

# **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**

*Learning Objectives*



# 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...**



# 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](https://direct.fda.gov/apex/f?p=100:LOGIN_DESKTOP:110075839484836)

# Product Listing and Certification

Home > Product Listing and Reporting

## SUBMISSIONS

[\(ADD SUBMISSION TYPE\)](#)

NDC/NHRIC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

**Product Listing and Certification**

## PRODUCT LISTING AND REPORTING

For assistance with validation errors in CDER Direct, contact [CDERdirect@fda.hhs.gov](mailto:CDERdirect@fda.hhs.gov). For general questions regarding electronic drug registration and listing, contact [eDRLS@fda.hhs.gov](mailto:eDRLS@fda.hhs.gov).




GO

ACTIONS ▾

SEARCH PRODUCT

CREATE NEW / UPLOAD FILE

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



# Create New Product Listing



## SUBMISSIONS

[\(ADD SUBMISSION TYPE\)](#)

NDC/NHRC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

Product Listing and Certification

## CREATE NEW PRODUCT LISTING

- Create a New Product Listing or Certification using a blank form
- Import an existing Product Listing or Certification SPL

SPL Document Type: \*

HUMAN COMPOUNDED DRUG LABEL 

Note: To update an existing submission, click on Cancel and select a submission with the status SUBMISSION ACCEPTED from the table in the prior page / Dashboard.

CONTINUE

CANCEL

# Header Details



**— HEADER DETAILS**

**Document Type:** \* HUMAN COMPOUNDED DRUG LABEL

**Set ID:** \* b060f90a-5326-f94c-e053-2995a90ad228 [Generate New](#)

**Version Number:** \* 1

**Root ID:** \* b060f90a-5327-f94c-e053-2995a90ad228 [Generate New](#)

**Reporting Period:** \* **Select a Reporting Period**

- Initial Reporting Period
- 2019-1 (12/01/2018 - 05/31/2019)
- 2019-2 (06/01/2019 - 11/30/2019)
- 2020-1 (12/01/2019 - 05/31/2020)
- 2020-2 (06/01/2020 - 11/30/2020)

**Title**

# Establishment Details



Home > Product Listing and Reporting > Products > Establishment Details

SAVE ESTABLISHMENT

DELETE ESTABLISHMENT

<< RETURN

## ESTABLISHMENT DETAILS

Establishment Name: \*

Establishment DUNS: \*  X

### BUSINESS OPERATION(S) ⓘ

BUSINESS OPERATION	
X	HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY <input type="checkbox"/>

# Add Products



**PRODUCTS** ADD PRODUCT

Do you have any products to report: \*

None.

# Product Data Elements



SAVE PRODUCT << RETURN

**PRODUCT DATA ELEMENTS**

NDC Product Code:  Proprietary Name: \*  Suffix:

Non Proprietary Name: \*  DEA Schedule:

Dosage Form: \*

Route of Administration: \*

- SUBMUCOSAL
- SUBRETINAL
- TRANSDERMAL
- TRANSDOCARDIAL
- TRANSMUCOSAL
- TRANSPLEURAL

**MARKETING DETAILS**

Marketing Category: \*

**INGREDIENTS** ADD INGREDIENT

None

**PRODUCT IMAGE (FOR SOLID ORAL DOSAGE FORMS ONLY)** UPLOAD IMAGE

Note: JPG files only. Package images and other labeling should be uploaded under the Content of Labeling tab.

Select a File:  Browse...

**CHARACTERISTICS** ADD CHARACTERISTIC

None

# Ingredient Details



Home > Product Listing and Reporting > Products > Product Details > Ingredient Details

SAVE INGREDIENT

<< RETURN

Note: The denominator strength and UOM for all Ingredients within a product should be the same. Should you need to change the values, all the ingredients added thus far should be deleted and added with the new values.

## INGREDIENT DETAILS

Denominator Strength: *	<input type="text" value="100"/>	Unit of Measure: *	<input type="text" value="mL"/>
Type: *	<input type="text" value="Active Ingredient, Ingredient is Basis of Strength"/>		
Ingredient UNII - Name: *	<input type="text" value="(ND2M416302) ISOPROPYL ALCOHOL"/>		
Strength: *	<input type="text" value="75"/>	Unit Of Measure: *	<input type="text" value="mL"/>
<input checked="" type="checkbox"/> Moiety Same as Ingredient			
Active Moiety: *	<input type="text" value="(ND2M416302) ISOPROPYL ALCOHOL"/>		

ADD ACTIVE MOIETY

Note: Please enter the NDC Product Code (ex. 12345-678) for the bulk or finished drug from which the active ingredient for the compounded drug was obtained. If there are multiple sources, include each Product NDC by clicking on the blue plus sign + to add additional rows.

+	SOURCE NDC
✗	<input type="text" value="0395-1249"/>

# Packaging Details

Home > Product Listing and Reporting > Products > Product Details > Packaging

SAVE PACKAGE

DONE

<< RETURN

## PACKAGING

### ONLY LEVEL

Check for Deletion 

Package NDC:

12345-6789-1

Package Type: \*

BOTTLE, PUMP



Quantity: \*

500

Unit of Measure: \*

mL



Number of Units Produced: \*

25000

ADD OUTER PACKAGE

DELETE

▲ TO TOP

# Review: Product Submission



SAVE PRODUCT
DELETE PRODUCT
<< RETURN

### PRODUCT DATA ELEMENTS

**NDC Product Code:** 
**Proprietary Name:** 
**Suffix:**

**Non Proprietary Name:** 
**DEA Schedule:**

**Dosage Form:**

**Route of Administration:**

AURICULAR (OTIC)	TOPICAL
BUCCAL	
CONJUNCTIVAL	
CUTANEOUS	
DENTAL	
ELECTRO-OSMOSIS	

---

### MARKETING DETAILS

**Marketing Category:**

---

### INGREDIENTS

ADD INGREDIENT

row(s) 1 - 1 of 1

	SUBSTANCE NAME	UNII / NDC	STRENGTH	TYPE
	ISOPROPYL ALCOHOL	ND2M416302	75 mL	ACTIB

---

### PRODUCT IMAGE (FOR SOLID ORAL DOSAGE FORMS ONLY)

UPLOAD IMAGE

Note: JPG files only. Package images and other labeling should be uploaded under the Content of Labeling tab.

Select a File:  Browse...

---

### CHARACTERISTICS

ADD CHARACTERISTIC

None

---

### PACKAGING

ADD PACKAGE

row(s) 1 - 1 of 1

	PACKAGE NDC	NO OF LEVELS	PACKAGE TYPE	QUANTITY	UNIT OF MEASURE	NUMBER OF UNITS PRODUCED	CLONE
	12345-0789-1	1	BOTTLE, PUMP	500	mL	25000	



# Content of Labeling



**Product saved.** [X]

Home > Product Listing and Reporting > Products > [User Icon]

**CONTENT OF LABELING** [SUBMIT SPL] [SAVE AS DRAFT] [SAVE AND VALIDATE] [DELETE] [RETURN]

Note: Click on the Data Element Name for each field below to display instructions and helpful hints for filling out this Products submission form. Red asterisk indicate required fields.

**HEADER DETAILS**

Document Type: \* HUMAN COMPOUNDED DRUG LABEL

Set ID: \* b061519b-31aa-001f-e053-2995a90a42db [Generate New](#) Version Number: \* [1]

Root ID: \* b061519b-31ab-001f-e053-2995a90a42db [Generate New](#) Reporting Period: \* 2020-2 (06/01/2020 - 11/30/2020) [v]

Title

[Empty text box]

**LABELER DETAILS**

Labeler Name: \* Park Inc Labeler DUNS: \* 123456789

**ESTABLISHMENTS** [ADD ESTABLISHMENT]

row(s) 1 - 1 of 1

	ESTABLISHMENT DUNS	ESTABLISHMENT NAME	CONFIDENTIAL
[Edit]	123456789	Park Inc	N

**PRODUCTS** [ADD PRODUCT]

Do you have any products to report: \* [Yes] [v]

[Search Icon] [GO] [ACTIONS v]

1 - 1 of 1

SELECT	PRODUCT NDC	PROPRIETARY NAME	DOSAGE FORM	CLONE PRODUCT
[Edit]	12345-6789	Hand Sanitizer 75%	LIQUID	[Clone Icon]



# 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)

Finished Products ⓘ    Unfinished Products ⓘ    Compounded Products ⓘ

**NDC finished products search**

**Search the NDC database for finished drug products**

Select Type ▼

Enter at least three characters

**Search** **Clear**



# Helpful Resources

## Outsourcing Facility Product Report

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

**Outsourcing Facility Product Report search**

**Search the Outsourcing Facility Product Report database**

Select Reporting Year

Select Type

Enter at least three characters

# Contact Us!



- eDRLS Helpdesk: [edrls@fda.hhs.gov](mailto:edrls@fda.hhs.gov)
- CDER Direct Helpdesk: [CDERdirect@fda.hhs.gov](mailto:CDERdirect@fda.hhs.gov)
- Compounding Helpdesk: [Compounding@fda.hhs.gov](mailto:Compounding@fda.hhs.gov)





