



**CDER** *Direct*

Electronic Submissions Portal

Office of Compounding Quality & Compliance  
CDER Office of Compliance  
U.S. Food and Drug Administration

# **CDER Direct – Human Compounded Drug Label**

Fall 2023



# Human Compounded Drug Label

The screenshot displays the CDER Direct Electronic Submissions Portal. The top navigation bar includes the FDA logo and the text "CDER Direct Electronic Submissions Portal". A "Home" button is located in the top left. The main content area is divided into two sections: "SUBMISSIONS" and "ALL SUBMISSIONS".

**SUBMISSIONS (ADD SUBMISSION TYPE)**

- NDC Labeler Code Request
- Establishment Registration** (highlighted with a red circle and a red arrow pointing to it with the text "Click on Establishment Registration")
- GDUFA Self-Identification
- Product Listing and Certification
- NDC Reservation
- WDD/3PL

**ALL SUBMISSIONS**

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).

Search bar with a magnifying glass icon, a "GO" button, and an "ACTIONS" dropdown menu.

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
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1 - 2



# Human Compounded Drug Label

The screenshot displays the CDER Direct Electronic Submissions Portal. At the top, the FDA logo and 'CDER Direct Electronic Submissions Portal' are visible. A navigation bar includes a 'Home' link and a dropdown menu for 'Establishment Registration', which is circled in red. A red arrow points to this menu with the text 'The menu level is indicated here'. On the left, a 'SUBMISSIONS' sidebar lists various submission types, with 'Establishment Registration' highlighted. The main content area is titled 'ESTABLISHMENT REGISTRATION' and includes a search bar with a 'GO' button and an 'ACTIONS' dropdown. Below the search bar, the text 'None' is displayed. To the right of the search bar are two buttons: 'SEARCH ESTABLISHMENT' and 'CREATE NEW / UPLOAD FILE'. A red arrow points to the 'CREATE NEW / UPLOAD FILE' button with the text 'Click on CREATE NEW// UPLOAD FILE'.

**FDA CDER Direct**  
Electronic Submissions Portal

Home **Establishment Registration**

**SUBMISSIONS**  
(ADD SUBMISSION TYPE)

- NDC Labeler Code Request
- Establishment Registration
- GDUFA Self-Identification
- Product Listing and Certification
- NDC Reservation
- WDD/3PL

**ESTABLISHMENT REGISTRATION**

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 [sDRLS@fda.hhs.gov](mailto:sDRLS@fda.hhs.gov).

Q  **GO** **ACTIONS**  **CREATE NEW / UPLOAD FILE**

None

Click on  
**CREATE NEW//  
UPLOAD FILE**



# Human Compounded Drug Label



**CDER Direct**  
Electronic Submissions Portal

## SUBMISSIONS

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

NDC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

Product Listing and Certification

NDC Reservation

WDD/3PL

## CREATE NEW ESTABLISHMENT REGISTRATION

☒ Create New Establishment Registration using a blank form

☐ Import an existing Establishment Registration RPL

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

Select radio  
button and  
click on  
CONTINUE

CDER Direct: [direct.fda.gov](https://direct.fda.gov)



# Human Compounded Drug Label

**FDA CDER Direct**  
Electronic Submissions Portal

Home Establishment Registration SPL Submission

**SAVE AS DRAFT** **<< RETURN**

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

**HEADER DETAILS**

Document Type: \* **Don't forget to select your Document Type**

Set ID: \* [Get Set ID](#)

Root ID: \* [Get Root ID](#)

Version Number: \* 1

Effective Date: \* 09-24-2023 [Calendar](#)

**REGISTRANT DETAILS**

Registrant Name: \* ABC Outsourcing Compounders

Registrant DUNS: \* 123456789

**REGISTRANT CONTACT DETAILS**

Contact Name: \* James Brown

Contact Email: \* james.brown@abcoc.com

Contact Phone: \* 1-202-555-1212 [Format](#)

Phone Extension: \*

**REGISTRANT CONTACT ADDRESS**

Country: \* United States

Street Address: \* 2001 Main St

City: \* Washington

State: \* District Of Columbia

Postal Code: \* 20001

**ESTABLISHMENTS**

None

**ADD ESTABLISHMENT**

**CONTACT HELP DESK**

CDER Direct: [direct.fda.gov](https://direct.fda.gov)



# Human Compounded Drug Label



**CDER Direct**  
Electronic Submissions Portal

Home Establishment Registration SPL Submission **Establishment**

Last - click  
**SAVE ESTABLISHMENT**

**SAVE ESTABLISHMENT**

<< RETURN

## ESTABLISHMENT DETAILS

Establishment Name: \* ABC Outsourcing Compounders

Establishment DUNS: \* 123456789

Establishment FEI: \*



## ESTABLISHMENT ADDRESS

Country: \* United States

Street Address: \* 2001 Main St

City: \* Washington

State: \* District Of Columbia

Postal Code: \* 20001

## ESTABLISHMENT CONTACT DETAILS

☒ Same as Registrant Contact Details

Contact Name: \* James Br

Contact Email: \* james.bro

Contact Phone: \* 1-202-555

Phone Extension:

### Business Operation/Qualifier

Business Operations:

HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY

Qualifier

- ☒ INTENT TO COMPOUND 505E (DRUG SHORTAGE) DRUGS
- ☐ NO INTENT TO COMPOUND 505E (DRUG SHORTAGE) DRUGS
- ☒ COMPOUNDING FROM BULK INGREDIENT
- ☐ NOT COMPOUNDING FROM BULK INGREDIENT
- ☒ COMPOUNDING STERILE PRODUCTS
- ☐ NOT COMPOUNDING STERILE PRODUCTS

CANCEL

SAVE

SAVE AND ADD

Then select and  
check qualifier

Note: Enter the one or more drug manufacturing and processing operations performed at the establishment.

**BUSINESS OPERATION(S)**

Click on ADD  
BUSINESS  
OPERATION


**ADD BUSINESS OPERATION**

Contact Help Desk


CDER Direct: [direct.fda.gov](http://direct.fda.gov)



# Human Compounded Drug Label

 **CDER Direct**  
Electronic Submissions Portal

Establishment information saved. ✕

[Home](#) > [Establishment Registration](#) > [SPL Submission](#) 

2

**SUBMIT SPL**

1

**SAVE AND VALIDATE**

**SAVE AS DRAFT** **DELETE** **<< RETURN**

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

— HEADER DETAILS

Document Type: \*

ESTABLISHMENT REGISTRATION

▼

Set ID: \*

063479c6-ad91-a072-e063-6b94af0a54ab

[Generate New](#)

Version Number: \*

1


Root ID: \*

063479c6-ad92-a072-e063-6b94af0a54ab

[Generate New](#)

Effective Date: \*

09-24-2023




Postal Code: \*

— ESTABLISHMENTS

**ADD ESTABLISHMENT**

row(s) 1 - 1 of 1

	ESTABLISHMENT DUNS	ESTABLISHMENT FEI	ESTABLISHMENT NAME
	123456789	-	ABC Outsourcing Compounders



# Human Compounded Drug Label



**CDER Direct**

Electronic Submissions Portal

Your SPL has been submitted to FDA and is awaiting additional in-depth validation. Check back on the status after a few minutes by refreshing the page or logging back into the CDER Direct Electronic Submissions Portal.

Home > Establishment Registration

## SUBMISSIONS

(ADD SUBMISSION TYPE)

NDC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

Product Listing and Certification

NDC Reservation

WDD/3PL

## ESTABLISHMENT REGISTRATION

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).

Q

GO

ACTIONS

SEARCH ESTABLISHMENT

CREATE NEW / UPLOAD FILE

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	REGISTRANT DUNS	REGISTRANT NAME	DOCUMENT LABEL	DETAILS	LAST MODIFIED USER	LAST MODIFIED DATE	
<a href="#">VALIDATION IN PROGRESS</a>	063479c6-ad91-a072-e063-6b04af0a54ab	063479c6-ad92-a072-e063-6b04af0a54ab		1	123456789	ABC Outsourcing Compounders	ESTABLISHMENT REGISTRATION	<a href="#">DETAILS</a>	James Brown	25-SEP-2023 15:16:35	

1 - 1

When successful  
you will see  
SUBMISSION ID

CDER Direct: [direct.fda.gov](https://direct.fda.gov)



# Human Compounded Drug Label

**FDA CDER Direct**  
Electronic Submissions Portal

Home Product Listing and Reporting

**SUBMISSIONS**  
(ADD SUBMISSION TYPE)

- NDC Labeler Code Request
- Establishment Registration
- QDUFA Self-identification
- Product Listing and Certification**
- NDC Reservation
- WDD/QPL

**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="#">SUBMISSION ACCEPTED</a>	05e4a4cb-3114-b38e-e063-6a94af0a1c3d	05e4a4cb-3115-b38e-e063-6a94af0a1c3d	cd5786412309-429637168@direct	1	HUMAN COMPOUNDED DRUG LABEL	-	<a href="#">DETAILS</a>	James Brown	21-SEP-2023 17:17:09

1 - 1

Click on Product Listing and Certification

Click here to begin new reporting



# Human Compounded Drug Label



**CDER Direct**  
Electronic Submissions Portal

## SUBMISSIONS

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

NDC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

Product Listing and Certification

NDC Reservation

WDD/3PL

## CREATE NEW PRODUCT LISTING AND REPORTING

☒ 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

Click on dash underlined words to get additional information

Then select  
**CONTINUE**

Red asterisk (\*) indicates mandatory

Select Human  
Compounded Drug Label

CDER Direct: [direct.fda.gov](https://direct.fda.gov)



# Human Compounded Drug Label

**FDA CDER Direct**  
Electronic Submissions Portal

Home Product Listing and Reporting **Products**

**SAVE AS DRAFT** **< 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	Version Number: *	1
Set ID: *	06231dfc-338a-f6c6-e063-6b94af0ae9b4 <a href="#">Generate New</a>	Effective Date: *	09-24-2023
Root ID: *	06231dfc-338b-f6c6-e063-6b94af0ae9b4 <a href="#">Generate New</a>	Reporting Period: *	—Select a Reporting Period— ▾
Title			

**LABELER DETAILS**

**PRODUCTS**

Do you have any products to report: \* No ▾

**ADD PRODUCT**

*Then - click on SAVE AS DRAFT*

*First - Select Reporting Period*



**FDA** **CDER Direct**  
Electronic Submissions Portal

*CDER Direct:* [direct.fda.gov](https://direct.fda.gov)



# Human Compounded Drug Label

**FDA CDER Direct**  
Electronic Submissions Portal

Home > Product Listing and Reporting > Products > Establishment Details

**Enter ESTABLISHMENT DETAILS**

**SAVE ESTABLISHMENT** **DELETE ESTABLISHMENT** << RETURN

**ESTABLISHMENT DETAILS**

Establishment Name: \* ABC Outsourcing Compounders

Establishment DUNS: \* 123456789

**BUSINESS OPERATION(S)** ⓘ

BUSINESS OPERATION	
✱	HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY ▼

**The BUSINESS OPERATION is defaulted to HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY**

**Then click on SAVE ESTABLISHMENT and be returned to prior screen to ADD PRODUCT**



# Human Compounded Drug Label

**FDA CDER Direct**  
Electronic Submissions Portal

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: \* HUMAN COMPOUNDED DRUG LABEL Version Number: \* 1

Set ID: \* 06238e1e-e089-ec18-e063-6a94af0a5279 [Generate New](#) Effective Date: \* 09-24-2023

Root ID: \* 06238e1e-e089-ec18-e063-6a94af0a5279 [Generate New](#) Reporting Period: \* 2023-2 (09/01/2023 - 11/30/2023)

**ESTABLISHMENTS** **ADD ESTABLISHMENT**

ESTABLISHMENT DUNS	ESTABLISHMENT NAME	CONFIDENTIAL
123456789	ABC Outsourcing Compounding	N

**PRODUCTS** **ADD PRODUCT**

Do you have any products to report: \* Yes **Select - Yes to report product**

**GO** **ACTIONS** **Then - ADD PRODUCT**



# Human Compounded Drug Label

**FDA CDER Direct**  
Electronic Submissions Portal

Home Product Listing and Reporting Products **Product Details**

**PRODUCT DATA ELEMENTS**

NDC Product Code: 12345-6789

Non Proprietary Name: Bupivacaine HCl

Proprietary Name: No Pain Bupivacaine PF

Suffix:

DEA Schedule: - Select DEA Schedule -

Dosage Form: INJECTION, SOLUTION

Route of Administration: PERINEURAL

**MARKETING DETAILS**

Marketing Category: - Select Marketing Category -  
- Select Marketing Category -  
OUTSOURCING FACILITY COMPOUNDED HUMAN DRUG PRODUCT (EXEMPT FROM APPROVAL REQUIREMENTS)  
OUTSOURCING FACILITY COMPOUNDED HUMAN DRUG PRODUCT (NOT MARKETED - NOT DISTRIBUTED)

**INGREDIENTS**

**PACKAGING**

**Buttons:** SAVE PRODUCT, DELETE PRODUCT, << RETURN, ADD INGREDIENT, ADD PACKAGE

**Annotations:**

- You may enter your assigned compounded drug NDC Product Code
- Enter the Non Proprietary Name
- Enter your assigned product Proprietary Name
- Select Dosage Form
- Select from list your product Route of Administration
- Select your product Marketing Category
- Last - click on ADD INGREDIENT



# Human Compounded Drug Label

**FDA CDER Direct**  
Electronic Submissions Portal

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

**SAVE INGREDIENT** **DELETE 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: \* 1 **Enter Denominator Strength**

Type: \* Active Ingredient, Reference Ingredient is Basis of Strength **Select Type of Ingredient**

Ingredient UNII - Name: \* (7TQO7W3VT8) BUPIVACAINE HYDROCHLORIDE **Enter/Select Ingredient UNII - Name**

Strength: \* 2.25 **Enter Strength**

☐ Moiety Same as Ingredient

Active Moiety: \* (7TQO7W3VT8) BUPIVACAINE HYDROCHLORIDE **Enter/Select Active Moiety**

**ADD ACTIVE MOIETY**

Reference Ingredient: \* (7TQO7W3VT8) BUPIVACAINE HYDROCHLORIDE **Enter/Select Reference Ingredient**

Note: Please enter the NDC Product Code (ex. 12345-678) for the bulk or finished drug from which the active ingredient for the compound is derived.

+	SOURCE NDC	DOCUMENT TYPE
✖	012345-678 <b>Enter ingredient SOURCE NDC</b>	

**Select Denominator Unit of Measure** mL

**Select "Numerator" Unit of Measure** mg



# Helpful Hints

## □ Ingredient Types

Active Ingredient, Active Moiety, or Reference Drug

- *use this ingredient selection to enable listing of ingredient NDC*

Inactive Ingredient

- *to list the inactive ingredient(s)*

Ingredient – Dietary Supplement

- *to identify the active ingredient used is a "dietary supplement ingredient"*



# Human Compounded Drug Label



**CDER Direct**  
Electronic Submissions Portal

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

SAVE INGREDIENT

DELETE 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:

1

Unit of Measure:

mL

Type: \*

Ingredient - Dietary Supplement

Select Ingredient -  
Dietary Supplement

Ingredient UNII - Name: \*

(P6YC3EG204) CYANOCOBALAMIN

Enter/select  
UNII - Name

Strength:

2.25

Unit Of Measure:

mg

## SOURCE NDC MANUFACTURER DETAILS

No Source NDC Information

☐

Check box if you have no Ingredient Source NDC

Source NDC: \*

0123-456

Enter Source Ingredient NDC

No Manufacture Information  
for this Source NDC

☐

Check box if you have no Ingredient Manufacturer Source NDC

Manufacturer DUNS: \*

011223344

Enter ingredient manufacturer registration/DUNS

Manufacturer Name: \*

Enter source dietary ingredient  
Manufacturer Name

CDER Direct: [direct.fda.gov](https://direct.fda.gov)





[Home](#)
[Product Listing and Reporting](#)
[Products](#)
[Product Details](#)

<< RETURN

## 123AF

Prov

ivacaine PE

## ADD INGREDIENT

row(s) 1 - 1 of 1

## CHARACTERISTICS

None

ADD CHARACTERISTIC

## — PACKAGING

None

ADD PACKAGE



# Helpful Hints

## Product NDC Codes

A single SPL file can contain multiple products with the same ingredients but different strengths

- *Each strength is a different product and thus requires a different product NDC*
- *After creating a product, save it, and return to the main screen to add another product with the same ingredients but different strength formulation*



# Human Compounded Drug Label



**CDER Direct**  
Electronic Submissions Portal

Home Product Listing and Reporting Products Product Details Packaging

## PACKAGING

ONLY LEVEL

Check for Deletion

Package NDC: 12345-6789-1

Package Type: SYRINGE, PLASTIC

Quantity: 5

Unit of Measure: mL

Number of Units Produced: 1000

SAVE PACKAGE

DONE

<< RETURN

When a single level  
of product package

Enter assigned  
Package NDC

Select  
Package Type

Last - click on  
SAVE PACKAGE

Select  
Unit of Measure

Enter the  
Number of Units Produced

ADD OUTER PACKAGE

DELETE

▲ TO TOP

Click on ADD OUTER PACKAGE  
for multi-level packaging

CDER Direct: [direct.fda.gov](https://direct.fda.gov)



# Human Compounded Drug Label

**FDA CDER Direct**  
Electronic Submissions Portal

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

**PACKAGING**

**INNERMOST LEVEL**  
Check for Deletion ☐

Package NDC: 12345-6789-1

Package Type: SYRINGE, PLASTIC

Quantity: 5

Unit of Measure: mL

**OUTERMOST LEVEL**  
Check for Deletion ☐

Package NDC: 12345-6789-0

Package Type: TRAY

Quantity: 1

Unit of Measure: mL

Number of Units Produced: 100

**Annotations:**

- When OUTER PACKAGE is added ONLY LEVEL becomes
- Last - click on SAVE PACKAGE
- A new section is called OUTER MOST LEVEL
- Enter assigned compounded product Package NDC
- Select Package Type
- Outermost package Quantity is normally "1"
- Select Unit of Measure
- Enter total Number of individual product Units Produced (i.e. total # of syringes)

**Buttons:** SAVE PACKAGE, DELETE PACKAGE, DONE, << RETURN, ADD OUTER PACKAGE, DELETE, ▲ TO TOP

Contact Help Desk



# Human Compounded Drug Label

**FDA CDER Direct**  
Electronic Submissions Portal

**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 asterisks indicate required fields.

**HEADER DETAILS**

Document Type:  Version Number:

**GO ACTIONS**

1 - 1 of 1

SELECT	PRODUCT NDC	PROPRIETARY NAME	DOSAGE FORM	INCLUDED IN SPL	INGREDIENTS	CLONE PRODUCT
	12345-6789	No Pain® Bupivacaine PF	INJECTION, SOLUTION	YES	<a href="#">SHOW INGREDIENTS</a>	



# Human Compounded Drug Label



**CDER Direct**  
Electronic Submissions Portal

Your SPL has been submitted to FDA and is awaiting additional in-depth validation. Check back on the status after a few minutes by refreshing the page or logging back into the CDER Direct Electronic Submissions Portal. ✕

Home

## SUBMISSIONS

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

NDC Labeler Code Request  
Establishment Registration  
GDUFA Self-Identification  
Product Listing and Certification  
NDC Reservation  
WDDI/JPL

## MANAGE ACCOUNT

Edit User Profile  
Manage Users

## ALL SUBMISSIONS

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).

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	
<a href="#">VALIDATION IN PROGRESS</a>	06236e1e-e089-ec18-e063-6a94af0a5279	06236e1e-e08a-ec18-e063-6a94af0a5279		1	HUMAN COMPOUNDED DRUG LABEL	James Brown	24-SEP-2023 22:18:58	
<a href="#">SUBMISSION ACCEPTED</a>	05e4a4cb-3114-b38e-e063-6a94af0a1c3d	05e4a4cb-3115-b38e-e063-6a94af0a1c3d	cd5786412309429637166@direct	1	HUMAN COMPOUNDED DRUG LABEL	James Brown	21-SEP-2023 17:17:09	

Note the STATUS is  
VALIDATION IN PROGRESS

-Note- if the STATUS is  
VALIDATION FAILURE, you  
will need to correct errors  
and click SUBMIT SPL

Note the SUBMISSION ID is blank  
until your submission status is  
SUBMISSION ACCEPTED

CDER Direct: [direct.fda.gov](https://direct.fda.gov)



## Helpful Hints

- To find Ingredient names, Active Moiety names, and their associated UNIIIs please go to the following website:


<https://precision.fda.gov/uniisearch>


- To find the corresponding Active Moiety to listed Active Ingredient please download reference [Active Ingredient-Active Moiety Relationship/Basis of Strength](#)

- does not apply to bulk ingredients



# Human Compounded Drug Label

 **CDER Direct**  
Electronic Submissions Portal

HomeProduct Listing and ReportingProducts

CONTENT OF LABELINGSUBMIT SPLSAVE AS DRAFTSAVE AND VALIDATEDELETEDELETE<< 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

Version Number: \*1

Set ID: \*06236e1e-e089-ec18-e063-6a94af0a5279Generate New

Effective Date: \*09-24-2023

Root ID: \*06236e1e-e08a-ec18-e063-6a94af0a5279Generate New

Reporting Period: \*2023-2 (06/01/2023 - 11/30/2023) v

Click **CONTENT OF LABELING** to submit compounded product labels



# Human Compounded Drug Label

SAVE SECTION

<< RETURN

## CREATE / EDIT SECTION

Section Type: \*

- Select Section Type -

Effective Date: \*



Parent Section:



Sequence: \*

2

Title:

Content:

**B** *I* U  $\times_2$   $\times^2$   $\frac{I}{x}$   $\frac{1}{=}$   $:=$   $\Omega$   $a^1$

Document Type: \*

*\*RED\** asterisk indicates field is mandatory

Registrant Name:

A dashed underline indicates help text if clicked on

CDER Direct: [direct.fda.gov](http://direct.fda.gov)



# Human Compounded Drug Label

## UPLOAD IMAGES

Note: JPG files only. Any image used above in the Content of Labeling must first be uploaded and displayed in the list of images below. Furthermore, any image uploaded and appearing on the list below must be referenced at least once in a section of the Content of Labeling.

Upload Image: \*

Browse...

UPLOAD

### IMAGES

None

Select a .jpg  
file to upload

then

Click UPLOAD to upload  
selected .jpg image file

Document Type: \*

*\*RED\** asterisk  
indicates field is  
mandatory

Registrant Name:

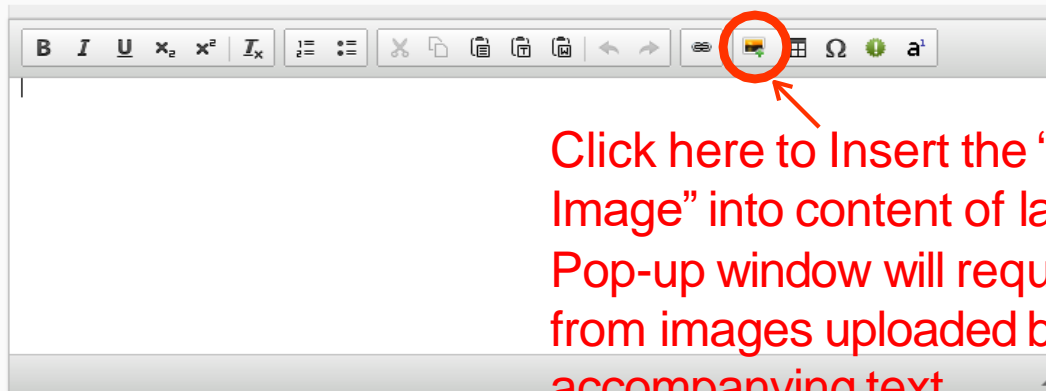
A dashed underline indicates  
help text if clicked on

CDER Direct: [direct.fda.gov](http://direct.fda.gov)



# Human Compounded Drug Label

Content:

A screenshot of a rich text editor toolbar. The toolbar includes various icons for text formatting (bold, italic, underline, subscript, superscript, strikethrough), alignment, bulleted and numbered lists, indentation, link, unlink, undo, redo, and a red circle highlights the 'Insert Image' icon. Below the toolbar is a large empty text area for content.

Click here to Insert the “Uploaded Image” into content of labeling.  
Pop-up window will request name from images uploaded below and accompanying text.

## UPLOAD IMAGES

UPLOAD



**Note:** JPG files only. Any image used above in the Content of Labeling must first be uploaded and displayed in the list of images below. Furthermore, any image uploaded and appearing on the list below must be referenced at least once in a section of the Content of Labeling.

Upload Image: \*

Browse...

After “Insert An Image” is saved this will change to “Yes”

## IMAGES

IMAGE NAME	IMAGE	DELETE IMAGE	REFERENCED
Jellyfish.jpg			No

CDER Direct: [direct.fda.gov](http://direct.fda.gov)



# Human Compounded Drug Label

DELETE SECTION

APPLY

<< RETURN

CREATE / EDIT SECTION

Section Type: \*

DIAGRAM OF DEVICE

Effective Date: \*

09-22-2023

Parent Section:

Sequence: \*

1

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Click APPLY to save  
CONTENT OF LABELING  
information before returning to main screen



# Human Compounded Drug Label

**FDA CDER Direct**  
Electronic Submissions Portal


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. Red asterisk indicate required fields.

**HEADER DETAILS**

Document Type: *	HUMAN COMPOUNDED DRUG LABEL	Version Number: *	1
Set ID: *	06236e1e-e089-ec18-e063-6a94af0a5279 <a href="#">Generate New</a>	Effective Date: *	09-24-2023 
Root ID: *	06236e1e-e08a-ec18-e063-6a94af0a5279 <a href="#">Generate New</a>	Reporting Period: *	2023-2 (06/01/2023 - 11/30/2023) ▼

Last - click on  
SUBMIT SPL

First click on  
SAVE AS DRAFT



# Where do I get more information?

Log on to CDER Direct: [direct.fda.gov](http://direct.fda.gov)

Compatible with the following browsers:

- Firefox version 28 and above
- Google Chrome
- Microsoft Edge
- Safari 10.0.1 and above

Help Desk: [CDERdirect@fda.hhs.gov](mailto:CDERdirect@fda.hhs.gov)

Compounding Helpdesk:  
[compounding@fda.hhs.gov](mailto:compounding@fda.hhs.gov)

