

**Manufacturers, Importers & Exporters
Conference
Inventories, Records, & Reports
National Harbor, MD
June 19, 2013**

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Arlington, Virginia
(202) 598-2283**

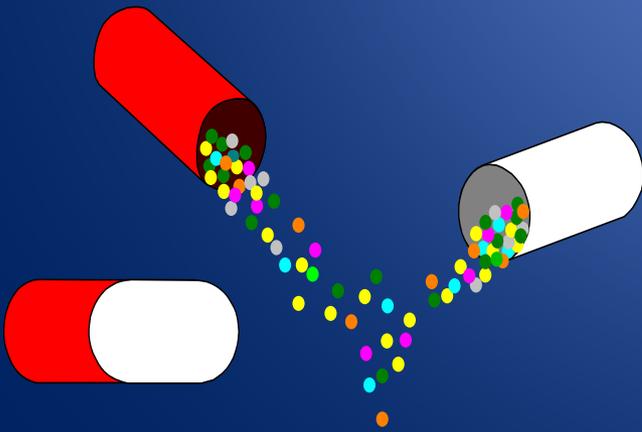
Office of Diversion Control

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

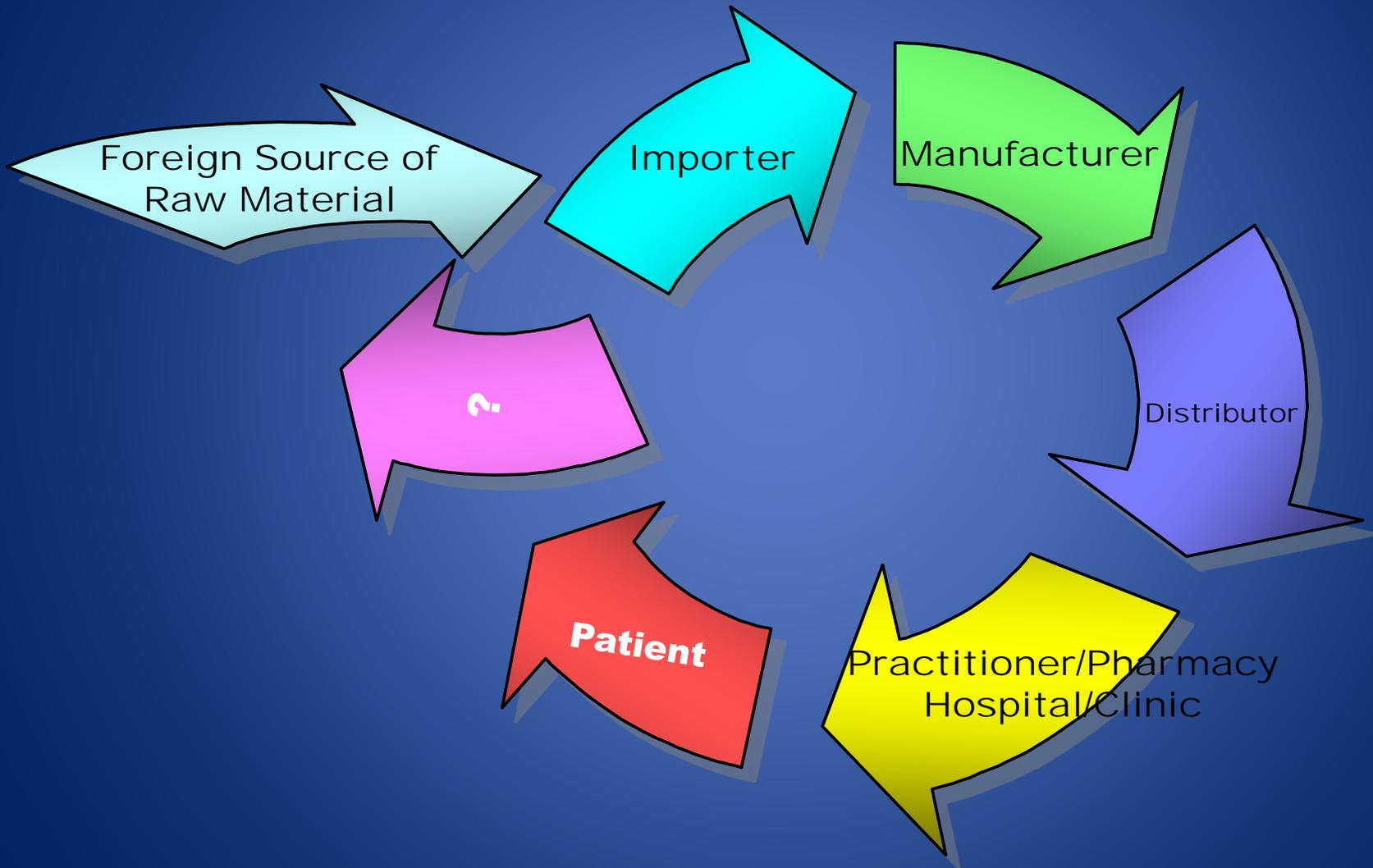


while

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



Closed System of Distribution



Inventories
21 CFR 1304.11 (a)

Inventories

- Inventory Requirements:
 - Complete and Accurate Record
 - All Substances “On Hand”
 - On The Date The Inventory is Taken
 - Maintained in Written, Typewritten, or Printed Form at the Registered Location
 - (OOB) Opening of Business/or (COB) Close of Business

Inventories:

- Separate
- Initial
- Biennial
- Newly Controlled Substances

CFR 1304.11 (b), 21 CFR 1304.11 (c), 21 CFR 1304.11 (d)

RECORDS

Records

All records should be:

- Readily Retrievable
- Easily Identifiable
- Must be kept for a minimum of 2 years

Records

- 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
 - Dates of Records

21 CFR 1304.21 (a) & 21 CFR 1304.21 (d)

Separate Records:

Schedule I & II:

- Maintained Separately from All Other Records

21 CFR 1304.04 (f)(1); (g); (h)(1)

Separate Records:

Schedules III, IV, & V:

- Separate from All Other Records
- or “Readily Retrievable”
- Separated Out from all other Records in a Reasonable Time Period

21 CFR 1304.04 (f)(2); (g); (h)(2)

Separate Records:

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

DEA Form 222

- Required for each distribution of Schedule I & II controlled substance
- Issued in books of 7 or 14 forms each
- DEA 222 Form has Three Copies
- Serially numbered and issued

21 CFR 1305

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.	TO BE FILLED IN BY PURCHASER			TO BE FILLED IN BY SUPPLIER																
	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

Schedules

XXXXXXXXXXXXXX

Registered as a

XXXXXXXXXXXXXX

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

DEA Form 222

- Purchaser must prepare and execute ...in triplicate
- Each DEA 222 Form has Ten Lines
- Only One Item Per Line
- Total # of Items Are Noted on Form
- Typewriter, Pen, or Indelible Pencil
- Legible signature of authorized person
- Attachments not allowed

DEA Form 222

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

REPORTS

Destruction of CS

- Destruction of Controlled Substances
- Complete a DEA Form 41

21 CFR 1307.21

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	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.	
Registrants will fill in Columns 1,2,3, and 4 ONLY.	1	2	3	4	5	6	7
1							
2							
3							
4							
5							
6							
7							
8							
9							

DEA Form 106
Reporting the Theft or
Significant Loss of
Controlled Substances



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.

OMB APPROVAL
No. 1117-0001

Complete the front and back of this form in triplicate. 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.

1. Name and Address of Registrant (Include ZIP Code)					2. Phone No. (Include Area Code)	
ZIP CODE						
3. DEA Registration Number		4. Date of Theft or Loss		5. Principal Business of Registrant (Check one)		
2 ltr. prefix <input type="text"/> <input type="text"/>				1 <input type="checkbox"/> Pharmacy		
7 digit suffix <input type="text"/> <input type="text"/>				5 <input type="checkbox"/> Distributor		
				2 <input type="checkbox"/> Practitioner		
				6 <input type="checkbox"/> Methadone 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?		8. Name and Telephone Number of Police Department (Include Area Code)		
		<input type="checkbox"/> Yes <input type="checkbox"/> No				
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:			12. Purchase value to Registrant of controlled substances taken?		13. Were any pharmaceuticals or merchandise taken?	
Killed? <input type="checkbox"/> No <input type="checkbox"/> Yes (How many) _____			\$		<input type="checkbox"/> No <input type="checkbox"/> Yes (Est. Value)	
Injured? <input type="checkbox"/> No <input type="checkbox"/> Yes (How many) _____					\$	
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?		E. If received, did it appear to be tampered with?		F. Have you experienced losses in transit from this same carrier in the past?		
<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No		<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 certain records maintained for statistical and analytical purposes. Disclosure of

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 30 minutes per

Thefts and/or Significant Loss

- Notify the Field Division Office in his/her area of any theft or significant loss of any controlled substances within one business day of discovery.
- “Significant Loss” is also defined here

21 CFR 1301.74(c), 1301.76 (b)

Thefts and/or Significant Loss

- 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

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

21 CFR 1301.76 (b)

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

Permit to Import – Controlled Substances

- DEA issues a DEA Form 35, Permit to Import
- DEA registered Importer completes column 6c on the DEA Form 357 when product received
 - Actual date and quantity received (base in grams per line item on the permit)
 - Ensure DEA Permit Number is noted on the form
 - Email completed 357 to csimex@usdoj.gov

21 CFR 1312.11 and 12

Permit to Import – Controlled Substances

Permit to Import is required for import:

- Schedule I and II controlled substances
- Narcotic controlled substance (CIII, CIV, or CV)
- Drug Code 7369 (Dronabinol)
- Non-Narcotic (CIV, CV) which is also listed in Schedule I or II of the International Psychotropic Convention

DEA registered Importer submits a DEA Form 357,
Application for Permit

21 CFR 1312.11 and 12

U.S. Department of Justice / Drug Enforcement Administration APPLICATION FOR PERMIT TO IMPORT CONTROLLED SUBSTANCES FOR DOMESTIC AND/OR SCIENTIFIC PURPOSES PURSUANT TO SECTION 1002, TITLE III, P.L. 91-513 <i>(Read instructions on reverse before completing)</i>	OMB APPROVAL No. 1117 - 0013 See reverse for Privacy Act
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TO: DRUG ENFORCEMENT ADMINISTRATION IMPORT / EXPORT UNIT (ODGI) 8701 MORRISSETTE DR., SPRINGFIELD, VA 22152	DATE _____ IMPORTER'S APPLICATION NUMBER _____
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Application is hereby made pursuant to the provisions of the Controlled Substances Import and Export Act and the regulations prescribed thereunder for a permit to import as follows:

1. NAME OF FOREIGN EXPORTER	2. ADDRESS OF FOREIGN EXPORTER
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3. FOREIGN PORT OF EXPORTATION	4. PORT OF ENTRY (U.S. Customs port where shipment will clear)	5. LATEST DATE SHIPMENT WILL LEAVE FOREIGN PORT
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6a. NAME AND QUANTITY OF DRUG PREPARATION TO BE IMPORTED (Enter names as shown on labels; numbers and sizes of packages; strength, CSA Drug Code, and NDC Number)	6b. CONTROLLED SUBSTANCE CONTENT OF DRUG OR PREPARATION TO BE IMPORTED expressed as acid, base or alkaloid (Enter name of controlled substance contained in the drug; compound, or preparation)	6c. DATE IMPORTED AND ACTUAL QUANTITY (Completed by registrant at time of import) DEA PERMIT No.:

7a. ASSIGNED QUOTA FOR THIS YEAR	7b. TOTAL KG. AUTHORIZED ON PERMITS THIS YEAR	7c. KG. OF 7b. IMPORTED TO DATE	7d. STOCK ON HAND & DATE
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8. IF SUBSTANCE(S) WILL BE IMPORTED FOR SCIENTIFIC PURPOSES ONLY, PLEASE COMPLETE:
 I hereby certify the above controlled substances are imported exclusively for scientific purposes, pursuant to 21 CFR 1312.13(a)(4) (see reverse), as follows:

Signature of Certifying Individual

NAME OF IMPORTER	ADDRESS OF IMPORTER
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IMPORTER'S TELEPHONE NO.	DEA REGISTRATION NO.	SIGNATURE AND TITLE OF PERSON MAKING APPLICATION
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NOTICE : Controlled Substances may not be imported by mail or parcel post.

DEA USE ONLY	APPROVED IMPORT PERMIT NUMBER	DATE IMPORT PERMIT NUMBER ISSUED
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Import Declaration

- DEA Form 236, Controlled Substances Import/Export Declaration for import:
 - Non-Narcotic controlled substances (CIII, CIV, CV)
- Must be submitted at least 15 Days before proposed Importation
- Transaction ID number issued by DEA
- DEA Registrant completes column 2c on DEA Form 236 when items received

21 CFR 1312.18 (b)

CONTROLLED SUBSTANCES IMPORT / EXPORT DECLARATION

(Read Instructions on reverse before completing)

OMB APPROVAL
No. 1117 - 0009

See reverse for Privacy Act

1. CHECK ONE **IMPORT DECLARATION** Nonnarcotic Substances in Schedules III, IV, V
 EXPORT DECLARATION Nonnarcotic Substances in Schedules III, and IV and all substances in Schedule V

U.S. CUSTOMS CERTIFICATION

Date of Departure / Arrival

IMPORTER/EXPORTER (Name and Address)

BROKER OR FORWARDING AGENT, IF USED (Name and Address)

Name of Carrier / Vessel

Date of Certification

Signature of Customs Official

DEA REGISTRATION NO.

2. CONTROLLED SUBSTANCES TO BE IMPORTED OR EXPORTED

2a. NAME AND QUANTITY OF DRUG or PREPARATION (Enter names as shown on labels; numbers and sizes of packages; strength of tablets, capsules, etc., CSA Drug Code and NDC Number)

2b. CONTROLLED SUBSTANCE CONTENT OF DRUG OR PREPARATION expressed as acid, base or alkaloid. (Enter names of controlled substances contained in the drug; compound, or preparation)

2c. DATE IMPORTED/EXPORTED AND ACTUAL QUANTITY (Completed by registrant at time of transaction)

3. FOREIGN DOMESTIC PORT OF EXPORTATION (last U.S. Customs Port) AND APPROX. DEPARTURE DATE

FOREIGN DOMESTIC PORT OF IMPORTATION (first U.S. Customs Port) AND APPROX. ARRIVAL DATE

4. MODE OF TRANSPORT; NAME OF VESSEL / CARRIER (if known)

NAME OF ALL INTERMEDIATE CARRIERS

5. NAME AND ADDRESS OF FOREIGN CONSIGNEE/CONSIGNOR

I hereby certify that the above named substance(s) to be Imported, Exported, are intended for Legitimate medical need, Scientific research, Other (If intended for reexport beyond the country of destination described in block 5 above, attach documentation per Title 21, CFR 1312.27.)

If used as "Export Declaration", attach documentation that importation is not contrary to the laws or regulations of the country of destination.

SIGNATURE OF AUTHORIZED INDIVIDUAL OF IMPORTER/EXPORTER, BROKER OR FORWARDING AGENT

DATE

NAME OF FIRM AND TELEPHONE NUMBER

Permit to Export – Controlled Substances

- DEA issues a DEA Form 36, Permit to Export
- DEA registered Exporter completes column 7c on the DEA Form 161 when product received
 - Actual date and quantity received (base in grams per line item on the permit)
 - Ensure DEA Permit Number is noted on the form
 - Email completed 161 to csimex@usdoj.gov

21 CFR 1312.11 and 12



PERMIT TO EXPORT

The Administrator of the Drug Enforcement Administration, being the official charged with the administration of the laws relating to the exportation of the dangerous drugs to which the Controlled Substances Import and Export Act and the several international treaties apply, authorizes and permits the following exportation of controlled substances from the United States.

31590

DATE OF ISSUE		EXPIRATION DATE		PERMIT NO.	
COMPETENT NATIONAL AUTHORITY				Date of Issue:	
Import Certificate No:					
Competent Authority:					
EXPORTER					
CONSIGNEE					
PORT OF EXPORT			FOREIGN PORT OF ENTRY		
Item No.	Number and Size of Packages	Name of Substance or Preparation	Controlled Substance Content		
*****			*****		
Total Number of Items			REEXPORTATION PROHIBITED		
The exportation is to be made in one consignment from the designated port of export and is not to be made by mail or parcel post.					
NOTES:					
Endorsement by U.S. Customs This is to certify that the controlled substance merchandise described herein was exported from this port. (Original and Duplicate)					
_____		_____		_____	
(Port)		(Signature/Title)		(Date)	
Endorsement by Government of Importing Country: This is to certify that the controlled substance merchandise described herein was imported. If quantity is different than permitted, please indicate in Notes section above.					
_____		_____		_____	
(Signature)		(Title)		(Date)	
For the Administrator: Sean P. Mahoney, Chief International Drug Unit			Address: Drug Enforcement Administration International Drug Unit (ODOI) Washington, DC 20537		

(Signature)					
DEA Form 36 (10/02)					

ORIGINAL --- TO ACCOMPANY SHIPMENT

Export Declaration

- DEA Form 236, Controlled Substances Import/Export Declaration for export:
 - Non-Narcotic Substance (CIII, CIV, CV)
 - Narcotic Substances (CV)
- Must be submitted at least 15 Days before proposed Exportation
- Transaction ID number issued by DEA
- DEA Registrant completes column 2c on DEA Form 236 when items received

21 CFR 1312.27

CONTROLLED SUBSTANCES IMPORT / EXPORT DECLARATION

(Read Instructions on reverse before completing)

OMB APPROVAL
No. 1117 - 0009

See reverse for Privacy Act

1. CHECK ONE <input type="checkbox"/> IMPORT DECLARATION Nonnarcotic Substances in Schedules III, IV, V <input type="checkbox"/> EXPORT DECLARATION Nonnarcotic Substances in Schedules III, and IV and all substances in Schedule V	U.S. CUSTOMS CERTIFICATION Date of Departure / Arrival Name of Carrier / Vessel Date of Certification Signature of Customs Official
IMPORTER/EXPORTER (Name and Address)	BROKER OR FORWARDING AGENT, IF USED (Name and Address)
DEA REGISTRATION NO.	

2. CONTROLLED SUBSTANCES TO BE IMPORTED OR EXPORTED		
2a. NAME AND QUANTITY OF DRUG or PREPARATION <i>(Enter names as shown on labels; numbers and sizes of packages; strength of tablets, capsules, etc., CSA Drug Code and NDC Number)</i>	2b. CONTROLLED SUBSTANCE CONTENT OF DRUG OR PREPARATION expressed as acid, base or alkaloid. <i>(Enter names of controlled substances contained in the drug; compound, or preparation)</i>	2c. DATE IMPORTED/EXPORTED AND ACTUAL QUANTITY <i>(Completed by registrant at time of transaction)</i>

3. <input type="checkbox"/> FOREIGN <input type="checkbox"/> DOMESTIC PORT OF EXPORTATION (last U.S. Customs Port) AND APPROX. DEPARTURE DATE	<input type="checkbox"/> FOREIGN <input type="checkbox"/> DOMESTIC PORT OF IMPORTATION (first U.S. Customs Port) AND APPROX. ARRIVAL DATE
4. MODE OF TRANSPORT; NAME OF VESSEL / CARRIER (if known)	NAME OF ALL INTERMEDIATE CARRIERS
5. NAME AND ADDRESS OF FOREIGN CONSIGNEE/CONSIGNOR	

I hereby certify that the above named substance(s) to be Imported, Exported, are intended for Legitimate medical need, Scientific research, Other (If intended for reexport beyond the country of destination described in block 5 above, attach documentation per Title 21, CFR 1312.27.)

If used as "Export Declaration", attach documentation that importation is not contrary to the laws or regulations of the country of destination.

SIGNATURE OF AUTHORIZED INDIVIDUAL OF IMPORTER/EXPORTER, BROKER OR FORWARDING AGENT	DATE	NAME OF FIRM AND TELEPHONE NUMBER

LISTED CHEMICALS

General Record Keeping

All records should be:

- Readily Retrievable
- Easily Identifiable
- Must be kept for 2 years/ 4 years

LISTED CHEMICAL RECORDS & REPORTS

- Regulated person is defined as any individual, who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine.....
- Regulated person must keep records of regulated transaction

21 CFR 1310.03

LISTED CHEMICAL REPORTS

- Report of regulated transaction extraordinary quantity
- Uncommon delivery method
- Excessive or unusual loss of listed chemical identified by DEA previously
- Transaction of regulated or encapsulating or tabulating machine

21 CFR 1310.05

Each Record Must Contain

- Identification of each party
- Name & Address
- DEA number, Date of Transaction, & Method of transfer
- Name, quantity & form of packaging of listed chemical
- Description of the tableting or encapsulating machine (make, model, and serial number)
- Type of ID used by purchaser (number)
- Normal Business records will suffice as long as the above info is contained within (not financial records)

Import/Export Declaration List I and List II Chemicals

- DEA Form 486, Import/Export Declaration List I and List II Chemicals
- Required for all imports and exports of List I and List II chemicals with the exception of importation of pseudoephedrine, ephedrine, and phenylpropanolamine

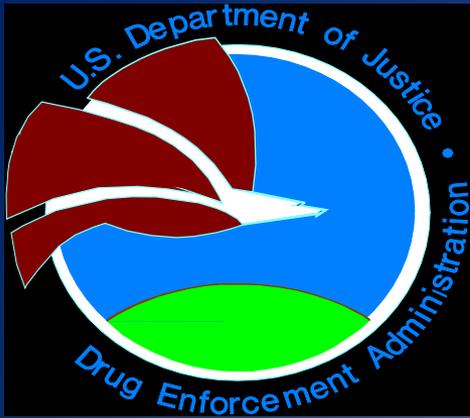
***EACH CHEMICAL BULK MANUFACTURER
SHALL SUBMIT ANNUALLY:***

- Manufacturing
- Inventory
- Use data
- Submitted to:

DEA

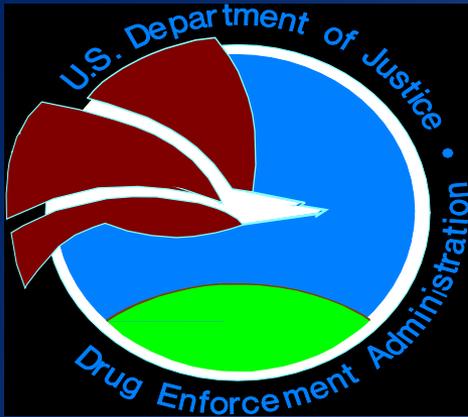
Attn: Drug & Chemical Evaluation
Section/ODE

8701 Morrisette Drive
Springfield, VA 22152



???QUESTIONS???

Contact Information



Marsha L.D. Ikner, Staff Coordinator
Synthetic Drugs & Chemicals Section
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22317
202-598-2283 (Office)
Marsha.l.ikner@usdoj.gov