

# AUTOMATION OF REPORTS AND CONSOLIDATED ORDERS SYSTEM



**ARCOS Unit**  
**Registration & Program Support Section**  
**Office of Diversion Control**  
**202-307-8600**  
**ARCOS\_Unit@usdoj.gov**  
**Registration Support Center: 1-800-882-9539**

## ***About the ARCOS Unit***

*The ARCOS Unit is located in the Registration & Program Support Section of the Office of Diversion Control, a component in the Operations Division of the Drug Enforcement Administration.*

*The Office of Diversion Control is headed by a Deputy Assistant Administrator who works with the senior leadership of the DEA, the Justice Department, the Office of National Drug Control Policy, the Department of Health and Human Services, and the Congress.*

# ***ARCOS Reporting (21 C.F.R. § 1304.33)***

**Manufacturers of bulk and/or dosage form controlled substances must report:**

- ***Inventories***
  - All controlled substances in Schedules I and II
  - All narcotic and gamma-hydroxybutyric acid (GHB) controlled substances in Schedule III
  - Selected psychotropic controlled substances in Schedules III & IV (see 21 C.F.R. § 1304.33(d))
- ***Acquisitions***
  - All controlled substances in Schedules I and II
  - All narcotic and gamma-hydroxybutyric acid (GHB) controlled substances in Schedule III

# ***ARCOS Reporting (21 C.F.R. § 1304.33)***

**Manufacturers of bulk and/or dosage form controlled substances must report (*cont'd*):**

- ***Disposition***
  - All controlled substances in Schedules I and II
  - All narcotic and gamma-hydroxybutyric acid (GHB) controlled substances in Schedule III
- ***Manufacturing Activities***
  - All controlled substances in Schedules I and II
  - All narcotic and gamma-hydroxybutyric acid (GHB) controlled substances in Schedule III
  - Selected psychotropic controlled substances in Schedules III and IV (see 21CFR §1304.33(d))

# *ARCOS Reporting (21 C.F.R. § 1304.33)*

**Distributors of controlled substances must report:**

- *Inventories, Acquisitions and Dispositions*
  - All controlled substances in Schedules I and II
  - All narcotic and gamma-hydroxybutyric acid (GHB) controlled substances in Schedule III

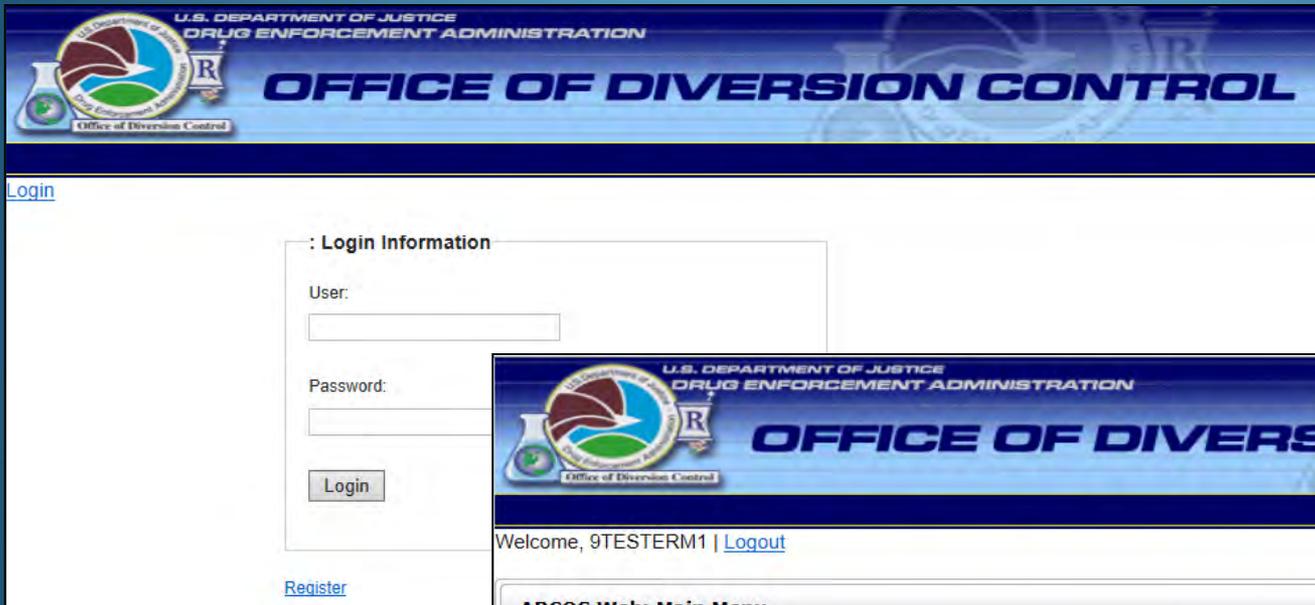
# ARCOS Reporting: Reporting Media

## Electronic Reporting (EDI)

<p>ARCOS</p> <p>DATE: _____</p> <p>COMPANY NAME: _____</p> <p>DEA REGISTRATION NUMBER: _____</p> <p>IF CENTRAL REPORTING, LIST SUBS _____ _____ _____</p> <p>CONTACT NAME/PHONE: _____</p> <p>ARCOS EDI CONTACT NAME/PHONE: _____</p> <p>ARCOS EDI CONTACT EMAIL ADDR: _____</p> <p>FREQUENCY OF TRANSMISSION: <input type="checkbox"/></p> <p>Signature _____</p> <p>Printed Name _____</p> <p><b>NOTICE TO USERS</b></p> <p>In order to adequately protect the information you must take responsibility for safeguarding assigned immediately notify the DEA of changes in person EDI system.</p> <p>Additional Information/Comments: _____</p>	<p style="text-align: center;"> <b>PC FIELD EDIT SOFTWARE REQUEST FORM</b></p> <p>Name of Re: _____ Point of Co: _____ DEA Registr: _____ Registrant's: _____ Telephone: _____ E-Mail Addr: _____ Estimated M: _____ Reporting F: _____ Current EDI: _____ Comments: _____ Call/Email M: _____ Mailed By: _____ Certified USPS Number: _____</p>	<p style="text-align: center;"> <b>EDI Reporting Upload Page</b></p> <p style="text-align: right;"><a href="#">Help</a></p> <p><b>Select Files To Upload</b></p> <table><tr><td>_____</td><td>Browse...</td></tr><tr><td>_____</td><td>Browse...</td></tr><tr><td>_____</td><td>Browse...</td></tr><tr><td>_____</td><td>Browse...</td></tr><tr><td>_____</td><td>Browse...</td></tr></table> <p>The upload time of your file(s) will vary depending on the size of the file(s) you attached and your connection speed. Please be patient and press the "Submit" button only once.</p> <p style="text-align: center;"><input type="button" value="Submit"/></p>	_____	Browse...								
_____	Browse...											
_____	Browse...											
_____	Browse...											
_____	Browse...											
_____	Browse...											

# ARCOS Reporting: Reporting Media

**\*\*Coming Soon: ARCOS Online\*\***



U.S. DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION  
**OFFICE OF DIVERSION CONTROL**

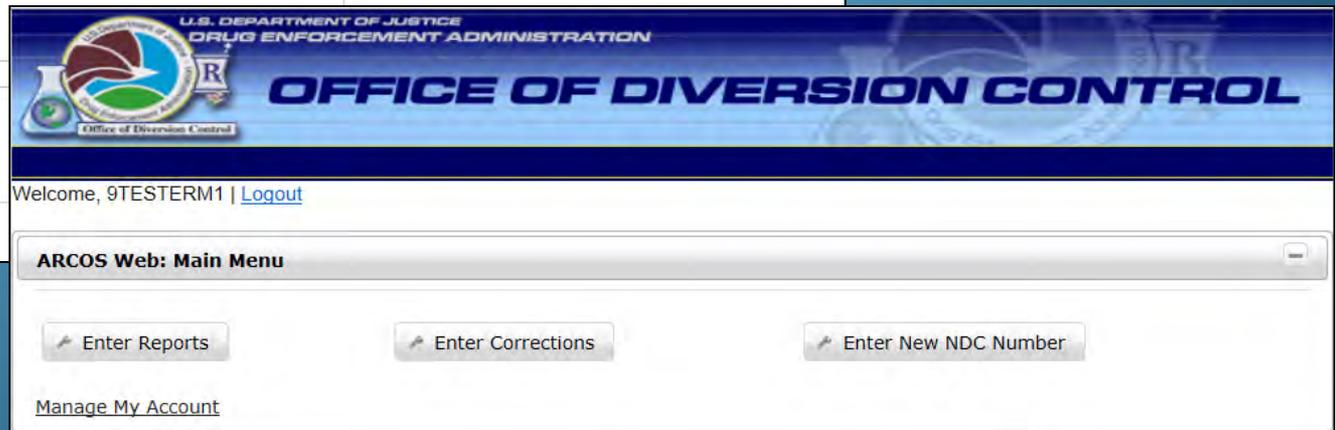
[Login](#)

**: Login Information**

User:

Password:

[Register](#)



U.S. DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION  
**OFFICE OF DIVERSION CONTROL**

Welcome, 9TESTERM1 | [Logout](#)

**ARCOS Web: Main Menu**

[Manage My Account](#)

# *ARCOS Reporting: Reporting Status*

## **Reporting Frequency:**

- Quarterly
- Monthly
- ❖ *Annually: Inventory and Manufacturing Activities are Included in the 4<sup>th</sup> Quarter or December Filing*

## **Reporting Status:**

- Single Reporter
- Central (registered location)
- Central (non-registered location)
  - **Note: Central Reporting requires authorization**

# ***ARCOS Reporting: Formatting***

**Control Record**

**Section 4 of the ARCOS  
Registrant Handbook**

**Transaction Record**

**Section 5 of the ARCOS  
Registrant Handbook**

# ARCOS Reporting: Formatting

REPORTING > Automation of Reports and Consolidated Orders System (ARCOS)

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

**Diversion Service Center**

1-800-882-9539 (8:30 am-6:00 pm EST)  
Fax: 202-307-8612

**Background: What is ARCOS and What Does it Do?**

**Electronic Data Interchange (EDI) Program**

[Download ARCOS EDI Request Form \(PDF\)](#)

**ARCOS Personal Computer (PC) Field Edit Program**

[Download ARCOS PC Field Edit Software Request Form \(PDF\)](#)

**ARCOS Reporting Notices**

**National Drug Code Dictionary**

[Download ARCOS NDC Dictionary File \(TEXT\)](#)  
[View the Readme NDC Dictionary Download Instructions \(TEXT\)](#)

**Questions & Answers**

**ARCOS Bulletins**

**Year 2000 Formatting Changes** ←

**ARCOS Participant Information Update Form (PDF)**

**ARCOS Registrant Handbook**

[View the PDF version for printing \(4.5 MB file\)](#)

**ARCOS**

- BCM Online
- Chemical Import/Export Declarations
- CSOS (Controlled Substances Ordering System)
- Drug Theft/Loss
- Import/Export
- Registrant Record of Controlled Substances Destroyed
- Quotas
- Reports Required by 21 CFR
- Submit a Tip to DEA
- Year-End Reports



# ***ARCOS Reporting: Transactions***

**Acquisitions**

**Dispositions**

**Inventory**

**Manufacturing**

**Miscellaneous**

**Section 5 of the ARCOS  
Registrant Handbook  
and  
Appendices 1 & 2 of the  
ARCOS Registrant  
Handbook**

## ***ARCOS Reporting: Manufacturing***

**The United States is a signatory to the (a) Single Convention on Narcotic Drugs, 1961, and (b) Convention on Psychotropic Substances, 1971, and as such is required to provide yearly manufacturing statistics to the United Nations (UN) International Narcotics Control Board. As a result, ARCOS was originally designed to capture manufacturing statistics for the United Nations.**

**Reports on Manufacturing Activities are required on an annual basis.**

# ARCOS Reporting: Manufacturing

5.17 STRENGTH

5.18 TRANSACTION IDENTIFIER

5.19 DOCUMENT IDENTIFIER

## Section 6: Manufacturing Activities

6.1 GENERAL

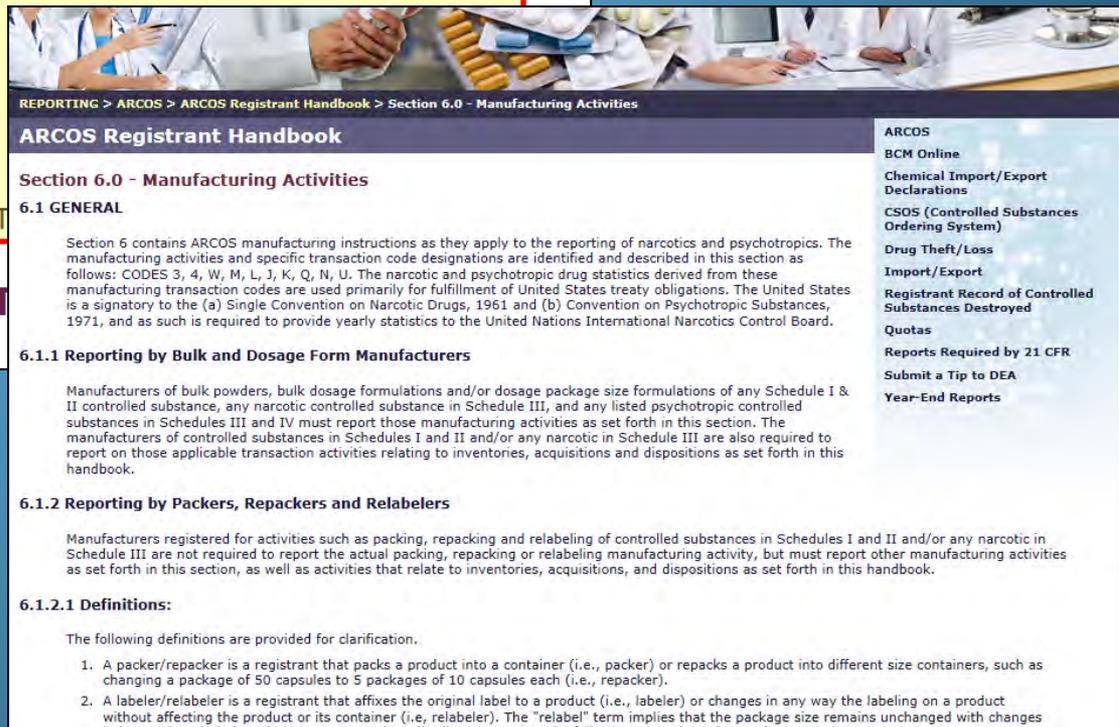
6.2 NARCOTICS

6.3 PSYCHOTROPICS

6.4 MANUFACTURING ACTIVITIES

## PART III: SYSTEM OUTPUT

### Section 7: Edit Listings



REPORTING > ARCOS > ARCOS Registrant Handbook > Section 6.0 - Manufacturing Activities

### ARCOS Registrant Handbook

#### Section 6.0 - Manufacturing Activities

##### 6.1 GENERAL

Section 6 contains ARCOS manufacturing instructions as they apply to the reporting of narcotics and psychotropics. The manufacturing activities and specific transaction code designations are identified and described in this section as follows: CODES 3, 4, W, M, L, J, K, Q, N, U. The narcotic and psychotropic drug statistics derived from these manufacturing transaction codes are used primarily for fulfillment of United States treaty obligations. The United States is a signatory to the (a) Single Convention on Narcotic Drugs, 1961 and (b) Convention on Psychotropic Substances, 1971, and as such is required to provide yearly statistics to the United Nations International Narcotics Control Board.

##### 6.1.1 Reporting by Bulk and Dosage Form Manufacturers

Manufacturers of bulk powders, bulk dosage formulations and/or dosage package size formulations of any Schedule I & II controlled substance, any narcotic controlled substance in Schedule III, and any listed psychotropic controlled substances in Schedules III and IV must report those manufacturing activities as set forth in this section. The manufacturers of controlled substances in Schedules I and II and/or any narcotic in Schedule III are also required to report on those applicable transaction activities relating to inventories, acquisitions and dispositions as set forth in this handbook.

##### 6.1.2 Reporting by Packers, Repackers and Relabelers

Manufacturers registered for activities such as packing, repacking and relabeling of controlled substances in Schedules I and II and/or any narcotic in Schedule III are not required to report the actual packing, repacking or relabeling manufacturing activity, but must report other manufacturing activities as set forth in this section, as well as activities that relate to inventories, acquisitions, and dispositions as set forth in this handbook.

##### 6.1.2.1 Definitions:

The following definitions are provided for clarification.

1. A packer/repacker is a registrant that packs a product into a container (i.e., packer) or repacks a product into different size containers, such as changing a package of 50 capsules to 5 packages of 10 capsules each (i.e., repacker).
2. A labeler/relabeler is a registrant that affixes the original label to a product (i.e., labeler) or changes in any way the labeling on a product without affecting the product or its container (i.e., relabeler). The "relabel" term implies that the package size remains unchanged with changes

ARCOS  
BCM Online  
Chemical Import/Export  
Declarations  
CSOS (Controlled Substances  
Ordering System)  
Drug Theft/Loss  
Import/Export  
Registrant Record of Controlled  
Substances Destroyed  
Quotas  
Reports Required by 21 CFR  
Submit a Tip to DEA  
Year-End Reports

# ***ARCOS Reporting: NDCs/Product Information***

**In order for transactions to be processed, the National Drug Code (NDC) associated with the product must be in the ARCOS dictionary ...**

**... The ARCOS Unit needs the drug label (preferred) or detailed product information for all ARCOS reportable materials from Manufacturers!!!**

# *ARCOS Reporting: NDCs/Product Information*



Email

[ARCOS\\_Unit@usdoj.gov](mailto:ARCOS_Unit@usdoj.gov)

Fax

202-307-8612

Upload (\*Coming Soon\*)  
Via ARCOS Online

# *ARCOS Reporting: NDCs/Product Information*

**NDC not in dictionary**



**Reporters receive errors (E76 error), for which they are held accountable**



**Potential for unhappy customers**

# *ARCOS Reporting: Partial Package Reporting*

**Quantity Must Be “1”**

**Strength Field Indicates Percentage of Package**

**Repackagers Must Obtain a Labeler Code From  
the Food and Drug Administration**

# *ARCOS Reporting: Unit and Strength*

**UNIT is blank, unless bulk liquid, raw material, dozens of packages (“D”), or thousands of packages (“K”)**

**STRENGTH is used to indicate purity of raw material or percentage for partial packages**

## ***ARCOS Reporting: Action Indicator***

- **Adjust (D/A) a previously submitted transaction**
- **Delete (D) a previously submitted transaction**
- **Insert (I) a transaction from a previous reporting period**
- **Will not be required when using new ARCOS Online reporting system**
  
- **Errors cannot be deleted**
- **The Action Indicator is not needed when submitting a correction**

# *ARCOS Reporting: Errors*

## **Top Errors as of 9/17/2015**

E76	NDC not in dictionary	675,296	40.87%
E16	Trans Date outside reporting period	219,380	13.28%
E38	Strength must be zero, blank or 100% for Quantity > 1	159,737	9.67%
E53	C-I and C-II drugs require Order Form Number	106,841	6.47%
E48	Invalid or missing Associate Registrant Number	66,498	4.02%
E52	Invalid Order Form Number	63,886	3.87%
E61	Transaction ID has incorrect length ***	53,879	3.26%
E45	Invalid or missing Associate Registrant Number	53,200	3.22%
E31	NDC requires blank, D, or K Unit Code	51,005	3.09%
E13	Transaction Code must be last day of reporting period	46,841	2.84%

**\*\*\* May be the result of length issue elsewhere in transaction**

# *ARCOS Reporting: Errors*

## **Correcting Errors**

- Error Reports act as receipts of processing the most recent submission, but they are NOT cumulative and do NOT show all existing errors for the registration
- Under normal circumstances, corrections can be submitted on the next ARCOS report; however, if errors must be made prior to the submission of the next report, a supplemental report must be generated for a previous reporting period
- Failure to include the Correction Number in the corrected transaction will result in the creation of a new transaction, and the error will remain uncorrected

# *ARCOS Reporting: Errors*

## **Correcting Errors**

**Requests for deletion of errors are handled on a case by case basis with multiple factors taken into consideration ...**

**... It is always best to correct errors on your own if at all possible!!**

# Questions?



**ARCOS Unit**  
**Registration & Program Support Section**  
**Office of Diversion Control**  
**202-307-8600**  
**ARCOS\_Unit@usdoj.gov**  
**Registration Support Center: 1-800-882-9539**

**ARCOS ONLINE**



U.S. DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION

# OFFICE OF DIVERSION CONTROL

[Login](#)

## : Login Information

User:

Password:

Login

[Register](#)

[Forgot Password](#)



Welcome, 9TESTERM1 | [Logout](#)

**ARCOS Web: Main Menu**

[Enter Reports](#)

[Enter Corrections](#)

[Enter New NDC Number](#)

[Manage My Account](#)

# **ENTERING REPORTS**



# OFFICE OF DIVERSION CONTROL

Welcome, 9TESTERM1 | [Logout](#)

Done



## Manage Reports

Participant Filter

Edit:  Correct:  Create:

### WW2323232 (TEST MANUFACTURER 1)

+ Create Report 5

WW2323232

Sep 2015

Pending

Edit/Submit

1

### WW4545454 (TEST MANUFACTURER 2)

+ Create Report 5

No records found.

### WW6767676 (TEST MANUFACTURER 3)

+ Create Report 5

No records found.

Done



U.S. DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION

# OFFICE OF DIVERSION CONTROL

Welcome, 9TESTERM1 | [Logout](#)

: Add/Edit Report

Reporting Period:

-Select Date-

WW2323232 (TEST MANUFACTURER 1)

 Help

 Add Transaction

## Transactions

Trans ID	Code	NDC	Qty	Units	Str.	Assoc.	Ord. Form#	Date	Options
----------	------	-----	-----	-------	------	--------	------------	------	---------

No records found.

(1 of 1)

10 

 Add Transaction

 Done



Welcome, 9TESTERM1 | [Logout](#)

: Add/Edit Report

Reporting Period:

12-2014

WW2323232 (TEST MANUFACTURER 1)



Help

Add Transaction

### Transactions

Trans ID	Code	NDC	Qty	Units	Str.	Assoc.	Ord. Form#	Date	Options
----------	------	-----	-----	-------	------	--------	------------	------	---------

No records found.

(1 of 1)

10

Add Transaction

Note: This is an end of reporting period report, but does not contain Transaction Code 8 (No Year End Inventory) or an Inventory Entry. Year End Reports should have at least one Year End Inventory entry.

Done

Submit Report





U.S. DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION

# OFFICE OF DIVERSION CONTROL

Welcome, 9TESTERM1 | [Logout](#)

: Add/Edit Report

**Reporting Period:** Aug 01 2015 - Aug 31 2015

WW2323232 (TEST MANUFACTURER 1)

: Add Transaction

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

Trans Code	NDC Number	Quantity	Unit Code	Strength	Assoc. Reg. #	Order Form #	Trans Date
7 	[Not Needed]	[Not Needed]	Aug 31 2015				

→ Submit New Transaction

⊞ Cancel



U.S. DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION

# OFFICE OF DIVERSION CONTROL

Welcome, 9TESTERM1 | [Logout](#)

: Add/Edit Report

**Reporting Period:** Nov 01 2014 - Nov 30 2014

WW2323232 (TEST MANUFACTURER 1)

: Add Transaction

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

Trans Code	NDC Number	Quantity	Unit Code	Strength	Assoc. Reg. #	Order Form #	Trans Date
<input type="text" value="-Select-"/>	<input type="text" value="12345"/> <input type="text" value="-6789"/> <input type="text" value="-02"/> <input type="button" value="+ Add NDC"/>	<input type="text"/>	<input type="text" value="-Optional-"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>



Welcome, 9TESTERM1 | [Logout](#)

: Add/Edit Report

Reporting Period: Aug 01 2015 - Aug 31 2015

WW2323232 (TEST MANUFACTURER 1)

: Add Transaction

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

Trans Code	NDC Number	Quantity	Unit Code	Strength	Assoc. Reg. #	Order Form #	Trans Date
1	79464 -4635 -46 <input type="button" value="Add NDC"/>	36000	1 - micrograms	2	[Not Needed]	[Not Needed]	7/11/15

**✘ The Strength Field must be 4 digits.**  
The NDC number provided is not part of our system. If you are sure you entered the correct NDC number, you may request that it be added using the Add NDC button.  
The Unit Code for this NDC must be blank, 'D', or 'K'  
Transaction Date must be within the reporting period of Aug 01, 2015 - Aug 31, 2015



U.S. DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION

# OFFICE OF DIVERSION CONTROL

Welcome, 9TESTERM1 | [Logout](#)

: Add/Edit Report

Reporting Period: Jul 01 2015 - Jul 31 2015

WW2323232 (TEST MANUFACTURER 1)

: Add Transaction

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

Trans Code	NDC Number	Quantity	Unit Code	Strength	Assoc. Reg. #	Order Form #	Trans Date
G	00378 -4605 -20	2	D - dozens		654564	[Not Needed]	7/31/15

**The associate registrant DEA number is invalid.**  
The Associate Registrant must be one of the DEA Designated Offices for Transaction Code Y,Z, and G.

→ Submit New Transaction

⊗ Cancel



U.S. DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION

# OFFICE OF DIVERSION CONTROL

Welcome, 9TESTERM1 | [Logout](#)

: Add/Edit Report

Reporting Period: May 01 2015 - May 31 2015

WW2323232 (TEST MANUFACTURER 1)

: Add Transaction

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

Trans Code	NDC Number	Quantity	Unit Code	Strength	Assoc. Reg. #	Order Form #	Trans Date
1	00378 -4600 -53	550000	D - dozens		[Not Needed]	[Not Needed]	5/1/15

→ Submit New Transaction

⊗ Cancel



Welcome, 9TESTERM1 | [Logout](#)

: Add/Edit Report

**Reporting Period:** May 01 2015 - May 31 2015      WW2323232 (TEST MANUFACTURER 1)

 Help

 Add Transaction

### Transactions

Trans ID	Code	NDC	Qty	Units	Str.	Assoc.	Ord. Form#	Date	Options
1	1	00378460053	550,00	D				2015-05-01	 Edit  Remove

(1 of 1)

1

10

 Add Transaction

 Done

 Submit Report



# OFFICE OF DIVERSION CONTROL

Welcome, 9TESTERM1 | [Logout](#)

[View/Print Report](#)

**i** Report successfully Submitted.

**?** Help

**Reporter: WW2323232 Reported By: 9TESTERM1**  
**Reporting Period: May 01 2015 - May 31 2015**  
**Report Submitted: Sep 15 2015**

ID	Code Select	NDC	Qty	Units	Str.	Assoc.	Ord. Form#	Date	Status
1	1	00378460053	550,000	D				2015-05-01	

(1 of 1)

1

10



[Download To PDF](#)

[Done](#)

1 / 1 76.8% Tools Fill & Sign Comment

Arcos Web Report

Reporting Period: 5/1/15 - 5/31/15

Reporter: WW2323232

Submitted By: 9TESTERM1 on 2015-09-15 Updated by: 9TESTERM1 on 2015-09-15

ID	Code	NDC	Qty	Units	Str.	Assoc.	Ord. Form#	Date	Status
1	1	0037846005 3	550,000	D				2015-05-01	

**ADD NEW NDC**



U.S. DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION

# OFFICE OF DIVERSION CONTROL

Welcome, 9TESTERM1 | [Logout](#)

ARCOS-WEB: Add NDC Form

**NDC Number**

 -  - 

→ Submit

⊗ Cancel

**Upload Scanned Label**  Help

Browse...

Upload

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



U.S. DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION

# OFFICE OF DIVERSION CONTROL

Welcome, 9TESTERM1 | [Logout](#)

## ARCOS Web: Main Menu

**i** NDC Entry successfully saved.

[Enter Reports](#)

[Enter Corrections](#)

[Enter New NDC Number](#)

[Manage My Account](#)

**CORRECTIONS**



Welcome, 9TESTERM1 | [Logout](#)

Done

Select User	
WW2323232 Corrections Waiting: 25	<a href="#">Correct Errors</a>
WW4545454 Corrections Waiting: 9	<a href="#">Correct Errors</a>
WW6767676 Corrections Waiting: 10	<a href="#">Correct Errors</a>

Done



# OFFICE OF DIVERSION CONTROL

Welcome, 9TESTERM1 | [Logout](#)

: Enter Corrections

## Error Transactions

Code Select	NDC	Qty	Units	Str.	Date	Options
3	00409909428	00000001		0720	20111231	- Correct
3	10019017844	00000001		0560	20111231	^ Correct
3	00409909431	00000001		0920	20111231	^ Correct
*						^ Correct

(1 of 1)

1

10

Done



U.S. DEPARTMENT OF JUSTICE  
DRUG ENFORCEMENT ADMINISTRATION

# OFFICE OF DIVERSION CONTROL

Welcome, 9TESTERM1 | [Logout](#)

: Enter Corrections

[pending]

WW6767676 (TEST MANUFACTURER 3)

: Transaction

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

Trans Code	NDC Number	Quantity	Unit Code	Strength	Assoc. Reg. #	Order Form #	Trans Date
3	00409 -9094 -28	1	-Optional-		[Not Needed]	[Not Needed]	Dec 31 2011

→ Submit Correction

→ Cancel