

Inventories, Records & Reports

Drug Enforcement Administration

Manufacturer/Distributor/Importer/
Exporter Conference

San Antonio, TX

September 6, 2018



Diversion Control Division

Mission

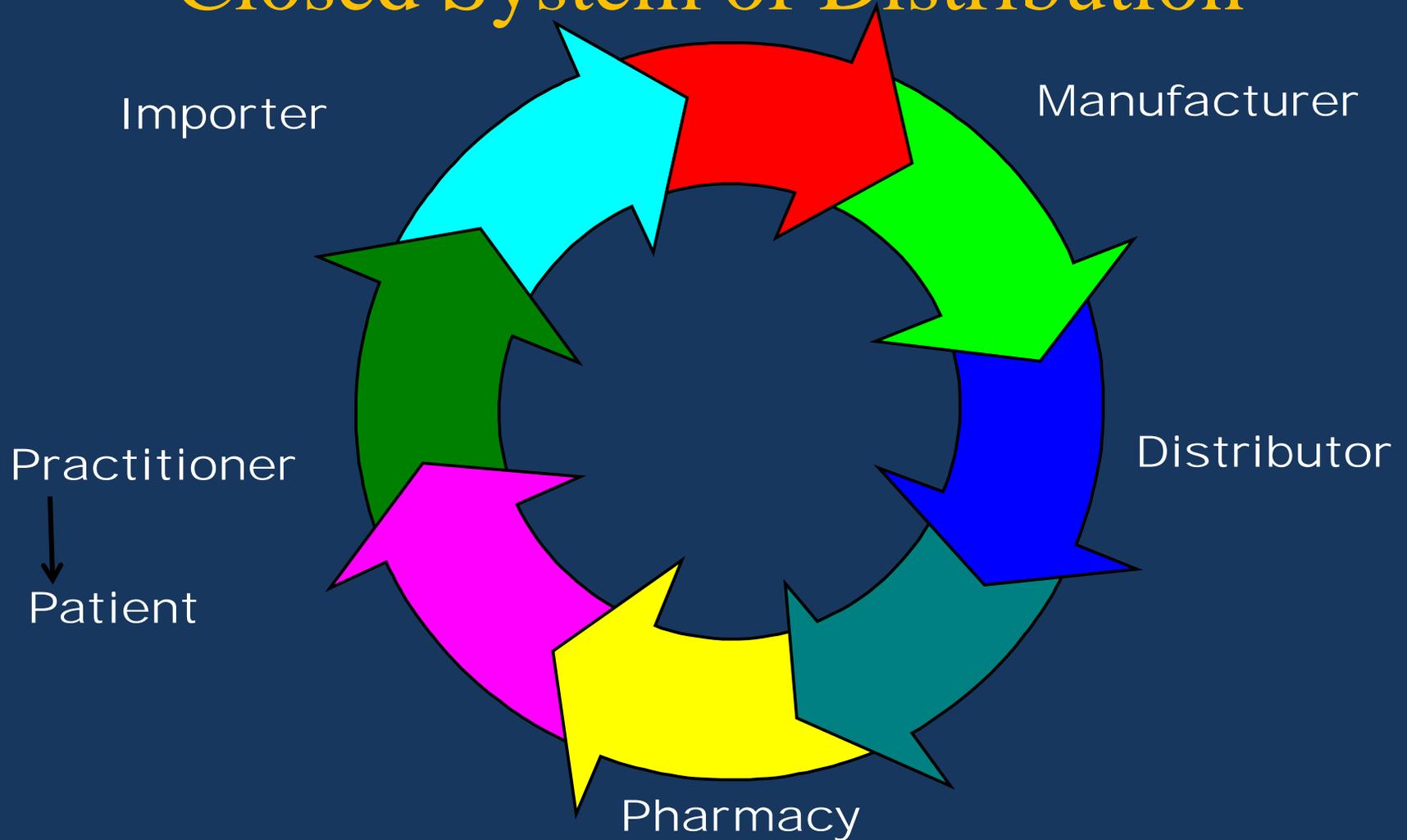
To prevent, detect, and investigate the diversion of controlled substances from legitimate sources

while

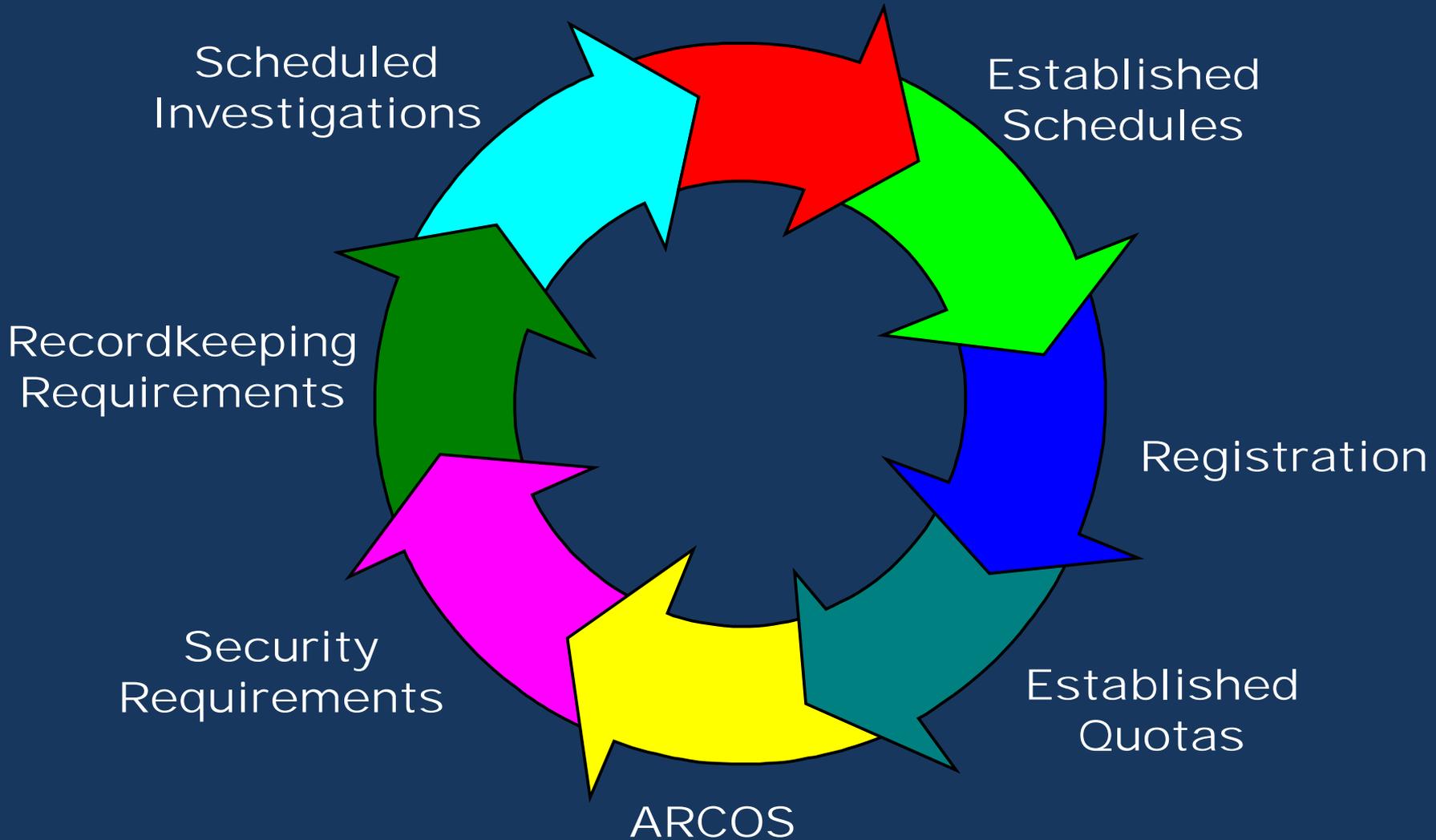


Ensuring an adequate and uninterrupted supply for legitimate medical and scientific purposes

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 - Part 1300

- 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 the manufacture or distribution ...”

Law: 21 USC § 827

All DEA Registrants Must:

- Take and Keep Inventories
- Make and Keep Records
- Make and Keep Reports

Law: 21 USC § 827(a)(1)

- 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(a)(3)

- “ every registrant under this subchapter 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 ...”
- Perpetual Inventory not required

Law: 21 USC § 827(b)

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

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.”
 - DEA needs to approve security at the new location *before* you begin handling and storing controlled substances there

INVENTORIES

Inventories: 21 C.F.R. § 1304.11(a)

- Inventory Requirements:
 - Complete and accurate record
 - All substances “On Hand” (In possession of or under the control of registrant) on the date the inventory is taken
 - Maintained in written, typewritten, or printed form at the registered location
 - May be taken **beginning of business (BOB)** or **close of business (COB)**

Initial Inventory

21 C.F.R. § 1304.11(b)

- Inventory of all stocks of controlled substances
 - 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

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
- (3) Inventories for Reverse Distributors
- (4) Inventories for Importers & Exporters

Inventories

21 C.F.R. § 1304.11(e)

- For each controlled substance in finished form include:
 - The **name** of the substance
 - Each **finished form** of the substance (e.g. 10 mg tablet)
 - The **number of units or volume** of each finished form in each commercial container (e.g. 100-tablet bottle)
 - The **number of commercial containers** of each such finished form (e.g. four 100-tablet bottles)

RECORDS

Required Records

- Inventories
- Receiving Records
- Distribution Records
- Theft & Loss
- Drug Destruction

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)

Schedule I & II

- Maintained separately from all of the records of the registrant

Separate Records

21 C.F.R. § 1304.04 (f)(2)

Schedules III, IV, & V

- Maintained separately from all other records of the registrant

OR

- “Readily retrievable” from the ordinary business records of the registrant;
 - Can be separated out from all other records in a reasonable time period
 - CS items asterisk, redlined, or in some manner which sets them visually apart

Separate Records

21 C.F.R. § 1304.21(b) & (c)

Separate records shall be maintained

- for each registered location and
- for each independent activity

Dates for Records

21 C.F.R. § 1304.21(d)

- Recorded dates must be the actual date the controlled substance was received, distributed, or otherwise transferred

Dates for Records

21 C.F.R. § 1304.21(d)

Recorded dates for **Imports** and **Exports**

- The anticipated date of release by a customs official for *permit applications* and *declarations*

21 C.F.R. § 1304.22

In-depth description of information required to be maintained as records for:

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

For Example: Distributors

21 C.F.R. § 1304.22(b)

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

Order Forms: 21 C.F.R. § 1305

- Order Forms are required for each transfer of a controlled substance 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

SUPPLIER'S 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.
DEAREGND

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

Schedules
XXXXXXXXXXXXXXXX

Registered as a
XXXXXXXXXXXXXXXX

No. of this Order Form
000000007

Order Forms: 21 C.F.R. § 1305

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

- Issued in books of seven forms each
- Each form has three copies:
 - Supplier's Copy 1 (brown)
 - DEA Copy 2 (green)
 - Purchaser's Copy 3 (blue)

Order Forms: 21 C.F.R. § 1305

Executing Order Forms:

- Purchaser must prepare and execute in triplicate
- Prepared by use of a typewriter, pen, or indelible pencil
- Each form has ten lines
- Only one item per line
- Identify the number of the “last line completed”

Order Forms: 21 C.F.R. § 1305

Executing Order Forms:

- Name and address of the supplier from whom the controlled substances 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 named on the form
- For an **active** (non-expired or revoked) registration
- Each order form shall be signed and dated by a **person authorized to sign an application for registration**
 - Or a person granted Power of Attorney by such an individual

Order Forms: 21 C.F.R. § 1305

- 21 CFR § 1301.13(j) explains who is authorized to sign an *application for registration* and who can therefore issue Power of Attorney to sign Order Forms
- Power of Attorney
 - The Power of Attorney form 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

- Power of Attorney
 - The signed Power of Attorney form 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

- Power of Attorney

- 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 supplied on each item and the date on which such containers are shipped

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

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 received** on each item and **the dates on which such containers are received** by the purchaser

Order Forms: 21 C.F.R. § 1305

- Filling Order Forms:
 - If a supplier cannot fill an order in its entirety, the order 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

- Unacceptable 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

Import-Export Form Guide

Controlled Substances Import-Export Form Guide

Controlled Substances Act Schedule	DEA-161 (Application for Export Permit)	DEA-357 (Application for Import Permit)	DEA-236 (Declaration)	
			Import	Export
Schedule I	X	X		
Schedule II	X	X		
Schedule III Narcotic	X	X		
Schedule III Nonnarcotic (<i>except for delta-9-THC which requires a permit</i>)			X	X
Schedule IV Narcotic	X	X		
Schedule IV Nonnarcotic			X	X
Schedule V Narcotic		X		X
Schedule V Nonnarcotic			X	X

DEA-161 Application for Export Permit

DEA-357 Application for Import Permit

DEA-236 Declaration

REPORTS

Destruction of Controlled Substances

21 C.F.R. § 1304.21(e)

“Shall maintain a record of destruction on a
DEA Form 41”

- The record shall be complete and accurate
- Shall include the name and signature of the **two employees** who witnessed the destruction
- Registrant is not required to submit this form to DEA unless requested to do so; must be maintained for minimum of 2 years

U. S. DEPARTMENT OF JUSTICE – DRUG ENFORCEMENT ADMINISTRATION
REGISTRANT RECORD OF CONTROLLED SUBSTANCES DESTROYED
 FORM DEA-41

A. REGISTRANT INFORMATION

Registered Name:	DEA Registration Number:	
Registered Address:		
City:	State:	Zip Code:
Telephone Number:	Contact Name:	

B. ITEM DESTROYED**1. Inventory**

Examples		National Drug Code or DEA Controlled Substances Code Number	Batch Number	Name of Substance	Strength	Form	Pkg. Qty.	Number of Full Pkgs.	Partial Pkg. Count	Total Destroyed
		1.		16590-598-60	N/A	Kadian	60mg	Capsules	60	2
2.		0555-0767-02	N/A	Adderall	5mg	Tablet	100	0	83	83 Tablets
3.		9050	B02120312	Codeine	N/A	Bulk	1.25 kg	N/A	N/A	1.25 kg
4.										
5.										
6.										
7.										

2. Collected Substances

Examples		Returned Mail-Back Package	Sealed Inner Liner	Unique Identification Number	Size of Sealed Inner Liner	Quantity of Packages(s)/Liner(s) Destroyed
		1.	X		MBP1106, MBP1108 - MBP1110, MBP112	N/A
2.		X	X	CRL1007 - CRL1027	15 gallon	21
3.			X	CRL1201	5 gallon	1
4.						
5.						
6.						
7.						

Form DEA-41

See instructions on reverse (page 2) of form.

DEA-41 Pg. 2

C. METHOD OF DESTRUCTION

Date of Destruction:	Method of Destruction:	
Location or Business Name:		
Address:		
City:	State:	Zip Code:

D. WITNESSES

I declare under penalty of perjury, pursuant to 18 U.S.C. 1001, that I personally witnessed the destruction of the above-described controlled substances to a non-retrievable state and that all of the above is true and correct.

Printed name of first authorized employee witness:	Signature of first witness:	Date:
Printed name of second authorized employee witness:	Signature of second witness:	Date:

E. INSTRUCTIONS

- Section A. REGISTRANT INFORMATION:** The registrant destroying the controlled substance(s) shall provide their DEA registration number and the name and address indicated on their valid DEA registration, in addition to a current telephone number and a contact name, if different from the name on the valid DEA registration.
- Section B. (1) Inventory:** This part shall be used by registrants destroying lawfully possessed controlled substances, other than those described in Section B(2). In each row, indicate the National Drug Code (NDC) for the controlled substance destroyed, or if the substance has no NDC, indicate the DEA Controlled Substances Code Number for the substance, if the substance destroyed is in bulk form, indicate the batch number, if available. In each row, indicate the name, strength, and form of the controlled substance destroyed, and the number of capsules, tablets, etc., that are in a full package (pkg. qty.). If destroying the full quantity of the controlled substance, indicate the number of packages destroyed (number of full pkgs.). If destroying a partial package, indicate the partial count of the capsules, tablets, etc. destroyed (partial pkg. count). If destroying a controlled substance in bulk form, indicate that the substance is in bulk form (form) and the weight of the substance destroyed (pkg. qty.). In each row, indicate the total number of each controlled substance destroyed (total destroyed).
- Section B. (2) Collected Substances:** This part shall be used by registrants destroying controlled substances obtained through an authorized collection activity in accordance with 21 U.S.C. 822(g). In each row, indicate whether registrant is destroying a mail-back package or an inner liner. If destroying a mail-back package, enter each unique identification number separated by a comma and/or as a list in a sequential range and total quantity of packages being destroyed. If destroying an inner liner, enter each unique identification number separated by a comma and/or as a list in a sequential range based on the size of the liners destroyed and the total quantity of inner liners being destroyed. In the case of mail-back packages or inner liners received from a law enforcement agency which do not have a unique identification number or clearly marked size, include the name of the law enforcement agency and, if known, the size of the inner liner or package. **DO NOT OPEN ANY MAIL-BACK PACKAGE OR INNER LINER; AN INVENTORY OF THE CONTENTS OF THE PACKAGES OR LINERS IS PROHIBITED BY LAW AND IS NOT REQUIRED BY THIS FORM.**
- If additional space is needed for items destroyed in Section B, attach to this form additional page(s) containing the requested information for each controlled substance destroyed.
- Section C. METHOD OF DESTRUCTION:** Provide the date, location, and method of destruction. The method of destruction must render the controlled substance to a state of non-retrievable and meet all applicable destruction requirements.
- Section D. WITNESSES:** Two authorized employees must declare by signature, under penalty of perjury, that such employees personally witnessed the destruction of the controlled substances listed in Section B in the manner described in Section C.
- You are not required to submit this form to DEA, unless requested to do so. This form must be kept as a record of destruction and be available by the registrant for at least two years in accordance with 21 U.S.C. 827.

Paperwork Reduction Act Statement: The information collected on this form is necessary for DEA registrants to record controlled substances destroyed in accordance with the Controlled Substances Act (CSA). The records that DEA registrants maintain in accordance with the CSA must be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General. 21 U.S.C. 827. DEA estimates that it will take approximately 30 minutes to complete this form, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The completion of this form by DEA registrants that destroy controlled substances is mandatory in accordance with 21 U.S.C. 827. Please note that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Comments regarding this information collection, including suggestions for reducing the burden estimate, should be directed to the Drug Enforcement Administration, DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, Virginia 22162.

Save

Print

Reset

Reports to ARCOS

21 C.F.R. § 1304.33

- Automated Reports & Consolidated Ordering System
- Who Must Report?
 - Manufacturers
 - Distributors
 - (Including Reverse Distributors)

Reports to ARCOS

21 C.F.R. § 1304.33

- What Must be Reported?
 - Acquisition/Distribution of:
 - Schedule I & II controlled substances
 - Narcotics in Schedule III
 - 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 Must it be Reported?
 - Every Quarter: No later than the 15th day of the month succeeding the quarter
 - All Stocks of CS on hand as of COB 12/31: No later than January 15th of the following year
- How Must it be Reported?
 - 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 but are not limited to:
 - 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

21 C.F.R. § 1301.74(c), 1301.76(b)

- The registrant must notify the Field Division Office of the Administration in his area of any theft or any significant loss of controlled substances within one business day of discovery
- The registrant must also complete, and submit..., **DEA Form 106** regarding the theft or loss
- Some of the factors to consider when determining if a loss is a “Significant Loss” are provided



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 <input type="checkbox"/> Pharmacy 5 <input type="checkbox"/> Distributor 2 <input type="checkbox"/> Practitioner 6 <input type="checkbox"/> Mediation Program 3 <input type="checkbox"/> Manufacturer 7 <input type="checkbox"/> Other (Specify) 4 <input type="checkbox"/> Hospital/Clinic
6. County in which Registrant is Located	7. Was Theft reported to Police? <input type="checkbox"/> Yes <input type="checkbox"/> 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 <input type="checkbox"/> Night Break-in 3 <input type="checkbox"/> Employee Pilferage 5 <input type="checkbox"/> Other (Explain) 2 <input type="checkbox"/> Armed Robbery 4 <input type="checkbox"/> Customer Theft 6 <input type="checkbox"/> Lost in Transit (Complete Item 14)		
11. If Armed Robbery, was Anyone: Killed? <input type="checkbox"/> No <input type="checkbox"/> Yes (How Many) _____ Injured? <input type="checkbox"/> No <input type="checkbox"/> Yes (How Many) _____		12. Purchase value to Registrant of Controlled Substances taken? \$ _____	13. Were any pharmaceuticals or merchandise taken? <input type="checkbox"/> No <input type="checkbox"/> 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? <input type="checkbox"/> Yes <input type="checkbox"/> No	E. If received, did it appear to be tampered with? <input type="checkbox"/> Yes <input type="checkbox"/> No	F. Have you experienced losses in transit from this same carrier in the past? <input type="checkbox"/> No <input type="checkbox"/> 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 29 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.

LIST OF CONTROLLED SUBSTANCES LOST OR STOLEN

Examples

Trade Name of Substance or Preparation	NDC Number	Name of Controlled Substance in Preparation	Dosage Strength	Dosage Form	Total Quantity Lost or Stolen
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

Theft or Loss Guidance

- Actual Theft or Loss
- Not an Inventory Adjustment
 - Do not use the DEA 106 form for balancing your inventory

Theft/Loss of Controlled Substances

21 C.F.R. § 1301.74(c)

- Thefts and significant losses must be **reported** regardless of whether the controlled substances are **subsequently recovered** and/or the responsible parties are identified and action taken against them

Theft/Loss of Controlled Substances

21 C.F.R. § 1301.74(c)

- The supplier shall be responsible for reporting in-transit losses of controlled substances by the common or contract carrier...within one business day of discovery of such theft or loss
- If purchasing registrant signs for (accepts) the shipment, it becomes the responsibility of the purchaser to report any thefts or losses

Theft of Controlled Substances

- In addition to completing and submitting a DEA Form 106 to the DEA:
 - The 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



Regulatory Section/DRGR

202-307-7194