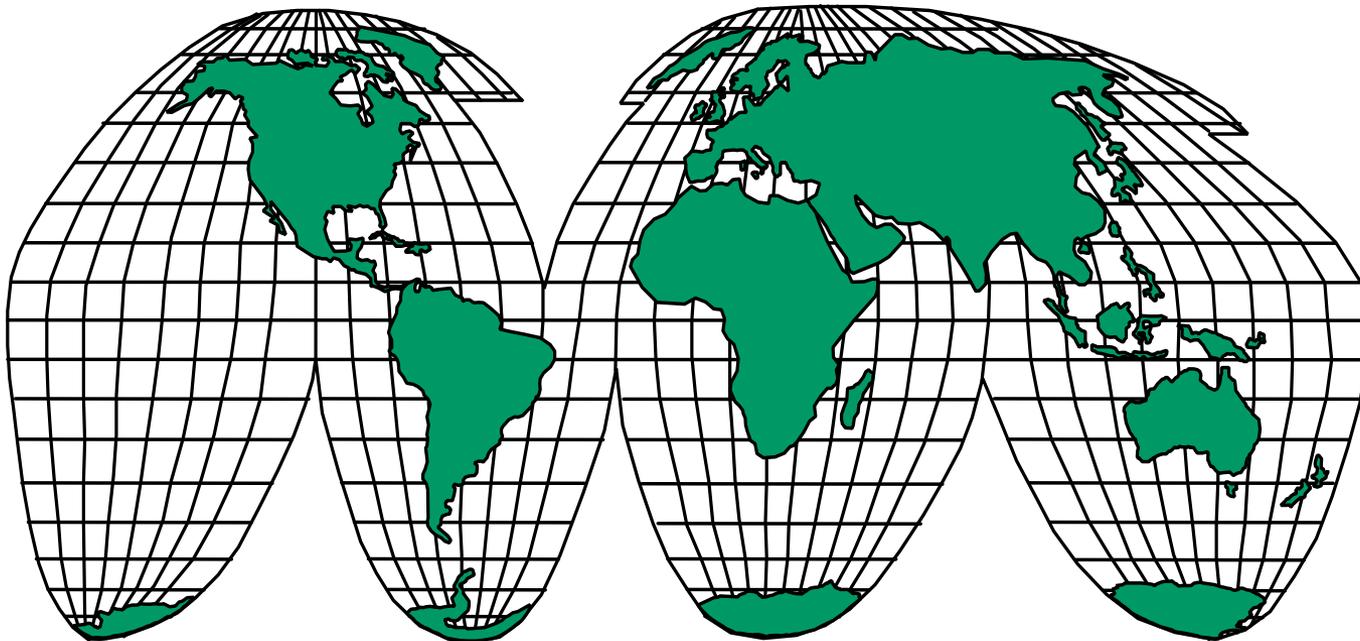




IMPORT/EXPORT UNIT

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

Drug Enforcement Administration Way Overdue Pharmaceutical Training Seminar April 2016





Drug Enforcement Administration

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

Per 21 CFR § 1312, DEA regulates the import, export, and transshipment of controlled substances.

Per 21 CFR § 1313, DEA regulates the import, export, and transshipment of listed chemicals.



Controlled Substances & List Chemicals

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

	DEA-357	DEA-161	DEA Form-236		DEA Form-486	
			Imports	Exports	Imports	Exports
Schedule I & II	✓	✓				
Schedule III Narcotic	✓	✓				
Schedule III Non-Narcotic (7369 requires a PERMIT)			✓	✓		
Schedule IV Narcotic	✓	✓				
Schedule IV Non-Narcotic			✓	✓		
Schedule V Narcotic	✓			✓		
Schedule V Non-Narcotic			✓	✓		
List I & II Chemicals					✓	✓
Ephedrine, Pseudoephedrine, & Phenylpropanolamine					✓	



DEA-357 Form

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

Purpose: To import controlled substances in schedules I, II, III narcotic, IV narcotic, or V narcotic into the United States.

To DEA: A completed DEA-357

From DEA: Import Permit

Note: Imports of controlled substances in schedules I, II, and III narcotic are usually (a) Narcotic Raw Material; (2) controlled substances in schedules II and III narcotic not readily available in the U.S.; (c) for clinical trials or scientific purposes.



DEA-161 Form

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

Purpose: To export controlled substances in schedules I, II, III narcotic, or IV narcotic from the United States.

To DEA: A completed DEA-161; A "readable" photocopy of import permit or letter of no objection

From DEA: Export Permit

Note: The affidavit is in lieu of the letter of "No Re-Exportation" and "medical, scientific, or other legitimate use" statement.



DEA-161R Form

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

Purpose: To export controlled substances in schedules I, II, III narcotic, or IV narcotic from the United States to a (1st) foreign country for subsequent re-export to other (2nd) foreign countries.

To DEA: A completed DEA-161R; A "readable" photocopy of import permit or letter of no objection from 1st country

From DEA: Export Permit

Note: The affidavit is in lieu of additional documentation; This form is for re-exports only ... do NOT use this form for re-exports that are not going to happen!



DEA-236 Form (Imports)

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

Purpose: To import non-narcotic controlled substances in schedules III, IV, or V into the United States from a foreign country.

To DEA: A DEA-236 at least 15 days prior to the import entering a U.S. port

From DEA: The Transaction ID



DEA-236 Form (Exports)

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

Purpose: To export non-narcotic controlled substances in schedules III or IV, or any controlled substances in schedule V from the United States to a foreign country.

To DEA: A DEA-236 at least 15 days prior to the export departing a U.S. port; A "readable" photocopy of import permit or letter of no objection; The letter of no re-exportation & statement of medical, scientific, or other legitimate use

From DEA: The Transaction ID



DEA-486 Form (Imports)

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

Purpose: To import listed chemicals into the United States from a foreign country.

To DEA: A DEA-486 with your Transferees at least 15 days prior to the import entering a U.S. port

From DEA: The Transaction ID

Note: Do not use the DEA-486 form to import Ephedrine, Pseudoephedrine, or Phenylpropanolamine into the United States; The 15 days can be waived if you are a regular importer of the listed chemical.



DEA-486 Form (Exports)

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

Purpose: To export listed chemicals from the United States to a foreign country.

To DEA: A DEA-486 at least 15 days prior to the export departing a U.S. port

From DEA: The Transaction ID

Note: The 15 days can be waived if you have regular customer status with your customer provided that you have shipped to your customer's address at least 1 time during the prior 6 months or 2 or more times during the prior 12 months.



DEA-486A Form (Imports)

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

Purpose: To import Ephedrine, Pseudoephedrine, or Phenylpropanolamine into the United States from a foreign country.

To DEA: A DEA-486A with your Transferees at least 15 days prior to the import entering a U.S. port

From DEA: The Transaction ID

Note: The 15 days is not waived even if you are a regular importer of these listed chemicals.



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PITA Issues

- Foreign Entities (name & address)
 - Substance (trade name vs. controlled substance)
 - Base Weight (do the math!, include the C.F.)
 - Ports (first port into/last port from a country)
 - Return Information (missing in action)
 - Name & Contact # (signature + print your name)
-



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PITA Issues

- Reference Number (DEA-236 & DEA-486)
 - Cancel vs. Delete (there is a difference)
 - National Drug Code ([Go Blue!](#))
 - [Air Waybills \(PDFs only\)](#)
 - [Estimates & Assessments \(check INBC website\)](#)
 - [Derivatives and weird substances \(ODE not ODG\)](#)
-



INCB Estimates

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

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EstMar16 - EstMar16.pdf

https://www.incb.org/documents/Narcotic-Drugs/Status-of-Estimates/2016/EstMar16.pdf

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ESTIMATED WORLD REQUIREMENTS OF NARCOTIC DRUGS IN GRAMS FOR 2016 (March update)

Morphine	78	Thebaine	28 196 435
Oxycodone	243	Tilidine	525
Pethidine	135	United Republic of Tanzania	
Tuvalu		Codeine	30 000
Codeine	60	Etorphine	20
Fentanyl	1	Fentanyl	20
Morphine	76	Methadone	120 000
Pethidine	40	Morphine	30 000
Uganda*		Pethidine	50 000
Codeine	117 600	Pholcodine	2 000
Etorphine	2	United States of America	
Fentanyl	18	3-Methylfentanyl	2
Morphine	97 000	3-Methylthiofentanyl	2
Pethidine	50 000	Acetylmethadol	2
Remifentanyl	1	Alfentanil	17 750
Ukraine		Allylprodine	2
Codeine	1 572 769	Alphacetylmethadol	2
Fentanyl	876	Alphameprodine	2
Methadone	701 805	Alphamethadol	2
Morphine	196 227	Alphaprodine	3
Thebaine	145	Betacetylmethadol	2
Trimeperidine	67 276	Betameprodine	2
United Arab Emirates		Betamethadol	4
Alfentanil	16	Betaprodine	2
Codeine	252 000	Cannabis	200 000
Diphenoxylate	500	Cannabis resin	100
Etorphine	15	Coca leaf	175 000 000
Fentanyl	900	Cocaine	100 000
Hydrocodone	250	Codeine	65 000 000
Hydromorphone	250	Conc. of poppy straw	
Methadone	200	ACA	34 609 317
Morphine	7 000	AMA	118 428 423
Oxycodone	700	AOA	51 480 394
Pethidine	15 000	ATA	207 344 128
Remifentanyl	750	Dextropropoxyphene	45
Sufentanil	2	Difenoxin	11 000
United Kingdom		Dihydrocodeine	40 000



INCB Assessments

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Office of Diversion Control, Regulatory Section

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Status of assessments (N)Afghanistan - 3_Assessme... +

https://www.incb.org/documents/Psychotropics/assessment/3_Assessments_Updated_31_March_2016.pdf

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PSYCHOTROPICS ASSESSMENTS IN GRAMS AS AT 31 MARCH 2016

<i>Substance</i>	<i>Grams</i>	<i>Substance</i>	<i>Grams</i>
Loprazolam	1 364	Phenobarbital	500 000
Lorazepam	56 880	<u>United States of America</u>	
Lormetazepam	506	2C-B	25
Mazindol	1	Allobarbitol	2
MDPV	2	Alprazolam	6 487 000
Mephedrone	2	Amfepramone	880 000
Meprobamate	1	Amphetamine	21 875 000
Metamphetamine	100	Aminorex	25
Metamphetamine racemate	6	Amobarbital	25 125
Methylone	2	Barbital	1 139 000
Methylphenidate	777 659	Benzphetamine	624 000
Midazolam	105 664	Bromazepam	4
BZP	2	Brotizolam	2
Nitrazepam	75 323	Buprenorphine	6 458 000
Nordazepam	25	Butalbital	45 421 000
Oxazepam	66 735	Butobarbital	94 000



Derivatives and Weird Substances

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

ODGI will no longer obtain a Controlled Substance Status Determination on behalf of registrants.

Registrants must obtain these from the Drug & Chemical Evaluation Section (ODE)

To DEA: Letter and chemical structure to ODE@usdoj.gov requesting DEA drug code and conversion factor

From DEA: Controlled Substance Status Determination

Submit this status with your DEA-357, DEA-161, or DEA-236.



Alphabet Bouillabaisse ... What?!?!

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DEA . . . CATAIR . . . AESTIR . . . CBP



AESTIR (Appendix Q) for Exports

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Office of Diversion Control, Regulatory Section

DEA form information necessary for
Customs & Border Protection (CBP) for U.S. exports
of controlled substances and listed chemicals:

DEA Permit or Transaction Number
Transaction Type (E)
DEA Registration or Company ID Number
DEA Drug Code*
Quantity* (Base Weight)
Unit of Measure* (KG, G, MG, MCG)

* Multiple occurring



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Resources - Controlled Subst... x +

www.deadiversion.usdoj.gov/schedules/index.html

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION

OFFICE OF DIVERSION CONTROL

HOME REGISTRATION REPORTING RESOURCES ABOUT US

RESOURCES > Controlled Substance Schedules

Controlled Substance Schedules

[List of Controlled Substances](#)
[Exempted Lists](#)

List of Controlled Substances

[Disclaimer](#)
[Abbreviations](#)
[Definition of Controlled Substance Schedules](#)

[Lists of Scheduling Actions, Controlled Substances, Regulated Chemicals \(PDF\)](#) (February 2016)
This document is a general reference and not a comprehensive list. This list describes the basic or parent chemical and does not describe the salts, isomers and salts of isomers, esters, ethers and derivatives which may also be controlled substances.

Scheduling Actions	Controlled Substances	List I and II Regulated Chemicals
Alphabetical Order	Alphabetical Order	Alphabetical Order
Chronological Order	DEA Drug Code Number	DEA Number
	CSA Schedule	List Number
		Illicit Uses and Threshold Quantities

Exempted Lists

View New Web Browser Security Requirements

- Cases Against Doctors
- Chemical Control Program
- CMEA (Combat Meth Epidemic Act)
- Controlled Substance Schedules
- DATA Waived Physicians
- Drug Disposal Information
- Drug and Chemical Information
- E-commerce Initiatives
- Federal Agencies & Related Links
- Federal Register Notices
- National Take-Back Initiative
- NFLIS
- Publications & Manuals
- Questions & Answers
- Significant Guidance Documents
- Synthetic Drugs
- Title 21 Code of Federal Regulations



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Questions?

concerning this material and
material not covered
