

Reference Guide: NDC Reservation

Welcome to NDC Reservation in the FDA Direct Portal

This guide provides the essential information you need to complete an NDC Reservation via FDA Direct.

For technical support, email the eDRLS Help Desk at CDERdirect@fda.hhs.gov.

**FDA Direct**
CDER Direct & Cosmetics Direct

LOGIN

Username:

Password:

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OR

CREATE NEW ACCOUNT

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WELCOME TO FDA DIRECT

FDA Direct is U.S. Food and Drug Administration's web-based and free structured product labeling (SPL) authoring tool. Previously CDER Direct, FDA Direct now includes CDER Direct and Cosmetics Direct. Users can create separate accounts, depending on drugs or cosmetics submissions, or a single account that includes both CDER Direct submissions as well as Cosmetics Direct submissions.

CDER Direct

CDER Direct allows users to easily create and submit data directly to the FDA. This system will provide information to FDA/CDER about drug manufacturers and private label distributors, outsourcing facilities, wholesale drug distributors and third-party logistics, and generic drug facilities, along with their drugs in U.S. commercial distribution. CDER Direct has several sections which allows submission of the following data to the FDA: Establishment Registration and Drug Listing, including NDC Labeler Code Requests and NDC Reservations, Outsourcing Facility and Product Reporting, DSCSA Annual Reporting, and Generic Drug Self-Identification.

Cosmetics Direct

On December 29, 2022, the President signed the Consolidated Appropriations Act, 2023 (Pub. L. 117-328) into law, which included the Modernization of Cosmetics Registration Act of 2022 (MoCRA). Among other provisions, MoCRA added section 607 to the Federal Food, Drug, and Cosmetic Act (FD&C Act), establishing requirements for cosmetic product facility registration and cosmetic product listing.

Section 607(a) of the FD&C Act requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility with FDA. Section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person submit to FDA "a cosmetic product listing." Certain small businesses, as defined in section 612 of the FD&C Act, are exempt from the registration and listing requirements. [Click here](#) to learn more about MoCRA.

This free tool allows you to create and submit the following types of data directly to the FDA: Registration of Cosmetic Product Facility and Cosmetic Product Listing. This system will provide information to FDA/Office of Cosmetics and Colors (OCAC) about cosmetic product manufacturers/processors and cosmetic products on the market.

Note: Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1993, requires that all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at <http://www.section508.gov/>.

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Click [here](#) to access the FDA Direct Portal

NDC Reservation	<u>3</u>
Cancelling NDC Reservation	<u>11</u>
Converting NDC Reservation to Active Listing	<u>15</u>

NDC Reservation

Step 1 Navigate to FDA Direct by accessing: <https://direct.fda.gov>

Step 2 Enter your login credentials, accept the terms of service, and click **Login**



FDA Direct

CDER Direct & Cosmetics Direct

LOGIN

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Password:

[Forgot your password?](#)

☐ [I accept the Terms of Service](#)

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Section 607(a) of the FD&C Act requires every person that owns or operates a facility that engages in the manufacturing or processing of a cosmetic product for distribution in the United States to register each facility with FDA no later than 1 year after the date of enactment. In addition to the registration requirements, section 607(c) of the FD&C Act requires that for each cosmetic product, the responsible person submit to FDA "a cosmetic product listing." Certain small businesses, as defined in section 612 of the FD&C Act, are exempt from the registration and listing requirements. [Click here](#) to learn more about MoCRA.

This free tool allows you to create and submit your submissions directly to the FDA. This system will provide information to FDA/Office of Cosmetics and Colors (OCC) about cosmetic manufacturers and products in the marketplace.

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1993, requires that all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at <http://www.section508.gov/>.

Step 3

Click on NDC Reservation

FDA Direct
CDER Direct & Cosmetics Direct

All Submissions

ESTABLISHMENT REGISTRATION & DRUG LISTING

Establishment Registration

NDC Labeler Code Request

Drug Listing and Certification

NDC Reservation

ALL SUBMISSIONS

For assistance with drug related validation errors please contact CDERDirect@fda.hhs.gov and for cosmetic related validation errors please contact CosmeticsDirect@fda.hhs.gov.

For general questions regarding electronic establishment registration and drug listing, contact eDRLS@fda.hhs.gov. For general questions regarding electronic registration and listing of cosmetic product facilities and products, contact eRLC@fda.hhs.gov.

Q v

GO

ACTIONS v

Step 4

Click on Create New/Upload File

Before proceeding, please review the important guidelines for NDC Reservation

FDA Direct
CDER Direct & Cosmetics Direct

All Submissions **NDC Reservation**

ESTABLISHMENT REGISTRATION & DRUG LISTING

Establishment Registration

NDC Labeler Code Request

Drug Listing and Certification

NDC Reservation

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING

Outsourcing Facility Registration

Compounded Drug Reporting

DSCSA ANNUAL REPORTING

Wholesale Drug Distributor and Third-Party Logistics Provider Reports

Important Guidelines for NDC Reservation

NDC RESERVATION

For assistance with validation errors in CDER Direct, contact CDERdirect@fda.hhs.gov. For general questions regarding electronic establishment registration and drug listing, contact eDRLS@fda.hhs.gov.

- NDC Reservation IS NOT a drug listing submission. It reserves an NDC for a future drug listing with the FDA, confirming availability of the NDC during product development.
- NDC reservation is not required prior to a drug listing submission
- NDC Reservation SPL Document Type should only be selected to reserve an NDC for up to 2 years
- DO NOT reserve an NDC if you do not intend to start commercial distribution within 2 years.
- Once commercial distribution begins, the NDC Reservation SPL must be updated to a Drug Listing SPL with all required data elements to list the drug product with FDA.

Q v

GO

ACTIONS v

None

SEARCH NDC RESERVATION

CREATE NEW / UPLOAD FILE

Step 5

Click on **Create a New NDC Reservation using a blank form** and select the appropriate SPL **Document Type** for the drug product you want to reserve. Then click **Continue**

U.S. Department of Health & Human Services

Welcome DRUGSRUS - DRUGSRUS | Logout

FDA Direct
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ESTABLISHMENT REGISTRATION & DRUG LISTING

Establishment Registration

NDC Labeler Code Request

Drug Listing and Certification

NDC Reservation

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING

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DSCSA ANNUAL REPORTING

Wholesale Drug Distributor and Third-Party Logistics Provider Reports

GENERIC DRUG SELF-IDENTIFICATION

CREATE NEW NDC RESERVATION

☒ Create a New NDC Reservation using a blank form

☐ Import an existing NDC Reservation

Reservation Product Type: *

-- Select Document Type --

-- Select Document Type --

BULK INGREDIENT

CELLULAR THERAPY

DRUG FOR FURTHER PROCESSING

HUMAN OTC DRUG LABEL

HUMAN PRESCRIPTION DRUG LABEL

NON-STANDARDIZED ALLERGENIC LABEL

PLASMA DERIVATIVE

STANDARDIZED ALLERGENIC

VACCINE LABEL

Note: To update an existing submission, click

SUBMISSION ACCEPTED from the table in the prior page / Dashboard.

CONTINUE

CANCEL

Step 6

The information under Header Details (Set ID, Root ID, Version Number, Effective Date) will be automatically populated

NOTE: Effective Date is not associated with the date the SPL is effective. The date an SPL is received by FDA is considered the date it is effective

All Submissions > NDC Reservation > 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.

Note: This form is only to Reserve a Product NDC. The Product NDC can be reserved for up to 2 years from the time of submission. After successfully reserving a NDC, it can be converted to an active listing.

HEADER DETAILS

Document Type: *

HUMAN OTC DRUG LABEL

NDC RESERVATION

Version Number: *

1

Set ID: *

4251cd1d-db47-b963-e063-6b94af0ae8ce

Generate New

Effective Date: *

10-29-2025

Root ID: *

4251cd1d-db48-b963-e063-6b94af0ae8ce

Generate New

Title

Step 7

Enter the **Labeler Details**.
This Labeler Name and Labeler DUNS is the information associated with the Labeler Code for which the drug listing is being completed

LABELER DETAILS

Labeler Name: *

Labeler DUNS: *

REGISTRANT DETAILS

Registrant Name:

Registrant DUNS:

☐ Confidential

Quick Tip!

Clicking on a fieldname that has a dotted underline will bring up Help Text to provide more information as to the type of information being requested

LABELER DETAILS

Labeler Name: *

Labeler Name

Enter the business name of the labeler provided in the NDC/NHRIC Labeler Code request SPL file.

Step 8

Click on **Add Product**

PRODUCTS

ADD PRODUCT

Q

GO

ACTIONS

None.

Step 9

Complete all required
Product Data Elements

PRODUCT DATA ELEMENTS

Product NDC: *

Proprietary Name:

Suffix:

Non Proprietary Name: *

DEA Schedule:

-- Select DEA Schedule --

Dosage Form: *

-Select Dosage Form-

Source NDC:

Route of Administration:

ADD

ROUTE OF ADMINISTRATION

1 - 1

MARKETING DETAILS

Marketing Status: *

--Select One--

Reserved Until Date: *

Marketing Category:

-Select Marketing Category-

INGREDIENTS

ADD INGREDIENT

Note: * At least one active ingredient is required.
None

Search

Step 10
Click on **Save Product**

SAVE PRODUCT<< RETURN

Note: NDC Reservation for Kits is currently not available, this feature is anticipated to be available soon.

PRODUCT DATA ELEMENTS

Product NDC: *

Step 11
Click on **Submit SPL**

All SubmissionsNDC ReservationProducts

PREVIEW SPLSUBMIT SPLSAVE AS DRAFTSAVE AND VALIDATEDELETE<< 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.

Note: This form is only to Reserve a Product NDC. The Product NDC can be reserved for up to 2 years from the time of submission. After successfully reserving a NDC, it can be converted to an active listing.

— HEADER DETAILS

Document Type: *HUMAN OTC DRUG LABELNDC RESERVATIONVersion Number: *1

Set ID: *4252a39c-e271-ea1c-e063-6b94af0a0a49Generate NewEffective Date: *10-29-2025

Root ID: *4252a39c-e272-ea1c-e063-6b94af0a0a49Generate New

Title

Cancelling NDC Reservation

If you no longer intend to manufacture or distribute the drug as previously planned, you should cancel the NDC Reservation.

Step 1

Click on **Submission Accepted** status for your reserved NDC

FDA

FDA Direct

CDER Direct & Cosmetics Direct

All Submissions

NDC Reservation

ESTABLISHMENT REGISTRATION & DRUG LISTING

Establishment Registration

NDC Labeler Code Request

Drug Listing and Certification

NDC Reservation

OUTSOURCING FACILITY REGISTRATION AND PRODUCT REPORTING

Outsourcing Facility Registration

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DSCSA ANNUAL REPORTING

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NDC RESERVATION

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Q

GO

ACTIONS

SEARCH NDC RESERVATION

CF

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	TITLE	PRODUCT DETAILS
SUBMISSION ACCEPTED	4252a39c-e271-ea1c-e063-6b94af0a0a49	4252a39c-e272-ea1c-e063-6b94af0a0a49	cd7051384296.7891652430@direct	1	HUMAN OTC DRUG LABEL NDC RESERVATION	-	DETAILS

Step 2

Click on **Create New Version**

All Submissions

NDC Reservation

Products

VIEW SPL

DOWNLOAD SPL

CREATE NEW VERSION

<< 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.

Note: The Product NDCs have been reserved until 10-01-2026

HEADER DETAILS

Document Type: *

HUMAN OTC DRUG LABEL

NDC RESERVATION

Version Number: *

1

Set ID: *

4252a39c-e271-ea1c-e063-6b94af0a0a49

Effective Date: *

10-29-2025

Root ID: *

4252a39c-e272-ea1c-e063-6b94af0a0a49

Title

Step 3

Select the reserved NDC to cancel

PRODUCTS

Q

GO

ACTIONS

1 - 1 of 1

SELECT	PRODUCT NDC	PROPRIETARY NAME	DOSAGE FORM
	99999-444	-	CAPSULE

Step 4

In the **Marketing Details** section, click on the **Marketing Status** dropdown and change the status from **Reserved** to **Cancelled**

MARKETING DETAILS

Marketing Status: *
Reserved Until Date: *
Marketing Category:

RESERVED

--Select One--

ACTIVE

CANCELLED

RESERVED

Category-

Step 5

Click on **Save Product**

SAVE PRODUCT<< RETURN

Note: NDC Reservation for Kits is currently not available, this feature is anticipated to be available soon.

PRODUCT DATA ELEMENTS

Product NDC: *99999-444

Proprietary Name:

Suffix:

Step 6

Then click on **Submit SPL**

All Submissions>NDC Reservation>Products

PREVIEW SPL

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.

Note: This form is only to Reserve a Product NDC. The Product NDC can be reserved for up to 2 years from the time of submission. After successfully reserving a NDC, it can be converted to an active listing.

HEADER DETAILS

Document Type: *HUMAN OTC DRUG LABELNDC RESERVATIONVersion Number: *2

Set ID: *4252a39c-e271-ea1c-e063-6b94af0a0a49Effective Date: *10-30-2025

Root ID: *42641eab-5260-a0f4-e063-6a94af0a9a1c

Title

Converting NDC Reservation to Active Listing

Converting NDC Reservation to Active Listing

At the time of commercial distribution, an NDC Reservation SPL should be converted to a Drug Listing SPL. At the latest, the listing for a new drug introduced into the U.S. market must be submitted to the agency in June or December of the same calendar year.

Step 1

Click on **Submission Accepted** status for your reserved NDC

FDA

FDA Direct

CDER Direct & Cosmetics Direct

All Submissions

NDC Reservation

ESTABLISHMENT REGISTRATION & DRUG LISTING

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NDC Labeler Code Request

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NDC RESERVATION

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Q

GO

ACTIONS

SEARCH NDC RESERVATION

CF

STATUS	SET ID	ROOT ID	SUBMISSION ID	VERSION	DOCUMENT LABEL	TITLE	PRODUCT DETAILS
SUBMISSION ACCEPTED	4252a39c-e271-ea1c-e063-6b94af0a0a49	4252a39c-e272-ea1c-e063-6b94af0a0a49	cd7051384296.7891652430@direct	1	HUMAN OTC DRUG LABEL NDC RESERVATION	-	DETAILS

Step 2

Click on **Create New Version**

All Submissions

NDC Reservation

Products

VIEW SPL

DOWNLOAD SPL

CREATE NEW VERSION

<< 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.

Note: The Product NDCs have been reserved until 10-01-2026

HEADER DETAILS

Document Type: *

HUMAN OTC DRUG LABEL

NDC RESERVATION

Version Number: *

1

Set ID: *

4252a39c-e271-ea1c-e063-6b94af0a0a49

Effective Date: *

10-29-2025

Root ID: *

4252a39c-e272-ea1c-e063-6b94af0a0a49

Title

Step 3

Select the reserved NDC to cancel

PRODUCTS

Q

GO

ACTIONS

1 - 1 of 1

SELECT	PRODUCT NDC	PROPRIETARY NAME	DOSAGE FORM
	99999-444	-	CAPSULE

Step 4

In the **Marketing Details** section, click on the **Marketing Status** dropdown and change the status from **Reserved** to **Active**

MARKETING DETAILS

Marketing Status: *
RESERVED

Reserved Until Date: *
--Select One--

Marketing Category: *
Category-

Step 5

Click on **Save Product**

SAVE PRODUCT<< RETURN

Note: NDC Reservation for Kits is currently not available, this feature is anticipated to be available soon.

PRODUCT DATA ELEMENTS

Product NDC: *99999-444

Proprietary Name:

Suffix:

Step 6

At this time, complete all required fields for an active listing (reference the Listing a Human Drug Product Quick Reference Guide) and click on **Submit SPL**

All Submissions> NDC Reservation> Products

PREVIEW SPL

SUBMIT SPL

SAVE AS DRAFT

SAVE AND VALIDATE

DELETE

<< RETURN

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