

CDER Direct

503B Product Reporting

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Learning Objectives

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

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

- **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

[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. For general questions regarding electronic drug registration and listing, contact eDRLSC@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	
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	-

8

Create New Product Listing



SUBMISSIONS

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

NDC/NHRIC Labeler Code Request

Establishment

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](#)

Root ID: *

b060f90a-5327-f94c-e053-2995a90ad228

[Generate New](#)

Title

Version Number: *

1

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)

Establishment Details



Home > Product Listing and Reporting > Products > Establishment Details

SAVE ESTABLISHMENT

DELETE ESTABLISHMENT

<< RETURN

ESTABLISHMENT DETAILS

Establishment Name: *

Park Inc

Establishment DUNS: *

123456789|X

BUSINESS OPERATION(S) ⓘ

BUSINESS OPERATION



HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY ▼



Add Product

PRODUCTS

ADD PRODUCT

Do you have any products to report: *

Yes
No



GO

ACTIONS ▼

None.

Product Data Elements

A screenshot of a web application form titled "PRODUCT DATA ELEMENTS". The form is divided into several sections. A red oval highlights the top section, which includes fields for "NDC Product Code" (12345-6789), "Proprietary Name" (Hand Sanitizer 75%), "Non Proprietary Name" (Isopropyl alcohol 75%), "Dosage Form" (LIQUID), "Route of Administration" (a list with "TOPICAL" selected), and "DEA Schedule" (-Select DEA Schedule-). Below this is the "MARKETING DETAILS" section with a "Marketing Category" dropdown set to "UNAPPROVED DRUG-OTHER". The "INGREDIENTS" section shows "None". The "PRODUCT IMAGE (FOR SOLID ORAL DOSAGE FORMS ONLY)" section has a "Select a File:" label and a "Browse..." button. The bottom section is "CHARACTERISTICS", also showing "None". On the right side of the form, there are buttons for "SAVE PRODUCT", "<< RETURN", "ADD INGREDIENT", "UPLOAD IMAGE", and "ADD CHARACTERISTIC".

PRODUCT DATA ELEMENTS

NDC Product Code: 12345-6789 Proprietary Name: Hand Sanitizer 75% Suffix:

Non Proprietary Name: Isopropyl alcohol 75% DEA Schedule: -Select DEA Schedule-

Dosage Form: LIQUID

Route of Administration: SUBMUCOSAL, SUBRETINAL, TRANSDERMAL, TRANSCARDIAL, TRANSMUCOSAL, TRANSPLEURAL, **TOPICAL**

MARKETING DETAILS

Marketing Category: UNAPPROVED DRUG-OTHER

INGREDIENTS

None

PRODUCT IMAGE (FOR SOLID ORAL DOSAGE FORMS ONLY)

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

Select a File: Browse...

CHARACTERISTICS

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: *

100

Unit of Measure: *

mL

Type: *

Active Ingredient, Ingredient is Basis of Strength

Ingredient UNII - Name: *

(ND2M416302) ISOPROPYL ALCOHOL

Strength: *

75

Unit Of Measure: *

mL

☒ Moiety Same as Ingredient

Active Moiety: *

(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 sources.

+	SOURCE NDC
✗	0395-1249

Packaging Section



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

Product Reporting SPL

SAVE PRODUCTDELETE PRODUCT<< RETURN

PRODUCT DATA ELEMENTS

NDC Product Code:

12345-6789

Proprietary Name:

Hand Sanitizer 75%

Suffix:

Non Proprietary Name:

isopropyl alcohol 75%

DEA Schedule:

-Select DEA Schedule-

Dosage Form:

LIQUID

Route of Administration:

AURICULAR (OTIC)
BUCCAL
CONJUNCTIVAL
CUTANEOUS
DENTAL
ELECTRO-OSMOSIS

TOPICAL


MARKETING DETAILS

Marketing Category:

UNAPPROVED DRUG OTHER

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)

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

Select a File:

Browse...

UPLOAD IMAGE



CHARACTERISTICS

None

ADD CHARACTERISTIC

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
	12345-6789-1	1	BOTTLE, PUMP	500	mL	25000	

Product Reporting SPL



Product saved.

Home > Product Listing and Reporting > Products >

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: *

Set ID: * [Generate New](#)

Root ID: * [Generate New](#)

Version Number: *

Reporting Period: *

Title

LABELER DETAILS

Labeler Name: *

Labeler DUNS: *

ESTABLISHMENTS

ADD ESTABLISHMENT

	ESTABLISHMENT DUNS	ESTABLISHMENT NAME	CONFIDENTIAL
	123456789	Park Inc	N

row(s) 1 - 1 of 1

PRODUCTS

ADD PRODUCT

Do you have any products to report: *

GO **ACTIONS**

1 - 1 of 1

SELECT	PRODUCT NDC	PROPRIETARY NAME	DOSE FORM	CLONE PRODUCT
	12345-6789	Hand Sanitizer 75%	LIQUID	

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 UNIs 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>

Data Files for Unfinished Drugs



- [NDC Unfinished Drugs Database File \(Zip Format\)](#)

Last updated:9/21/2020 .

- [NDC Unfinished Drugs Excluded Database File \(Zip Format\)](#)

Last updated:9/21/2020

Helpful Resources

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

Outsourcing Facility Product Report search

Search the Outsourcing Facility Product Report database

Select Reporting Year



Select Type



Enter at least three characters

Search

Clear



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 registers 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



