U.S. FOOD & DRUG ADMINISTRATION

CDER Direct Product Listing

Troy Cu
Technical Information Specialist
Office: CDER/OC/OPRO/DRLS

Overview

- Who must list
- When
- How to submit a Drug Listing SPL using CDER Direct
- Updating listing and Delisting
- Summary
- Do’s & Don’ts/ Helpful Resources

“Who”

- Unless exempt, ALL registrants must list all drugs manufactured for commercial distribution
- Contract manufactures (CMO) must list under their own labeler code
- CMO who manufacture for private label distributors (PLD) must also list for PLDs, using the PLD’s labeler code. PLDs may list their own products as an authorized agent.

“When”

- Initial- Listing information must be submitted within 3 days of the initial registration
- Updates- You can update any changes to the listing every June and December, preferably ASAP.
- Annual listing certification- Accepted updates to the listing certifies your listing for the calendar year and the next calendar year

How to submit a Drug Listing SPL using CDER Direct

FDA

CDER *Direct*
Electronic Submissions Portal

This is a TESTING ONLY application. Click here to log into the Production Environment. Any submissions made in the application are not officially submitted to FDA.

COVID-19 Update - As a courtesy, the FDA is providing standardized hand sanitizer templates that can be used to prepopulate the listing, and customize for your product. Additional information can be obtained after logging in. (Not applicable to 503B outsourcing or compounding facilities)

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
- Resources
- Tutorials
- Help Desk
- FAQs

SUBMISSIONS
(ADD SUBMISSION TYPE)

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

MANAGE ACCOUNT

- Edit User Profile
- Manage Users

COVID-19

(Not applicable to 503B outsourcing or compounding facilities)

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

ALL SUBMISSIONS

For help with your SPL submission, contact CDERdirect@fda.hhs.gov. For questions related to Drug Establishment Registration and Product Listing, contact eDRLS@fda.hhs.gov.

GO ACTIONS

Status = 'SUBMISSION ACCEPTED'

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	LAST MODIFIED USER	LAST MODIFIED DATE
SUBMISSION ACCEPTED	50d8376c-9ada-48c6-acfd-a0dba9fe8ed d	86456381-0a46-2b6b-e053-2991ab0a66c5	cd7012658439.68529130 47@direct	3	HUMAN OTC DRUG LABEL	Troy Cu	11-APR-2019 15:17:09
SUBMISSION ACCEPTED	76e03707-07b7-2a4b-e053-2991ab0a8598	772c5665-c9c7-8105-e053-2a91ab0ae4d1	-	2	HUMAN OTC DRUG LABEL NDC RESERVATION	Troy Cu	01-OCT-2018 11:03:37
SUBMISSION ACCEPTED	76e03707-07b7-2a4b-e053-2991ab0a8598	76e03707-07b8-2a4b-e053-2991ab0a8598	cd6270941583.63209584 17@direct	1	HUMAN OTC DRUG LABEL NDC RESERVATION	Troy Cu	27-SEP-2018 15:51:12
SUBMISSION ACCEPTED	73905eb9-32e5-fb9d-e053-2991ab0aa212	73905eb9-32e6-fb9d-e053-2991ab0aa212	cd6435298107.62809154 73@direct	1	HUMAN OTC DRUG LABEL NDC RESERVATION	Troy Cu	11-SEP-2018 14:57:13
SUBMISSION ACCEPTED	5b60c037-4a78-5fd1-e053-2a91ab0a2633	5b60c037-4a79-5fd1-e053-2a91ab0a2633	cd8320941576.48392750 16@direct	1	BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING	Troy Cu	12-OCT-2017 17:38:11
SUBMISSION ACCEPTED	66a45f4c-f058-4090-8874-a5f6df838e92	58b28fd5-0ae8-e55d-e053-2a91ab0a581e	cd1354928607.18735924 60@direct	2	ESTABLISHMENT REGISTRATION	Troy Cu	08-SEP-2017 14:36:08
SUBMISSION ACCEPTED	0c3cd42a-76da-578a-e054-00144ff9ffe2	54989fb1-bb63-0833-e053-2a91ab0a1e6a	cd2943680571.74651892 30@direct	6	HUMAN COMPOUNDED DRUG LABEL	Troy Cu	18-JUL-2017 09:51:10
SUBMISSION ACCEPTED	dc49e24f-1067-4b45-8773-25b254ce1c91	4e9dd1df-4197-7478-e053-2a91ab0a65bd	cd6451378902.38791524 6@direct	5	NDC LABELER CODE INACTIVATION	Troy Cu	25-MAY-2017 09:58:17
SUBMISSION ACCEPTED	22b2ff93-4587-4e65-ac64-74449e5bb712	4936b0d9-44f1-1eba-e054-00144ff8a759	cd3915267480.87419302 65@direct	11	ESTABLISHMENT REGISTRATION	Troy Cu	23-FEB-2017 13:11:30
SUBMISSION ACCEPTED	42082b51-d9cd-4a69-b397-b3a885bce894	48aae9dd-71af-4266-e054-00144ffa2cc4	cd3589462071.52631048 97@direct	21	ESTABLISHMENT REGISTRATION	Troy Cu	16-FEB-2017 13:36:30
SUBMISSION ACCEPTED	0c3cd42a-76da-578a-e054-00144ff9ffe2	486a5a67-8897-401b-e054-00144ffa2cc4	cd6347259081.31786504 29@direct	5	HUMAN COMPOUNDED DRUG LABEL	Troy Cu	14-FEB-2017 13:41:30
SUBMISSION ACCEPTED	140bbfd2-5c66-42a1-905d-7ae3e67ddd82	487f077c-0c48-23c5-e054-00144ffa2cc4	cd7621840539.13204896 57@direct	2	BULK INGREDIENT	Troy Cu	14-FEB-2017 10:51:31

CDER Direct
Electronic Submissions Portal

Home

SUBMISSIONS
(ADD SUBMISSION TYPE)

- NDC/NHRIC Labeler Code Request
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ALL SUBMISSIONS

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SUBMISSION ACCEPTED	50d8376c-9ada-48c6-acfd-a0dba9fe8edd	86456381-0a46-2b6b-e053-2991ab0a86c5	cd701265843968529130 47@direct	3	HUMAN OTC DRUG LABEL	Troy Cu	11-APR-2019 15:17:09
SUBMISSION ACCEPTED	76e03707-07b7-2a4b-e053-2991ab0a8598	772c5665-c9c7-8105-e053-2a91ab0ae4d1	-	2	HUMAN OTC DRUG LABEL NDC RESERVATION	Troy Cu	01-OCT-2018 11:03:37
SUBMISSION ACCEPTED	76e03707-07b7-2a4b-e053-2991ab0a8598	76e03707-07b8-2a4b-e053-2991ab0a8598	cd6270941583.6320958417@direct	1	HUMAN OTC DRUG LABEL NDC RESERVATION	Troy Cu	27-SEP-2018 15:51:12
SUBMISSION ACCEPTED	73905eb9-32e5-fb9d-e053-2991ab0aa212	73905eb9-32e6-fb9d-e053-2991ab0aa212	cd6435298107.6280915473@direct	1	HUMAN OTC DRUG LABEL NDC RESERVATION	Troy Cu	11-SEP-2018 14:57:13

FDA

CDER Direct
Electronic Submissions Portal

Home > Product Listing and Reporting

SUBMISSIONS
(ADD SUBMISSION TYPE)

- NDC/NHRIC Labeler Code Request
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PRODUCT LISTING AND REPORTING

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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	af5c7384-bdc3-3896-e053-2995af0ad362	af5c7384-bdc4-3896-e053-2995af0ad362	-	1	HUMAN OTC DRUG LABEL		DETAILS	Troy Cu	15-SEP-2020 11:50:49	-
DRAFT	4abdab69-194b-4607-84ad-dee264d49fd3	af5cd31c-9f34-067d-e053-2995af0aac27	-	3	HUMAN OTC DRUG LABEL	Geri Care 44-249	DETAILS	Troy Cu	15-SEP-2020 11:41:39	-
DRAFT	9eca1b41-6747-48ae-942b-c102dc88173d	af5cd31c-9f28-067d-e053-2995af0aac27	-	8	HUMAN OTC DRUG LABEL	Aspirin 325 mg	DETAILS	Troy Cu	15-SEP-2020 11:30:10	-

U.S. Department of **Health & Human Services**

CDER *Direct*
Electronic Submissions Portal

SUBMISSIONS
(ADD SUBMISSION TYPE)

- NDC/NHRIC 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: *

-- Select Document Type --
BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING
BULK INGREDIENT
CELLULAR THERAPY
DRUG FOR FURTHER PROCESSING
HUMAN COMPOUNDED DRUG LABEL
HUMAN OTC DRUG LABEL
HUMAN PRESCRIPTION DRUG LABEL
NDC RESERVATION
NON-STANDARDIZED ALLERGENIC LABEL
PLASMA DERIVATIVE
STANDARDIZED ALLERGENIC
VACCINE LABEL

Note: To update an existing submission, click ... m the table in the prior page / Dashboard.

CONTINUE | CANCEL

CDER Direct
Electronic Submissions Portal
SUBMISSIONS
(ADD SUBMISSION TYPE)
NDC/NHRIC Labeler Code Request
Establishment Registration
GDUFA Self-Identification
Product Listing and Certification
WDD/3PL
CREATE
Create a
Import a
SPL Docum
Note: To up
Dashboard.
CONTI
ble in the prior page /
Message from webpage
As a courtesy, the FDA is providing standardized hand sanitizer templates that can be used to prepopulate the listing, and customize for your product. If you would like to use a template please select OK and then choose a template. Otherwise select Cancel and continue.
OK
Cancel

U.S. Department of **Health & Human Services**

CDER *Direct*
Electronic Submissions Portal

SUBMISSIONS
(ADD SUBMISSION TYPE)

- NDC/NHRIC Labeler Code Request
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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 OTC DRUG LABEL

Template Type:
-- Select Template Type --
ALCOHOL 80%
ISOPROPYL ALCOHOL 75%

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

CONTINUE CANCEL

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.

COVID-19 Update – To help assist industry with creating listings for hand sanitizers, FDA has created a guide. Download the guide here - CDER Direct Hand Sanitizer.

HEADER DETAILS

Document Type: * HUMAN OTC DRUG LABEL

Set ID: * af60b537-965d-9505-e053-2a95af0adf31 Generate New

Version Number: * 1

Root ID: * af60b537-965e-9505-e053-2a95af0adf31 Generate New

Effective Date: * 10-08-2020

Title

LABELER DETAILS

Labeler Name: * CDER Direct, LLC

Labeler DUNS: * 012345678

REGISTRANT DETAILS

Registrant Name:

Registrant DUNS:

☐ Confidential

ESTABLISHMENTS

ADD ESTABLISHMENT

None

PRODUCTS

ADD PRODUCT

GO ACTIONS

None.

RELATED DOCUMENTS

Type Code: --Select One--

+	ROOT ID	SET ID	VERSION NUMBER
✖			

Home > Product Listing and Reporting > Products > Establishment Details

SAVE ESTABLISHMENT | DELETE ESTABLISHMENT | << RETURN

ESTABLISHMENT DETAILS

Establishment Name: * CDER Direct, LLC

Establishment DUNS: * 012345678

☐ Confidential

BUSINESS OPERATION(S)

	BUSINESS OPERATION	PRODUCT NDC
✖	MANUFACTURE	1234-0567
✖	PACK	1234-0567
✖	LABEL	1234-0567

ESTABLISHMENTS

ADD ESTABLISHMENT

row(s) 1 - 1 of 1

	ESTABLISHMENT DUNS	ESTABLISHMENT NAME	CONFIDENTIAL
	012345678	CDER Direct, LLC	N

PRODUCTS

ADD PRODUCT

GO ACTIONS

None.

CDER Direct
Electronic Submissions Portal

Home | Product Listing and Reporting | Products | Product Details

SAVE PRODUCT | DELETE PRODUCT | << RETURN

PRODUCT DATA ELEMENTS

NDC Product Code: * 1234-0567

Proprietary Name: * Aspirin

Suffix:

Non Proprietary Name: * Aspirin

DEA Schedule: -Select DEA Schedule-

Dosage Form: * TABLET

Route of Administration: *

AURICULAR (OTIC)
BUCCAL
CONJUNCTIVAL
CUTANEOUS
DENTAL
ELECTRO-OSMOSIS

ORAL

Source NDC:

MARKETING DETAILS

Marketing Status: * ACTIVE

Marketing Start Date: * 10-08-2020

Marketing Category: * OTC monograph not final

Application Number/ Regulatory Citation: part343

INGREDIENTS

ADD INGREDIENT

row(s) 1 - 2 of 2

	SUBSTANCE NAME	UNII / NDC	STRENGTH	TYPE
	ASPIRIN	R16CO5Y76E	325 mg	ACTIB
	STARCH, CORN	O8232NY3SJ		IACT

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: * 1

Type: * Active Ingredient, Ingredient is Basis of Strength

Ingredient UNII - Name: * (R16CO5Y76E) ASPIRIN

Strength: * 325

Unit Of Measure: * mg

☐ Moiety Same as Ingredient

Active Moiety: * (R16CO5Y76E) ASPIRIN

ADD ACTIVE MOIETY

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

row(s) 1 - 5 of 5

	CHARACTERISTIC	VALUE	ADDITIONAL DESCRIPTION
	SPLCOLOR	WHITE	-
	SPLSIZE	10 mm	-
	SPLSHAPE	ROUND	-
	SPLSCORE	1	-
	SPLIMPRINT	44;157	-

PACKAGING
ADD PACKAGE
None

SAVE PACKAGE | DELETE PACKAGE | DONE | << RETURN

PACKAGING

ONLY LEVEL

Check for Deletion	☐
Is this a sample package ?	☐
Package NDC:	1234-0567-01
Package Type: *	BOTTLE
Quantity: *	100
Unit of Measure: *	1
Combination Product Type:	Type 0: Not a Combination Product
Marketing Status:	active
Marketing Start Date:	10-08-2020
Marketing End Date:	

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.

COVID-19 Update – To help assist industry with creating listings for hand sanitizers, FDA has created a guide. Download the guide here - CDER Direct Hand Sanitizer.

HEADER DETAILS

Document Type: * HUMAN OTC DRUG LABEL

Set ID: * af5c7384-bdc3-3896-e053-2995af0ad362 Generate New

Version Number: * 1

Root ID: * af5c7384-bdc4-3896-e053-2995af0ad362 Generate New

Effective Date: * 10-08-2020

Title

Home > Product Listing and Reporting > Products > Content of Labeling

EXPAND SECTIONS | CLASSIC | ADD SECTION | << RETURN

[SPL UNCLASSIFIED SECTION]	EDIT
Active Ingredient(s) [OTC - ACTIVE INGREDIENT SECTION]	EDIT
Purpose [OTC - PURPOSE SECTION]	EDIT
Use [INDICATIONS & USAGE SECTION]	EDIT
Warnings [WARNINGS SECTION]	EDIT
Do not use [OTC - DO NOT USE SECTION]	EDIT
[OTC - WHEN USING SECTION]	EDIT
[OTC - STOP USE SECTION]	EDIT
[OTC - KEEP OUT OF REACH OF CHILDREN SECTION]	EDIT
Directions [DOSAGE & ADMINISTRATION SECTION]	EDIT
Other information [STORAGE AND HANDLING SECTION]	EDIT
Inactive ingredients [INACTIVE INGREDIENT SECTION]	EDIT
Package Label - Principal Display Panel [PACKAGE LABEL.PRINCIPAL DISPLAY PANEL]	EDIT

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 asterisk indicate required fields.

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Set ID: * af60b537-965d-9505-e053-2a95af0adf31 Generate New

Version Number: * 1

Root ID: * af60b537-965e-9505-e053-2a95af0adf31 Generate New

Effective Date: * 10-08-2020

Title

Updating a Previous listing

- Create a new version of the most recent accepted submission
- Do not change the Set ID!
- A new Root ID and version number will generate automatically

- Modify all listing data elements and labeling information as appropriate
- Submit

Delisting a product

- Create a new version of the most recent accepted submission
- Change the marketing status from “Active” to Complete
- Enter the end marketing date for the product (e.g., Expiration date of last lot in distribution)
- Submit

Summary

- Listing allows FDA to maintain an inventory of all drugs commercially distributed in the U.S and their representative labeling
- Listing data is also used by the public and other organizations in academia and industry
- Remember to delist when no longer in commercial distribution
- Have a standard operation procedure or system in place to verify the accuracy of listing at least twice a year

In a Nutshell

WE ALL NEED THIS INFORMATION TO BE ACCURATE, COMPLETE AND UP TO DATE!

Do’s & Don’ts

Product Listing

Do’s

- Visit our website- Electronic Drug Registration and Listing instructions
- Provide the Set ID/Submission ID of the failed submission
- Submit SPL
- Ask questions

Don’ts

- Provide inaccurate data
- Make any change to the SPL file
- Modify data elements
- Include multiple email addresses when requesting for assistance

Helpful resources

- Electronic Drug Registration and Listing instructions
- Strength Conversion in Drug Listing
- OTC Active Ingredients
- Electronic Code of Federal Regulations
- edrls@fda.hhs.gov

Challenge Question #1

True or False: You are required to provide establishment information in product listing.

- True
- False

Challenge Question #2

True or False: A product listing can be listed without labeler code.

- True
- False