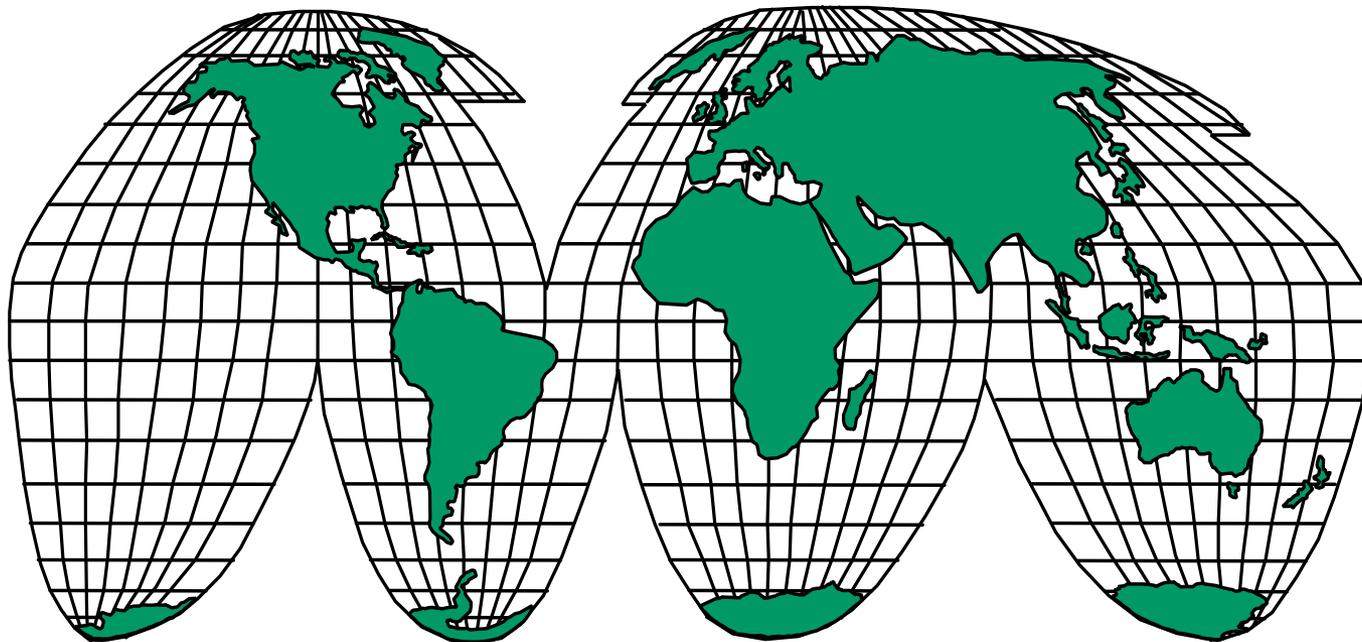




IMPORT/EXPORT UNIT

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

Drug Enforcement Administration Import/Export Pharmaceutical Training Seminar May 2017





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					✓	



Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

DEA-357 Form

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 (DEA Form 35)

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.



Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

DEA-161 Form

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 (DEA Form 36)

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



Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

DEA-161R Form

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 (DEA Form 36)

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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Discrepancies

- 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)
-



Discrepancies (cont.)

Drug Enforcement Administration
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- 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)
-



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.



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	<u>United Republic of Tanzania</u>	
<u>Tuvalu</u>		Codeine	30 000
Codeine	60	Etorphine	20
Fentanyl	1	Fentanyl	20
Morphine	76	Methadone	120 000
Pethidine	40	Morphine	30 000
<u>Uganda*</u>		Pethidine	50 000
Codeine	117 600	Pholcodine	2 000
Etorphine	2	<u>United States of America</u>	
Fentanyl	18	3-Methylfentanyl	2
Morphine	97 000	3-Methylthiofentanyl	2
Pethidine	50 000	Acetylmethadol	2
Remifentanil	1	Alfentanil	17 750
<u>Ukraine</u>		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
<u>United Arab Emirates</u>		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
Remifentanil	750	Dextropropoxyphene	45
Sufentanil	2	Difenoxin	11 000
<u>United Kingdom</u>		Dihydrocodeine	40 000



INCB Assessments

Drug Enforcement Administration
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



Websites

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

Important Websites

- www.incb.org/incb/en/narcotic-drugs-estimates.html
- www.incb.org/incb/en/psycotropic-substances/status-of-assesments.html
- <https://www.dea diversion.usdoj.gov>



Import/Export Point of Contacts

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

Exports/161-161R

Beth Fox (202)307-722 - beth.a.fox@usdoj.gov

Barbara Clacks (202)-353-1080 - barbara.a.clacks@usdoj.gov

Aaronita Perry (202)307-8624 - aaronita.v.perry@usdoj.gov

Imports/357

Dawin Cruz (202)307-5240 - dawin.cruz.gonzalez@usdoj.gov

Lisa Edelen (202)307-7285 - lisa.a.edelen@usdoj.gov

Import/Exports 236

Kara Sweeny (202)307-4989 - kara.a.sweeney@usdoj.gov

Sally Brown (202)307-4881 - sally.brown3@usdoj.gov

Import/Exports 486-486A

Carmencita Hamer (202)307-0545 - carmencita.a.humer@usdoj.gov

Betty Vinny (202) 307-7181 - betty.j.veney@usdoj.gov

Harry McFadden (202) 307-4761 - harry.l.mcfadden@usdoj.gov



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Questions?
