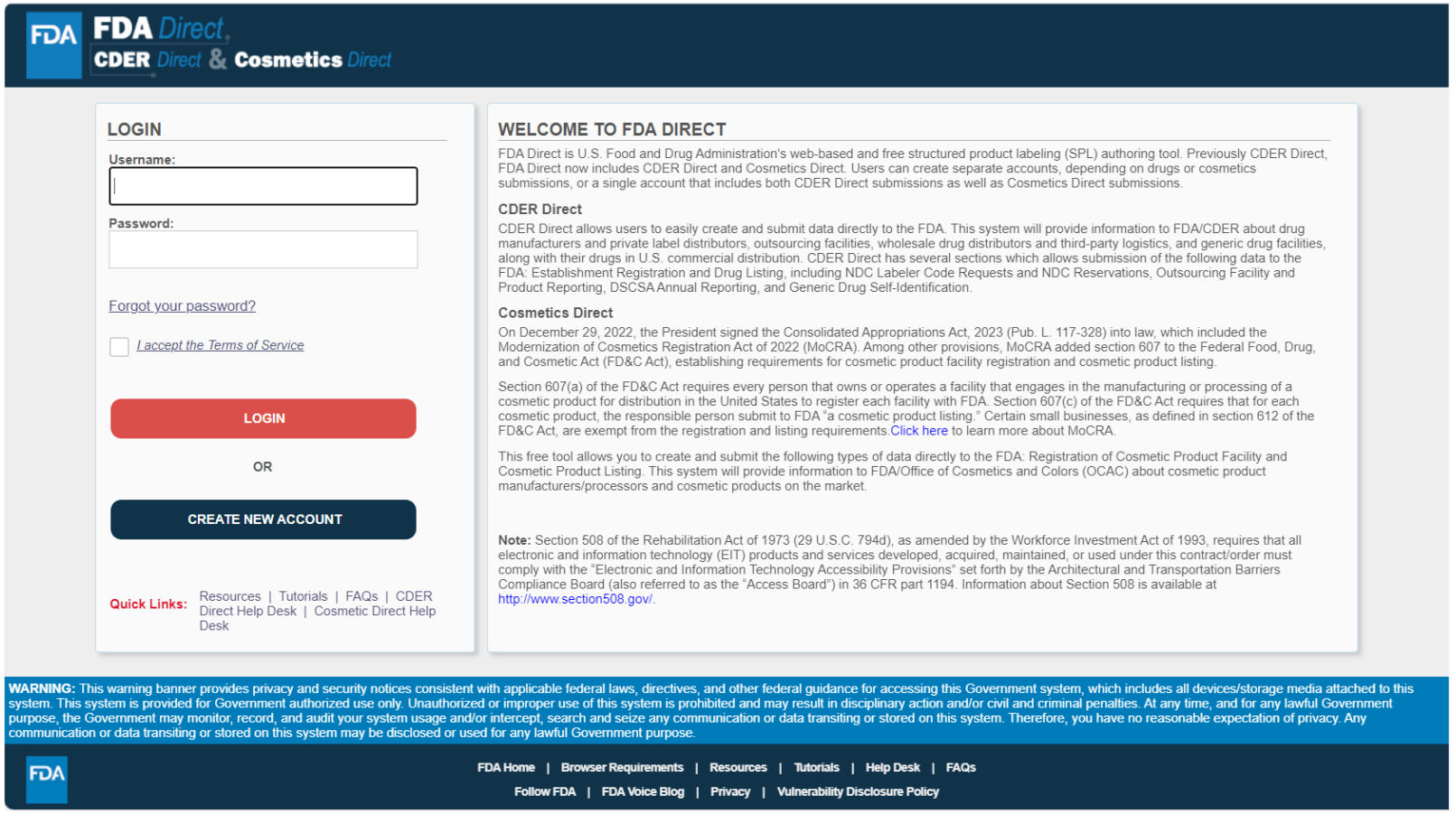
Reference Guide:
NDC Reservation

Welcome to NDC Reservation in the FDA Direct Portal

This guide provides the essential information you need to complete an NDC Reservation via FDA Direct.

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



Click here to access the FDA Direct Portal

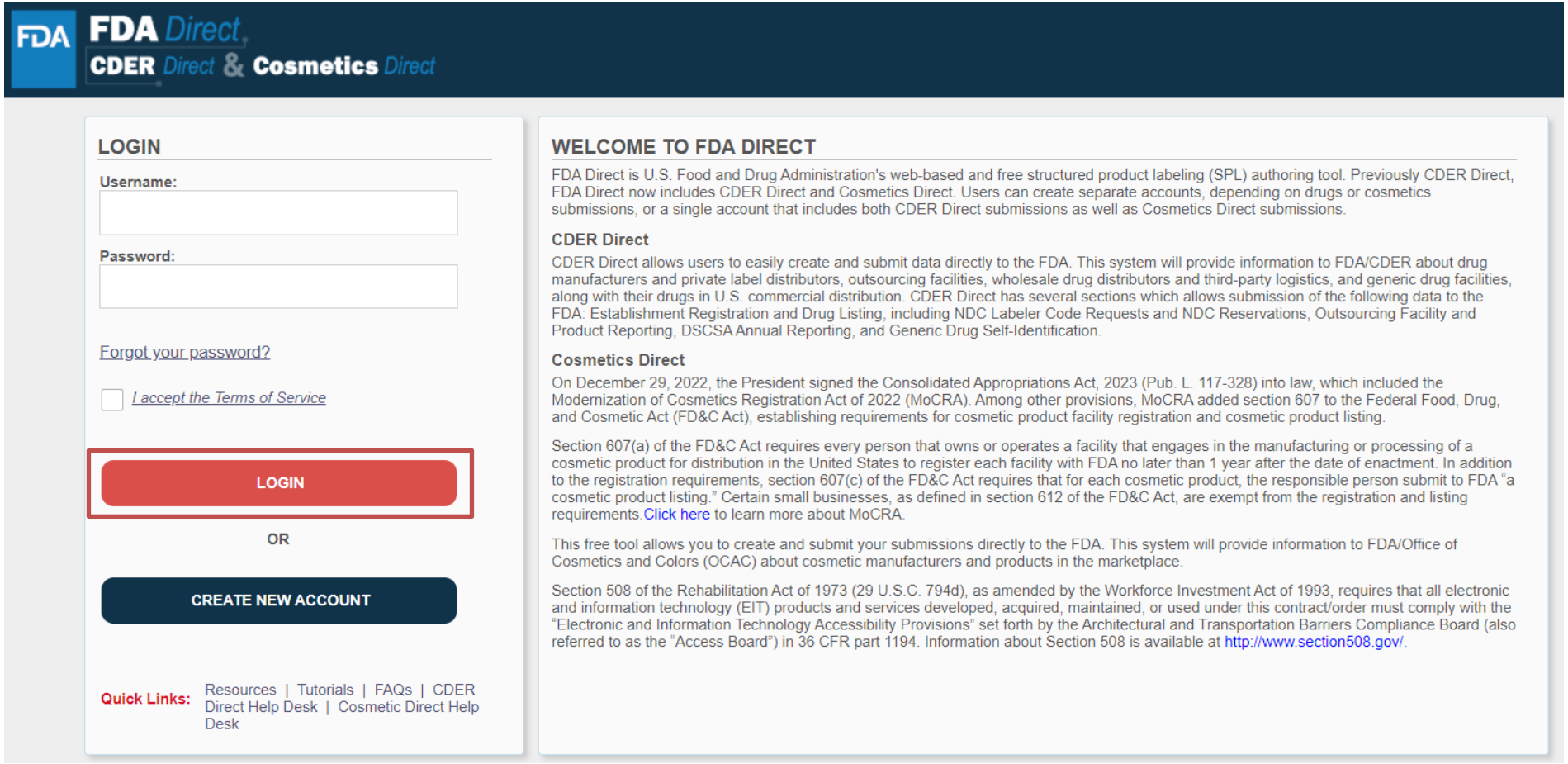
Table of Contents

NDC Reservation

NDC Reservation

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

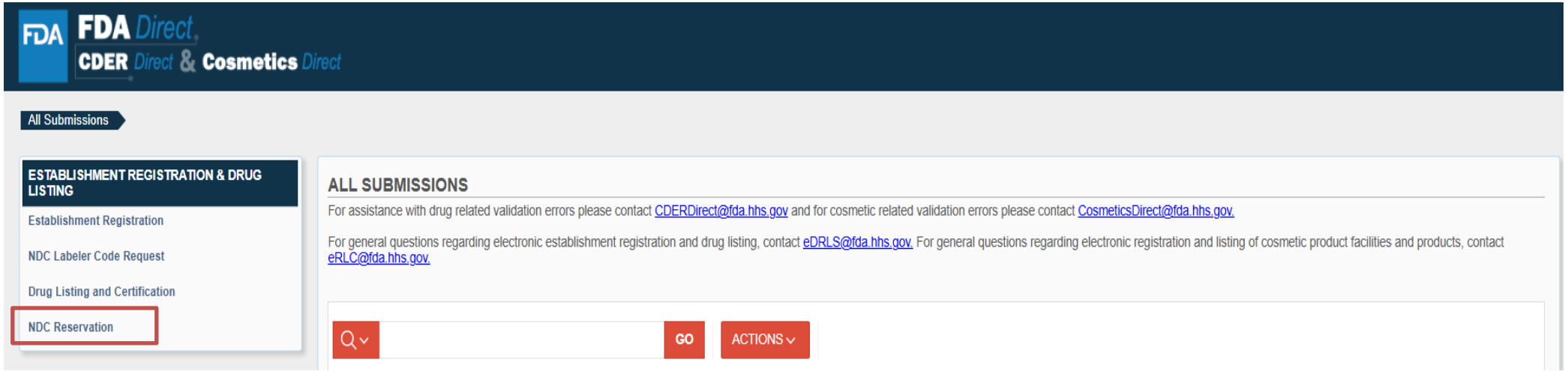
Step 2 Enter your login credentials, accept the terms of service, and click **Login**



NDC Reservation

Step 3

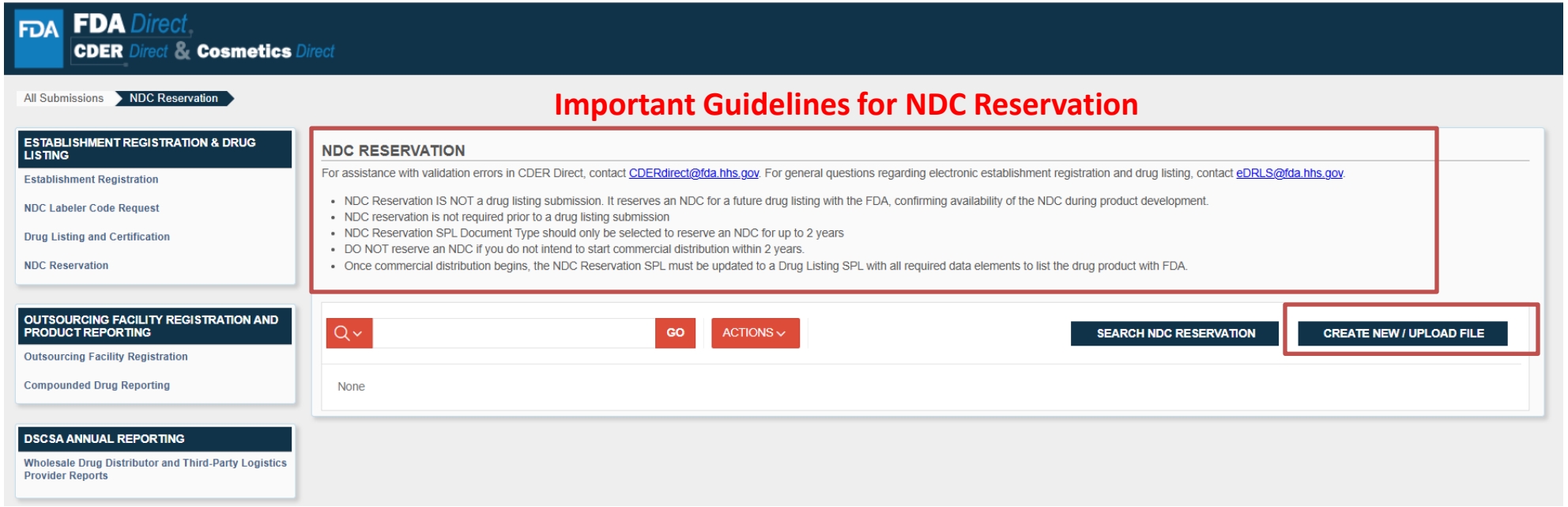
Click on **NDC Reservation**



Step 4

Click on **Create New/Upload File**

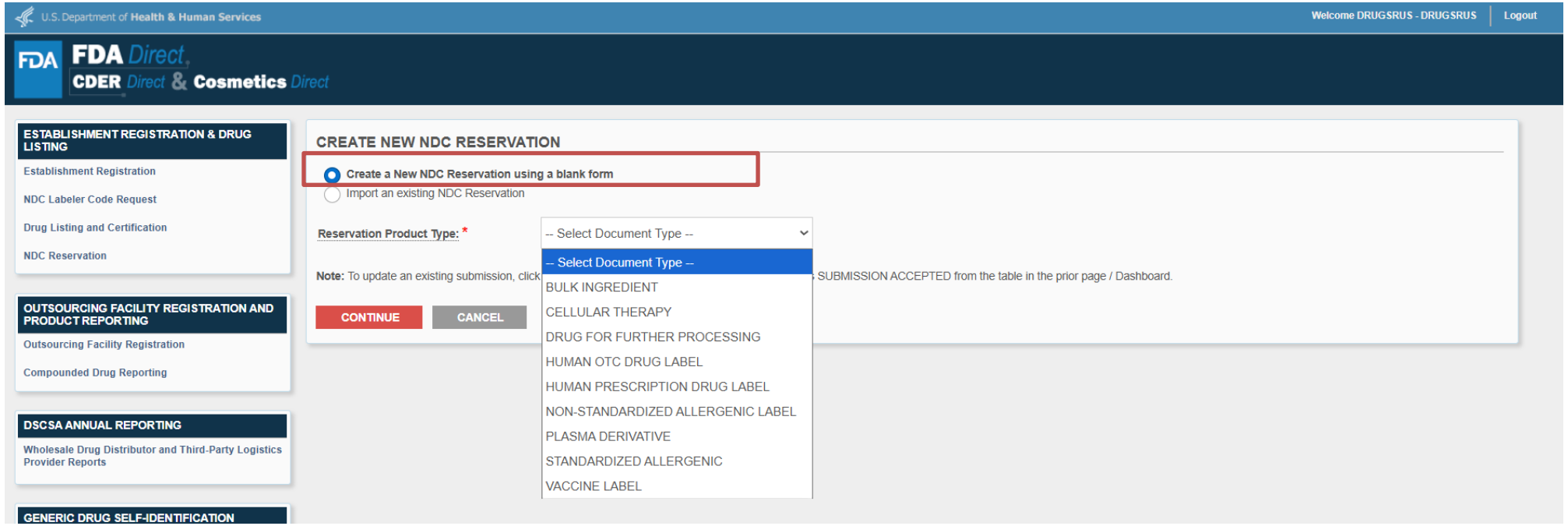
Before proceeding, please review the important guidelines for NDC Reservation



NDC Reservation

Step 5

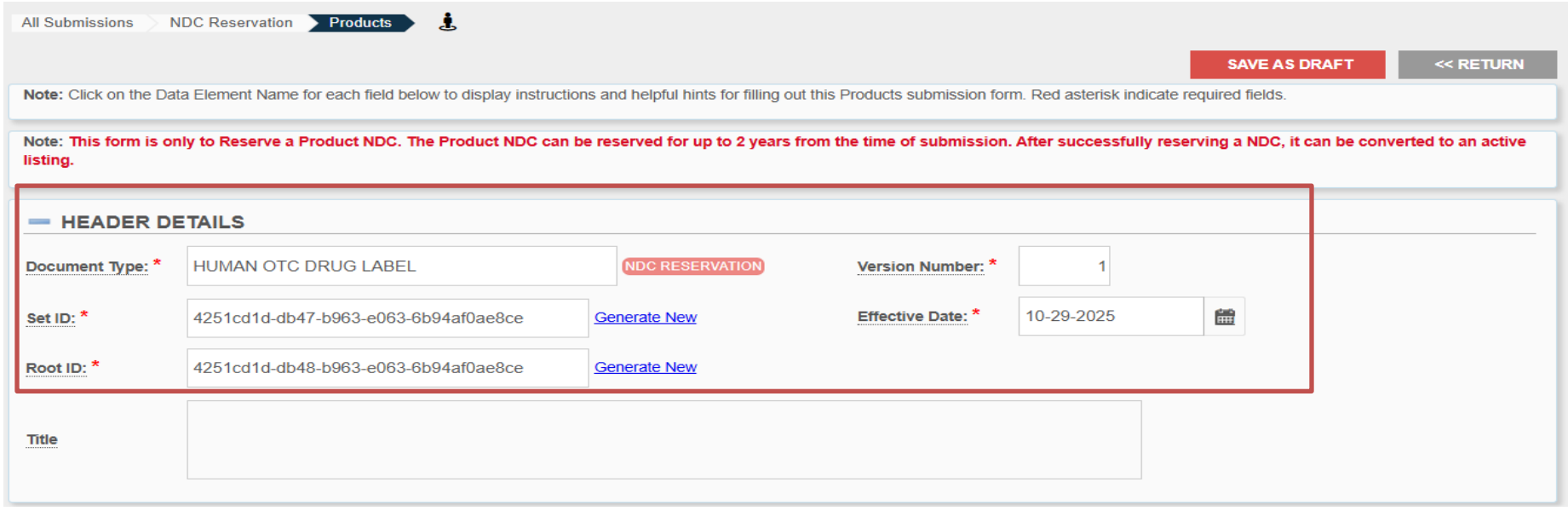
Click on **Create a New NDC Reservation using a blank form** and select the appropriate SPL **Document Type** for the drug product you want to reserve. Then click **Continue**



Step 6

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

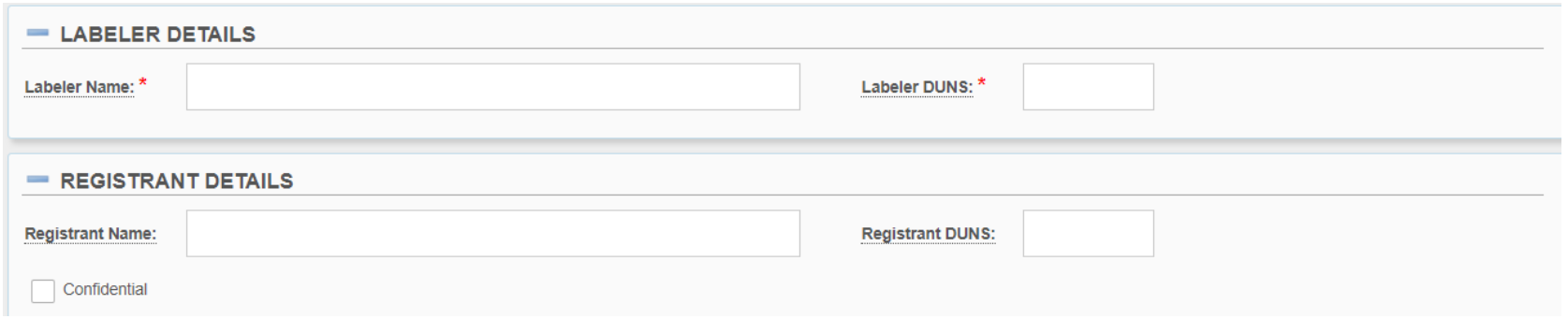
NOTE: Effective Date is not associated with the date the SPL is effective. The date an SPL is received by FDA is considered the date it is effective



NDC Reservation

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

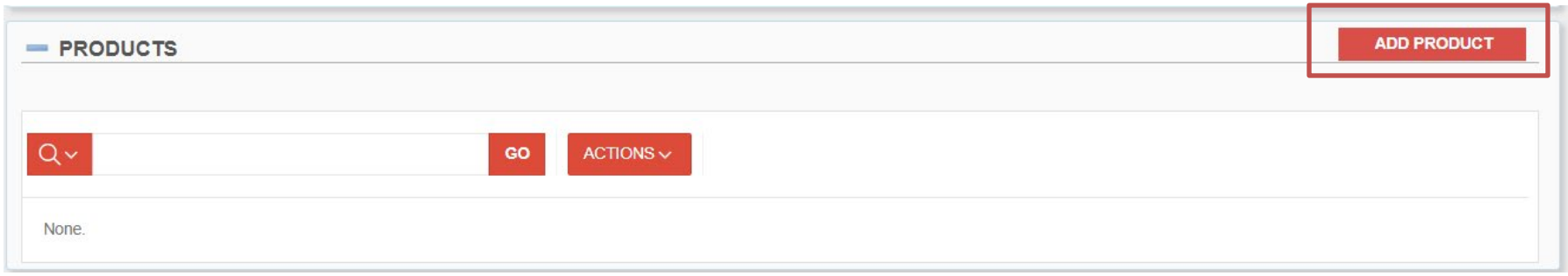


Quick Tip!

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

Step 8

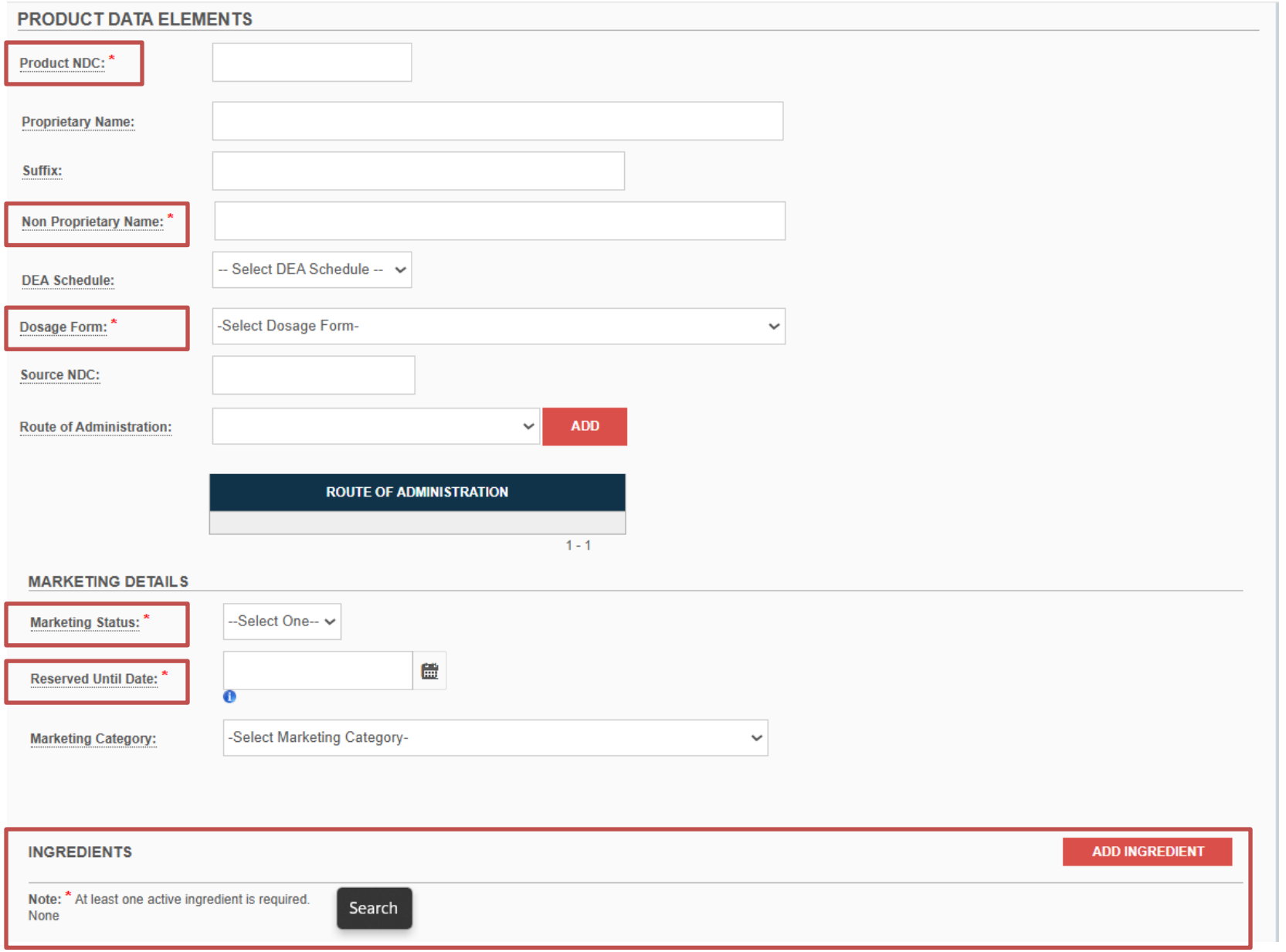
Click on **Add Product**



NDC Reservation

Step 9

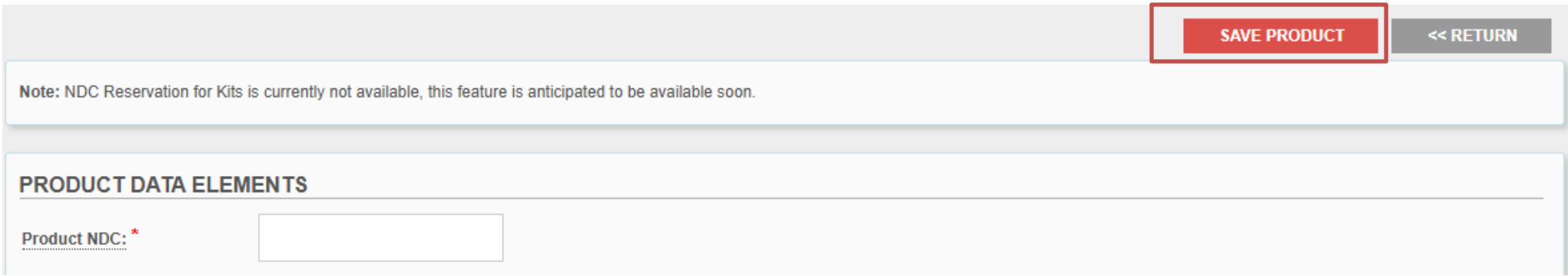
Complete all required **Product Data Elements**



NDC Reservation

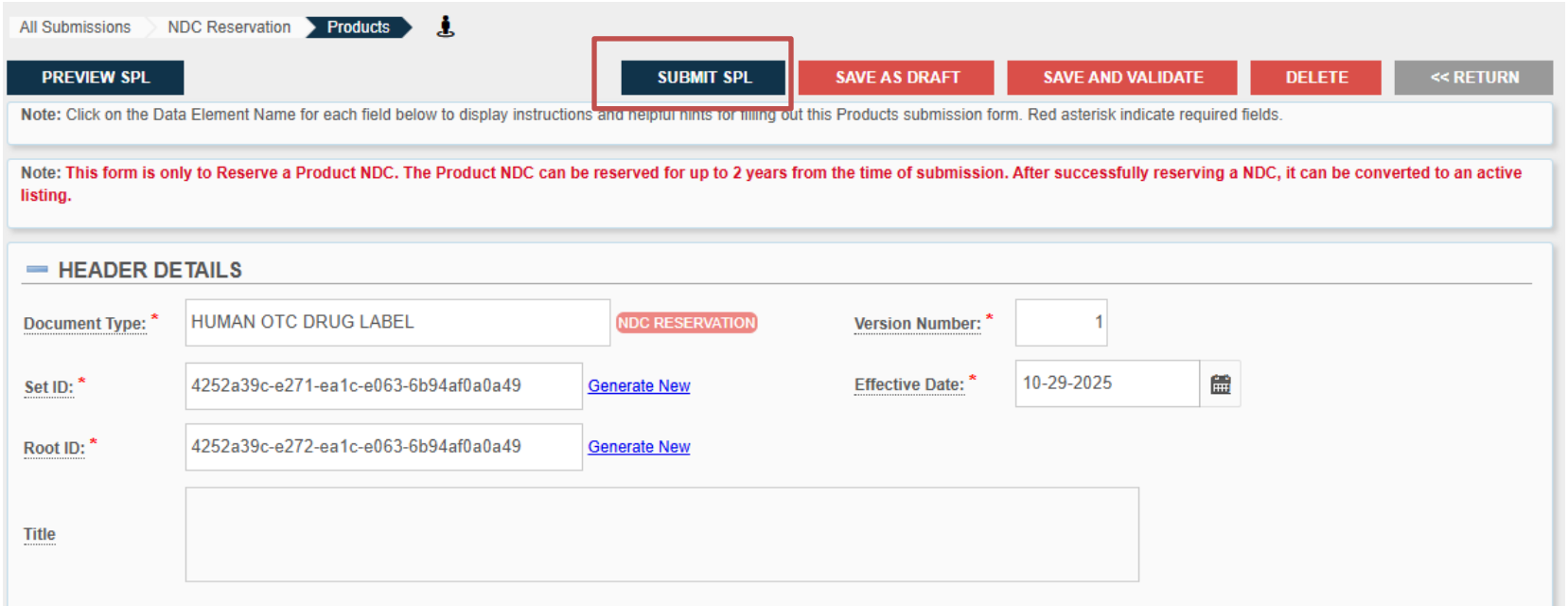
Step 10

Click on **Save Product**



Step 11

Click on **Submit SPL**



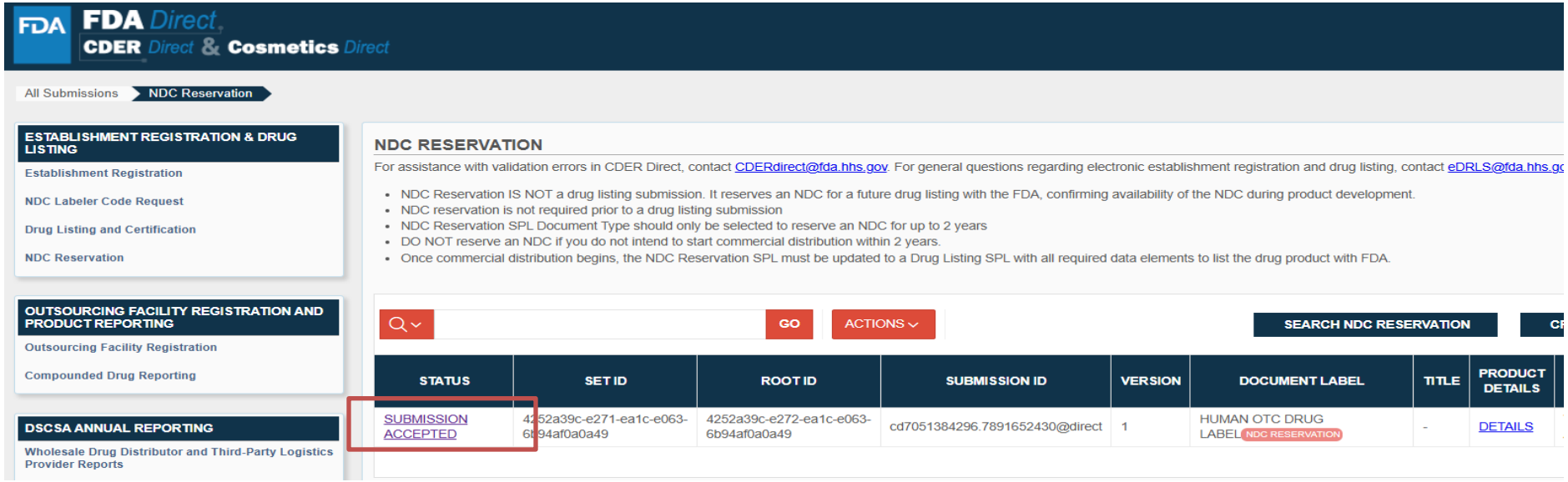
Cancelling NDC Reservation

Cancelling NDC Reservation

If you no longer intend to manufacture or distribute the drug as previously planned, you should cancel the NDC Reservation.

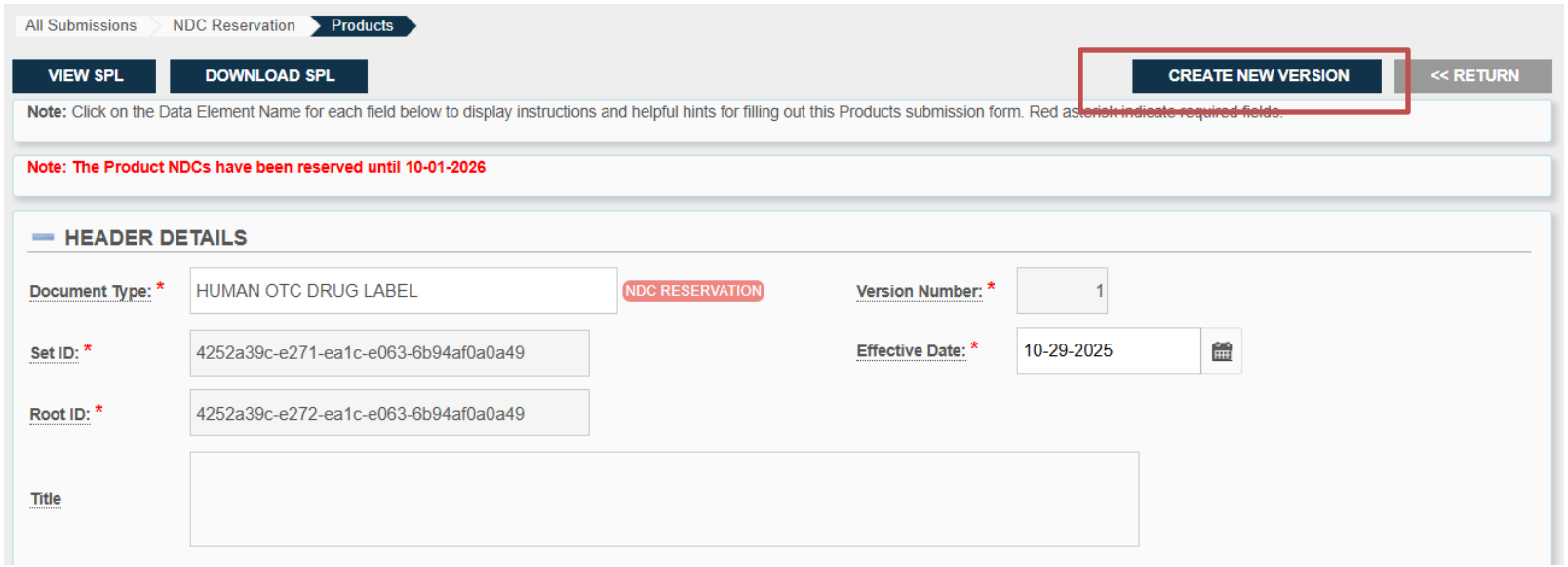
Step 1

Click on **Submission Accepted** status for your reserved NDC



Step 2

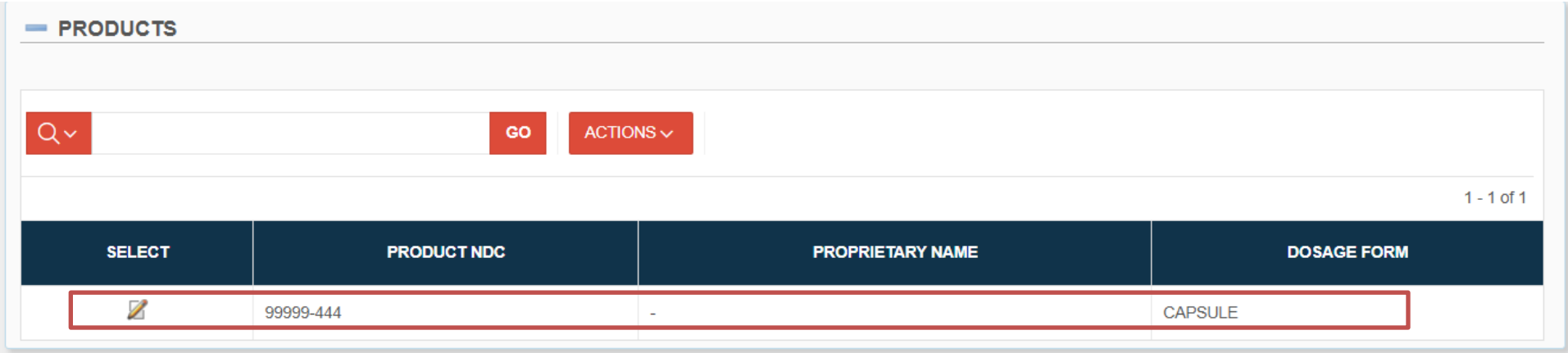
Click on **Create New Version**



Cancelling NDC Reservation

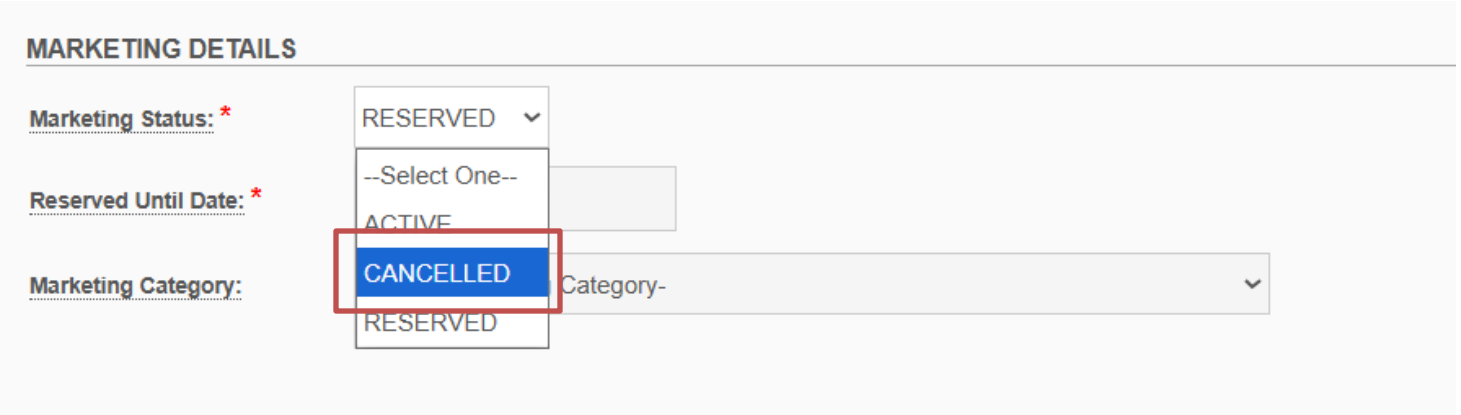
Step 3

Select the reserved NDC to cancel



Step 4

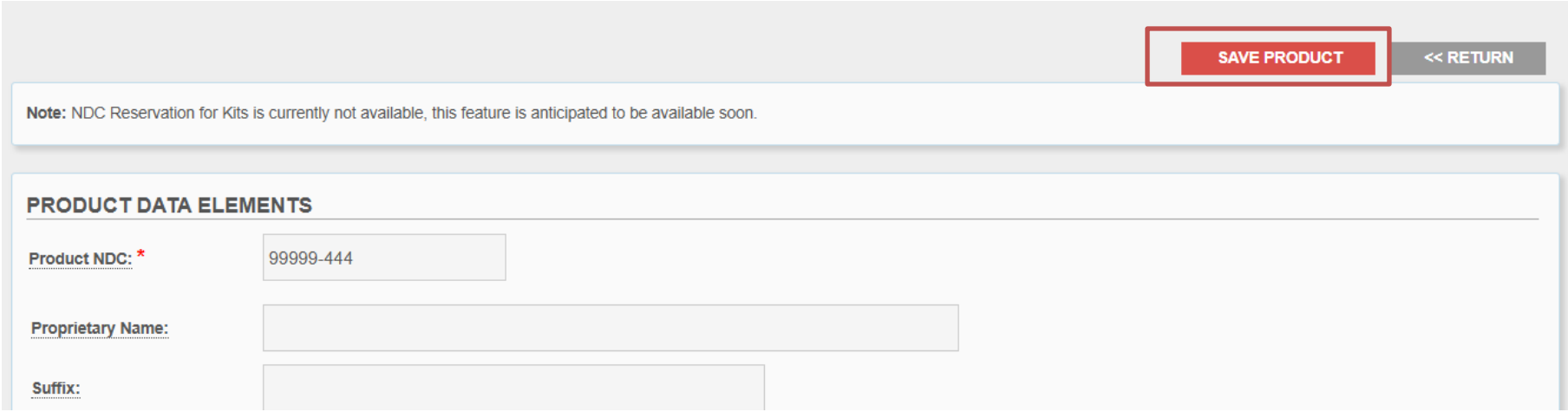
In the **Marketing Details** section, click on the **Marketing Status** dropdown and change the status from **Reserved** to **Cancelled**



Cancelling NDC Reservation

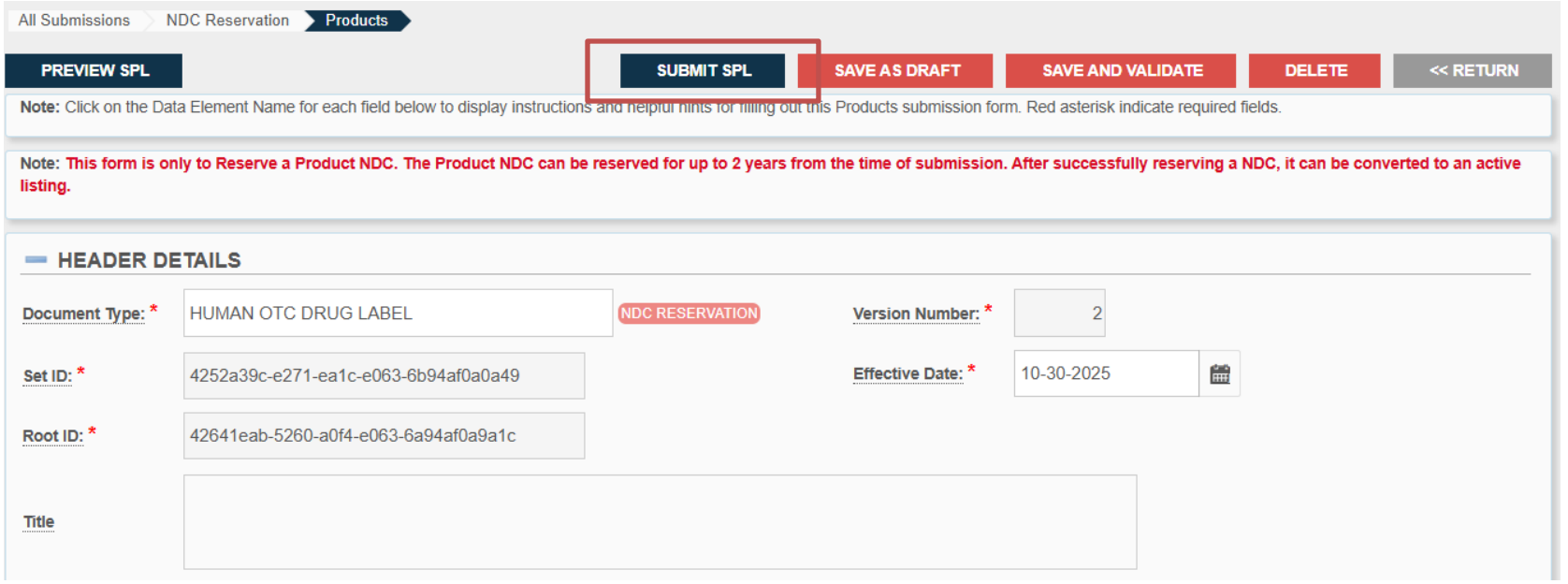
Step 5

Click on **Save Product**



Step 6

Then click on **Submit SPL**



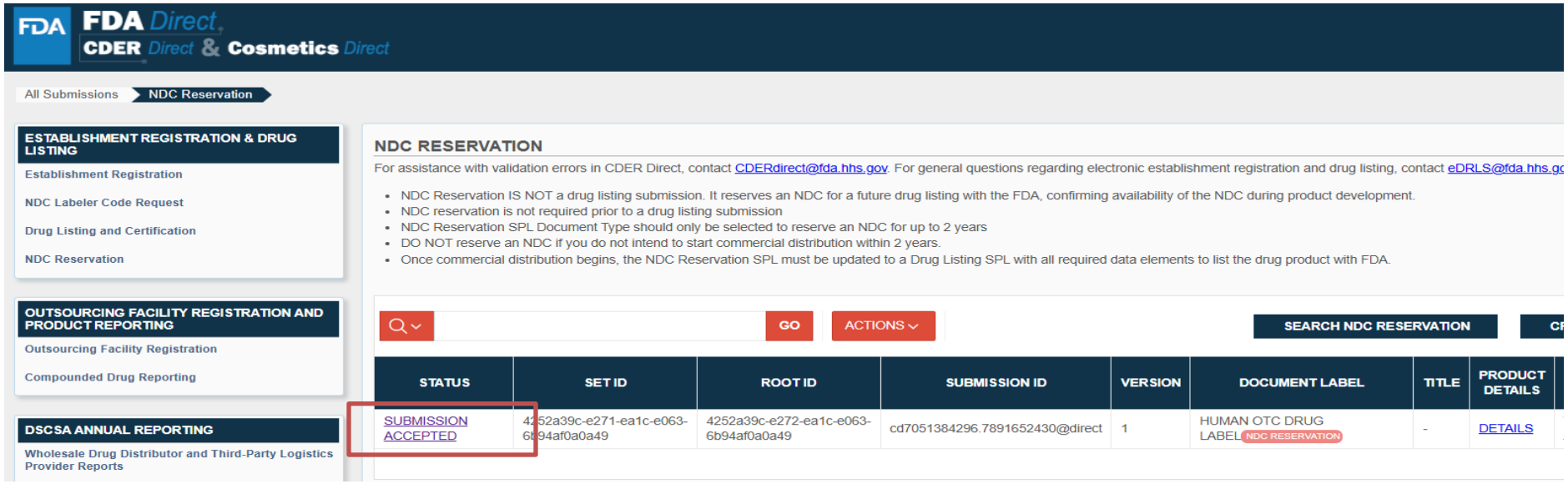
Converting NDC Reservation to Active Listing

Converting NDC Reservation to Active Listing

At the time of commercial distribution, an NDC Reservation SPL should be converted to a Drug Listing SPL. At the latest, the listing for a new drug introduced into the U.S. market must be submitted to the agency in June or December of the same calendar year.

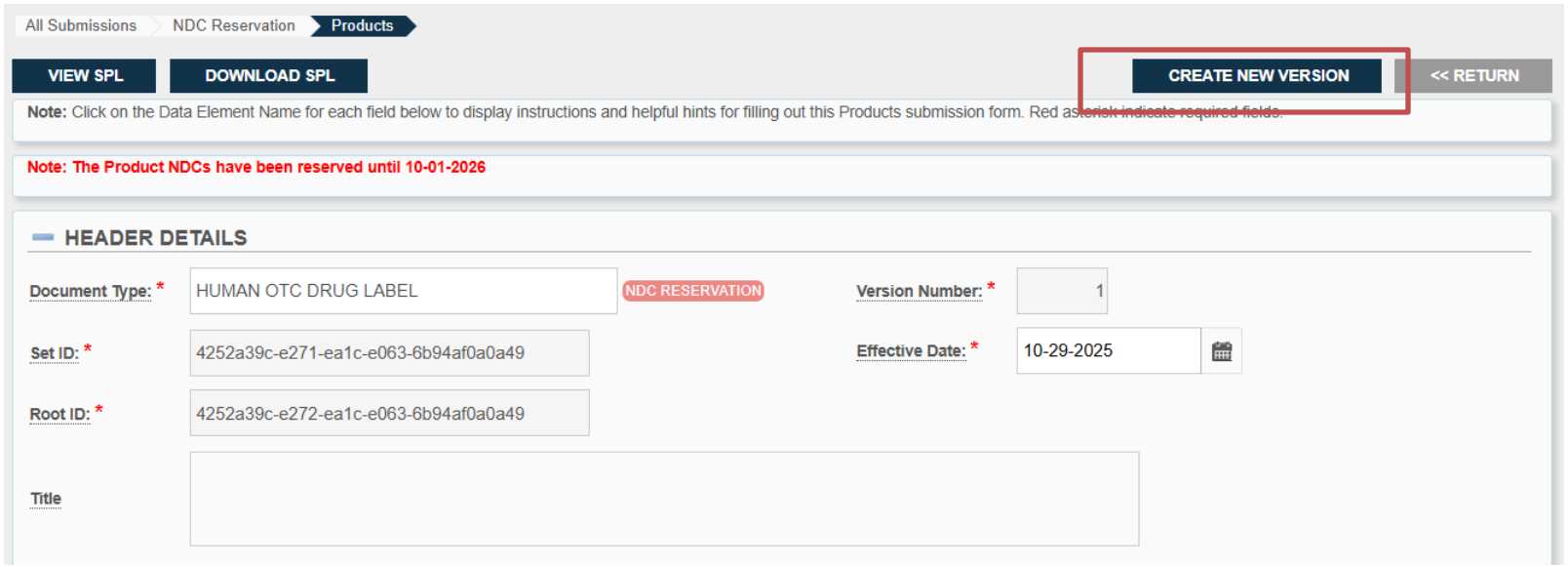
Step 1

Click on **Submission Accepted** status for your reserved NDC



Step 2

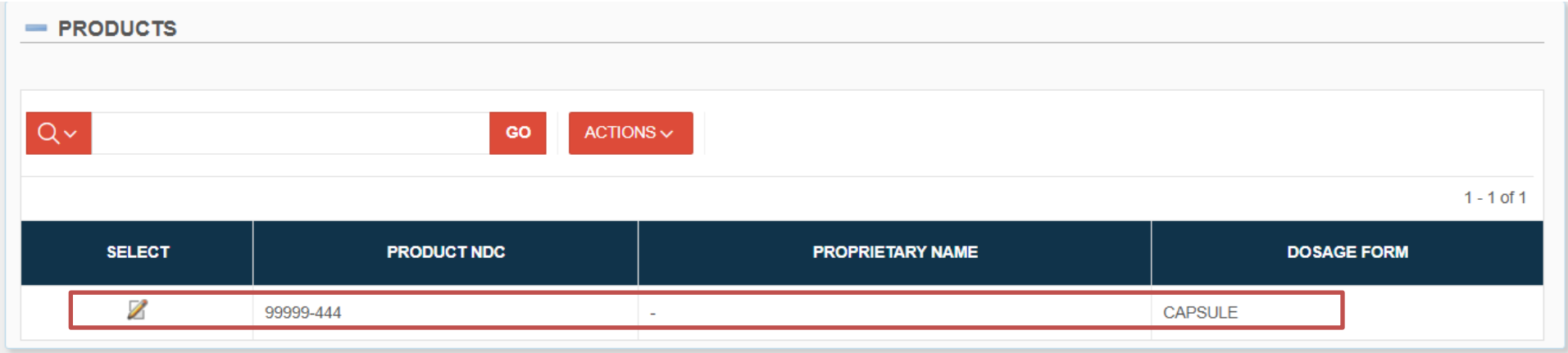
Click on **Create New Version**



Converting NDC Reservation to Active Listing

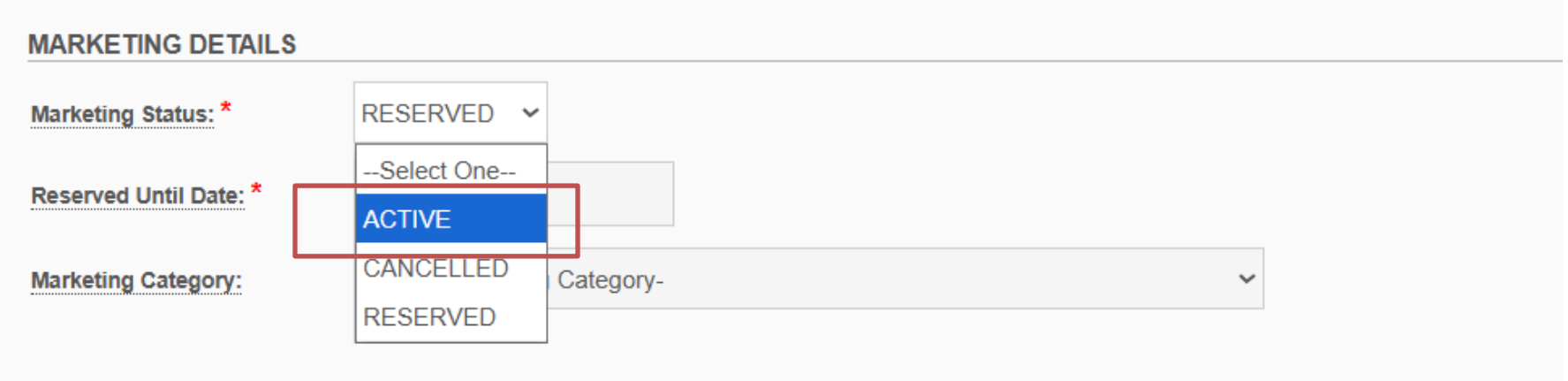
Step 3

Select the reserved NDC to cancel



Step 4

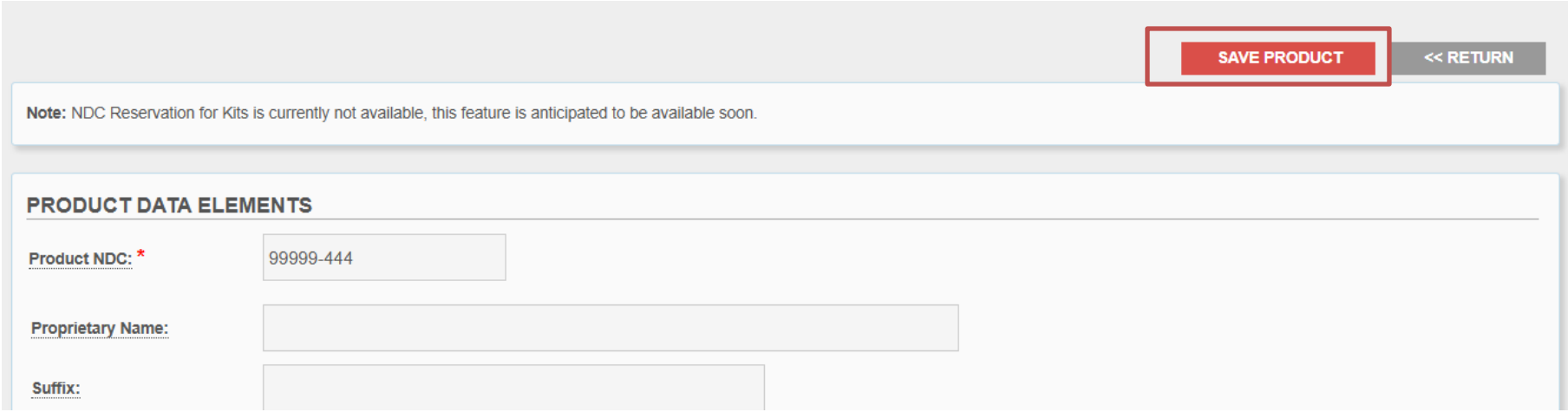
In the **Marketing Details** section, click on the **Marketing Status** dropdown and change the status from **Reserved** to **Active**



Converting NDC Reservation to Active Listing

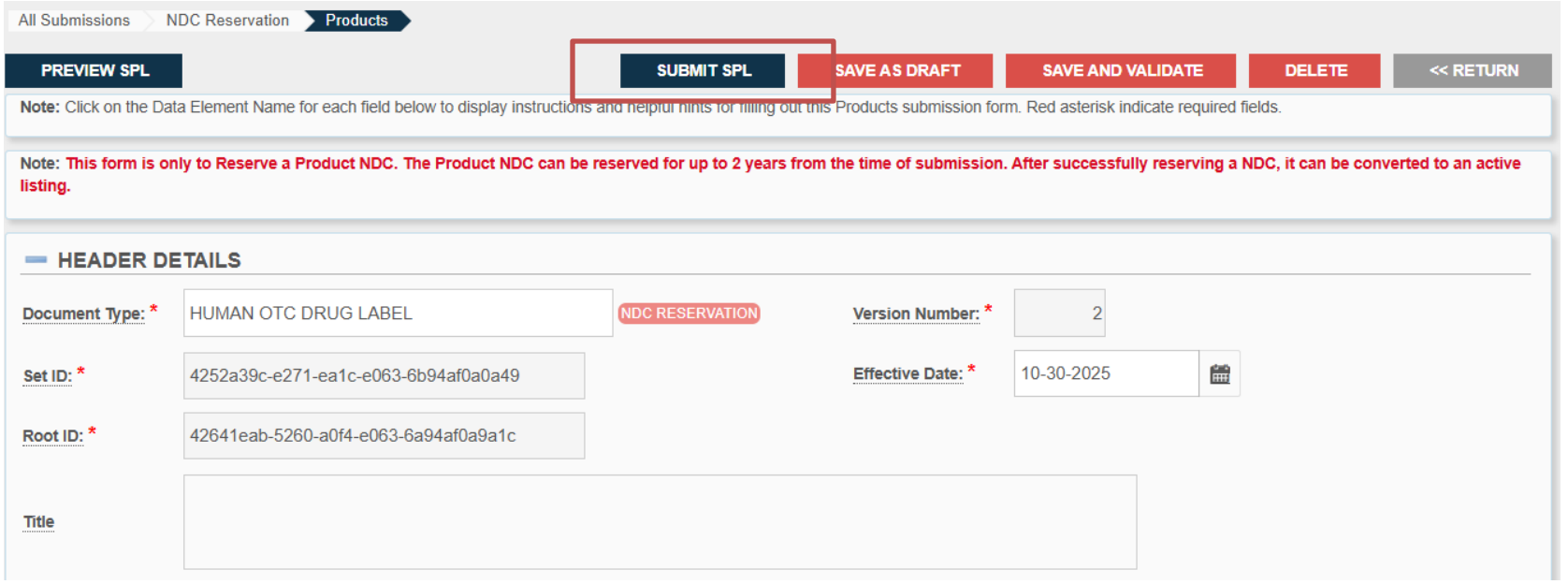
Step 5

Click on **Save Product**



Step 6

At this time, complete all required fields for an active listing (reference the Listing a **Human Drug Product Quick Reference Guide**) and click on **Submit SPL**



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