



**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

**FDA 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
- WDD/3PL

**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).

Q ▾ GO ACTIONS ▾

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE	🔒

1 - 2

**Click on Establishment Registration**



# Human Compounded Drug Label

Home **Establishment Registration**

The menu level is indicated here

## SUBMISSIONS

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

NDC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

Product Listing and Certification

NDC Reservation

WDD/3PL

## ESTABLISHMENT REGISTRATION

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GO

ACTIONS

SEARCH ESTABLISHMENT

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
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- Product Listing and Certification
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- WDD/3PL

## CREATE NEW ESTABLISHMENT REGISTRATION

- Create New Establishment Registration using a blank form
- Import an existing Establishment Registration SPL

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**



# 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 filling out this Establishment Registration submission form. Red asterisk indicate required fields.

**HEADER DETAILS**

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

Set ID: \*  [Generate New](#) Version Number: \*

Root ID: \*  [Generate New](#) Effective Date: \*  

**REGISTRANT DETAILS**

Registrant Name: \*

Registrant DUNS: \*

**REGISTRANT CONTACT DETAILS**

Contact Name: \*

Contact Email: \*

Contact Phone: \*  [Format](#)

Phone Extension:

**REGISTRANT CONTACT ADDRESS**

Country: \*

Street Address: \*


City: \*

State: \*

Postal Code: \*

**ESTABLISHMENTS**

None

**ADD ESTABLISHMENT**  **Then Click on ADD ESTABLISHMENT**

Contact Help Desk



# Human Compounded Drug Label

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.br...

Contact Phone: \* 1-202-555...

Phone Extension:

**Business Operation/Qualifier**

Business Operations: HUMAN DRUG COMPOUNDING OUTSOURCING FACILITY

Qualifier

- INTENT TO COMPOUND 508E (DRUG SHORTAGE) DRUGS
- NO INTENT TO COMPOUND 508E (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

Click on ADD  
BUSINESS  
OPERATION

ADD BUSINESS OPERATION

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

BUSINESS OPERATION(S)

Contact Help Desk



# Human Compounded Drug Label



CDER Direct  
Electronic Submissions Portal

Establishment information saved. ✕

Home > Establishment Registration > SPL Submission

2

SUBMIT SPL

SAVE AS DRAFT

1

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 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: \*

Root ID: \* 063479c6-ad92-a072-e063-6b94af0a54ab [Generate New](#)

Effective Date: \* 09-24-2023

Postal Code:

Then  
SUBMIT SPL

Click on  
SAVE AND VALIDATE

## ESTABLISHMENTS

[ADD ESTABLISHMENT](#)

row(s) 1 - 1 of 1

	ESTABLISHMENT DUNS	ESTABLISHMENT FEI	ESTABLISHMENT NAME
	123456789	-	ABC Outsourcing Compounders

?

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



# Human Compounded Drug Label

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

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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-e083-6b94af0a54ab	063479c6-ad92-a072-e063-6b94af0a54ab		1	123456789	ABC Outsourcing Compounders	ESTABLISHMENT REGISTRATION	<a href="#">DETAILS</a>	James Brown	25-SEP-2023 15:16:35	-

When successful you will see SUBMISSION ID





# Human Compounded Drug Label

## SUBMISSIONS

(ADD SUBMISSION TYPE)

NDC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

Product Listing and Certification

NDC Reservation

WDD/3PL

## 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).

<input type="text"/>	<input type="button" value="GO"/>	<input type="button" value="ACTIONS"/>	<input type="button" value="SEARCH PRODUCT"/>	<input type="button" value="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	cd5786412309.429537168@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

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

- NDC Labeler Code Request
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- 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



# Human Compounded Drug Label



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 [Generate New](#)

Effective Date: \* 09-24-2023

Root ID: \* 06231dfc-338b-f6c6-e063-6b94af0ae9b4 [Generate New](#)

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

Title

Then - click on  
SAVE AS DRAFT

First - Select  
Reporting Period

## LABELER DETAILS

## PRODUCTS

Do you have any products to report: \* No

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: \* 06236e1e-e089-ec18-e063-6a94af0a5279      Effective Date: \* 09-24-2023

Root ID: \* 06236e1e-e08a-ec18-e063-6a94af0a5279      Reporting Period: \* 2023-2 (06/01/2023 - 11/30/2023)

**LABELER DETAILS**

Labeler Name: \* ABC Outsourcing Compounders      Labeler DUNS: \* 123456789

**ESTABLISHMENTS**

None

**PRODUCTS**

Do you have any products to report: \* Yes

Q GO ACTIONS

None

Contact Help Desk



# 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: \*  Establishment DUNS: \*

**BUSINESS OPERATION(S)**

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

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

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



# 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: \* 06236e1e-e089-ec18-e063-6a94af0a5279 [Generate New](#)    Effective Date: \* 09-24-2023

Root ID: \* 06236e1e-e08a-ec18-e063-6a94af0a5279 [Generate New](#)    Reporting Period: \* 2023-2 (06/01/2023 - 11/30/2023)

**ESTABLISHMENTS**    **ADD ESTABLISHMENT**

	ESTABLISHMENT DUNS	ESTABLISHMENT NAME	CONFIDENTIAL
	123456789	ABC Outsourcing Compounders	N

row(s) 1 - 1 of 1

**PRODUCTS**    **ADD PRODUCT**

Do you have any products to report: \* Yes

**GO**    **ACTIONS**

None.

*Select - Yes to report product*    *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

**Proprietary Name:** No Pain Bupivacaine PF

**Non Proprietary Name:** Bupivacaine HCl

**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**

**ADD INGREDIENT**

**ADD PACKAGE**

text Help Desk

SAVE PRODUCT DELETE PRODUCT << RETURN



# 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: \*  **Enter Denominator Strength**

Type: \*  **Select Type of Ingredient**

Ingredient UNII - Name: \*  **Enter/Select Ingredient UNII - Name**

Strength: \*  **Enter Strength**

Unit of Measure: \*  **Select Denominator Unit of Measure**

Moiety Same as Ingredient

Active Moiety: \*  **Enter/Select Active Moiety**

**ADD ACTIVE MOIETY**

Reference Ingredient: \*  **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	

**Enter ingredient SOURCE NDC**





# 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

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

Enter/select  
UNII - Name

Ingredient UNII - Name: \*

(P6YC3EG204) CYANOCOBALAMIN

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



# Human Compounded Drug Label

**FDA CDER Direct**  
Electronic Submissions Portal

Home > Product Listing and Reporting > Products > Product Details

SAVE PRODUCT    DELETE PRODUCT    << RETURN

PRODUCT DATA ELEMENTS

1234567890    Bupivacaine PE

INGREDIENTS ADD INGREDIENT

row(s) 1 - 1 of 1

	SUBSTANCE NAME	UNII / NDC	STRENGTH	TYPE	SOURCE NDC
	BUPIVACAINE HYDROCHLORIDE	7TQ07W3VT8	2.25 mg	ACTIR	012345-878

CHARACTERISTICS ADD CHARACTERISTIC

None

PACKAGING ADD PACKAGE

None

Contact Help Desk

Click here to ADD PACKAGE information



# 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

ADD OUTER PACKAGE DELETE ▲ TO TOP

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

Click on ADD OUTER PACKAGE for multi-level packaging



# Human Compounded Drug Label

**FDA CDER Direct**  
Electronic Submissions Portal

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

**PACKAGING**

**INNERMOST LEVEL** (circled in red)

Check for Deletion

Package NDC: 12345-6789-1

Package Type: SYRINGE, PLASTIC

Quantity: 5

Unit of Measure: mL

**OUTERMOST LEVEL** (circled in red)

Check for Deletion

Package NDC: 12345-6789-0

Package Type: TRAY

Quantity: 1

Unit of Measure: mL

Number of Units Produced: 100

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

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)

Contact Help Desk



# Human Compounded Drug Label



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.

You may click  
SUBMIT SPL

You can either SAVE AS DRAFT or  
SAVE AND VALIDATE

## HEADER DETAILS

Document Type: \* HUMAN COMPOUNDED DRUG LABEL

Version Number: \* 1



GO

ACTIONS

1 - 1 of 1

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

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



# 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

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

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- Establishment Registration
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- Product Listing and Certification
- NDC Reservation
- WDD/3PL

## MANAGE ACCOUNT

- Edit User Profile
- Manage Users

## ALL SUBMISSIONS

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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	cd5786412309.429537168@direct	1	HUMAN COMPOUNDED DRUG LABEL	James Brown	21-SEP-2023 17:17:09	

1 - 2

Note the STATUS is **VALIDATION IN PROGRESS**

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

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





# 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

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.

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

## HEADER DETAILS

Document Type: \* HUMAN COMPOUNDED DRUG LABEL

Version Number: \* 1

Set ID: \* 06236e1e-e089-ec18-e063-6a94af0a5279

[Generate New](#)

Effective Date: \* 09-24-2023



Root ID: \* 06236e1e-e08a-ec18-e063-6a94af0a5279

[Generate New](#)

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

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



# Human Compounded Drug Label

SAVE SECTION

<< RETURN

## CREATE / EDIT SECTION

Section Type: \*

- Select Section Type -

Effective Date: \*













Parent Section:

Sequence: \*

Title:

Content:

**B** *I* U  $x_2$   $x^2$   $I_x$           

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:

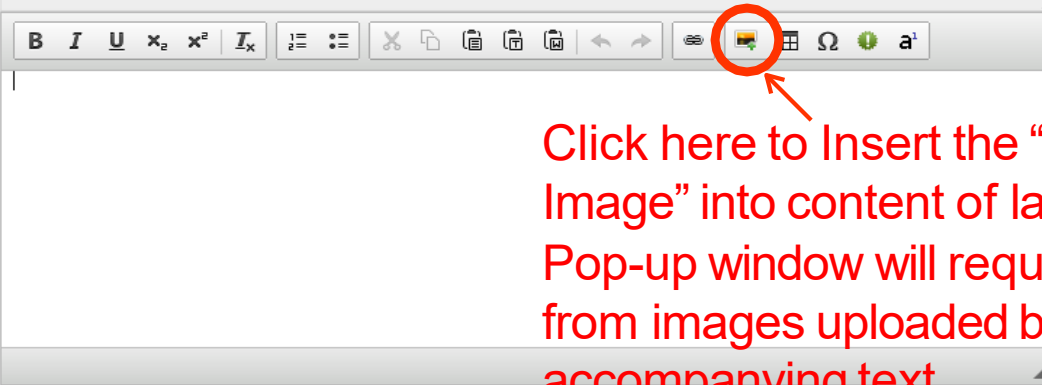
A dashed underline indicates help text if clicked on

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



# Human Compounded Drug Label

Content:



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: \*

After "Insert An Image" is saved this will change to "Yes"

## IMAGES

IMAGE NAME	IMAGE	DELETE IMAGE	REFERENCED
Jellyfish.jpg			No



# 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

Title:

Content:

A rich text editor interface with a blue background. The toolbar includes icons for bold (B), italic (I), underline (U), subscript (x<sub>2</sub>), superscript (x<sup>2</sup>), strikethrough (I<sub>x</sub>), bulleted list, numbered list, cut, copy, paste, undo, redo, link, unlink, table, link icon, and a text icon (a<sup>1</sup>). The main content area is currently blank.

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



# Human Compounded Drug Label

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 [Generate New](#)

Effective Date: \* 09-24-2023 

Root ID: \* 06236e1e-e08a-ec18-e063-6a94af0a5279 [Generate New](#)

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)

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

