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### **United Nations Drug Control Treaties**



The three International Drug Control
Treaties that shape DEA's implementation
of the US Controlled Substances Act.



Single Convention on Narcotic Drugs, 1961

Convention on Psychotropic Substances 1971

Convention Against Illicit Traffic in Narcotic Drugs 1988 The United States is a party to all three treaties

### **U.S. Controlled Substances Act (CSA)**



Establishes statutory
guidelines for chemicals
that are used to manufacture
controlled substances and
illicit drugs

Executes the international obligation with United Nations treaties



Provides a series of statutory requirements for substances with abuse potential creating a closed system

Establishes statutory requirements to register and monitor importers and exporters of controlled substances and chemicals

### **U.S. Controlled Substances Act (CSA)**



With respect to controlled substances and regulated chemicals DEA's responsibility is twofold:



- 1. To prevent diversion and abuse of these substances.
- 2. To insure an adequate and uninterrupted supply is available to meet the country's legitimate medical, scientific, and research needs.

# **U.S.** Controlled Substances Act (CSA)



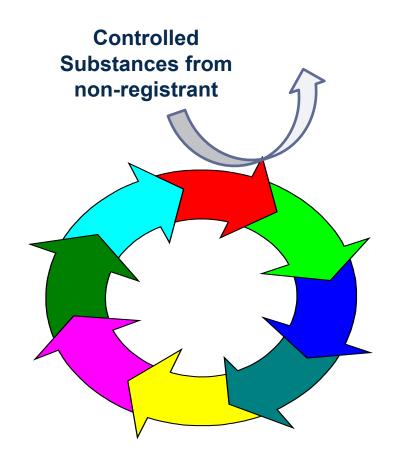
Under the framework of the CSA, all controlled substance transactions take place within a "closed system" of distribution established by Congress.

Within this closed system, all legitimate importers and exporters of controlled substances and regulated chemicals, must be registered with DEA and maintain strict accounting for all transactions.

## **DEA's Import and Export Registration System**



- □ Does not allow for controlled substances and chemicals to be brought into the closed system without proper vetting and registration.
- □ U.S. Importers and Exporters must be registered with the DEA to enter the system.



### **DEA's Import and Export Registration System**





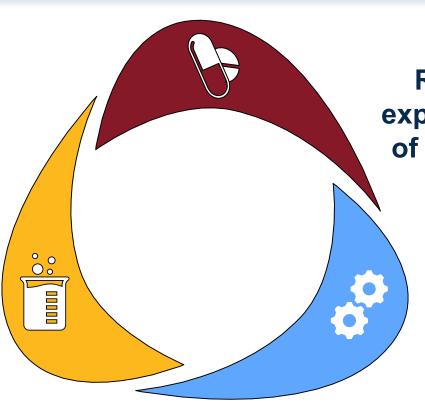


### **Code of Federal Regulations**



### 21 CFR § 1313

Regulates the import, export, and transshipment of listed chemicals



### 21 CFR § 1312

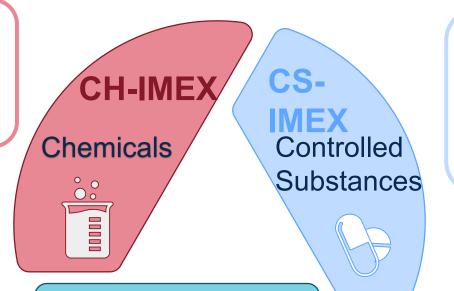
Regulates the import, export, and transshipment of controlled substances

21 CFR § 1310

Regulates the records/reports and importation/exportation of tableting and encapsulating machines



Chemical IMEX
Imports and exports of
chemicals for DEA Forms
486 and 486A records



Controlled Substances IMEX
Imports and exports of
controlled substances for DEA
Forms 161, 236 and 357
records

Regulated Machines
Imports, exports
and domestic transfers of
tableting and encapsulating
for DEA Form 452 records



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Watching recorded presentation?
Email questions to DOI@DEA.GOV





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## **Code of Federal Regulations**



§ 1312.22 Application for export or re-export permit; return information.

§ 1312.23 Issuance of Export Permit.

§ 1312.24 Distribution of Export Permit.



# Controlled Substances Import & Export Form Guide



	Per	mits	Declarations			
Schedules I-V	DEA-357	DEA-161	DEA Form-236			
<u>odnodalos I V</u>	(Imports)	(Exports)	Imports	Exports		
Schedule I and II						
Schedule III Narcotic						
Schedule III Non-Narcotic (7369 requires a PERMIT)			>			
Schedule IV Narcotic			>			
Schedule IV Non-Narcotic				<b>/</b>		
Schedule V Narcotic				<b>/</b>		
Schedule V Non-Narcotic			<b>/</b>	<b>/</b>		

# **Export Permit Application: Form 161**

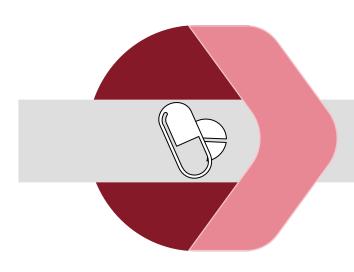


Initial exp	ort permi	t
DEA Fo	orm 161	

	ON FOR PE	ERMIT TO EXP CTION 1003(a)	PORT CONTROLI (b), (c) & (d), Ti and Privacy Act Informat	LED SUI	
To: Drug Enforcement Administration Office of Diversion Control Import / Export Unit (ODG) 8701 Morrissette Drive, Springfield, VA 22152			DATE		
		EXPORTER'S APPLICATION	NUMBER		
Application is hereby ma regulations prescribed the			e Controlled Substances	Import and	Export Act and the
1. NAME OF CONSIGNEE			2. ADDRESS OF CONSIGNER		
3. BUSINESS OF CONSIGNEE			4. FOREIGN PORT OF ENTR	Y (City & Count	in)
Sa. PORT OF EXPORTATION (City & U.S. Customs part)	State of last 5	5b. NAME OF EXPORTING (Air, Ship)	CARRIER OR VESSEL	5c. APPROX	DATE OF EXPORTATION
5. FOREIGN IMPORT LICENSE OR F	MERNIT NO		****	DATE:	EXPIRE DATE:
7a. NAME AND QUANTITY OF DRUG BE EXPORTED (fifter names numbers and stoke of packag- capsules, etc., CSA Drug Code, a	as shown on lab es; strength of table	etz: PREPARATION etz. base, or alkaloid	SUBSTANCE CONTENT OF DI TO BE EXPORTED expressed ((Chief name of controlled subside ((Chief name of controlled subside chief, compound, or preparation	as acid, ance	To DATE EXPORTED AND ACTUAL QUANTITY (Completed by registrant at time of export) DEA PERMIT NO.:
	start in another annual	with 21 C.F.R. Part 302 an	at the first board of the boards for	and belief, the	e importing country has instituted ar
maintains a system for the control of the import; the substances are to be applied medical or scientific uses within such of within the country of import and the pro-	nese substances; the fied exclusively to me country, the substance	drugs are consigned to a h edical or scientific uses wit is will not be re-exported th	older of such permits or license thin the country of import; there erefrom; except, in the case of t	is an actual n	need for the controlled substances fi saloid, the substance will be processed
The packages to be exported are lab maintains a system for the control of the import; the substances are to be appli- medical or scientific uses within such within the country of import and the pro NAME OF EXPORTER	nese substances; the fied exclusively to me country, the substance	drugs are consigned to a h edical or scientific uses wit is will not be re-exported th	older of such permits or license thin the country of import; there erefrom; except, in the case of t ice with Paragraph 2, Article 31	is an actual n	need for the controlled substances fi saloid, the substance will be processed
maintains a system for the control of the import; the substances are to be applied medical or scientific uses within such of within the country of import and the pro-	rese substances; the fied exclusively to me country; the substance solucts therefrom may	drugs are consigned to a h edical or scientific uses wit is will not be re-exported th	older of such permits or license thin the country of import; there erefrom; except, in the case of t ice with Paragraph 2, Article 31	is an áctual n sulk cocaine alk of the Single Co	seed for the controlled substances if saleid, the substance will be processe envention on Narcotic Drugs, 1961.
maintains a system for the cortext of tri inport, the substances are to be appreciated or scientific uses within such a within the country of import and the pri NAME OF EXPORTER  EXPORTER'S TELEPHONE NO.	rese substances; the find exclasively to me country; the substance oducts therefrom may EXPORTER'S DEA!	drugs are consigned to a he dictal or accientific uses will as will not be re-exported the be re-exported in accordant REGISTRATION NO.	older of such permits or leanuse thin the country of import; then erefrom; except, in the case of to ce with Paragraph 2, Article 31 ADDRESS OF EXPORTER	is an actual n suft cocains all of the Single Co	need for the controlled substances stabled, the substance will be process sometime on Narcotic Drugs, 1961. The process of the process of the process NG APPLICATION

### **DEA Form 161 and 161R (Reexport) Overview**





This form is to be used in notifying DEA of all EXPORTS of controlled substances in Schedule I & II; Narcotics in Schedule III & IV

**Purpose** 



### To DEA

Foreign Import Permit or Letter of No Objection (LONO), Certificate of No Objection (CNO) from the Competent National Authority



### From DEA

DEA Form 36 Export Permit

### DEA Form 161 and 161R (Reexport) Required Information



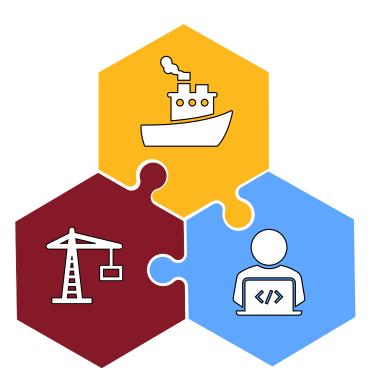
### **Import Export Product**

**US Exporter/Exporter Name** and Address

Foreign Importer/Exporter
Name and Address

Product name, packaging detail and strength

Foreign Import Permit or LONO from the Competent National Authority



### **Transportation**

Port of Importation/Exportation

**Mode of Transportation** 

Name of Vessel/Carrier

DEA

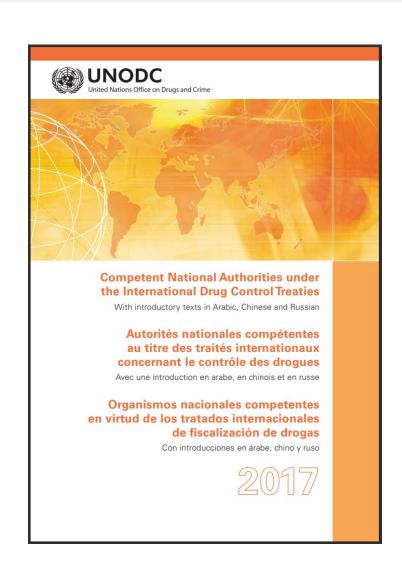
**Authorizing Individual** 

**DEA Registration Number** 

# DEA's Acceptance Criteria for International Permits and Declarations



- The DEA only accepts a foreign permit or Letter of No Objection (LONO) that is issued and signed by the Competent National Authorities for that country.
- The DEA follows the United Nations
  Office on Drugs and Crime.



# **English Language Requirement for Import Licenses** or Permits



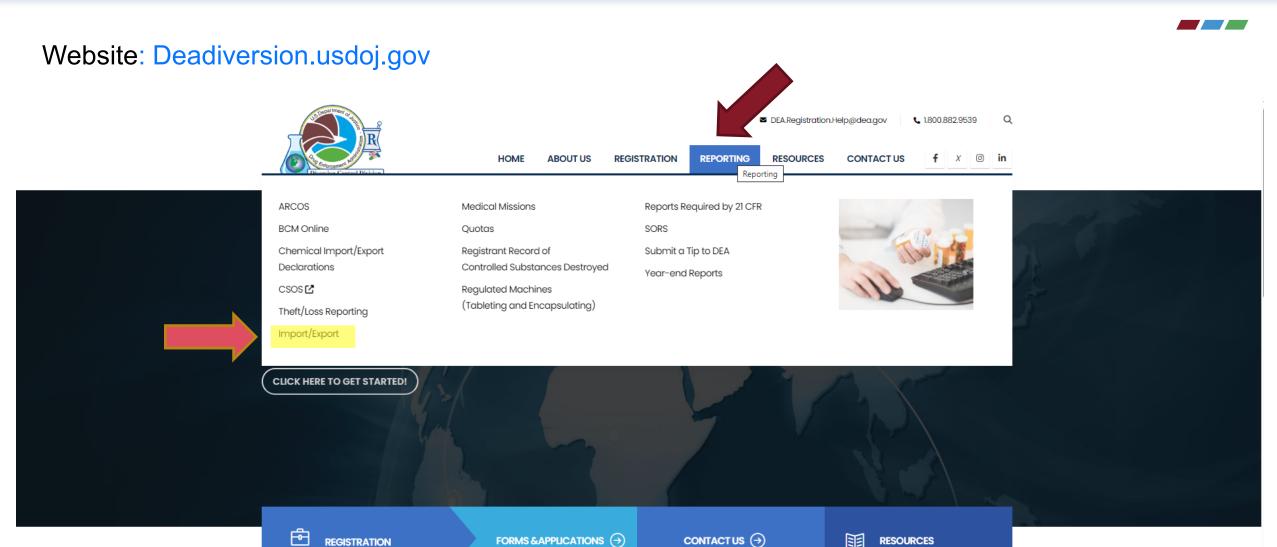
### § 1312.22 Application for export or reexport permit; return information.

(d)(1) Except as provided in paragraph (d)(2) of this section, the applicant must also submit with the application any import license or permit or a certified copy of any such license or permit issued by the competent national authority in the country of destination, or other documentary evidence deemed adequate by the Administration, showing: That the merchandise is consigned to an authorized permittee; that it is to be applied exclusively to medical or scientific use within the country of destination; that it will not be reexported from such country (unless the application is submitted for reexport in accordance with paragraphs (f), (g), and (h) of this section); and that there is an actual need for the controlled substance for medical or scientific use within such country or countries. If the import license or permit, or the certified copy of such, is not written in English or bilingual with another language and English, the registrant must also submit with their application a certified translation of the permit or license. For purposes of this requirement, certified translation means that the translator has signed the translation legally attesting the accuracy of the translation. (In the case of exportation of bulk coca leaf alkaloid, the applicant need only include with the application the material outlined in paragraph (c) of this section.)











### Import/Export Permit Applications and Declarations

HOME > REPORTING
> 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

#### 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 Purposes

**Assistance and Support with Medical Missions** 







To acquire a new IMEX login account, or have any other IMEX inquires, please submit your request or questions to our CSIMEX inbox at

CSIMEX@dea.gov.



# IMEX Demonstration for an Export Permit DEA Form 161



### **Code of Federal Regulations**



### § 1312.22(f) Reexports outside of the European Economic Area



### Permit Application Process: 161R (Reexport)



### Import/Export Permit Applications and Declarations

HOME > REPORTING
> IMPORT/EXPORT PERMIT APPLICATIONS AND
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DEA Form 236 - Controlled Substances Import/Export Declaration

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

**Assistance and Support with Medical Missions** 

### Permit Application Process: 161R (Reexport)



### DEA Form 161R

> IMPORT/EXPORT PERMIT APPLICATIONS AND

DECLARATIONS

> DEA FORM 161R

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

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

Instructions PDF

### INFORMATION AND INSTRUCTIONS, DEA FORM 161R

This application must be completed in triplicate. The original is sent to DEA HQs: Drug Enforcement Administration, Diversion Control Division, Import/Export Unit, 8701 Morrissette Drive, Springfield, VA 22152. See Instructions 5a and 9 for copies two and three.

# Permit Application Process: 161R Form (Reexport)



Print three copies of	f this form. Follow instructions for ap	opropriate use of each copy.				
	OME	3 APPROVAL NO. 1117-0004 2/28/2027				
U.S. DEPA	RTMENT OF JUSTICE - DRUG ENFORCE		 			APPROVAL NO. 1117-0004 2/28/2027
	OR PERMIT TO EXPORT COM				RUG ENFORCEMENT ADMI	
	FOR SUBSEQUENT REEX	PORT		FOR SUBSEQUEN	XPORT CONTROLLE T REEXPORT (page	2)
	(See Instructions and Privacy Act Info	ormation)	 9a. NAME OF CONSIGNEE IN SECOND COUNTRY	9b. ADDRESS OF CONS	IGNEE IN SECOND COUNTRY	9c. AMOUNT TO BE REEXPORTED TO SECOND COUNTRY (Enter name of controlled
	EXPORTER APPLICA	ATION NUMBER (If applicable)	 COCCURA			substances (7b) and net weight in gms)
EE IN FIRST COUNTRY	2. ADDRESS OF CON	SEGNEE IN FIRST COUNTRY				
OF CUMBUNUE BY FREST COUP	4. FOREIGN PORT OF	F ENTRY (City & Country)				
EXPORTATION (City & state of	5b. NAME OF EXPORTING CARRIER OR	Sc. APPROX. DATE OF EXPORTATION				
ms port)	VESSEL (Air, Ship)					
			10a. NAME OF CONSIGNEE IN SECOND COUNTRY	10b. ADDRESS OF CON-	SIGNEE IN SECOND COUNTRY	10c. AMOUNT TO BE REEXPORTED TO SECOND COUNTRY (Enter name of controlled
N IMPORT LICENSE OR PERMIT N	10.	ISSUE DATE: EXPIRE DATE:				substances (7b) and net weight in gms)
AND QUANTITY OF DRUG OR	7b. CONTROLLED SUBSTANCE CONTENT OF	7c. DATE RELEASED AND ACTUAL QUANTITY				
ATION TO BE EXPORTED (Enter hown on labels; numbers and sizes of	DRUG OR PREPARATION TO BE EXPORTED expressed as acid, base, or alkaloid (Enter name of	(Completed and signed by registrant at time of export and returned within 30 days to DEA.)				
; bulk or tablets/capsules, strength of apsules, etc, CSA Drug Code, and NDC	controlled substance contained in the drug, compour preparation.)	DEA PERMIT NO:				
		DATE ACTUALLY SHIPPED:				
		LOSS ACTUALLY SHIPED				
			II. NAME OF CONSTRUCTOR BUSINESS	III. ADDDEDGGG CO	CHANGE BY GEOGRAP CONT.	ALL AND DE DESTRUMBERS OF
			 11a. NAME OF CONSIGNEE IN SECOND COUNTRY	116. ADDRESS OF CON	SIGNEE IN SECOND COUNTRY	11c. AMOUNT TO BE REEXPORTED TO SECOND COUNTRY (Enter name of controlled
						substances(7b) and net weight in gms)
			PLEASE ATTACH ADDITIONAL SHEE	TS OF FORM DEA 161R OR D	OCUMENTATION PER TITLE	21 CFR 1312.22.
					FIDAVIT	
			To the best of my knowledge and belief	(1) both the first country to which	ch the controlled substance(s) a	are exported from the United States and the
			second country to which the controlled s on Psychotropic Substances, 1971; (2) f	substances are exported are pa	rties to the Single Convention of	on Narcotic Drugs, 1961, and the Convention
			substances; (3) the drugs will be consig	ned to a holder of such permits	or licenses as may be required	in the country of import and that a permit or ubstances will be reexported from the first
		SIGNATURE OF RESPONSIBLE COMPANY OFFICIAL:	country to the second country no late	r than 180 days after exporta	tion from the United States; (	5) the packages are labeled in conformance
			with the Single Convention on Narcotic I treaties; (6) the controlled substances a	re to be applied exclusively to n	nedical, scientific, or other legiti	, 1971, and any amendments to these imate uses within the second country; and (7)
CONSIGNEE IN SECOND	8b. ADDRESS OF CONSIGNEE IN SECOND	8c. AMOUNT TO BE REEXPORTED TO SECOND	the controlled substances will not be exp NAME OF EXPORTER	ported from the second country	ADDRESS OF EXPORTER	
CONSISTED IN SECURE	COUNTRY	COUNTRY (Enter name of controlled substances (7b) and net weight in gms)				
			EXPORTER'S TELEPHONE NO. EXPOR	RTER'S DEA REGISTRATION NO.	PRINTED NAME & SIGNATURE AND	D TITLE OF PERSON MAKING APPLICATION
			NOTICE: Co	entrolled Substances ma	y not be exported by ma	il or parcel post.
			DEA USE ONLY	WED EXPORT PERMIT NUMBER	DATE EXPO	RT PERMIT NUMBER ISSUED
EA 161-R			FORM DEA 161-R	Reset Form	Print Form	

# Permit Application Process: 161R Form (Reexport)



OMB APPROVAL NO. 1117-0004 2/28/2027

U.S. DEPARTMENT OF JUSTICE - DRUG ENFORCEMENT ADMINISTRATION

## APPLICATION FOR PERMIT TO EXPORT CONTROLLED SUBSTANCES FOR SUBSEQUENT REEXPORT

PURSUANT TO SECTION 1003(f), Title III, PL 109-57

(See Instructions and Privacy Act Information)

DATE: June 10, 2025		EXPORTER APPLICATION NUMBER (If applicable) 1-2025						
1. NAME OF CONSIGNEE IN FIRST COUNTRY			2. ADDRESS OF CONSIGNEE IN FIRST COUNTRY					
ABC Pharmacia LLC			123 Martin Rd					
		Cartagena 10210, Colombia						
3. BUSINESS OF CONSIGNEE IN FIRST COUNTRY		4. FOREIGN PORT OF ENTRY (City & Country)						
Pharmaceutical			Cartagena, Colombia					
5a. PORT OF EXPORTATION (City & state of	5b. NAME OF EXPORTING CARRIER OR			5c. APPROX. DATE OF EXPORTATION				
last U.S. Customs port) Chicago, IL	VESSEL (Air, Ship) Colombia Express (Air)		09/01/2025					
6. FOREIGN IMPORT LICENSE OR PERMIT NO. COL-123/2025 ISSUE DATE: 06/01/2025 EXPIRE DATE: 12/01/2025								



7a. NAME AND QUANTITY OF DRUG OR PREPARATION TO BE EXPORTED (Enter names as shown on labels; numbers and sizes of packages; bulk or tablets/capsules, strength of tablets, capsules, etc, CSA Drug Code, and NDC Number) 7b. CONTROLLED SUBSTANCE CONTENT OF DRUG OR PREPARATION TO BE EXPORTED expressed as acid, base, or alkaloid (Enter name of controlled substance contained in the drug, compound, or preparation.) 7c. DATE RELEASED AND ACTUAL QUANTITY (Completed and signed by registrant at time of export and returned within 30 days to DEA.)

DEA PERMIT NO:

DATE ACTUALLY SHIPPED:

Suboxone 12mg/3mg Sublingual Film

28 Films per Pack

2,113 Packs

NDC: 12496-5712-28

CSA Drug Code: 9064

Drug Schedule: 3

Buprenorphine =

2,113 Packs x 28 Film Strips =

59,164 x 12mg =

709,968 / 1,000 = 709.968 GM

SIGNATURE OF RESPONSIBLE COMPANY OFFICIAL:

Brenda Covarrubias



		0. 0
8a. NAME OF CONSIGNEE IN SECOND COUNTRY	8b. ADDRESS OF CONSIGNEE IN SECOND COUNTRY	8c. AMOUNT TO BE REEXPORTED TO SECOND COUNTRY (Enter name of controlled substances (7b) and net weight in gms)
GBX Supply Pharma, LLC	101 Summer Drive Brampton, ON I8T 6PG CANADA	Buprenorphine = 709.968 GM

FORM DEA 161-R

OMB APPROVAL NO. 1117-0004 2/28/2027

U.S. DEPARTMENT OF JUSTICE - DRUG ENFORCEMENT ADMINISTRATION

#### APPLICATION FOR PERMIT TO EXPORT CONTROLLED SUBSTANCES FOR SUBSEQUENT REEXPORT (page 2)

TOR SUBSEQUENT REEXPORT (page 2)							
9a. NAME OF CONSIGNEE IN SECOND COUNTRY	9b. ADDRESS OF CONSIGNEE IN SECOND COUNTRY	9c. AMOUNT TO BE REEXPORTED TO SECOND COUNTRY (Enter name of controlled substances (7b) and net weight in gms)					



#### PLEASE ATTACH ADDITIONAL SHEETS OF FORM DEA 161R OR DOCUMENTATION PER TITLE 21 CFR 1312.22.

#### **AFFIDAVIT**

To the best of my knowledge and belief (1) both the first country to which the controlled substance(s) are exported from the United States and the second country to which the controlled substances are exported are parties to the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971; (2) the first and second countries have each instituted and maintain a system for the control of these substances; (3) the drugs will be consigned to a holder of such permits or licenses as may be required in the country of import and that a permit or license for importation will be issued for such import into the second country; (4) that the controlled substances will be reexported from the first country to the second country no later than 180 days after exportation from the United States; (5) the packages are labeled in conformance with the Single Convention on Narcotic Drugs, 1961 and the Convention on Psychotropic Substances, 1971, and any amendments to these treaties; (6) the controlled substances are to be applied exclusively to medical, scientific, or other legitimate uses within the second country; and (7) the controlled substances will not be exported from the second country.

DEA USE ONLY	APPROVED EXPORT PERMIT NUMBER	DATE EXPORT PERMIT NUMBER ISSUED						
NOTIC	NOTICE: Controlled Substances may not be exported by mail or parcel post.							
EXPORTER'S TELEPHONE NO.		PRINTED NAME & SIGNATURE AND TITLE OF PERSOM MAKING APPLICATION Brenda Covarrubias Program Analyst Brenda Covarrubias						
DEA Solutions, LLC		123 West Rd Arlington VA 22204						
NAME OF EXPORTER		ADDRESS OF EXPORTER						

FORM DEA 161-R

Reset Form

Print Form

# Controlled Substances Export Reform Act of 2005 DEA Form 161R



### Re-exportation of Controlled Substances to a Second Country

The Controlled Substances Export Reform Act of 2005 (CSERA) was enacted on August 2, 2005. The Act amends the Controlled Substances Import and Export Act (CSIEA) to provide authority for the Attorney General (and DEA, by delegation) to authorize the export of controlled substances in schedules I and II, and narcotic controlled substances in schedules III and IV, from the United States to another country for subsequent export from that country to a second country, if certain conditions and safeguards are satisfied.

# Controlled Substances Export Reform Act of 2005 DEA Form 161R



Controlled substances may be exported from the United States to a "first country" for re-export to more than one "second country" (but no further export from any second country to a third country), provided the exporter notifies DEA of this intent in the application for export permit, and provided that the CSERA is fully complied with in all other respects.



# Reexports: European Economic Area (EEA)



# § 1312.22(g) Re-exports among members of the European Economic Area (on DEA Form 161R-EEA)



# Reexports: European Economic Area (EEA)



Belgium	(BE)	Spain	(ES)	Hungary	(HU)	Slovakia	(SK)
Bulgaria	(BG)	France	(FR)	Malta	(MT)	Finland	(FI)
Czechia	(CZ)	Croatia	(HR)	Netherlands	(NL)	Sweden	(SE)
Denmark	(DK)	Italy	(IT)	Austria	(AT)	Germany	(DE)
Cyprus	(CY)	Poland	(PL)	Iceland	(IS)	Estonia	(EE)
Latvia	(LV)	Portugal	(PT)	Liechtenstein	(LI)	Ireland	(IE)
Lithuania	(LT)	Romania	(RO)	Norway	(NO)	Greece	(EL)
Luxembourg	(LU)	Slovenia	(SI)				

The EEA includes 27 European Union Countries as well as Iceland, Liechtenstein and Norway.



#### **Submission of 161R Application:**

Please submit the completed 161R reexport application along with supporting documents to our 161 inbox at <a href="mailto:DEA161@dea.gov">DEA161@dea.gov</a>.



# Return Requirement for Export & Reexport Permits



Section: 21 CFR 1312.22(e) Application for export or reexport permit: return information

- Key Requirement: Submission of return information.
- Deadline: Return information must be submitted within 30 Calendar days after the controlled substance is released by customs officer at the port of export or 10 days after being contacted by DEA.



Significance: This ensures regulatory compliance for controlled substance export.

# **Questions & Email Inquiries**



**Email Communication & Issue Resolution:** Always mention your reference number, permit number and/or tracking number in the subject line for quick reference. Include your DEA Registration number and contact telephone number in the body of the email when seeking assistance.

#### Send all inquiries to our DEA 161 Inbox at <a href="mailto:DEA161@dea.gov">DEA161@dea.gov</a>.



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Email questions to DOI@DEA.GOV



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# **Code of Federal Regulations**



§ 1312.12 Application for import permit; return information.



# Controlled Substances Import & Export Form Guide



	Perr	nits	Declarations		
Schedules I-V	DEA-357	DEA-161	DEA Form-236		
<u>oonoanoo i v</u>	(Imports)	(Exports)	Imports	Exports	
Schedule I and II	<b>\</b>	<b>\</b>			
Schedule III Narcotic					
Schedule III Non-Narcotic (7369 requires a PERMIT)			>		
Schedule IV Narcotic			<b>\</b>		
Schedule IV Non-Narcotic					
Schedule V Narcotic				<b>/</b>	
Schedule V Non-Narcotic			<b>/</b>	<b>/</b>	

# **Import Permit Application: Form 357**



Initial	import	permit:
DF	A Form	357

APPLICATION FOR	FOR PERMIT TO R DOMESTIC AN SURSUANT TO SEC	ce / Drug Enforcement Ad TO IMPORT CONTROL ND/OR SCIENTIFIC PU TION 1002, TITLE III, P.L. : s on reverse before completi	LLED SUBSTAN IRPOSES 91-513	ICES		OMB APPROVAL No. 1117-0013 Expiration Date: 2/28/2027 See reverse for Privacy Act
DRUG ENFORCEM			2/	DATE	'	
O: IMPORT/EXPORT		IMPORTER'S	S APPLICATI	ION NUMBER		
8701 MORRISSET		IELD, VA 22152 ade pursuant to the provision	ns of the Controlle	d Substances	Import	nd Evnort
		prescribed thereunder for a	permit to import a	s follows:		id Export
. NAME OF FOREIGN EXPORTER			2. ADDRESS OF FO	OREIGN EXPO	RIER	
. FOREIGN PORT OF EXPORTATION		<ol> <li>PORT OF ENTRY (U.S. Custom clear)</li> </ol>	s port where shipme	nt will	5. LATEST D PORT	ATE SHIPMENT WILL LEAVE FOREIGN
a. NAME AND QUANTITY OF DRUG P		6b. CONTROLLED SUBSTANCE				E RELEASED AND ACTUAL QUANTITY
IMPORTED (Enter names as show and sizes of packages; strength, C		PREPARATION TO BE IMP alkaloid (Enter name of c	controlled substance of	acid, base or contained in		empleted by registrant at time of port)
NDC Number)		the drug, compound, or	preparation)		DEA PE	RMIT NO:
a. ASSIGNED QUOTA FOR THIS		ORIZED ON PERMITS THIS	7c. KG OF 7b. IMP	ORTED TO DAY	TE 7	7d. STOCK ON HAND & DATE
ra. ASSIGNED QUOTA FOR THIS YEAR	7b. TOTAL KG AUTH YEAR	ORIZED ON PERMITS THIS	7c. KG OF 7b. IMPI	ORTED TO DAY	TE 7	7d. STOCK ON HAND & DATE
YEAR  I. IF SUBSTANCE(S) WILL BE IMPORTE	YEAR  D FOR SCIENTIFIC PURI		:			
YEAR  I. IF SUBSTANCE(S) WILL BE IMPORTE	YEAR  D FOR SCIENTIFIC PURI	POSES ONLY, PLEASE COMPLETE	: entific purposes, purso Signatur		t 1312.13(a)	
YEAR  I. IF SUBSTANCE(S) WILL BE IMPORTE I hereby certify the above	YEAR  D FOR SCIENTIFIC PURI	POSES ONLY, PLEASE COMPLETE	: entific purposes, purso Signatur	uant to 21 CFR	t 1312.13(a)	
YEAR  I. IF SUBSTANCE(S) WILL BE IMPORTE I hereby certify the above	YEAR  D FOR SCIENTIFIC PUR controlled substances	POSES ONLY, PLEASE COMPLETE	Signatur	uant to 21 CFR e of Certifying S OF IMPORTE	t 1312.13(a) Individual	
YEAR  I. IF SUBSTANCE(S) WILL BE IMPORTE  I hereby certify the above  I hereby certify the above  I have considered the substance of the subst	YEAR D FOR SCIENTIFIC PUR Controlled substances	POSES ONLY, PLEASE COMPLETE are imported exclusively for scie	Signatur ADDRESS	e of Certifying S OF IMPORTE	Individual R	)(4) (see reverse), as follows:
YEAR  I. IF SUBSTANCE(S) WILL BE IMPORTE I hereby certify the above  HAME OF IMPORTER  MPORTER'S TELEPHONE NO.	YEAR D FOR SCIENTIFIC PUR Controlled substances	POSES ONLY, PLEASE COMPLETE are imported exclusively for scie sistration No. trolled Substances may not	Signatur ADDRESS	e of Certifying S OF IMPORTE URE AND TITLE	Individual R OF PERSON	)(4) (see reverse), as follows:

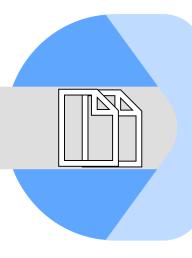
### **DEA Form 357 Overview**





#### **Purpose**

This form is to be used in notifying DEA of all IMPORTS of Schedule I, II and all narcotics in Schedule III, IV & V



#### To DEA

15 calendar days Notice for imports.

DEA supporting documents which is maintained by the registrant



DEA Form 35 Import Permit

# **DEA Form 357 Required Information**



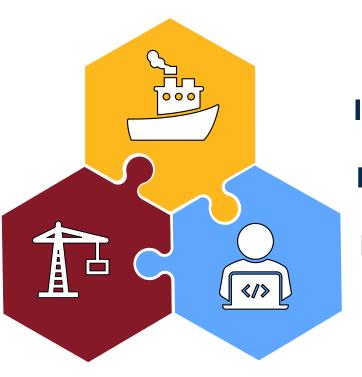
#### **Import Export Product**

US Importer/Exporter Name & Address

Foreign Exporter Name & Address

Product name, packaging detail and strength

Supporting documentation for any conversion factor changes that need to be made (i.e. determination letter)



#### **Transportation**

Port of Importation/Exportation

**Mode of Transportation** 

Name of Vessel/Carrier

DEA

**Authorizing Individual** 

**DEA Registration Number** 

## **DEA Form 357: Coincidental Activities**



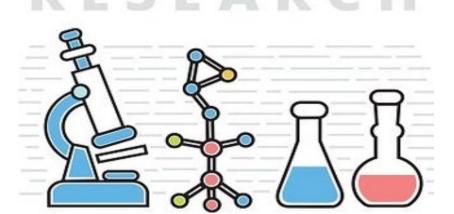
#### **Code of Federal Regulations**

§ 1301.13 (1)(v) – Research (Schedule I)

§ 1301.13 (1)(vi) – Research (Schedule II-V)

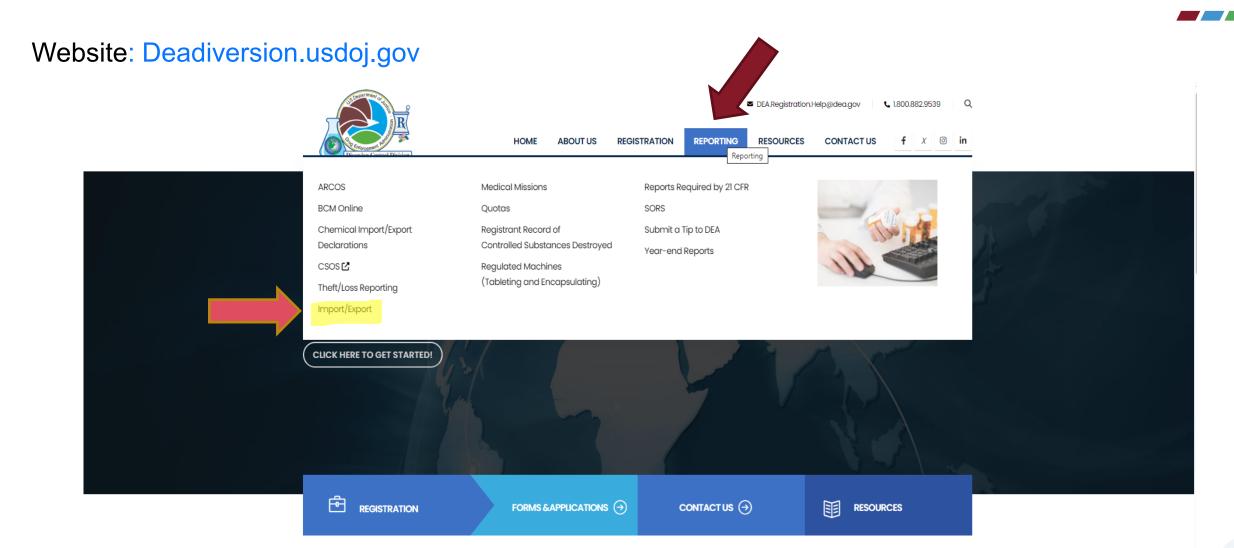
#### **Coincident Activities Allowed**

As a researcher, you're able to import controlled substances that are approved under your DEA researcher registration.











#### Import/Export Permit Applications and Declarations

HOME > REPORTING
> 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

#### 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 Purposes

**Assistance and Support with Medical Missions** 







To acquire a new IMEX login account, or have any other IMEX inquires, please submit your request or questions to our CSIMEX inbox at

CSIMEX@dea.gov.



# IMEX Demonstration for Import Permit DEA Form 357

# Return Requirement for Import Permit



#### Section: 21 CFR 1312.12(d) Application for import permit; return information

- Key Requirement: Submission of return information.
- Deadline: Return information must be submitted within
   30 calendar days after the actual receipt of
   controlled substance at the importer's registered location,
   or 10 days after being contacted by DEA.
- Significance: This ensures regulatory compliance for controlled substance imports.



# **Questions & Inquiries**



**Email Communication & Issue Resolution:** Always mention your reference number, permit number and/or tracking number in the subject line for quick reference. Include your DEA Registration number and contact telephone number in the body of the email when seeking assistance.

Send all inquiries to our DEA 357 Inbox at <a href="mailto:DEA357@dea.gov">DEA357@dea.gov</a> or call the following number 571-362-8270.



# **Submit a Question**



# During the live presentation, scan QR or follow link in the comments to submit a question.



Watching recorded presentation?
Email questions to DOI@DEA.GOV



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# **Copyright Disclaimer**



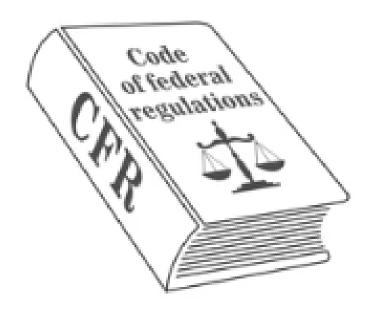


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# **Code of Federal Regulations**



- § 1312.18 Import Declaration.
- § 1312.19 Distribution of Import Declaration.
- § 1312.27 Export/Reexport Declaration.
- § 1312.28 Distribution of Export Declaration



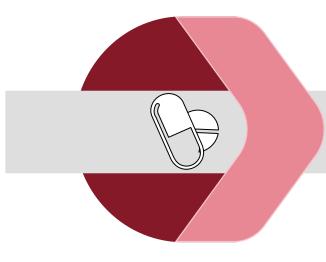
# **Controlled Substances Import & Export Form Guide**



	Peri	mits	Declarations		
Schedules I-V	DEA-357	DEA-161	DEA Form-236		
Ochedules I V	(Imports)	(Exports)	Imports	Exports	
Schedule I and II	<b>/</b>				
Schedule III Narcotic	<b>/</b>				
Schedule III Non-Narcotic (7369 requires a PERMIT)				<b>/</b>	
Schedule IV Narcotic	<b>/</b>	<b>/</b>	<b>/</b>		
Schedule IV Non-Narcotic				<b>/</b>	
Schedule V Narcotic	<b>/</b>			<b>/</b>	
Schedule V Non-Narcotic			<b>/</b>	<b>/</b>	

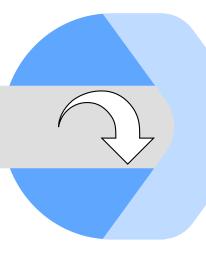
# **DEA Form 236 (Import) Overview**





#### **Purpose**

This form is to be used in declaring to DEA of imports of <u>ALL NON-NARCOTIC</u> controlled substances in Schedule III, IV, and V



#### To DEA

DEA supporting documents for imports, which is maintained by the registrant

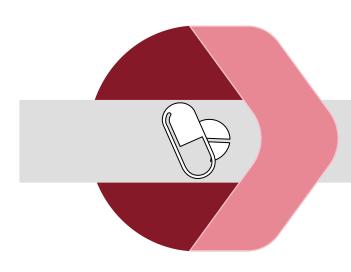


#### From DEA

Transaction identification number

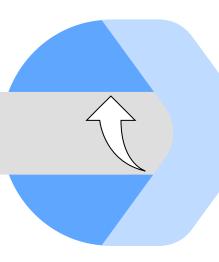
# **DEA Form 236 (Export) Overview**





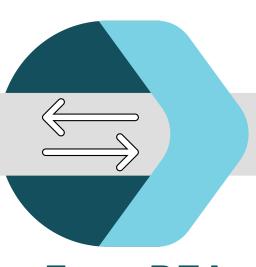
This form is to be used in declaring to DEA of exports of non-narcotic controlled substances in Schedule III, IV & V; Narcotics in Schedule V

**Purpose** 



#### To DEA

Foreign Export
Permit or Letter of
No Objection (LONO)
and "no re-export
statement"



#### **From DEA**

Transaction identification number

## **DEA Form 236 Required Information**



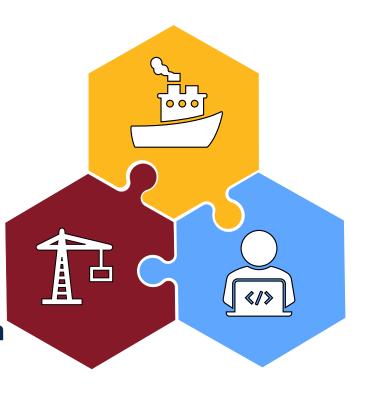
#### **Import Export Product**

US Importer/Exporter Name and Address

Foreign Importer/Exporter
Name and Address

Product name, packaging detail and strength

Any supporting documentation (copy of the foreign permit, license or registration issued by the competent national authority, & no re-export letter required for Exports only)



#### **Transportation**

Port of Importation/Exportation

**Mode of Transportation** 

Name of Vessel/Carrier

**DEA** 

**Authorizing Individual** 

**DEA Registration Number** 

# DEA's Acceptance Criteria for International Permits and Declarations



- The DEA only accepts a foreign permit or Letter of No Objection (LONO) that is issued and signed by the Competent National Authorities for that country.
- The DEA follows the United Nations Office on Drugs and Crime.



# **English Language Requirement for Import Licenses** or Permits

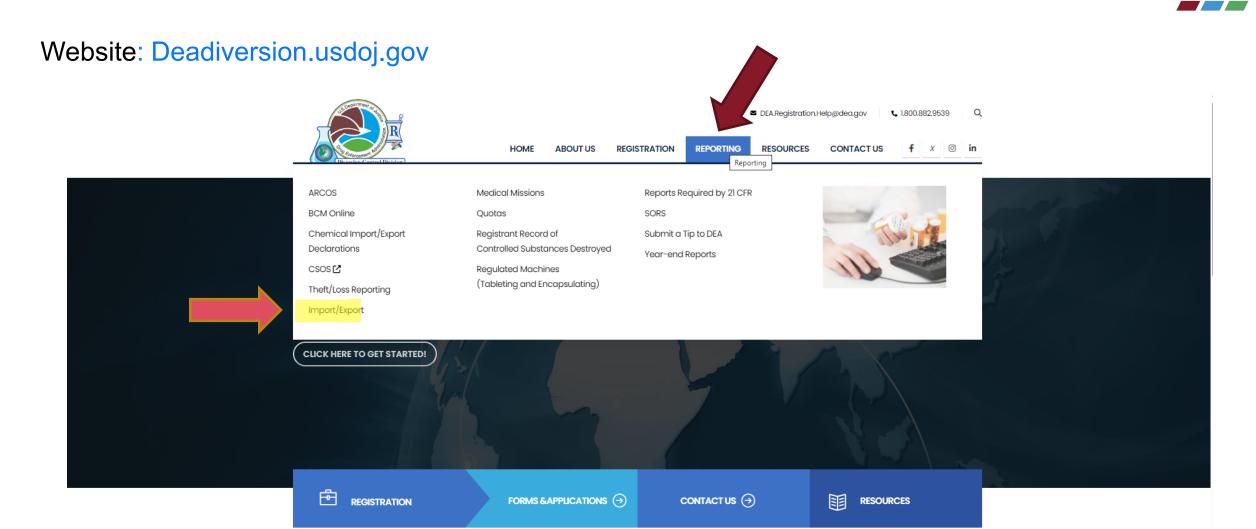


#### § 1312.22 Application for export or reexport permit; return information.

(d)(1) Except as provided in paragraph (d)(2) of this section, the applicant must also submit with the application any import license or permit or a certified copy of any such license or permit issued by the competent national authority in the country of destination, or other documentary evidence deemed adequate by the Administration, showing: That the merchandise is consigned to an authorized permittee; that it is to be applied exclusively to medical or scientific use within the country of destination; that it will not be reexported from such country (unless the application is submitted for reexport in accordance with paragraphs (f), (g), and (h) of this section); and that there is an actual need for the controlled substance for medical or scientific use within such country or countries. If the import license or permit, or the certified copy of such, is not written in English or bilingual with another language and English, the registrant must also submit with their application a certified translation of the permit or license. For purposes of this requirement, certified translation means that the translator has signed the translation legally attesting the accuracy of the translation. (In the case of exportation of bulk coca leaf alkaloid, the applicant need only include with the application the material outlined in paragraph (c) of this section.)









#### Import/Export Permit Applications and Declarations

HOME > REPORTING
> 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

#### 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 Purposes

**Assistance and Support with Medical Missions** 







To acquire a new IMEX login account, or have any other IMEX inquires,

please submit your request or questions to our CSIMEX inbox at <a href="mailto:CSIMEX@dea.gov">CSIMEX@dea.gov</a>.



# IMEX Demonstration for an Export & Import Declaration DEA Form 236





#### Import/Export Permit Applications and Declarations

HOME > REPORTING
> 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

#### 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 Purposes

**Assistance and Support with Medical Missions** 



DEA Form 236

HOME > REPORTING
> IMPORT/EXPORT PERMIT APPLICATIONS AND
DECLARATIONS
> DEA FORM 236

#### Download DEA Form 236 (PDF)

**View Instructions or Download Instructions PDF** 

**Privacy Information** 

#### **INSTRUCTIONS FOR COMPLETING DEA FORM 236**

This form is to be used in notifying DEA of all Imports or Exports as required by Title III, PL91-513, Sections 1002 and 1003, as amended (Controlled Substances Import and Export Act, 21 U.S.C. 952 and 953). This form may be prepared and signed by the actual Importer or Exporter or by the Broker or Forwarding Agent used. The following instructions supplement the parts of the DEA-236 which are not completely self-explanatory.



## Initial reexport declaration: DEA Form 236

U.S. Department of Ju CONTROLLED SUBSTANC (read instructions		EXPORT DECLAR	ATION	OMB Approval No. 1117-0009 Expiration Date: 2/28/2027
Type of Declaration:  IMPORT Non-narcotic substances in Schedules III, IV, or V  EXPORT Non-narcotic substances in Schedules III or IV and all substances in		ubstances in Schedule V	DEA Transaction I Date of Issue: Date of Expiration	
*This declaration is not deemed filed, and therefore is not valid, until the Drug Enforcement Admi				
1a. Importer/Exporter (U.S. company name and addr	ess)	1b. Broker/Forwarding	Agent (company name a	and address)
DEA Registration No.:				
2. Controlled Substances to be Imported or Exported			,	I
<ol> <li>Name and quantity of drug or preparation (nam labels; number and size of packages; strength of dr preparation; CSA Drug Code; NDC Number)</li> </ol>	ength of drug or weight calculation expressed in base and acid or alkaloid			2c. Return Information (see instructions)
3a. Port of Export:		3b. Port of Import:		
and anticipated Date of Departure:		and anticipated Date of	Arrival:	
Mode of Transport and name(s) of carrier or vessel     Foreign Consignee/Consignor (company name and		Date	eign Import Permit No.: e of Issue: e of Expiration:	
		-		r U.S. exports)
I hereby certify the substances listed in Section 2 are and are intended for Medical Scientific, or The substances listed in Section 2 will be Re-Export of this form is being used as an "Export Declaration", attacrecieve the controlled substances. If the controlled substances in substrated under the	Other legitimate orted to: (attached do not have doucumentation the conces are being re-export	(conforms to 21 U.S.C. § 95 e uses (attach explanation f cumentation per Title 21 C onsignee is authorized under ed from the first country to se	or other legitimate uses F.R. § 1312.27(b)(5)) the laws and regulations econd countries, attach do	of the country of destination to
				on submitting DEA Form-236
Signature of Authorized Individual of Importer/Expor Forwarding agent	ter, Broker, or	Name of Firm and Cont		
Forwarding agent	Date:	Name of Firm and Cont		-



U.S. Department of Justice / Drug Enforcement Administration

#### **CONTROLLED SUBSTANCES IMPORT / EXPORT DECLARATION**

(read instructions and Privacy Act before completing)

OMB Approval No. 1117-0009 Expiration Date: 2/28/2027

Type of Declaration:		DEA Transaction No.*:			
IMPORT Non-narcotic substances in Schedules III, IV, or V		Date of Issue:			
EXPORT Non-narcotic substances in Schedules III or IV and all substances in Schedule V		Date of Expiration:			
*This declaration is not deemed filed, and therefore is not valid, until the Drug Enforcement Administration (DEA) has issued a DEA Transaction number					
1a. Importer/Exporter (U.S. company name and address)	1b. Broker/Forwarding Agen	t (company name and address)			
ABC Pharma LLC 123 West Rd Alexandria, VA 56789	BAC Solutions 5555 North Drive Suite 7 Memphis, TN 12345				
DEA Registration No.: RJ012312134					



2. Controlled Substances to be Imported or Exported				
2a. Name and quantity of drug or preparation (name on labels; number and size of packages; strength of drug or preparation; CSA Drug Code; NDC Number)	2b. Controlled substance content of drug/preparation and weight calculation expressed in base and acid or alkaloid	2c. Return Information (see instructions)		
Lacosamide Syrup	5,000 bottles x 200ml 100,000 ml x .010 = 10,000,000 GM			
5,000 bottles				
200 ml each				
10 mg				
CSA# 2748				
NDC# 00131-54-1071				
3a. Port of Export: Philadelphia, PA	3b. Port of Import: Cartagena, Colombia	•		
and anticipated Date of Departure: 09/30/2025	and anticipated Date of Arrival: 10/01/2025	and anticipated Date of Arrival: 10/01/2025		



5. Foreign Consignee/Consignor (company name and address)	Foreign Import Permit No.: DSS-123/2025				
II Supply Group	Date of Issue: 06/01/2025				
JJ Supply Group Calle 1010 Martinez	Date of Expiration: 12/01/2025				
Cartagena 130000 Coolmbia	(Required for U.S. exports)				
	Reference No.: BAC-1-25				
I hereby certify the substances listed in Section 2 are to be: Imported (conforms to 21 U.S.C. § 952(b)) Exported (conforms to 21 U.S.C. § 953(e)) and are intended for Medical Scientific, or Other legitimate uses (attach explanation for other legitimate uses.)					
The substances listed in Section 2 will be Re-Exported to: (attached documents)	mentation per Title 21 C.F.R. § 1312.27(b)(5))				
If this form is being used as an "Export Declaration", attach doucumentation the consignee is authorized under the laws and regulations of the country of destination to receive the controlled substances. If the controlled substances are being re-exported from the first country to second countries, attach documentation the consignee(s) in the country of ultimate destination is authorized under the laws and regulations of that country to receive the controlled substances.					
Signature of Authorized Individual of Importer/Exporter, Broker, or	Name of Firm and contact information of person submitting DEA Form-236				
Forwarding agent	ABC Pharma LLC 703-575-9429				
Print Name: Brenda Covarrubias Date: 07/24/2025	7.50 T Halling 220				
DEA Form-236  Print Form	Reset Form				



#### **Submission of 236 Reexport Application:**

Please submit the completed 236 reexport application along with supporting documents to our 236 inbox at <a href="mailto:DEA236@dea.gov">DEA236@dea.gov</a>.



## Return Requirement for Import & Export Declarations



Section: 21 CFR 1312.18(e) Import Declaration; return information

Section: 21 CFR 1312.27(d) Export/reexport Declaration; return information

Key Requirement: Submission of return information.

 Deadline: Return information must be submitted within 30 Calendar days after the controlled substance is released by customs officer at the port of export or 10 days after being contacted by DEA.



• **Significance:** This ensures regulatory compliance for controlled substance export.

#### **Questions & Inquiries**



**Email Communication & Issue Resolution:** Always mention your reference number, Transaction ID number and/or tracking number in the subject line for quick reference. Include your DEA Registration number and contact telephone number in the body of the email when seeking assistance.

Send all inquiries to our DEA 236 Inbox at <a href="mailto:DEA236@dea.gov">DEA236@dea.gov</a>.





## Best Practice for DEA Submission of an Application



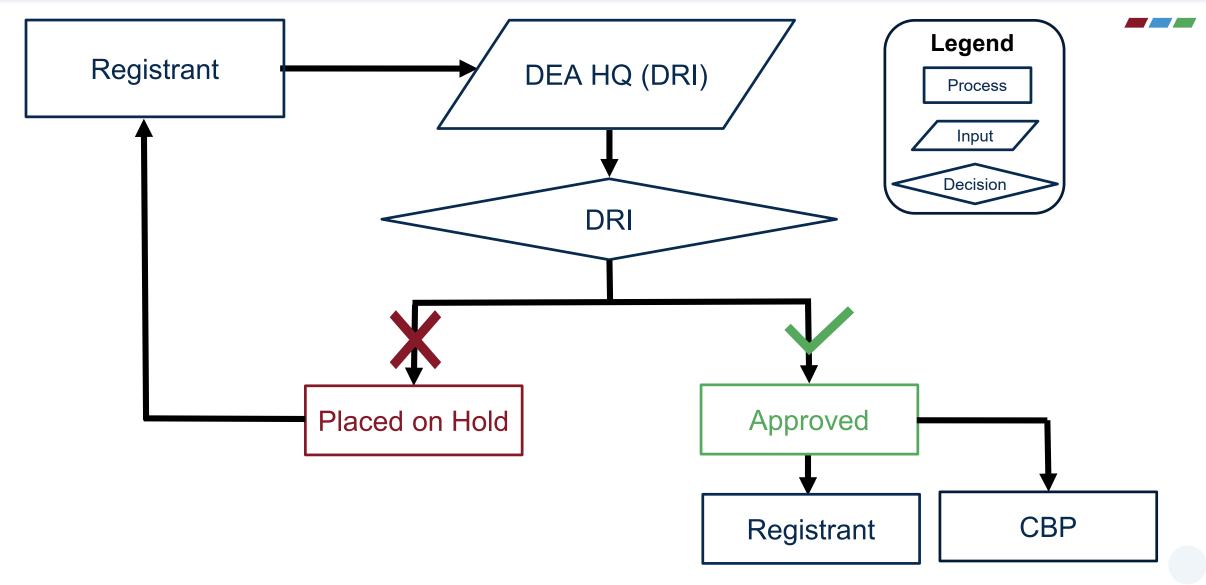
- **DEA Registration Number & Drug Codes:** Make sure the drug codes for all controlled substances have been added onto the designated DEA Registration number.
- **Documentation**: Please have all required documentation and information ready prior to applying to export.
- **Uploading Attachments:** Ensure all PDF attachments, including permits, are clearly labeled before uploading online. Refrain from including any non-essential information.



• Review, Review: Please make sure to review all information on the foreign permit document to reflect what is on the application. And that all fields of the application have been completed properly.

#### **Process for Permits & Declarations**





## Reviewing & Processing of Permits & Declarations



#### Applications placed on hold and or require an amendment:

- Foreign permit information is incorrect cannot be amended and will require a new application submission
- Under Controlled Substance section:
  - NDC number not reflecting base or salt appropriately or the packaging details
  - Packaging details (i.e. tablets vs capsules, not enough information)
  - Amount requested cannot exceed what is stated on the foreign document
- Date of Importation/Exportation be at least 15 days out from day of submission
- Signed translated document is not provided if one is required
- Assessment per INCB has been reached



#### **Submit a Question**



# During the live presentation, scan QR or follow link in the comments to submit a question.



Watching recorded presentation?
Email questions to DOI@DEA.GOV



#### **Disclaimer**





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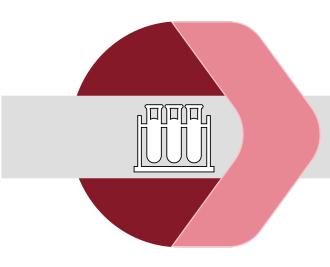




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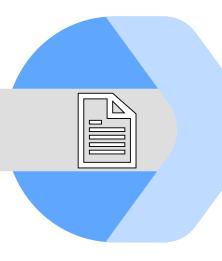
#### **DEA Form 486 Overview**





#### **Purpose**

This form is to be used in notifying DEA of all imports, exports, and international transactions of listed chemicals



#### To DEA

A DEA Declaration
Form 486 with the required information, per the regulations at least 15 calendar days prior to the export.



#### From DEA

Transaction identification number

## **DEA 486 Forms for Chemicals**





DEA Form #	DEA Form	Listed Chemical	Supporting Documents	Issued to Registrant
DEA Form 486	Export Declaration	List I & II	Foreign Import Permit or Foreign License* (N/A for some countries)	Transaction ID Number
DEA Form 486	Import Declaration	List I & II	N/A	Transaction ID Number
DEA Form 486A	Import Declaration	Ephedrine Pseudoephedrine Phenylpropanolamine	Quota from DEA UN Reporting via DEA form <b>455</b> *instructions on deadiversion.usdoj.gov	Transaction ID Number
DEA Form 486	International Declaration	List I & II	N/A	Transaction ID Number

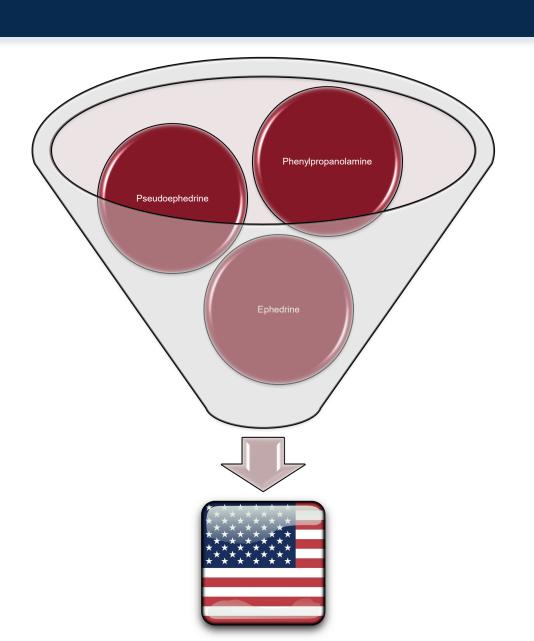
## **DEA Form 486A (Imports)**



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

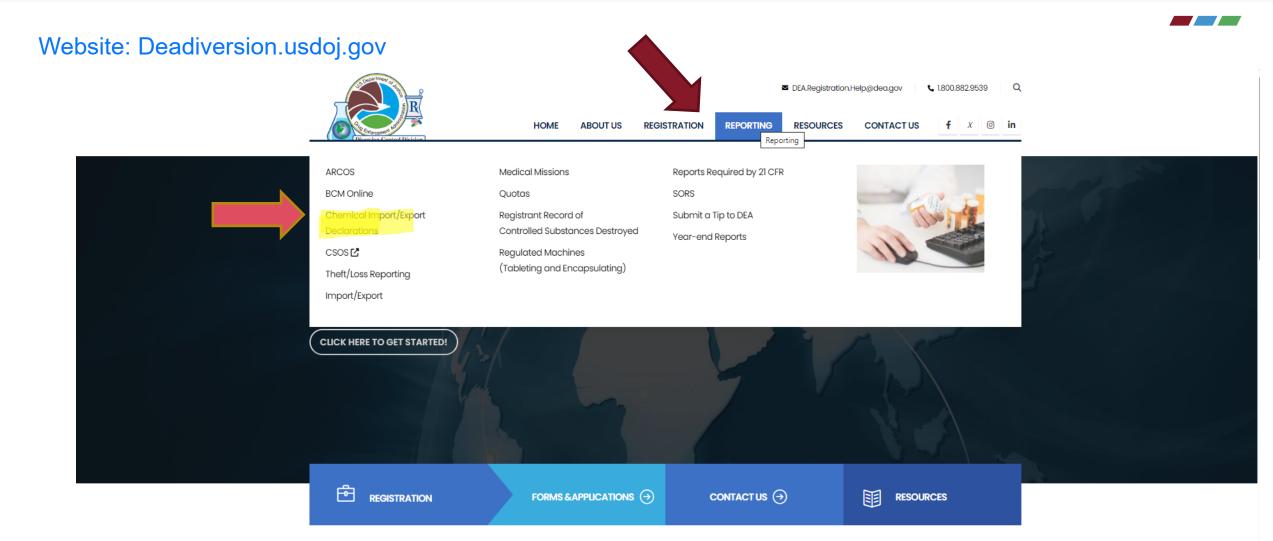
To DEA: A DEA Form 486A with the Transferees at least 15 days prior to the import entering a U.S. port (no regular customer).

From DEA: The Transaction ID number.



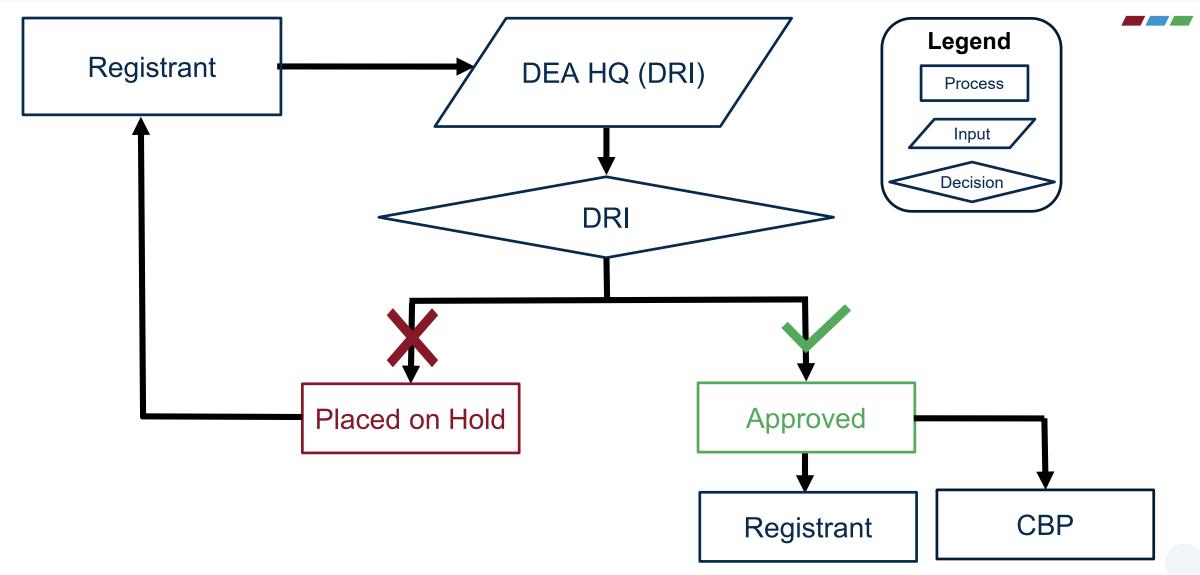






#### **DEA Form 486 Process**





#### **DEA Form 486 & 486A Information**



#### **Import Export Product**

**US Importer/Exporter Address** 

Purchase/Invoice number

Foreign Importer/Exporter Address

\*Product name, substance, packaging detail, & weight

Any supporting documentation (copy of the foreign permit, license or registration issued by the competent national authority)



#### **Transportation**

Port of Importation/Exportation

**Mode of Transportation** 

Name of Vessel/Carrier

DEA

**Authorizing Individual** 

**DEA Registration Number** 

**Return Information** 

#### Regular Customer Status



#### **EXPORTS**

If a registrant wants to wave the 15 days advanced notification and establish Regular Customer Status, they must export to the same foreign consignee at the same location at least once every six months or twice every twelve months (not calendar months).

As a result, they are only required to provide 3 business days advanced notification prior to the export date.

#### **IMPORTS**

If a registrant wants to wave the 15 days advanced notification and establish Regular Customer Status, they must import the same chemical at least once every six months or twice every twelve months (not calendar months).

As a result, they are only required to provide 3 business days advanced notification prior to the import date.



## Reviewing of 486/486A Applications



#### Applications placed on hold and or require amendments:

- 3 business days advanced notification
- Packaging details
- Purchase/invoice number





## **Return Information**



All return information is required within 30 days of the actual import or export date.

### **Code of Federal Regulations:**

§ 1313.17 Return declarations for imports

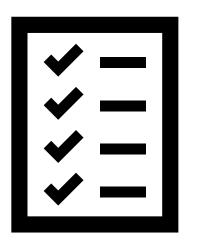
§ 1313.27 Return declarations for exports

§ 1313.35 Return declaration or amendment to Form 486 for international transactions.

# Best Practice for DEA Submission: Form 486/486A



- Confirmation: of supporting documentations (i.e. foreign permits/license)
- **Documentation:** Please have all required documentation and information ready prior to applying to export.
- Labeling Attachment: Ensure all PDF attachments, including declarations, are clearly labeled before uploading. Refrain from including any non-essential information.



# **Questions and Inquiries**



**Email Communication & Issue Resolution:** Always mention your reference number, permit number and/or tracking number in the subject line for quick reference. Include your DEA Registration number and contact telephone number in the body of the email when seeking assistance.

Send all inquiries to our DEA 486 Inbox at <a href="mailto:DEA486@dea.gov">DEA486@dea.gov</a>.





# IMEX Demonstration for Import & Export Declarations DEA Form 486 & 486A

# **Submit a Question**



# During the live presentation, scan QR or follow link in the comments to submit a question.



Watching recorded presentation?

Email questions to

DEA486@dea.gov



# **Disclaimer**





The contents of this document do not have the force and effect of law and are not meant to bind the public or DEA in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

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# **Code of Federal Regulations**



21 CFR § 1310 Records and Reports of Listed Chemicals and certain machine: importation and exportation of certain machines.

- § 1300.02 Definitions relating to listed chemicals.
- § 1310.04 Maintenance of records.
- § 1310.05 Reports.
- § 1310.06 Content of records and reports.
- § 1310.07 Proof of identity.



# **DEA Form 452 - Reports for Regulated Machines**

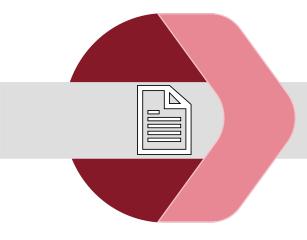


# Tabulating & Encapsulating Machines

DEA Form #	DEA Form	Regulated Machine(s)	Supporting Documents	Issued to Regulated Person
DEA Form 452	Tableting & Encapsulated Machines	Report is provided by U.S. importer, exporter, or domestic supplier	N/A	Transaction ID No.

## **DEA Form 452**





# This form is to be used in notifying DEA of all imports, exports, and domestic transactions of regulated machines.

**Purpose** 



### To DEA

at least 15 calendar days before the anticipated arrival at the port of entry or port of export and within 15 calendar days after the order has been shipped by the seller for a domestic transaction.



### **From DEA**

Transaction Identification Number

# DEA Form 452 Reports for Regulated Machines Information





## **Transportation**

#### **DEA**



Seller, Buyer, Broker with address

**Point of Contact** 

**Date of Transaction** 

**Purpose and Need** 

Serial Number (if any), type, make, model, power, description



Port of Importation/Exportation with date

**Mode of Transportation** 

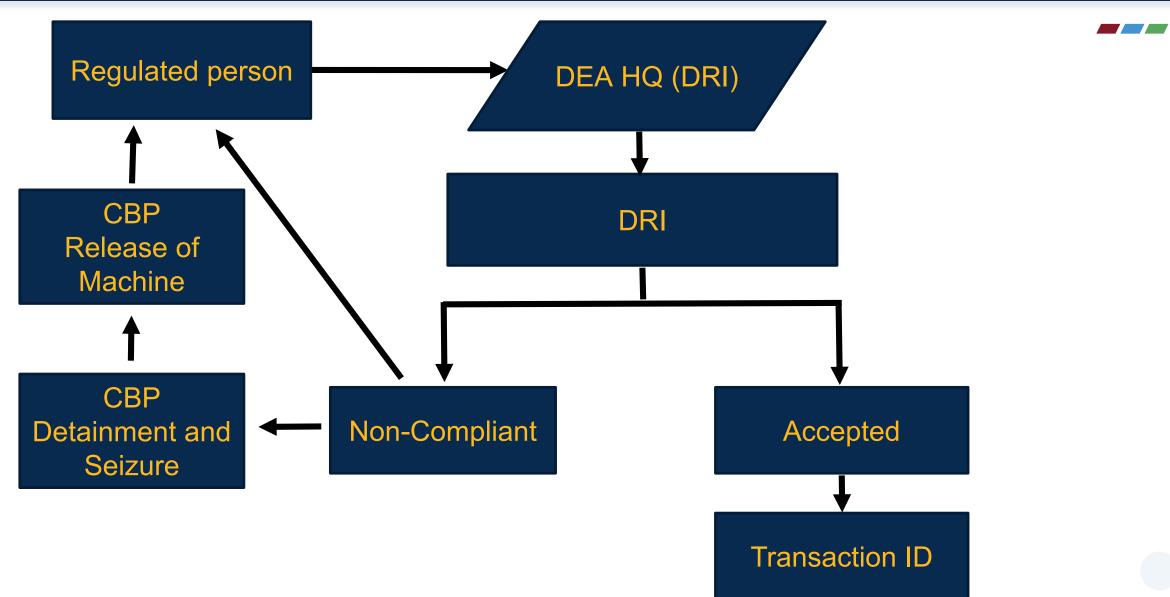


**Authorizing Individual** 

DEA Registration Number (if any)

# **Process for DEA 452 forms**









Website: www.deadiversion.usdoj.gov ■ DEA.Registration.Help@dea.gov **L** 1.800.882.9539 HOME **ABOUT US** REGISTRATION REPORTING RESOURCES **CONTACT US** ARCOS Medical Missions Reports Required by 21 CFR **BCM Online** Quotas SORS Chemical Import/Export Registrant Record of Submit a Tip to DEA Declarations Controlled Substances Destroyed Year-end Reports CSOS [2] Regulated Machines Tableting and Encapsulating) Theft/Loss Reporting Import/Export **CLICK HERE TO GET STARTED!** FORMS & APPLICATIONS → CONTACTUS (→) REGISTRATION **RESOURCES** 



Reports for Regulated Machines - DEA Form 452

HOME > REPORTING

> REPORTS FOR REGULATED MACHINES - DEA FORM 452

#### Regulated Machines (Tableting and Encapsulating)

The Import/Export Section administers and monitors DEA's Import and Export program for controlled substances, chemicals, and **transactions of regulated machines**. Regulated transactions include domestic distribution, importation, or exportation of a tableting machine or encapsulating machine. Regulated machines include tableting and encapsulating machines ranging from manual, semi-automatic, and fully automatic equipment.

Letter from DEA Administrator Anne Milgram: E-Commerce Platforms Selling Pill Press Machines

#### Pill Press Threat

Drug traffickers use pill presses to press fentanyl into pills and punches and dies to imprint markings and logos onto those pills, producing pills that look like legitimate prescription medication — like oxycodone, Xanax, and Adderall — when those pills actually contain fentanyl, methamphetamine, and other deadly drugs.

Pill Press Seizures

Pill Press Resources





Transactions of Regulated Machines Online

**Regulated Machines Online** 

DEA Form 452 - Import, Export, or Domestic Transactions of Tableting and Encapsulating Machines





# **Applications for Submitting a DEA Form 452**



- Registering or Creating a Company/Individual User Account
- Application to Import Machines (DEA Form 452 Import)
- Application to Export Machines (DEA Form 452 Export)
- Application to Transfer Machines Domestically (DEA Form 452 Domestic)
- Return information

# Detainment, Seizure, and Release of Regulated Machines



- Failure of the regulated person to comply with the applicable laws and regulations may result in detainment and seizure of the shipment by the Customs and Border Protection (CBP) or the Drug Enforcement Administration (DEA).
- Regulated persons will need to coordinate with their local DEA Diversion Field Offices and CBP regarding the release of detained machines and reporting to the DEA.

# **Questions & Email Inquiries**



**Email Communication & Issue Resolution:** Always mention your reference number, permit number and/or tracking number in the subject line for quick reference. Include your DEA Registration number and contact telephone number in the body of the email when seeking assistance.

Send all inquiries to our DEA Inbox at <a href="mailto:Table-EncapsuleMachine@dea.gov.">Table-EncapsuleMachine@dea.gov.</a>





# IMEX Demonstration for Reports of Regulated Machines DEA Form 452

# **Contact Information**





Form	Email	Topic	
161	DEA161@dea.gov	Exports of Schedule I, II, III Narcotic and IV Narcotic substances.	
236	DEA236@dea.gov	Imports/Exports of Schedule III non-narcotics, IV Non-narcotic and all V.	
486	DEA486@dea.gov	List I and II chemicals including Ephedrine, Pseudoephedrine, Phenylpropanolamine and Chemical transshipments.	
357	DEA357@dea.gov	Imports of Schedule I, II, III narcotic, IV narcotic and V narcotic.	
452	Tablet-EncapsuleMachine@dea.gov	Regulated Machines	
Return Information	CSIMEX@dea.gov	Return Information and IMEX account setup	
General Inquiries	DRI@dea.gov	All general inquires	

# **Concludes Training**





# **Submit a Question**



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