IMEX


DIVERSION CONTROL DIVISION
EXPORT
IMPORT
DEA IMPORT & EXPORT SECTION

Disclaimer

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Objectives

1

Explain our

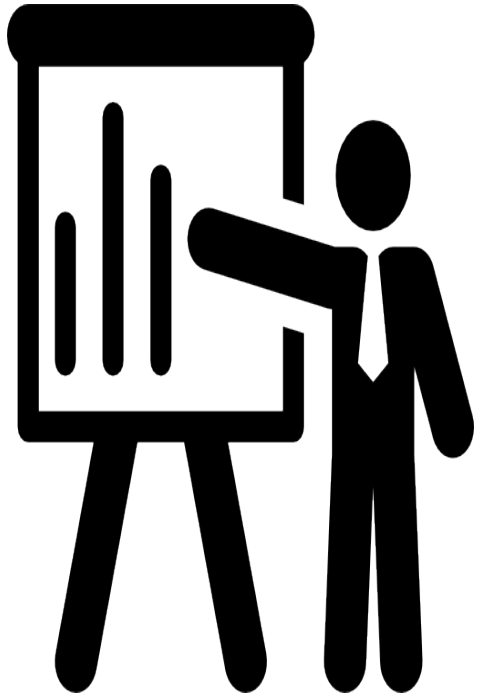
Mission/function and roles, responsibilities and regulations to import, export

2

Explain how registrants report and business processes for permits and declarations

3

Discuss new application features in IMEX



DEA Import and Export Section Mission Statement

Administers and monitors DEA's Import and Export program for controlled substances, chemicals, and regulated machines

Issues import and export permits, declarations, monitors transshipments and regulated machines, and issues Status Notifications Letters

Implements programs in accordance with U.S. congressional legislation and international treaties

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 (1970)

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

Executes the United States' obligations with international treaties

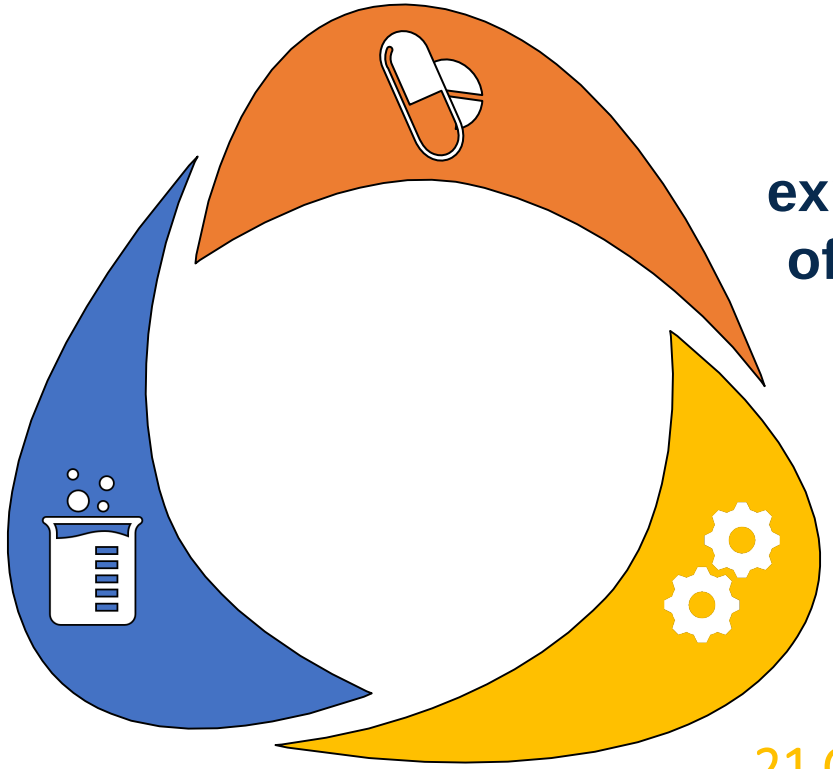
Provides a series of statutory requirements for substances with abuse potential creating a closed system

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

Code of Federal Regulations

21 CFR Part 1312

Regulates the import, export, and transshipment of controlled substances



21 CFR Part 1313

Regulates the import, export, and transshipment of listed chemicals

21 CFR Part 1310

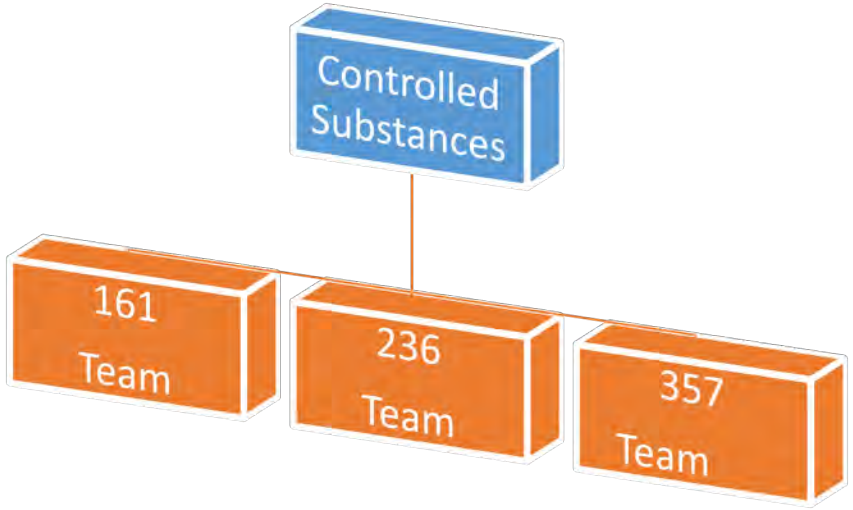
Regulates the records/reports of listed chemicals and tableting/encapsulating machines and importation/exportation of tableting and encapsulating machines

Imports/Exports of Chemicals and Controlled Substances

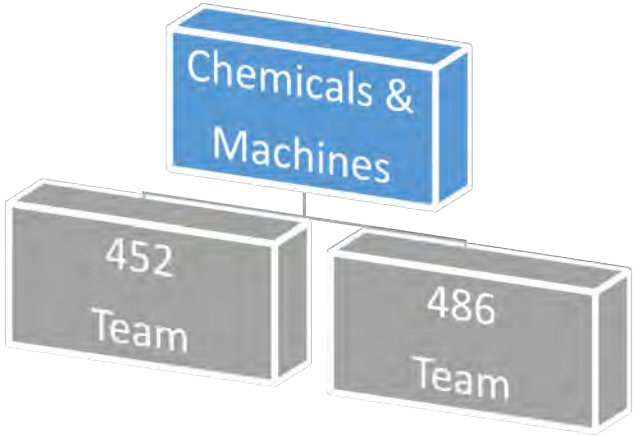
	DEA-357 (imports)	DEA-161 (exports)	DEA Form-236		DEA Form-486/A	
			Imports	Exports	Imports	Exports
Schedule I and II	✓	✓				
Schedule III Narcotic	✓	✓				
Schedule III Non-Narcotic (7369 requires a PERMIT)			✓	✓		
Schedule IV Narcotic	✓	✓				
Schedule IV Non-Narcotic			✓	✓		
Schedule V Narcotic	✓	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

DEA's Import/Export Section

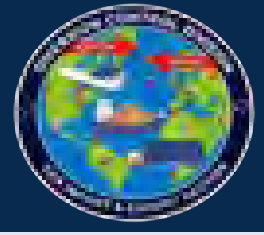
DRII (Controlled Substances)



DRIC (Chemicals and Machines)



Contacts



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 account setup
General Inquiries	DRI@dea.gov	All general inquires

Thomas Fahmy

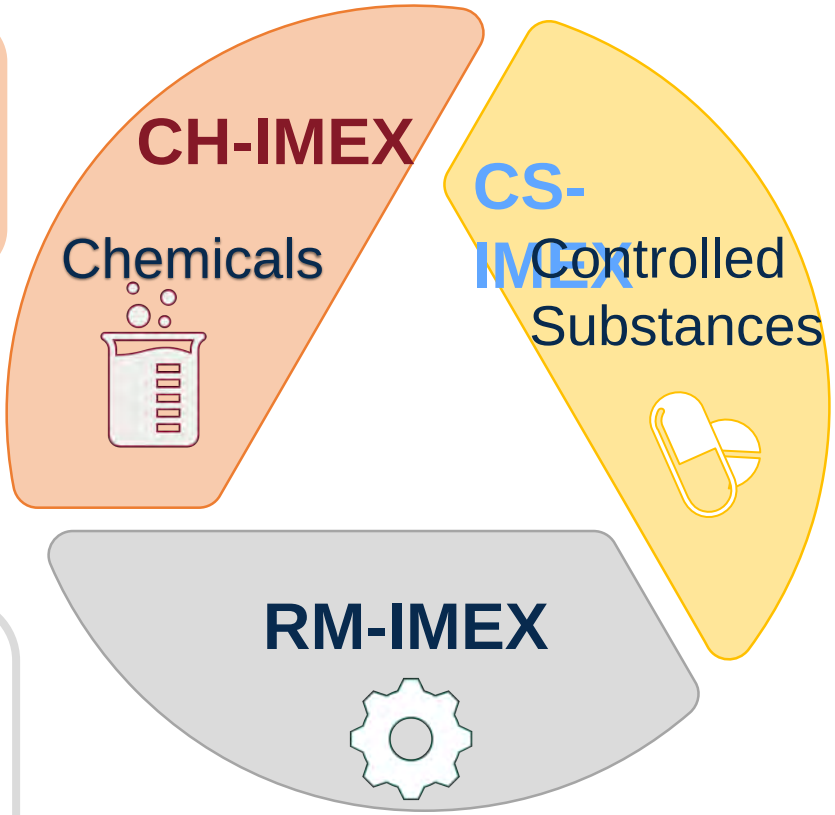
Program Analyst

Import Export

(IMEX) Online System

IMEX Online System

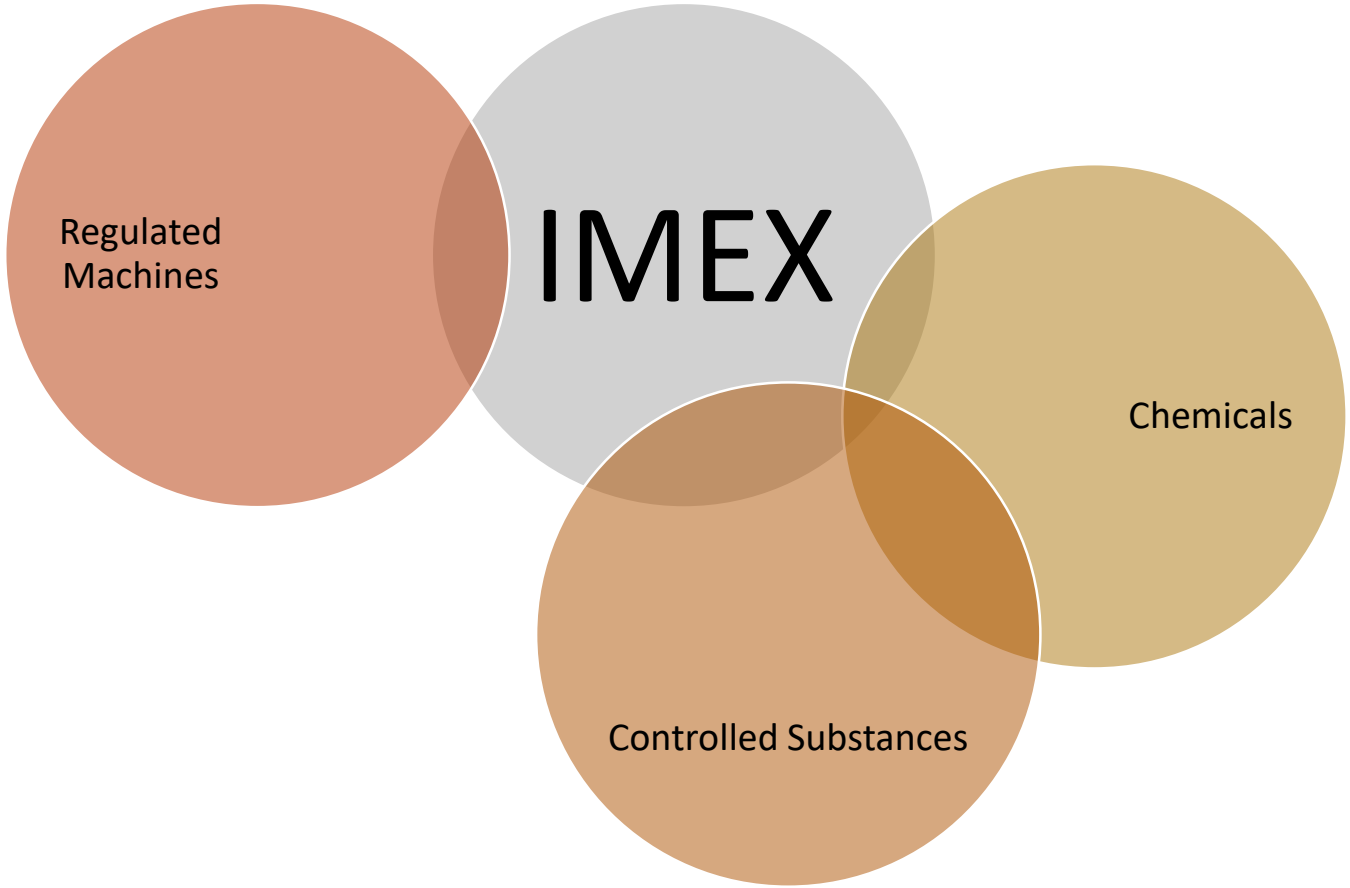
Chemical IMEX
Imports and exports of chemicals for DEA Forms 486 and 486A records



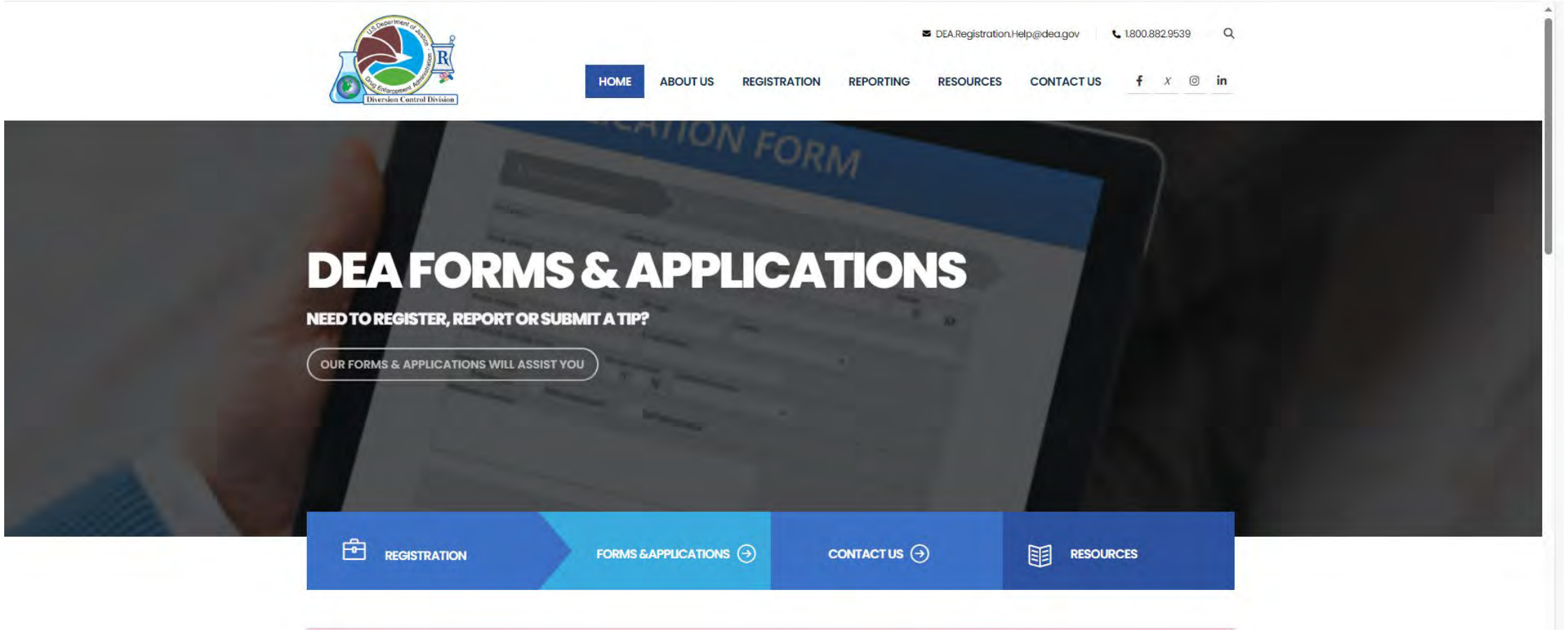
Controlled Substances IMEX
Imports and exports of controlled substances for DEA Forms 161, 236 and 357 records

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

Platform Differentiation within the IMEX Online System



IMEX Online System Deadiversion.usdoj.gov



IMEX Online System Deadiversion.usdoj.gov

DEA Import/Export Guidelines

- DEA's Acceptance Criteria for International Permits.
- Time lines for Importing and Exporting after the DEA Authorizes an application.
- Import/Export Requirement for return information for Controlled Substances.
- Importer/Exporter are responsible for ensuring their licenses are available in English.
- Best Practice for DEA Submission and Correspondence

DEA's Acceptance Criteria for International Permits

- The DEA only accepts a foreign permit or Letter of No Objection (LONO) that is issued by the Competent National Authorities for that country.

- The DEA follows the United Nations Office on Drugs and Crime.

Timelines for Importing and Exporting after DEA Authorizes an application

DEA Form	Must-file timeline	CFR Citation
DEA-357	No timeline. Registrant can ship 48 hours after application is approved or once registrant obtain the permit.	21 CFR 1312.12 - Application for import permit; return information.
DEA-161	No timeline. Registrant can ship 48 hours after application is approved or once registrant obtain the permit.	21 CFR 1312.22 - Application for export or reexport permit; return information.
DEA-236	Must submit 15 calendar days prior to the date of release by customs. However, once the application is approved, the remaining days to the 15 days are waved.	21 CFR 1312.18 - Import declaration and 21 CFR 1312.19 - Distribution of import declaration.
DEA-236	Must submit 15 calendar days prior to the date of release by customs. However, once the application is approved, the remaining days of the 15 days are waved.	21 CFR 1312.27 - Export/reexport declaration and 21 CFR 1312.28 - Distribution of export declaration.
Form-486	Must submit 15 calendar days prior to the date of release by customs. Once the registrant meets regular customer status, only 3 business days advanced notification is required.	21 CFR 1313-Importation and Exportation of List I and List II Chemicals
Form-486A	Must submit 15 calendar days prior to the date of release by customs. The 15 days advanced notification can not be waived.	21 CFR 1313.12 - Notification prior to import.

Import Requirement for Controlled Substances

Section: 21 CFR 1312.12 – Application for Import Permit

- **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.
- **Significance:** This ensures regulatory compliance for controlled substance imports.

Export Requirement for Controlled Substances

21 CFR 1312.21 and 1312.22(e)

Requirement of Authorization to Export

- **Key Requirement:** Submission of return information post-export.
- **Deadline:** Return information must be submitted within 30 Calendar days after the controlled substance is released by customs officer at the port of export.
- **Significance:** This ensures regulatory compliance for controlled substance export.

English Language Requirement for Import Licenses

§ 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.)**

Best Practice for DEA Submission and Correspondence

- **Labeling Attachment:** Ensure all PDF attachments, including permits, are clearly labeled before uploading. Refrain from including any non-essential information.

- **Email Communication:** Always mention your reference number, permit number, and tracking number in the subject line for quick reference.

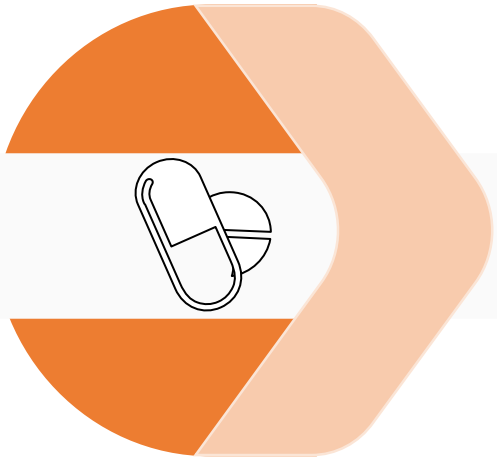
- **Issue Resolution:** Include your DEA Registration number and contact telephone number in the body of the email when seeking assistance from DRI.

Controlled Substances

Controlled Substances

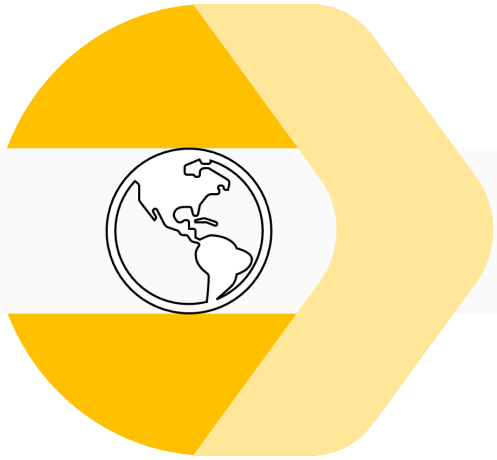
DEA Form #	DEA Form	Controlled Substance	Supporting Documents	Issued to Registrant
DEA-161	Export Permit	All Schedule I & II Narcotics in Schedule III & IV	Foreign Import Permit or Letter of No Objection (LONO) Certificate of No Objection (CNO) Determination Letters	DEA-36 Export Permit
DEA-161R	Export Permit For Re-exporting	All Schedule I & II Narcotics in Schedule III & IV	Foreign Import Permit or Letter of No Objection (LONO) Certificate of No Objection (CNO) (from 1st country only)	DEA-36 Export Permit
DEA-357	Import Permit	All Schedule I & II Narcotics in Schedule III, IV & V	Determination Letters	DEA-35 Import Permit
DEA-236	Export Declaration	Non-Narcotics in Schedule III, IV & V Narcotics in Schedule V	Foreign Import Permit or Letter of No Objection No Re-export Statement	DEA Transaction Identification Number
DEA-236	Export Declaration For Re-exporting	Non-Narcotics in Schedule III, IV & V Narcotics in Schedule V	Foreign Import Permit or Letter of No Objection from 1st and 2nd Countries No Re-export Statement from 2nd Countries C.F. (labeled)	DEA Transaction Identification Number
DEA-236	Import Declaration	Non-Narcotics in Schedule III, IV & V	N/A	DEA Transaction Identification Number

Controlled Substances Overview



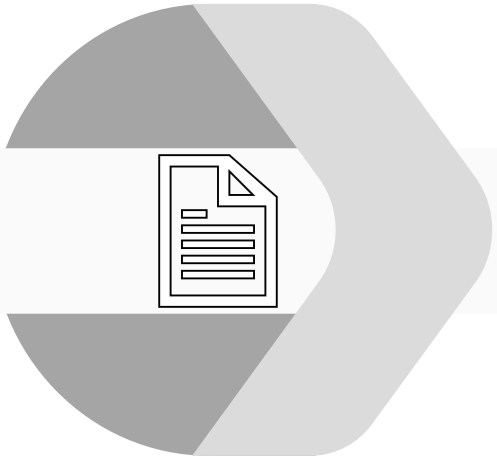
Purpose

Notifying DEA of all Exports and Imports of Controlled Substances



To DEA

Foreign Import Permit or Letter of No Objection (LONO) from Country National Authority



From DEA

DEA Form Export Permit or DEA Transaction Identification Number

Application Information

Import Export Product

US Exporter Address

Foreign Importer Address

Application number

Purchase and Invoice

Product name, substance, packaging detail, and weight

Foreign Import Permit or

LONO from Country National Authority

Transportation

Port of Importation/Exportation

Mode of Transportation

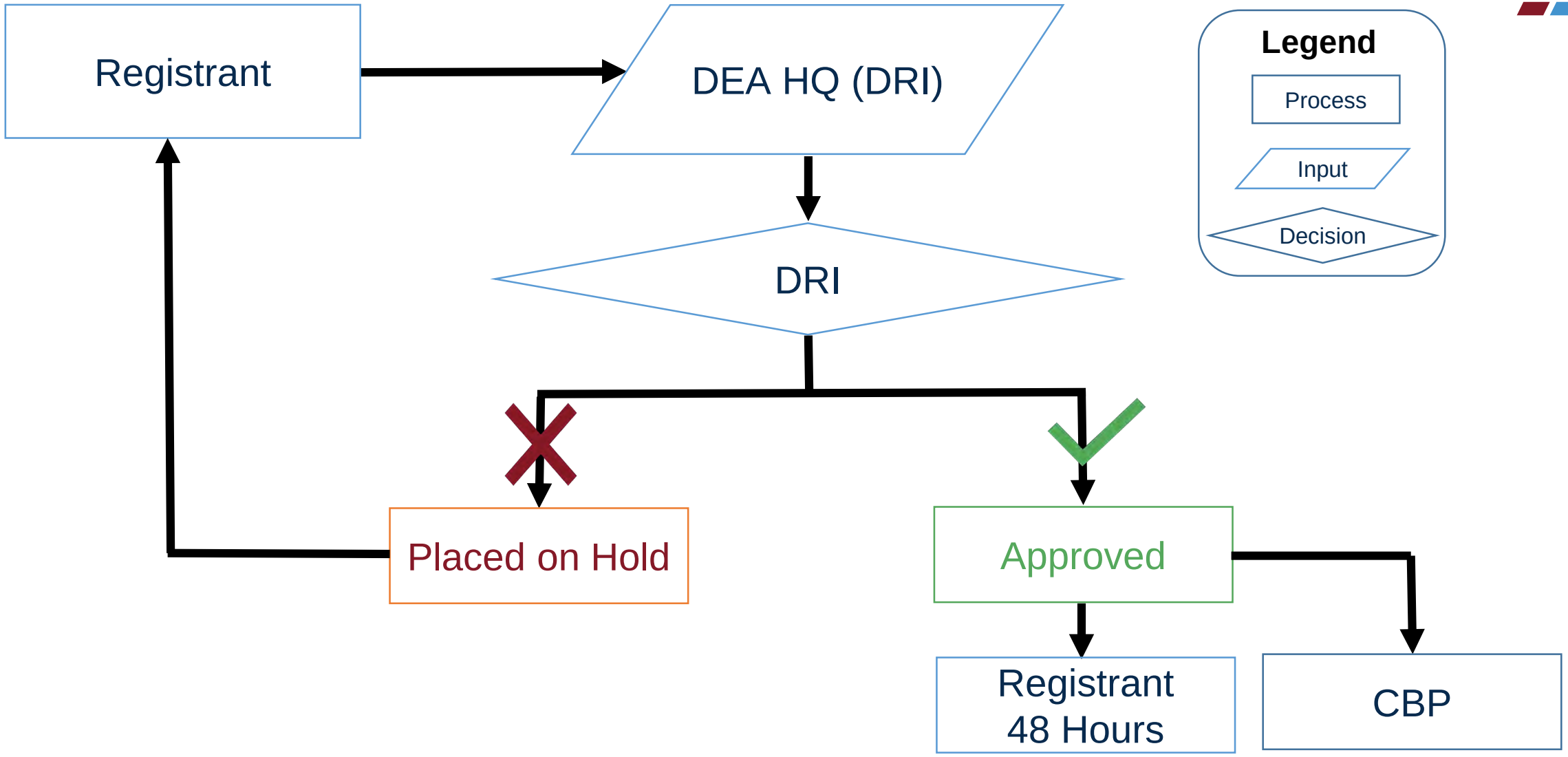
Name of Vessel/Carrier

DEA

Authorizing Individual

DEA Registration Number

Controlled Substances Process



DRUG ENFORCEMENT ADMINISTRATION

Aaronita Perry
Import/Export Specialist

DEA Form 161 and 161R

Purpose

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

To DEA

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

From DEA

DEA Form 36 Export Permit

DEA Form 161 and 161R Information

Import Export Product

US Exporter Address

Foreign Importer Address

Product name, packaging detail and weight

Foreign Import Permit or

LONO from Country National Authority

Transportation

Port of Importation/Exportation

Mode of Transportation

Name of Vessel/Carrier

DEA

Authorizing Individual

DEA Registration Number

English Language Requirement for Import Licenses

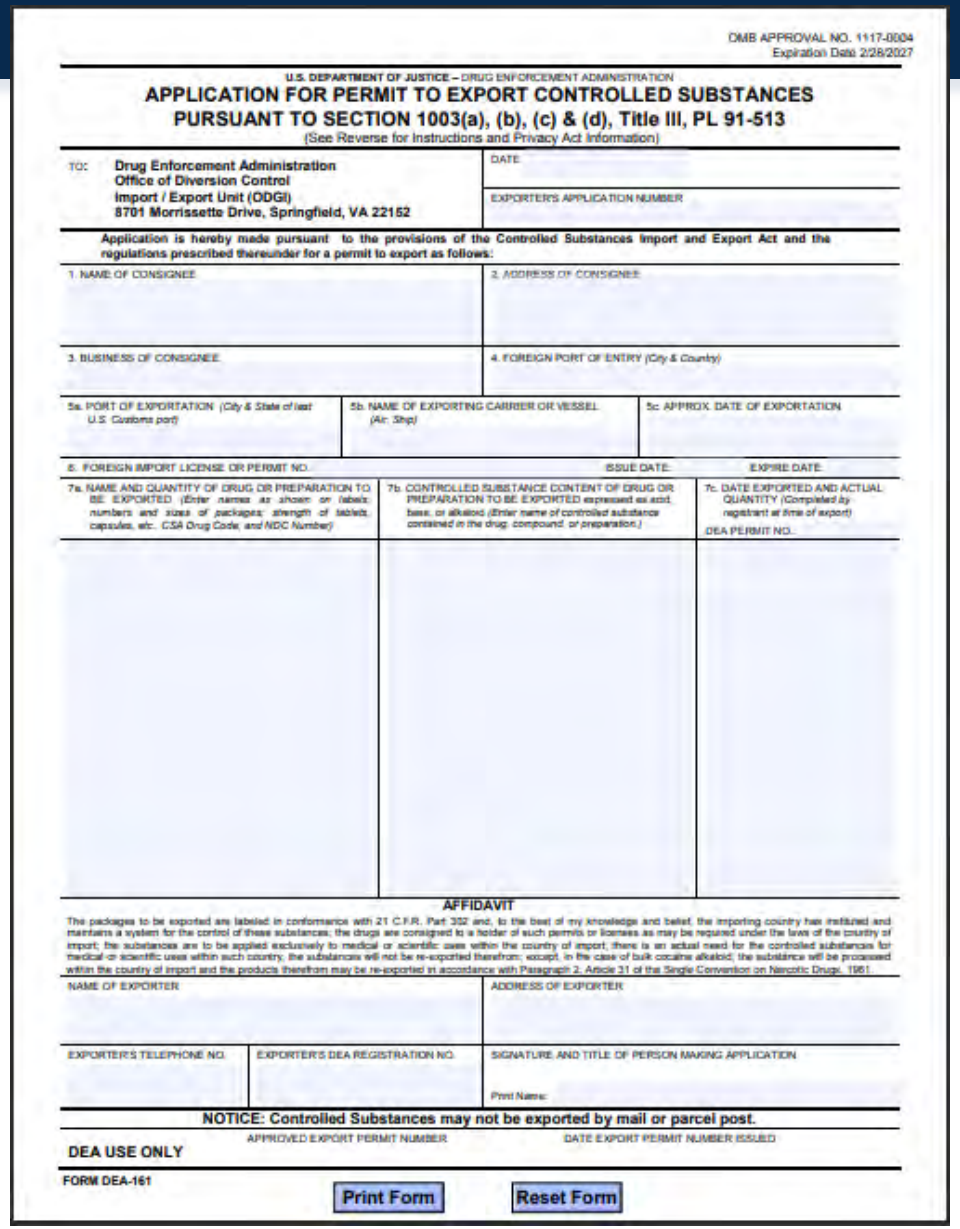
§ 1312.22 Application for export or reexport permit; return information.

(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.)**

Permit Application Process

- Initial export permit: DEA Form 161.



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

U.S. DEPARTMENT OF JUSTICE – DRUG ENFORCEMENT ADMINISTRATION

APPLICATION FOR PERMIT TO EXPORT CONTROLLED SUBSTANCES PURSUANT TO SECTION 1003(a), (b), (c) & (d), Title III, PL 91-513

(See Reverse for Instructions and Privacy Act Information)

TO: **Drug Enforcement Administration**
Office of Diversion Control
Import / Export Unit (ODGI)
8701 Morrissette Drive, Springfield, VA 22152

DATE

EXPORTER'S APPLICATION NUMBER

Application is hereby made pursuant to the provisions of the Controlled Substances Import and Export Act and the regulations prescribed thereunder for a permit to export as follows:

1. NAME OF CONSIGNEE

2. ADDRESS OF CONSIGNEE

3. BUSINESS OF CONSIGNEE

4. FOREIGN PORT OF ENTRY (City & Country)

5a. PORT OF EXPORTATION (City & State of last U.S. Customs port)

5b. NAME OF EXPORTING CARRIER OR VESSEL (Air: Ship)

5c. APPROX. DATE OF EXPORTATION

6. FOREIGN IMPORT LICENSE OR PERMIT NO. ISSUE DATE: EXPIRE DATE:

7a. NAME AND QUANTITY OF DRUG OR PREPARATION TO BE EXPORTED (Enter names as shown on labels; numbers and sizes of packages; 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 EXPORTED AND ACTUAL QUANTITY (Completed by registrant at time of export)
DEA PERMIT NO.

AFFIDAVIT

The packages to be exported are labeled in conformance with 21 C.F.R. Part 352 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.

NAME OF EXPORTER

ADDRESS OF EXPORTER

EXPORTER'S TELEPHONE NO.

EXPORTER'S DEA REGISTRATION NO.

SIGNATURE AND TITLE OF PERSON MAKING APPLICATION

Print Name:

NOTICE: Controlled Substances may not be exported by mail or parcel post.

DEA USE ONLY

APPROVED EXPORT PERMIT NUMBER

DATE EXPORT PERMIT NUMBER ISSUED

FORM DEA-161

Print Form Reset Form

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

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.

DEA Form 161R
Controlled Substances Export Reform Act of 2005. (Continued)

The CSERA requires the following:

1. Both the country to which the controlled substance is exported from the United States (referred to in this subsection as the 'first country') and the country to which the controlled substance is exported from the first country (referred to in this subsection as the 'second country') are parties to the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971.

2. The first country and the second country have each instituted and maintain, in conformity with such Conventions, a system of controls of imports of controlled substances which the DEA deems adequate.

3. With respect to the first country, the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance has been issued by the country.

DEA Form 161R
Controlled Substances Export Reform Act of 2005. (Continued)

4. With respect to the second country, substantial evidence is furnished to the DEA by the person who will export the controlled substance from the United States that:

(A) The controlled substance is to be consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance is to be issued by the country; ands

(B) The controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country.

5. The controlled substance will not be exported from the second country.

DEA Form 161R
Controlled Substances Export Reform Act of 2005. (Continued)

6. A permit to export the controlled substance from the United States has been issued by the DEA.

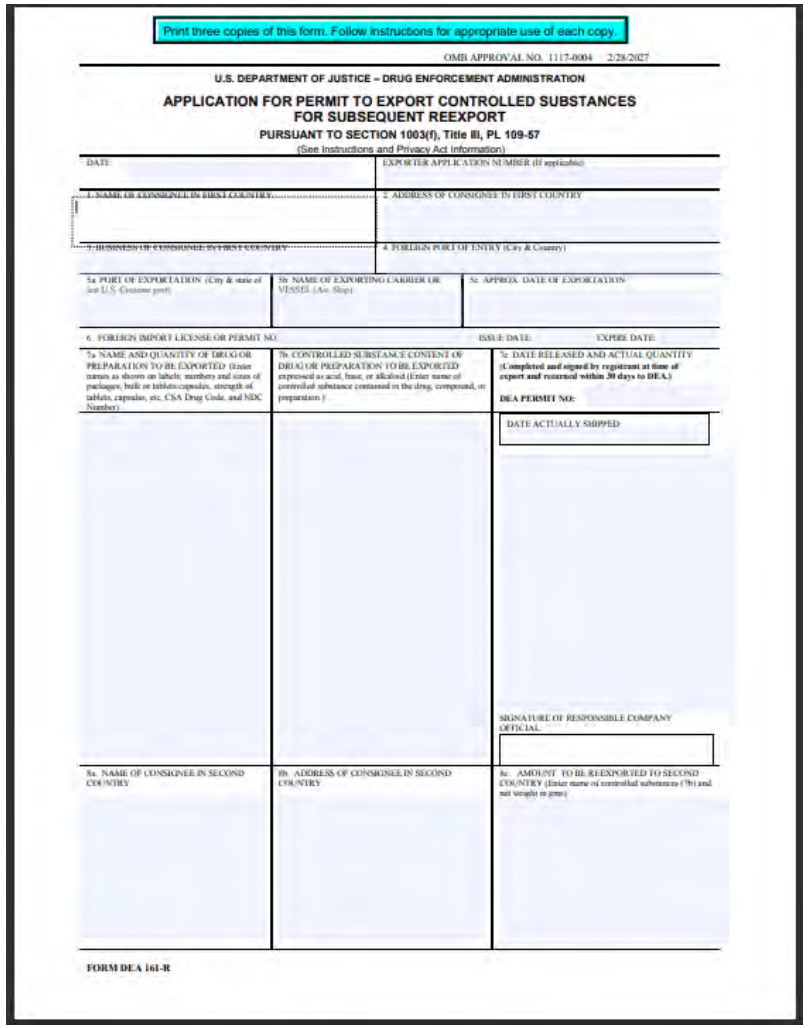
If either the first or second country refuses the shipment, the reexporter may seek authorization from the DEA to return the shipment to the United States. Shipments that have been rejected by the second country may not be returned to the first country.

Controlled substances may be exported from the United States to a “first country” for reexport 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.

An application for a permit to export controlled substances shall be made on DEA Form 161, and an application for a permit to reexport controlled substances shall be made on DEA Form 161R.

Permit Application Process

- **Initial export permit: DEA Form 161R.**



Print three copies of this form. Follow instructions for appropriate use of each copy.

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 | EXPORTER APPLICATION NUMBER (If applicable)

1. NAME OF CONSIGNEE IN FIRST COUNTRY | 2. ADDRESS OF CONSIGNEE IN FIRST COUNTRY

3. BUSINESS OF CONSIGNEE IN FIRST COUNTRY | 4. FOREIGN PORT OF ENTRY (City & Country)

5a. PORT OF EXPORTATION (City & state of last U.S. Customs port) | 5b. NAME OF EXPORTING CARRIER OR VESSEL (Air, Ship) | 5c. APPROX. DATE OF EXPORTATION

6. FOREIGN IMPORT LICENSE OR PERMIT NO. | ISSUE DATE: | EXPIRE DATE:

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.)**

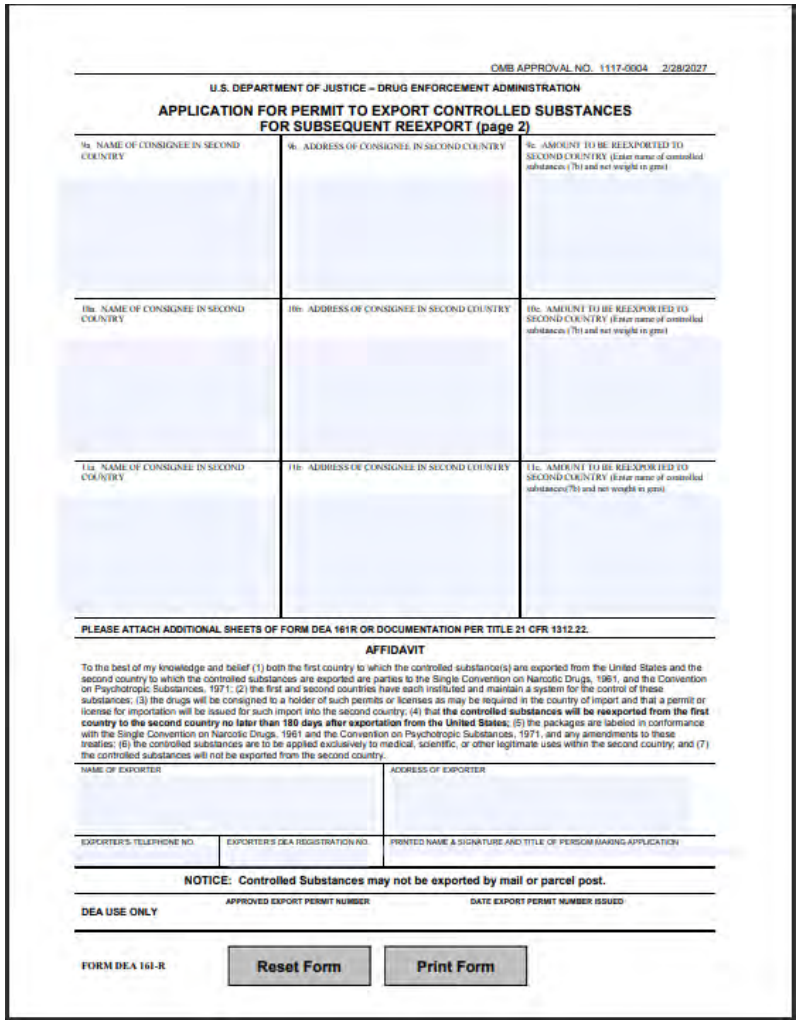
DEA PERMIT NO:

DATE ACTUALLY SHIPPED

SIGNATURE OF RESPONSIBLE COMPANY OFFICIAL

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)

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)

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)

10a. NAME OF CONSIGNEE IN SECOND COUNTRY | 10b. ADDRESS OF CONSIGNEE IN SECOND COUNTRY | 10c. AMOUNT TO BE REEXPORTED TO SECOND COUNTRY (Enter name of controlled substances (7b) and net weight in gms)

11a. NAME OF CONSIGNEE IN SECOND COUNTRY | 11b. ADDRESS OF CONSIGNEE 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 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.

NAME OF EXPORTER | ADDRESS OF EXPORTER

EXPORTER'S TELEPHONE NO. | EXPORTER'S DEA REGISTRATION NO. | PRINTED NAME & SIGNATURE AND TITLE OF PERSON MAKING APPLICATION

NOTICE: Controlled Substances may not be exported by mail or parcel post.

DEA USE ONLY | APPROVED EXPORT PERMIT NUMBER | DATE EXPORT PERMIT NUMBER ISSUED

FORM DEA 161-R

Reset Form | Print Form

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

DEA Form 357

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

DEA supporting documents for imports, which is maintained by registrant

From DEA

DEA Form 35 Import Permit

DEA Form 357 Information

Import Export Product

US Importer Address

Foreign Exporter Address

Product name, packaging detail and 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

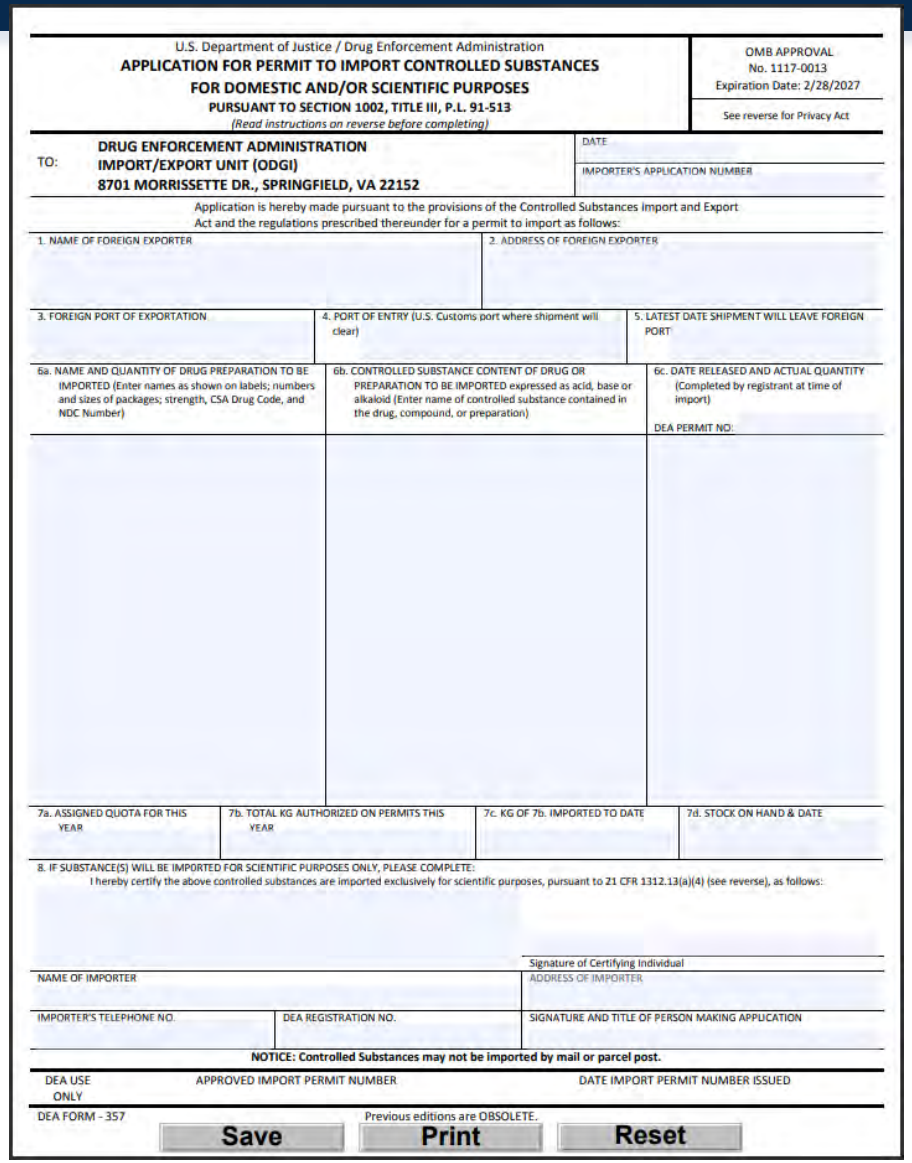
DEA

Authorizing Individual

DEA Registration Number

Permit Application Process

- Initial import permit: DEA Form 357.



U.S. Department of Justice / Drug Enforcement Administration

APPLICATION FOR PERMIT TO IMPORT CONTROLLED SUBSTANCES FOR DOMESTIC AND/OR SCIENTIFIC PURPOSES

PURSUANT TO SECTION 1002, TITLE III, P.L. 91-513

(Read instructions on reverse before completing)

OMB APPROVAL
No. 1117-0013
Expiration Date: 2/28/2027

See reverse for Privacy Act

TO: **DRUG ENFORCEMENT ADMINISTRATION**
IMPORT/EXPORT UNIT (ODGI)
8701 MORRISSETTE DR., SPRINGFIELD, VA 22152

DATE

IMPORTER'S APPLICATION NUMBER

Application is hereby made pursuant to the provisions of the Controlled Substances Import and Export Act and the regulations prescribed thereunder for a permit to import as follows:

1. NAME OF FOREIGN EXPORTER
2. ADDRESS OF FOREIGN EXPORTER
3. FOREIGN PORT OF EXPORTATION
4. PORT OF ENTRY (U.S. Customs port where shipment will clear)
5. LATEST DATE SHIPMENT WILL LEAVE FOREIGN PORT
6a. NAME AND QUANTITY OF DRUG PREPARATION TO BE IMPORTED (Enter names as shown on labels; numbers and sizes of packages; strength, CSA Drug Code, and NDC Number)
6b. CONTROLLED SUBSTANCE CONTENT OF DRUG OR PREPARATION TO BE IMPORTED expressed as acid, base or alkaloid (Enter name of controlled substance contained in the drug, compound, or preparation)
6c. DATE RELEASED AND ACTUAL QUANTITY (Completed by registrant at time of import)
DEA PERMIT NO:
7a. ASSIGNED QUOTA FOR THIS YEAR
7b. TOTAL KG AUTHORIZED ON PERMITS THIS YEAR
7c. KG OF 7b. IMPORTED TO DATE
7d. STOCK ON HAND & DATE
8. IF SUBSTANCE(S) WILL BE IMPORTED FOR SCIENTIFIC PURPOSES ONLY, PLEASE COMPLETE:
I hereby certify the above controlled substances are imported exclusively for scientific purposes, pursuant to 21 CFR 1312.13(a)(4) (see reverse), as follows:

Signature of Certifying Individual

NAME OF IMPORTER
ADDRESS OF IMPORTER
IMPORTER'S TELEPHONE NO.
DEA REGISTRATION NO.
SIGNATURE AND TITLE OF PERSON MAKING APPLICATION

NOTICE: Controlled Substances may not be imported by mail or parcel post.

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

DEA FORM - 357
Previous editions are OBSOLETE.

Save Print Reset

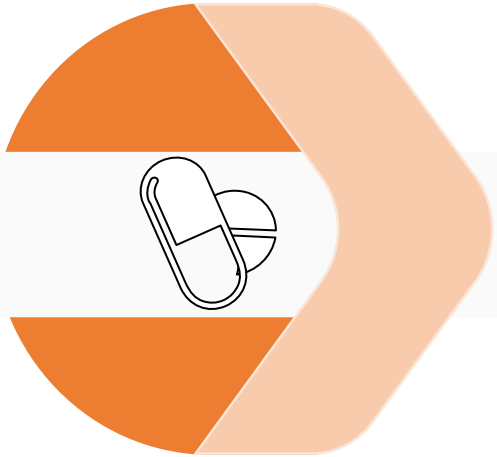
21 CFR 1312.12 - Application for import permit; return information.

DRUG ENFORCEMENT ADMINISTRATION

Barbara Clacks

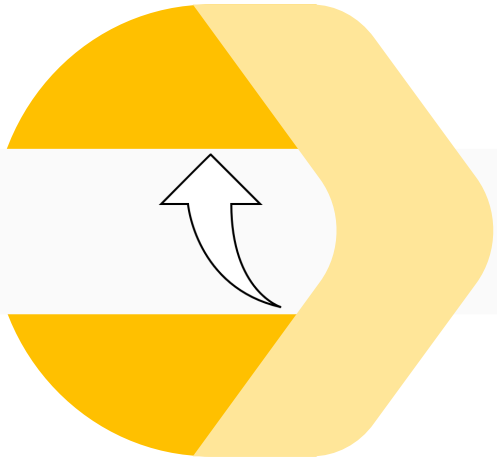
Import/Export Specialist

DEA Form 236 (Export)



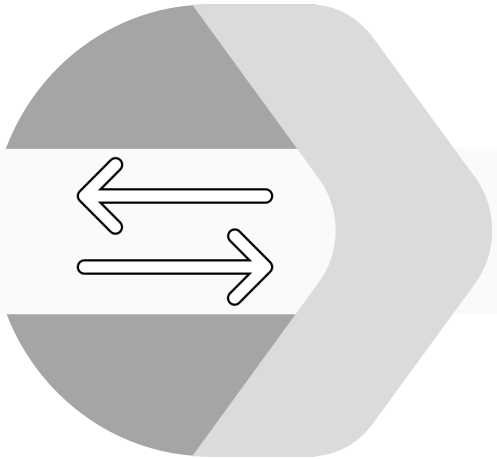
Purpose

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



To DEA

Foreign Export Permit of No Objection (LONO) and “no re-export statement”



From DEA

Transaction identification number

DEA Form 236 Information

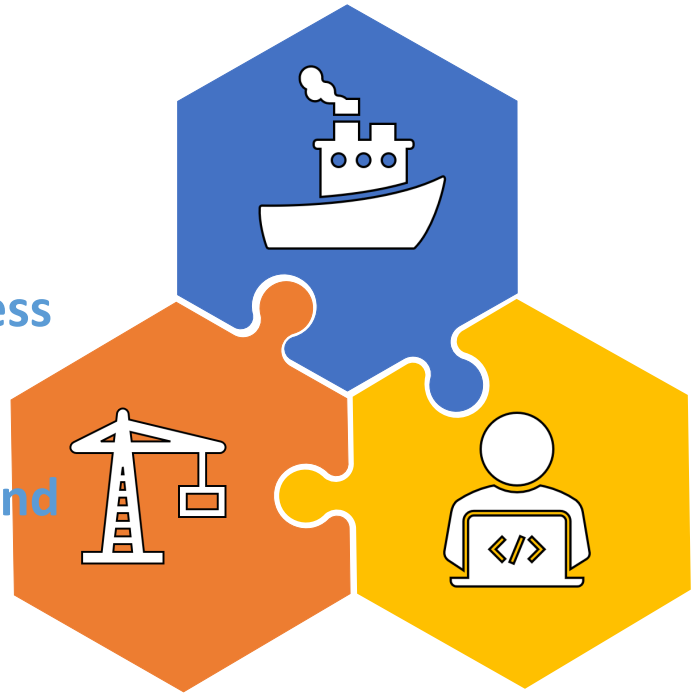
Import Export Product

US Importer/Exporter Address

Foreign Importer/Exporter Address

Product name, packaging detail and 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

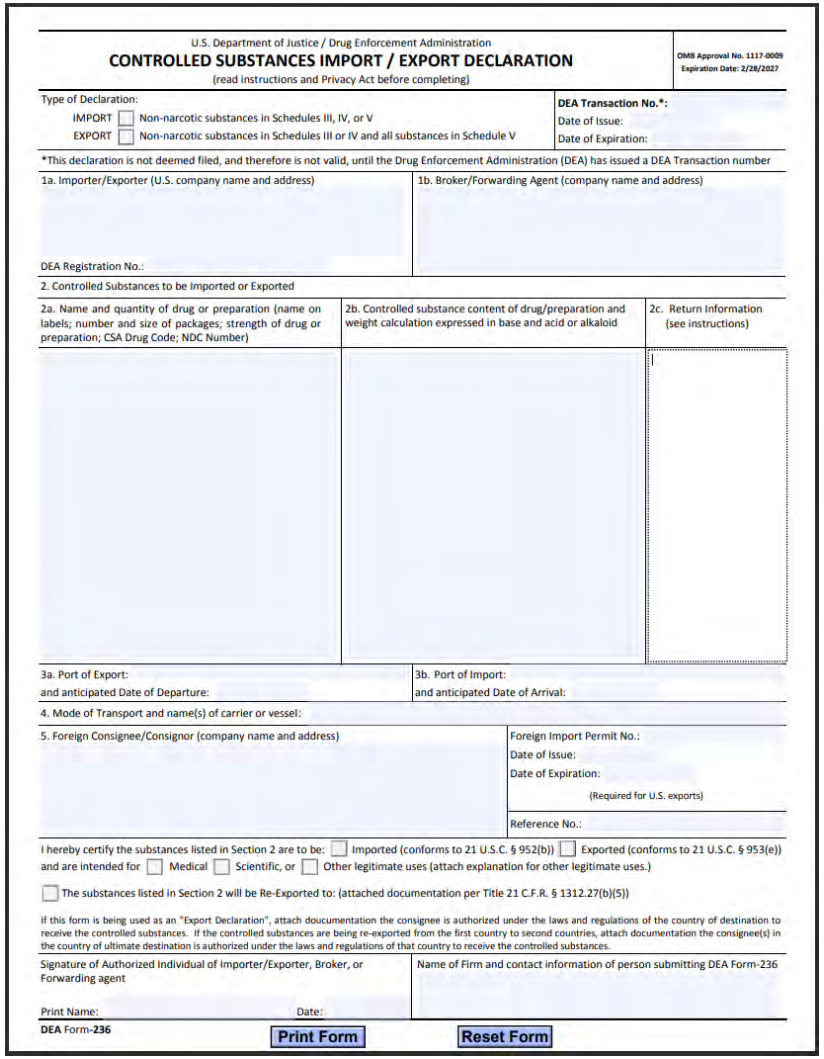
DEA

Authorizing Individual

DEA Registration Number

Declaration Application Process

- Initial export declaration: DEA Form 236.



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:
IMPORT ☐ Non-narcotic substances in Schedules III, IV, or V
EXPORT ☐ Non-narcotic substances in Schedules III or IV and all substances in Schedule V

DEA Transaction No.*:
Date of Issue:
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)

DEA Registration No.:

1b. Broker/Forwarding Agent (company name and address)

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)

3a. Port of Export:
and anticipated Date of Departure:

3b. Port of Import:
and anticipated Date of Arrival:

4. Mode of Transport and name(s) of carrier or vessel:

5. Foreign Consignee/Consignor (company name and address)

Foreign Import Permit No.:
Date of Issue:
Date of Expiration:
(Required for U.S. exports)

Reference No.:

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 documentation 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 Forwarding agent

Print Name:

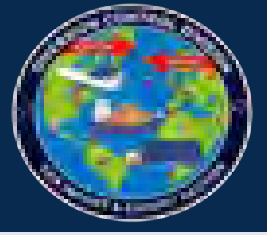
Date:

Name of Firm and contact information of person submitting DEA Form-236

DEA Form-236

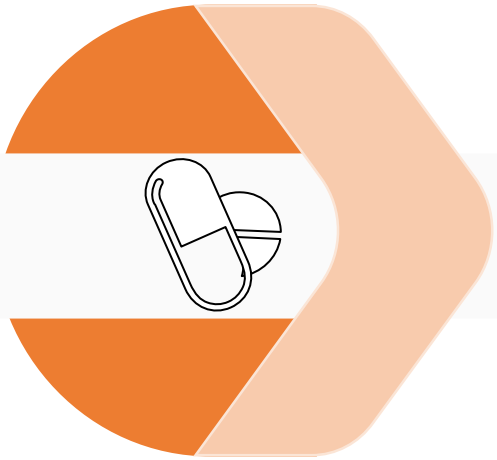
Print Form

Reset Form



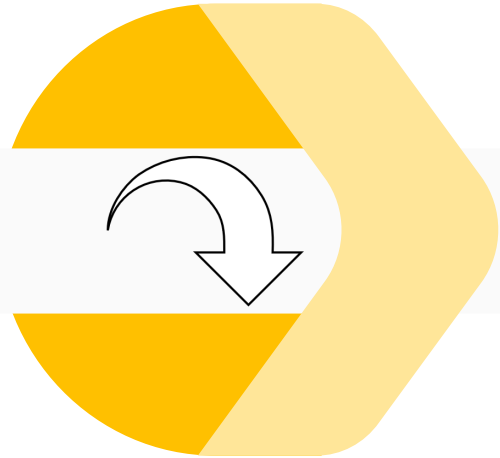
§ 1312.27 Export/reexport declaration.

DEA Form 236 (Re-export)



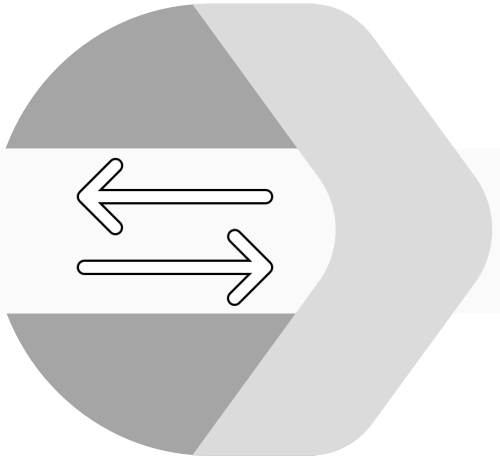
Purpose

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



To DEA

Foreign Export Permit of No Objection (LONO) and “no re-export statement”



From DEA

Transaction identification number

DEA Form 236 (Re-export) Information

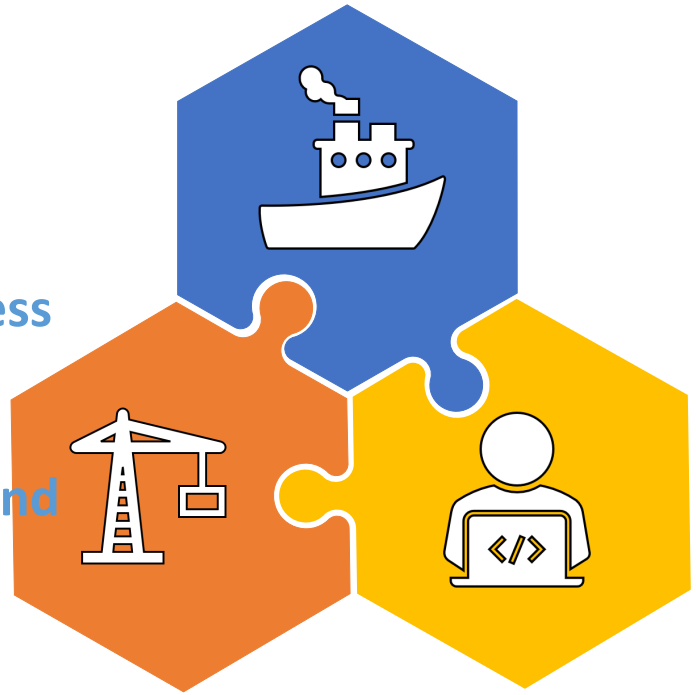
Import Export Product

US Importer/Exporter Address

Foreign Importer/Exporter Address

Product name, packaging detail and 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

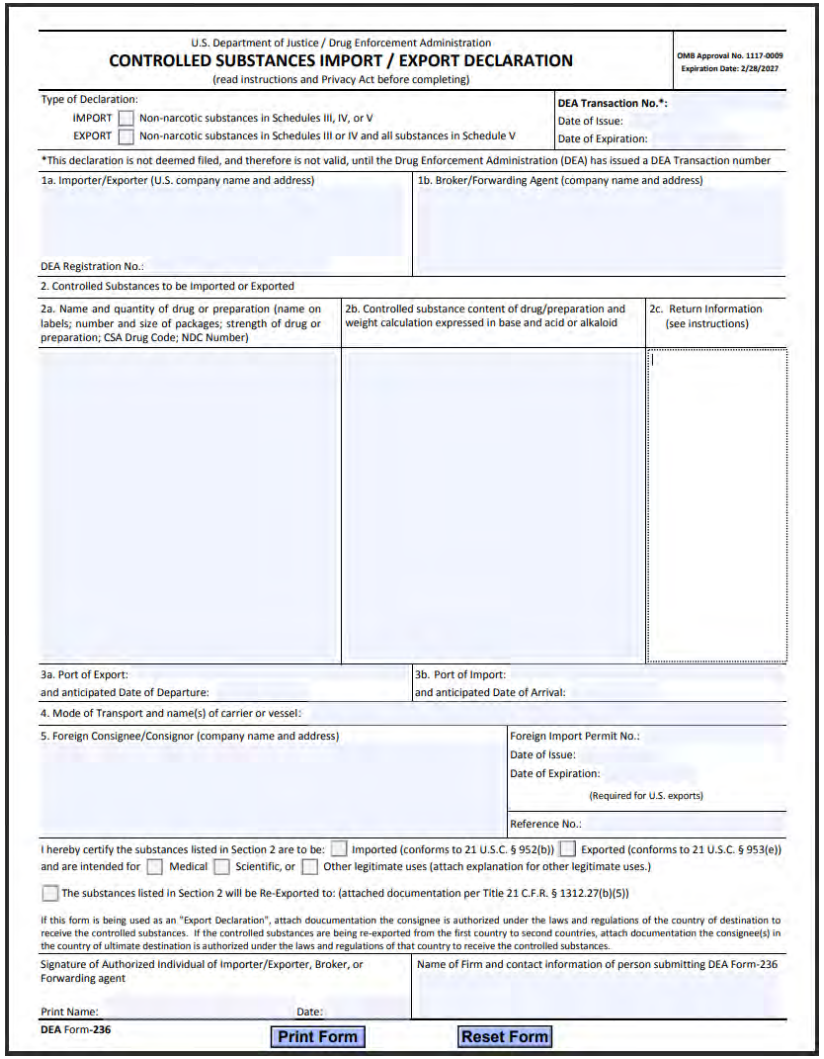
Authorizing Individual

DEA Registration Number

Declaration Application Process

- Initial export declaration: DEA Form 236

  (re-export).



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:
IMPORT ☐ Non-narcotic substances in Schedules III, IV, or V
EXPORT ☐ Non-narcotic substances in Schedules III or IV and all substances in Schedule V

DEA Transaction No.*:
Date of Issue:
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)

DEA Registration No.:

1b. Broker/Forwarding Agent (company name and address)

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)

3a. Port of Export:
and anticipated Date of Departure:

3b. Port of Import:
and anticipated Date of Arrival:

4. Mode of Transport and name(s) of carrier or vessel:

5. Foreign Consignee/Consignor (company name and address)

Foreign Import Permit No.:
Date of Issue:
Date of Expiration:
(Required for U.S. exports)

Reference No.:

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 documentation 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 Forwarding agent

Print Name:

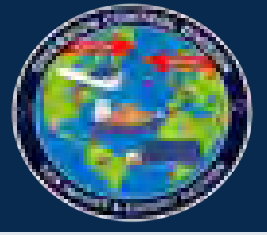
Date:

Name of Firm and contact information of person submitting DEA Form-236

DEA Form-236

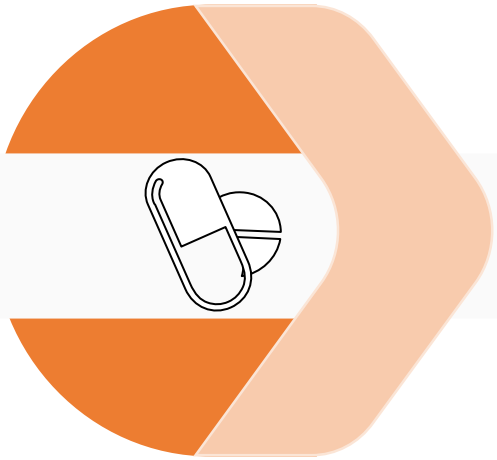
Print Form

Reset Form



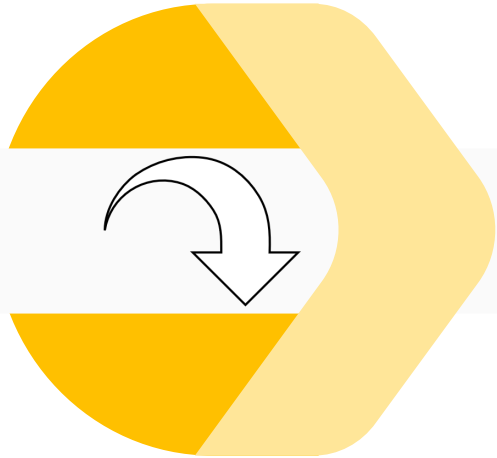
§ 1312.27 Export/reexport declaration.

DEA Form 236 (Import)



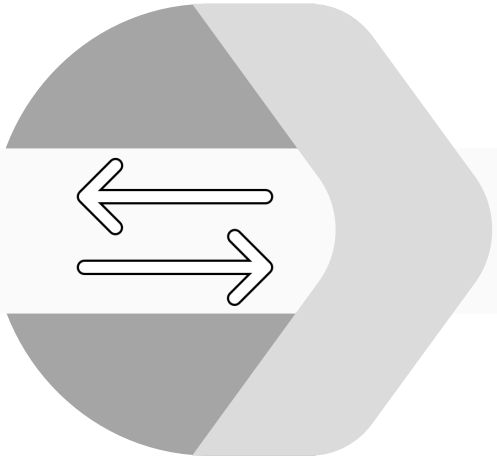
Purpose

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



To DEA

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



From DEA

Transaction identification number

DEA Form 236 Import Information

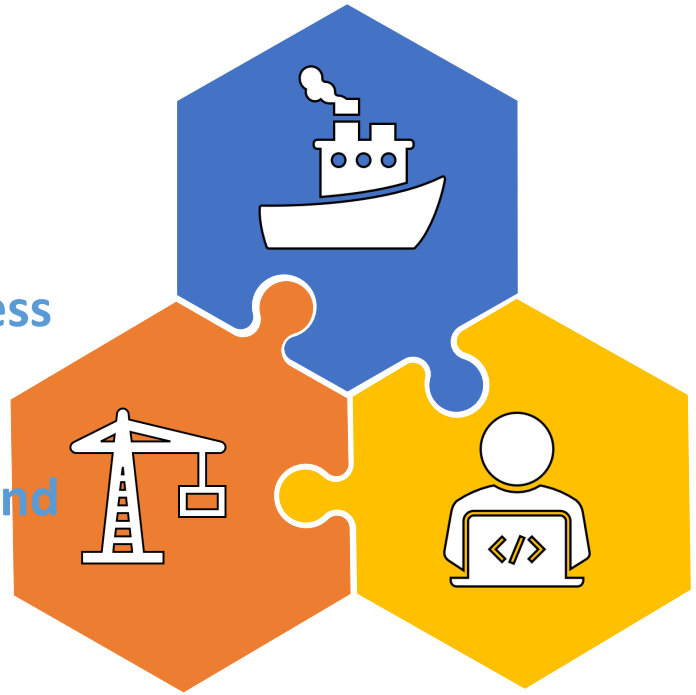
Import Export Product

US Importer Address

Foreign Importer/Exporter Address

Product name, packaging detail and weight

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



Transportation

Port of Importation

Mode of Transportation

Name of Vessel/Carrier

DEA

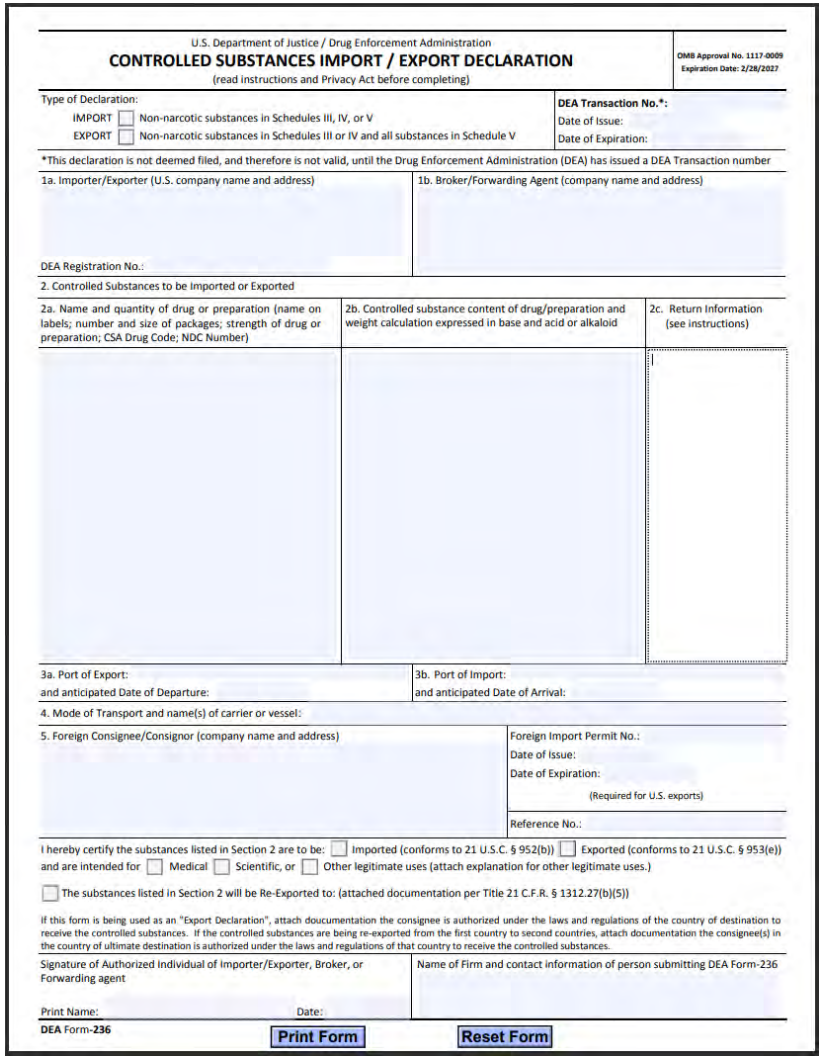
Authorizing Individual

DEA Registration Number

Declaration Application Process

- Initial export declaration: DEA Form 236

  (Import)



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:
IMPORT ☐ Non-narcotic substances in Schedules III, IV, or V
EXPORT ☐ Non-narcotic substances in Schedules III or IV and all substances in Schedule V

DEA Transaction No.*:
Date of Issue:
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)

DEA Registration No.:

1b. Broker/Forwarding Agent (company name and address)

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)

3a. Port of Export:
and anticipated Date of Departure:

3b. Port of Import:
and anticipated Date of Arrival:

4. Mode of Transport and name(s) of carrier or vessel:

5. Foreign Consignee/Consignor (company name and address)

Foreign Import Permit No.:
Date of Issue:
Date of Expiration:
(Required for U.S. exports)

Reference No.:

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 documentation 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 Forwarding agent

Print Name:

Date:

Name of Firm and contact information of person submitting DEA Form-236

DEA Form-236

Print Form

Reset Form

§ 1312.18 Import declaration.

§ 1312.19 Distribution of import declaration.

Chemical Import/Export Declaration

DEA Form 486

DEA Form 486

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 486	International 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 455 *instructions on deadiversion.usdoj.gov	Transaction ID Number

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 or import.

From DEA

Transaction identification number

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).

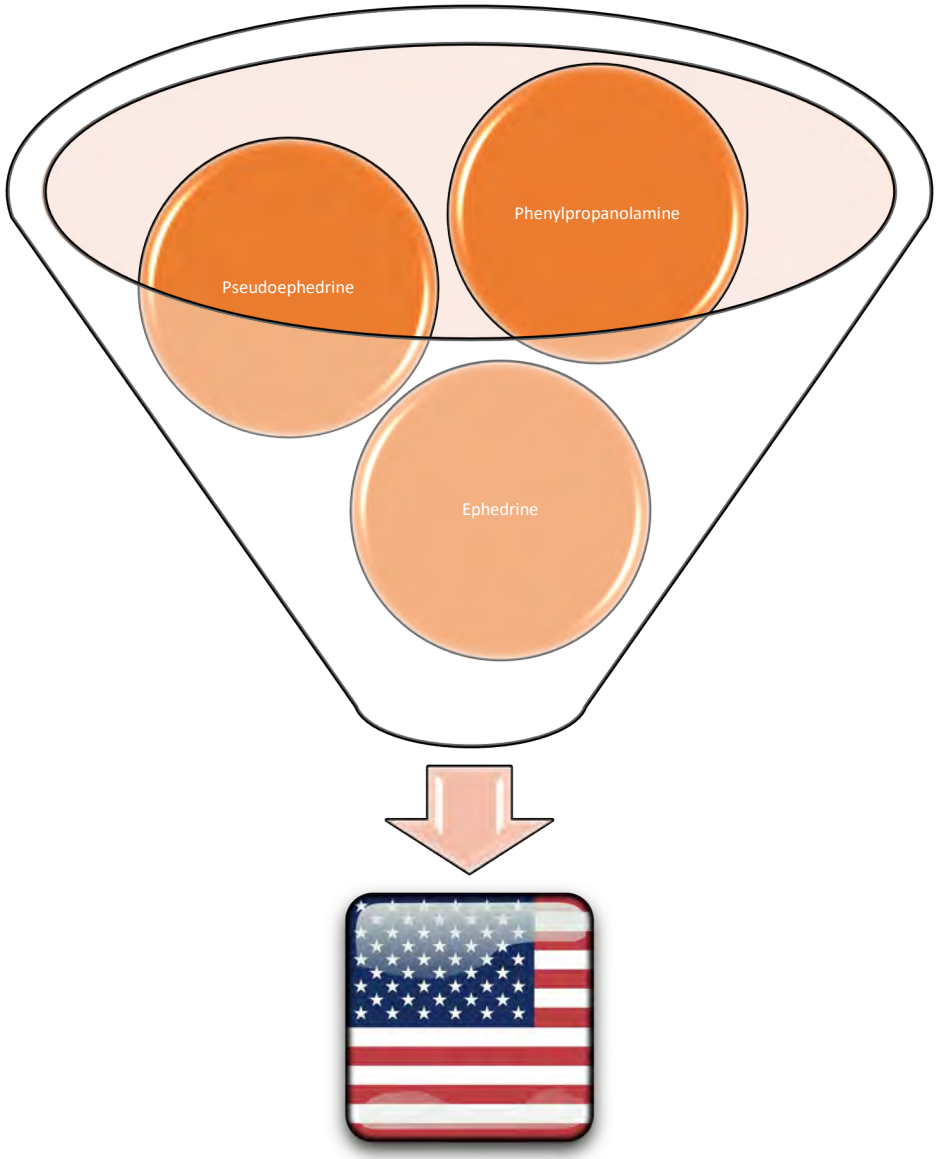
As a result, they are only required to provide 3 business days advanced notification prior to the import date.

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 Information

Import Export Product

US 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 Exportation

Mode of Transportation

Name of Vessel/Carrier

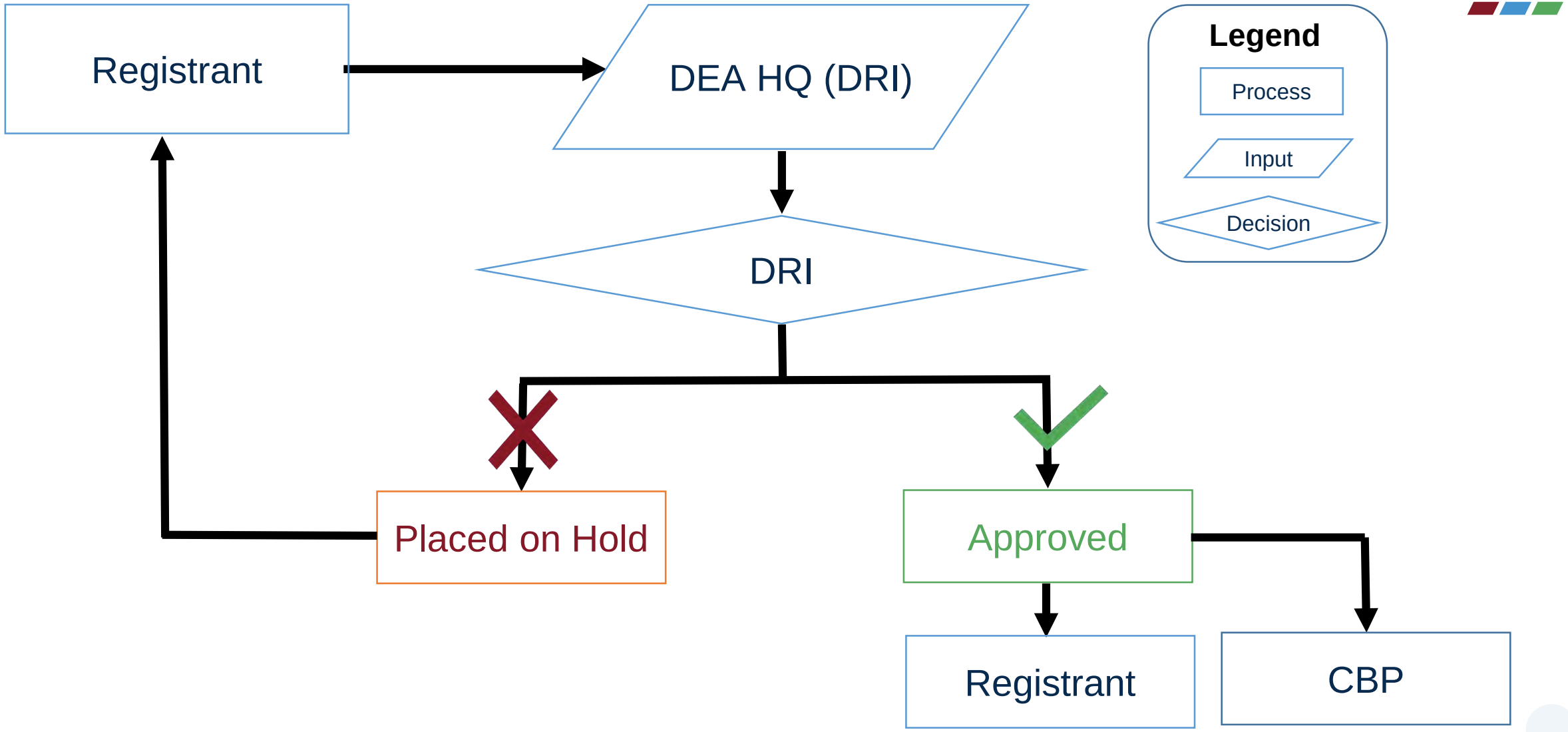
DEA

Authorizing Individual

DEA Registration Number

Return Information

DEA Form 486 Process




DIVERSION CONTROL DIVISION
EXPORT
IMPORT
DEA IMPORT & EXPORT SECTION

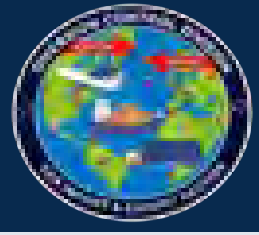
BREAK

Regulated Machines

DEA Form 452

Thomas Fahmy

Objectives



- Definitions
- Tableting & Encapsulating Machines
- Laws, Regulations, and Reporting Requirements
- Reports for Regulated Machines
- DEA Form 452 – Reports of Regulated Machines
- Required Recordkeeping
- Proof of Identification
- Seizure and Release of Regulated Machines
- Contacts

Definitions

- Title 21 United States Code (USC) Controlled Substances Act (CSA)

§802. Definitions

- **Regulated Person:**

  (38) The term "regulated person" means a person who manufactures, distributes, imports, or exports a listed chemical, a tableting machine, or an encapsulating machine or who acts as a broker or trader for an international transaction involving a listed chemical, a tableting machine, or an encapsulating machine.

- **Regulated Transaction:**

  (39) The term "regulated transaction" means —

  (B) a distribution, importation, or exportation of a tableting machine or encapsulating machine.

Tableting Machines

Manual

Desktop (Model TDP)

Floor

Tableting Machine means any manual, semi-automatic, or fully automatic equipment which may be used for the compaction or molding of powdered or granular solids, or semi-solid material, to produce coherent solid tablets. Title 21 C.F.R. 1300.02

Encapsulating Machines

Manual

Desktop (Model TDP)

Floor

Encapsulating Machine means any manual, semi-automatic, or fully automatic equipment which may be used to fill shells or capsules with any powdered, granular, or semi-solid material, or liquid material. Title 21 C.F.R. 1300.02

Law, Regulations, and Reporting Requirements

- **Title 21 C.F.R. 1310.05(b)(2) The regulated person also must file a report of the transaction (on DEA Form 452) with the Administration through the DEA Diversion Control Division secure network application.**

- **Domestic Transfer: DEA form 452 must be filed *within 15 calendar days* after the shipment of the machine to the purchaser.**

- **Import and Export Transfer: DEA form 452 must be filed *within 15 calendar days* before the shipment of the machine to the purchaser.**

Reports for Regulated Machines

IMEX Online System Deadiversion.usdoj.gov

Reports for Regulated Machines

DEA.Registration.Help@dea.gov 1.800.882.9539

HOME ABOUT US REGISTRATION REPORTING RESOURCES CONTACT US

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.

NEW! Letter from DEA Administrator Anne Milgram: E-Comerce Platforms Selling Pill Press Machines

Transactions of Regulated Machines Online

Regulated Machines Online

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

Statutes and Regulations

Please see Title 21, Chapter 13, of the United States Code and Title 21, Parts 1300 to 1321, of the Code of Federal Regulations for

Reports for Regulated Machines

HOME ABOUT US REGISTRATION REPORTING RESOURCES CONTACT US

Content of records and reports: 21 C.F.R. § 1310.06.

Proof of identity: 21 C.F.R. § 1310.07.

Submit a report using the DEA Form 452 Online

In order to submit a report for an import, export, or domestic transaction of a regulated machine using the DEA Form 452, you must first set up an account through DEA's secure network system. Once an account has been set up, you may begin electronically submitting transactions through the secure network application. Reference guides are provided below:

Registering/Creating a Company User Account (PDF)

Completing a DEA Form 452 for Import (PDF)

Completing a DEA Form 452 for Export (PDF)

Completing a DEA Form 452 for Domestic Transfer (PDF)

Contact:

For assistance, please contact the Import/Export Section via email at: Tablet-EncapsuleMachine@dea.gov

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

Purpose

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

To DEA

- **A DEA Notification Form 452 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.**

For the DEA Form 452

Import/Export & Product	Transportation	DEA
		
Seller, Buyer, Broker with address	Port of Importation/Exportation with date	Authorizing Individual
Point of Contact	Mode of Transportation	DEA Registration Number (if any)
Date of Transaction		
Purpose and Need		

DEA Form 452 - Reports for Regulated Machines

Drug Enforcement Administration
Reports for Regulated Machines

Web Tracking No.:

Federal Regulations require a regulated person to submit a detailed report of any Import or Export of tableting or encapsulating machines. A tableting machine or encapsulating machine may not be imported or exported until a DEA transaction identification has been filed by the Administration. Federal regulations require a regulated person to submit a detailed report of all domestic regulated transactions in a tableting machine or encapsulating machine.

1. Type of Request: — OMB Approval No. 1117-0024 — Expiration Date: 11/[redacted]

2. Type of Submission: ☐ ORIGINAL ☐ AMENDED ☐ WITHDRAWAL

3. Purpose Need: ☐ Medical ☐ Commercial ☐ Scientific ☐ Other (please describe):

4. Proposed Date of Import:
Anticipated Port of Entry:

DEA Transaction ID:

5. Regulated Person: (Business Name, Business Address):

Registration Number (required if registered):
POC Name:
Email address:
Business Phone:

6. Broker/Forwarding Agent: (Business Name, Business Address):

Country:
POC Name:
Email address:
Business Phone:

7. Consignor: (Business Name, Business Address):

Country: CHINA
POC Name:
Email address:
Business Phone:

E-SIGNATURE OF AUTHORIZED INDIVIDUAL:

DATE:

PRIVACY ACT INFORMATION

AUTHORITY: Section 301 of the Controlled Substances Act of 1970 (PL 91-513).
PURPOSE: Report of Regulated Machines.
ROUTINE USES: The Controlled Substances Act authorizes the production of special reports required for statistical and analytical purposes. Disclosures of information from this system are made to the following categories of users for the purposes stated:
A. Other Federal law enforcement and regulatory agencies for law enforcement and regulatory purposes.
B. State and local law enforcement and regulatory agencies for law enforcement and regulatory purposes.
EFFECT: Failure to report may result in penalties under Section 402 and 403 of the Controlled Substances Act.
Under the Paperwork Reduction Act, a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Public reporting burden for this collection of information is estimated to average 15 minutes per response for imports, exports, and domestic transactions, and 5 minutes per response for Return Declarations, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Drug Enforcement Administration, Attn: Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, VA 22152; and to the Office of Management and Budget, Paperwork Reduction Project No. 1117-0024, Washington, D.C. 20503.
Freedom of Information: Please prominently identify any confidential business information per 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). In the event DEA receives a FOIA request to obtain such information, DEA will give written notice to the registrant to obtain such information. DEA will give written notice to the registrant to allow an opportunity to object prior to the release of information.

DEA FORM - 452 (Previous version obsolete.)

8. Description of Each Machine		DEA Transaction ID:
Machine Type: ☐ Encapsulating ☐ Tableting Serial #: Make: Model: ☐ Electric ☐ Manual Description:	Machine Type: ☐ Encapsulating ☐ Tableting Serial #: Make: Model: ☐ Electric ☐ Manual Description:	Machine Type: ☐ Encapsulating ☐ Tableting Serial #: Make: Model: ☐ Electric ☐ Manual Description:
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Required Recordkeeping

§1310.04 Maintenance of records.

(a) Every record required to be kept subject to §1310.03 for a List I chemical, *a tableting machine, or an encapsulating machine* shall be kept by the regulated person for 2 years after the date of the transaction.

Proof of Identification

- Regulated persons must identify the other party to the transaction.

- Transactions with a business: Use such methods as checking a telephone directory, credit bureau, Better Business Bureau, or DEA registration number. 21 C.F.R. 1310.07(b).

- When transacting business with a new representative of a firm, the regulated person must verify the claimed agency status of the representative. 21 C.F.R. 1310.07(c).

- Transactions with an individual or cash purchasers: Required to obtain proof of identity such as signature of the purchaser, drivers license, and one other form of identification. 21 C.F.R. 1310.07 (d).

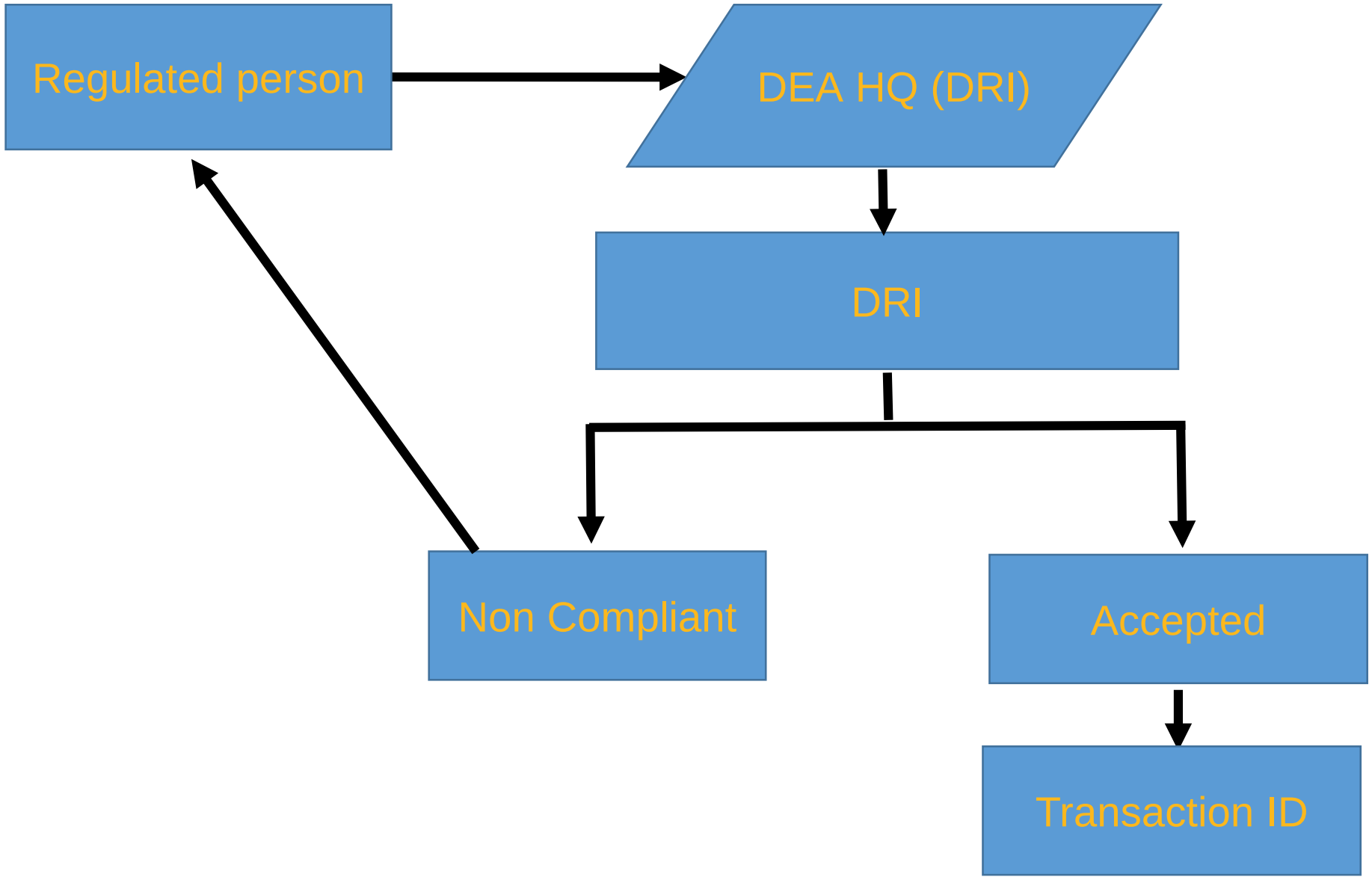
- Transactions with a new customer who is not an individual or cash customer, the regulated person shall establish the identity of the authorized purchasing agent or agents and have on file that person's signature, electronic password, or other identification. 21 C.F.R. 1310.07(e).

Retention and Release of Regulated Machines

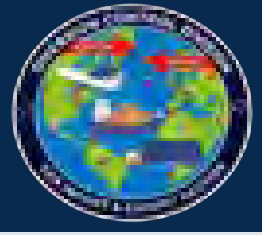
- **Failure of the regulated person to comply with the applicable laws and regulations may result in seizure of the shipment by the Customs and Border Protection (CBP) or Drug Enforcement Administration (DEA).**

- **Regulated persons will need to coordinate with their local DEA field offices and/or CBP in order to release detained machines.**

Process for DEA 452 forms



Contacts



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 account setup
General Inquiries	DRI@dea.gov	All general inquires