



# Chemical Conference 2025

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# Objectives



1

**Explain DEA's mission/function and roles, responsibilities and regulations to import and export Listed Chemicals**



2

**Explain how registrants report and business processes declarations for Listed Chemicals**



3

**Explain the requirements of reporting a regulated transactions for tableting and encapsulating machines**



# 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 issue Status  
Clarification 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



**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**

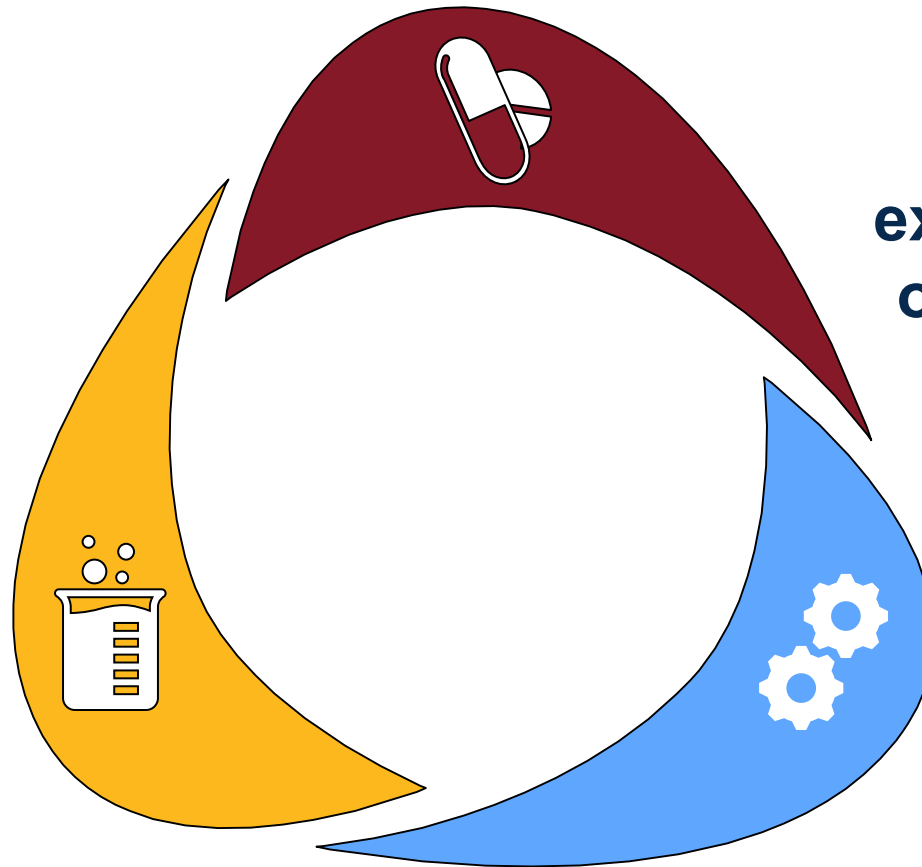
**Establishes statutory requirements to register and monitor importers and exporters of controlled substances and chemicals**



# 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**





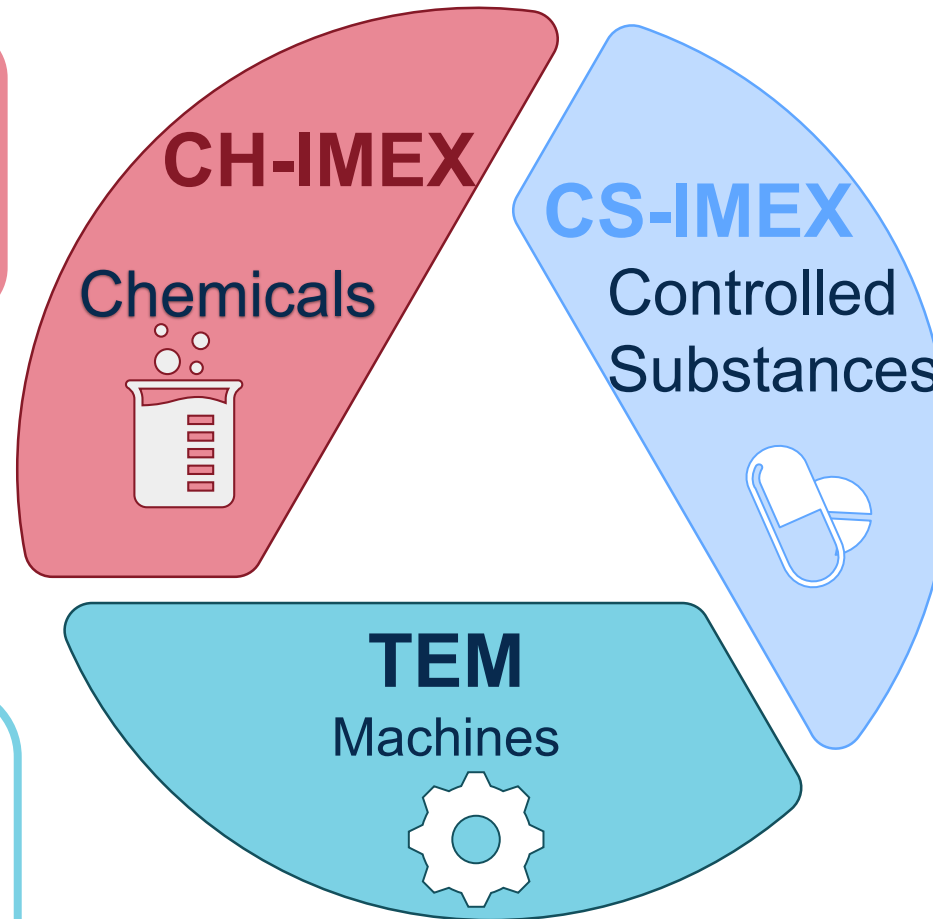
# Import Export Online System



# 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 TEM**  
Imports, Exports  
and Domestic transfers of  
tableting and encapsulating  
for DEA Form 452 records

# IMEX Online System

Deaiversion.usdoj.gov



DEA.Registration.Help@dea.gov

1.800.882.9539



HOME

ABOUT US

REGISTRATION

REPORTING

RESOURCES

CONTACT US



Reporting

ARCOS

BCM Online

Chemical Import/Export  
Declarations

CSOS

Theft/Loss Reporting

Import/Export

Medical Missions

Quotas

Registrant Record of  
Controlled Substances Destroyed

Regulated Machines  
(Tableting and Encapsulating)

Reports Required by 21 CFR

SORS

Submit a Tip to DEA

Year-end Reports



CLICK HERE TO GET STARTED!



REGISTRATION

FORMS & APPLICATIONS

CONTACT US



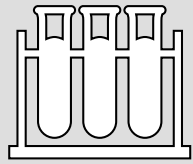
RESOURCES



# Chemical Import/Export Declaration DEA Form 486

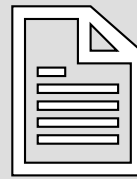


# DEA Form 486 Overview



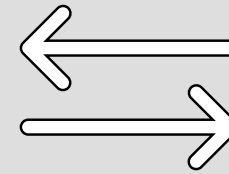
## Purpose

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 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 <a href="https://deadiversion.usdoj.gov">deadiversion.usdoj.gov</a>	Transaction ID Number

## Timelines for Importing and Exporting after DEA Authorizes an application



DEA Form	Must-file timeline	CFR Citation
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 cannot be waived.	21 CFR 1313.12 - Notification prior to import.

# Application Information



## Import Export Product

US Exporter Address

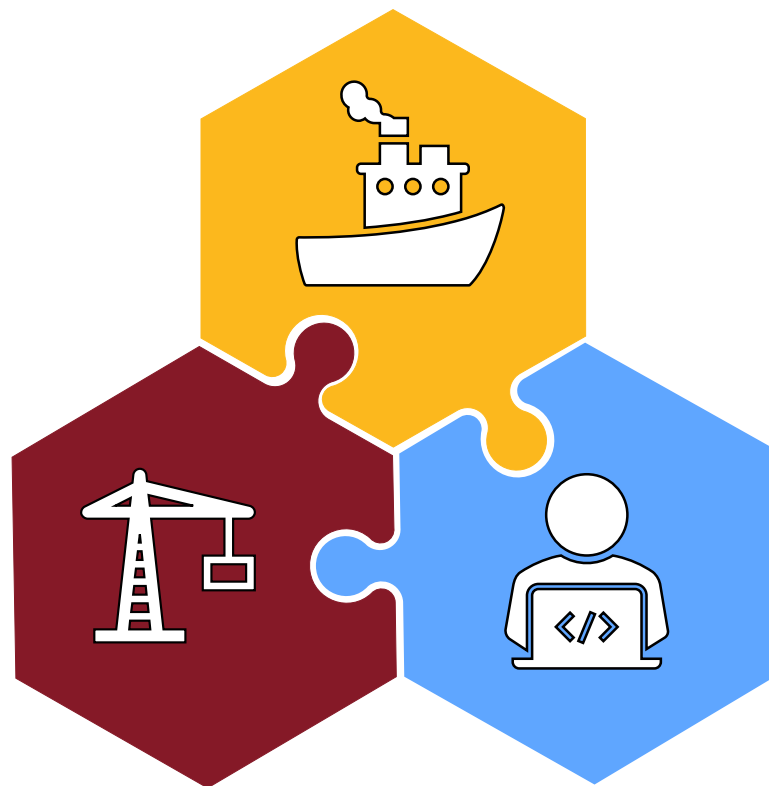
Foreign Importer Address

Application number

Purchase and Invoice

Product name, substance, packaging  
detail, and weight

Foreign Import Permit or  
Any supporting documentation from  
the Country's National Authority



## Transportation

Port of  
Importation/Exportation

Mode of Transportation

Name of Vessel/Carrier

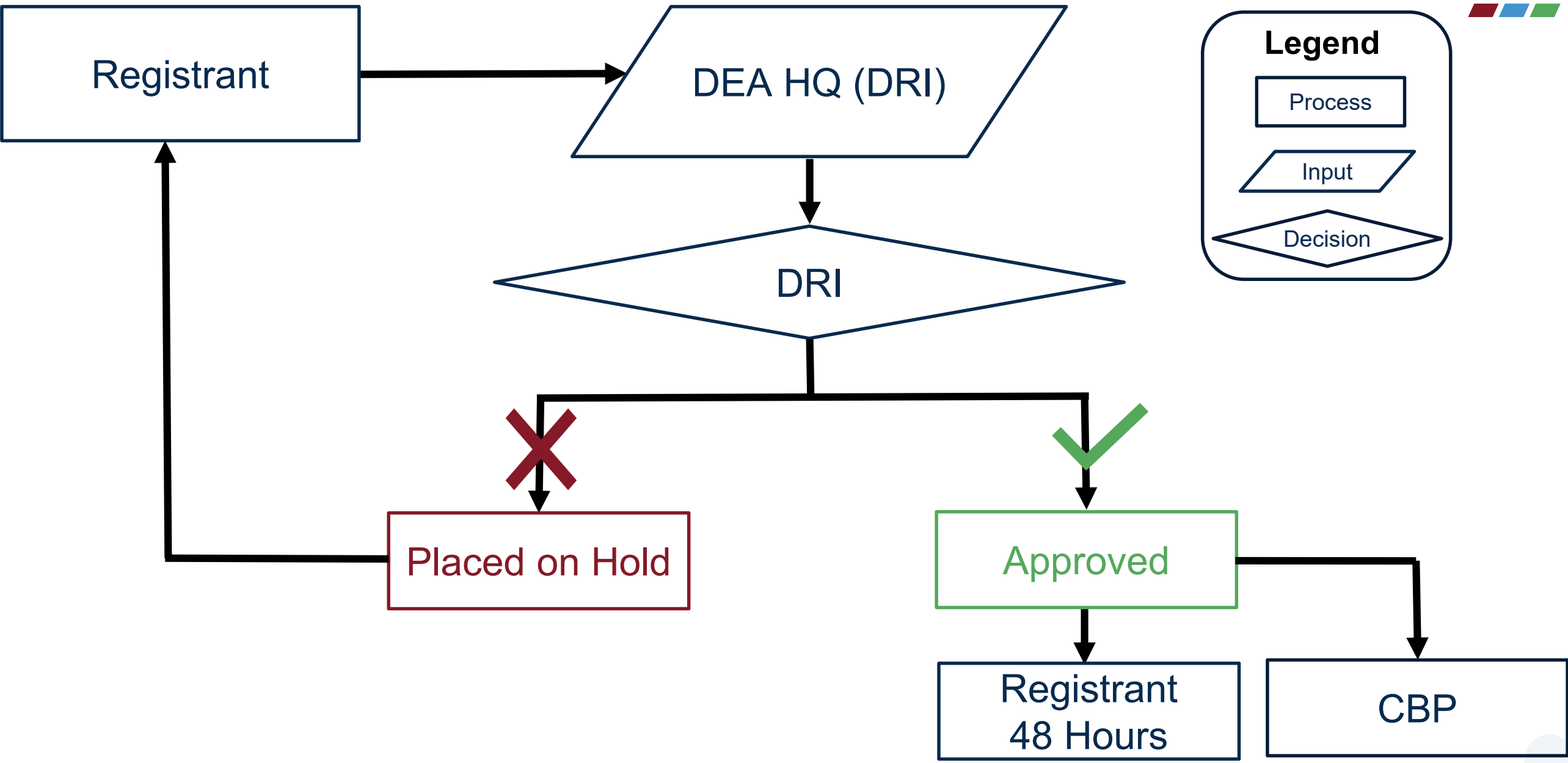
DEA

Authorizing Individual

DEA Registration Number



# Process



# 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.



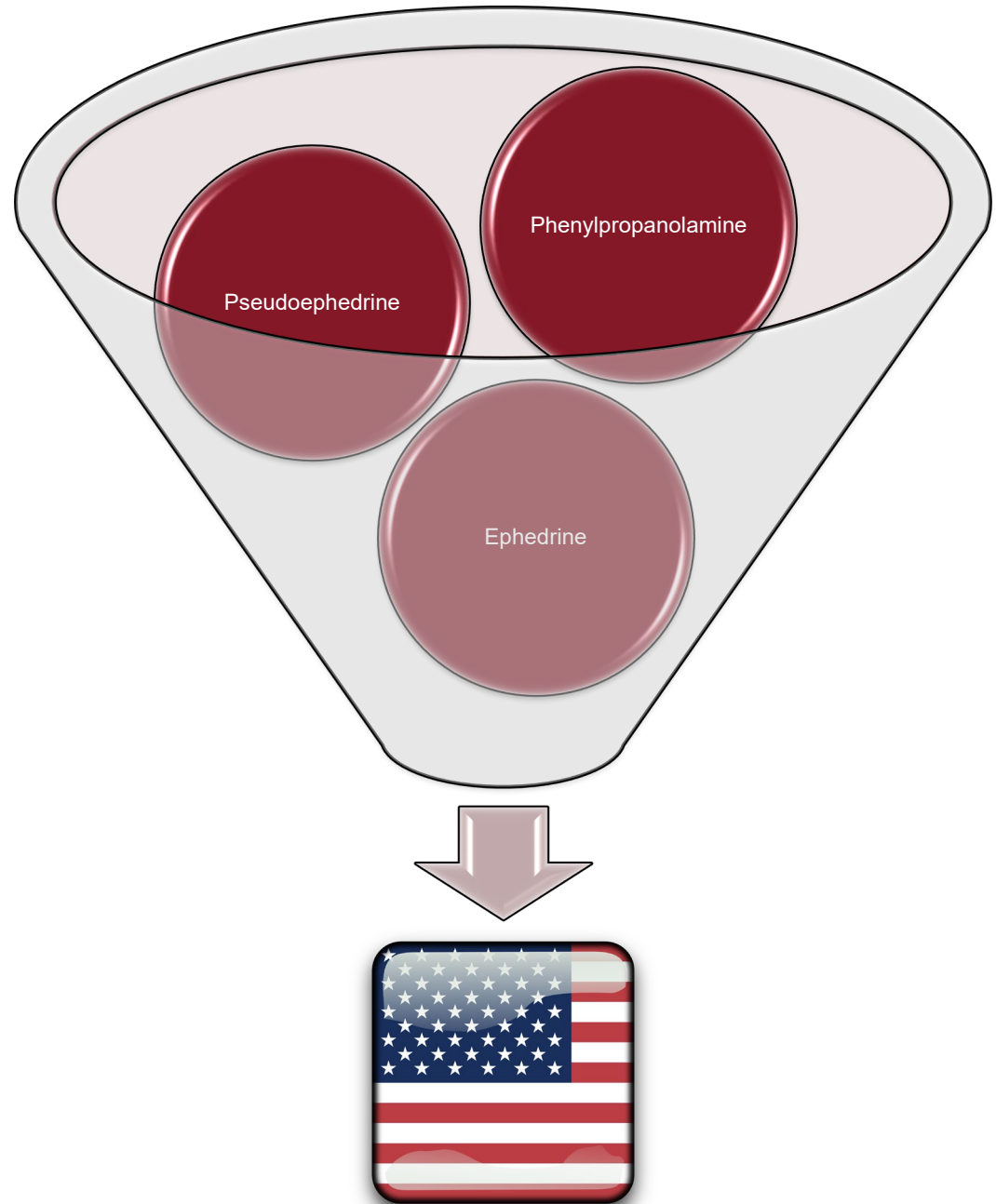
# DEA Form 486A (Imports)



**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.





# Regulated Machines

## DEA Form 452 Report for Regulated Machines



# 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.



# 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



## 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- Reports for Regulated Machines



## Import/Export & Product



**Seller, Buyer, Broker with address**

**Point of Contact**

**Date of Transaction**

**Purpose and Need**

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

## Transportation



**Port of Importation/Exportation with date**

**Mode of Transportation**

## DEA



**Authorizing Individual**

**DEA Registration Number (if any)**



## §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, driver's 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).



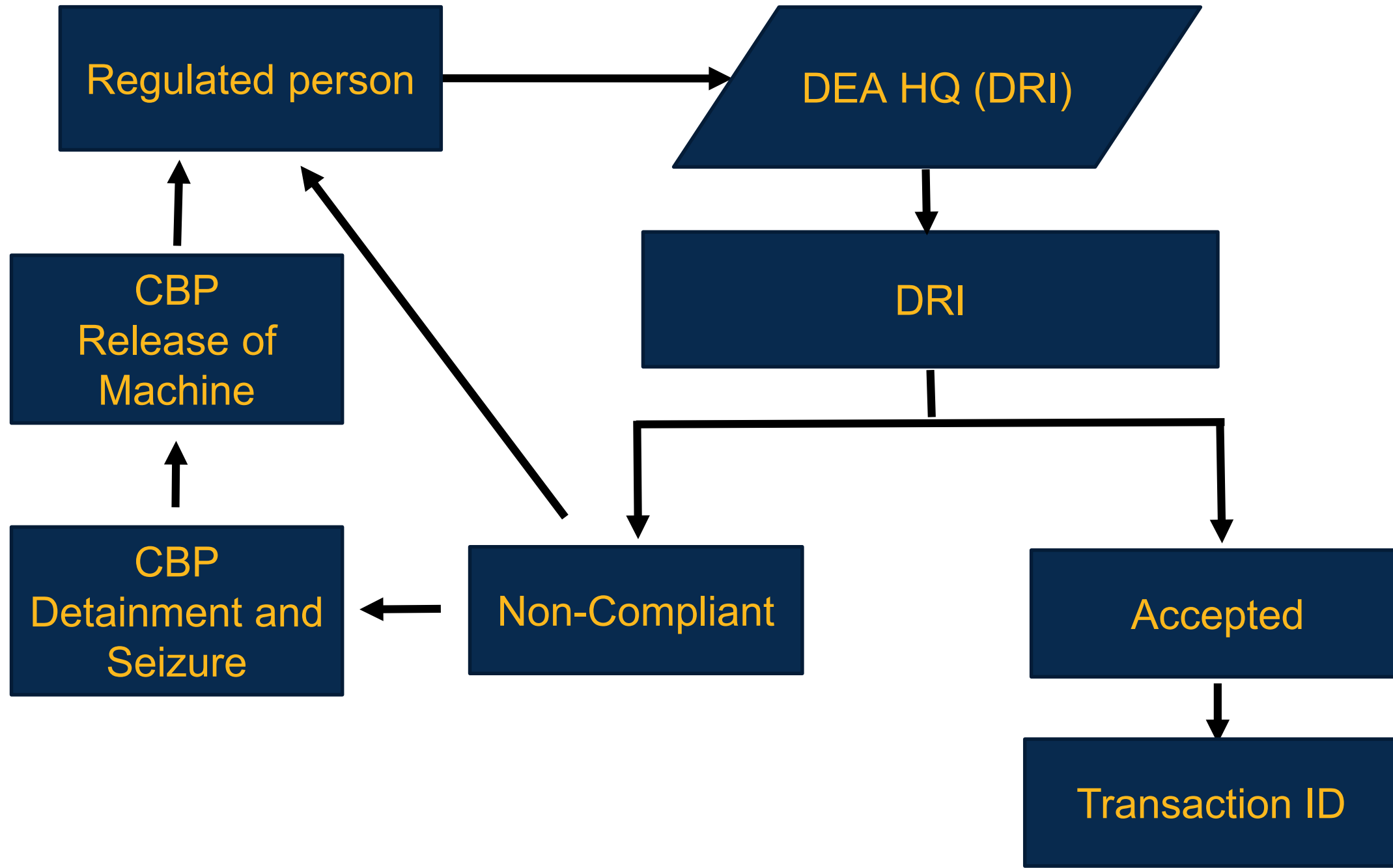
# **Detainment, Seizure, and Release of Regulated Machines**



- **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.**



# Process for DEA 452 forms



# Contacts



Form	Email	Topic
486	DEA486@dea.gov	List I and II chemicals including Ephedrine, Pseudoephedrine, Phenylpropanolamine and Chemical transshipments.
452	Tablet-EncapsuleMachine@dea.gov	Regulated Machines
Status Clarification Letters	SCL@dea.gov	
General Inquiries	DRI@dea.gov	All general inquires

