Inventories, Records, & Reports

Drug Enforcement Administration

Pharmaceutical Training Seminar

Richmond, VA

April 24-27, 2017

Minneapolis, MN

May 8-11, 2017

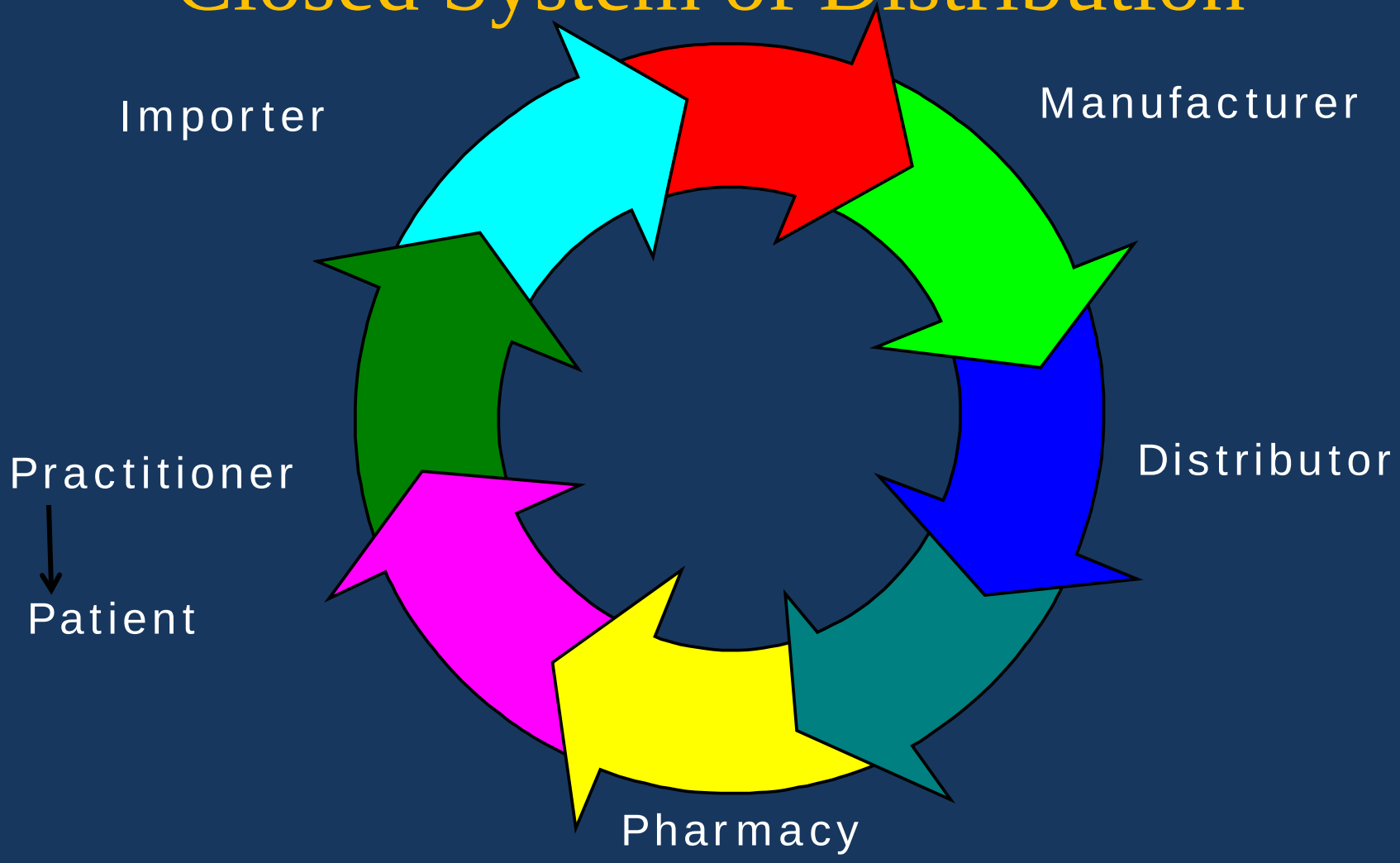
Diversion Control Division Mission

To prevent, detect, and investigate the diversion of controlled substances from legitimate sources

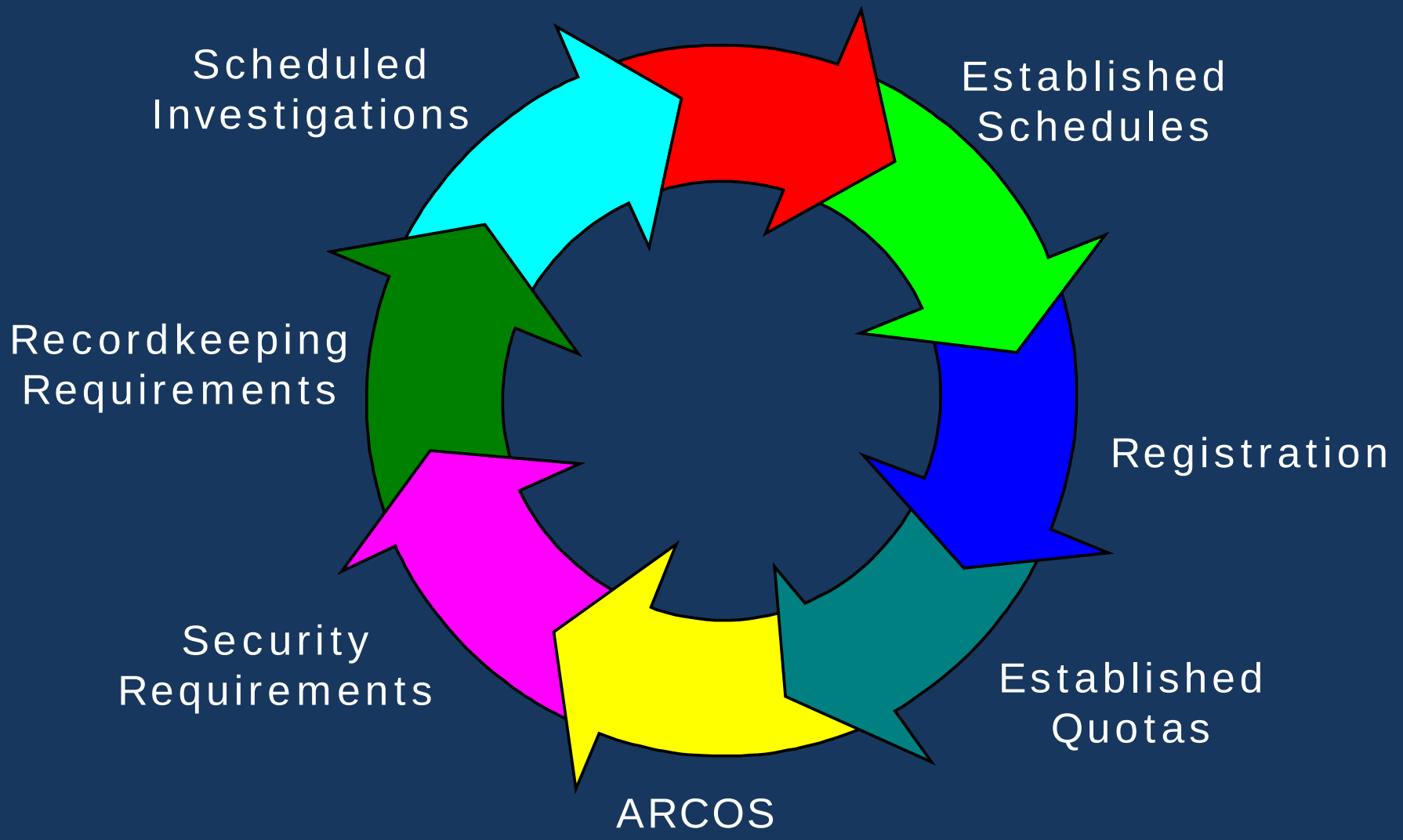
while

Ensuring an adequate and uninterrupted supply for legitimate medical and scientific purposes

The CSA's Closed System of Distribution



Maintaining the CSA's Closed System of Distribution



Authority:

- Law

  Controlled Substance Act
  United States Code:
  Title 21 Food & Drugs

- Regulations

  Code of Federal Regulations

  Title 21 Food & Drugs

- Policy

  Policy response letters, Manuals, Postings

  Rulemaking published in Federal Register

Introduction:

- The Law
- The Regulations which further define and clarify the law
- The Violation of the law
- The Penalties for the violation of the law

Law: 21 USC § 822 (a) (1)

- Persons Required to Register:
- “Every person who manufactures or distributes any Controlled Substance or List I Chemical or who proposes to engage in ..”

Law: 21 USC § 822 (a) (2)

- Persons Required to Register:
- “Every person who dispenses, or who proposes to dispense any controlled substance...”

Law: 21 USC § 827 (a)(3)

- " every registrant under this (title) manufacturing, distributing, or dispensing a controlled substance…shall maintain, on a current basis, a complete and accurate record of each substance manufactured, received, sold, delivered, or otherwise disposed of …"

Law: 21 USC 827 (a)(1),(2)

- Inventories:
  - When registrant first engages in the manufacture/distribution/dispensing
  - Every second year thereafter
  - Complete and accurate record of all stocks on hand

Law: 21 USC § 827 (b)

- Availability of Records:
  - Contain information and be in a form as required by regulation.
  - Be in a form that is Readily Retrievable.
  - Be kept and available for Two years.

Law: 21 USC § 827 (d)

- Periodic Reports
  Every Manufacturer…at such time…and in such form as the Attorney General may require, make periodic reports to the Attorney General of every sale, delivery, or other disposal by him of any controlled substance, and each distributor shall make such reports...

Law: 21 USC § 827 (g)

- Every registrant under this subchapter shall be required to report any change of professional or business address in such manner as the Attorney General shall by regulation require.

INVENTORIES

Inventories: 21 C.F.R. § 1304.11(a)

- Inventory Requirements:
  - Complete and accurate record
  - All substances “On Hand” (In possession and under the control of registrant)
  - On the date the inventory is taken
  - Maintained in written, typewritten, or printed form at the registered location.

Separate Inventories: 21 C.F.R.§1304.11(a)

- Separate inventories for each Registered Location and each Independent Activity.
- May be taken:

  (BOB) Beginning of Business

  (COB) Close of Business

Initial Inventory Date: 21 C.F.R. § 1304.11 (b)

- Inventory of all Stocks of CS
  - On The Date: First Engages in the manufacture, distribution, or dispensing of controlled substances
  - Should Be Labeled "Initial Inventory"
  - Nothing on Hand: Record "0"

Biennial Inventory Date: 21 C.F.R.§ 1304.11(c)

- After the Initial Inventory
  - New Inventory at least Every Two Years
  - On any date which is within two years of the previous Biennial Inventory date
  - Should be labeled "Biennial Inventory"
  - Nothing on hand: Record "0"

Newly Controlled Substances: 21 C.F.R. § 1304.11 (d)

- For any newly Controlled Substance
  - Inventory of all stocks on hand
  - On the effective date of the rule

Inventories:
21 C.F.R. § 1304.11(e)

(1) Inventories for Manufacturers

(2) Inventories for Distributors & Reverse Distributors

(3) Inventories for Dispensers & Researchers

(4) Inventories for Importers & Exporters

(5) Inventories for Chemical Analysts

RECORDS

Records:
21 C.F.R. § 1304.21(a)

- Maintain on a Current Basis...
  - Complete and Accurate record of each substance…Manufactured, Imported, Exported, Received, Sold, Delivered, or otherwise disposed of ...
  - Except No registrant is required to maintain a Perpetual Inventory

Separate Records:
21 C.F.R. § 1304.04(f)(1); (g); (h)(1)

- Schedule I & II:
  - Maintained Separately from all other records

Separate Records:
21 C.F.R.§ 1304.04 (f)(2); (g); (h)(2)

- Schedules III, IV, & V
  - Separate from All Other Records
- or "Readily Retrievable"
  - Separated out from all other records in a reasonable time period
  - CS Items asterisk, redlined, or in some manner which sets them visually apart
  - Red letter "C" lower right corner

Separate Records:
21 C.F.R. § 1304.21(b) & (c)

- Separate Records.. For each Registered Location and each Independent Activity.

Dates for Records: 21 C.F.R. § 1304.21(d)

- Dates must be the Actual Date of transfer (Received, Imported, Exported, Distributed, or otherwise Transferred, etc.)

Records: 21 C.F.R. § 1304.22

- Manufacturers
  - Bulk Form
  - In-Process
  - Finished Goods
- Distributors
- Importers/Exporters
- Dispensers/Researchers

Records: (Distributors) 21 C.F.R. § 1304.22(b)

- Records for Distributors

  - Maintain Records with the same information required of manufacturers pursuant to (a)(2), (i), (ii), (iv), (vii), (viii), and (ix) of this section.

Records: (Distributors) 21 C.F.R. § 1304.22(b)

- Records for Distributors
  - Name of CS
  - Finished Form
  - # of Containers
  - # of Units Distributed
  - Name, Address, and DEA# from whom received or to whom distributed.

Records: (Dispenser/Research) 21 C.F.R. § 1304.22(c)

- Shall maintain records with the same information required of manufacturers pursuant to paragraph (a)(2)(i), (ii), (iv), (vii), and (ix) of this section.

Records: 21 C.F.R. § 1304.22(c)

- Records for Dispensers and Researchers:
  - Name of CS, Form, Quantity, Strength
  - Number of Units or Volume of Finished Form dispensed
  - Name, address of the person to whom it was dispensed
  - Date of dispensing

Records: 21 C.F.R. § 1304.22(c)

- Records for Dispensers and Researchers
  - Written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser
  - Amount disposed of in any other manner

Order Forms: 21 C.F.R. §1305

- Order Forms are required for each transfer of a CS in Schedule I & II except…:
  - Distributions to persons exempt from registration
  - Exports from the U.S.
  - Deliveries to …analytical laboratory
  - Deliveries from a central fill pharmacy…to a retail pharmacy

See Reverse of PURCHASER'S Copy for Instructions	No order form may be issued for Schedule I and II substances unless a completed application form has been received, (21 CFR 1305.04).	OMB APPROVAL No. 1117-0010

TO: *(Name of Supplier)*

STREET ADDRESS

CITY and STATE

DATE

TO BE FILLED IN BY SUPPLIER

SUPPLIERS DEA REGISTRATION No.

TO BE FILLED IN BY PURCHASER

LINE No.	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

◀ LAST LINE COMPLETED *(MUST BE 10 OR LESS)*

SIGNATURE OF PURCHASER OR ATTORNEY OR AGENT

Date Issued: 20010101

DEA Registration No.: DEAREGNO

Name and Address of Registrant: VOID VOID VOID VOID VOID VOID VOID VOID VOID VOID VOID VOID VOID VOID VOID

Schedules: XXXXXXXXXXXXX

Registered as a: XXXXXXXXXXXXX

No. of this Order Form: 000000007

DEA Form -222 (Oct. 2004)

U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II

DRUG ENFORCEMENT ADMINISTRATION

SUPPLIER'S Copy 1

111381999

Order Forms: 21 C.F.R. § 1305

- Obtaining Order Forms:
  - Order Forms are Issued in Books of Seven Forms Each.

- Obtaining Order Forms:
  - Each Form has three copies:
    - Supplier
    - DEA
    - Purchaser

Order Forms: 21 C.F.R. § 1305

- Obtaining Order Forms:
  - Order Forms are serially numbered and issued with
  - Name
  - Address
  - Registration # of the Registrant
  - Authorized activity and schedules of the registrant

Order Forms: 21 C.F.R. § 1305

- Executing Order Forms:
  - Purchaser must prepare and execute …in triplicate by means of interleaved …sheets
  - Each form has three parts…
  - Each form has ten lines
  - Only one item per line
  - Total # of items are noted on form

Order Forms: 21 C.F.R. § 1305

- Executing Order Forms:
  - Prepared and executed by the purchaser in triplicate.
  - Prepared by use of a typewriter, pen, or indelible pencil.
  - Signature should be legible.
  - Attachments to order forms will not be used.

Order Forms: 21 C.F.R. § 1305

- Executing Order Forms:
  - Name and address of the supplier from whom the CS are being ordered shall be entered on the form.
  - Only one supplier may be listed on any one form.

Order Forms: 21 C.F.R. § 1305

- Executing Order Forms:
  - An order form may be executed only on behalf of the Registrant name on the form.
  - And only if his Registration has not expired, been revoked, or suspended.
  - Each order form shall be dated and signed by a person authorized to sign an application for registration.

Order Forms: 21 C.F.R. § 1305

- Executing Order Forms:
  - This may be the person who signed the original application
  - Or by a person to whom he gave Power of Attorney.
  - The Power of Attorney must be signed by:
    - the person who signed the most recent application;
    - the person to whom the power of attorney is being granted;
    - and two witnesses.

Order Forms: 21 C.F.R. § 1305

- Executing Order Forms:
  - The Power of Attorney must be filed with the Executed Order Forms of the purchaser.
  - The Power of Attorney must be available for inspection along with other order records.

Order Forms: 21 C.F.R. § 1305

- Executing Order Forms:
  - A Power of Attorney must be revoked by the person who signed the most recent application for DEA registration or re-registration, and two witnesses.
  - DEA does not print Power of Attorney or Notice of Revocation Forms.

Order Forms: 21 C.F.R. § 1305

- Filling Order Forms:
  - The Purchaser must Submit Copy 1 and copy 2 of the Order Form to the supplier and retain copy 3 in (their) Files.
  - The supplier must fill the entire order, if possible and the supplier desires to do so, and must record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which such containers are shipped.

Order Forms: 21 C.F.R. § 1305

- Filling Order Forms:
  - If an order cannot be filled in it's entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the order form.
  - No order form is valid more than 60 days after its execution by the purchaser.

Order Forms: 21 C.F.R. § 1305

- Filling Order Forms:
  - The supplier must retain Copy 1 of the order form for his own files and forward Copy 2 to the DEA office in the region where the supplier is located.
  - Copy 2 must be forwarded at the close of the month during which the final shipment is made or the 60 day validity period expires.

Order Forms: 21 C.F.R. § 1305

- Filling Order Forms:
  - The purchaser must record on Copy 3 of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

Order Forms: 21 C.F.R. § 1305

- Unaccepted Order Forms:
  - No order form shall be filled if :

    The order is not complete, legible or properly prepared, executed or endorsed or shows any alteration, erasure or change of description.

  - A defective order form may not be corrected; it must be replaced by a new order form.

Order Forms: 21 C.F.R. § 1305

- Preservation of Order Forms:
  - Order forms must be maintained separately from all other records of the registrant.
  - They are required to be kept available for inspection for a period of two years.

REPORTS

Destruction of CS: 21 C.F.R. § 1307.21

- Destruction of Controlled Substances
  - If a Registrant:
    - DEA Form 41 - Three Copies

OMB Approval No. 1117-0007

U.S. Department of Justice / Drug Enforcement Administration

REGISTRANTS INVENTORY OF DRUGS SURRENDERED

PACKAGE NO.

The following schedule is an inventory of controlled substances which is hereby surrendered to you for proper disposition.

FROM: *(Include Name, Street, City, State and ZIP Code in space provided below.)*

Signature of applicant or authorized agent

Registrant's DEA Number

Registrant's Telephone Number

NOTE: CERTIFIED MAIL (Return Receipt Requested) IS REQUIRED FOR SHIPMENTS OF DRUGS VIA U.S. POSTAL SERVICE. See instructions on reverse (page 2) of form.

NAME OF DRUG OR PREPARATION Registrants will fill in Columns 1, 2, 3, and 4 ONLY	Number of Containers	CONTENTS (Number of grams, tablets, ounces or other units per container)	Controlled Substance Content, (Each Unit)	FOR DEA USE ONLY		
				DISPOSITION	QUANTITY	
					GMS	MGS
1	2	3	4	5	6	7
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						

FORM DEA-41 (9-91) Previous edition dated 6-86 is usable. *See instructions on reverse (page 2) of form.*

Destruction of CS: 21 C.F.R. § 1307.21

- If not a Registrant:
  - Letter
  - Name and Address of Person
  - Name & Quantity of All Substances to Be Disposed of
  - How the person obtained the substance, if known; and name, address, and registration number…of person who possessed (it) prior

Reports to ARCOS : 21 C.F.R. § 1304.33

- Automated Reports & Consolidated Ordering System
- Who Must Report?

  -Manufacturers (All)

  -Distributors

  (Including Reverse Distributors)

Reports to ARCOS: 21 C.F.R.§ 1304.33

- What Must They Report?
  - Acquisition/Distribution of:
    - Schedule I & II
    - Narcotics in Schedule I
    - GHB drug products in Schedule III
    - Selected psychotropic substances in Schedules III & IV (Manufacturers only)

Reports to ARCOS: 21 C.F.R. § 1304.33

- When
  - Every Quarter: No Later Than the 15th
  - All Stocks of CS on Hand as of COB 12/31
- How Must They Report?
  - On-line Reporting
  - Or DEA Form 333

Suspicious Orders : 21 C.F.R.§ 1301.74 (b)

- The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office …in his area of suspicious orders when discovered by the registrant.

Suspicious Orders

- Suspicious Orders Include:
  - Orders of Unusual Size
  - Orders Deviating Substantially From a normal pattern
  - Orders of Unusual Frequency

Reporting the Theft or Loss of Controlled Substances

Paper or Online Submission

REPORT OF THEFT OR LOSS OF CONTROLLED SUBSTANCES

Federal Regulations require registrants to submit a detailed report of any theft or loss of Controlled Substances to the Drug Enforcement Administration. Complete page 1, and either page 2 or 3. Make two additional copies of the completed form. Forward the original and duplicate copies to the nearest DEA Office. Retain the triplicate copy for your records. Some states may also require a copy of this report.

OMB APPROVAL
No. 1117-0001
(Expiration Date 9/30/2017)

1. Name and Address of Registrant (Include ZIP Code)

2. Phone No. (Include Area Code)

3. DEA Registration Number

4. Date of Theft or Loss

5. Principal Business of Registrant (Check one)
1 ☐ Pharmacy
2 ☐ Practitioner
3 ☐ Manufacturer
4 ☐ Hospital/Clinic
5 ☐ Distributor
6 ☐ Methadone Program
7 ☐ Other (Specify) _____

6. County in which Registrant is Located

7. Was Theft reported to Police?
☐ Yes ☐ No

8. Name and Telephone Number of Police Department (Include Area Code)

9. Number of Thefts or Losses Registrant has Experienced in the Past 24 Months

10. Type of Theft or Loss (Check one and complete items below as appropriate)
1 ☐ Night Break-in
2 ☐ Armed Robbery
3 ☐ Employee Pilferage
4 ☐ Customer Theft
5 ☐ Other (Explain)
6 ☐ Lost in Transit (Complete Item 14)

11. If Armed Robbery, was Anyone:
Killed? ☐ No ☐ Yes (How Many) _____
Injured? ☐ No ☐ Yes (How Many) _____

12. Purchase value to Registrant of Controlled Substances taken?
$

13. Were any pharmaceuticals or merchandise taken?
☐ No ☐ Yes (Est. Value)
$

14. IF LOST IN TRANSIT, COMPLETE THE FOLLOWING:

A. Name of Common Carrier

B. Name of Consignee

C. Consignee's DEA Registration Number

D. Was the carton received by the customer?
☐ Yes ☐ No

E. If received, did it appear to be tampered with?
☐ Yes ☐ No

F. Have you experienced losses in transit from this same carrier in the past?
☐ No ☐ Yes (How Many) _____

15. What identifying marks, symbols, or price codes were on the labels of these containers that would assist in identifying the products?

16. If Official Controlled Substance Order Forms (DEA-222) were stolen, give numbers.

17. What security measures have been taken to prevent future thefts or losses?

PRIVACY ACT INFORMATION

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).

PURPOSE: Report theft or loss of Controlled Substances.

ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:

A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.

B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.

EFFECT: Failure to report theft or loss of controlled substances may result in penalties under Section 402 and 403 of the Controlled Substances Act.

In accordance with the Paperwork Reduction act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The Valid OMB control number for this collection of information is 1117-0001. Public reporting burden for this collection of information is estimated to average 20 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Freedom of Information: Please prominently identify any confidential business information per 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.

FORM DEA-106 Previous editions obsolete

CONTINUE ON REVERSE

Form DEA-106 (9/30/2017) Pg. 2

LIST OF CONTROLLED SUBSTANCES LOST OR STOLEN

	Trade Name of Substance or Preparation	NDC Number	Name of Controlled Substance in Preparation	Dosage Strength	Dosage Form	Total Quantity Lost or Stolen
Examples	**Desoxyn**	**00074-3377-01**	**Methamphetamine Hydrochloride**	**5 mg**	**Tablets**	**300**
	Demerol	**00409-1181-30**	**Meperidine Hydrochloride**	**50 mg/ml**	**Vial**	**150 ml**
	Robitussin A-C	**00031-8674-25**	**Codeine Phosphate**	**2 mg/cc**	**Liquid**	**5676 ml**
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						
17.						
18.						
19.						
20.						

Remarks: (Optional)

Express Quantity in Dosage Units, or Milliliters for Liquids

21 C.F.R. § 1301.74(c), 1301.76(b)

- The registrant shall notify the Field Division Office of the Administration in his area of any theft or significant loss of any controlled substances within one business day of discovery.
- The registrant shall also complete, and submit DEA Form 106…
- "Significant Loss" is also defined here.

21 C.F.R. § 1301.74(c), 1301.76(e)

- The supplier shall be responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to paragraph (e) of this section within one business day of discovery of such theft or loss.

Theft/Loss of CS (DEA 106) : 21 C.F.R. § 1301.74 (c), 1301.76 (b)

- The registrant shall also complete DEA Form 106 regarding such theft or loss.
  - Theft should be reported to local police with jurisdiction where the theft occurred.
  - Theft should also be reported to any state agency which requires such reports.

21 C.F.R. § 1301.74(c)

- Thefts and significant losses must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

Theft or Loss Defined

- Actual Theft or Loss
- Not an Inventory Adjustment (not for balancing inventory)
- Loss (Unexplained Disappearance).
- Any discovered shortage which the firm cannot convincingly establish to have been diverted after reasonable review/ investigation should generally be considered as a reportable loss.

Theft or Loss Defined

- Does not include Breakage, Damage, and/or Spillage which is still recoverable.
- Options (for Recoverable Substances):
  - DEA 41- Permission to Destroy
  - Reverse Distributor

DEA POLICY:
Who Should Report?

- In-Transit Losses: Supplier
- As soon as the registrant signs for the (accepts) shipment it becomes the responsibility of the purchaser to report any thefts or losses.
- If the purchaser does not sign for (accept) the shipment it is the responsibility of the shipper to report the theft/loss of the material.

Contact Information:

Scott Doubet , Regulatory Unit Chief
Regulatory Section/DRGR
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

202-307-8149 (Office)
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