Supply Chain Conference Houston, Texas



Imports & Exports

The Laws and Regulations relating to U.S. Imports and Exports

- Title 21 § 951 Definitions
- Title 21 § 952 Importation of controlled substances
- Title 21 § 953 Exportation of controlled substances

 21 CFR § 1312 - Importation and Exportation of controlled substances



Imports & Exports

	DEA 257	DEA 4C4	DEA Fo	orm-236	DEA For	m-486/A
	DEA-331	DEA-357 DEA-161	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						
EPH, PSE, & PPA						



DEA-161

<u>Purpose:</u> The "Application for Permit to Export Controlled Substances" is for any controlled substance in schedule I or II, or any narcotic controlled substance III or IV

To DEA: DEA-161, the foreign import permit or Letter of No Objection (LONO) from the Competent National Authority, and necessary supporting documents for the export

From DEA: DEA 36 (DEA Permit to Export)



DEA-357

Purpose: The "Application for Permit to Import Controlled Substances" is for any controlled substance in schedule I or II, or any narcotic controlled substance III, IV, or V

To DEA: DEA-357, and necessary supporting documents for the import

From DEA: DEA 35 (DEA Permit to Import)



DEA-236 (for Imports & Exports)

Purpose: The "Controlled Substances Import/Export Declaration" is for non-narcotic drugs schedule III, IV, or V (imports) and non-narcotic drugs in schedule III or IV or any controlled substances in schedule V (exports)

To DEA: DEA-236; the foreign Import Permit or Letter of No Objection from the Competent National Authority (for exports); and necessary supporting documents

From DEA: Transaction ID





What's New

U.S. DEPARTMENT OF JUSTICE * DRUG ENFORCEMENT ADMINISTRATION

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Attention Registrants: DATA-Waived Registration Update

REGISTRATION RESOURCES ABOUT US REPORTING ARCOS Registration Support **9 Information Page** Call: 1-800-882-9539 (8:30 am-5:50 pm ET) **BCM Online** Email: DEA.Registration.Help@dea.gov WARNING: **Contact Local Registration Specialist** Chemical Import/Export Declarations Renewal Applications Extortion Scam by **New Applications CSOS (Controlled Substances** Check the Status of My Application **DEA Special Agent** Ordering System) **Registrant Validation Toolset** Theft/Loss Reporting Request Copy of DEA Certificate Impersonators Request Copy of Last Application/Receipt Import/Export Make Changes to My DEA Registration Order Form Request (DEA Form 222) **Medical Missions** Registration for Disposal of Controlled Substances Search for Year Round Pharmaceutical Disposal Locations Registrant Record of Controlled Substances Destroyed In The News Get Email U DEA Forms & Publications Regulated Machines (Tableting **Applications** and Encapsulating) & Manuals Former Nurse Sentenced for Stealing Opioids from Kansas H Reports Required by 21 CFR Defendants Convicted and Sentenced in Long-Term Metham Oxycodone Drug Trafficking Investigation in Bay County (M Ouestions & Meetinas & Greenwood Village Psychiatrist Pleads Guilty to Illegal Distr Controlled Substances and Financial Crimes (March 09, 2023 Answers Events Submit a Tip to DEA Indiana Man Sentenced to 5 Years' Probation for Obtaining Substance by Deception (March 08, 2023) Year-End Reports Laurence Doud, Former CEO of Pharmaceutical Distributor, Quick Links Months in Prison for Conspiring to Unlawfully Distribute Controlled Substances and Defrauding the DEA (March 08, 2023) ARCOS (Automation of Reports & Consolidated Orders System) DOJ and Lincoln Pharmacy in Tacoma Settle Allegations the Pharmacy Failed to Follow the Controlled Substances Act (February 28, 2023) **Chemical Control Program**

Controlled Substance Schedules

CSOS (Controlled Substances Ordering System)

EPCS (Electronic Prescriptions for Controlled Substances)





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HOME REGISTRATION REPORTING RESOURCES ABOUT US

REPORTING > Reports Required by 21 CFR > Import/Export Permit Applications and Declarations

Import/Export Permit Applications and Declarations

Only those persons registered with and authorized by DEA to import or export controlled substances may utilize/submit declarations and applications for permits.

Import/Export Online

DEA Form 161 - Application for Permit to Export Controlled Substances

DEA Form 236 - Controlled Substances Import/Export Declaration

DEA Form 357 - Application for Permit to Import Controlled Substances for Domestic and/or Scientific Purposes

DEA Form 453 - Notification of Domestic Transactions Involving Listed Chemicals (Coming Soon)

Import/Export PDF Format

DEA Form 161 - Application for Permit to Export Controlled Substances

DEA Form 161R - Application for Permit to Export Controlled Substances for Subsequent Reexport

DEA Form 236 - Controlled Substances Import/Export Declaration

DEA Form 357 - Application for Permit to Import Controlled Substances for Domestic and/or Scientific

Assistance and Support with Medical Missions

References

Quick Reference Guide for Importers/Exporters of Controlled Substances

This is a detailed guide to filling out DEA Forms 357, 161, and 236:

Conversion Factors for Controlled Substances

An alphabetical listing of many Schedules I-V controlled substances as listed in Title 21 Codes of Federal Regulations, and their corresponding DEA code numbers and conversion factors.

Get Email Updates:

ARCOS BCM Online

Chemical Import/Export Declarations

CSOS (Controlled Substances Ordering System)

Theft/Loss Reporting

Import/Export

Medical Missions

Quotas

Registrant Record of Controlled Substances Destroyed

Regulated Machines (Tableting and Encapsulating)

Reports Required by 21 CFR

SORS

Submit a Tip to DEA

Year-End Reports





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Import/Export



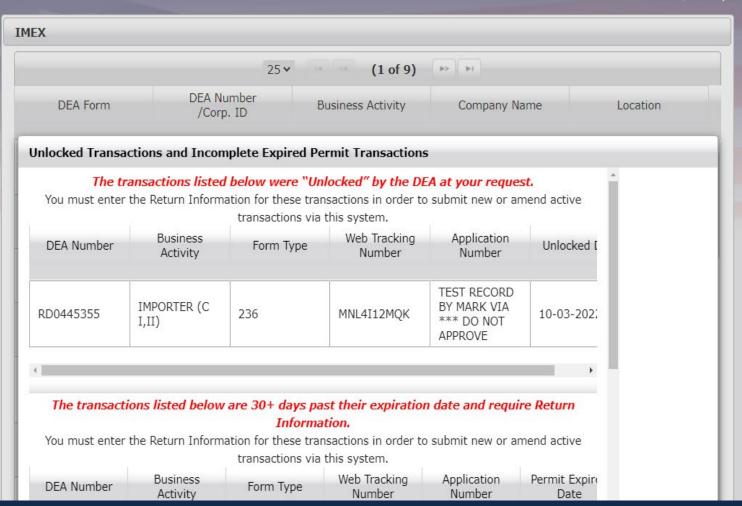




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APPLICATION FOR PERMIT TO EXPORT CONTROLLED SUBSTANCES (DEA FORM 161)

* Back

DEA Registration Number:

Business Activity:

Company Name:

Street Address:

RD0445379

EXPORTER

DEA-DRGI-TEST

600 ARMY NAVY DR

City: ARLINGTON
State: VA
Postal Code: 22202

Create New DEA Form 161 Query & Print DEA Form 161 / Permit Form 36

Create Amendments Enter Return Information or Cancel Transactions Update Permit

Delete Transactions





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Welcome, DEACorpAdmin | Langua

APPLICATION FOR PERMIT TO EXPORT CONTROLLED SUBSTANCES (DEA FORM 161) Back Next Cancel No person shall export a controlled substance listed in Schedule I or II or any narcotic controlled substance in Schedule III or IV unless and until such person is properly registered under the Act and the Administrator has issued an export permit to do so. See 21 CFR § 1312.21 (a)

A Registrant must furnish an application for an export permit (DEA Form 161) to the Import/Export Unit, Drug Enforcement Administration, prior to the exportation. See 21 CFR § 1312.22 (a)

Please upload a PDF image of the Foreign Authorization (Permit or Letter of No Objection) and Statement of No Re-Export if this is not stated on the Authorization. A maximum of 5 PDF files can be uploaded.





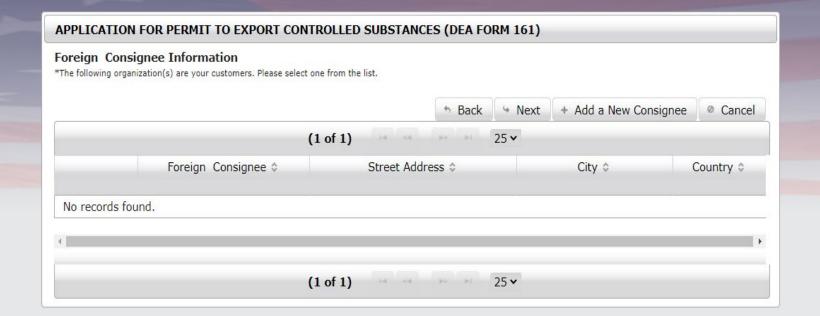


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Add A Foreign Consignee

* indicates required fields

Company Name*
Address 1*

Address 2

City* PARIS

Country* FRANCE

Postal Code

ABC-1234

ABC-1234

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Add Controlled Substan	ces		ANCES (DEA FORM 161)			
		stances for each	submission at this time.			
				□ Clear	5 Back	Next © Cance
	Controlled Subst	ance Informatio	n Expected Quantity*	Container Type/	Unit of Measu	ıre*
Controlled Substance*	Select One	•		Select One	¥	
Product Name*				Select One	*	/
Salt Type*	Select One			Select One	•	1
Formulation	Raw Material	O Preparation		Select One	•	/
NDC Number*	-	-		Validate NDC		Search NDCs
INCB			Conversion Factor			%
<i>2</i>					+ Add C	ontrolled Substance
		Controll	ed Substances To Export			
Controlled	d Substance	Drug Code	Product Name	Net Wt(Gram)	Base Wt(Gram)	Product Package Details



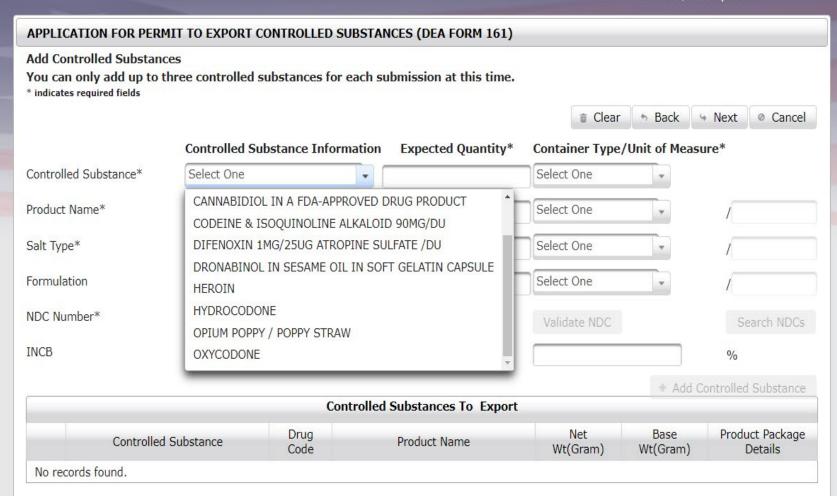


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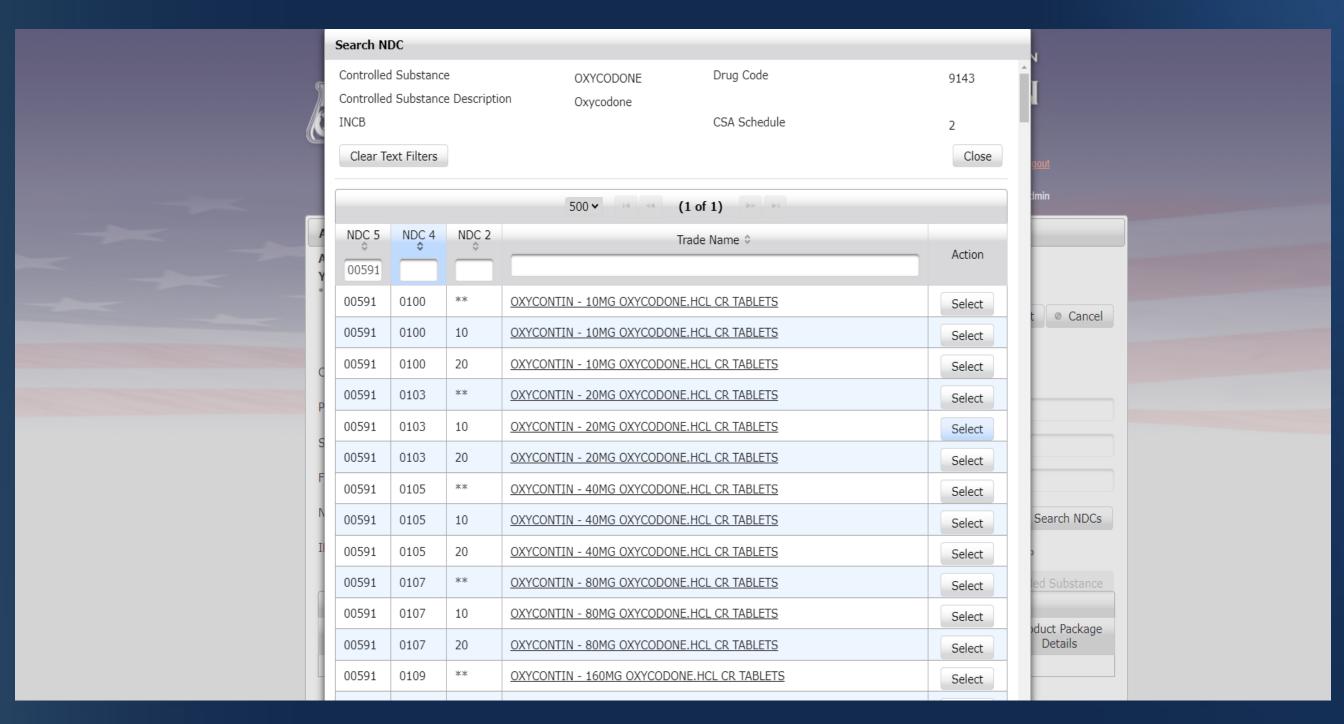
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Add Controlled Substan		batawana fan aash	aubusianian at this time			
* indicates required fields	three controlled Su	DStances for each	submission at this time.			
				⊕ Clear	5 Back	Next Ø Cancel
	Controlled Sub	stance Informatio	on Expected Quantity*	Container Type/	Unit of Measu	ıre*
Controlled Substance*	OXYCODONE	*		Select One	*	
Product Name*				Select One	*	/
Salt Type*	Select One	•		Select One	*	1
Formulation	Select One BASE	Preparation		Select One	*	Í
NDC Number*	HCL]-		Validate NDC		Search NDCs
INCB	HCL (1 H2O)	_	Conversion Factor			%
-		1240 AD VIII AN -			+ Add C	ontrolled Substance
		Controll	ed Substances To Export			
Controlled	d Substance	Drug Code	Product Name	Net Wt(Gram)	Base Wt(Gram)	Product Package Details









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APPLICATION FOR PERMIT TO EXPORT CONTROLLED SUBSTANCES (DEA FORM 161)							
Add Controlled Substance You can only add up to the indicates required fields	ces three controlled substances for each	submission at this time.					
			⊕ Clear	Next © Cancel			
	Controlled Substance Information	Expected Quantity*	Container Type/Unit of Measure*	f			
Controlled Substance*	OXYCODONE	1000	BOTTLE(S)				
Product Name*	OXYCONTIN - 20MG OXYCODONE.H	1 50	TABLET(S)	BOTTLE(S)			
Salt Type*	HCL	20	MG	TABLET(S)			
Formulation	O Raw Material Preparation		Select One	MG			
NDC Number*	00591 - 0103 - 10	OXYCONTIN - 20MG OXYCODONE.HCL CR TABLETS	Validate NDC	Search NDCs			
INCB	NARCOTIC	Conversion Factor	90.0	%			
			+ Add Cor	ntrolled Substance			
	Controll	ed Substances To Export					
Controlled	Substance Drug	Product Name	Net Base	Product Package			





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APPLICATION FOR PERM	MIT TO EXPORT CONTROLLED	SUBSTANCES (DEA FORM 161)		
Add Controlled Substand You can only add up to t * indicates required fields	797)	or each submission at this time	е.		
				5 Back	• Next Ø Cancel
	Controlled Substance Inf	ormation Expected Quantity	* Container Type/	Unit of Meas	ure*
Controlled Substance*	Select One	- T	Select One	*	
Product Name*			Select One	*	I
Salt Type*	Select One		Select One	•	1
Formulation	Raw Material Prep	paration	Select One	·	1
NDC Number*			Validate NDC		Search NDCs
INCB		Conversion Factor			%
				+ Add 0	Controlled Substance
	· ·	Controlled Substances To Expo	ort		
Controlled	Substance Drug Code	Product Name	Net Wt(Gram)	Base Wt(Gram)	Product Package Details
EDIT: OXYCODO	ONE 9143.000	OXYCONTIN - 20MG OXYCODONE.HCL CR TABLETS	1000.000	900	1,000 BOTTLES; 50 TABLETS; 20 MILLIGRAMS





DIVERSION CONTROL DIVISION

		Welcome Welcome, DEACorpAdmin
		Welcome, DE Coup Aumin
APPLICATION FOR PERMIT TO EX	PORT CONTROLLED SUBSTANCES (DEA FORM 161)	
Add Shipment Information * indicates required fields		
		Back
Port of Exportation	Port of Importation	
Port Name*	Port Name*	
ALEXANDRIA^ VIRGINIA	PARIS^ FRANCE	*
Export Date*		
04/14/2023		
Transport Information		
Mode of Transport*		
SEA -		
Name of Vessel/Carrier Name		
Name of Vessel/Carrier Name GOOD SHIP LOLLIPOP		
GOOD SHIP LOLLIPOP Documentation Information	TO DEFEDENCE IT TO VOLID DATA	
GOOD SHIP LOLLIPOP	TO REFERENCE IT TO YOUR DATA	
GOOD SHIP LOLLIPOP Documentation Information Exporter's Application No	TO REFERENCE IT TO YOUR DATA I/2023/03/1234	
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APPLICATION FOR PERMIT TO EXPORT CONTROLLED SUBSTANCES (DEA FORM 161) *Please confirm all information before submitting this declaration. To make changes, click on the corresponding header label. **Exporter** Edit Foreign Consignee DEA-DRGI-TEST THE TOM THUMB COMPANY 600 ARMY NAVY DR 600 STRAIT ST ARLINGTON, VA 22202 PARIS, FRANCE ABC-1234 DEA Number: RD0445379 Edit Controlled Substances To Export Controlled Net Wt Drug Base Wt Product Name **Product Package Details** Substance Code (Gram) (Gram) OXYCONTIN - 20MG OXYCODONE.HCL 1,000 BOTTLES; 50 TABLETS; 20 1000.000 OXYCODONE 900 CR TABLETS MILLIGRAMS Edit Port of Exportation Edit Port of Importation Port Name: ALEXANDRIA VIRGINIA Port Name: PARIS FRANCE Date: 04/14/2023 Edit Transport Information Edit Documentation Information Exporter's Application No: TO REFERENCE IT TO YOUR DATA Mode of Transport: SEA Foreign Permit No: I/2023/03/1234 Name of Vessel/Carrier Name: GOOD SHIP LOLLIPOP Issue Date: 03/01/2023 Expiration Date: 05/31/2023 Certification I certify the controlled substances listed herein are necessary and intended for medical or scientific needs in the country of import and will not be re-exported therefrom; and the information I'm providing to the Drug Enforcement Administration is, to the best of my knowledge and belief, complete and accurate. The packages to be exported are labeled in conformance with 21 C.F.R. Part 302 and, to the best of my knowledge and belief, the importing country has instituted and maintains a system for the control of these substances; the drugs are consigned to a holder of such permits or licenses as may be required under the laws of the country of import; the substances are to be applied exclusively to medical or scientific uses within the country of import; there is an actual need for the controlled substances for medical or scientific uses within such country; the substances will not be re-exported therefrom; except, in the case of bulk cocaine alkaloid, the substance will be processed within the country of import and the products therefrom may be re-exported in accordance with Paragraph 2, Article 31 of the Single Convention on Narcotic Drugs, 1961. **Authorized Individual** Name of Firm and Telephone Number **Submit Date**

03/29/2023

MARK VIA

DEA-DRGI-TEST





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APPLICATION FOR PERMIT TO EXPORT CONTROLLED SUBSTANCES (DEA FORM 161)

The DEA Form information you submitted has been sent to the Drug Enforcement Administration. The Drug Enforcement Administration will provide a Transaction ID after the information has been reviewed.

In the meantime, please take a note of this web tracking number CB9K9CJWRY.

Download Submitted Form PDF





APPLICATION FOR PERMIT TO EXPORT CONTROLLED SUBSTANCES (DEA FORM 161)

DEA Registration Number:

Business Activity:

Company Name:

Street Address:

RD0445379

EXPORTER

DEA-DRGI-TEST

600 ARMY NAVY DR

City: ARLINGTON

State: VA
Postal Code: 22202

Create New DEA Form 161 Query & Print DEA Form 161 / Permit Form 36

Create Amendments Enter Return Information or Cancel Transactions Update Permit

* Back

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Delete Transactions



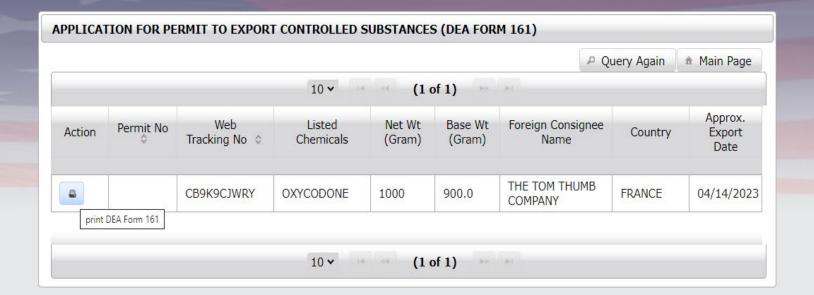


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Imports & Exports

The Import and Export Section (DRI) requires some forms to be e-mailed for the following situations:

- No standard conversion to base*
- Schedule V substances without an official drug code
- Amphetamine Combination Salts Drug Products
- Re-exports within and outside of the EEA



No Standard Conversion Factor

Memorandum



Control Status of 2-(5-methoxy-1H-indol-3-yl)-N,N-bis(methyl-d3)ethan-1-amine-1,1,2,2-d4 fumarate

Date

December 20, 2022

To

Aziz Elkholy, Chief Import/Export Section Diversion Control Division From 728

Terrence L. Boos, Ph.D., Chief Drug and Chemical Evaluation Section Diversion Control Division

This memo is in response to a request from DRI on November 16, 2022, to evaluate the control status and calculate a conversion factor for 2-(5-methoxy-1*H*-indol-3-yl)-*N*,*N*-bis(methyl-*d*₃)ethan-1-amine-1,1,2,2-*d*₄ fumarate (5-MeO-DMT-*d*₁₀ fumarate). DOE conducted a scientific analysis of the chemical structure of this substance in accordance with the definitions within the Controlled Substances Act (CSA) and its implementing regulations. Based on this review, DOE determined that 5-MeO-DMT-*d*₁₀ fumarate is a schedule I controlled substance under the CSA.

Title 21 of the Code of Federal Regulations (CFR) § 1308.11(d)(15) controls 5-MeO-DMT and its salts, isomers, and salts of isomers in schedule I. The CSA does not distinguish isotopically labeled compounds, and deuterated 5-MeO-DMT is treated the same as 5-MeO-DMT. 5-MeO-DMT- d_{10} fumarate is assigned the Controlled Substances Code Number (CSCN) 7431, which is that of 5-MeO-DMT. The conversion factor (CF) for 5-MeO-DMT- d_{10} fumarate to 5-MeO-DMT base is 0.6338.

The chemical structure used to make this determination is shown below.

2-(5-methoxy-1*H*-indol-3-yl)-*N*,*N*-bis(methyl-*d*₃)ethan-1-amine-1,1,2,2-*d*₄ fumarate schedule I CSCN: 7431 CF: 0.6338



Schedule V substances

		CSA		
SUBSTANCE	CSCN	SCH	NARC	OTHER NAMES
Remimazolam (4H-imidazol[1,2-a][1,4]benzodiazepine- 4-propionic acid)	2846	IV	7	8-bromo-1-methyl-6-(2-pyridinyl)-(4S)-methyl ester, benzenesulfonate (1:1) and also, methyl 3-[(4S)-8-bromo- 1-methyl-6-pyridin-2-yl-4H-imidazo[1,2- a][1,4]benzodiazepin- 4yl]propanoate benzenesulfonic acid
Serdexmethylphenidate	1729	IV	N	
Sibutramine	1675	IV	N	Meridia
Solriamfetol (2-amino-3-phenylpropyl car-bamate; benzenepropanol, beta-amino-, carbamate (ester))	1650	IV	N	
SPA	1635	IV	N	1-dimethylamino-1,2-diphenylethane, Lefetamine
Suvorexant	2223	IV	N	MK-4305, [(7R)-4-(5-chloro-1,3-benzoxazol-2-yl)-7-methyl 1,4-diazepan-1-yl][5-methyl-2-(2H-1,2,3-triazol-2-yl)phenyl]methanone
Temazepam	2925	IV	N	Restoril
Tetrazepam	2886	IV	N	Myolastan, Musaril
Tramadol (2-[(dimethylamino)methyl]-1-(3- methoxyphenyl)cyclohexanol)	9752	IV	Y	Tramadol
Triazolam	2887	IV	N	Halcion
Zaleplon	2781	IV	N	Sonata
Zolpidem	2783	IV	N	Ambien, Ivadal, Stilnoct, Stilnox
Zopiclone	2784	IV	N	Lunesta
Brivaracetam	2710	~	N	BRV, UCB-34714, Briviact, ((2S)-2-[(4R)-2-oxo-4- propylpyrrolidin-1-yl] butanamide)
Cenobamate [(1R)-1-(2-chlorophenyl)-2-(tetrazol-2- yl)ethyl]carbamate	2720	~	N	2H-tetrazole-2-ethanol, alpha-(2-chlorophenyl)-, carbamate (ester), (alphaR)-; carbamic acid (R)-(+)-1-(2-chlorophenyl)-2-(2H-tetrazol-2-yl)ethyl ester)
Codeine preparations - 200 mg/(100 ml or 100 gm)		V	Y	Cosanyl,Robitussin A-C,Cheracol,Cerose,Pediacof
Difenoxin preparations - 0.5 mg/25 ug AtSO4/du		V	Y	Motofen
Dihydrocodeine preparations 100mg/(100 ml or 100 gm)		~	Y	Cophene-S, various others
Diphenoxylate preparations 2.5 mg/25 ug AtSO4		V	Y	Lomotil, Logen
Ethylmorphine preparations 100 mg/(100 ml or 100 gm)		~	~	
Ezogabine	2779	v	N	Potiga
Ganaxolone (3α-hydroxy-3β-methyl-5α-pregnan-20-one)	2401	V	N	
Lacosamide	2746	V	N	Vimpat
Lasmiditan [2,4,6-trifluoro-N-(6-(1-methylpiperidine-4- carbonyl)pyridine-2-yl-benzamide]	2790	~	N	Reyvow
Opium preparations - 100 mg/(100 ml or 100 gm)		V	Y	Parepectolin, Kapectolin PG, Kaolin Pectin P.G.
Pregabalin	2782	V	N	Lyrica
Pyrovalerone	1485	v	N	Centroton, Thymergix



Amphetamine Combination Salts

Amfetamine	Acetylsalicylate		42.9
	Adipate		48.1
	Aspartate		50.4
	Aspartate monohydrate	851591-76-9	64.2
	Bitartrate		47.0
	Hydrochloride	27-06-50-5	79.2
	Para-aminophencylacetate		47.2
	Parachlorophenoxyacetate		42.0
	Pentobarbiturate		37.4
	Phosphate (1 mol. base)	139-10-6	58.0
	Phosphate (2 mol. base)		73.4
	Resinate		_
	Sulfate (2 mol. base)	60-10-6	73.4
	Tannate		29.6
	Tartrate (2 mol. base)		64.3



Amphetamine Combination Salts

Dexamfetamine	Adipate		48.1
	Carboxymethylcellulose		_
	Hydrochloride	1462-73-3	79.2
	Pentobarbiturate		37.4
	Phosphate (2 mol. base)		73.4
	Phosphate	7528-0-9	58.0
	Resinate		_
	Saccharate (monobasic)		39.1
	Sulfate (2 mol. base)	51-63-8	73.4
	Tannate		29.6
	Tartrate		47.4



Re-Exports

Controlled Substances Export Reform Act (2005)

- From the US to a 1st country; from the 1st country to one or more 2nd countries; No re-export from the 2nd countries
- The DEA-161-R is required; Information concerning the consignees of re-export must be provided to the DEA on the initial submission
- Re-exports from the 1st country to the 2nd must occur within 180-days after departure from the US



Re-Exports

Improving Regulatory Transparency for New Medical Therapies Act (2015)

- From the US to an EEA country; from the 1st EEA country to other EEA countries; unlimited re-export within the EEA; cannot re-export outside of the EEA
- The DEA-161-R application is required in lieu of a DEA-161-R-EEA; Use EEA Countries for re-export destination; Information concerning the consignees of re-export must be provided to the DEA with the Return Information



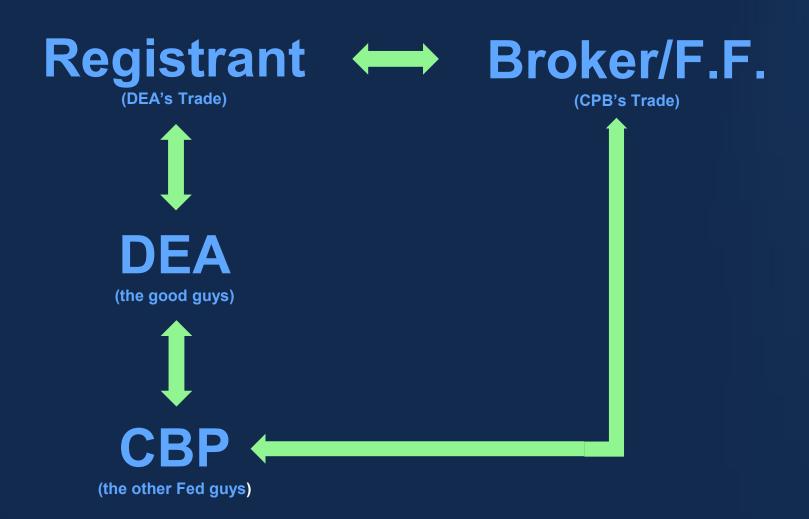
Re-Exports

Improving Regulatory Transparency for New Medical Therapies Act (2015)

- By law, there is no time limit for re-exports
- The 1st country must always be an EEA country
- The EEA includes EU countries and also Iceland, Liechtenstein, and Norway. Switzerland and the UK are not members of the EU or EEA



Imports & Exports





Imports & Exports

The crucial ITDS/ACE data:

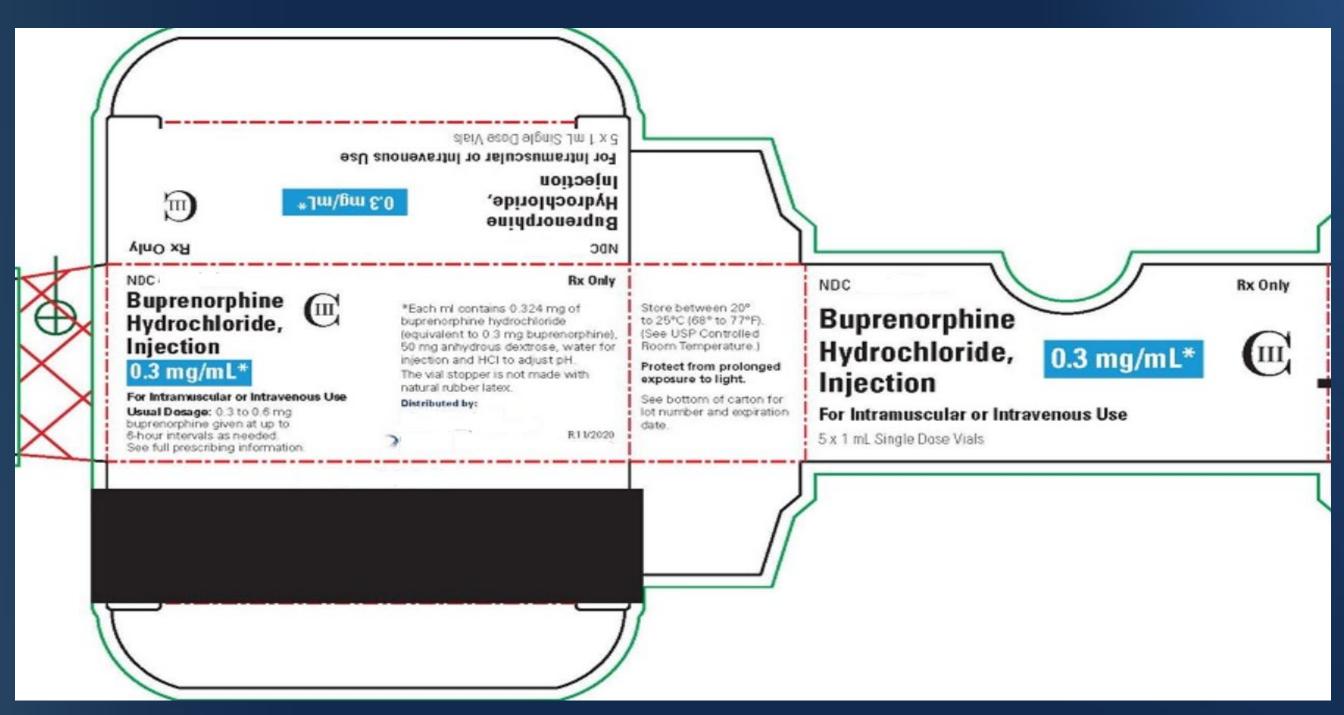
- DEA Registration #
- Permit #/Transaction ID #
- Drug Code
- Base Weight & Unit of Measure (UOM)



- Uploading a foreign import permit or LONO that is not issued by the Competent National Authority (CNA); i.e. the Central Bureau of Narcotics, not the CDSCO, is the CNA of India
- Incorrect use of base/salt relative to the NDC #
- Importing or Exporting on the same day the DEA authorized your application or declaration
- Providing Return Information prior to the shipment departing the US



Base/Salt Example





- DRI has to review each uploaded attachment. Please label PDF uploads (permit, LONO, etc.) and don't upload extraneous information
- Provide your reference number, permit #, tracking #, in the subject line of any e-mails you send to DRI
- Provide your DEA Registration # and your telephone number in your e-mail if you need DRI to resolve an issue
- The DEA approved my prior submission



- If you have an importer or exporter registration for controlled substances, that registration cannot be used to import or export Ephedrine,
 Pseudoephedrine, Phenylpropanolamine API or bulk finished dosage forms; Per the regulations, the dosage units must be in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act)
- Check the INCB Status of Estimates and Status of Assessments at www.INCB@org



If you submit an application or declaration and DRI
has approved it, and you later submit an amendment
to the original, then by regulation you must use the
amended DEA permit or declaration; the DEA permit
or declaration must accompany the shipment