CDER Direct
503B Product Reporting

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Office: CDER/OC/OPRO/DRLS

Learning Objectives

- Regulation
  - 503B Registration
  - 503B Product Reporting
- Product Reporting Demo & Common Errors
- Summary
- Related Resources
- Challenge Question

Regulations

- **The Drug Quality and Security Act**
  - Created a new section 503B in the FDCA
  - A compounder can become an “outsourcing facility”
- **Outsourcing Facility is…**

FDA REGISTERED
503B Outsourcing Facility

Regulations

- **Outsourcing Facilities are:**
  - Exempted from FDA approval requirements
  - Exempted from certain labeling requirements
  - NOT exempted from cGMP Requirements

Regulations

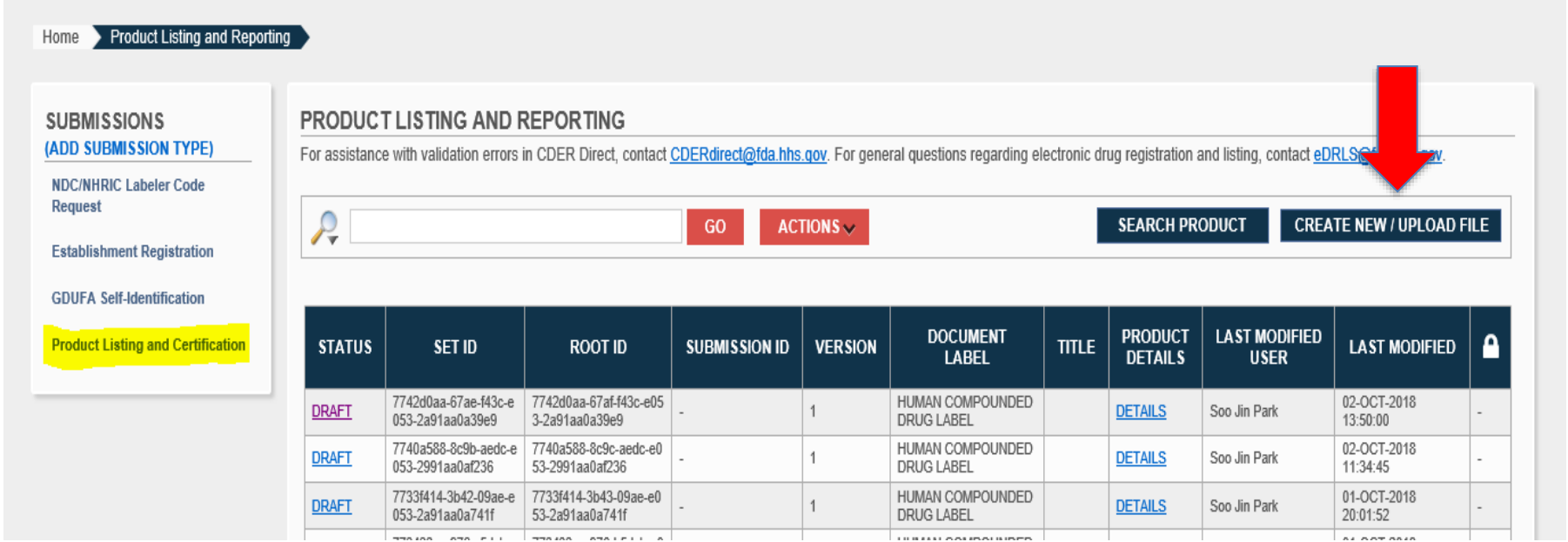
- **Upon Registration, an outsourcer must:**
  - Submit an initial product reporting of all compounded products
  - Must submit in June and December

What to include in PR

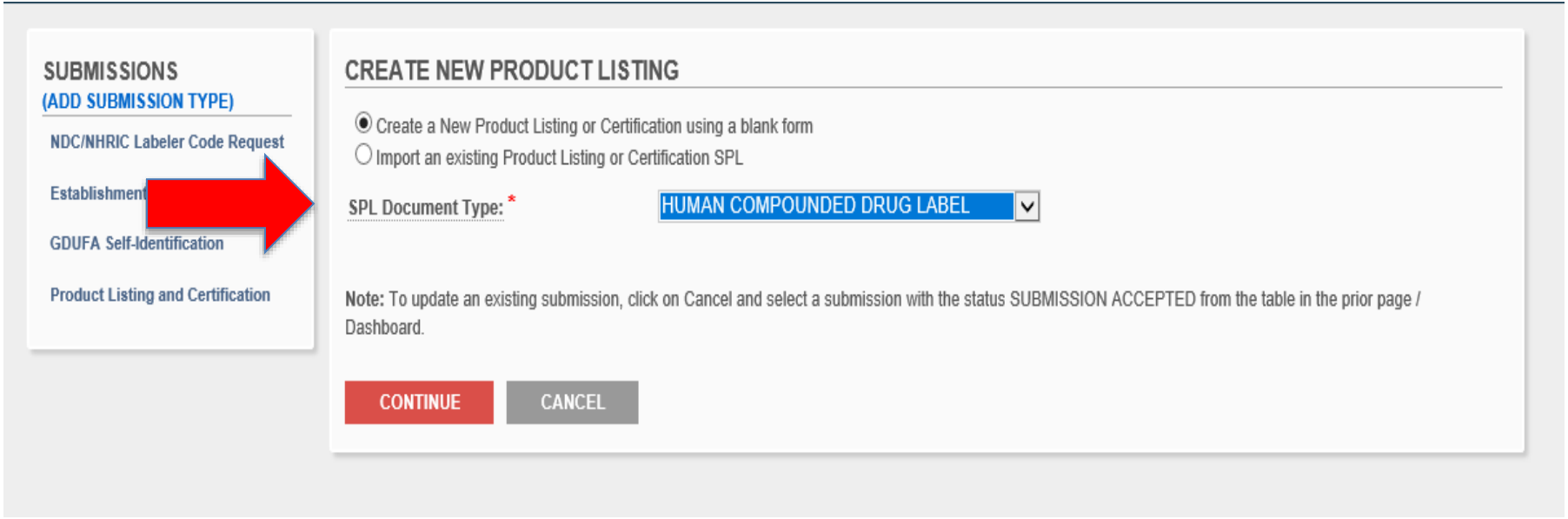
- Active ingredient and strength of active ingredient per unit
- Source of the active ingredient and NDC of the source drug or bulk active ingredient
- Dosage form and route of administration
- Package description
- Number of individual units produced
- NDC number of the final product, if assigned

CDER Direct Product Reporting Submission Demo & Common Errors

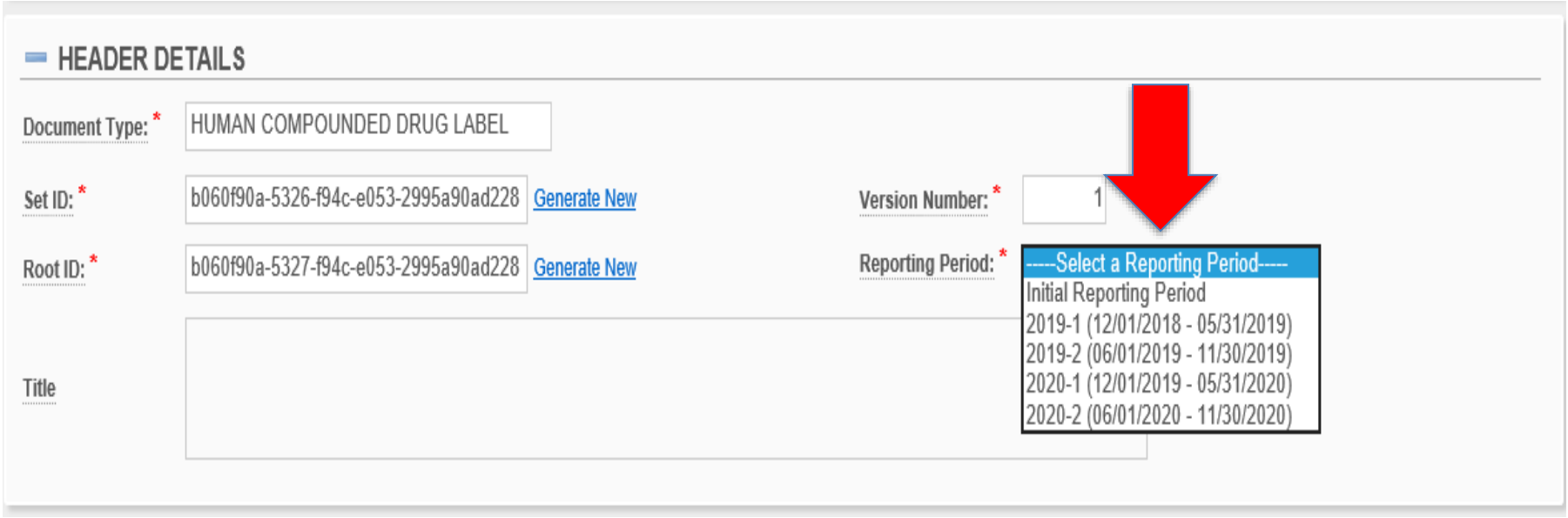
CDER Direct Product Reporting



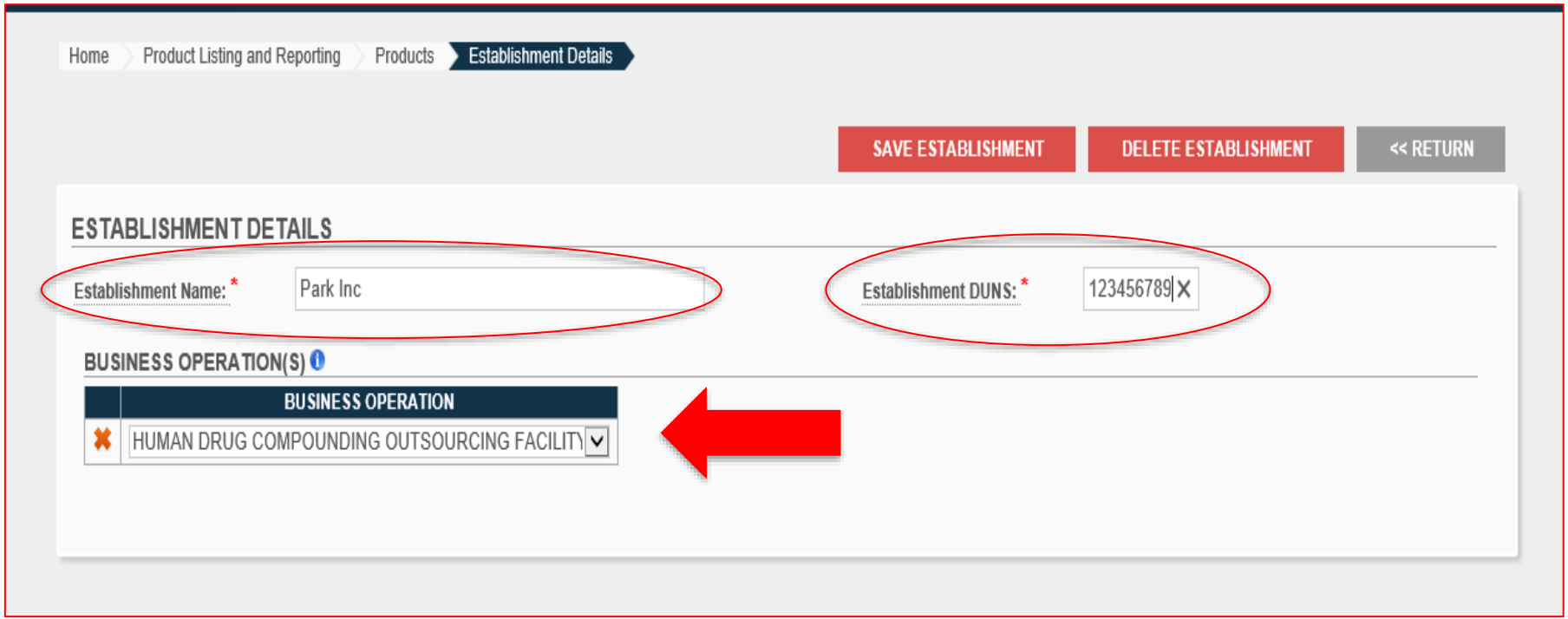
Create New Product Listing



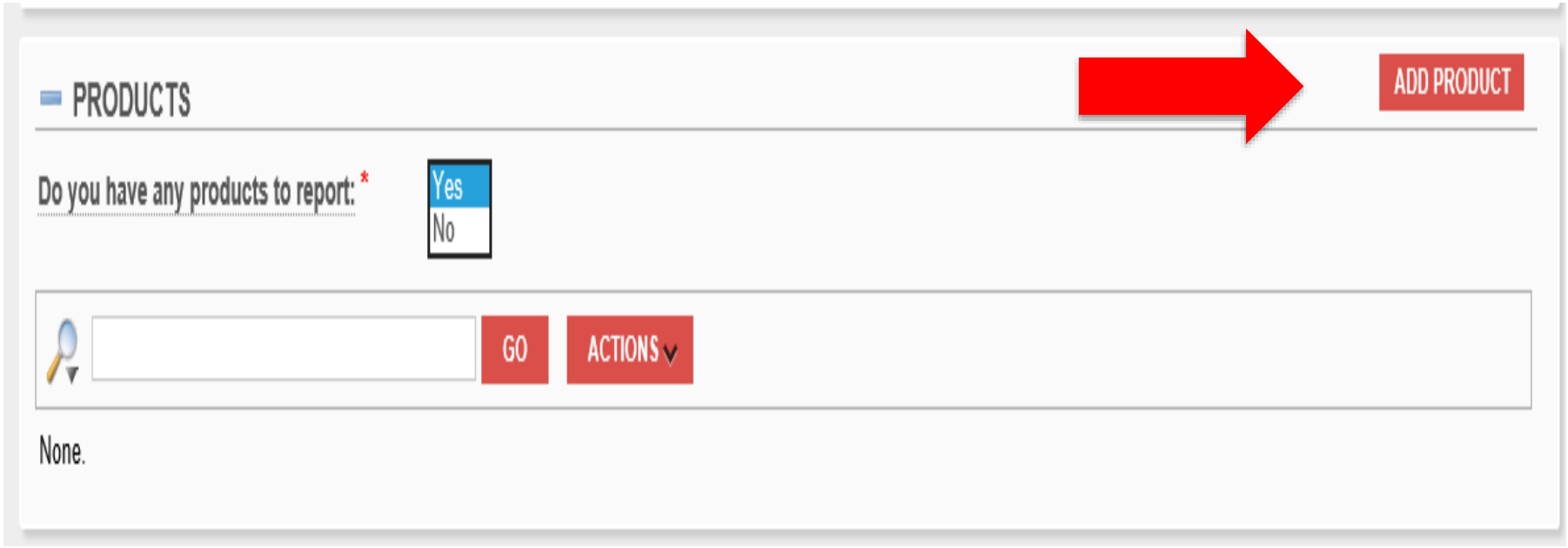
Header Details



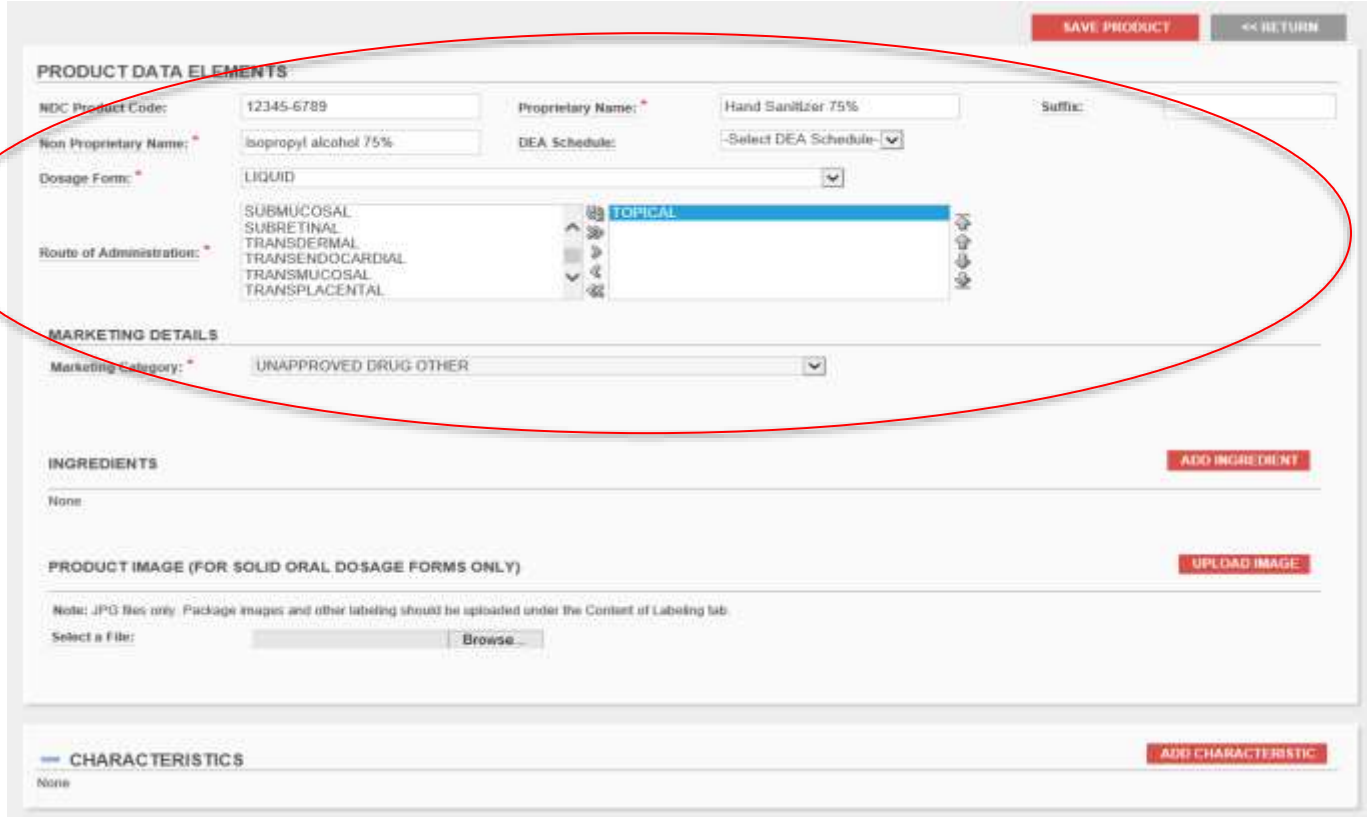
Establishment Details



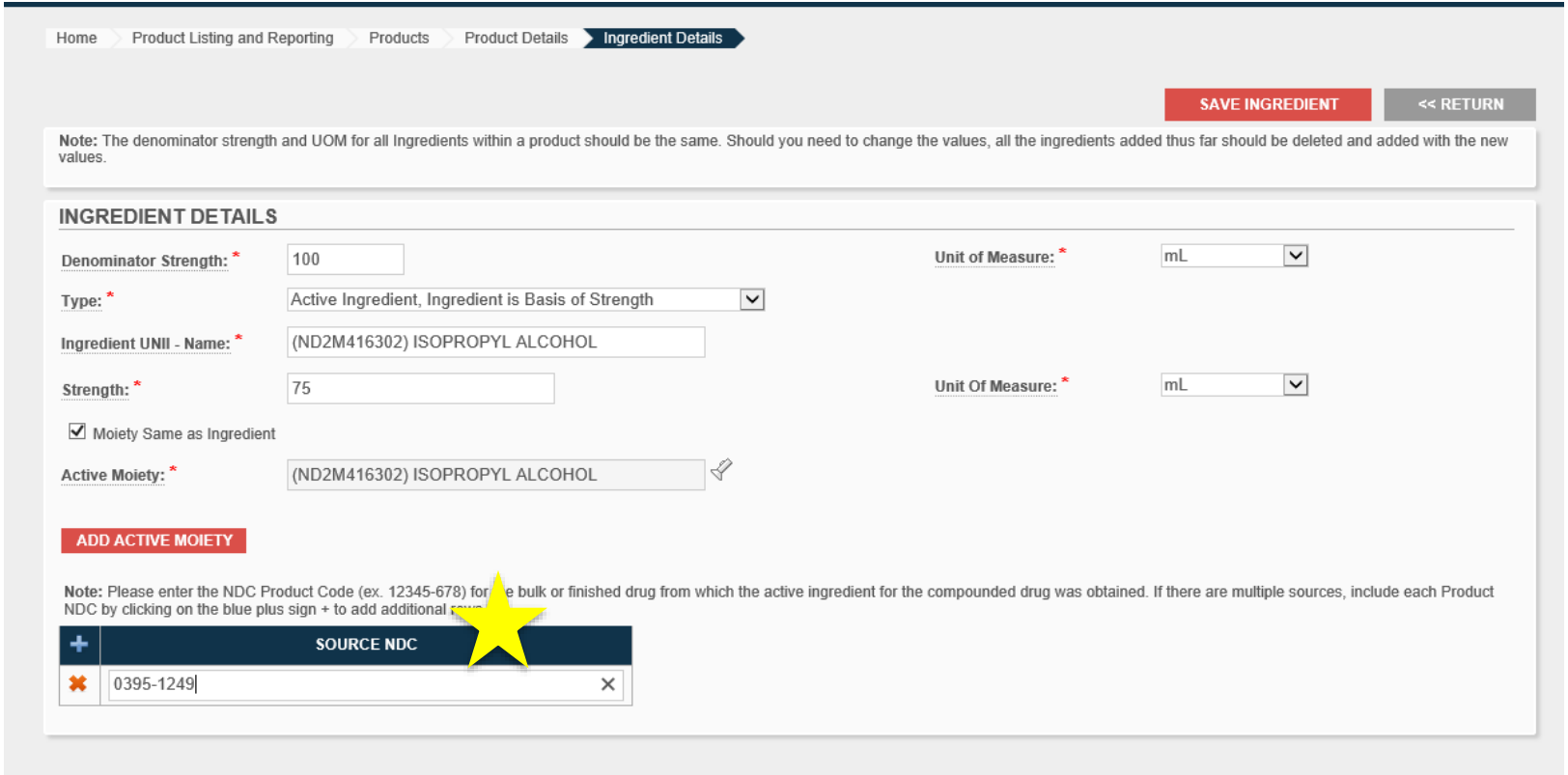
Add Product


PRODUCTS
ADD PRODUCT
Do you have any products to report: *
Yes
No
GO
ACTIONS
None.

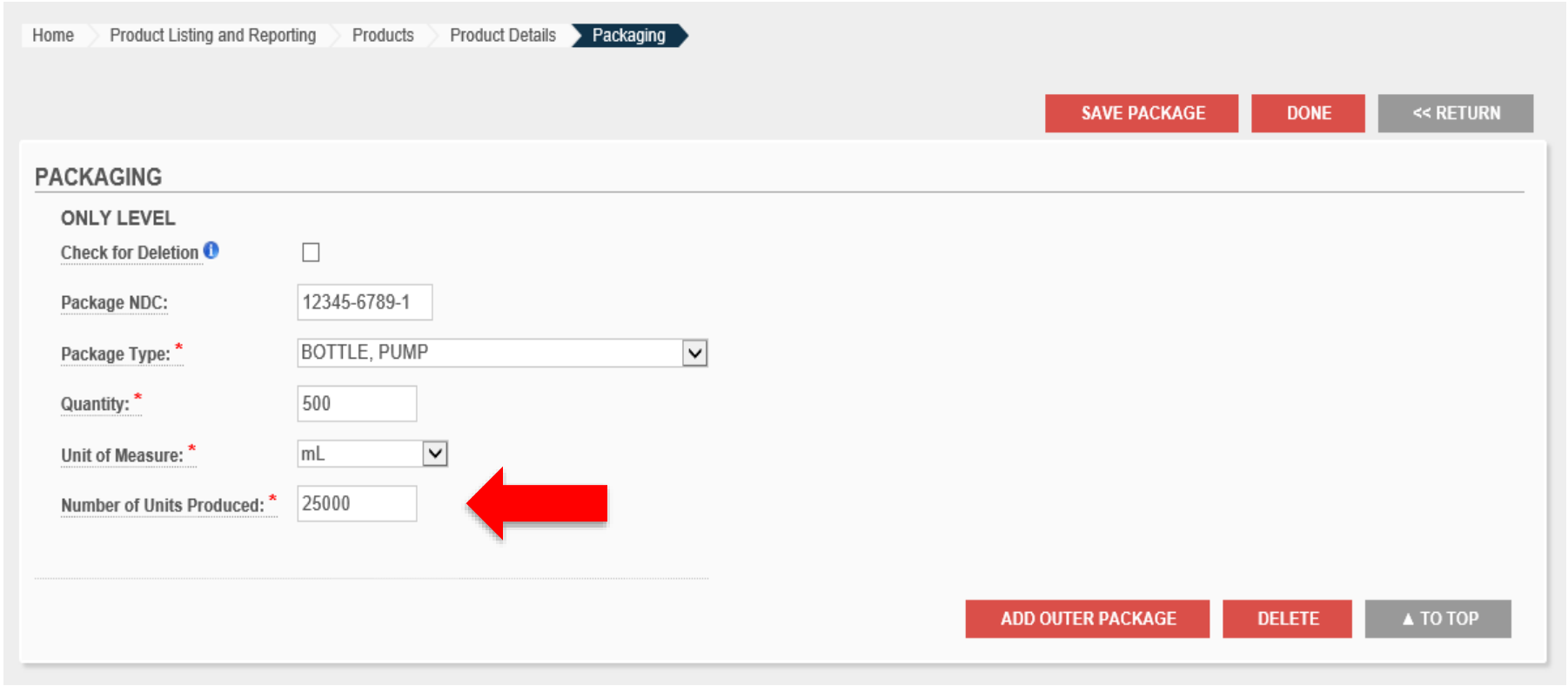
Product Data Elements



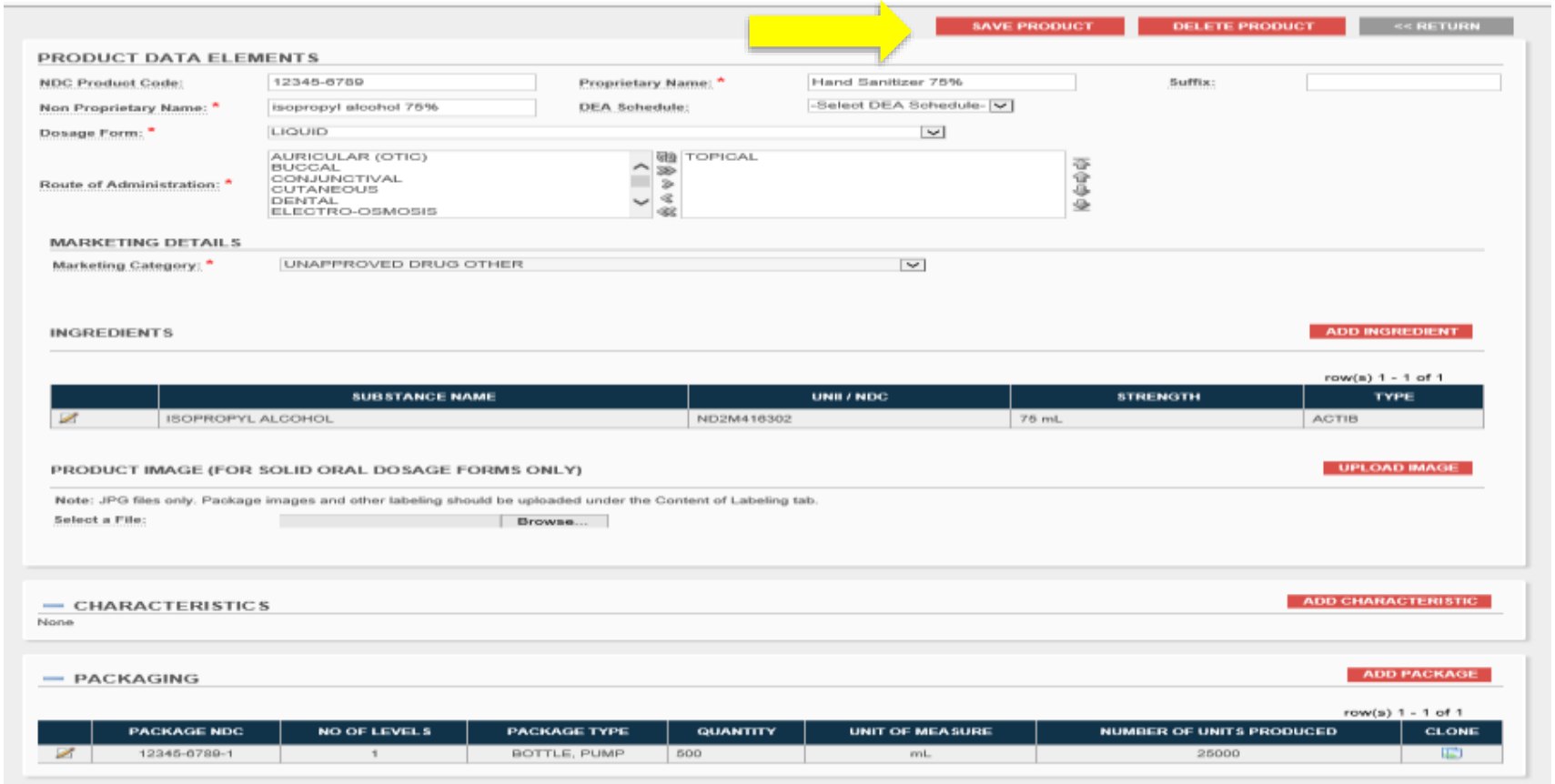
Ingredient Details



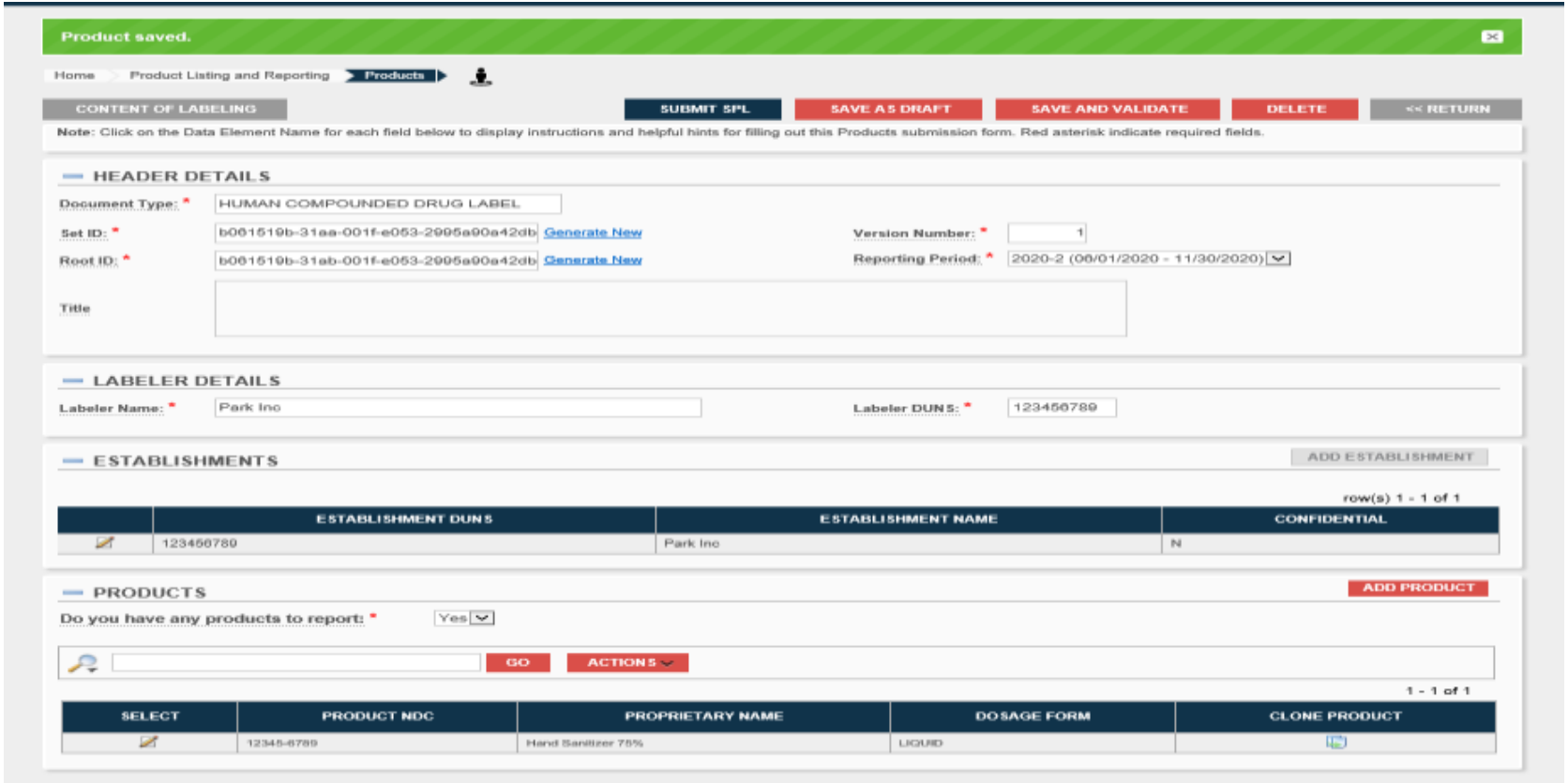
Packaging Section



Product Reporting SPL



Product Reporting SPL



PR Common Errors

- Ingredient source NDC MUST have been previously submitted to FDA
  - Must be a known listed product
  - Verify listing status of source NDC
- SAME active ingredient as the compounded drug product

PR Common Errors

- If the NDC product code was previously submitted, then following must remain the same as in the most recent submission for this NDC product code:

- Product Name, Nonproprietary Name

- Active ingredient UNIIs and active ingredient strengths

Summary

- Required to submit product reporting in June and December
- Source NDC is REQUIRED for all source drug ingredients
- Data Files for Unfinished Drugs are available on FDA's National Drug Code (NDC) Directory: https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm
- Prepare ahead of time to get ingredient NDCs and verify listing status

Helpful Resources

- **The Drug Quality and Security Act: Human Drug Compounding Outsourcing Facility:** http://wcms.fda.gov/FDAgov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376732.htm

- **Guidance for Industry: Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (Final Guidance):** http://wcms.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM424303.pdf

Helpful Resources

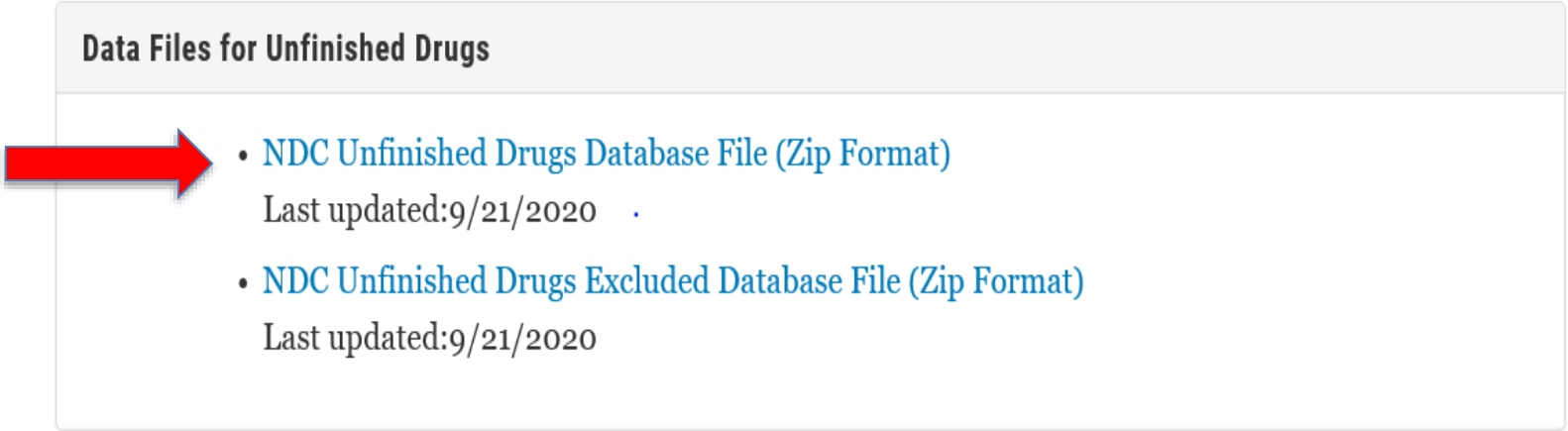
- **Electronic Drug Registration and Listing Instructions:** https://www.fda.gov/drugs/drug-registration-and-listing-system-drls-and-edrls/electronic-drug-registration-and-listing-instructions

- **Human Drug Compounding Website:** https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding

- **503B Compounding Dashboard:** http://wcms.fda.gov/FDAgov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm

Helpful Resources

- **National Drug Code Directory:**
  https://www.fda.gov/drugs/informationondrugs/ucm142438.htm



Helpful Resources

https://www.accessdata.fda.gov/scripts/cder/outsourcingfacility/index.cfm

Challenge Question

Which of the following are TRUE statements related to 503B Outsourcing Facility and Product Reporting?

A. Source NDC must be listed with FDA.

B. They are exempted from cGMP Requirements.

C. Assignment of an NDC number to a final product is not required.

D. If a firm register in April 2021, they are not required to submit an initial product reporting as long as they submit one by end of June 2021.

Contact Us!

- **eDRLS Helpdesk:** edrls@fda.hhs.gov
- **CDER Direct Helpdesk:** CDERdirect@fda.hhs.gov
- **Compounding Helpdesk:** Compounding@fda.hhs.gov


THANK
YOU