



# Supply Chain Conference 2024

## ARCOS Reporting

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# Overview



**21 U.S.C. § 827(b) – Availability of Records**

**21 U.S.C. § 827(d) – Periodic Reports**

**21 U.S.C. § 827(j) – Electronic Reporting**

**[<https://uscode.house.gov/>]**





**21 C.F.R. § 1304.04 – Maintenance of Records**

**21 C.F.R. § 1304.33 – Reports to ARCOS**

**[<https://www.ecfr.gov/>]**





- ❖ **Manufacturers, to include re-packagers & re-labelers (per 21 U.S.C. § 802(15))**
- ❖ **Distributors**
- ❖ **Reverse Distributors**





- ❖ **If a company has additional registration types, only those three registration types report to ARCOS**
- ❖ **Any other registration type would only appear on the other end of an ARCOS transaction (associate registration)**







- ❖ **If a company has multiple reportable registrations, central reporting is an option**
- ❖ **Notify us before beginning this type of reporting so we can set up our system accordingly**





- ❖ **Quarterly or monthly**
- ❖ **All submissions must reflect your selected reporting frequency**
- ❖ **Please wait until the end of a quarter to change reporting frequencies**





- ❖ **ARCOS reportable drugs are ...**
  - ✓ **All Schedule 1 controlled substances**
  - ✓ **All Schedule 2 controlled substances**
  - ✓ **Schedule 3 narcotics and GHB preps**
  - ✓ **Selected Schedule 3 and 4 psychotropics, for which manufacturing must be reported (21 C.F.R. § 1304.33(d))**





- ❖ **Notes regarding reportable drugs:**
  - ❖ **We are currently reviewing manufacturing reporting requirements as part of our Handbook update**
  - ❖ **Avoid submitting transactions involving non-reportable drugs**





- ❖ **In general, any increases and decreases to inventory of ARCOS reportable drugs, along with end-of-year inventory and manufacturing activities**





- ❖ **Increases to inventory include ...**
  - ✓ **Purchases/Receipt of supply**
  - ✓ **Returns from customers**
  - ✓ **Returns from Gov't or law enforcement**
  - ✓ **Received for the purpose of destruction**





- ❖ **Decreases to inventory include ...**
  - ✓ **Sales/transfer of supply**
  - ✓ **Thefts, losses, spillage**
  - ✓ **Destruction**
  - ✓ **Seizure/receipt by Gov't**





- ❖ **Manufacturing activities (examples) ...**
  - ✓ **Material manufactured**
  - ✓ **Use of material to create a preparation in another schedule**
  - ✓ **Waste recovered from manufacturing**
  - ✓ **Stability or quality testing**







- ❖ **ARCOS inventory reporting:**
  - ✓ **End-of-year; snapshot of what was on hand (ARCOS reportable) at close of business December 31st**
  - ✓ **Inventory reporting resulting from a schedule change; substance becomes ARCOS reportable**





- ❖ **Notes regarding reportable activities:**
  - ❖ **Again, we are currently reviewing manufacturing reporting requirements as part of our Handbook update**
  - ❖ **Must report “no activity”**
  - ❖ **Must report “no end-of-year inventory”**





- ❖ **Notes regarding reportable activities:**
  - ❖ **Increases and decreases should be reported using the date on which the activity actually occurred**
  - ❖ **Manufacturing totals should be reported per period or per year**





- ❖ **Notes regarding reportable activities:**
- ❖ **Transactions are to be reported from the perspective of the reporting registrant**





# Transaction Record

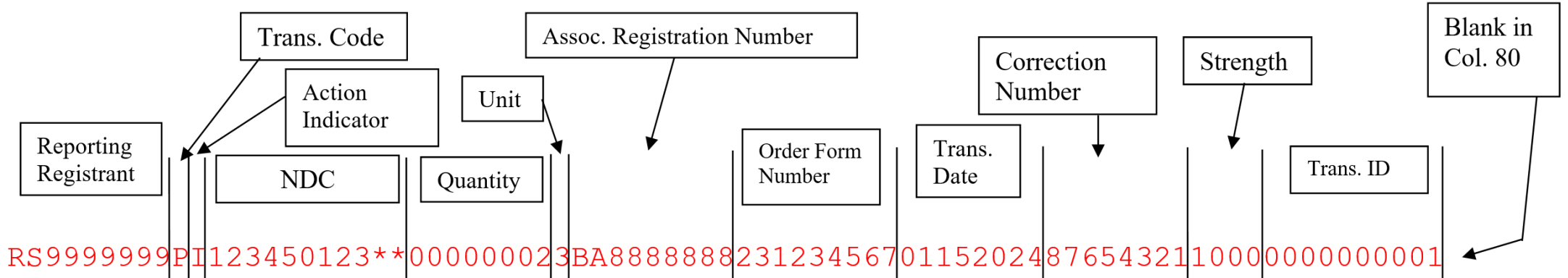
# TRANSACTION RECORD / 80-CHARACTER STRING



FIELD	POSITION (TEXT FILE)	SAMPLE DATA
REPORTING REGISTRANT	1 - 9	RS9999999
TRANSACTION CODE	10	P
ACTION INDICATOR	11	I
NATIONAL DRUG CODE	12 - 22	123450123**
QUANTITY	23 - 30	00000002
UNIT	31	3
ASSOCIATE REGISTRATION	32 - 40	BA8888888
ORDER FORM NUMBER	41 - 49	231234567
TRANSACTION DATE	50 - 57	01152024
CORRECTION NUMBER	58 - 65	87654321
STRENGTH	66 - 69	1000
TRANSACTION IDENTIFIER	70 - 79	0000000001
(BLANK)	80	



# TRANSACTION RECORD / 80-CHARACTER STRING



# TRANSACTION RECORD / 80-CHARACTER STRING



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ARCOS/SORS Online: Add/Edit Report

Reporting Period: Jan 01 2024 - Jan 31 2024

ARCOS/SORS Online: Add Transaction

 Trans Code Key (Enter '=' to set a field to the value from the most recently entered transaction, which, if present, is shown next)

 Help

Tr. Code	NDC Number	Quantity	Unit Code	Strength	Assoc. Reg. #	Order Form #	Trans Date
-?- <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	-Optional- <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	





- ❖ **Increases to inventory:**
  - **P → Purchase/Receipt**
  - **R / V → Return/Unsolicited Return**
  - **G → Received from Government**





## ❖ Decreases to inventory:

- **S → Sale/Transfer**
- **T → Theft**
- **Y → Destruction**
- **Z → Seizure/Transfer to Government**





## ❖ Inventory:

- **1 → Schedule Change Inventory**
- **3 → End-of-Year Inventory**
- **4 → In-Process End-of-Year Inventory**
- **8 → No Reportable End-of-Year Inventory**





## ❖ **Manufacturing:**

- **M → Substance Manufactured**
- **K → Used in Creating a Preparation**
- **N → Non-recoverable Waste**
- **W → Recovered Waste**
- **U → Used in Production/Conversion**





## ❖ **Manufacturing:**

- **L → Reversing/Recovery of Original Substance**
- **Q → Samples Pulled (quality testing, etc.)**
- **J → Return of Samples Pulled**





❖ **Other:**

- **7 → No ARCOS Reportable Activity**
- **X → Lost-in-Transit (explanatory only)**





- ❖ **Notes regarding Transaction Codes:**
  - ❖ **Do not use Trans Code “5” (Special Inventory) unless directed to do so**
  - ❖ **Destruction (Code “Y”) must be reported by the registrant performing the actual destruction; transfer to reverse distributor uses Code “S” (sale/transfer)**





- ❖ **Used to initiate 3 “actions”:**
  - **Action Indicator “I” → Insert a transaction from a prior reporting period**
  - **Action Indicator “D” → Delete a transaction from a previously submitted report**
  - **Action Indicators “D” & “A” paired → Adjust a previously submitted transaction**







- ❖ **Notes regarding Action Indicators:**
  - ❖ **Only apply to text file submissions; ARCOS Online uses buttons**
  - ❖ **Action Indicator “D” cannot be used to delete an error transaction; this must be done in ARCOS Online**





- ❖ **Notes regarding Action Indicators:**
  - ❖ **Action Indicators “D” & “A” cannot be used to adjust an error transaction; the error transaction must first be corrected**



# NATIONAL DRUG CODE (NDC)



**12345 – 0123 – 01**

**↑**  
**Labeler  
Code**

**↑**  
**Product  
Code**

**↑**  
**Package  
Code**





- **Labeler Code ... Identifies the firm that owns the product**
- **Product Code ... Identifies the strength, dosage form, and formulation of the product**
- **Package Code ... Identifies the package size and type**





- ❖ **For ARCOS reporting, NDCs must be converted to a 5-digit labeler code, 4-digit product code, and 2-digit package code**
- ❖ **Leading zero must be added to the beginning of the section that falls short of the required number of digits**





## EXAMPLES:

12345 - 123 - 01

12345 - 0123 - 01

1234 - 1234 - 01

01234 - 1234 - 01





## EXAMPLES:

12345 - 1234 - 1

12345 - 1234 - 01





## ❖ **Notes regarding NDCs:**

- **“Generic” NDCs are available if product does not have its own NDC assigned; includes ARCOS reporting or import/export purposes**







## ❖ **Notes regarding NDCs:**

- **NDCs are unique to a specific product, including labeler, formulation, and package size**





## ❖ Notes regarding NDCs:

- **PLEASE submit NDCs for addition; email or upload through the ARCOS Online system**
- **NDCs are not automatically added to our dictionary**





## ❖ **Notes regarding NDCs:**

- **Let us know if an NDC needs to be hidden from publication on our website; still available for use but not included in monthly text file version**





- ❖ **Use of this field is dependent upon what the NDC represents:**
  - **NDC ends -\*\* and represents bulk tablets, capsules, etc. → Quantity reports number of individual units (tablets, capsules, etc.)**





- ❖ **Use of this field is dependent upon what the NDC represents:**
  - **NDC ends -\*\* and represents bulk raw material or bulk powder → Quantity is used in conjunction with Unit and Strength fields to report weight**





- ❖ **Use of this field is dependent upon what the NDC represents:**
  - **NDC ends -\*\* and represents bulk liquid → Quantity is used in conjunction with Unit and Strength fields to report volume**





- ❖ **Use of this field is dependent upon what the NDC represents:**
  - **NDC ends -00 to -99 → Quantity is used to report number of packages; used in conjunction with Unit and Strength fields in limited circumstances**





- ❖ **Mandatory when reporting bulk powder, raw material, and liquid:**
  - **1 → micrograms**
  - **2 → milligrams**
  - **3 → grams**
  - **4 → kilograms**
  - **5 → milliliters**
  - **6 → liters**







❖ **Optional to multiply quantity reported by 12 or 1,000:**

- **D → dozens (x 12)**
- **K → thousands (x 1,000)**





- ❖ **In general, the registration of the entity on the other end of the transaction**
- ❖ **When reporting a purchase or receipt (Code “P”), the Associate Registration is the supplier or sender**
- ❖ **When reporting a sale or transfer (Code “S”), the Associate Registration is the recipient or customer**





- ❖ **Left blank when reporting manufacturing activities and inventory, along with Codes “7” (no activity) and “8” (no inventory)**
- ❖ **Reflects DEA field office when reporting a destruction (Code “Y”); contact us if you need an appropriate registration number for this**





- ❖ **Required when reporting the transfer of C-I or C-II drugs**
- ❖ **Number on pre-printed DEA Form 222 or CSOS order**



# ORDER FORM NUMBER



DEA FORM-222 U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II DRUG ENFORCEMENT ADMINISTRATION OMB APPROVA

<b>PURCHASER INFORMATION</b>		<b>REGISTRATION INFORMATION</b>		SUPPLIER DEA NUMBER:# <input type="text"/>				
		REGISTRATION #: REGISTERED AS:		<b>PART 2: TO BE FILLED IN BY PURCHASER</b>				
		SCHEDULES: <b>ORDER FORM NUMBER:</b>		BUSINESS NAME				
		DATE ISSUED:		STREET ADDRESS				
				CITY, STATE, ZIP CODE				
<b>PART 1: TO BE FILLED IN BY PURCHASER</b>			<b>PART 5: TO BE FILLED IN BY PURCHASER</b>		<b>PART 3: ALTERNATE SUPPLIER IDENTIFICATION</b> - to be filled in (name in part 2) if order is endorsed to another supplier to fill.			
Print or Type Name and Title					ALTERNATE DEA # <input type="text"/>			
Signature of Requesting Official (must be authorized to sign order form)			Date		Signature- by first supplier			
					OFFICIAL AUTHORIZED TO EXECUTE ON BEHALF OF SUPPLIER			
					DATE			
ITEM	NO. OF PACKAGES	PACKAGE SIZE	NAME OF ITEM	NUMBER REC'D	DATE REC'D	<b>PART 4: TO BE FILLED IN BY SUPPLIER</b>		NUMBER SHIPPED
1						NATIONAL DRUG CODE		



# ORDER FORM NUMBER



## CSOS Transaction Record

Example Data	Field Name	Column Position
AA1234567	Registrant DEA Registration Number	1-9
P	Transaction Code	10
D	Action Indicator	11
000543751**	NDC Number	12-22
00000002	Quantity	23-30
4	Unit	31
BB1234567	Associate Registrant Number	32-40
00X453890	Order Form Number	41-49
01312006	Transaction Date (mmddyyyy)	50-57
91070022	Correction Number	58-65
0985	Strength	66-69
0000000088	Transaction ID	70-79
	Leave Blank	80
000543751**	NDC Number	81-91
0000002	Quantity	92-99
4	Unit	100
0985	Strength	101-104
	End of Line Carriage Return	105





- ❖ **Normally, the date on which a transaction actually occurs**
- ❖ **For purchases/receipt (“P”), the date on which possession is taken**
- ❖ **For sales/transfers (“S”), the date on which the drug product left your possession**





- ❖ **For manufacturing activities, the date will be the last day of the reporting period or year**
- ❖ **For end-of-year inventory transactions (“3,” “4,” and “8”), the date will be the last day of the year**







- ❖ **For no-activity transactions (Code “7”), the date will be the last day of the reporting period**
- ❖ **The Transaction Date must fall within the reporting period represented by the header record – unless an Action Indicator or Correction Number is used**





- ❖ **Only needed if correcting error transactions in a text file submission; links corrected transaction to error transaction**
- ❖ **Must contact us to request this number**
- ❖ **ARCOS Online error correction does not require this number**





- ❖ **Should only be used for one of two reasons:**
  - ❖ **Required to indicate purity of a bulk raw material, bulk powder, or bulk liquid**
  - ❖ **Reporting a partial ( $< 100\%$ ) or combined ( $> 100\%$ ) package; Quantity field must reflect 1 package**





- ❖ **Should NOT be used in any of the following situations:**
- ❖ **NDC represents bulk finished product (i.e., one capsule, one tablet, etc.)**
- ❖ **To reflect the strength of a tablet, capsule, etc.**





❖ **NOTE: There is an implied decimal after the 3<sup>rd</sup> digit of the Strength**

1000	=	100%
0100	=	10%
0010	=	1%
0001	=	0.1%





- ❖ **Each Transaction Identifier should only be used once per reporting period**
- ❖ **If adjustments, deletions, or insertions are made, a Transaction Identifier may appear more than once in a submission; however, the reporting period should be different**





- ❖ **If adding a transaction to a prior reporting period, note what the next available Transaction Identifier should be**





- ❖ **Users of the ARCOS Online system cannot manually assign Transaction Identifiers**
- ❖ **If using both ARCOS Online and text file submissions, create the ARCOS Online report first**







# Reporting Formats



- ❖ **Electronic reporting is mandatory, per the SUPPORT Act (2018)**
- ❖ **Accounts are now created upon creation of participant files for new ARCOS reportable registrations; no need to send separate requests**





- ❖ **Notes regarding ARCOS Online:**
- ✓ **Web interface – user friendly**
- ✓ **Transactions validated up front**
- ✓ **Account management; additional users**
- ✓ **Error corrections**
- ✓ **No formatting worries; “buttons”**



# ARCOS ONLINE REPORTING SYSTEM

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## Automation of Reports and Consolidated Orders System (ARCOS)

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### What is ARCOS and What Does it Do?

The Controlled Substances Act of 1970 (§ 827) created the requirement for Manufacturers and Distributors to report their controlled substances transactions to the Attorney General. The Attorney General delegates this authority to the Drug Enforcement Administration (DEA).

ARCOS is an automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions. Included in the list of controlled substance transactions tracked by ARCOS are the following: All Schedules I and II materials (manufacturers and distributors); Schedule III narcotic and gamma-hydroxybutyric acid (GHB) materials (manufacturers and distributors); and selected Schedule III and IV psychotropic drugs (manufacturers only).

ARCOS accumulates these transactions which are then summarized into reports which give investigators in Federal and state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the United States (U.S.) by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts.

[ARCOS Reporting](#)[Resources](#)[Diversion Service Center](#)

### ARCOS Reporting

- [ARCOS Online Reporting System](#)
- [ARCOS EDI Request Form \(PDF\)](#)
- [ARCOS Participant Information Update Form \(PDF\)](#)

# ARCOS ONLINE REPORTING SYSTEM



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## ARCOS/SORS Online Reporting: Login

### Login Information

User:

Password:

Login

[SORS Registration \(for Non-ARCOS Reporters\)](#)

[Recover Account/Reset Password](#)



# ARCOS ONLINE REPORTING SYSTEM



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**ARCOS/SORS Online: Main Menu**

- ARCOS MENU ▾
  - Enter ARCOS Reports
  - Enter ARCOS Corrections
  - Enter New NDC Number
  - Manage Participant Data
  - Upload and Manage ARCOS Report Files
  - Lookup Retail Buyer Statistics
  - Manage Users
- SORS MENU ▾

[Change Password](#)

**Notice:**  
New User features have b

Please see the ARCOS/SORS User Manuals for information on new User Management features that have been added. These features allow creation of administrator and data-only users for ARCOS, SORS, and Retail Statistics. Additionally, you may specify access to only certain DEA Numbers for a user (for those accounts reporting for more than one DEA number).



## **“Enter ARCOS Reports”**

- ✓ **Create a new ARCOS report**
  - ✓ **NOTE: You can enter transactions throughout the reporting period but cannot submit until the end of the period**
- ✓ **Adjust previously submitted reports**





## “Enter ARCOS Reports”

- ✓ **NOTE: If you submit a text file report, transactions that successfully process will not appear in ARCOS Online; only error transactions will appear in an ARCOS Online report when they are corrected**







## “Enter ARCOS Reports”



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[Help](#)

**Manage Reports** Participant Filter Edit:  Correct:  Create:

##### ( REGISTRANT NAME ) DESCENDING

+ Create Report 5

RA0223432	Dec 2023	Submitted	<a href="#">Adjustments</a> <a href="#">View/Print</a>
RA0223432	Sep 2023	Submitted	<a href="#">Adjustments</a> <a href="#">View/Print</a>

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# “Enter ARCOS Corrections”



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Select User	
##### Corrections Waiting: 8375	<a href="#">Correct Errors</a> 





## “Enter ARCOS Corrections”

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ARCOS/SORS Online: Enter Corrections

##### ( REGISTRANT NAME ) [Help](#)

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Error Transactions					
Code/ID	NDC	Qty	Date	Error Text	Options
Select					
P 0000016056	55289095110	00000500	20100212	Transaction code requires a valid associate registrant number.Order form number is required for schedule 1 and 2 drugs.	<a href="#">Correct Error</a> <a href="#">Delete Transaction</a>
P 0000016056	55289095110	00000500	20100212	Transaction code requires a valid associate registrant number.Order form number is required for schedule 1 and 2 drugs.	<a href="#">Correct Error</a> <a href="#">Delete Transaction</a>






## **“Enter New NDC Number”**

- ✓ **At any time, go into the ARCOS Online system and submit a new NDC for addition to the dictionary**
- ✓ **Supporting documentation is required**
- ✓ **Can also be done upon entering a transaction when an NDC is not found**





## “Enter New NDC Number”



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**ARCOS/SORS Online: Add NDC Form**

The DEA uses 11 digit NDC numbers, in the 5-4-2 format (e.g. 12345-6789-01)  
Shorter forms should pad zeros to the LEFT.

Examples of properly formatting an NDC:

Original = 1234-0123-01	Original = 12345-123-01	Original = 12345-0123-1
ARCOS = 01234-0123-01	ARCOS = 12345-0123-01	ARCOS = 12345-0123-01

**Upload Scanned Label** [? Upload Help](#)

[? Important Information about Scanned Labels content](#)

Current File: **File Not Uploaded, please Upload the file.**

**NDC Number**  -  -



## “Enter New NDC Number”

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ARCOS/SORS Online: Add/Edit Report

Reporting Period: Mar 01 2024 - Mar 31 2024

ARCOS/SORS Online: Add Transaction

 Trans Code Key (Enter '=' to set a field to the value from the most recently entered transaction, which, if present, is shown next)  Help

Tr. Code	NDC Number	Quantity	Unit Code	Strength	Assoc. Reg. #	Order Form #	Trans Date
S	54321 -1234 -01 → Add NDC		-Optional-				

→ Submit New Transaction    ⊗ Cancel



## **“Manage Participant Data”**

- ✓ **Update central reporting point of contact**
- ✓ **Update contact information for individual registrations**





## “Upload and Manage ARCOS Report Files”

- ✓ Feature not yet released
- ✓ Real-time error checks for uploaded text files







## **“Lookup Retail Buyer Statistics”**

- ✓ **Research your customers before becoming their suppliers**
- ✓ **Feature requested by industry as a due diligence tool**





## “Lookup Retail Buyer Statistics”

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ARCOS/SORS Online: Retail Buyer Statistics Lookup

Enter a Retail or NTP DEA Number and Drug Code to see the number of distinct sellers for that DEA Number and Drug Code. The time span for lookup data is:  
**Time Span Start:** 04/01/2020  
**Time Span End:** 09/30/2020

Retail or NTP DEA Number: \*

Drug Code Selection

Available Drugs		
	Code	Name
<input type="checkbox"/>	1100	AMPHETAMINE
<input type="checkbox"/>	1105	METHAMPHETAMINE
<input type="checkbox"/>	1205	LISDEXAMFETAMINE
<input type="checkbox"/>	1724	METHYLPHENIDATE
<input type="checkbox"/>	9050	CODEINE
<input type="checkbox"/>	9064	BUPRENORPHINE
<input type="checkbox"/>	9143	OXYCODONE

Clear Text Filters

Add -->

<-- Remove

Selected Drugs	
Code	Name
No Drugs Entered	



## **“Manage Users”**

- ✓ **The primary ARCOS point of contact has the ability to set up additional user profiles in the ARCOS Online system**
- ✓ **Only the primary user has the ability to log into the EDI upload portal to submit text file reports**



# ARCOS ONLINE REPORTING SYSTEM



## “Manage Users”

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**: Manage Users**

10 (1 of 1)

Role	Username	Name	Enabled?	Action
ROLE_ARCOS_ADMIN	email@emailaddress.com	SMITH, JOHN	Yes	<a href="#">Edit</a> <a href="#">Reset Pwd</a>
ROLE_SORS_ADMIN ROLE_BUYER_STATS_ADMIN ROLE_ARCOS_ADMIN	emailaddress@email.com	COSE, R.	Yes	<a href="#">Edit</a> <a href="#">Reset Pwd</a>
ROLE_BUYER_STATS_ADMIN	ARCOSreporter@email.com	DOE, JOHN	Yes	<a href="#">Edit</a> <a href="#">Reset Pwd</a>
ROLE_ARCOS_ADMIN	Accurate_Reporting@emailaddress.com	BOOK, C. F. R.	Yes	<a href="#">Edit</a> <a href="#">Reset Pwd</a>
ROLE_ARCOS_USER	imincompliance@email.com	DOH, JANE	Yes	<a href="#">Edit</a> <a href="#">Reset Pwd</a>
ROLE_BUYER_STATS	ARCOS_genius@company.com	COMPLIANCE, N.	Yes	<a href="#">Edit</a> <a href="#">Reset Pwd</a>

10 (1 of 1)

[+ Add User](#) [Back](#)





## “Manage Users”

ROLE	USER CAN ...
ROLE_BUYER_STATS	Utilize Buyer Statistics Tool
ROLE_BUYER_STATS_ADMIN	Utilize Buyer Statistics Tool Administer Users w/ ROLE_BUYER_STATS Administer Users w/ ROLE_BUYER_STATS_ADMIN
ROLE_SORS_USER	Enter SORS Data
ROLE_SORS_ADMIN	Enter SORS Data Administer Users w/ ROLE_SORS Administer Users w/ ROLE_SORS_ADMIN
ROLE_ARCOS_ADMIN	Enter ARCOS & SORS data; Utilize Buyer Statistics Tool Administer All Users
ROLE_ARCOS_USER	Enter ARCOS & SORS data; Utilize Buyer Statistics Tool





## ❖ **Notes regarding text file uploading:**

- ✓ **Better for larger volume**
- ✓ **Automated uploads (allowed, not supported)**
- ✓ **Limited users – one login**
- ✓ **Error notifications after processing**
- ✓ **Importance of proper formatting**





- ❖ **Header (Control) Record with at least one Transaction Record**





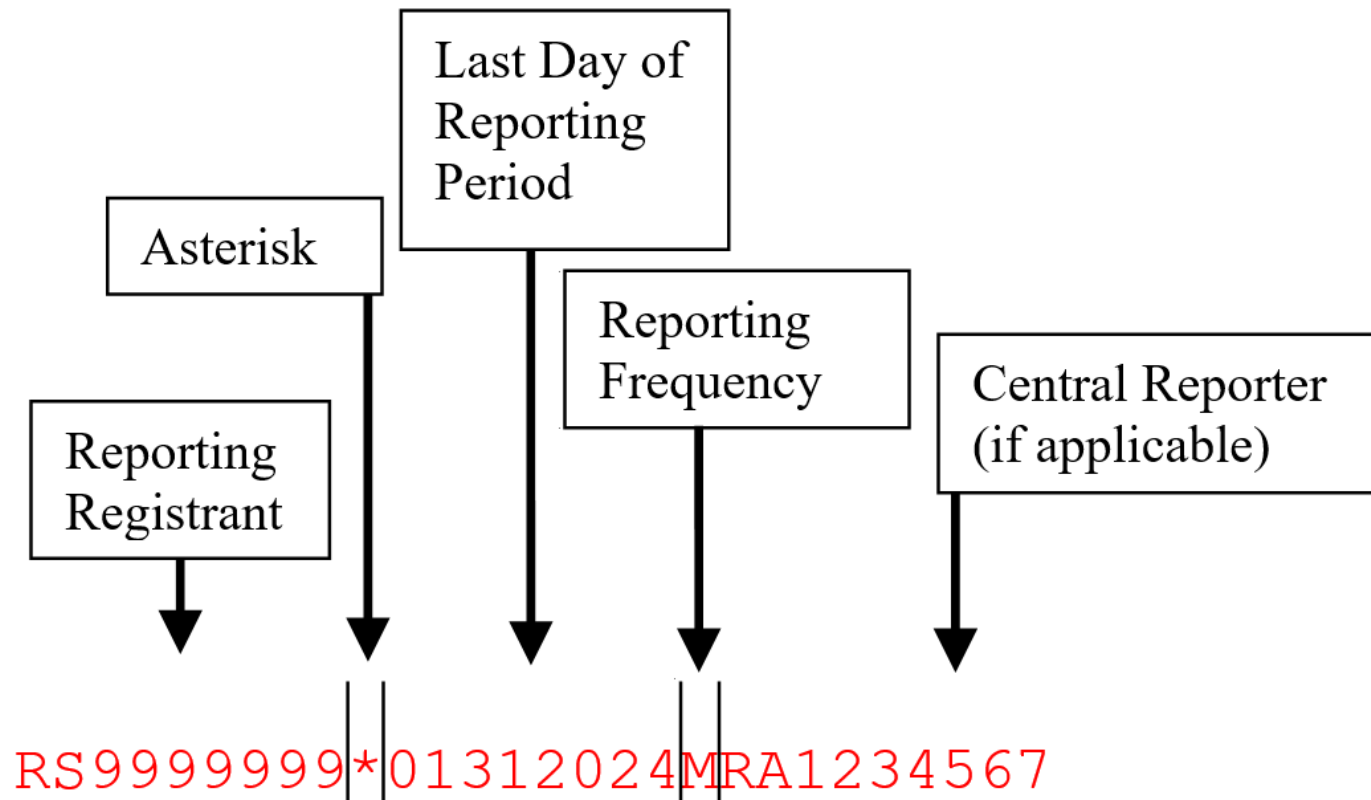
## Header (Control) Record

FIELD	POSITION (TEXT FILE)	SAMPLE DATA
REPORTING REGISTRANT	1 - 9	RS9999999
ASTERISK	10	*
LAST DAY OF REPORTING PERIOD	11 - 18	01312024
REPORTING FREQUENCY	19	M
CENTRAL REPORTER	20 - 28	RA1234567





# Header (Control) Record





# Header Record + Transaction Record = ARCOS Report

RS9999999\*01312024MRA1234567

RS9999999PI123450123\*\*000000023BA888888823123456701152024876543211000000000001





# **Delinquencies, Errors, and Common Issues**



➤ **Issues include, but are not limited to:**

- X Use of TAB key in spacing; check in MS Word**
- X Transactions extending beyond 80-character limit with additional spaces; template available**
- X Blank lines at the end of the report**
- X Switching back and forth between reporting registration numbers without a new header record**





- **Issues include, but are not limited to:**
  - X Using dashes in formatting NDC**
  - X Using decimal in Quantity entry**
  - X Uploading a file type other than text**
  - X Invalid or non-printable characters**





- ❖ **Our programmers are compiling additional information regarding properly formatted text files**





- **Unless a substance becomes ARCOS reportable during the year and an “initial inventory” of that drug is required, the only inventory reported to ARCOS is end-of-year**
- **End-of-year inventory is separate from YERS (Quota) and should be included in the 4th quarter or December ARCOS submission**





- **Know what the NDC you are using represents ... for example:**
  - **Are you attempting to report a raw material by weight using a finished package NDC?**
  - **Are you using a finished package NDC to report individual units?**
  - **Does the product have both inner and outer package NDCs?**







- **Know what the NDC you are using represents ... for example:**
  - **Are you using an NDC you found on our website because it looks like it matches the product in your transaction?**
  - **Is the drug ARCOS reportable?**





- **Keep in mind that ARCOS is a ledger system of pluses and minuses, with the end-of-year inventory providing the starting point for the following year**
- **Make sure you are reporting both increases and decreases to inventory, whether a financial transaction is involved or not**





- **Don't forget to report your end-of-year inventory of ARCOS reportable controlled substances; report Code "8" if there was nothing reportable on hand**
- **Be sure to report Code "7" for any reporting period during which there was no ARCOS reportable activity (increases, decreases, or manufacturing)**





- **Error transactions represent data that could not be processed for a variety of reasons, and it is the responsibility of the reporter to correct these errors**
- **Complete and accurate reporting is required under the Controlled Substances Act (U.S.C. § 827(a))**





## Analysis of Uncorrected Error Transactions (submitted 1/1/2022 – 12/31/2023)

- **18,095 uncorrected error transactions**
- **19,029 individual errors**

ISSUE	# ERRORS	% TOTAL ERRORS
Trans Date	7,820	41%
Transaction Length	4,616	24%
Order Form	2,295	12%
NDC	1,917	10%
Unit Code	838	4%
Associate Registration	766	4%
Strength	623	3%
Quantity	149	<1%
Trans Code	4	<1%
Trans ID	1	<1%





- **Make sure your supplier's or customer's DEA registration number has not changed; avoid accidentally reporting a transaction to or from a retired registration or a registration not authorized to handle a drug schedule**





- **Please do not make up 9-digit numbers to submit a C-I or C-II transaction**
- **If you have questions regarding an order form number, please contact your local office for a solution**





- **Send an email to [ARCOS\\_Unit@dea.gov](mailto:ARCOS_Unit@dea.gov)**
- **Use the “Manage Participant Data” feature in the ARCOS Online system**
- **ARCOS contact information is not automatically updated from other systems**







- **ARCOS point of contact should be the individual you want notified of submission problems, confirmations of submission, uncorrected errors, and any other ARCOS related correspondence for a specific registration**





- **Conversion factors are built into NDCs**
- **For example:**

**NDC 82393-0122-05**  
**OXYCODONE HYDROCHLORIDE; 5 GRAMS**  
**BASE DRUG → 5 GRAMS HCL x 0.8965**  
**= 4.4825 GRAMS OXYCODONE BASE**

**\*\* You would just report the number of packages**





- **Conversion factors are built into NDCs**
- **Another example:**

**NDC 82393-0122-\*\***  
**OXYCODONE HYDROCHLORIDE; BULK**  
**BASE DRUG = 0.8965 GRAM PER 1 GRAM**

**\*\* You would just report the weight of material**





- **Avoid resubmitting transactions that were already successfully processed**
- **If you need to add transactions to a reporting period, either submit only those transactions in another report for that period or insert them in a future report**





# Resources and Conclusion



- **Updated ARCOS Registrant Handbook**
- **Text file formatting guidance**
- **Text file upload feature in ARCOS Online**





**Online Version of NDC Dictionary  
(updated monthly; no “trade secret” entries)**



# RESOURCES



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## Automation of Reports and Consolidated Orders System (ARCOS)

HOME > REPORTING > ARCOS

### What is ARCOS and What Does it Do?

The Controlled Substances Act of 1970 (§ 827) created the requirement for Manufacturers and Distributors to report their controlled substances transactions to the Attorney General. The Attorney General delegates this authority to the Drug Enforcement Administration (DEA).

ARCOS is an automated, comprehensive drug reporting system which monitors the flow of DEA controlled substances from their point of manufacture through commercial distribution channels to point of sale or distribution at the dispensing/retail level - hospitals, retail pharmacies, practitioners, mid-level practitioners, and teaching institutions. Included in the list of controlled substance transactions tracked by ARCOS are the following: All Schedules I and II materials (manufacturers and distributors); Schedule III narcotic and gamma-hydroxybutyric acid (GHB) materials (manufacturers and distributors); and selected Schedule III and IV psychotropic drugs (manufacturers only).

ARCOS accumulates these transactions which are then summarized into reports which give investigators in Federal and state government agencies information which can then be used to identify the diversion of controlled substances into illicit channels of distribution. The information on drug distribution is used throughout the United States (U.S.), by U.S. Attorneys and DEA investigators to strengthen criminal cases in the courts.

- ARCOS Reporting >
  - Resources** >
  - Diversion Service Center >
- Resources**
    - National Drug Code Dictionary (TEXT) ←
    - Readme NDC Dictionary Instructions (TEXT) ←
    - Retail Drug Summary Reports
    - Automated Transaction Record Text File Format





# **Retail Summary Reports (updated every six months)**



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# **Control & Transaction Record Text File Format**



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# **Controlled Substance Schedules** **(published by Drug & Chemical Evaluation)**



# RESOURCES

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## → [Lists of Scheduling Actions, Controlled Substances, Regulated Chemicals \(PDF\)](#) → (December 2023)

*This document is a general reference and not a comprehensive list. This list describes the basic or parent chemical and does not describe the salts, isomers and salts of isomers, esters, ethers and derivatives which may also be controlled substances.*

<b>Scheduling Actions</b>	<b>Controlled Substances</b>	<b>List I and II Regulated Chemicals</b>
<a href="#">Alphabetical Order</a>	<a href="#">Alphabetical Order</a>	<a href="#">Alphabetical Order</a>
<a href="#">Chronological Order</a>	<a href="#">Controlled Substance Code Number</a>	<a href="#">DEA Chemical Code Number</a>
	<a href="#">CSA Schedule</a>	<a href="#">List Number</a>
		<a href="#">Illicit Uses and Threshold Quantities</a>

### Exempted Lists

[Exempt Anabolic Steroid Products](#)

+

[Exempt Chemical Preparations](#)

+

[Exempted Prescription Products](#)

+





**DailyMed; National Library of Medicine  
(<https://dailymed.nlm.nih.gov/dailymed/>)**





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ANIMAL DRUGS

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Enter drug, NDC code, drug class, or Set ID



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## LABEL: HYDROCODONE BITARTRATE AND ACETAMINOPHEN tablet

LABEL RSS

### VIEW PACKAGE PHOTOS



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[Presence in Breast Milk](#)

**NDC Code(s):** 65162-675-10, 65162-675-11, 65162-675-50

**Packager:** Amneal Pharmaceuticals LLC

**Category:** HUMAN PRESCRIPTION DRUG LABEL

**DEA Schedule:** CII

**Marketing Status:** Abbreviated New Drug Application

### DRUG LABEL INFORMATION

Updated January 9, 2024

If you are a consumer or patient please visit [this version](#).

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MEDICATION GUIDE: [HTML](#) [i](#)

OFFICIAL LABEL (PRINTER FRIENDLY) [B](#)

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**Food & Drug Administration – Labeler Codes  
(<https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes>)**





## NDC/NHRIC Labeler Codes



### Structured Product Labeling Resources

[Business Entity Identifiers](#)

[Business Operation](#)

[Business Operation Qualifier](#)

 [Electronically Submitted NDC/NHRIC Labeler Codes](#)

This is a list of NDC/NHRIC Labeler Codes which have been electronically submitted.

Was this helpful?





**Food & Drug Administration – NDC Directory  
([https://www.accessdata.fda.gov/scripts/cder/ndc/  
index.cfm](https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm))**



# RESOURCES



## National Drug Code Directory

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The National Drug Code (NDC) Directory is updated daily.  
Current through: 3/12/2024

- NDC Application Programming Interface (API) (Firefox and Chrome recommended)

Finished Products ⓘ  Unfinished Products ⓘ  Compounded Products ⓘ

### NDC finished products search

Search the NDC database for finished drug products

Select Type

Enter at least three characters



**ARCOS Input Team:**  
**[ARCOS\\_Unit@dea.gov](mailto:ARCOS_Unit@dea.gov)**

