

ARCOS

Automation of Reports and Consolidated Orders System

ARCOS Unit

Registration and Program Support Section

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Overview

Overview

Controlled Substances Act of 1970:

- **Manufacturers and Distributors**
- **Controlled substance transactions**
- **Delegated to DEA = ARCOS**

Overview

ARCOS Reportable Data:

- Purchases
- Manufacturing
- Sales
- Inventory
- Returns
- Loss and Destruction
- Lack of Activity
- Lack of Inventory

Overview

ARCOS Reportable Data:

- 80 million transactions per year
- 1,100 to 1,200 reporters
 - Ø Manufacturers
 - Ø Distributors
 - Ø Reverse Distributors

Overview

ARCOS Reportable Controlled Substances:

- All Schedule I and II
- Schedule III narcotics and GHB

Overview

Manufacturers Only:

- Schedule III and IV psychotropic
- See 21 C.F.R. § 1304.33(d)

Overview

ARCOS Transactions Contain:

- Seller and Purchaser
- Drug and Quantity
- Date of Transaction

Overview

Reporting Methods:

- **ARCOS Online**
- **EDI (text file)**
- **DEA Form 333 (paper)**

Overview

Reporting Frequency:

- Quarterly or monthly
- 15th day of the following month
 - Ø Inventory = January 15th

Overview

Extensions and Exceptions:

- **ARCOS Unit cannot grant extension**
- **ARCOS Unit cannot grant exception/exemption**
- **Exceptions = Assistant Administrator**

Issues

Issues

Out of Date Contact Information:

- Reporting issue notifications
- Announcements
- Update: Email, fax, letter, or online

Issues

Transaction Codes:

- Transaction Codes "1" and "5"
 - Ø Contact ARCOS Unit
- Transaction Code "F"
 - Ø Do not use to request forms

Issues

Transaction Codes:

- Transaction Code "Y"
 - Ø Reported by registrant performing destruction
 - Ø "S" – transfer to Reverse Distributor

Issues

Transaction Codes:

- Transaction Codes "P" and "R"
 - Ø "P" = receiving supply
 - Ø "R" = return of product
- Transaction Codes "3" and "4"
 - Ø Required for inventory
 - Ø Otherwise use "8"

Issues

Action Indicator:

- Cannot use to delete errors
- Adjustments must be pairing of "D" and "A"
- Not same as Transaction Code

Issues

National Drug Code (NDC):

- Need labels or product information
 - Ø Email, fax, or upload
- Incorrect format – remember zeros
- Non-reportable and non-scheduled

Issues

Using the Quantity field:

- Cannot be zero
- Depends on NDC
 - Ø Bulk finished
 - Ø Raw material
 - Ø Package

Issues

Using the Quantity field:

- **Depends on NDC**
 - Ø Bulk finished
= total # individual units
 - Ø Raw material
= w/ Unit & Strength fields
 - Ø Package
= # packages; Strength if partial or combined

Issues

Unit field – needed vs. not needed:

- Raw material = yes
- Bulk liquid = yes
- Bulk finished product = no
- Package = no

Issues

Order Form Number:

- Required when reporting movement of C-I and C-II drugs
- DEA Form 222 or CSOS

Issues

Using the Strength field:

- Purity of raw material with Quantity and Unit fields
- Partial or combined package with Quantity of 1

Issues

Active registrations not reporting:

- Must report, even if no activity
- Must report, even if no inventory
- Reporting requirements based on type of registration, business activity, and drug schedules on registration

Recommendations

Recommendations

- Request an online account
- Uncertain about reportable activity?
 - Ø Email ARCOS Unit details
- Only report what is reportable
 - Ø Activities and substances

Reminders

Reminders

- EDI confirmation different from confirmation of processing
- Cannot file prior to end of period
- PC Field Edit no longer supported
 - Ø Be careful using it
 - Ø Switch to ARCOS Online

Reminders

- Manufacturing = 4th quarter report and cumulative for year
- Inventory = 4th quarter report; on hand close of business 12/31
- Correct errors immediately
 - ∅ Easily accessible in ARCOS Online

Reminders

- Transaction Date = date of physical change of possession
- If packaging or repackaging, obtain a labeler code (FDA)

Reminders

If a drug is used to produce a product that is the same drug in the same schedule – this is not reportable

- Ø For example, pressing a tablet
- Ø Still must report waste, sampling, etc.

Reminders

Generic ("G" number) NDCs may be used for non-commercial activities

- Ø Reverse Distribution
- Ø Manufacturing
- Ø Import/Export

Resources

Resources

ARCOS Registrant Handbook

- Sections 5, 6, and Appendix 1

“Resources” tab

- Controlled Substance Schedules
- C.F.R. and U.S.C.

“Year 2000 Formatting Changes”

Resources

NDC dictionary in text file format

- **ARCOS website**
- **Updated online monthly**
- **“Readme” file for formatting**

Resources

Food and Drug Administration (FDA)

- EDRLS@fda.hhs.gov
- Labeler code and NDC issues

DailyMed website

- <https://dailymed.nlm.nih.gov>

Questions?