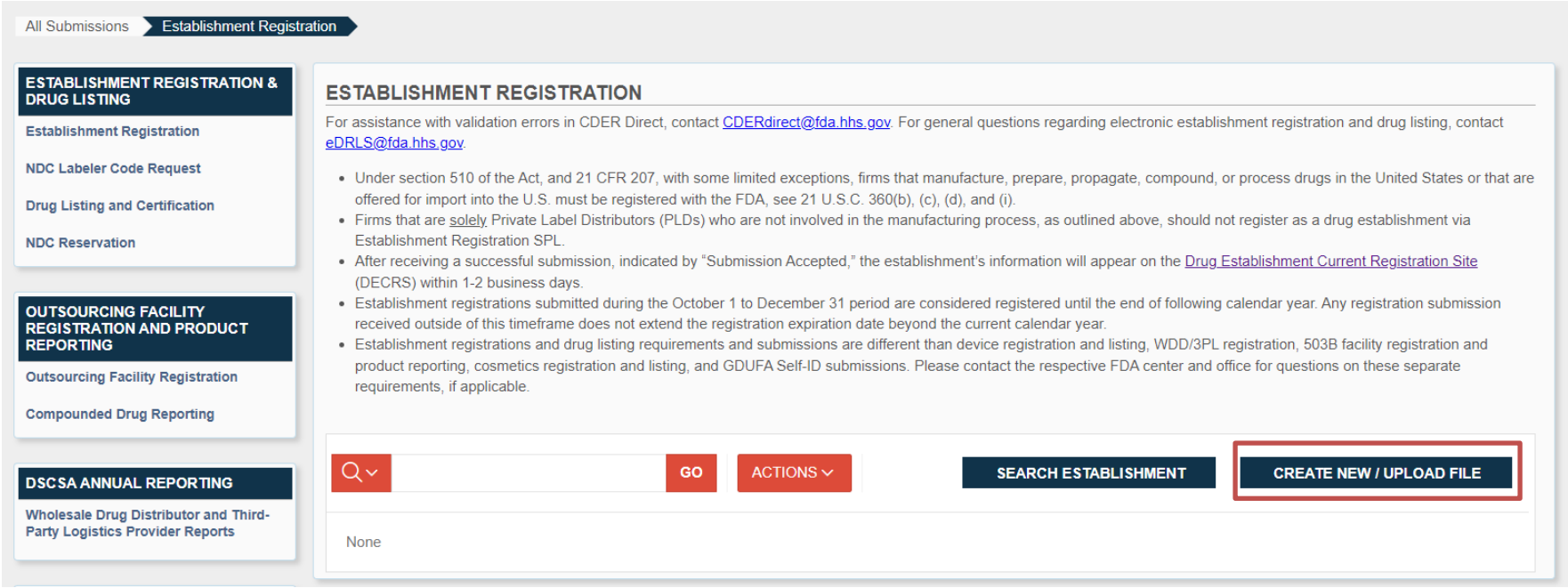
Step 3

Click on **Drug Listing and Certification**



Step 4

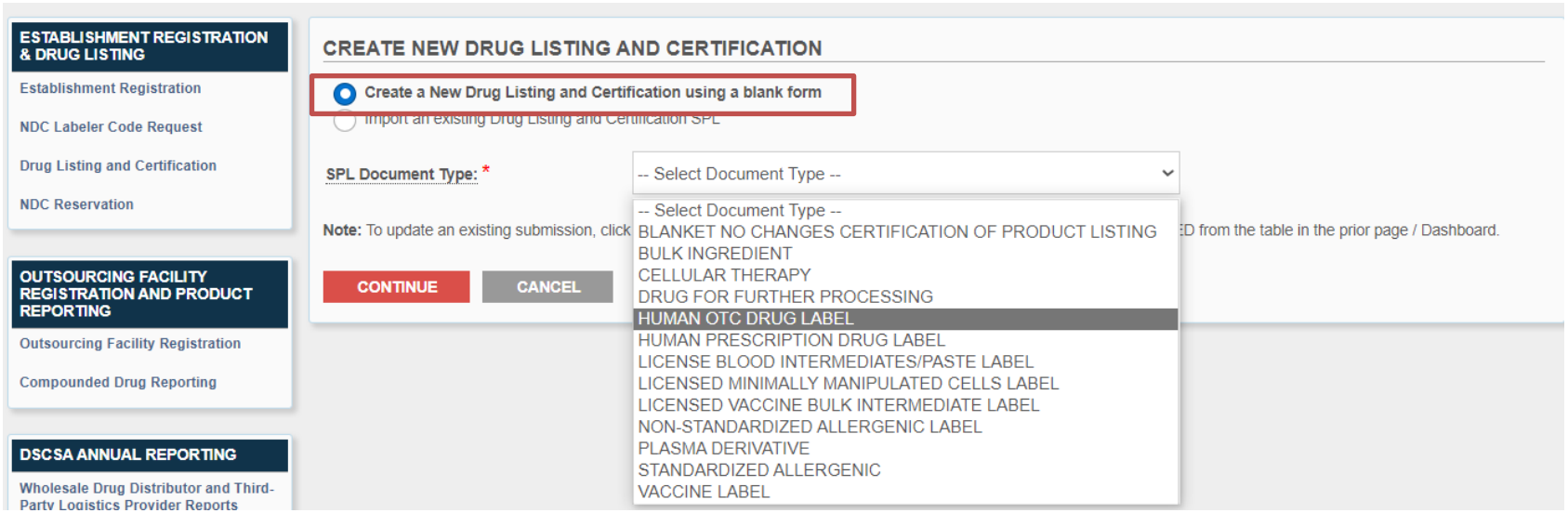
Click on **Create New/Upload File**



Listing a Human Drug Product

Step 5

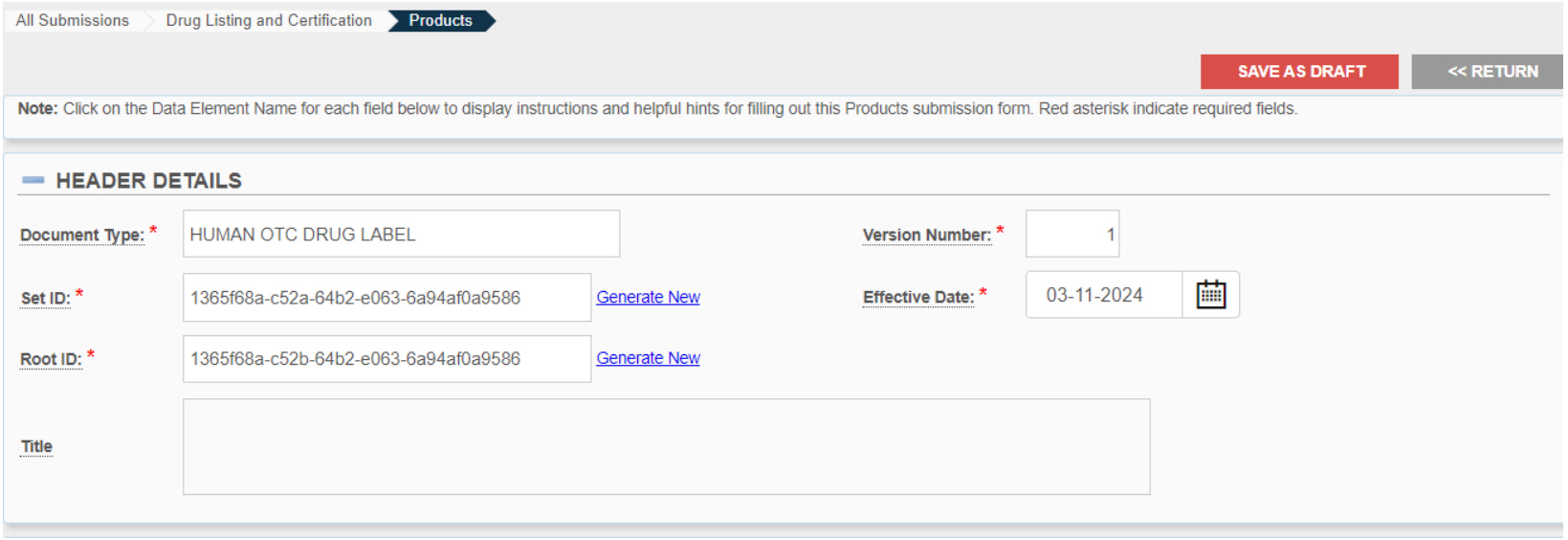
Click on **Create a New Drug Listing and Certification using a blank form** and **Select the appropriate SPL Document Type** for the drug product you want to list. Then click **Continue**



Step 6

The information under Header Details (Set ID, Root ID, Version Number, Effective Date) will be automatically populated

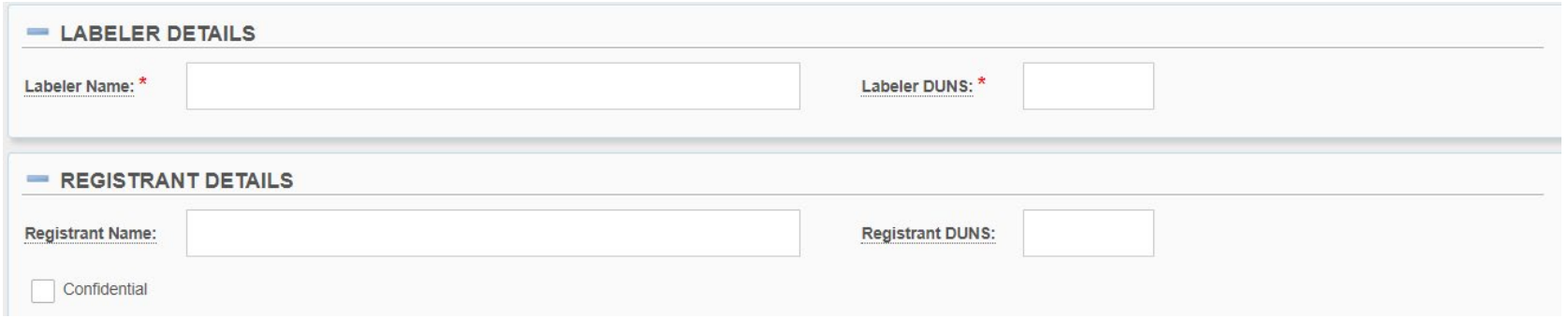
NOTE: Effective Date is not associated with the date the SPL is effective. The date an SPL is received by FDA is considered the date it is effective.



Listing a Human Drug Product

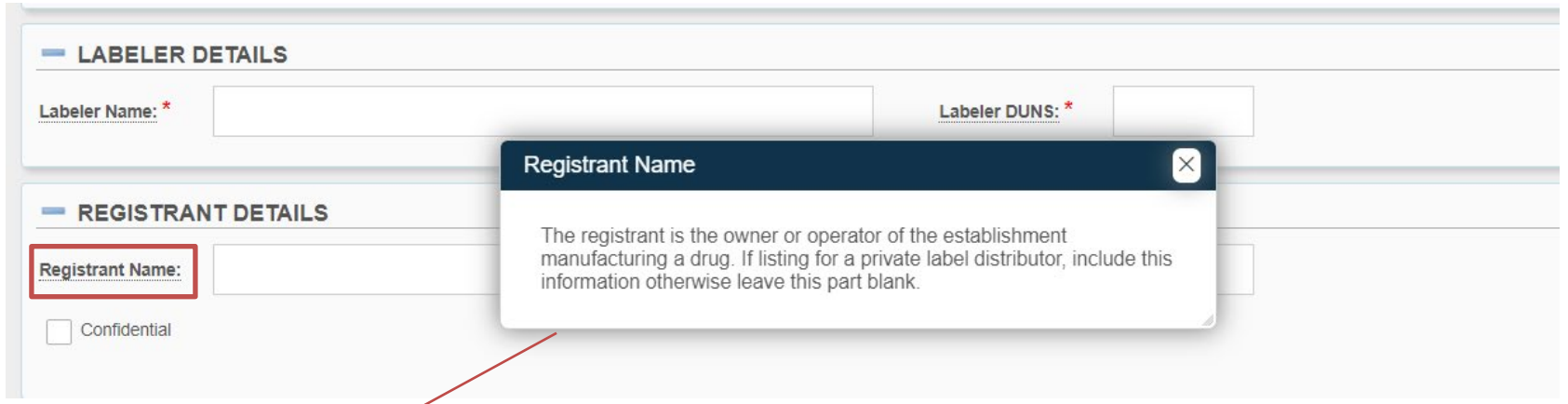
Step 7

Enter the Labeler Details. This Labeler Name and Labeler DUNS is the information associated with the Labeler Code for which the drug listing is being completed.



Quick Tip!

Clicking on a fieldname that has a dotted underline will bring up Help Text to provide more information as to the type of information being requested

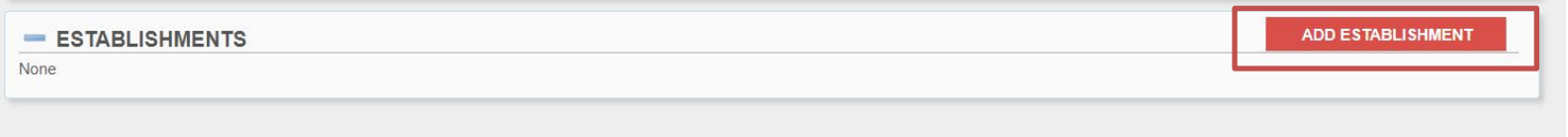


NOTE: Registrant Name and Registrant DUNS does not refer to the firm submitting the listing.

Listing a Human Drug Product

Step 8

Click on **Add Establishment**



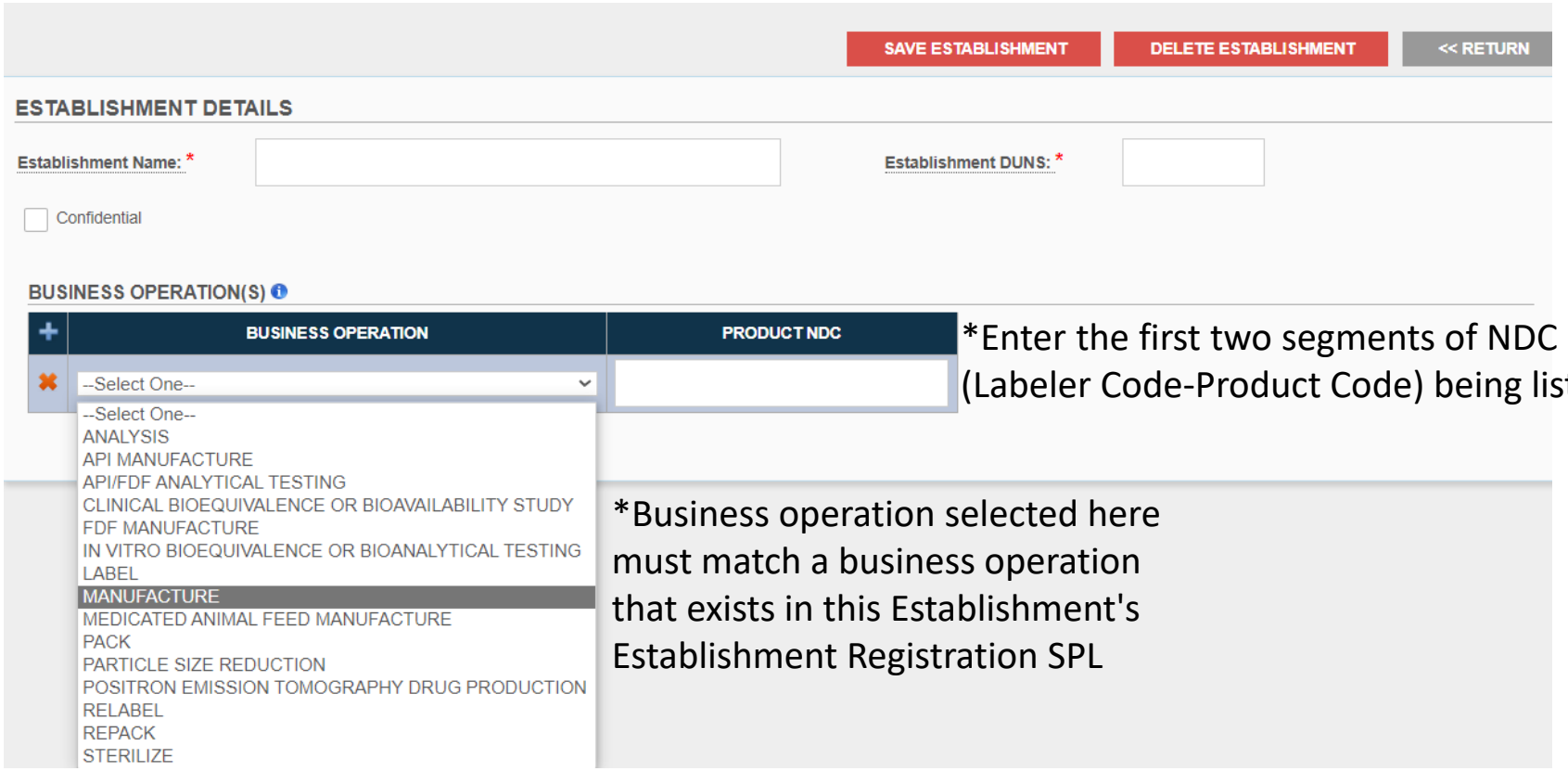
Step 9

Enter the Establishment Details for the Establishment performing a business operation on the drug product.

Select the Business Operation being performed on the **Product NDC** being listed. Click the + to add multiple business operations or Product NDCs.

Click on Save Establishment.

Repeat Steps 8 and 9 for additional establishments



*Enter the first two segments of NDC (Labeler Code-Product Code) being listed

*Business operation selected here must match a business operation that exists in this Establishment's Establishment Registration SPL

Listing a Human Drug Product

Step 10

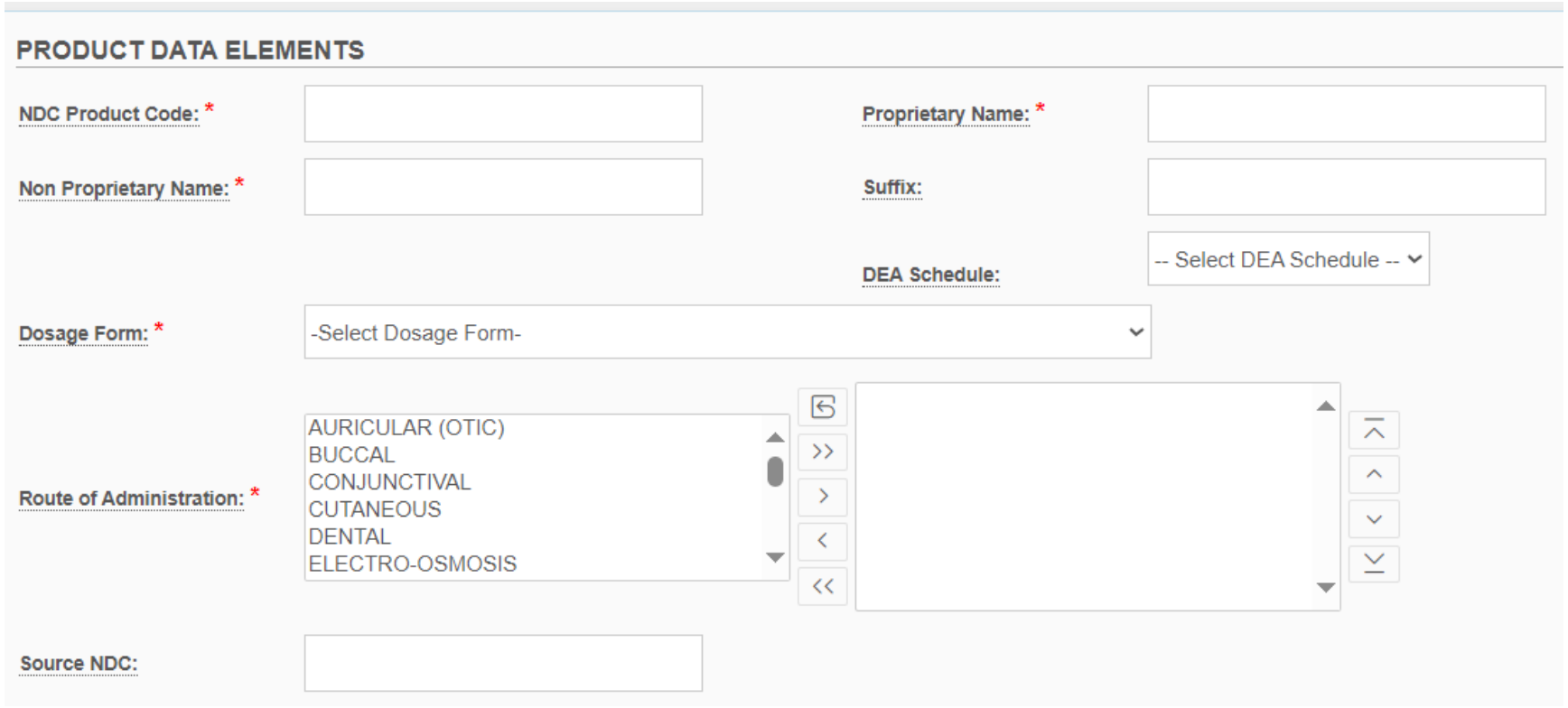
Click on Add Product

Step 11

Enter the information regarding the drug product being listed.

The first segment of the Product NDC should be the Labeler Code associated with the Labeler DUNS from Step 7.

Click on the fieldname with the dotted underline for a description of what should be entered in each field.

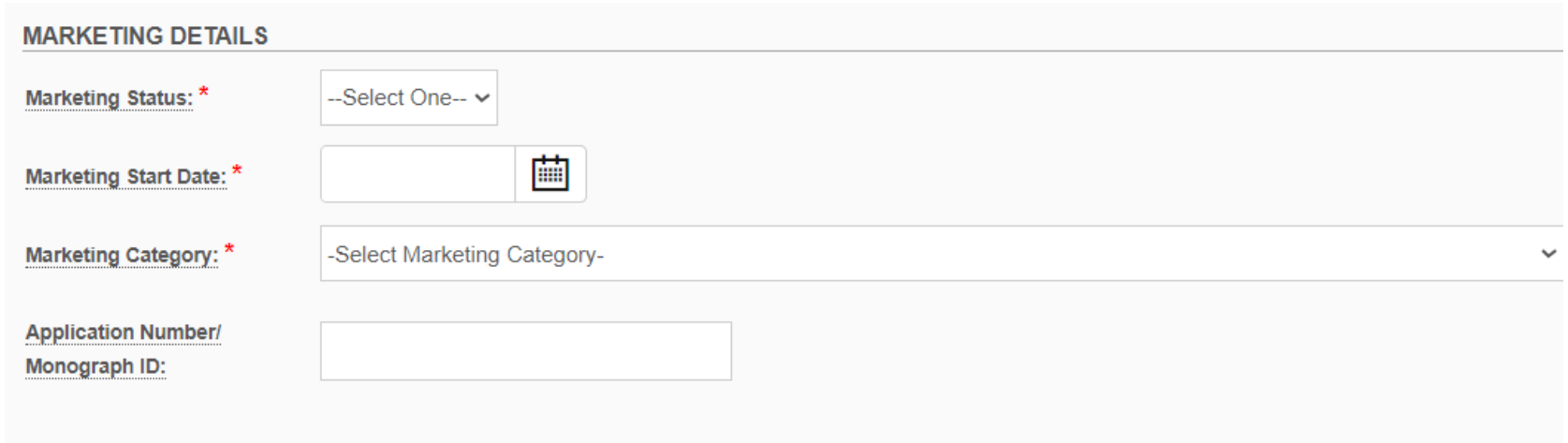


Listing a Human Drug Product

Step 12

Enter the Marketing Details for the Product.

Marketing Start Date should correspond to the date that the product enters commercial distribution in the United States.



Step 13

Click on Add Ingredient

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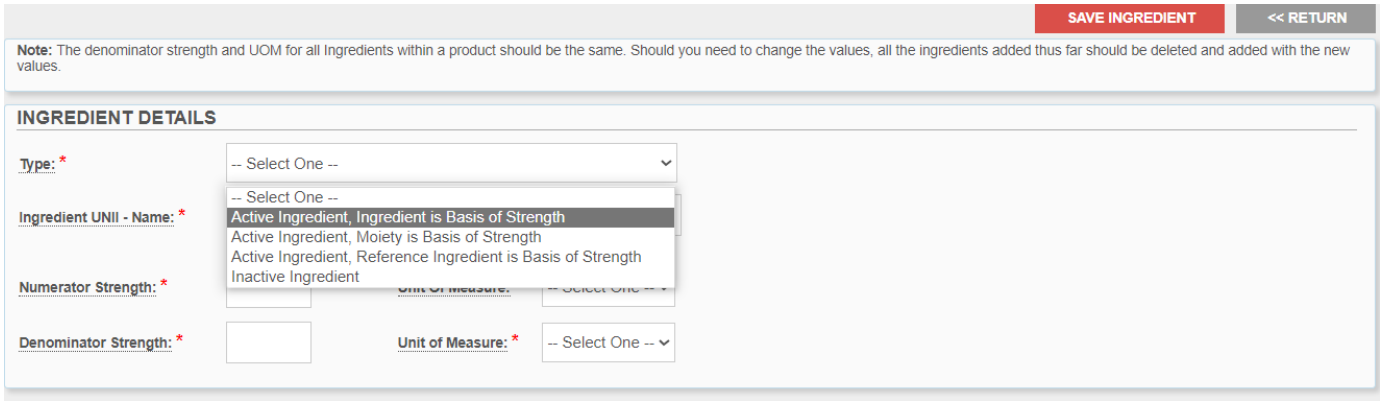
Step 14a

Select the appropriate “Type” and enter the information regarding the Active Ingredient(s) individually and Save Ingredient.

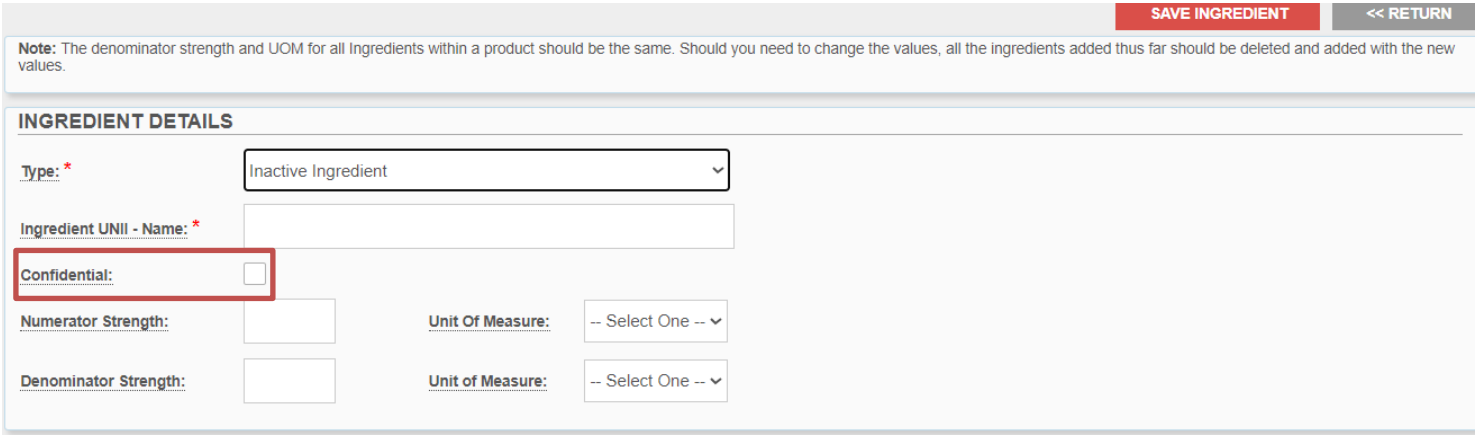
*The strength of the active ingredient should be expressed as a fraction (numerator/denominator).



Step 14b

After clicking on Save Ingredient, click on Add Ingredient to add additional ingredients such as Inactive Ingredients.

Inactive Ingredients can be marked Confidential to prevent information from being released to public repositories.



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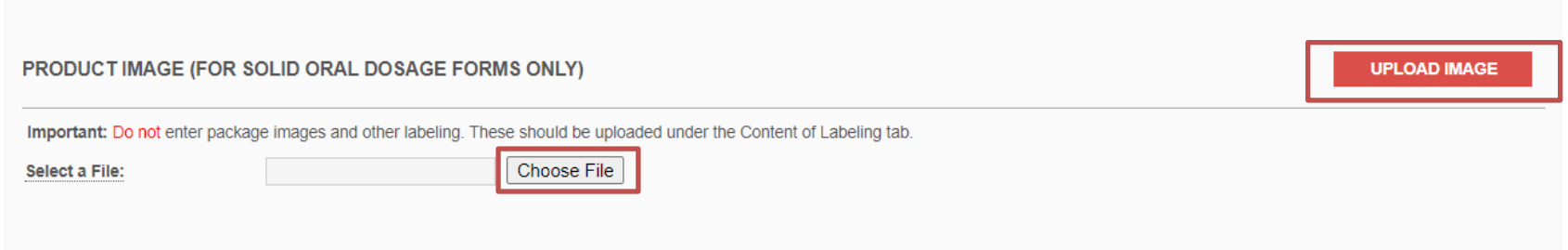
Step 15

If the product is in a solid oral dosage form (i.e. tablet), click on Choose File, locate and select a JPG image of the product (i.e. tablet) and click Open.

Once the file path is visible in the gray box, click Upload Image.

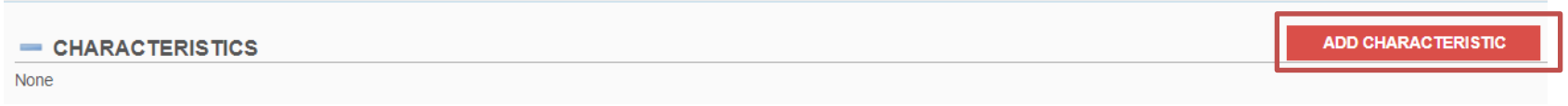


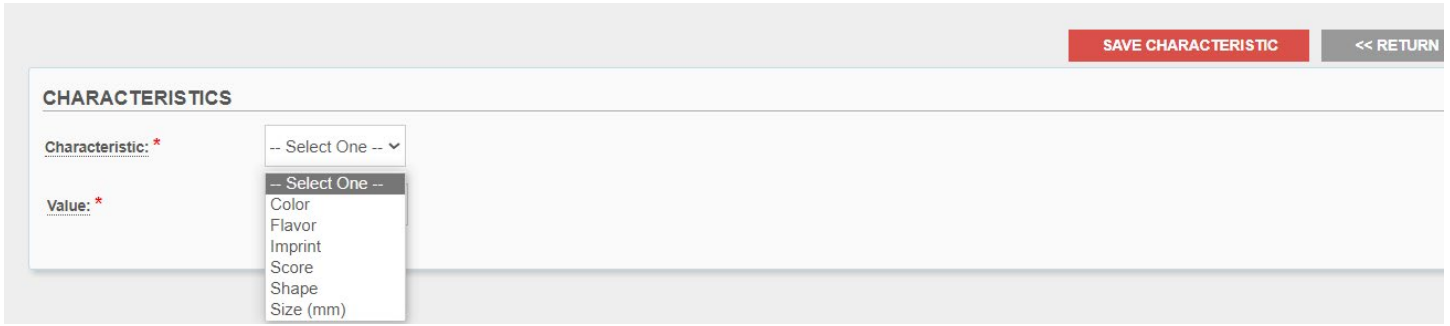
Step 16

If the product is in a solid oral dosage form, Click on Add Characteristic to add characteristics as needed.

Click on Save Characteristic and repeat this step for each characteristic.

Color, Shape, Size, and Score are <u>required</u> for solid oral dosage forms.





Listing a Human Drug Product

Step 17

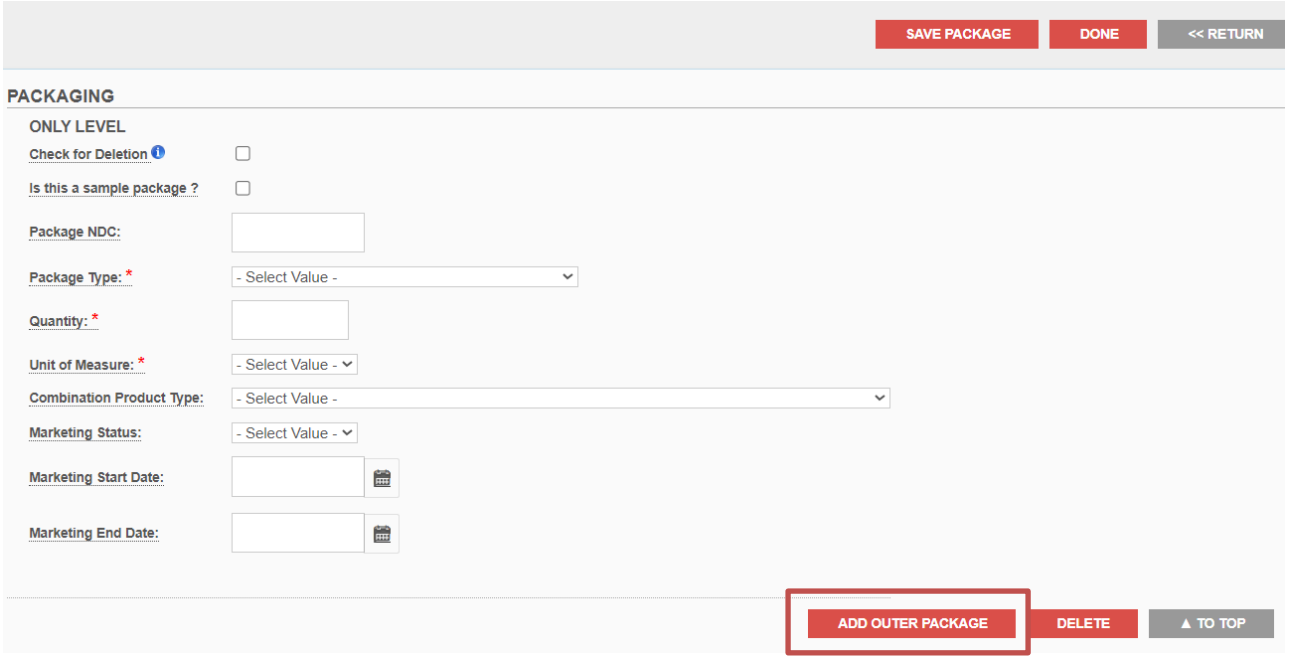
To add Package details, click on Add Package.

Step 18

Enter the Package information.

Click on “Add Outer Package” for additional levels of packaging (ie bottle within a carton).

Click on Save Package



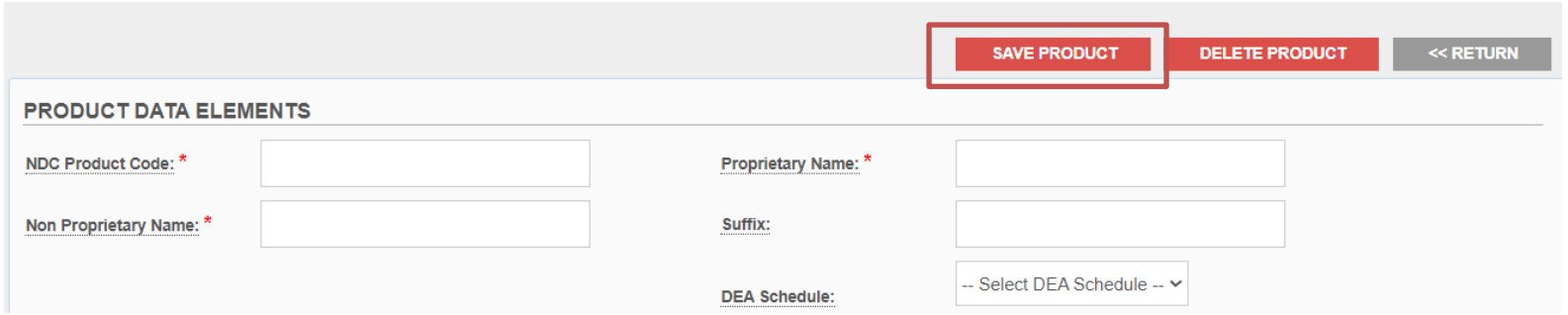
Step 19

Repeat steps 17 and 18 to add additional package presentations associated with the product

Listing a Human Drug Product

Step 20

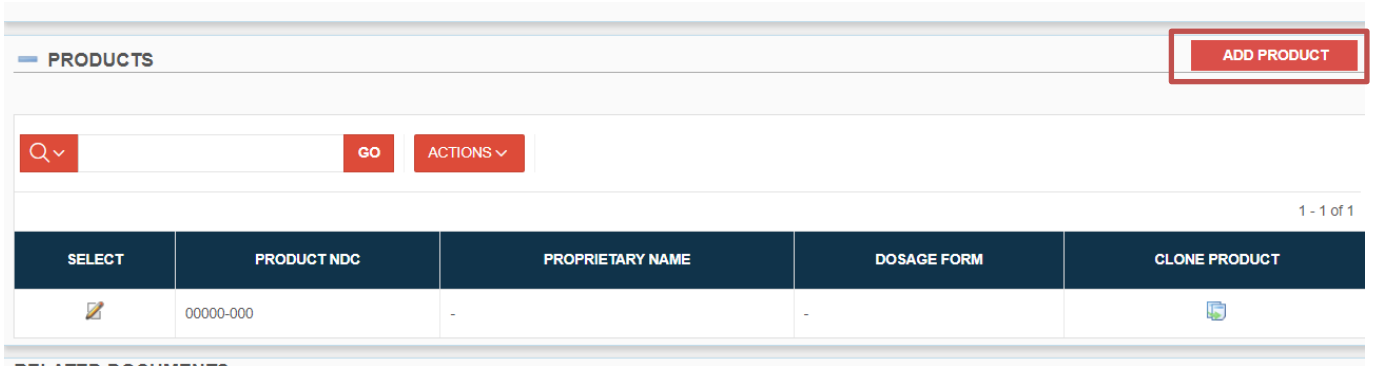
After completing the fields for the Product Data Elements, click on Save Product



Step 21

To add another product, click on “Add Product” and repeat steps 11-20.

*Please note that multiple Product NDCs can only be listed in the same Product Listing SPL if the Product NDCs share the same Content of Label. Otherwise, you must create a new, different Product Listing SPL.



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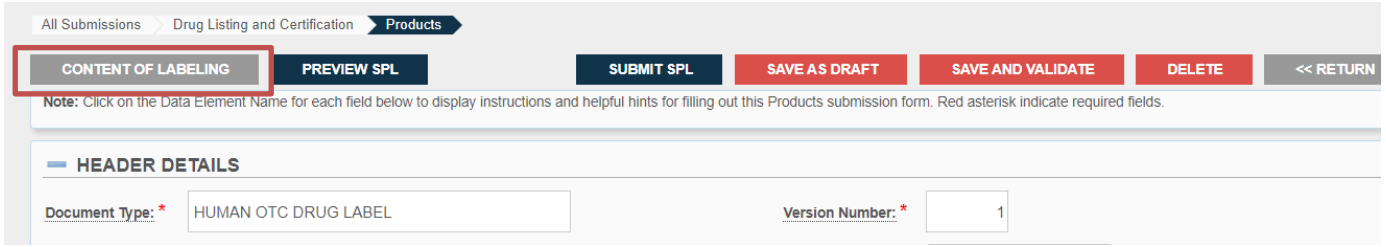
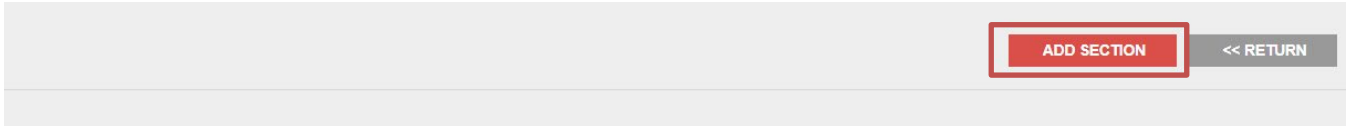
Step 20

To add Content of Labeling information, click on Content of Labeling.



Step 21

To add a Section, click on Add Section

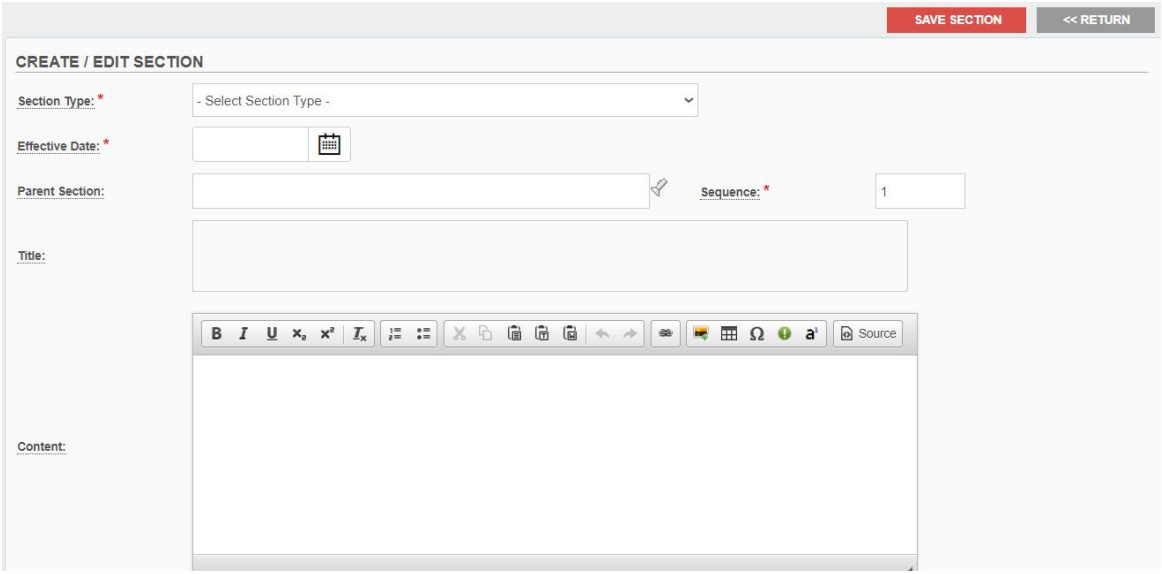


Step 22

Select the Section Type from the drop-down menu and enter Effective Date.

Enter the information for the Section in the “Content” editor.

Once finished with a section, click on “Save Section”



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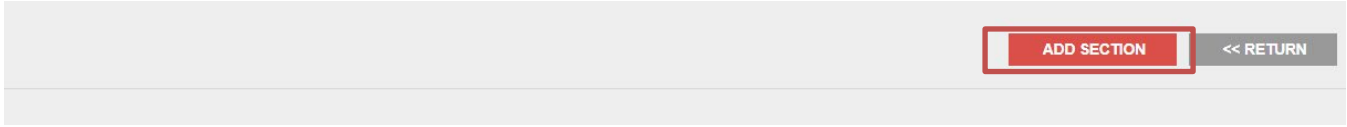
Step 23

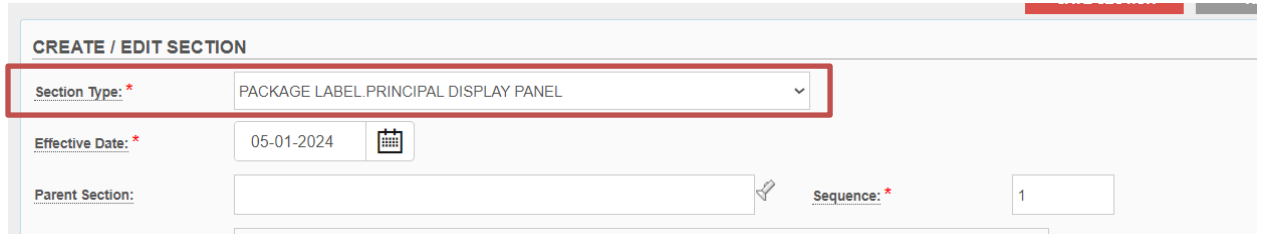
To add multiple sections, repeat steps 21 and 22.

To add an image of the Package Label, click on Add Section



Step 24

For Section Type, select Package Label Principal Display Panel

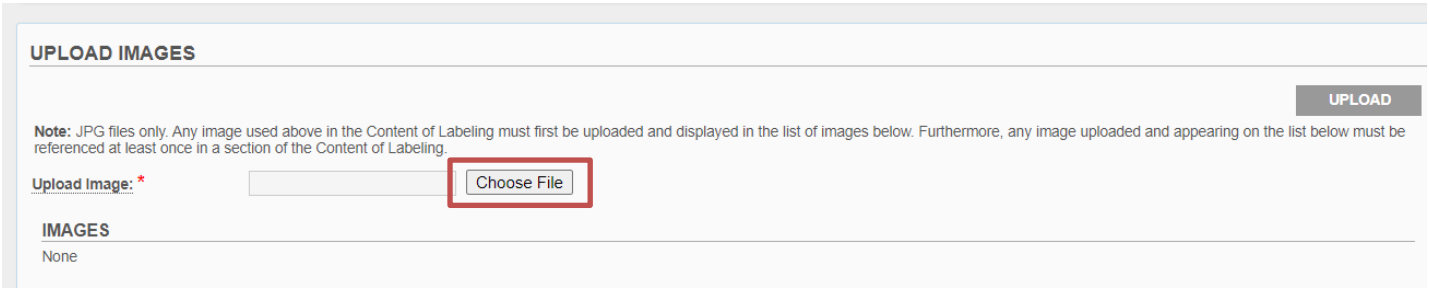


Step 25

Click on “Choose File” to select the package label image you want to upload.

Locate and select the image file you want to upload.

*Only .jpg or .jpeg files less than 1MB are accepted



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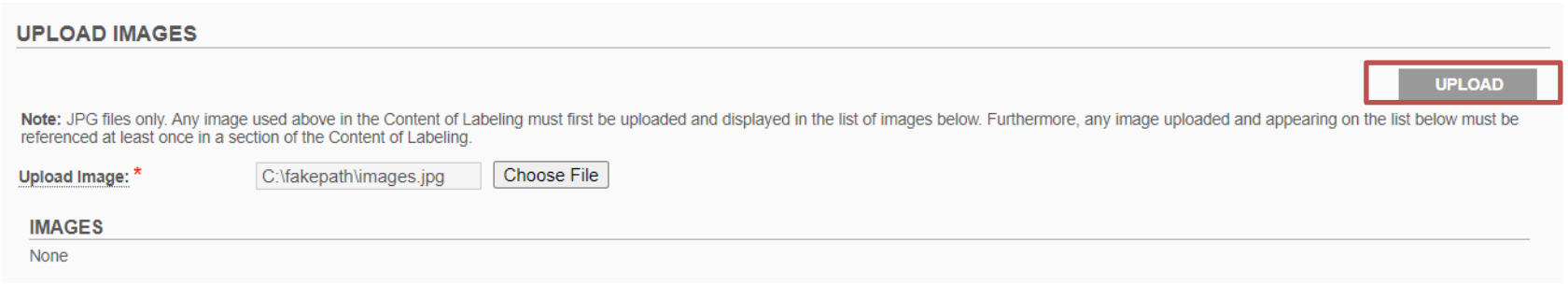
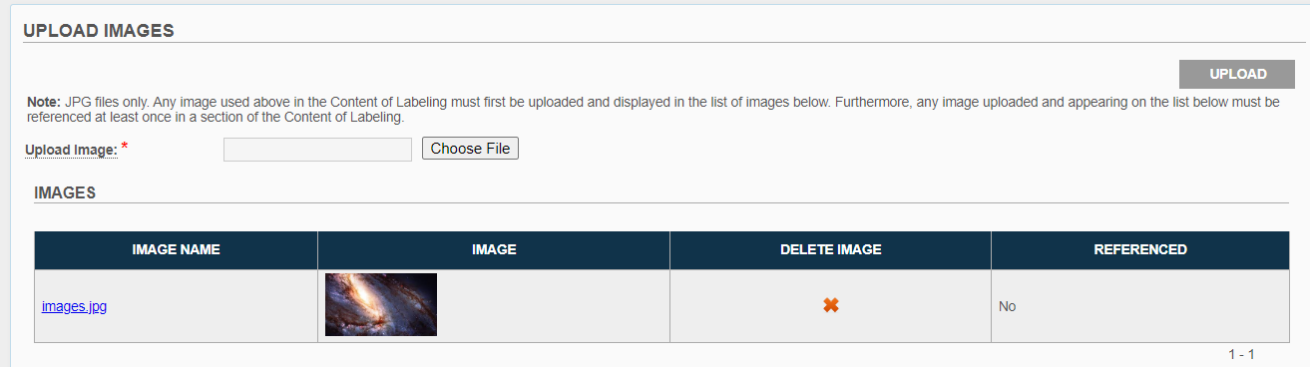
Step 26

The file path will populate to the left of “Choose File”. Click on Upload.



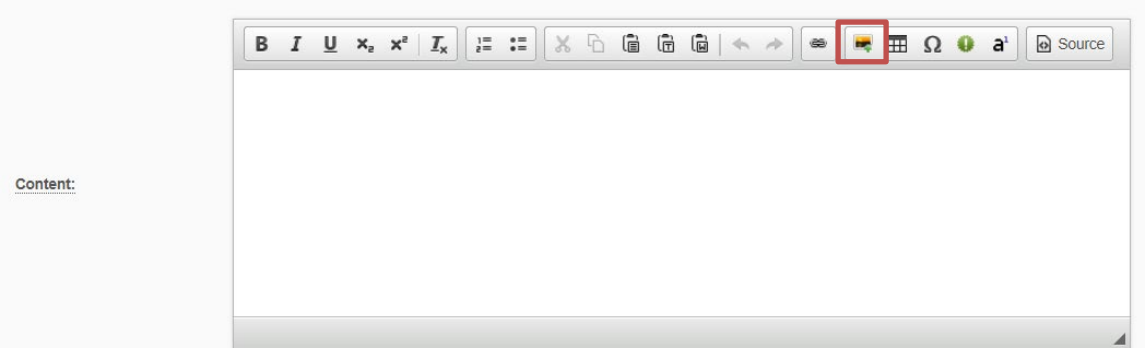
Step 27

If successful, the image will appear under “Images”.



Step 28

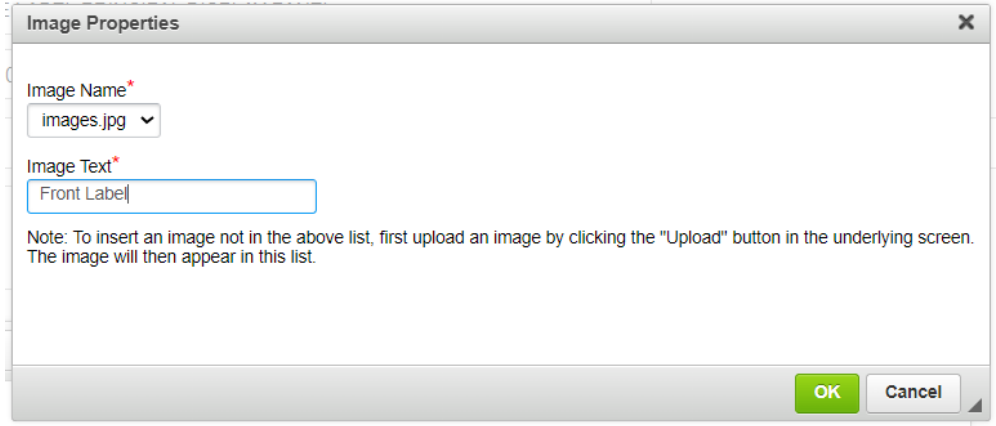
To add the image into the Content box, click on the “Insert an image” icon (sunset with green plus sign)



Listing a Human Drug Product

Step 29

Select the Image you want to add, enter Image Text and click OK

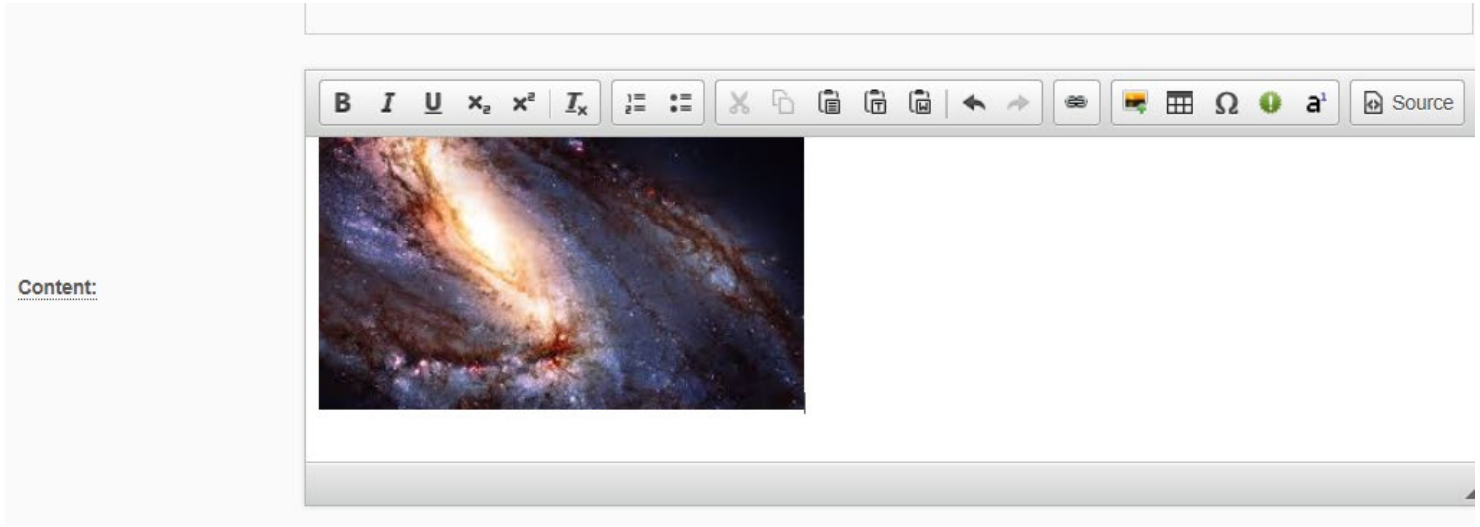


Step 30

The image should now appear in the Content box.

To add another Package Label image, repeat steps 25-29

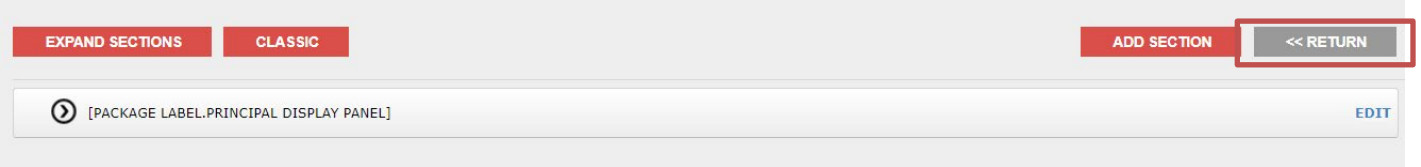
When the section is complete, click Save Section



Listing a Human Drug Product

Step 29

Once all sections have been added, click on Return



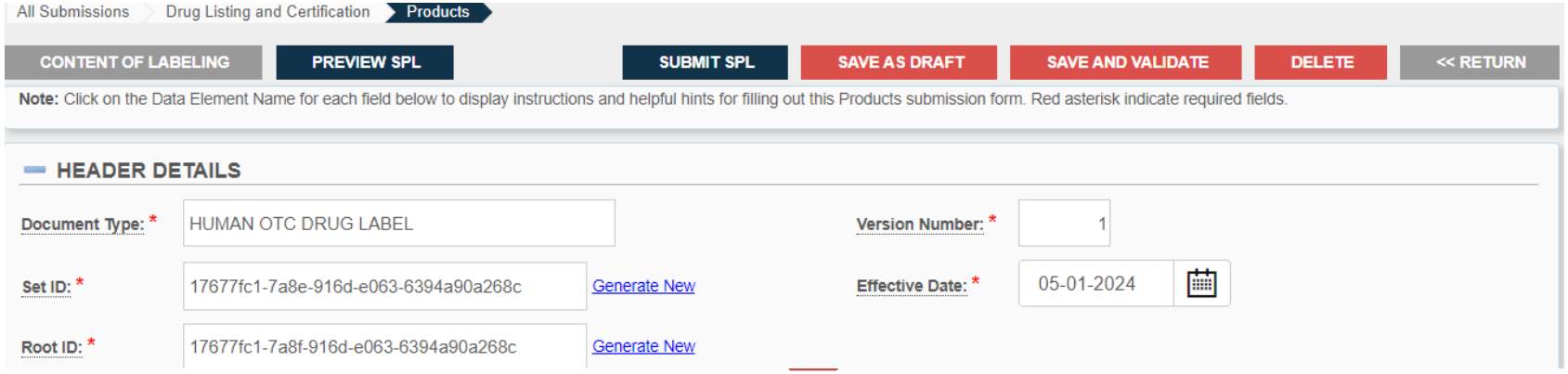
Step 30

To Preview SPL, click on "Preview SPL"

To Submit SPL to FDA, click on Submit SPL

To save work and return for completion at a different time, click Save as Draft

To check for validation errors prior to submitting to FDA, click on Save and Validate



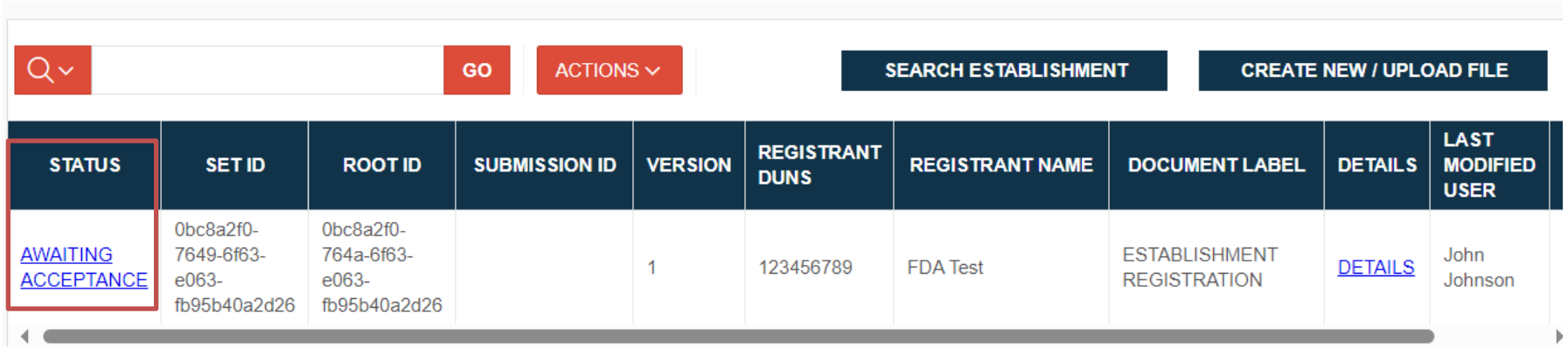
Listing a Human Drug Product

What happens after I click "Submit SPL"?

After clicking on Submit SPL, the submission undergoes an automated, technical validation indicated by the status of "Awaiting Acceptance". This process takes approximately 15 minutes.

If the submission passes technical validation, the status will change to "Submission Accepted".

If the submission fails technical validation, the status will change to "Submission Failed". Click on **Submission Failed** to view and correct the errors identified. Then click on **Submit SPL** to resubmit.



Uploading a Drug Product Listing SPL File

Uploading a Drug Product Listing SPL File

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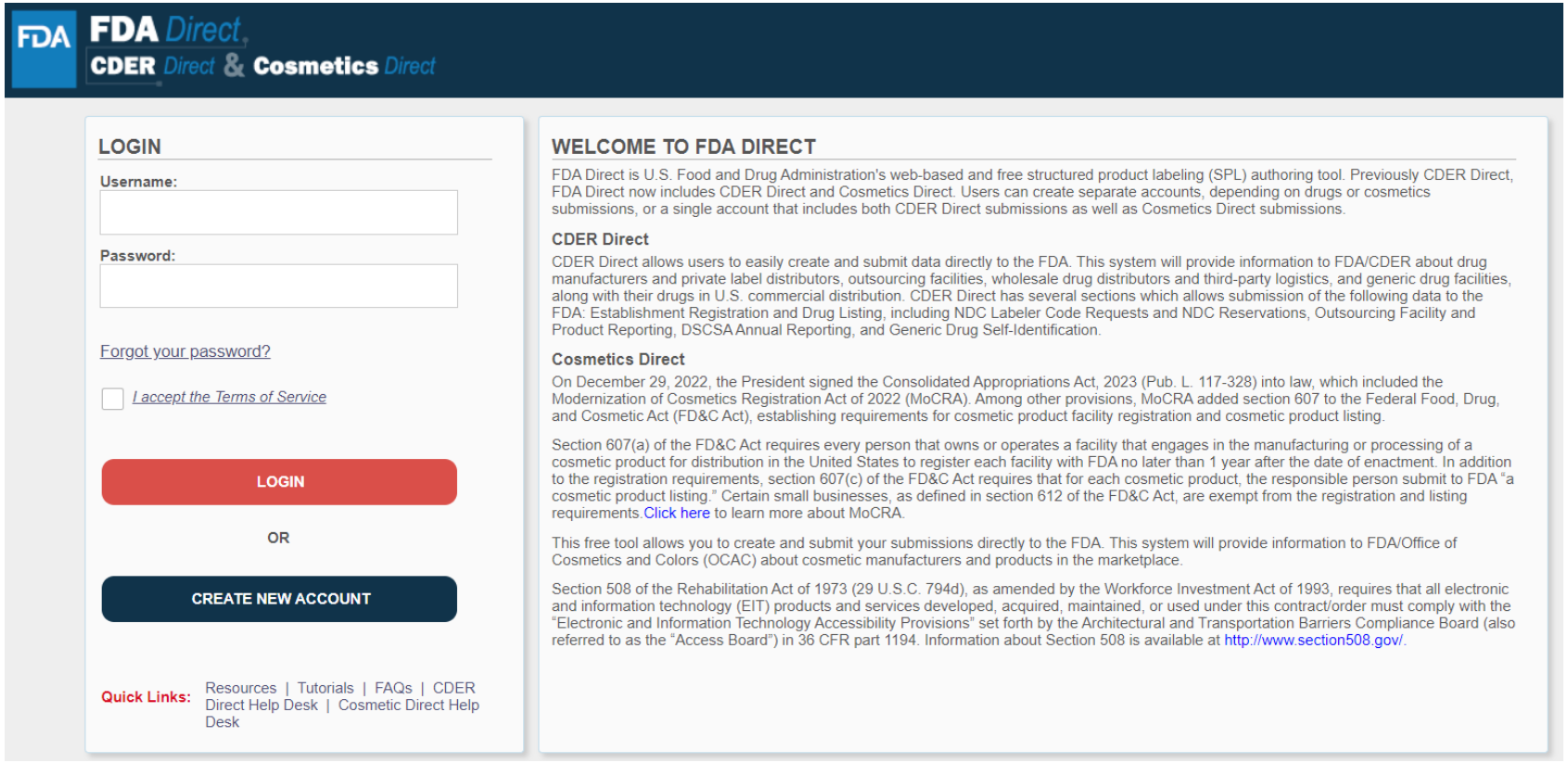
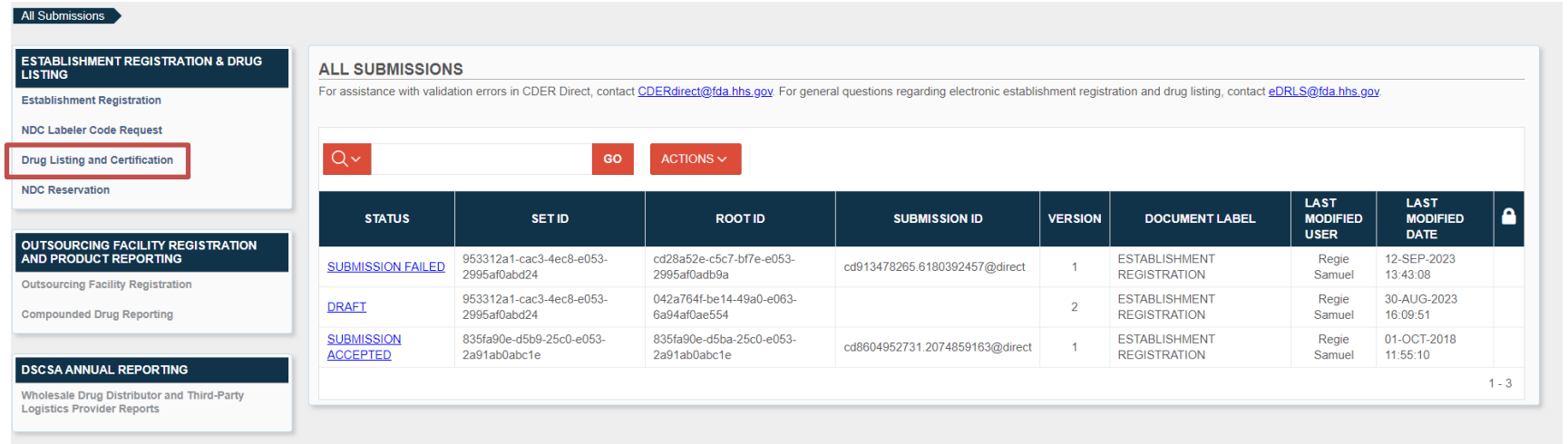


Uploading a Drug Product Listing SPL File

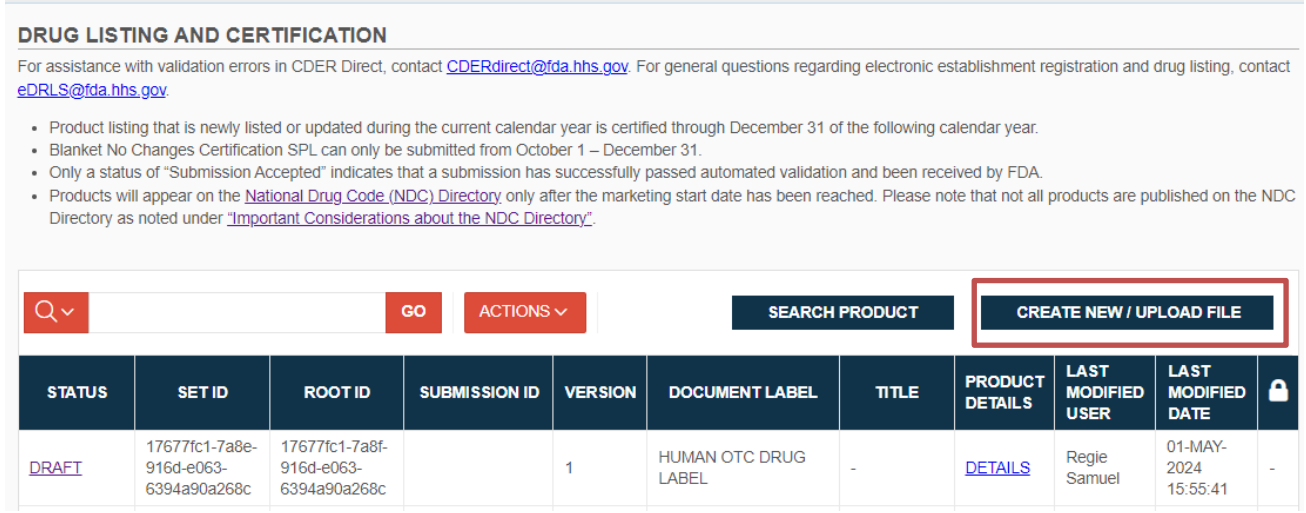
Step 3

After logging in, click on **Drug Listing and Certification** from the navigation pane on the left



Step 4

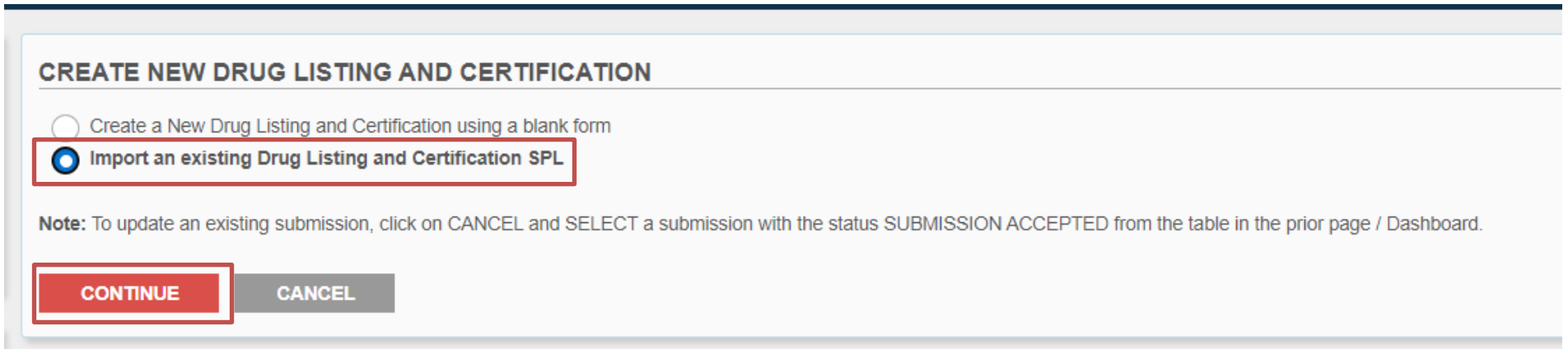
Click on **Create New/Upload File**



Uploading a Drug Product Listing SPL File

Step 5

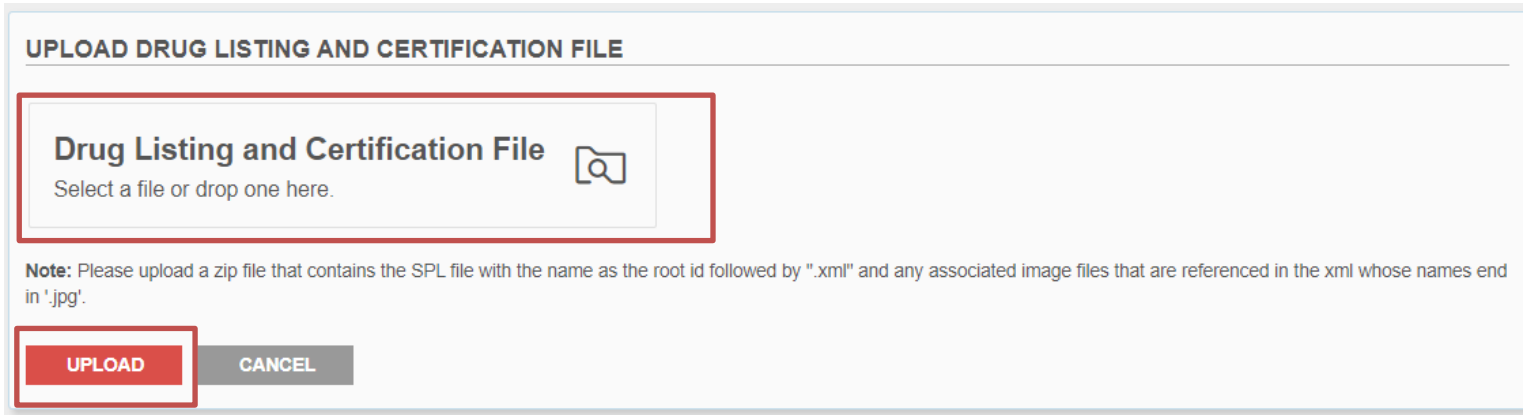
Click on **Import an existing Drug Listing and Certification SPL** and then Continue



Step 6

Click on **Drug Listing and Certification File**

Locate and select the Establishment Registration ZIP file to upload into CDER Direct and click **Upload**



For assistance with errors received in CDER Direct, contact **CDERdirect@fda.hhs.gov.**