



CDER *Direct*

Electronic Submissions Portal

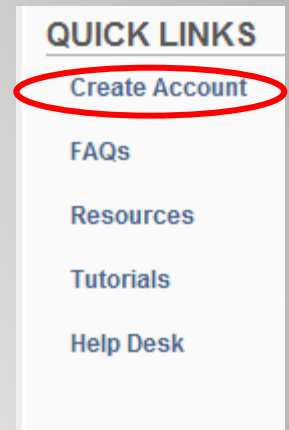
CDER Direct – Quick Start Guide

Accessing the Application

To access CDER Direct, enter direct.fda.gov into IE 8

First Time Users – Select Create Account; enter all the requested user and company information

Activating - Once you click submit, you must activate your account within 48 hours.



Login Screen



CDER Direct

Electronic Submissions Portal

Username or Password entered is incorrect.

LOGIN

Username:

Password:

Under [18 U.S.C. 1001](#), anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

☐ I Understand.

LOGIN

[Forgot your password?](#)

QUICK LINKS

[Create Account](#)

[FAQs](#)

[Resources](#)

[Tutorials](#)

[Help Desk](#)

CDER Direct: direct.fda.gov

Creating Account

ORGANIZATION INFORMATION

Name: * Cannonsburg Supply

DUNS: * 000000000

Brief Description: * pharmaceutical supply house

27 of 1000

ORGANIZATION ADDRESS

Country: * United States ▼

Street Address: * 8769 East Ninth Street

City: * Lafayette

State: * Arkansas ▼

Postal Code: 00000

CONTACT INFORMATION

First Name: * Jane

Middle Name: *

Last Name: * Doe

Job Title: Project Manager

Contact Email: * jane.doe@cannonsburg supply

CONTACT PHONE

Country Code: * United States of America (+1) ▼

Phone Number: * 123-000-4000

Phone Extension: 213

FORM ACCESS

Labeler Code Request/Activation

☒ NDC LABELER CODE REQUEST

Establishment Annual Registration

☒ ESTABLISHMENT REGISTRATION

GDUFA Facility Self-Identification

☒ GENERIC DRUG FACILITY IDENTIFICATION SUBMISSION

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

☒ I have read and agree to the Terms and Conditions stated above.

SUBMIT

CANCEL

CDER Direct: direct.fda.gov

Activating Your Account

To activate your account:

1. Open your email account
2. Open the email from cdirect@fda.gov.
3. Click on the activation link in the email.
4. Enter a user name and password following the guidelines that appear on the screen
5. Select three security questions and enter the answer to each question.
6. Click **Submit**.

(If you do not receive an email, please check your Spam filters)

Activating Your Account

ACTIVATE ACCOUNT

Username must be at least 8 characters and no more than 32 characters. It can consist of any combination of capital and lowercase letters, numbers, a period, or an underscore (" _").

Username: *

Password must be at least 10 characters and no more than 32 characters. It must include a capital letter, a lowercase letter, a number, and a special character.

Password: *

Confirm Password: *

Select and answer security questions. If you forget your password, you will need to provide this information. [Show Answers](#)

Security Question 1: *

Security Answer 1: *

Security Question 2: *

Security Answer 2: *

Security Question 3: *

Security Answer 3: *

SUBMIT

CANCEL

Login Credential Requirements

- Username
 - eight characters including:
 - upper and lower case letters
 - numbers
 - a period or an underscore (" _")
- Password
 - least ten characters including:
 - an upper and a lower case letter
 - a number
 - a non-alphanumeric character

All forms that
you have
access to

Using the Home Page

Home

SUBMISSIONS

NDC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

MANAGE ACCOUNT

Edit User Profile

Manage Users

- Update profile information
- Manage sub-user accounts

ALL SUBMISSIONS

View all submissions
you have access to

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE
AWAITING ACCEPTANCE	f2dc6c82-db2b-2468-e044-00144ffaa30a	f32e14dd-b256-6ebf-e044-00144ffaa30a	cd9072581364.3172649085@direct	3	NDC LABELER CODE REQUEST	Jane Doe	26-MAR-2014 18:19:02
DRAFT	f5884a77-08a7-476a-e044-00144ffaa30a	f5884a77-08a8-476a-e044-00144ffaa30a	-	1	ESTABLISHMENT REGISTRATION	Jane Doe	26-MAR-2014 17:22:25
SUBMISSION SUCCESSFUL	f3f58480-b65e-74f4-e044-00144ffaa30a	f3f58480-b65f-74f4-e044-00144ffaa30a	cd2153768490.2795610843@direct	1	ESTABLISHMENT REGISTRATION	Jane Doe	18-MAR-2014 15:02:16
SUBMISSION SUCCESSFUL	f4461a3a-a4c9-3551-e044-00144ffaa30a	f4461a3a-a4ca-3551-e044-00144ffaa30a	cd8532764901.4872951603@direct	1	GENERIC DRUG FACILITY IDENTIFICATION SUBMISSION	Jane Doe	18-MAR-2014 15:02:16

CDER Direct: direct.fda.gov

Where do I get more information?

Log on to CDER Direct: direct.fda.gov

Compatible with the following browsers:

- *IE version 8 and above*
- *Firefox version 28 and above*
- *Chrome version 44.0.2403.130*

Help Desk: CDERdirect@fda.hhs.gov



CDER *Direct*

Electronic Submissions Portal

CDER Direct – Establishment Registration

Establishment Registration



Home > Establishment Registration

First, click "Establishment Registration"

SUBMISSIONS

NDC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

ESTABLISHMENT REGISTRATION



GO

ACTIONS ▼

CREATE NEW

None.

Then, click here to begin a new registration

CDER Direct: direct.fda.gov

Establishment Registration



CDER Direct

Electronic Submissions Portal

SUBMISSIONS

NDC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

Click here to create
SPL from scratch

CREATE NEW ESTABLISHMENT REGISTRATION

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

Note: To update an existing submission set, please select the submission from the table.

CONTINUE

CANCEL

Click here to upload
previously created SPL

CDER Direct: direct.fda.gov

Establishment Registration



Home > Establishment Registration > SPL Submission

SAVE AS DRAFT

<< RETURN

HEADER DETAILS

Document Type: *

--Select One--
--Select One--
ESTABLISHMENT DE-REGISTRATION
ESTABLISHMENT REGISTRATION
NO CHANGE NOTIFICATION
OUT OF BUSINESS NOTIFICATION

[Generate New](#)

[Generate New](#)

Set ID: *

Version Number: *

1

Root ID: *

Effective Date: *

07-28-2014



Select "Establishment Registration"

Document Type: *

State/Province: *

A **RED** asterisks indicates field is mandatory

A dashed underline indicates help text if clicked on

CDER Direct: direct.fda.gov

Helpful Hints

- Document Types
 - Establishment Registration
 - *to register your establishment(s)*
 - No change notification
 - *each year when the information is updated, if there is no change*
 - Out of Business
 - *if the registrant goes out of business*
 - Establishment De-Registration
 - *de-register your establishment(s)*

Establishment Registration

REGISTRANT DETAILS

Registrant Name: *

Registrant DUNS: *

REGISTRANT CONTACT DETAILS

Contact Name: *

Contact Email: *

Contact Phone: *

[Format](#)

Phone Extension:

Document Type: * *A *RED* asterisks indicates field is mandatory*

State/Province: *A dashed underline indicates help text if clicked on*

REGISTRANT CONTACT ADDRESS

Country: *

Street Address: *

City: *

State: *

Postal Code:

CDER Direct: direct.fda.gov

Establishment Registration

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:

Click here to add
an establishment.

Multiple
establishments can
be added.



ADD ESTABLISHMENT

ESTABLISHMENTS

None

CDER Direct: direct.fda.gov

Establishment Registration

Ensure that the Establishment Name and Address match exactly what is in the DUNS record.

SAVE ESTABLISHMENT

<< RETURN

ESTABLISHMENT DETAILS

Establishment Name: *

XYZ Drug Company

Establishment DUNS: *

888888888

Establishment FEI:

Document Type: *

State/Province:

A *RED* asterisks indicates field is mandatory

A dashed underline indicates help text if clicked on

ESTABLISHMENT ADDRESS

Country: *

United States

Street Address: *

123 Road

City: *

Silver Spring

State: *

Maryland

Postal Code:

CDER Direct: direct.fda.gov

Establishment Registration

Note: This is the contact information for the Establishment, not the Registrant

ESTABLISHMENT CONTACT DETAILS

Contact Name: *

Jane Doe

Contact Email: *

jane.doe@gmail.com

Contact Phone: *

333-333-3333

[Format](#)

Phone Extension:

Document Type: *

A *RED* asterisks indicates field is mandatory

State/Province:

A dashed underline indicates help text if clicked on

ESTABLISHMENT CONTACT ADDRESS

Country: *

United States

Street Address: *

444 Street

City: *

Silver Spring

State: *

Maryland

Postal Code:

CDER Direct: direct.fda.gov

Establishment Registration

U.S. AGENT

Agent Name: *

John Doe

Agent DUNS: *

666666666

Agent Email: *

john.doe@gmail.com

Agent Phone: *

444-444-4444

If the establishment is in the United States, the US Agent section will not appear

Note: Enter the one or more drug manufacturing and processing operations performed at the establishment. Click on + button to select multiple business operations, or alternatively importers.

IMPORTERS



	NAME	DUNS	EMAIL	PHONE
				
				

Click on the "+" button to select multiple importers

CDER Direct: direct.fda.gov

Establishment Registration

BUSINESS OPERATION(S)

	BUSINESS OPERATION	QUALIFIER
 	MANUFACTURE	--Select One--

Click on the "+" button to select multiple business operations

Select "Manufactures Human Over-the-Counter Drug Products Produced Under a Monograph"

Establishment Registration

Click here to save Establishment information before returning to the previous screen

SAVE ESTABLISHMENT

<< RETURN

ESTABLISHMENT DETAILS

Establishment Name: *

XYZ Drug Company

Establishment DUNS: *

888888888

Establishment FEI:

ESTABLISHMENT ADDRESS

Country: *

United States

Street Address: *

123 Road

City: *

Silver Spring

State: *

Maryland

Postal Code:

CDER Direct: direct.fda.gov

Establishment Registration



CDER Direct
Electronic Submissions Portal

Establishment information saved.



Home > Establishment Registration > SPL Submission

SUBMIT SPL

SAVE AS DRAFT

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: * fcd83a74-188b-6773-e044-00144ffa2cc4 [Generate New](#)

Root ID: * fcd83a74-188c-6773-e044-00144ffa2cc4 [Generate New](#)

Version Number: * 1

Effective Date: * 06-27-2014

Please "Save As Draft"
before Submitting SPL

REGISTRANT DETAILS

Registrant Name: * Registrant Company

CDER Direct: direct.fda.gov

Where do I get more information?

Log on to CDER Direct: direct.fda.gov

Compatible with the following browsers:

- *IE version 8 and above*
- *Firefox version 28 and above*
- *Chrome version 44.0.2403.130*

Help Desk: CDERdirect@fda.hhs.gov



CDER *Direct*

Electronic Submissions Portal

CDER Direct – NDC Labeler Code Request

NDC Labeler Code Request



CDER Direct

Electronic Submissions Portal

Home Labeler Code Requests

SUBMISSIONS

NDC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

First, click "NDC Labeler Code Request"

NDC LABELER CODE REQUEST



GO

ACTIONS ▼

CREATE NEW

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

First, click here to begin a new labeler code request

CDER Direct: direct.fda.gov

NDC Labeler Code Request



CDER Direct

Electronic Submissions Portal

SUBMISSIONS

NDC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

CREATE NEW LABELER CODE REQUEST

- ☒ Create a new NDC Labeler Code Request using a blank form
- ☐ Import an existing NDC Labeler Code Request SPL

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

CONTINUE

CANCEL

Click here to
create SPL from
scratch

Click here to upload
previously created SPL

CDER Direct: direct.fda.gov

NDC Labeler Code Request

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 Labeler Code Request submission form. Red asterisk indicate required fields.

HEADER DETAILS

Document Type: *

Set ID: *
Root ID: *

[Generate New](#) [Generate New](#)

Version Number: *

Effective Date: *

Select NDC Labeler
Code Request

Document Type: *

A ***RED*** asterisks indicates
field is mandatory

State/Province:

A dashed underline indicates help
text if clicked on

CDER Direct: direct.fda.gov

Helpful Hints

- Document Type
 - NDC Labeler Code Request
 - *if you are requesting a labeler code or completing a labeler code process*

NDC Labeler Code Request

— HEADER DETAILS

Document Type: * NDC LABELER CODE REQUEST ▼

Set ID: * 0126cb19-373e-6fa5-e054-00144ffa2cc4 [Generate New](#)

Version Number: * 1

Root ID: * 0126cb19-373f-6fa5-e054-00144ffa2cc4 [Generate New](#)

Effective Date: * 08-21-2014 

The Labeler Name should match the name or DBA in the DUNS record.

— LABELER DETAILS

Labeler Name: * Abcd Company

Labeler Code:

Labeler DUNS: * 666666666

— LABELER CONTACT DETAILS

Contact Name: * John Doe Jr

Contact Email: * johndoe2@gmail.com

Contact Phone: * 111-111-1121

[Format](#)

Phone Extension:

— LABELER CONTACT ADDRESS

Country: * United States ▼

Street Address: * 789 Road

City: * Rockville

State: * Maryland ▼

Postal Code:

Document Type: *

A ***RED*** asterisks indicates field is mandatory

State/Province:

A dashed underline indicates help text if clicked on

CDER Direct: direct.fda.gov

Helpful Hints

- Labeler Code
 - When first requesting a labeler code
 - ***leave this field blank***
 - When confirming the Labeler Code after you have been assigned a Labeler Code by FDA
 - *enter the 5 digit number assigned by FDA as the NDC Labeler Code*

NDC Labeler Code Request

— ADDITIONAL LABELER DETAILS (Optional - Including the following information will expedite the processing of your request)

LABELER ADDRESS

Country: *

Street Address: *

City: *

State/Province:

Postal Code:

The Labeler Address information should match the address in the DUNS record.

U.S. AGENT

Agent Name: *

Agent DUNS: *

Agent Email: *

Agent Phone: *

Phone Extension:

[Format](#)

Select "...Human Over-the-Counter Drug Products"

BUSINESS OPERATION(S)

BUSINESS OPERATION	QUALIFIER
<input type="button" value="+"/> <input type="text" value="MANUFACTURE"/>	<input type="text" value="--Select One--"/>

Click on the "+" button to select multiple business operations.

CDER Direct: direct.fda.gov

NDC Labeler Code Request



Home > Labeler Code Requests > SPL Submission

SUBMIT SPL

SAVE AS DRAFT

DELETE

<< RETURN

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

Please "Save As Draft"
before Submitting SPL

HEADER DETAILS

Document Type: * NDC LABELER CODE REQUEST

Set ID: * 0126cb19-373e-6fa5-e054-00144ffa2cc4 [Generate New](#)

Version Number: * 1

Root ID: * 0126cb19-373f-6fa5-e054-00144ffa2cc4 [Generate New](#)

Effective Date: * 08-21-2014

LABELER DETAILS

CDER Direct: direct.fda.gov

Where do I get more information?

Log on to CDER Direct: direct.fda.gov

Compatible with the following browsers:

- *IE version 8 and above*
- *Firefox version 28 and above*
- *Chrome version 44.0.2403.130*

Help Desk: CDERdirect@fda.hhs.gov

FDA is providing standardized hand sanitizer listing templates that can be used to prepopulate much of the listing data. If you are not currently registered as a drug manufacturing facility and do not already have a labeler code assigned by FDA, please complete an Establishment Registration and Labeler Code Request prior to submitting your Product Listing. For additional instructions on how to submit an Establishment Registration and Labeler Code Request, please review the user guide documents located in CDER Direct after logging into the portal. **Please note that this template should not be used by 503B outsourcing or compounding facilities as their requirement for "product reporting" is different than "drug listing".**

COVID-19

To list Hand Sanitizers you first need to submit a Labeler Code Request and an Establishment Registration. When these have been completed you can then submit a Product Listing. Please view the user guides below for each submission type.

[Labeler Code Request.](#)

[Establishment Registration.](#)

[Product Listing - Hand Sanitizer.](#)

FDA has created a hand sanitizer drug listing template pursuant to the current WHO guidelines to be used for the duration of the COVID-19 public health emergency. It remains the submitting firm's responsibility to review the suggested data to ensure that the information provided in the drug listing matches the product's formulation and labeling. This template is not *required* to be used during the COVID-19 public health emergency, and a company has discretion whether to utilize this template or a blank Product Listing form instead.

To use the hand sanitizer template, please do the following:

1. Select "Product Listing and Certification" on the left-hand side of the page under the SUBMISSIONS header, and then select CREATE NEW/UPLOAD File.

Home > Product Listing and Reporting

SUBMISSIONS

NDC/NHRC Labeler Code Request

Establishment Registration

GDUFA Self-Identification

Product Listing and Certification

WDD/3PL

PRODUCT LISTING AND REPORTING

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	
VALIDATION FAILURE	9850d3e5-d40d-1ce6-e053-2991ae0ab36f	a1259843-05e5-196-e053-0a91-b40e4e57	cd753206b194.637542916@direct	2	HUMAN OTC DRUG LABEL	These highlights do not includ...	DETAILS	Travis Haney	24-MAR-2020 11:46:55	-
SUBMISSION FAILED	a127e1c0-0048-293c-e053-0791b40a8f93	a127dcfc-3138-3254-e053-0a91-b40ae596	cd426718953.5830942761@direct	1	HUMAN OTC DRUG LABEL		DETAILS	Travis Haney	24-MAR-2020 11:44:57	-
	Dc9f69f3-39e3	a106217-ee85-			HUMAN				17-MAR-2020	

2. Select the "Create a New Product Listing or Certification using a blank form" bubble. Select HUMAN OTC DRUG LABEL as the SPL Document Type. Select "OK" on the popup window that appears to confirm that you would like to use a Hand Sanitizer template. Select the Template Type that best reflects your product.

Please be aware that the list of template options provided in the dropdown only includes formulations pursuant to WHO and FDA's recent guidance: [Temporary Policy for Preparation of Certain Alcohol Based Hand Sanitizer Products During the Public Health Emergency \(COVID-19\)](#) for the duration of pandemic. FDA recommends other active or inactive ingredients are not added. Different or additional ingredients might impact the quality and potency of the product. This template can be used to prepopulate the product listing file.

SUBMISSIONS

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

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: *

Template Type:

Note: To update an existing submission, click [icon] with the status SUBMISSION ACCEPTED from the table in the prior page / Dashboard.

CONTINUE **CANCEL**

ALCOHOL 80%
ISOPROPYL ALCOHOL 75%

3. Select "Generate New" next to the Set ID field.

HEADER DETAILS

Document Type: *

Set ID: * [Generate New](#)

Version Number: *

Root ID: * [Generate New](#)

Effective Date: *

Title:

4. Enter the Labeler Name and DUNS number that was used in your Labeler Code Request.

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](#)

Version Number: *

Root ID: * [Generate New](#)

Effective Date: *

Title:

LABELER DETAILS

Labeler Name: *

Labeler DUNS: *

5. Select the Edit Icon next to Establishment DUNS located under the ESTABLISHMENTS header.

ESTABLISHMENTS
ADD ESTABLISHMENT

row(s) 1 - 1 of 1

	ESTABLISHMENT DUNS	ESTABLISHMENT NAME	CONFIDENTIAL
	000000000	Enter Establishment Name	N

6. Enter the establishment name and DUNS number provided in your establishment registration, followed by the Business Operation(s) performed and the Product NDC.

Note: The NDC Product Code is the first 2 segments of the NDC. It is the 4- or 5-digit NDC Labeler Code assigned to the company whose name is on the label and the 3- or 4-digit product code segment of the NDC identifying the formulation and dosage form, separated by a hyphen. Examples: 12345-678, 23456-7890.

For more information on NDC and its assignment to drugs visit [Code of Federal Regulations Title 21 Part 207 Subpart C](#).

ESTABLISHMENT DETAILS

Establishment Name: *
Enter Establishment Name
Establishment DUNS: *
000000000

☐ Confidential

BUSINESS OPERATION(S) ⓘ

	BUSINESS OPERATION	PRODUCT NDC
	MANUFACTURE	00000-000

7. Select the Edit icon next to the Product NDC located under the PRODUCTS header.

PRODUCTS
ADD PRODUCT

GO
ACTIONS ▼

1 - 1 of 1

SELECT	PRODUCT NDC	PROPRIETARY NAME	DOSAGE FORM	CLONE PRODUCT
	00000-000	Hand Sanitizer	LIQUID	

8. Update the Product NDC, Proprietary Name (if any), and Dosage Form of your product. Select OK, on the popup message that will be displayed after selecting a Dosage Form.

PRODUCT DATA ELEMENTS

NDC Product Code: * 00000-000 Proprietary Name: * Hand Sanitizer Suffix:

Non Proprietary Name: * ISOPROPYL ALCOHOL DEA Schedule: -Select DEA Schedule- ▼

Dosage Form: * -Select Dosage Form- ▼

Route of Administration: *

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


Source NDC:

9. Enter the Marketing Start Date of your product and then select "OTC monograph not final" for the Marketing Category. Select OK, on the popup message that will be displayed after changing the Marketing Category.

Regulatory Citation: Please note, that your selection of the Marketing Category "OTC monograph not final" and Regulatory Citation "part333A" represents an affirmation that the drug included in this product listing satisfies all regulatory requirements under this OTC monograph. If any change occurs to the drug formulation represented in this listing, please ensure that the product conforms to all relevant requirements outlined under part333A of the OTC monograph.

MARKETING DETAILS

Marketing Status: * ACTIVE ▼

Marketing Start Date: * 03-30-2020 





Marketing Category: * OTC monograph not final ▼

Application Number/
Regulatory Citation: part333A

10. Review the Ingredients in the INGREDIENTS SECTION.

Note: For formulation, refer to Item 1 on the guidance document : [Temporary Policy for Preparation of Certain Alcohol Based Hand Sanitizer Products During the Public Health Emergency \(COVID-19\)](#)

According to the guidance document, other active or inactive ingredients should not be added. Different or additional ingredients may impact the quality and potency of the product.

	SUBSTANCE NAME	UNII / NDC	STRENGTH	TYPE
	ALCOHOL	3K9958V90M	80 mL	ACTIB
	WATER	059QF0K00R		IACT
	GLYCERIN	PDC6A3C00X	1.45 mL	IACT
	HYDROGEN PEROXIDE	BBX060AN9V	0.125 mL	IACT

- Package NDC:** Enter the full 10-digit code separated by a hyphen. The third segment, the package code, identifies package sizes and types. Depending on the firm's NDC configuration, the package code can be 1- or 2-digits. Different package sizes and types are required to be identified with different package codes. Details concerning all packaging configurations must be included in the packaging section.

PACKAGING									
ADD PACKAGE									
row(s) 1 - 1 of 1									
	PACKAGE NDC	NO OF LEVELS	PACKAGE TYPE	QUANTITY	UNIT OF MEASURE	MARKETING STATUS	MARKETING START DATE	MARKETING END DATE	CLONE
	00000-000-00	1	BOTTLE	00	mL	ACTIVE	03-30-2020	-	

- SAVE PACKAGE


DELETE PACKAGE

DONE

<< RETURN

PACKAGING

ONLY LEVEL

Check for Deletion 

☐

Is this a sample package ?

☐

Package NDC:

Package Type: *


Quantity: *

Unit of Measure:


Combination Product Type:

Marketing Status:

Marketing Start Date:



Marketing End Date:



ADD OUTER PACKAGE

DELETE

▲ TO TOP

PACKAGING									ADD PACKAGE
									row(s) 1 - 1 of 1
	PACKAGE NDC	NO OF LEVELS	PACKAGE TYPE	QUANTITY	UNIT OF MEASURE	MARKETING STATUS	MARKETING START DATE	MARKETING END DATE	CLONE
	00000-000-10	1	BOTTLE, SPRAY	232	mL	ACTIVE	03-30-2020	-	

When all packages have been added, select **SAVE PRODUCT**.

13. Select Content of Labeling at the top of the page and the Expand Sections icon.

The screenshot shows a green notification bar at the top that says "Product saved." with a close button. Below it is a breadcrumb trail: Home > Product Listing and Reporting > Products. A yellow box highlights the "CONTENT OF LABELING" tab. To its right are buttons: "SUBMIT SPL", "SAVE AS DRAFT", "SAVE AND VALIDATE", "DELETE", and "<< RETURN". A note below the buttons reads: "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." Below the note is a section with two tabs: "EXPAND SECTIONS" (highlighted in yellow) and "CLASSIC". To the right of these tabs are "ADD SECTION" and "<< RETURN" buttons. Below the tabs is a list of sections: "[OTC - ACTIVE INGREDIENT SECTION]" and "[OTC - PURPOSE SECTION]". Each section has an "EDIT" link to its right.

14. Review all sections to ensure that all sections are complete and accurate. If any changes are required, select the Edit icon for that section.

The screenshot shows a section titled "Active Ingredient(s) [OTC - ACTIVE INGREDIENT SECTION]" with a yellow "EDIT" button to its right. Below the title is a text field containing "Alcohol 80% v/v. Purpose: Antiseptic".

15. Scroll to the last section titled, Package Label. Principal Display Panel section, and select edit.

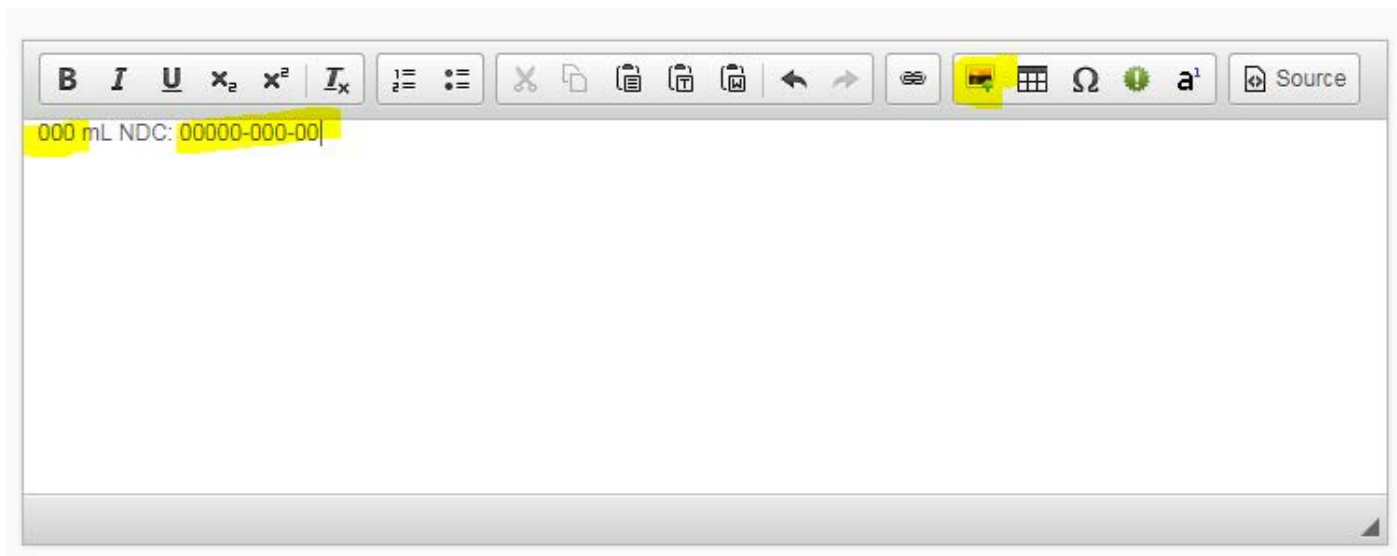
The screenshot shows a section titled "Package Label - Principal Display Panel [PACKAGE LABEL.PRINCIPAL DISPLAY PANEL]" with a yellow "EDIT" button to its right. Below the title is a text field containing "000 mL NDC: 00000-000-00".

16. In the Upload Images region, select Choose File and select the package label for your product and then select upload. Repeat this step for each package previously entered.

Note: Both the front and back images of the packaging should be included.

The screenshot shows a section titled "UPLOAD IMAGES" with a yellow "UPLOAD" button to its right. Below the title is a note: "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." Below the note is a text field labeled "Upload Image:" with a "Choose File" button to its right. Below the text field is a section titled "IMAGES" with a list containing "None".

17. Add the Package Quantity, Package NDC and then select "Insert an image Icon" in the Content editor region



18. Select the Image Name for the package and then add image text that accurately describes the image. Select OK when finished. Repeat this process for all packages uploaded and included in the listing.

Note: The file name must contain only alphanumeric characters. No special characters can be used.

19. When finished, select Apply
20. Review your submission for completeness and accuracy and then Select Save and Validate. If Validation Passes, proceed to the final step. If Validation Fails, then correct any errors before Saving, and attempt to Validate the file again.

