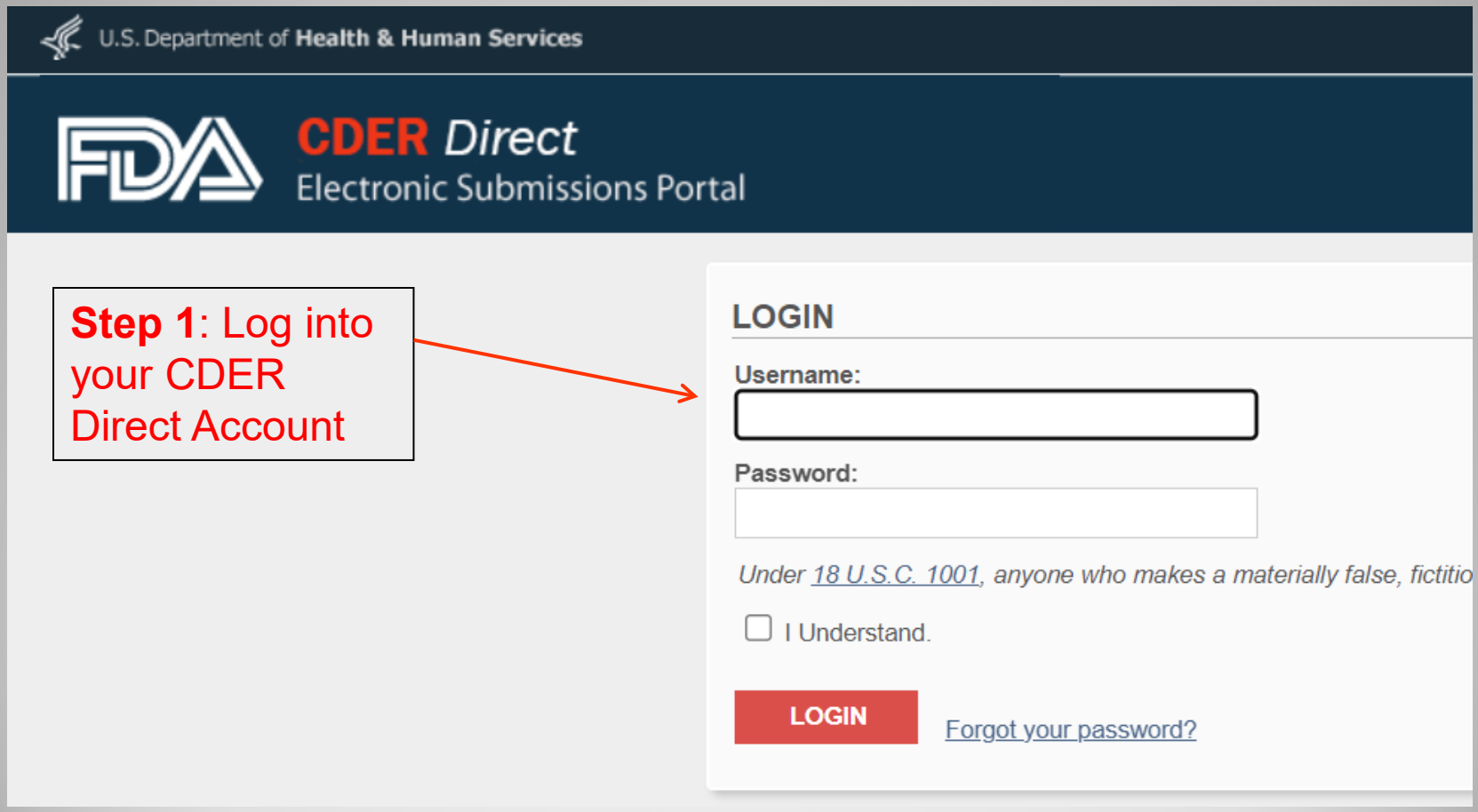
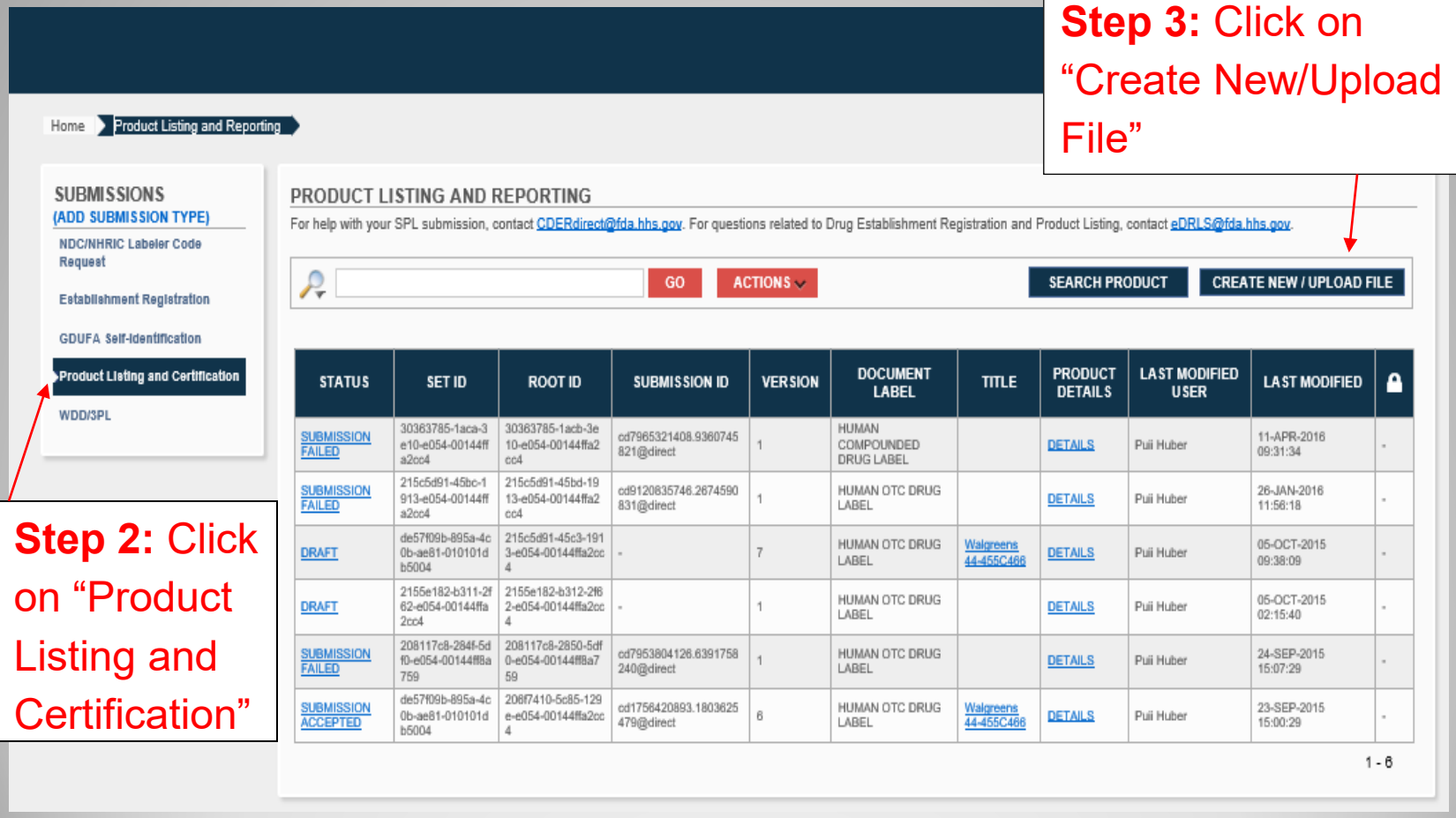
CDER Direct – Blanket No Changes Certification of Product Listing

Blanket No Changes Certification



CDER Direct: direct.fda.gov

Blanket No Changes Certification

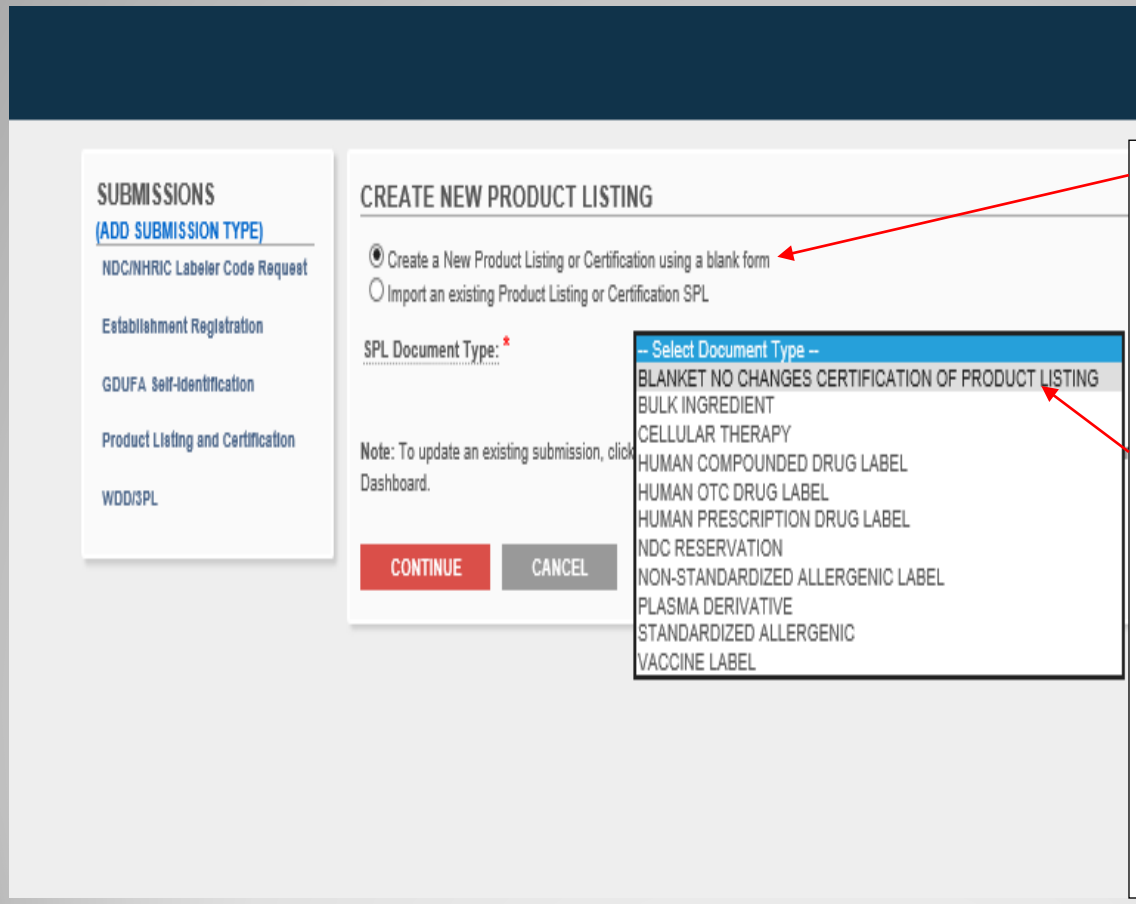


Step 3: Click on "Create New/Upload File"

Step 2: Click on "Product Listing and Certification"

CDER Direct: direct.fda.gov

Blanket No Changes Certification

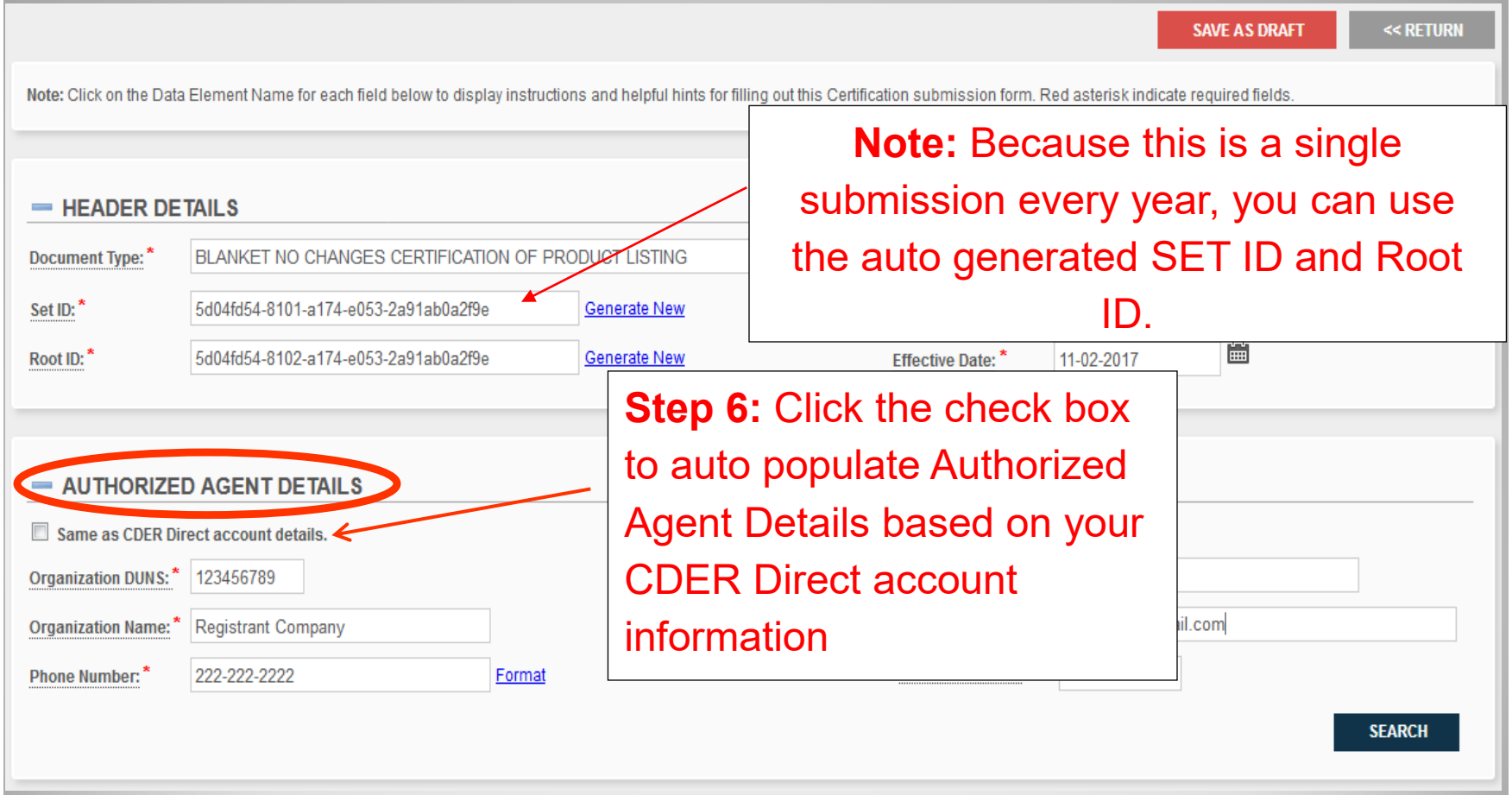


Step 4: Select the radio button "Create a New Product Listing or Certification using a blank form"

Step 5: Select the SPL Document Type – "Blanket No Changes Certification of Product Listing"

CDER Direct: direct.fda.gov

Blanket No Changes Certification

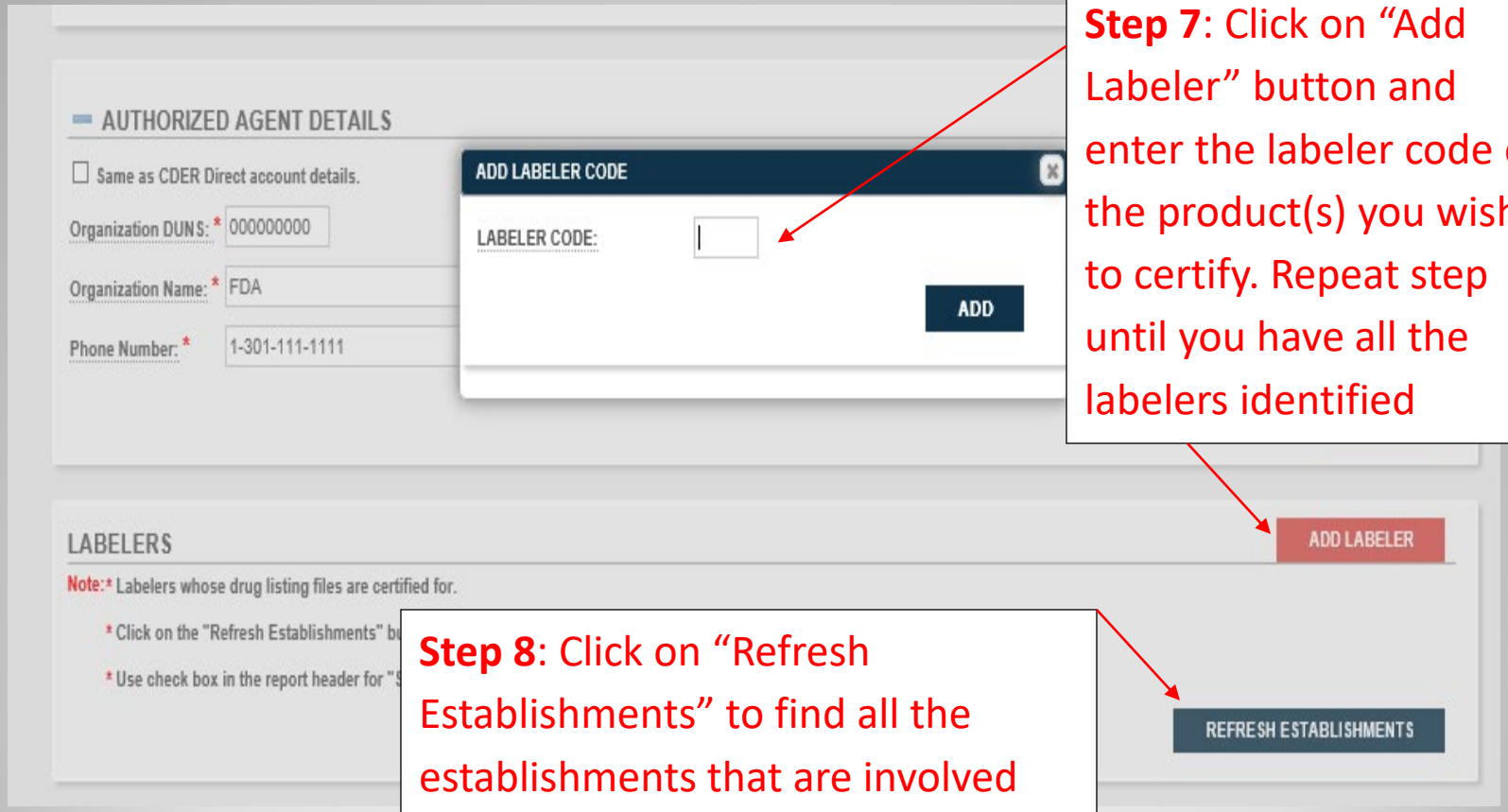


Note: Because this is a single submission every year, you can use the auto generated SET ID and Root ID.

Step 6: Click the check box to auto populate Authorized Agent Details based on your CDER Direct account information

CDER Direct: direct.fda.gov

Blanket No Changes Certification



Step 7: Click on "Add Labeler" button and enter the labeler code of the product(s) you wish to certify. Repeat step until you have all the labelers identified

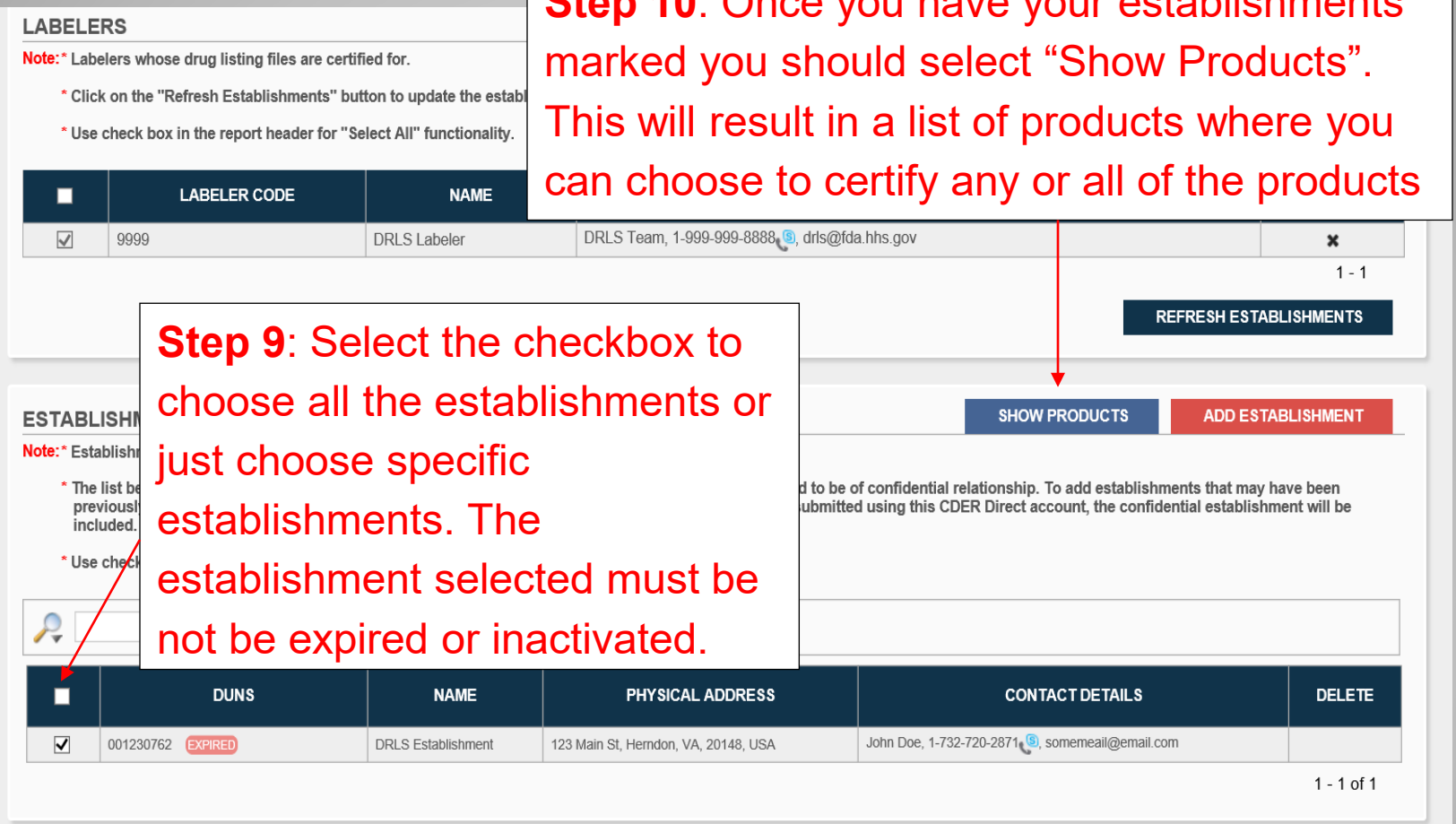
Step 8: Click on "Refresh Establishments" to find all the establishments that are involved with the Labeler(s) products

CDER Direct: direct.fda.gov

Blanket No Changes Certification

Step 10: Once you have your establishments marked you should select “Show Products”. This will result in a list of products where you can choose to certify any or all of the products

Step 9: Select the checkbox to choose all the establishments or just choose specific establishments. The establishment selected must be not be expired or inactivated.



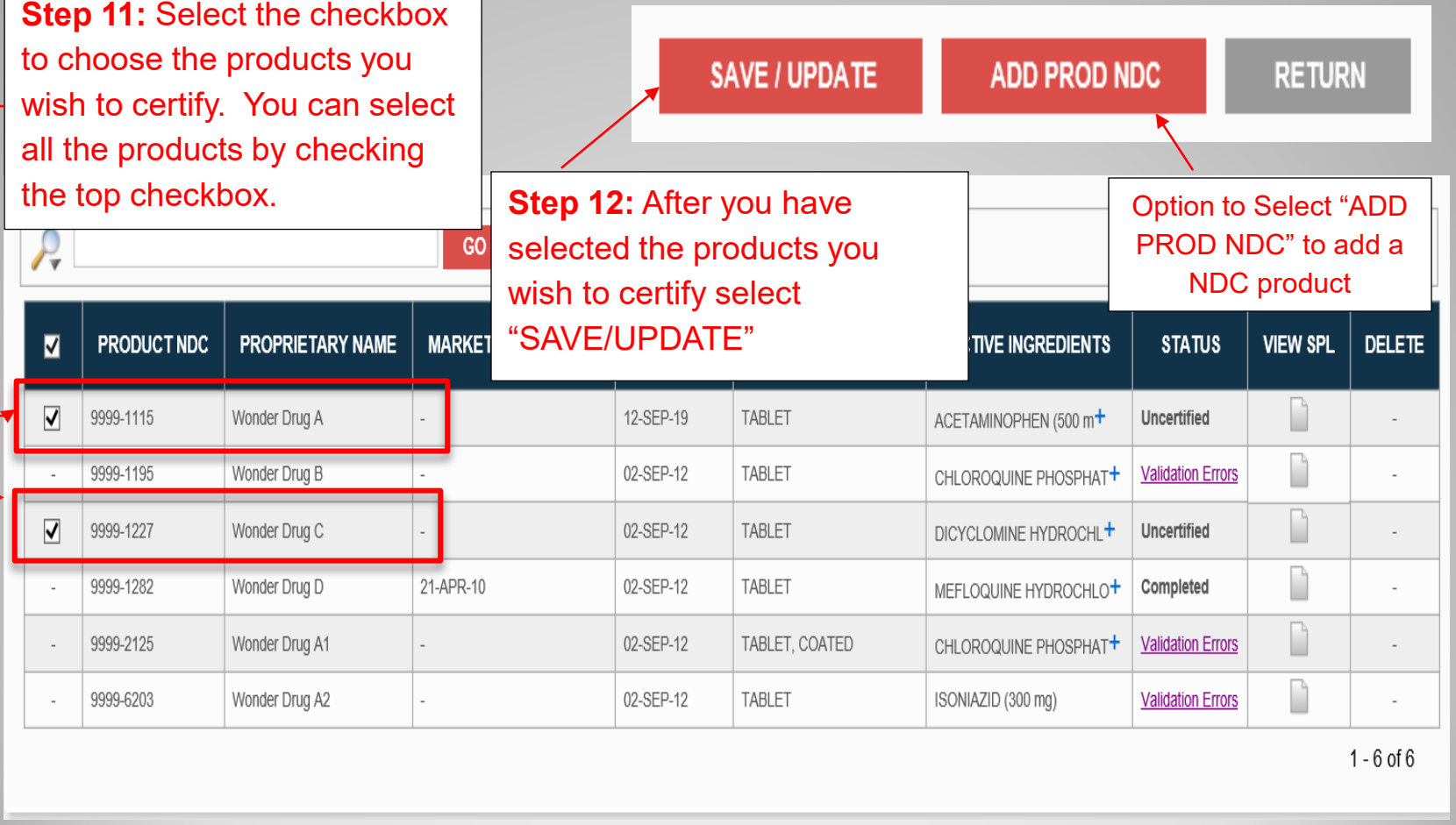
CDER Direct: direct.fda.gov

Blanket No Changes Certification

Step 11: Select the checkbox to choose the products you wish to certify. You can select all the products by checking the top checkbox.

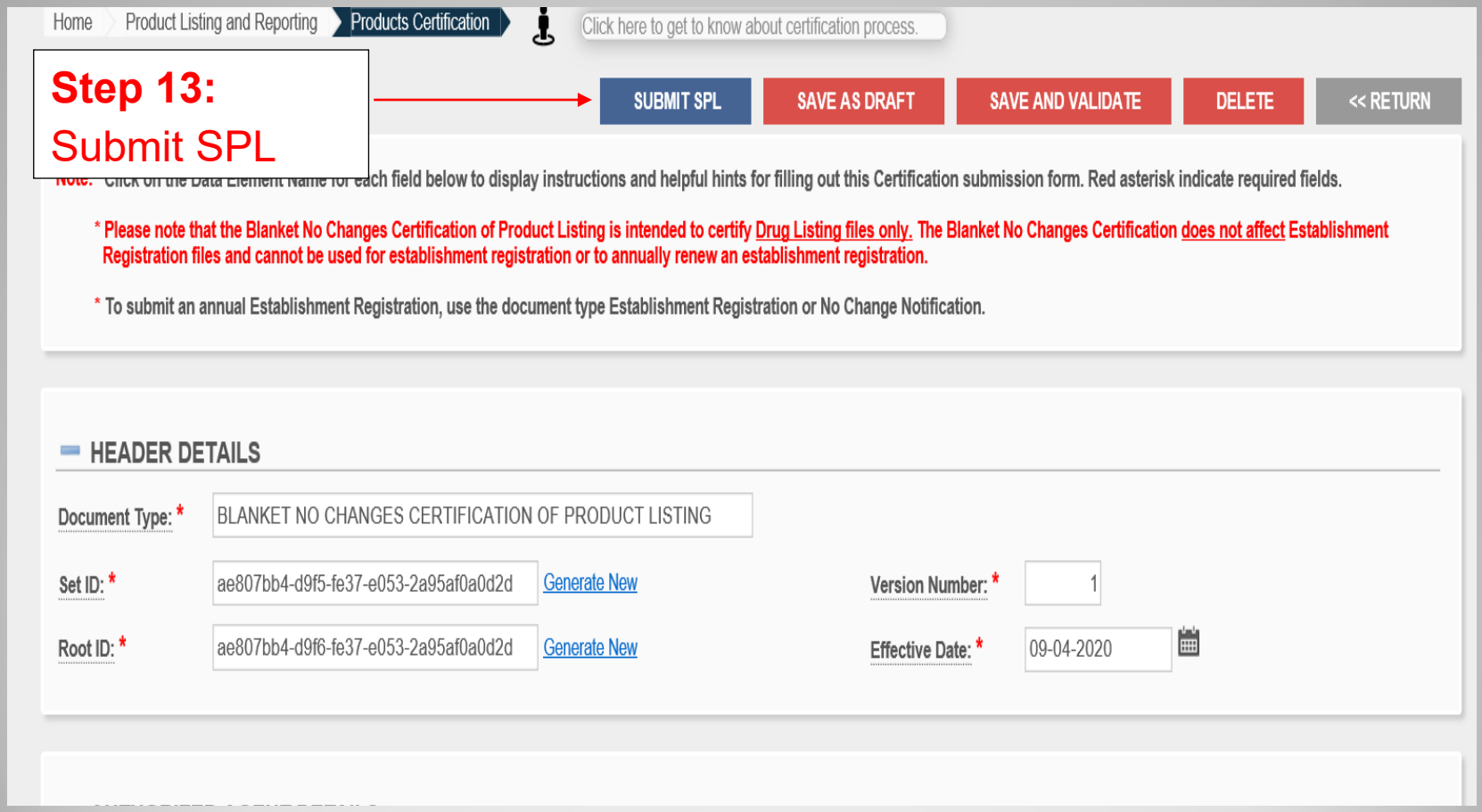
Step 12: After you have selected the products you wish to certify select "SAVE/UPDATE"

Option to Select "ADD PROD NDC" to add a NDC product



CDER Direct: direct.fda.gov

Blanket No Changes Certification



CDER Direct: direct.fda.gov

Helpful Hints

- Blanket No Changes Certification of Product Listing is intended to certify Drug Listing files only.
- The Blanket No Changes Certification does not affect Establishment Registration files and cannot be used for establishment registration or to annually renew an establishment registration.
- Blanket No Changes Certification of Product Listings can only be submitted between October 1st and December 31st.
- For more information, visit Drug Listing Certification Quick Start Guide - FDA
- https://www.fda.gov/media/108725/download

For more information

Log on to CDER Direct: direct.fda.gov

The CDER Direct portal currently works best with the following browsers:

- *Microsoft Edge*
- *Firefox version 28 and above*
- *Google Chrome*
- *Safari 10.0.1 and above*

Help Desk: CDERdirect@fda.hhs.gov