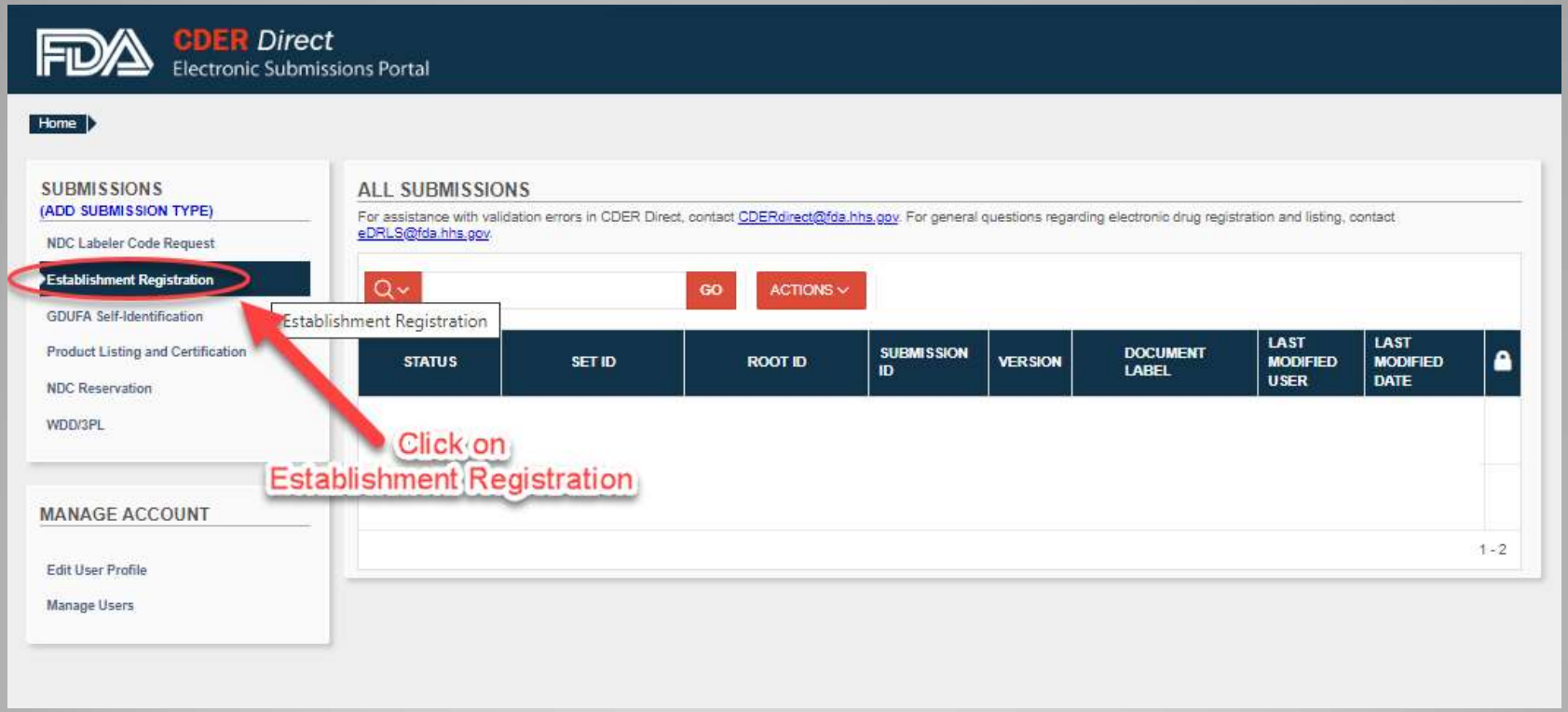
CDER Direct
Electronic Submissions Portal

Office of Compounding Quality & Compliance
CDER Office of Compliance
U.S. Food and Drug Administration

# CDER Direct – Human Compounded Drug Label

Fall 2023

# Human Compounded Drug Label

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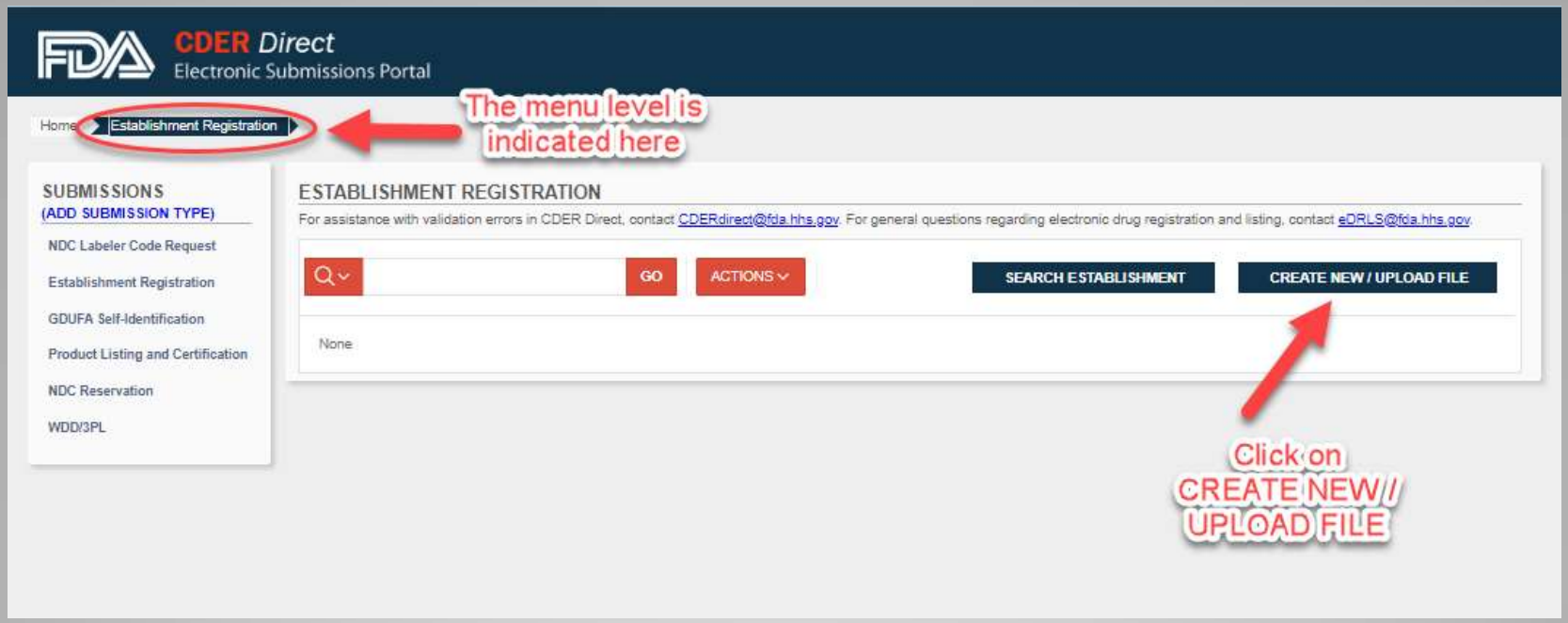


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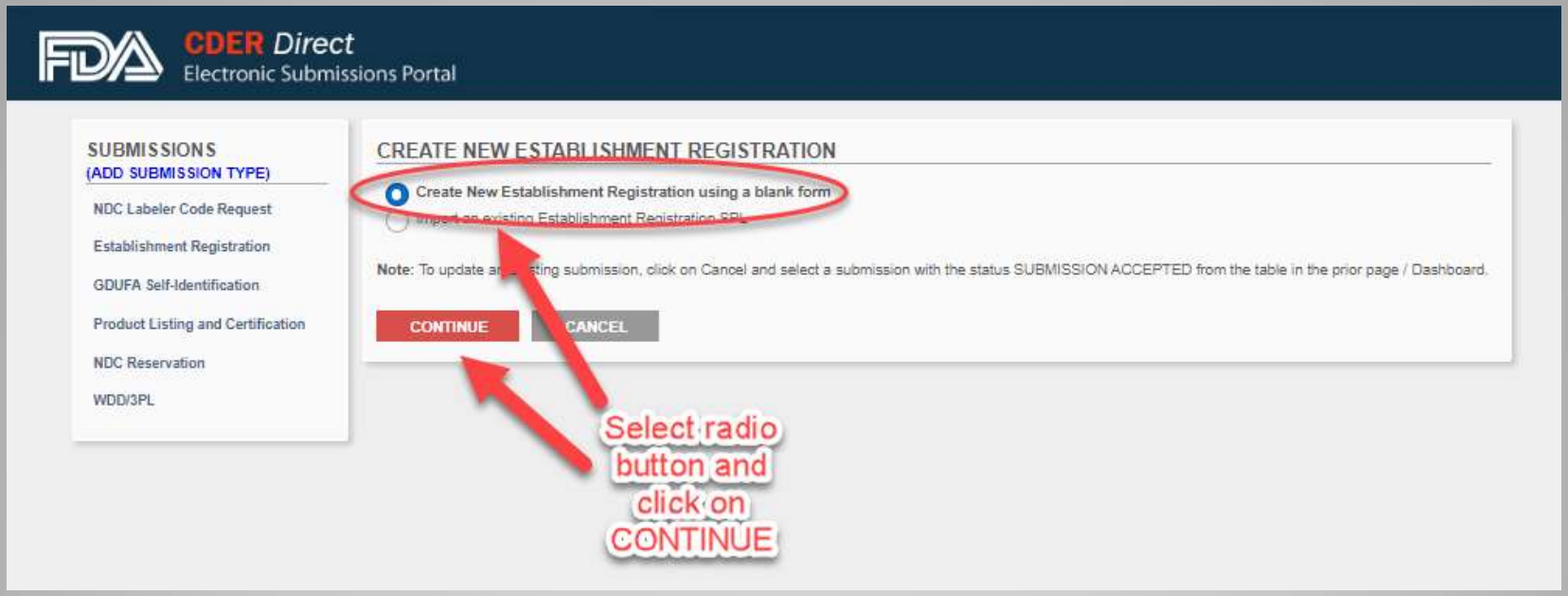


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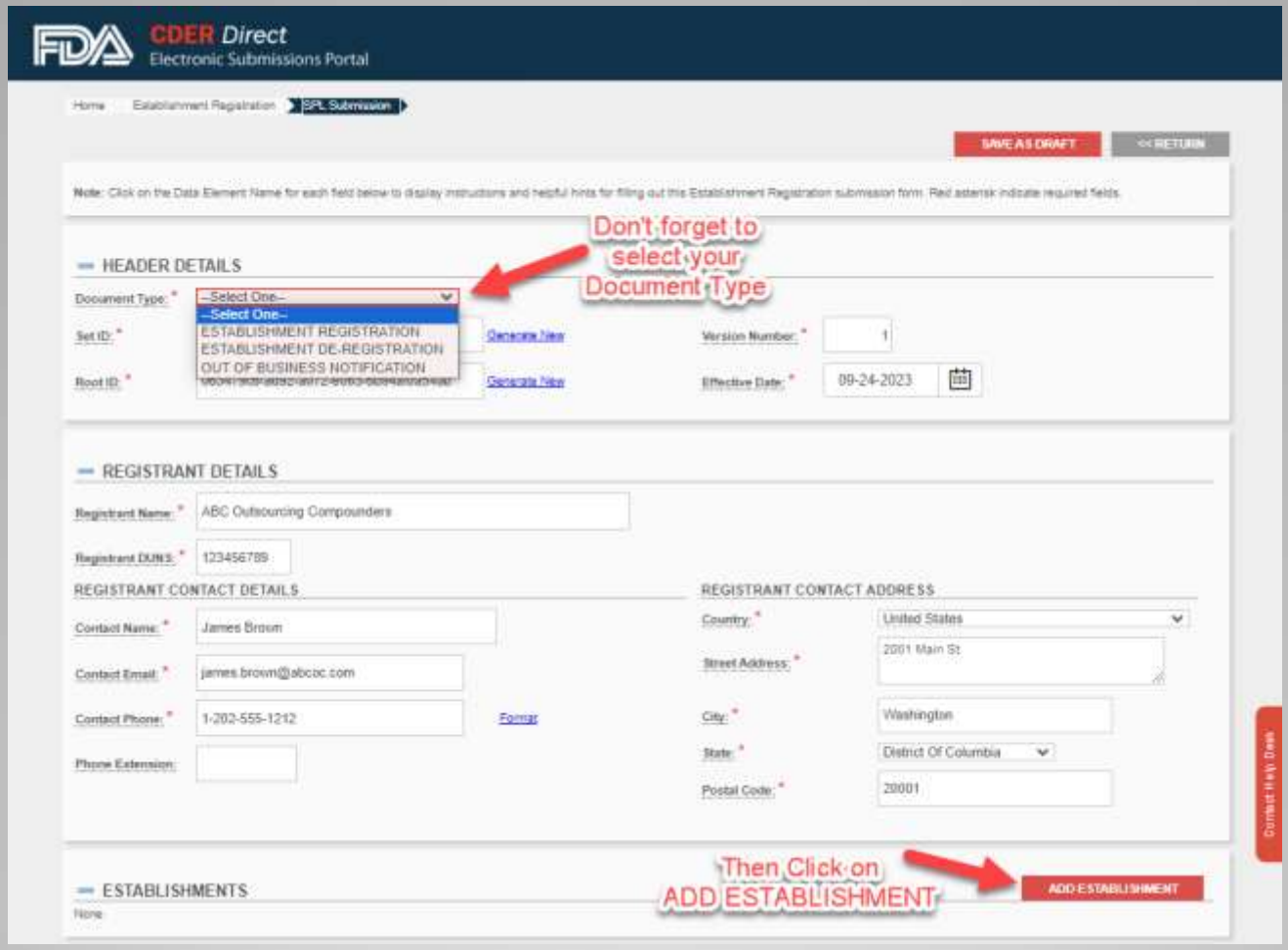


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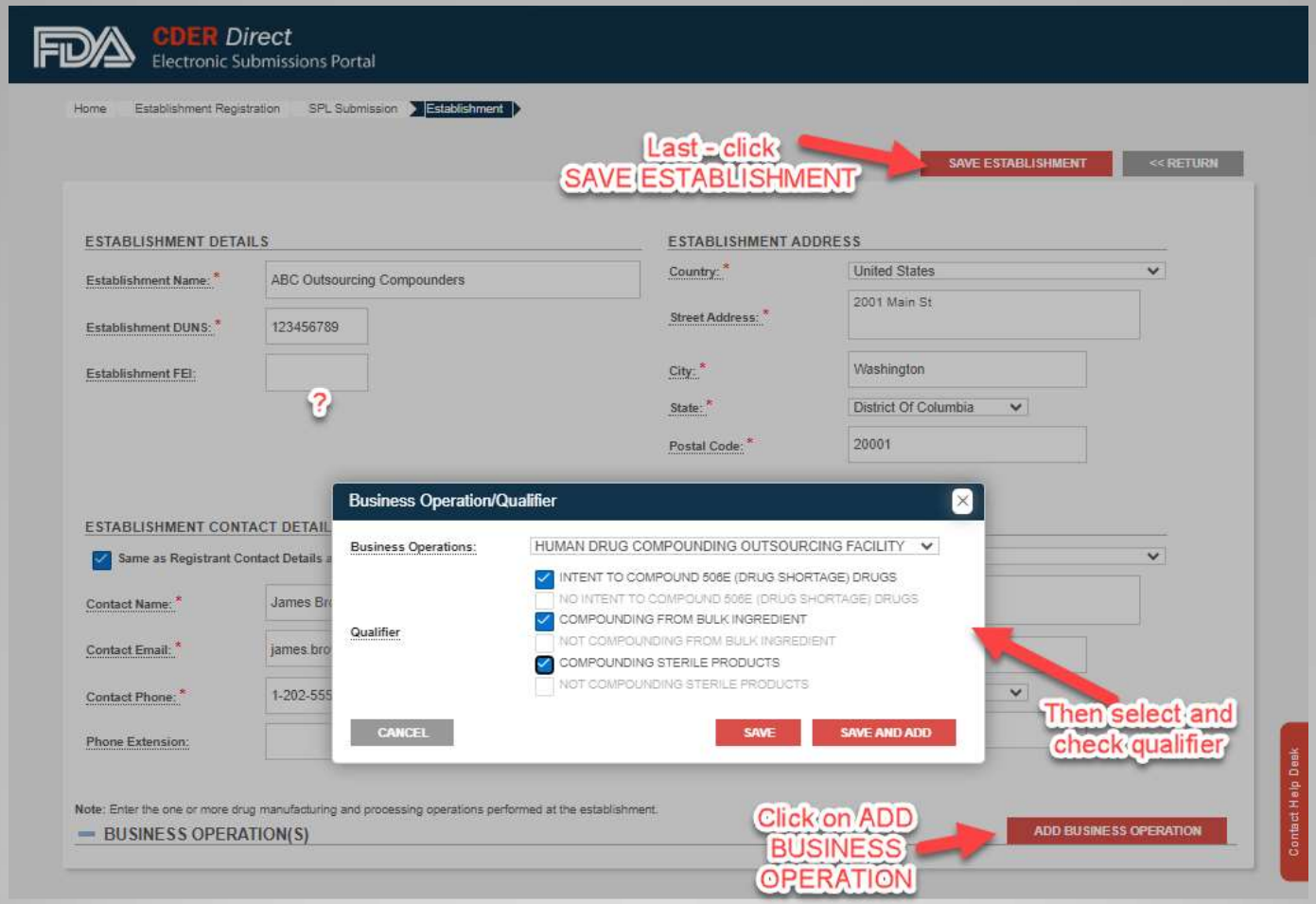


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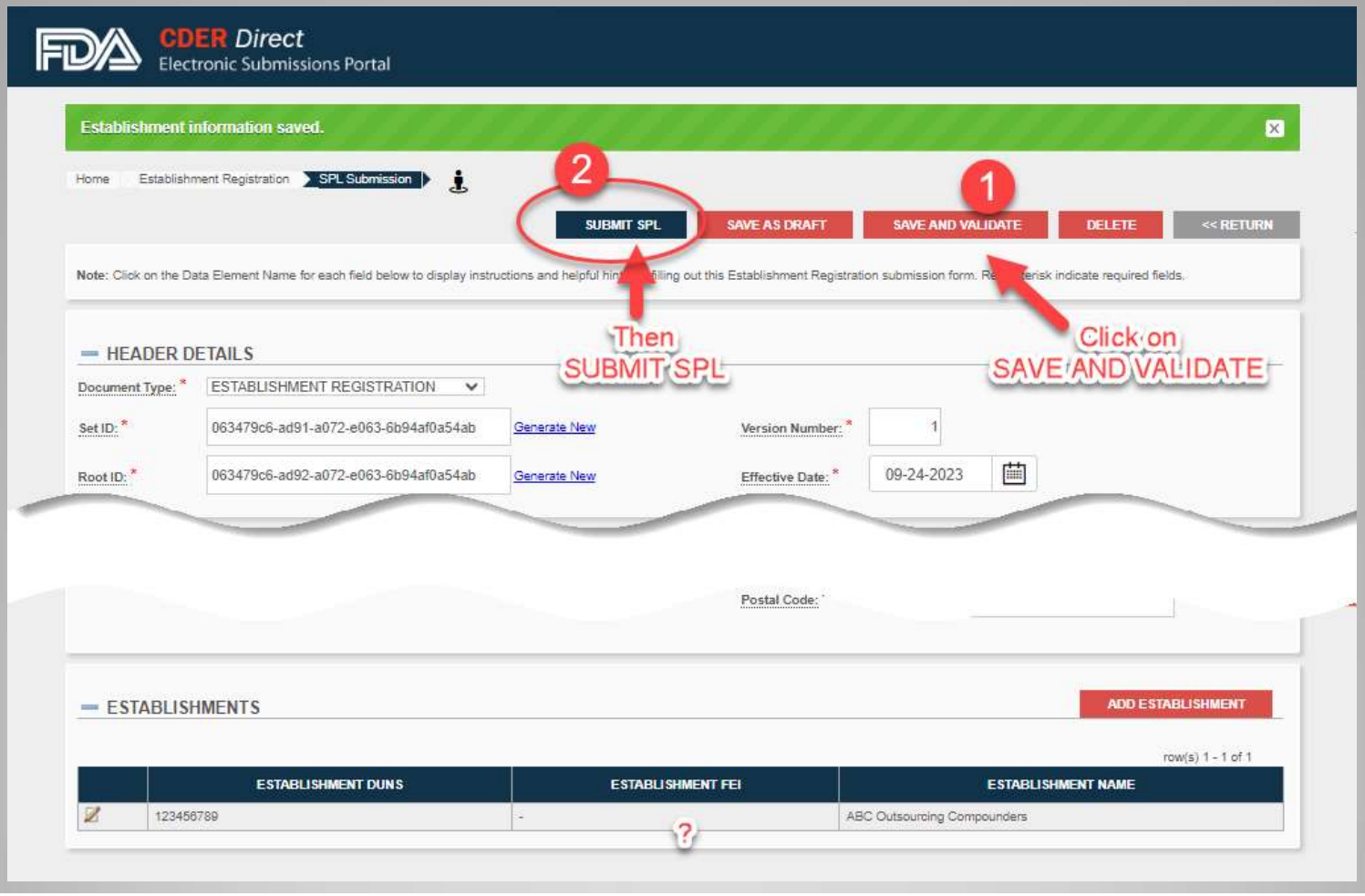


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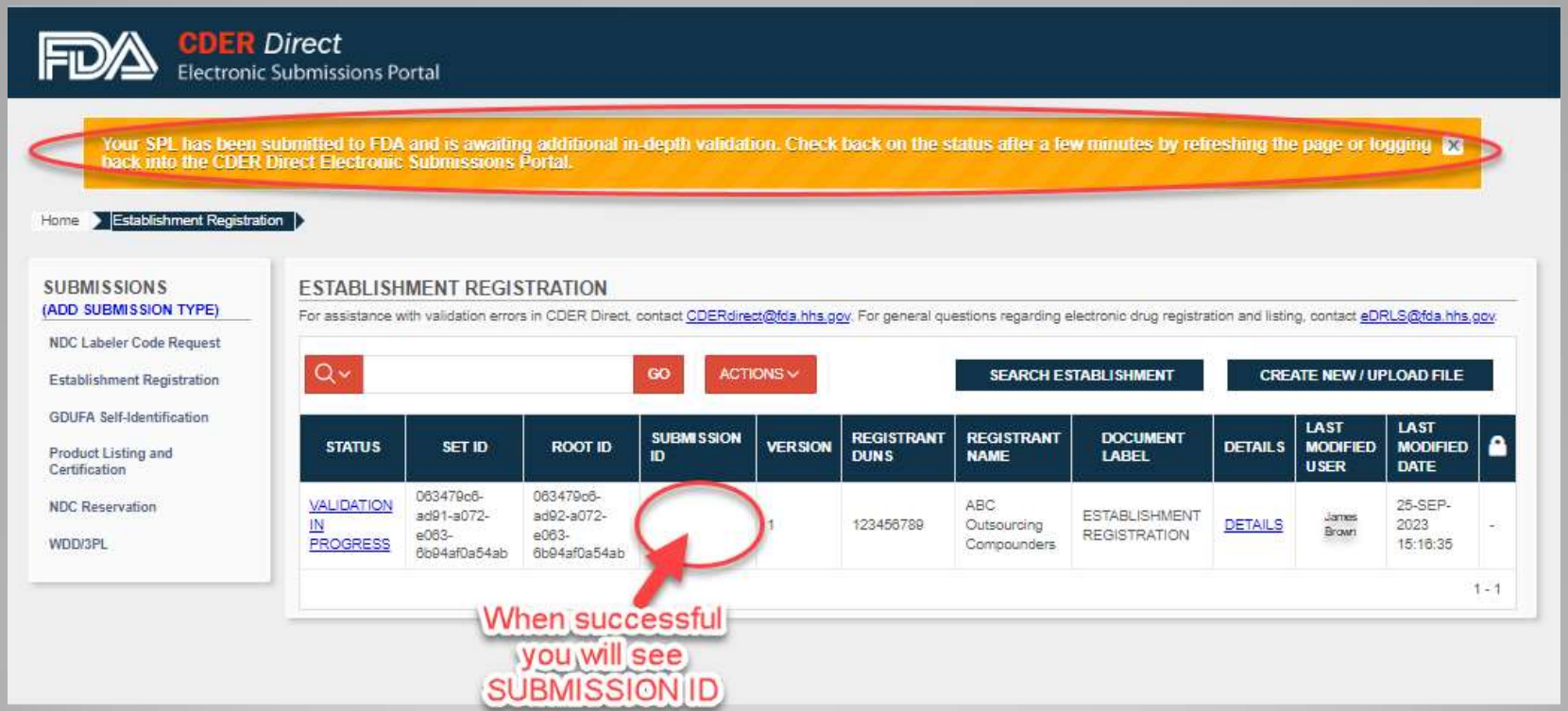


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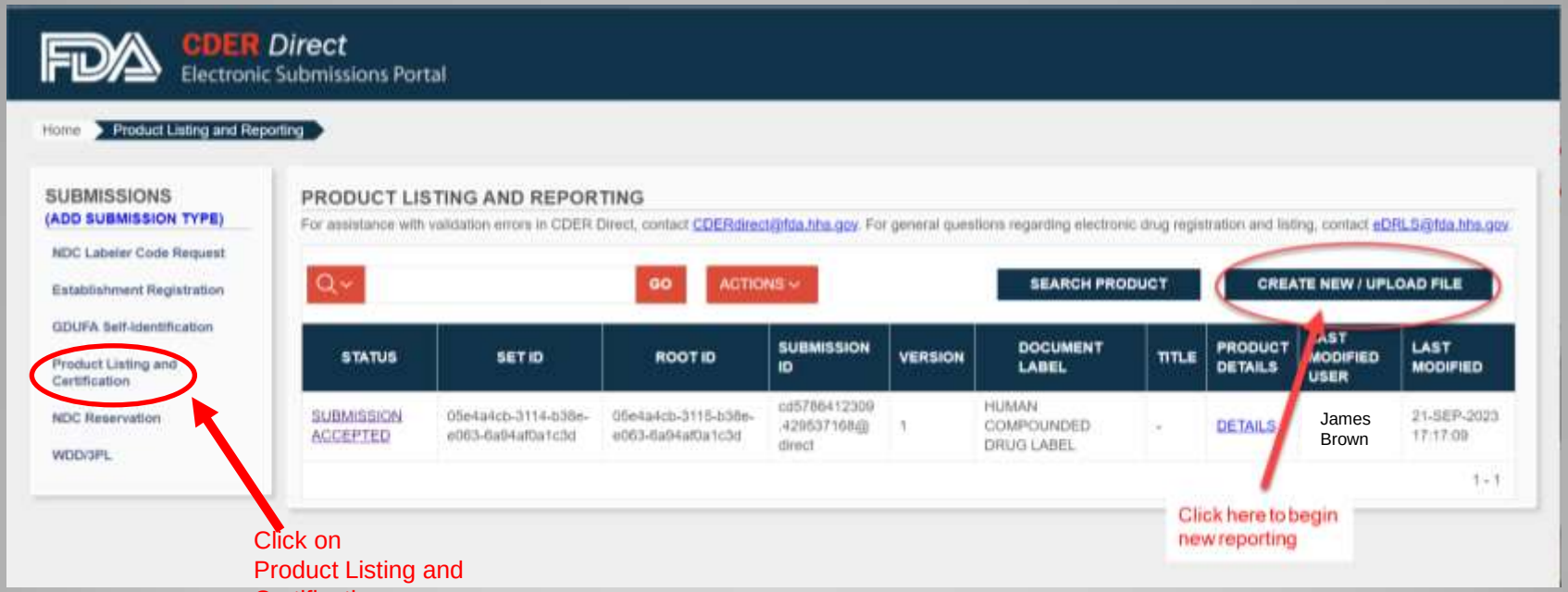


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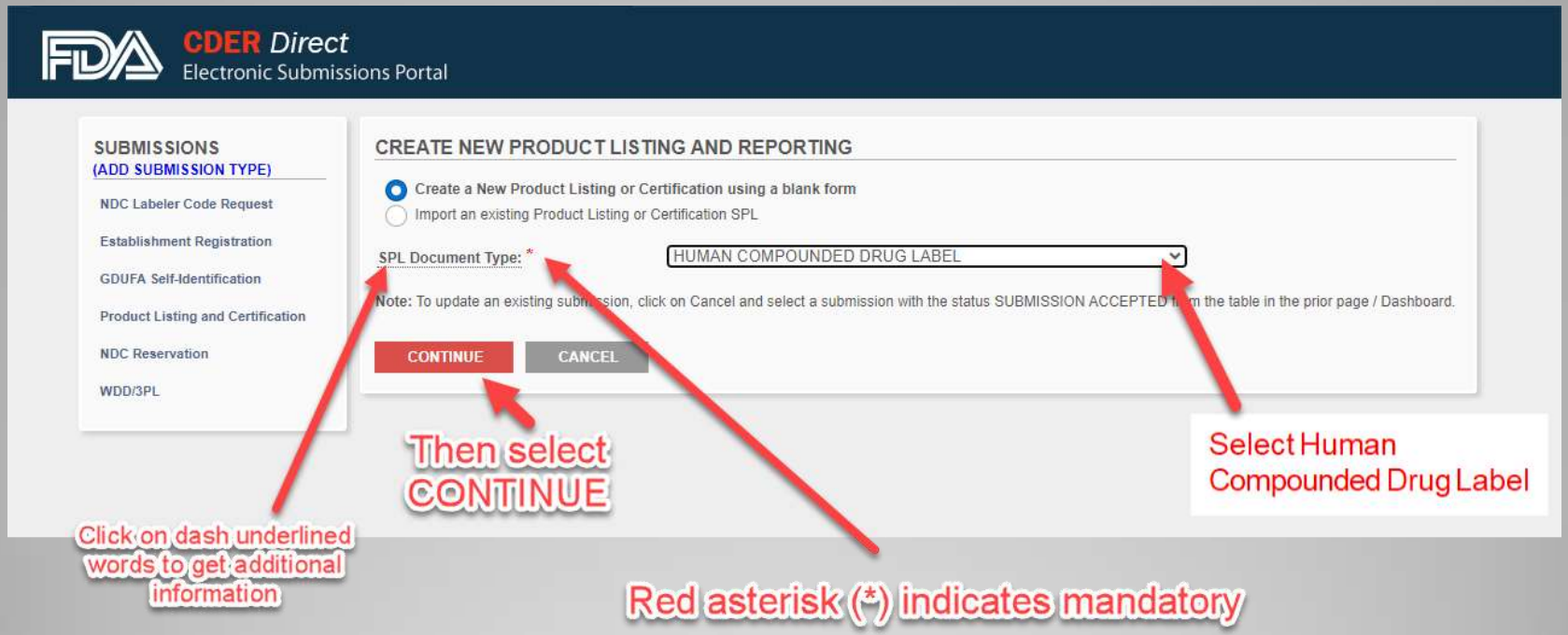


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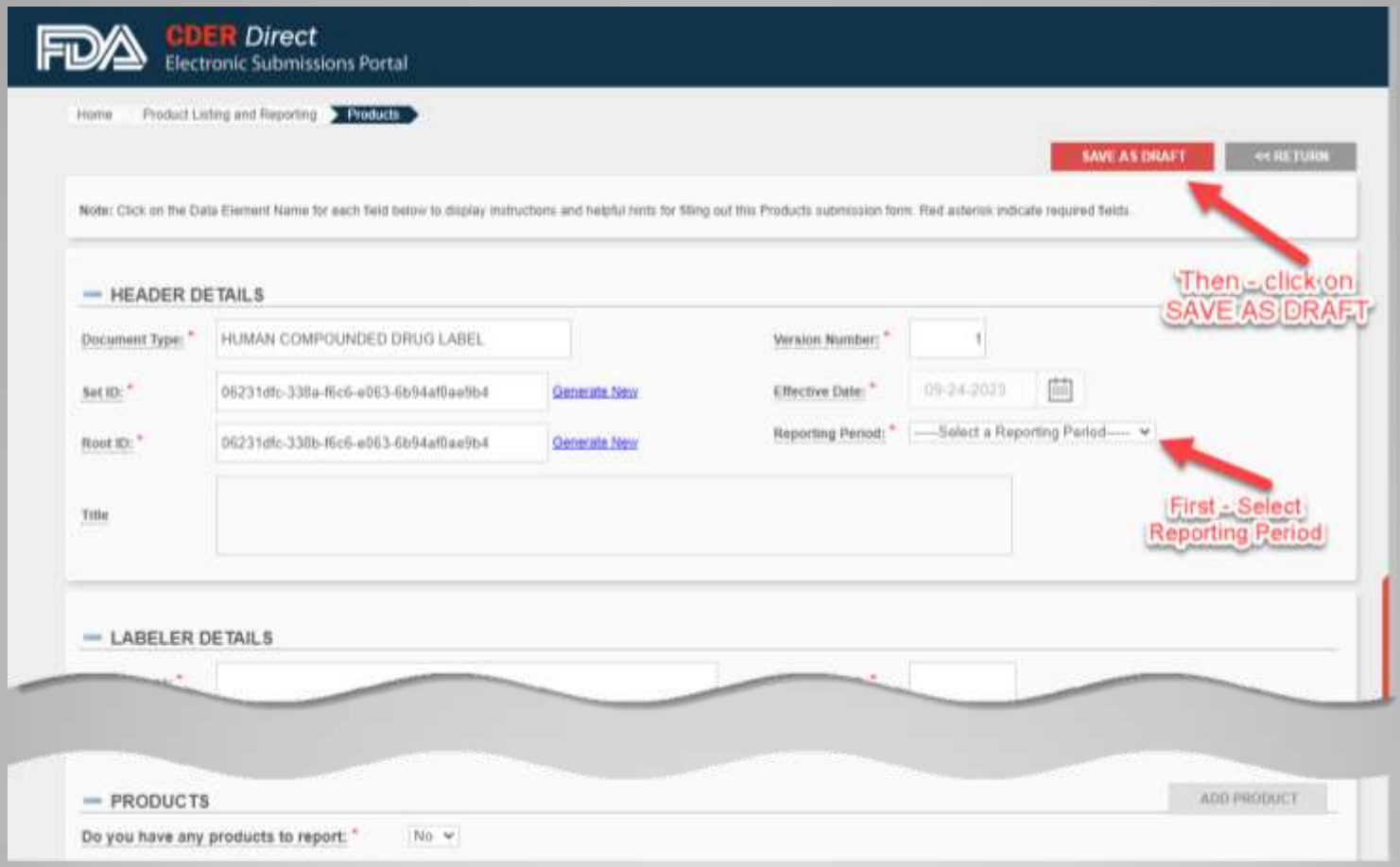


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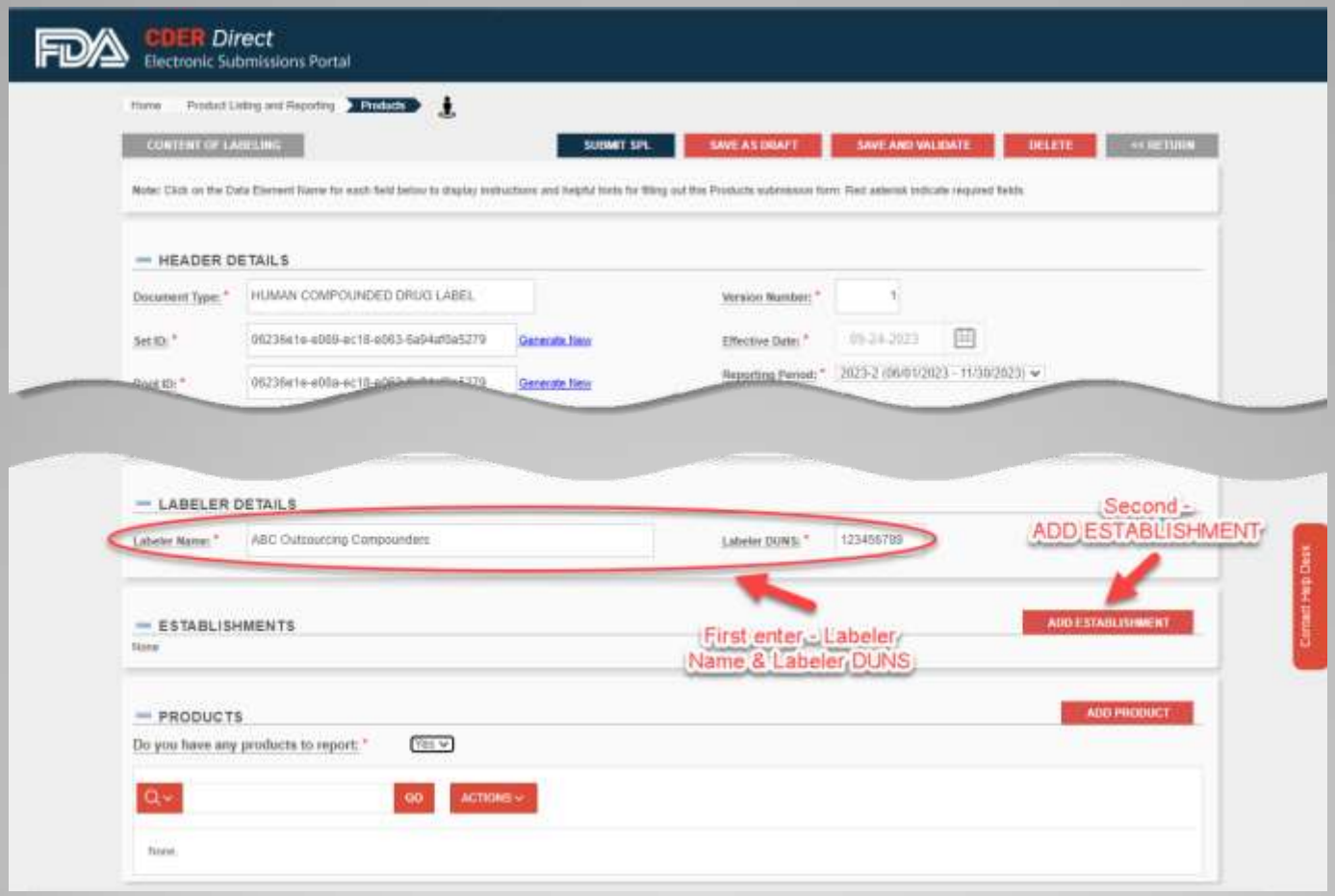


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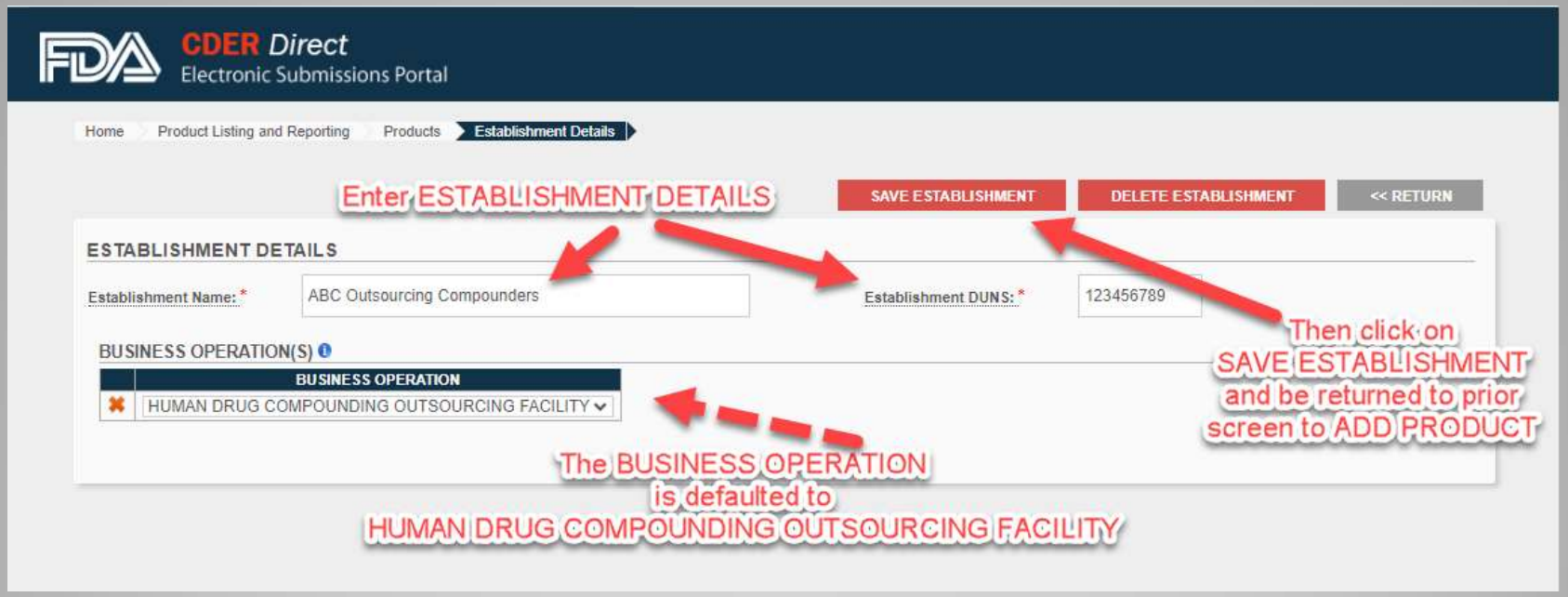


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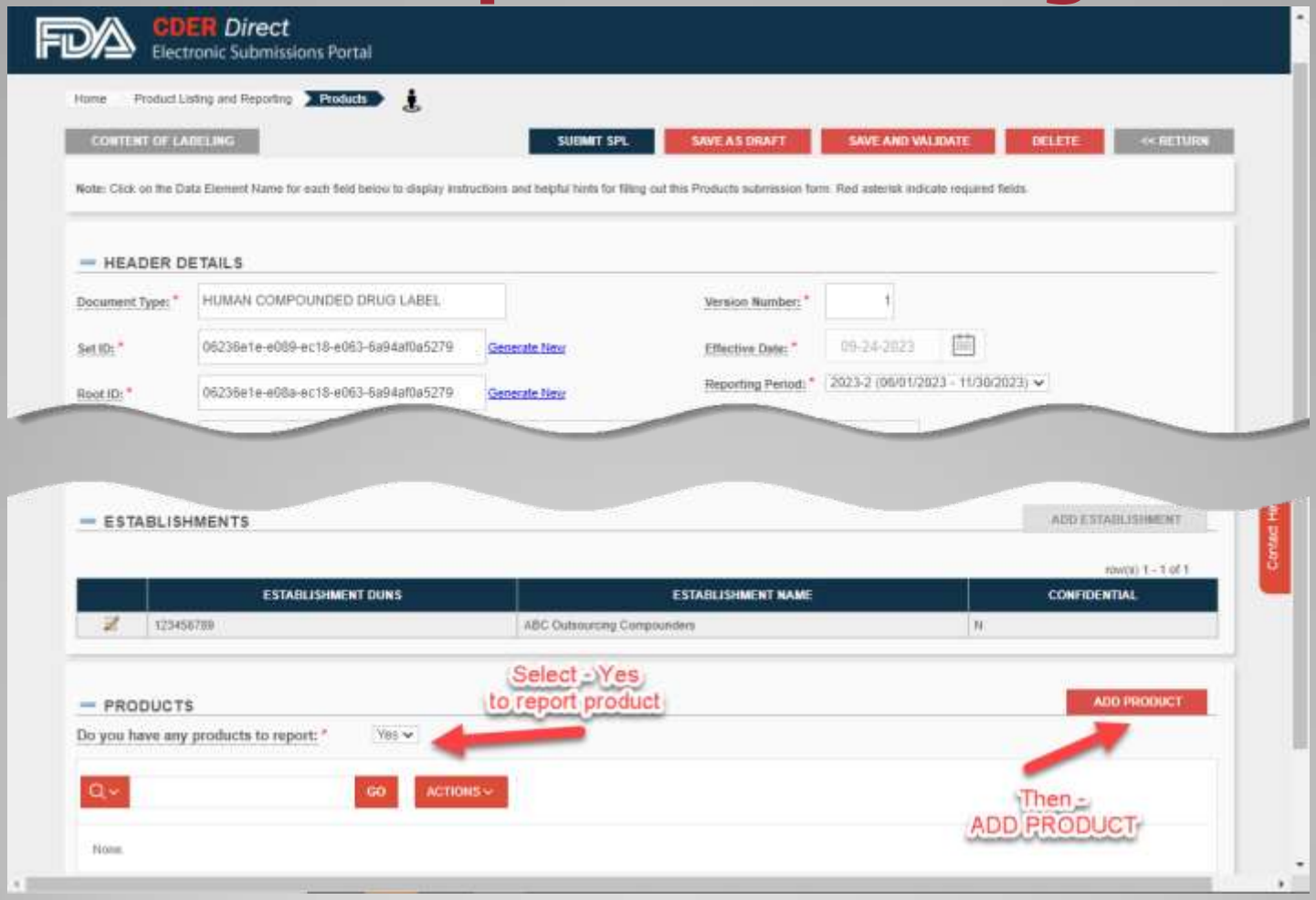


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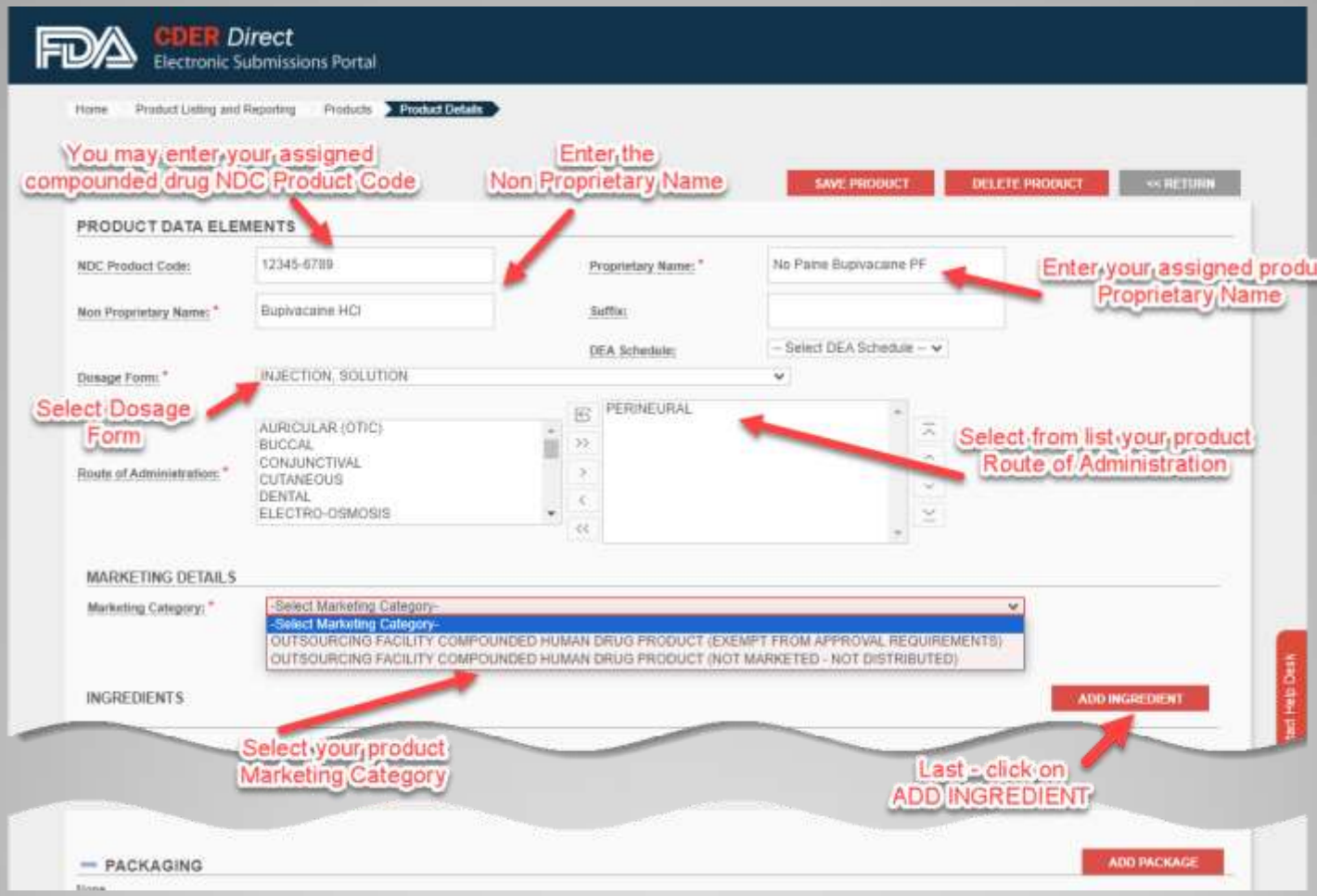


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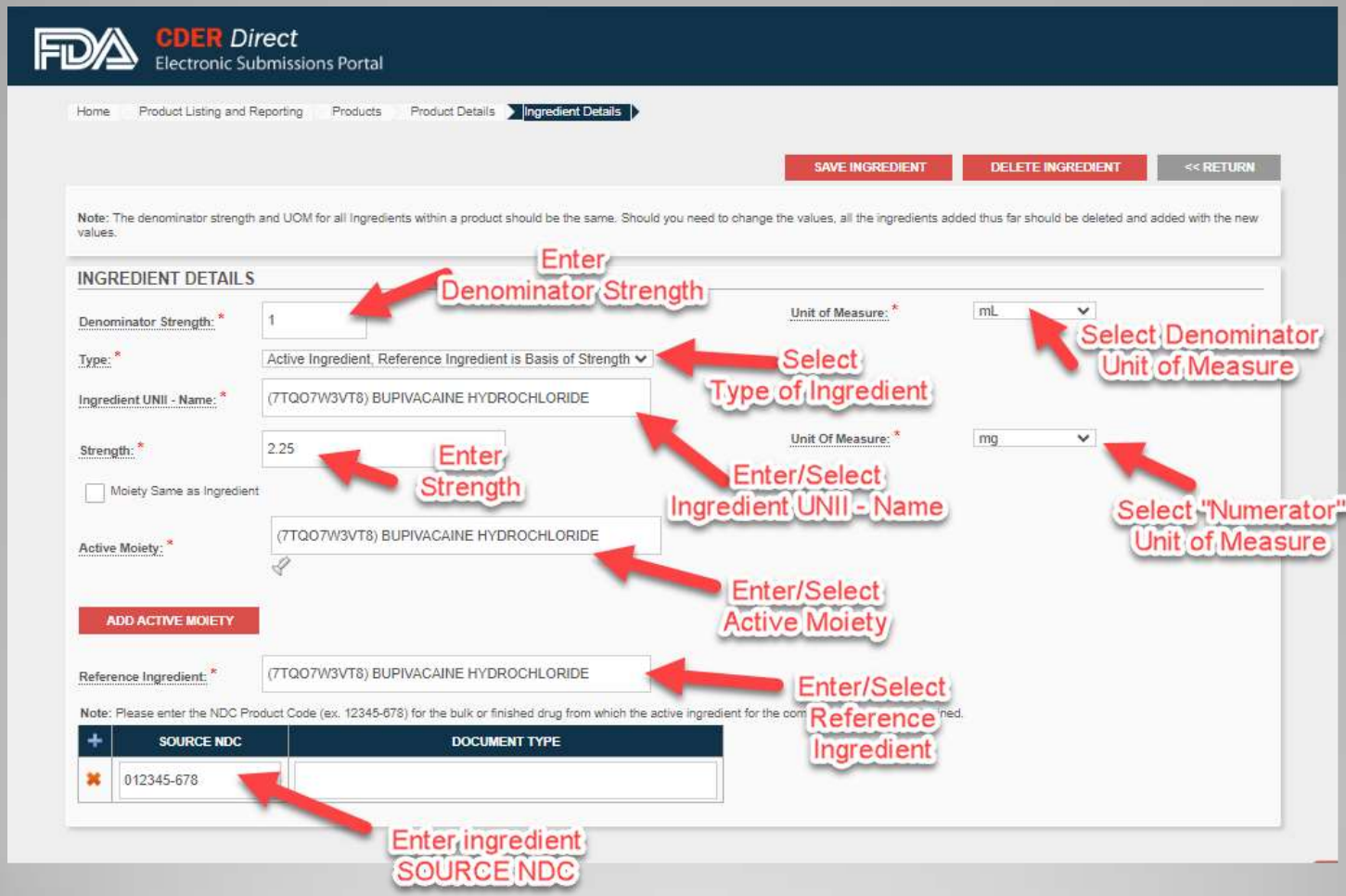


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# Helpful Hints

## Ingredient Types

Active Ingredient, Active Moiety, or Reference Drug

- *use this ingredient selection to enable listing of ingredient NDC*

Inactive Ingredient

- *to list the inactive ingredient(s)*

Ingredient – Dietary Supplement

- *to identify the active ingredient used is a "dietary supplement ingredient"*

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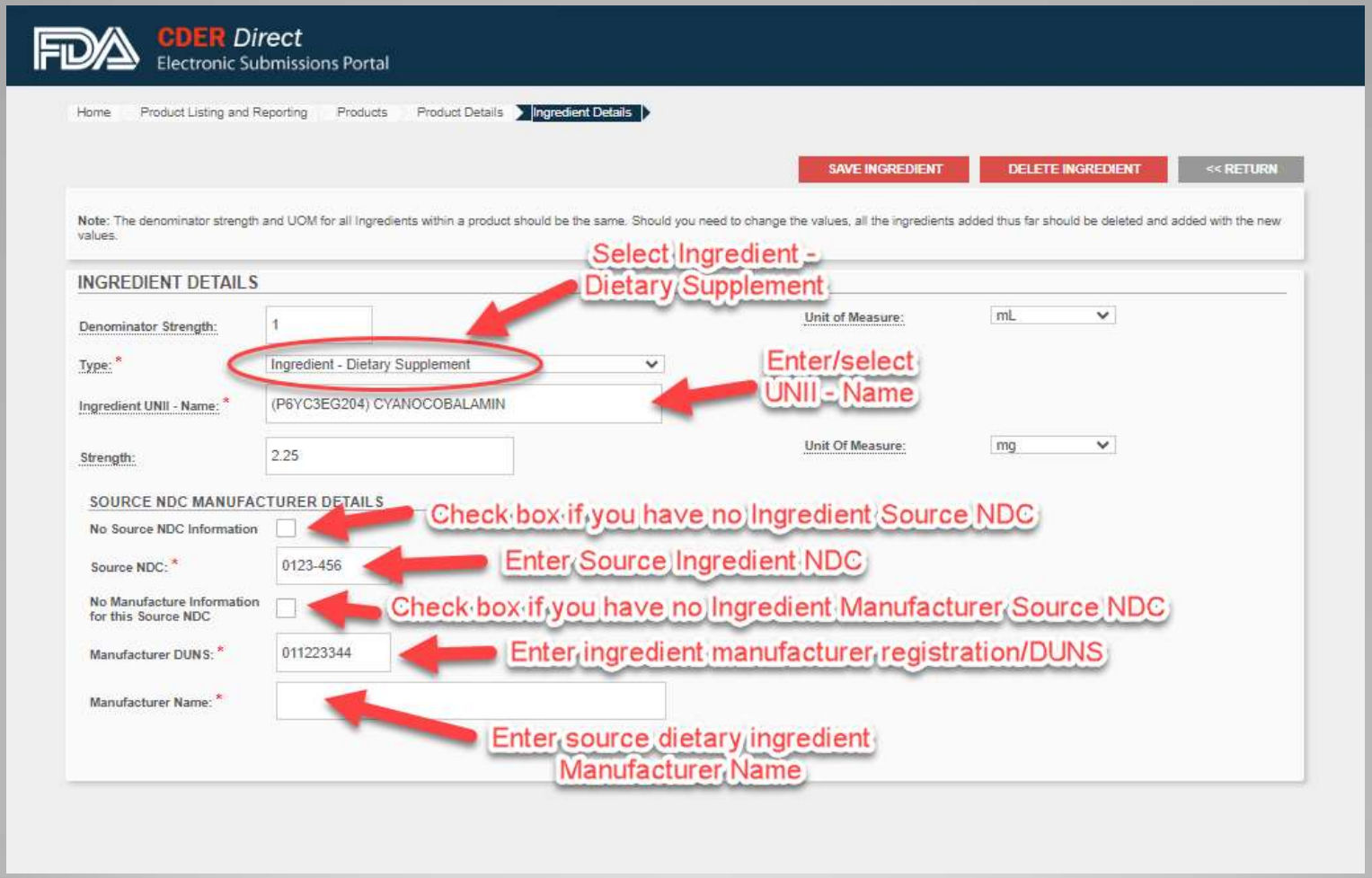


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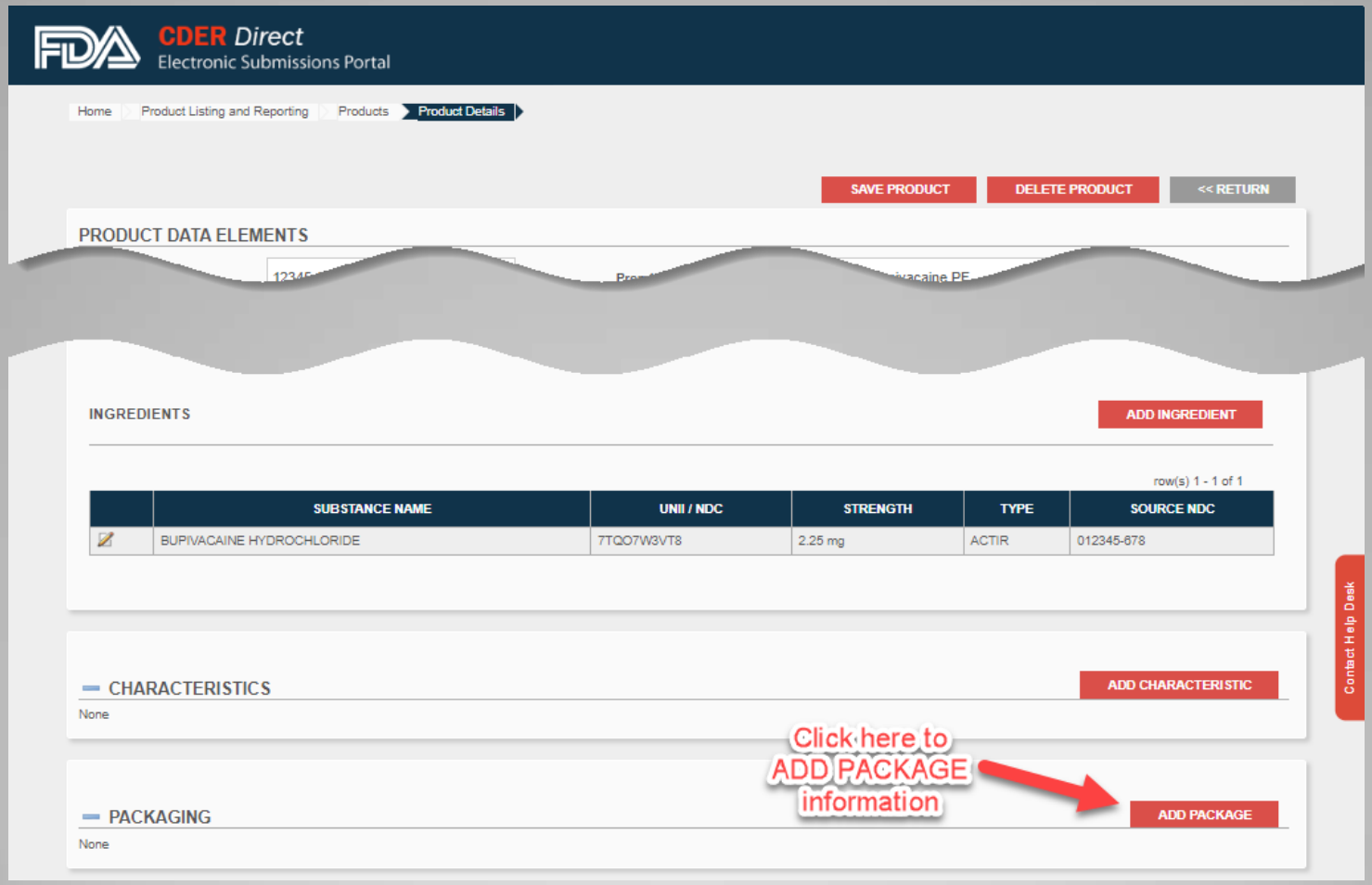


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# Helpful Hints

## Product NDC Codes

A single SPL file can contain multiple products with the same ingredients but different strengths

- *Each strength is a different product and thus requires a different product NDC*
- *After creating a product, save it, and return to the main screen to add another product with the same ingredients but different strength formulation*



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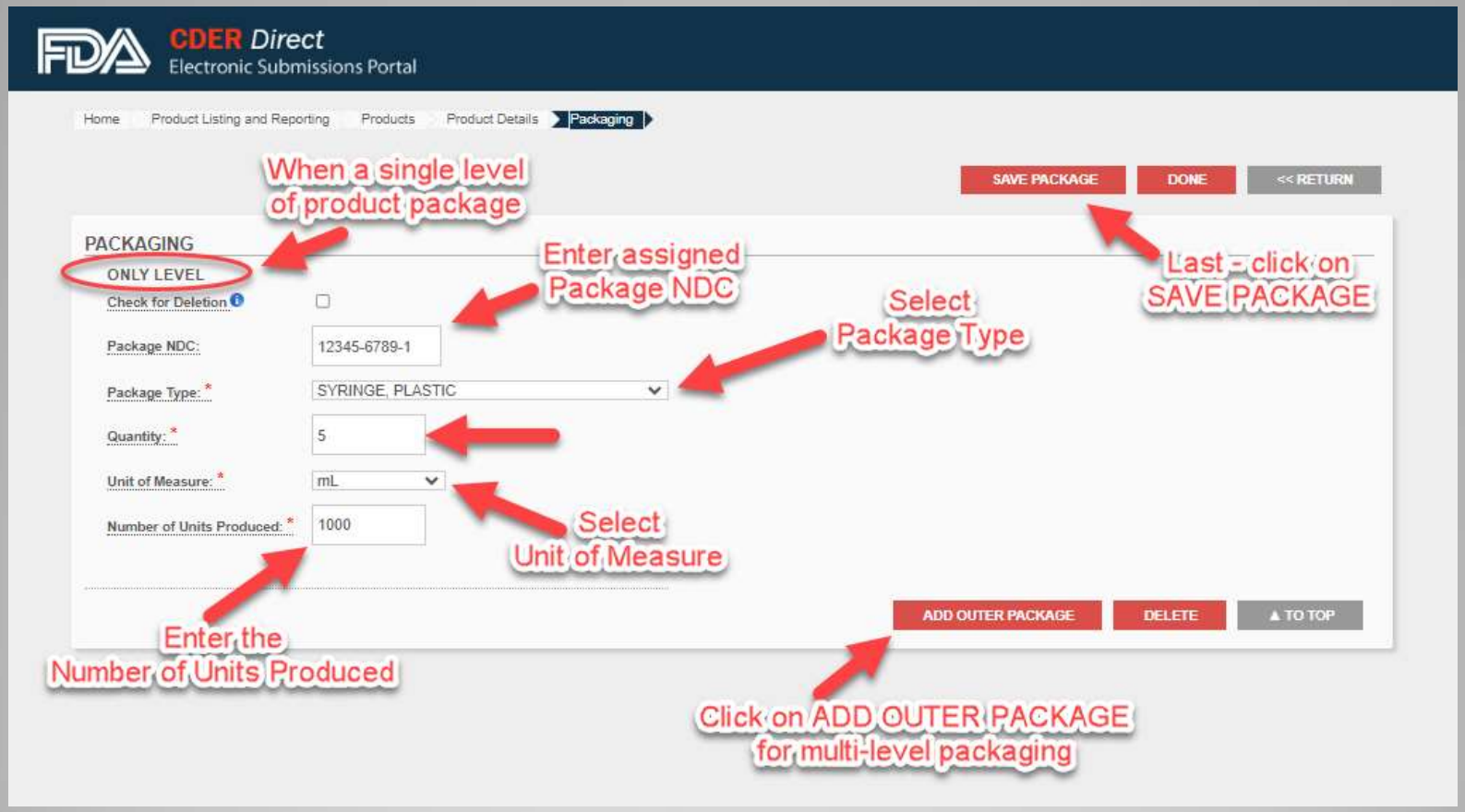


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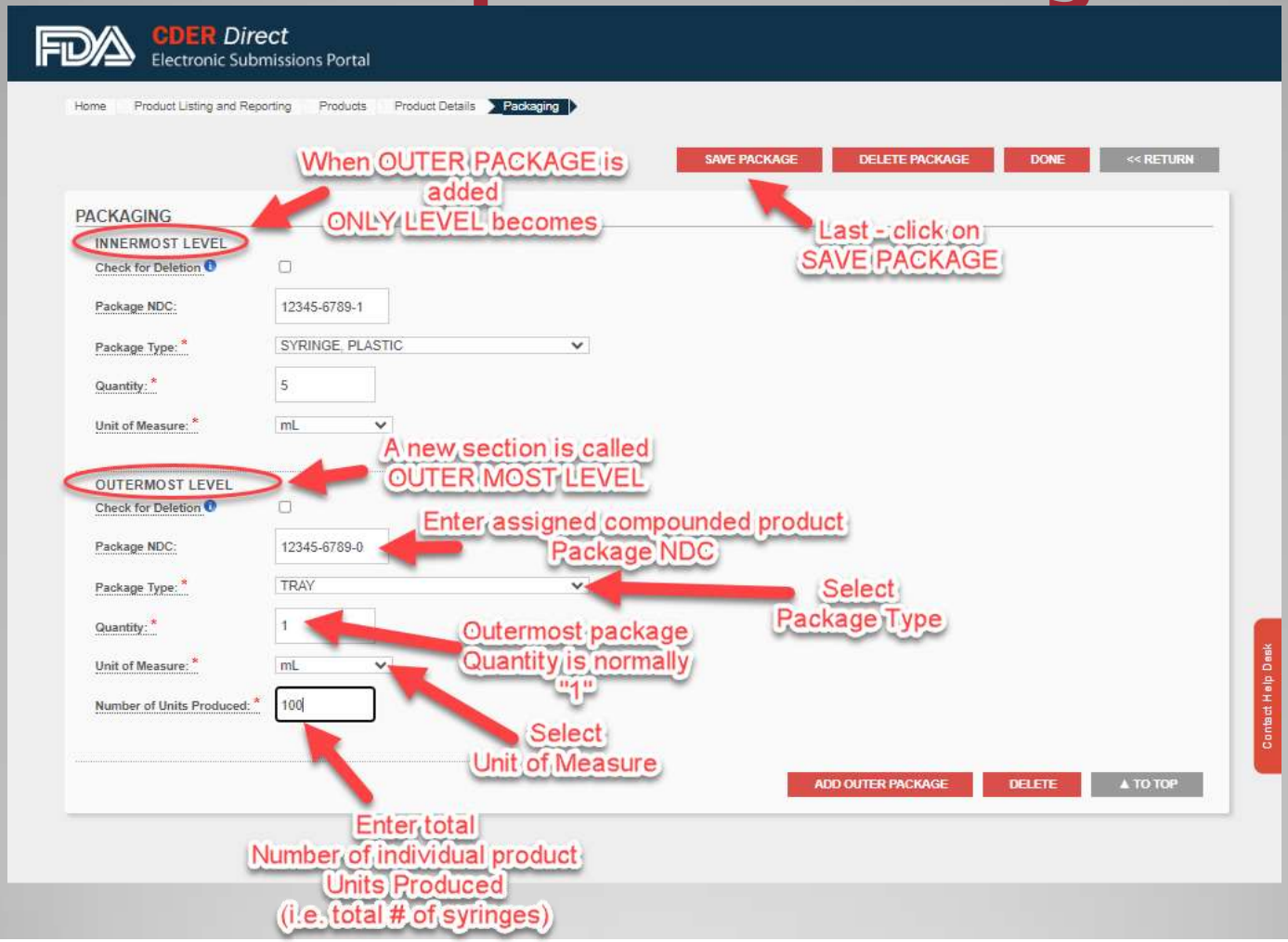


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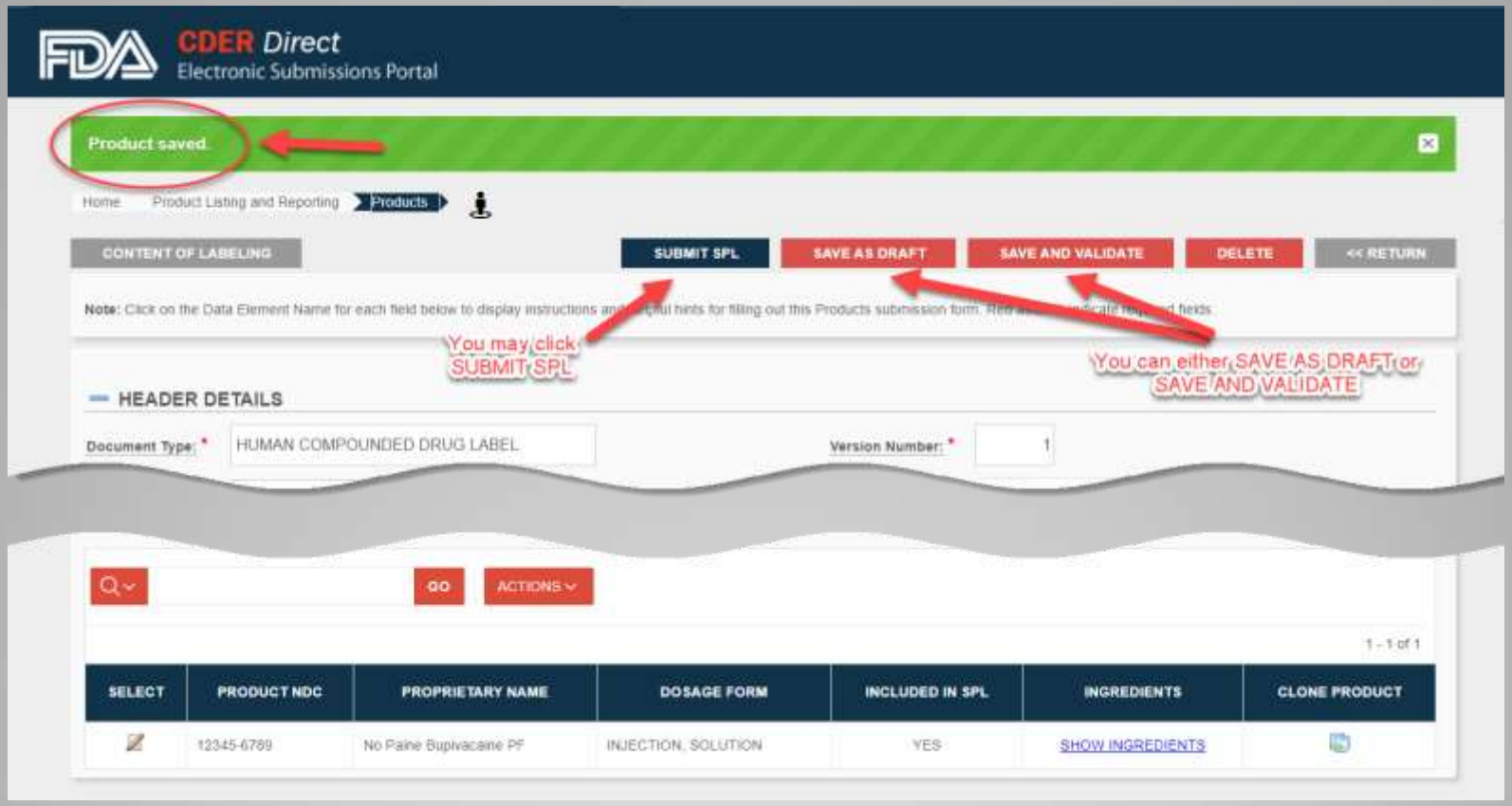


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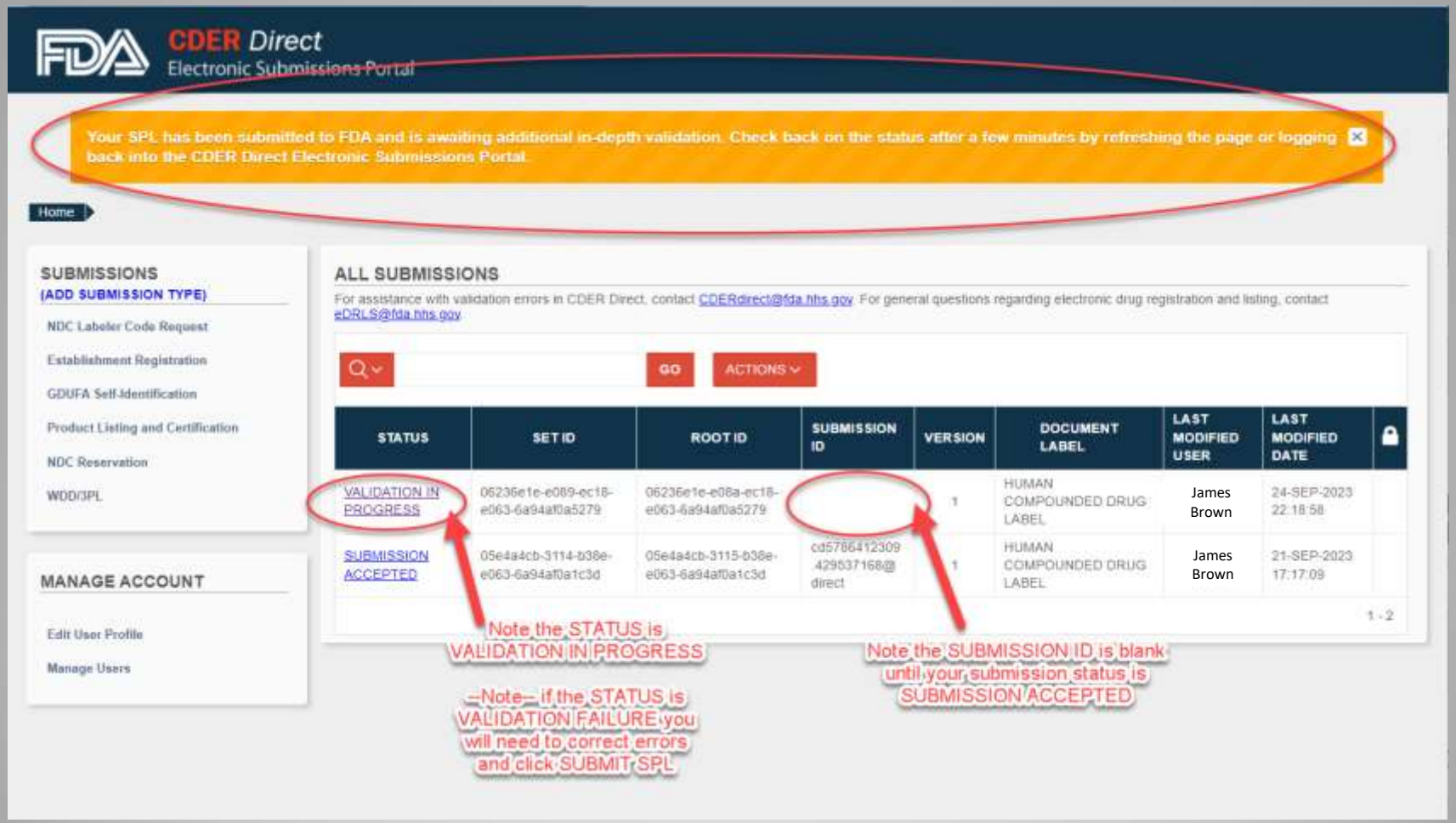


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# Helpful Hints

- To find Ingredient names, Active Moiety names, and their associated UNIIs please go to the following website: https://precision.fda.gov/uniisearch

To find the corresponding Active Moiety to listed Active Ingredient please download reference Active Ingredient-Active_Moiety Relationship/Basis of Strength

- does not apply to bulk ingredients

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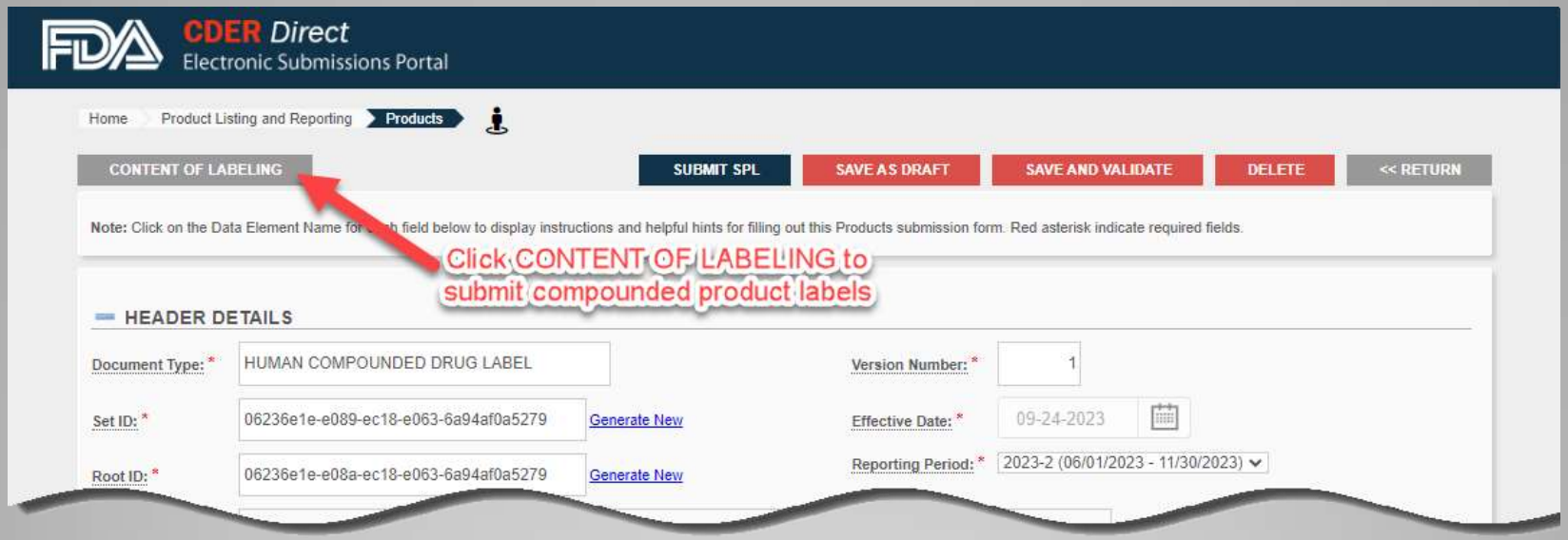


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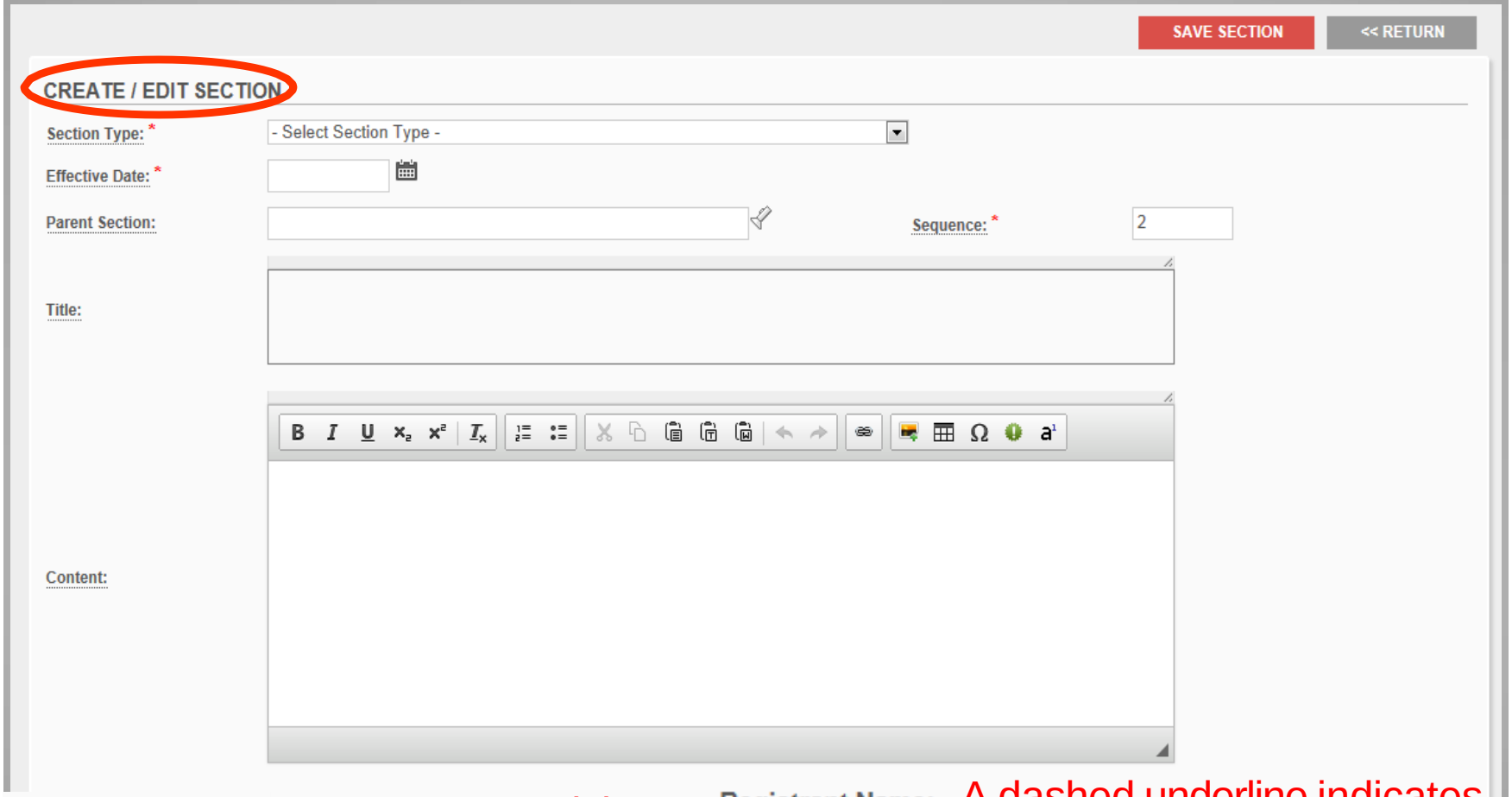


**RED** asterisk indicates field is mandatory

A dashed underline indicates help text if clicked on

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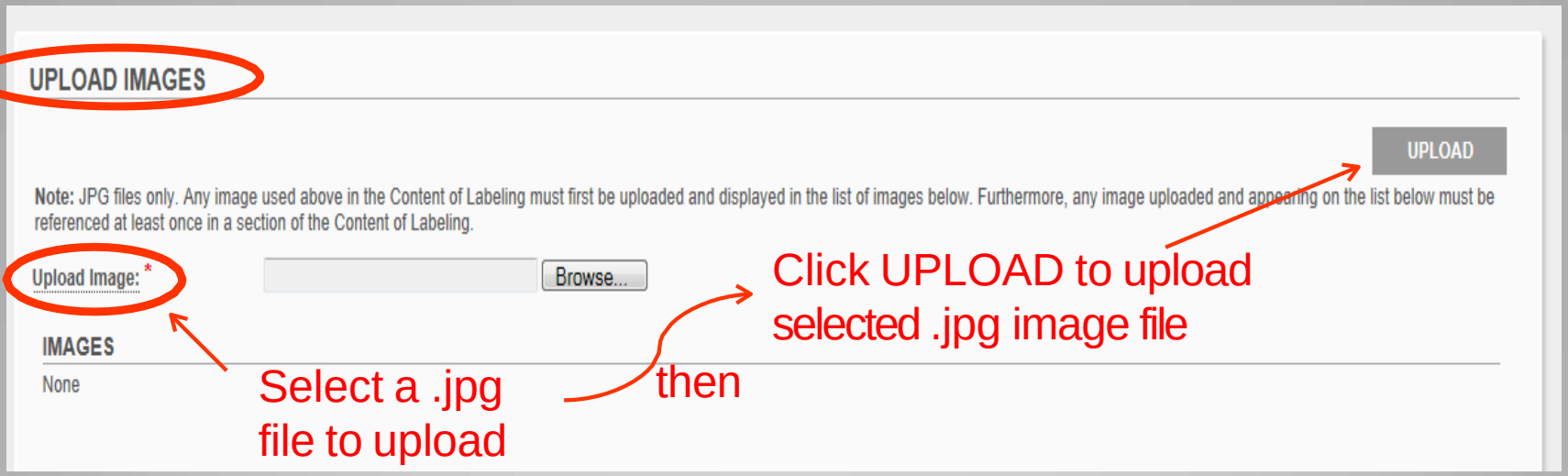


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Registrant Name: A dashed underline indicates help text if clicked on

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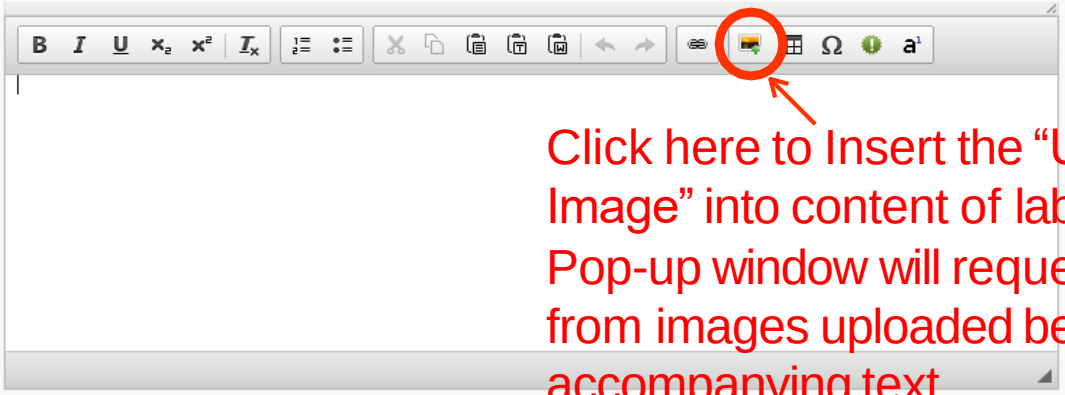
# Human Compounded Drug Label

Content:



Click here to Insert the “Uploaded Image” into content of labeling. Pop-up window will request name from images uploaded below and accompanying text.

## UPLOAD IMAGES

UPLOAD

**Note:** JPG files only. Any image used above in the Content of Labeling must first be uploaded and displayed in the list of images below. Furthermore, any image uploaded and appearing on the list below must be referenced at least once in a section of the Content of Labeling.

Upload Image: * Browse...

After “Insert An Image” is saved this will change to “Yes”

### IMAGES

| IMAGE NAME | IMAGE | DELETE IMAGE | REFERENCED |
|---|---|---|---|
| Jellyfish.jpg |  | ✖ | No |

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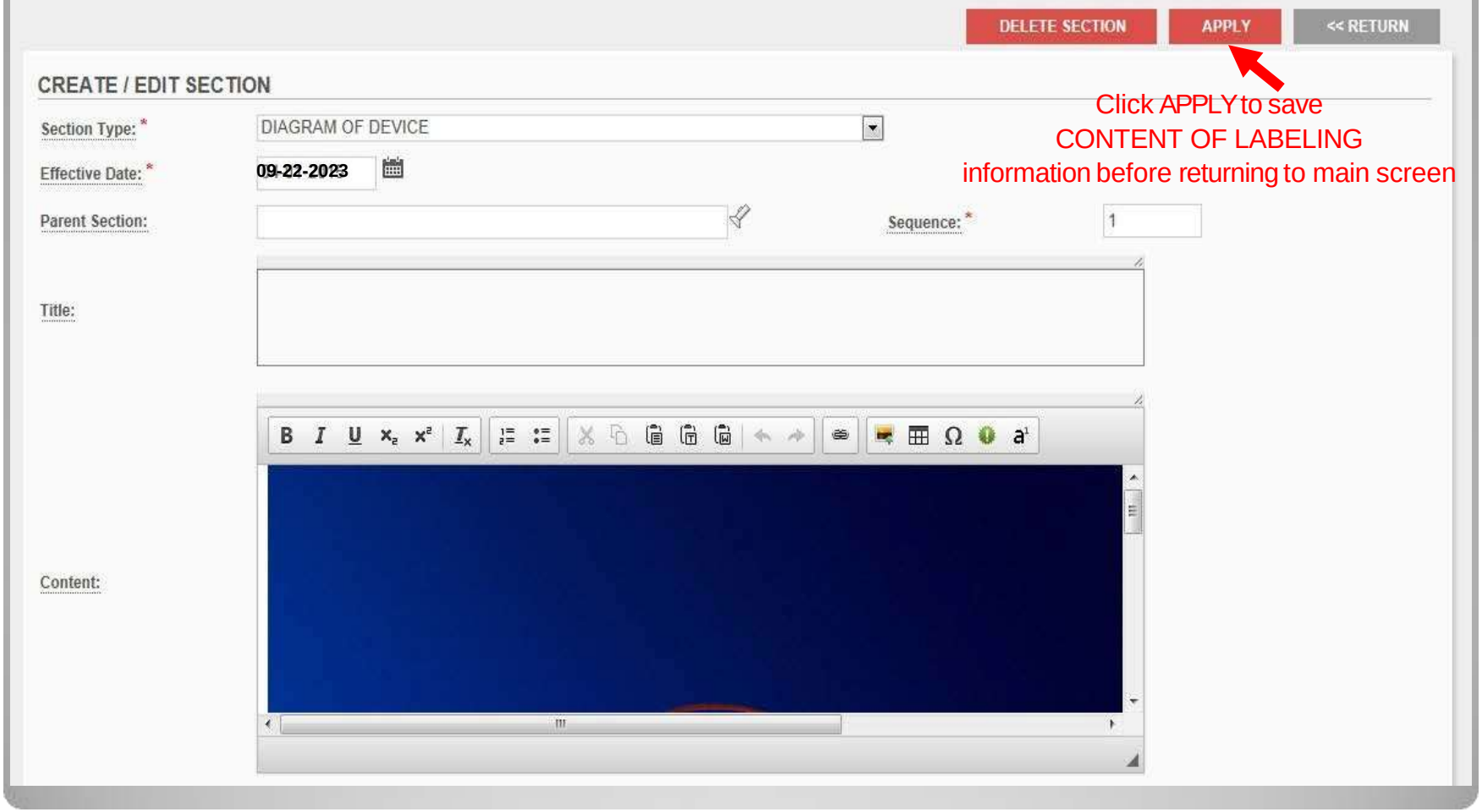

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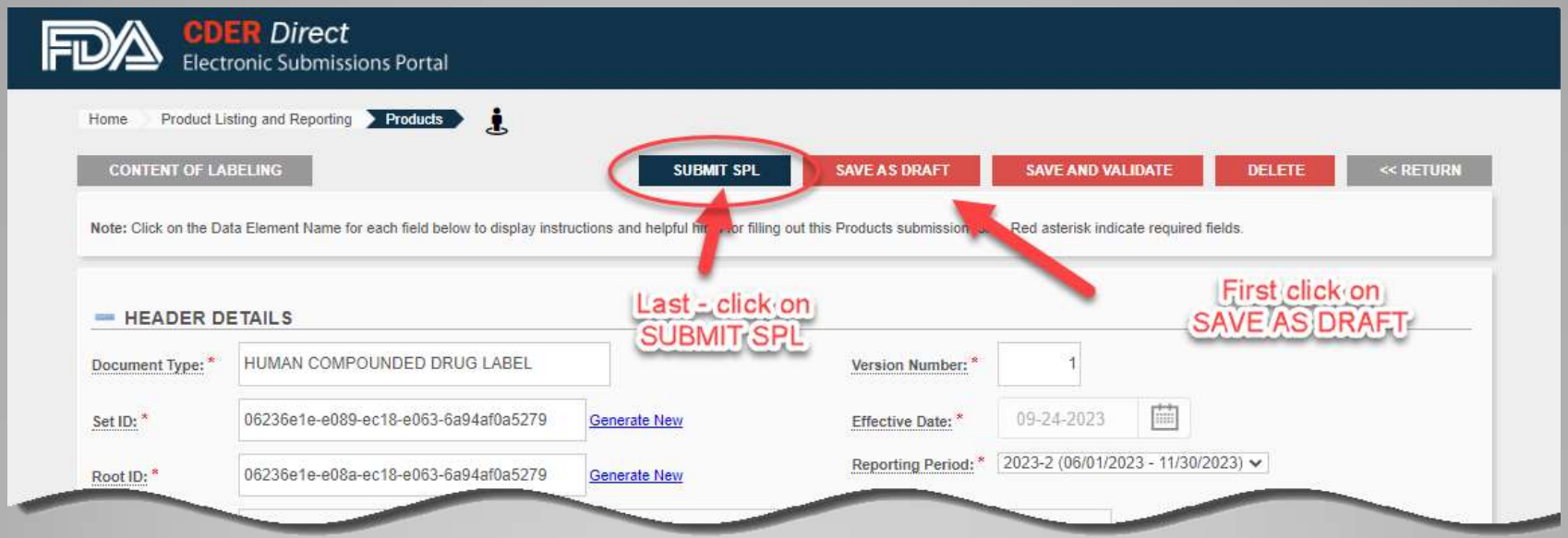


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