503B Outsourcing Facilities: Regulations and Product Reporting submission using CDER Direct

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Learning Objectives

- Regulation
  - 503B Registration
  - 503B Product Reporting
- CDER Direct Demo
  - 503B Product Reporting
- Summary
- Related Resources

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

If all conditions in section 503B are met, drugs compounded by outsourcing facilities are:

- Exempted from FDA approval requirements
- Exempted from certain labeling requirements

Outsourcing facilities are NOT exempted from cGMP Requirements

Regulations

- **Upon Registration, an outsourcer must:**
  - Submit an initial product reporting of all drugs compounded in the previous six months
  - Submit twice a year thereafter, in June and December

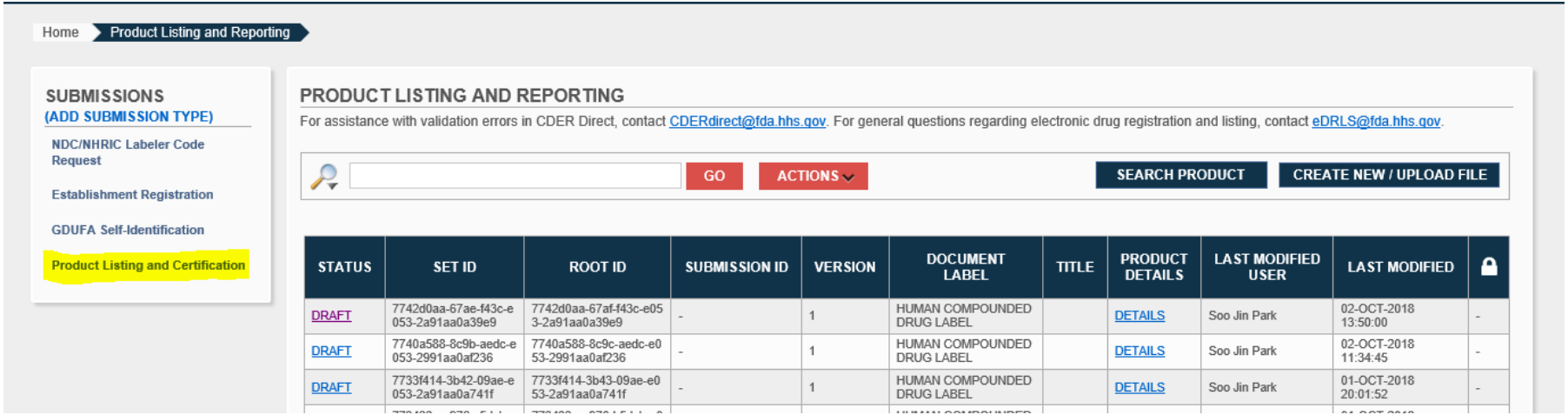
What to include in PR

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

Product Reporting Submission Using CDER Direct

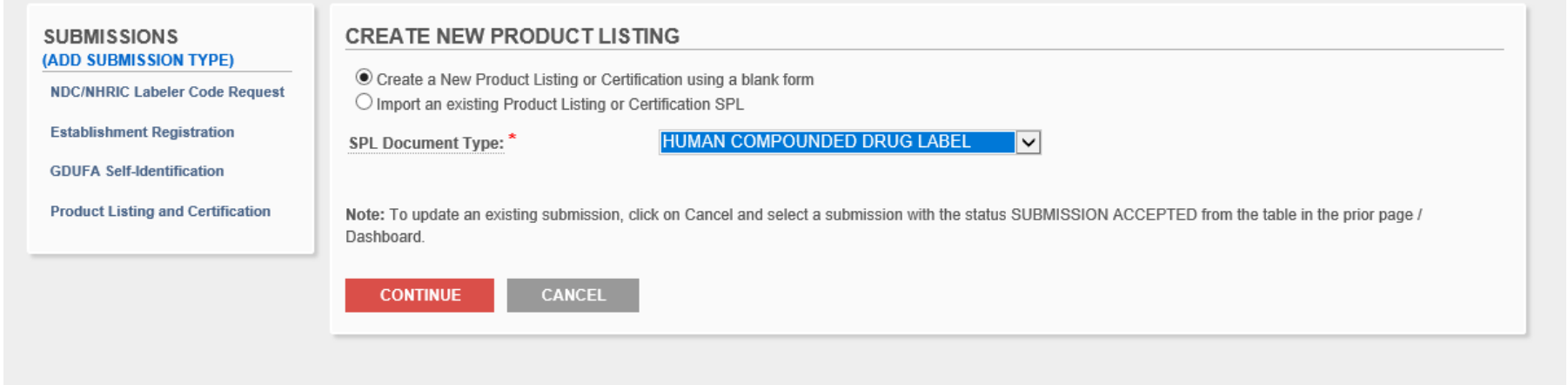
https://direct.fda.gov/apex/f?p=100:LOGIN_DESKTOP:110075839484836

Product Listing and Certification

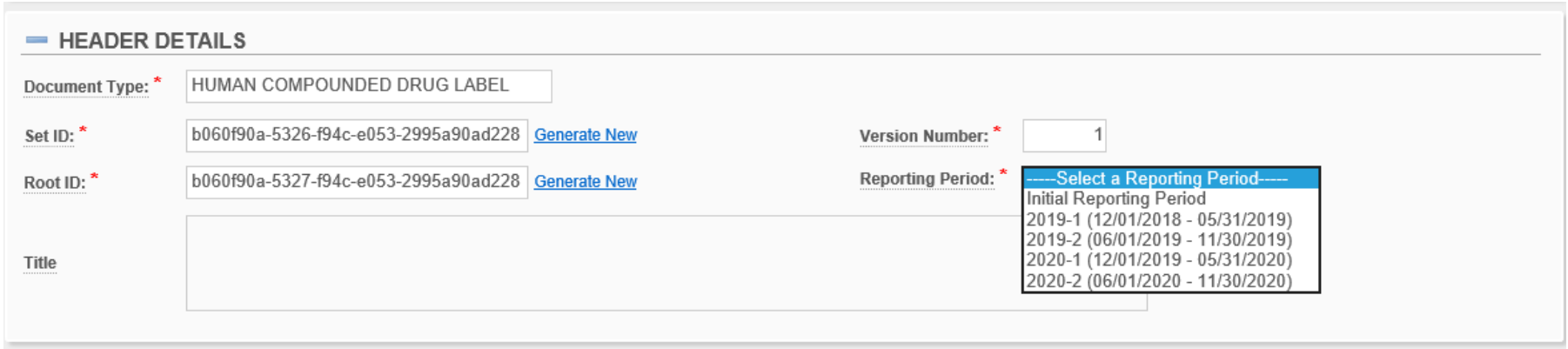


STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	TITLE	PRODUCT DETAILS	LAST MODIFIED USER	LAST MODIFIED	
DRAFT	7742d0aa-67ae-f43c-e053-2a91aa0a39e9	7742d0aa-67af-f43c-e053-2a91aa0a39e9	-	1	HUMAN COMPOUNDED DRUG LABEL		DETAILS	Soo Jin Park	02-OCT-2018 13:50:00	-
DRAFT	7740a588-8c9b-aedc-e053-2991aa0af236	7740a588-8c9c-aedc-e053-2991aa0af236	-	1	HUMAN COMPOUNDED DRUG LABEL		DETAILS	Soo Jin Park	02-OCT-2018 11:34:45	-
DRAFT	7733f414-3b42-09ae-e053-2a91aa0a741f	7733f414-3b43-09ae-e053-2a91aa0a741f	-	1	HUMAN COMPOUNDED DRUG LABEL		DETAILS	Soo Jin Park	01-OCT-2018 20:01:52	-

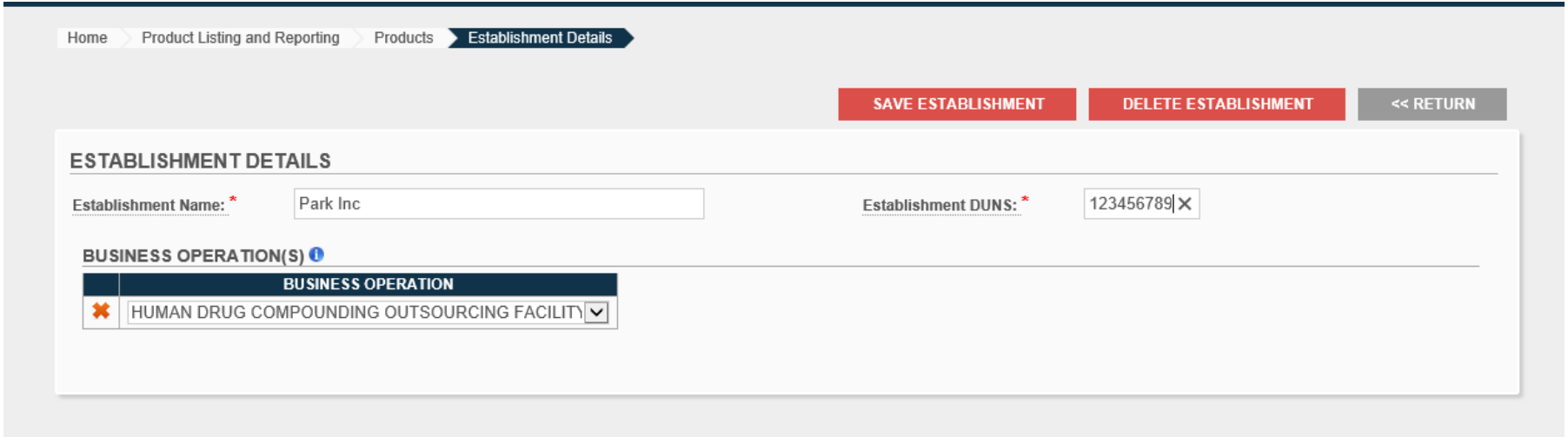
Create New Product Listing



Header Details

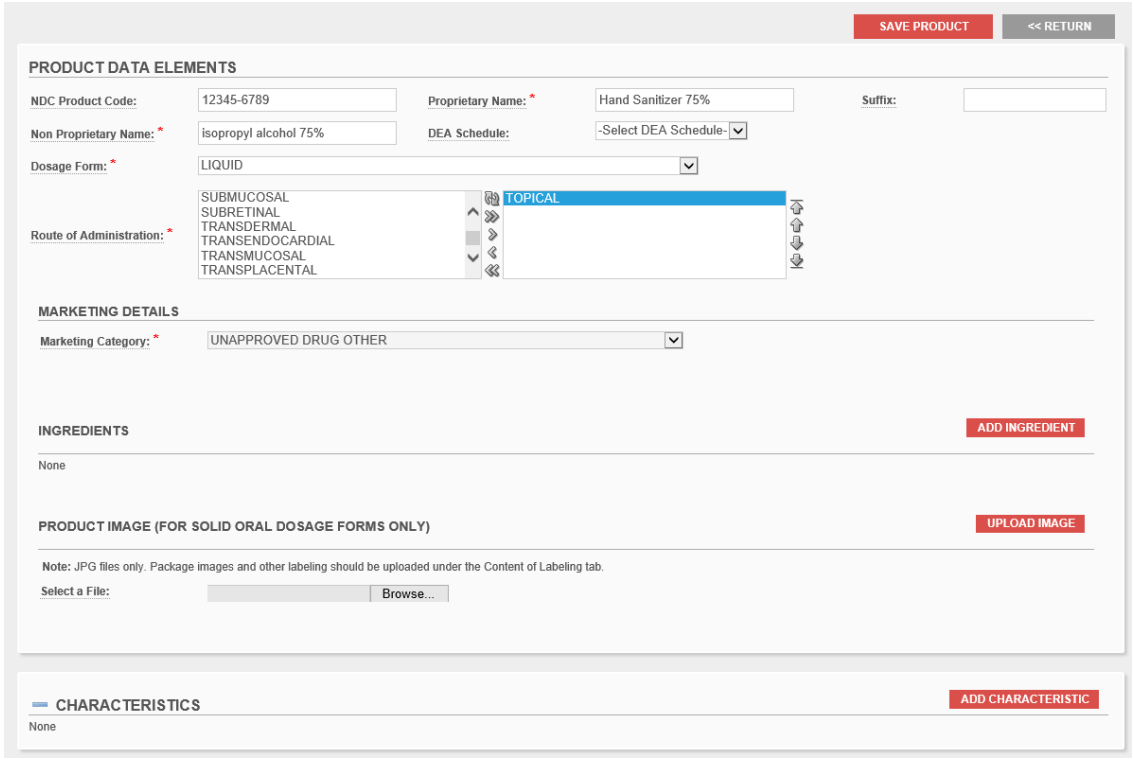


Establishment Details

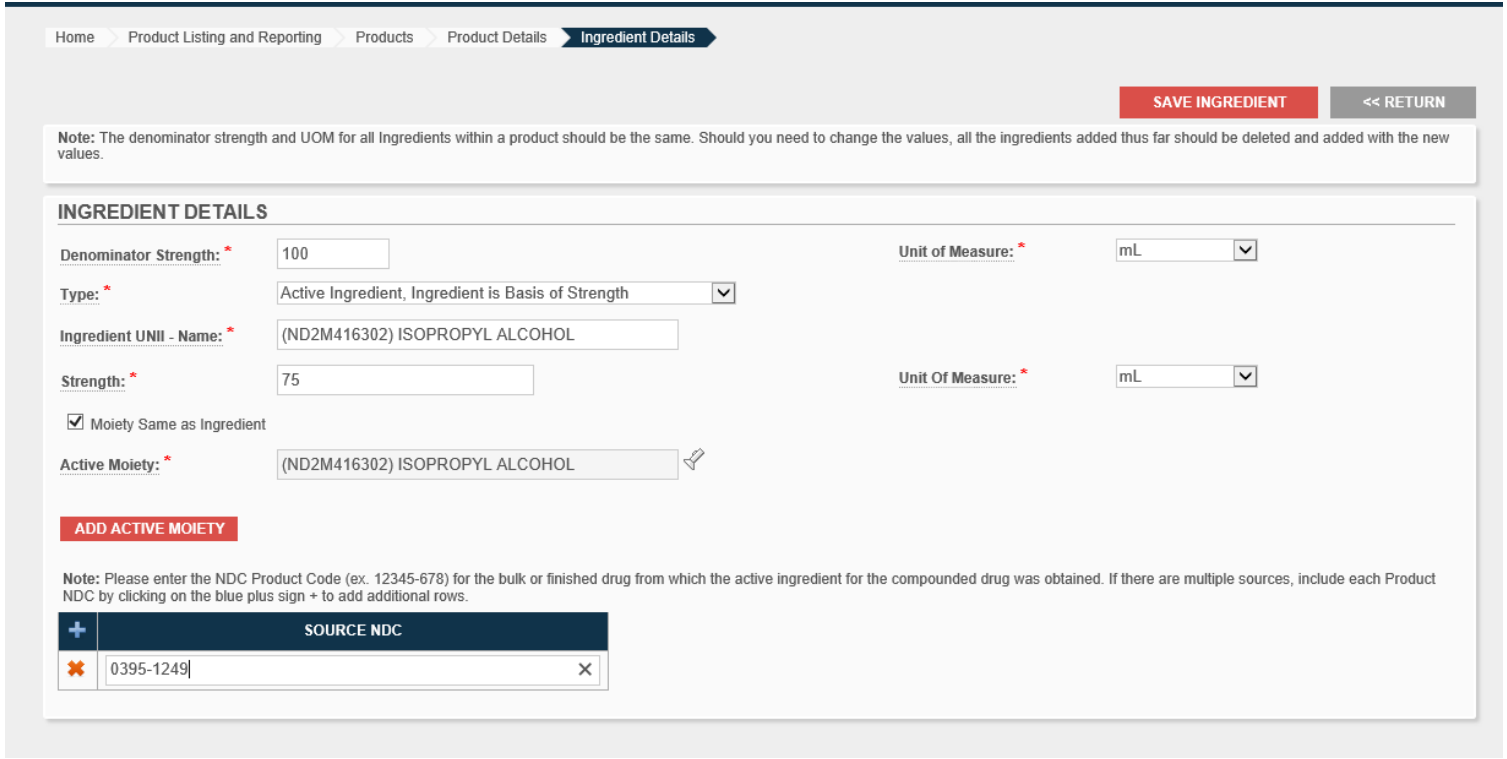


Add Products

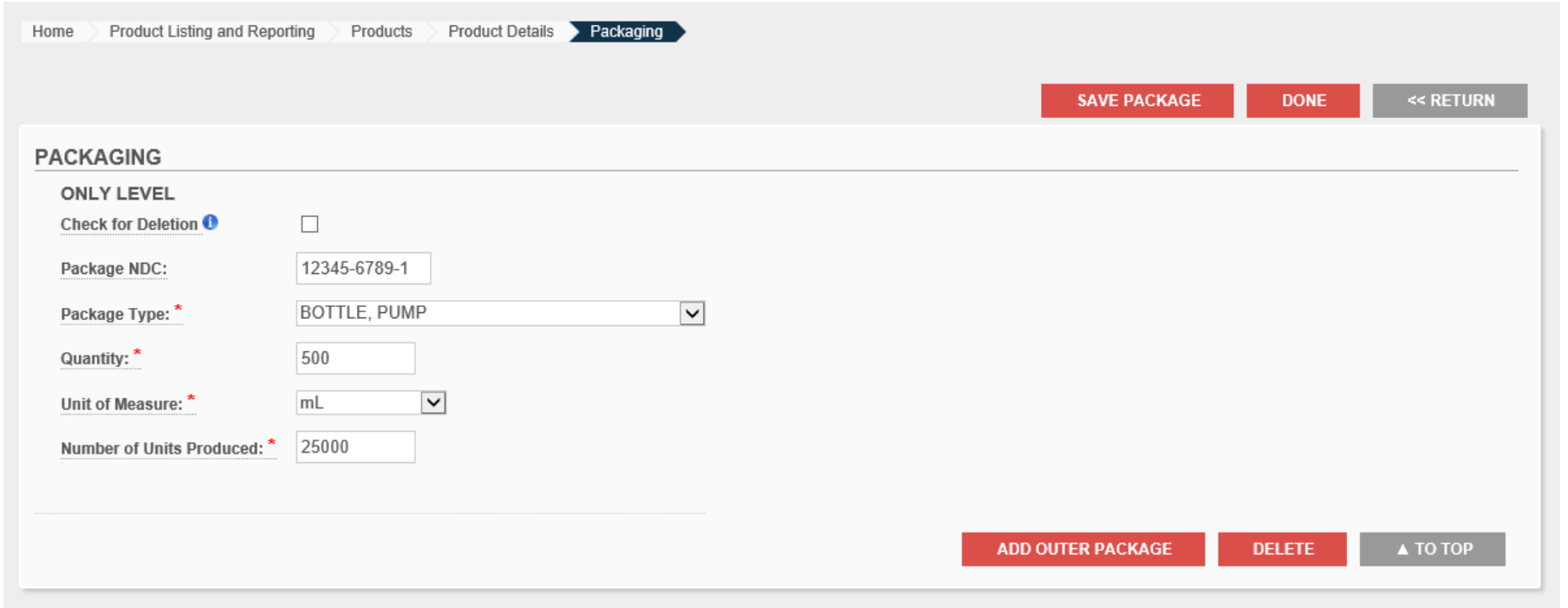
Product Data Elements



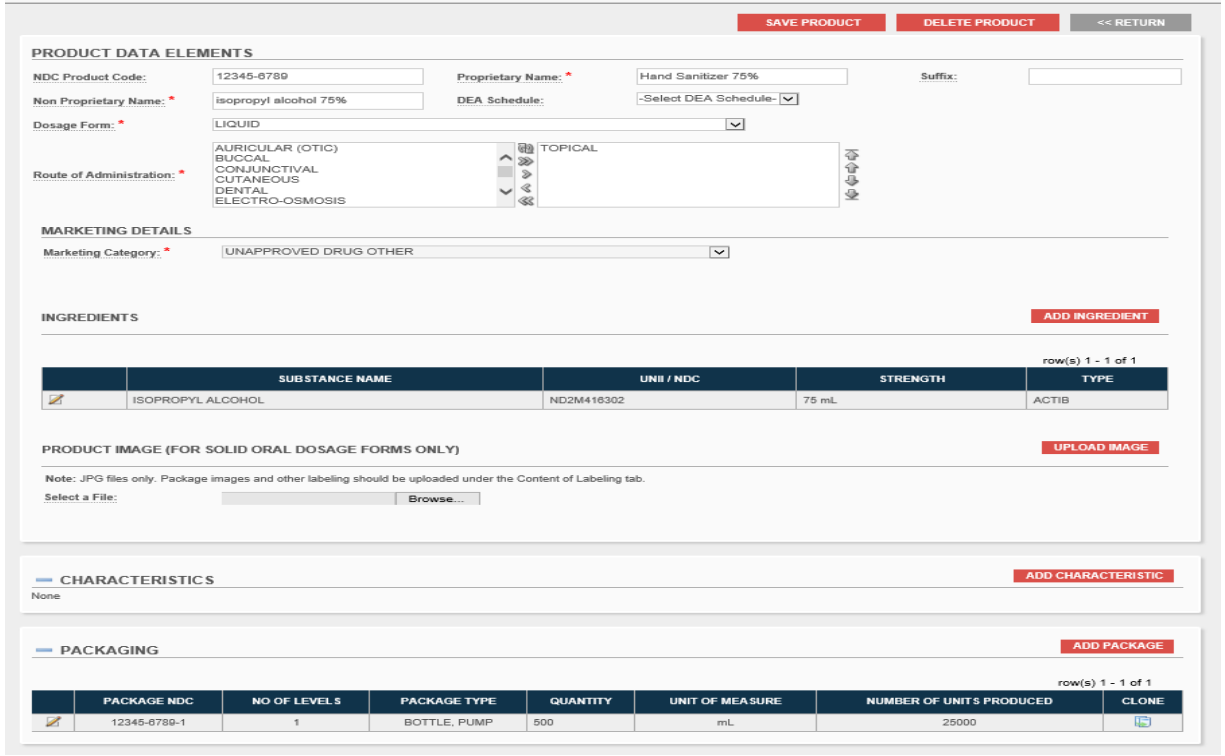
Ingredient Details



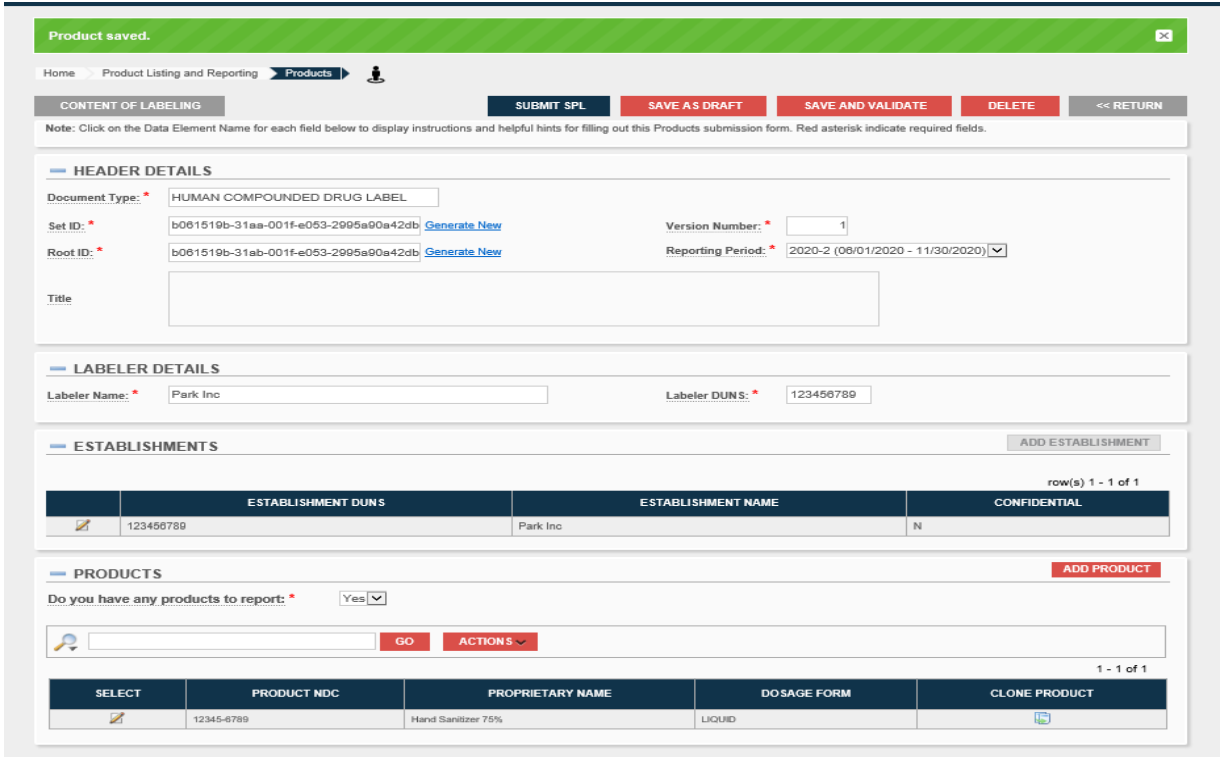
Packaging Details



Review: Product Submission



Content of Labeling



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

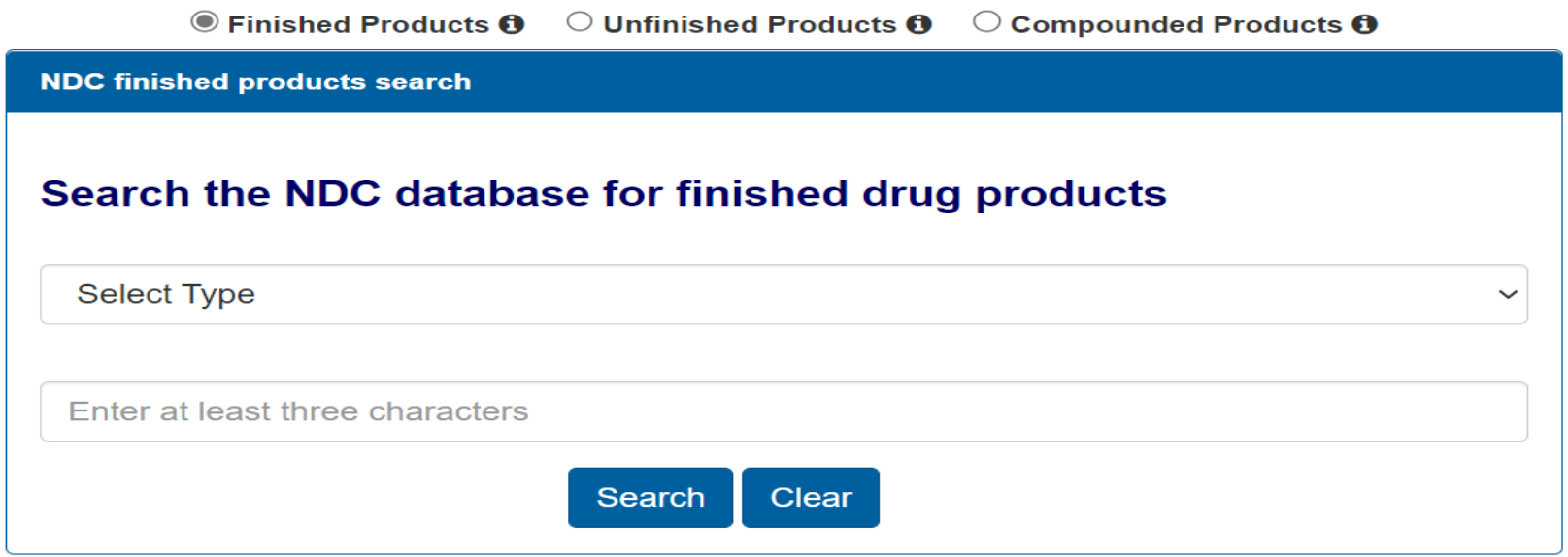
Helpful Resources

- **National Drug Code (NDC) Directory: https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory**
  - Finished compounded human drug products produced by outsourcing facilities that have elected to assign NDCs to their products
  - The marketing category “Outsourcing Facility Compounded Human Drug Product (Exempt from Approval Requirements)”
  - Includes the last two years (last four reporting periods)
    - beginning with the 2021-2 reporting period, i.e., June 01, 2021, thru November 30, 2021.

Helpful Resources

The National Drug Code (NDC) Directory is updated daily.
Current through: 7/12/2022

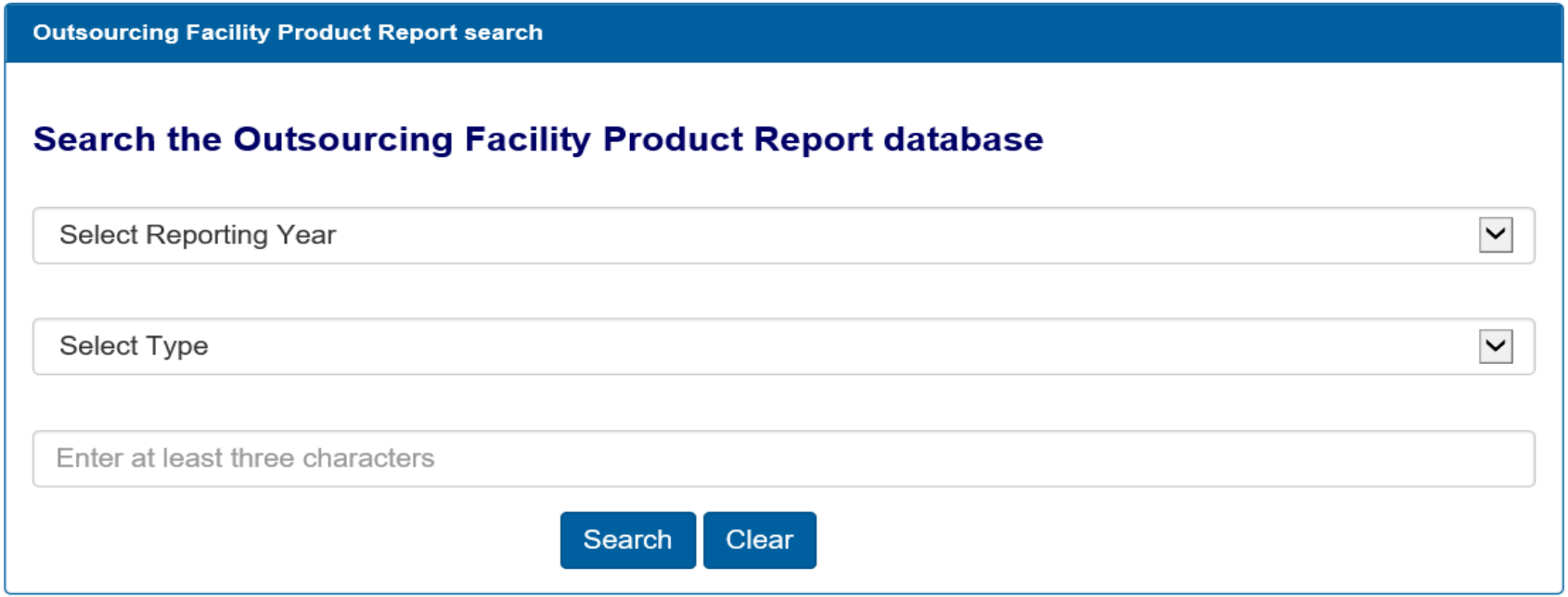
- NDC Application Programming Interface (API) (Firefox and Chrome recommended)



Helpful Resources

Outsourcing Facility Product Report

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



Contact Us!

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


THANK
YOU