

# Drug Enforcement Agency (DEA) ACE Filer Guidance

## Drug Enforcement Agency (DEA)

The DEA implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are known as the “Controlled Substances Act” and the “Controlled Substances Import and Export Act,” respectively, and are collectively referred to as the “Controlled Substances Act” or “CSA”.

Controlled substances generally include narcotics, stimulants, depressants, and hallucinogens that have a potential for abuse and physical and psychological dependence, as well as anabolic steroids.

Listed chemicals are separately classified based on their use and importance to the illicit manufacture of controlled substances (List I or List II chemicals).

The Office of Diversion Control carries out the mission of the DEA to prevent, detect, and eliminate the diversion of these substances into the illicit drug market, and has oversight of the importation and exportation of controlled substances and listed chemicals.

Permit applications and declarations must be filed directly with DEA prior to their arrival into the United States. Effective August 1, 2017 DEA PGA line data is required to be filed in ACE with the ACE Cargo Release; paper or DIS filings will no longer be accepted.

Import Authority: 81 FR 96992 (12/30/16)



<https://www.deadiversion.usdoj.gov/index.html>

## List of Controlled Substances, List I and II regulated Chemicals

<https://www.deadiversion.usdoj.gov/schedules/index.html>

## Drug Enforcement Agency (DEA) Webinar on ACE Filing

<https://www.cbp.gov/trade/trade-community/border-interagency-executive-council-biec/biec-webinars>

## Points of Contact:

Name	Email
DEA Point of Contact	<a href="mailto:Stephen.m.via@usdoj.com">Stephen.m.via@usdoj.com</a> om

The DEA must authorize all imports of controlled substances and listed chemicals prior to their arrival into the United States. Permit applications and declarations must be filed directly with DEA prior to

filing the PGA Message Set for imports of controlled substances and listed chemical. The DEA Message set includes the below records:

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**ACE DEA PGA Message Set Tips**

**OI: Commercial Description**

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**PG01**

Data Element	Information
Government Agency Code	“DEA”
Government Agency Program Code	“DEA”
Confidential Information Indicator	“Y” if not disclaimed

**PG06: Country of Shipment**

Data Element	Information
Source Type Code	“CSH” for Country of Shipment
Country Code	Country Code of the country from where substance <b>is shipped</b> as provided to DEA by the registrant or regulated person (Review Applicable DEA Form)

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**PG14 – LPCO (License/Permit/Certificate)**

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LPCO Number is the Permit / Transaction ID authorization number issued by DEA and found on applicable DEA Forms

Data Element	Information
LPCO Transaction Type	“1” for single use
LPCO Number	DEA permit or transaction ID number (See DEA Form examples below)

The DEA issues one-time use only permits and declarations for each shipment of controlled substances or listed chemicals. The LPCO Number must be entered. This number is **seven alphanumeric characters in length (do not include the dash or amendment number)**

**PG19: Entity Role Code for Registrant or Regulated person**

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Data Element	Information
Entity Role Code	“LAP” for the registrant or regulated person
Entity Identification Code	“164”
Entity Number	DEA registration or company ID number

DEA registration or company ID - 9 characters in length – Can be found on Applicable DEA Form or provided by the Importer.

- Registration number for companies that handle controlled substances. Typically 2 alpha with 7 digit (total 9 characters) i.e. AB1234567
- Chemical company (List 1) if registered with DEA, first 6 Numeric and last 3 are alpha numeric i.e. 123456XYZ
- Company that does not handle controlled substances or List 1 chemicals but List 2 Chemicals has a pseudo Registration Number to allow reporting on DEA web site. Generally a 4 numeric, 3 alpha 2 numeric i.e. 1234ASD78

**PG22 – Document Identifier Code**

Report the Document Identifier Code only, **the form does NOT need to be uploaded in DIS**. DIS is NOT supported/required by ACE for DEA

DEA Form	Information	Document Identifier
DEA-35	Import permit for the import of any controlled substance listed in schedule I or II or any narcotic controlled substance listed in schedule III, IV, or V	911
DEA-236	Declaration for the import of any non-narcotic controlled substance listed in schedule III, IV, or V	921
DEA-486	Declaration for the import of any List I or II substance except Ephedrine, Pseudoephedrine, or Phenylpropanolamine	922
DEA-486A	Declaration for the import of Ephedrine, Pseudoephedrine, or Phenylpropanolamine	923

**PG30: Date of Anticipated Arrival**

The Anticipated Arrival date must be on/or after issue or approval date of the DEA application/declaration and on or before permit /declaration expires. Permit is issued for 180 days (generally) but sometimes shorter.

Filer will receive a warning message if the Anticipated Arrival date transmitted is outside of the above parameters

**PG02: "C" Component**

Data Element	Information
Product Code Number	DEA drug code

**Product Code Number:** Must be the DEA drug code of the controlled substance or listed chemical. Each controlled substance and listed chemical has its own unique DEA drug code. These codes are four characters in length, all numeric and can be found on the applicable DEA form or must be obtained from the importer. The DEA drug code is unique to DEA code. No actual drug name is transmitted in the message set due to possible miss spelling or spelled different in a different country.


**PG04: Quantity and Unit of Measure (Constituent Element)**

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Data Element	Information
Quantity of Constituent Element	<b>Base weight</b> of the controlled substance or listed chemical
Unit of Measure (Constituent Element)	Unit of measure ("KG", "G", "MG", "MCG") of Constituent Element

The Quantity of Constituent Element **must be the base weight** (not the salt or derivative weight) of the controlled substance or listed chemical. The Base weight is indicated on the applicable DEA Form. DEA will call the DEA registrant if quantity exceeds the amount registered.

**Example DEA 236 Form** - Declaration for the import of any non-narcotic controlled substance listed in schedule III, IV, or V

U.S. Department of Justice / Drug Enforcement Administration <b>CONTROLLED SUBSTANCES IMPORT / EXPORT DECLARATION</b> <i>(Read Instructions on reverse before completing)</i>		OMB APPROVAL No. 1117-0009 EXPIRATION DATE: 9/30/2016 <i>See reverse for Privacy Act</i>
<b>1. CHECK ONE</b> <input checked="" type="checkbox"/> <b>IMPORT DECLARATION</b> Nonnarcotic Substances in Schedules III, IV, V <input type="checkbox"/> <b>EXPORT DECLARATION</b> Nonnarcotic Substances in Schedules III, and IV and all substances in Schedule V		<b>U.S. CUSTOMS CERTIFICATION</b> Date of Departure/Arrival Date of Certification Signature of Customs Official
<b>IMPORTER/EXPORTER (Name and Address)</b> DEA-ODGI-TEST 600 ARMY NAVY DRIVE ARLINGTON, VA 22202		<b>BROKER OR FORWARDING AGENT, IF USED (Name and Address)</b> 
<b>DEA REGISTRATION NO. RD0445355</b> <b>PG19</b> <b>2. CONTROLLED SUBSTANCES TO BE IMPORTED</b>		<b>DEA Transaction ID</b> 1QQSOU4-2 <b>PG14</b>
<b>2a. NAME AND QUANTITY OF DRUG OR PREPARATION</b> <small>(Enter names as shown on labels; numbers and sizes of packages; strength of tablets, capsules, etc., CSA Drug Code and NDC number)</small> BOLDENONE - 1,144 BOTTLES, 100 GRAMS/BOTTLE DRUG CODE 4000 NDC # G4000-0200-** <b>PG02 - C</b>	<b>2b. CONTROLLED SUBSTANCE CONTENT OF DRUG OR PREPARATION</b> <small>(Expressed as acid, base or alkalioid. [Enter names of controlled substances contained in the drug, compound, or preparation])</small> 1,144 X 100 = 114,400 GRAMS (BASE) <b>PG04</b>	<b>2c. DATE IMPORTED/EXPORTED AND ACTUAL QUANTITY</b> <small>(Completed by registrant at time of transaction)</small>
<b>3a. <input checked="" type="checkbox"/> FOREIGN (for U.S. import) <input type="checkbox"/> DOMESTIC (for U.S. export) PORT OF EXPORTATION AND APPROX. DEPARTURE DATE</b> BEIJING, CHINA    11/07/2015 <b>PG06</b>		<b>3b. <input type="checkbox"/> FOREIGN (for U.S. export) <input checked="" type="checkbox"/> DOMESTIC (for U.S. import) PORT OF IMPORTATION AND APPROX. ARRIVAL DATE</b> JFK AIRPORT NEW YORK    11/10/2015
<b>4a. MODE OF TRANSPORT; NAME OF VESSEL / CARRIER (if known)</b> BRITISH AIR		<b>4b. NAME OF ALL INTERMEDIATE CARRIERS</b>
<b>5. NAME AND ADDRESS OF FOREIGN CONSIGNEE/CONSIGNOR</b> TOPSY-TURVY PHARMACEUTICAL CO. HUTONG NO. 45 BEIJING, CHINA		
I hereby certify that the substance(s) listed in Section 2 are to be <input checked="" type="checkbox"/> imported (conform to 21 U.S.C. § 952(b)) <input type="checkbox"/> Exported (conform to 21 U.S.C. § 953(e)) and are intended for <input checked="" type="checkbox"/> Medical, <input type="checkbox"/> Scientific, or <input type="checkbox"/> Other legitimate uses (attach explanation for other legitimate use). <input type="checkbox"/> The above named substances are to be Re-Exported (Attach documentation per Title 21, CFR 1312.27) to (list countries):		
<small>If the form is being used as an "Export Declaration" attach documentation that 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 that the consignee in the country of ultimate destination is authorized under the laws and regulations of that country to receive the controlled substances.</small>		
<b>SIGNATURE OF AUTHORIZED INDIVIDUAL OF IMPORTER/EXPORTER, BROKER OR FORWARDING AGENT</b> _____	<b>DATE</b> 10/24/2015	<b>NAME OF FIRM AND TELEPHONE NUMBER</b> DEA-ODGI-TEST
<b>Print Name:</b> MARK V		<b>DEA FORM-236</b> <b>PG22 - Document Identifier "921"</b> <b>COPY 1</b>

**Example DEA 486A Form - Declaration for the import of Ephedrine, Pseudoephedrine, or Phenylpropanolamine**

U.S. Department of Justice		Import Declaration for Ephedrine, Pseudoephedrine and Phenylpropanolamine		Drug Enforcement Administration
SEE INSTRUCTIONS FOR PRIVACY ACT		OMB Approval No. 1117-0023		Expiration Date: 2/29/2016
1. Type of Submission: <input checked="" type="checkbox"/> ORIGINAL <input type="checkbox"/> AMENDED <input type="checkbox"/> WITHDRAWAL		DEA TRANSACTION ID NUMBER: Y27TFG7-0 <b>PG14</b>		
<b>NOTICE!</b> A 15-day advance notice is required for all U.S. imports of Ephedrine, Pseudoephedrine, and Phenylpropanolamine.				
2a. NAME OF IMPORTER DEA-ODGI-TEST		2b. ADDRESS OF IMPORTER 600 ARMY NAVY DRIVE ARLINGTON, VA 22202		
2c. DEA REGISTRATION NUMBER: RD0445355 <b>PG19</b>				
2d. TELEPHONE NO. OF IMPORTER 202-307-1000	2e. E-MAIL ADDRESS OF IMPORTER		2f. PURCHASE/INVOICE NO. (optional) *** TEST FORM ***	
3a. NAME OF FOREIGN EXPORTER FOREIGN COMPANY		3b. ADDRESS OF FOREIGN EXPORTER PLOT NOS. 81/1, 81/3, & 81/5 NEW DELHI, INDIA		
4a. NAME OF FOREIGN MANUFACTURER (if same as 3a, enter "Same as 3a") SAME AS 3A		4b. ADDRESS OF FOREIGN MANUFACTURER		
5a. NAME OF FOREIGN DISTRIBUTOR (if applicable)		5b. ADDRESS OF FOREIGN DISTRIBUTOR (if applicable)		
EPHEDRINE, PSEUDOEPHEDRINE, AND PHENYLPROPANOLAMINE TO BE IMPORTED				
6a. Name and Description of chemical appearing on label or container and DEA Chemical Code (see 21 CFR §1310.02).	6b. Import Quota	6c. Number of containers, net weight (express as base) in kilograms for each chemical listed. For drug products, show number of dosage units.	6d. Actual Date of Import, Name of each chemical imported and its Actual Net Weight (To be completed by importer).	
COUGH & COLD TABLETS CONTAINING PSEUDOEPHEDRINE (120'S) HCL (8112) <b>PG02 - Component 1</b>	Current year Quota [ 2015 ] 17,500 GRAMS	1,988 BOTTLES X 50 TABLETS/BOTTLE X 120 MG/TABLET = 11,928 GRAMS 11,928 GRAMS X 82% = 9,780.96 GRAMS	<b>PG04 - #1</b>	
	Quota used to date for current year 2,500 GRAMS	1,590 BOTTLES X 50 TABLETS/BOTTLE X 60 MG/TABLET = 4,770 GRAMS 4,770 GRAMS X 82% = 3,911.40 GRAMS	<b>PG04 - #2</b>	
COUGH & COLD TABLETS CONTAINING PSEUDOEPHEDRINE (60'S) HCL (8112) <b>PG02 - Component 2</b>	Amount of Quota remaining 15,000 GRAMS			
7a. FOREIGN PORT OF EXPORTATION: NEW DELHI, INDIA <b>PG06</b>		APPROX. DEPARTURE DATE: 10/07/2015		
7b. DOMESTIC PORT OF IMPORTATION: MEMPHIS, TN		APPROX. ARRIVAL DATE: 10/10/2015		
8. MODE OF TRANSPORTATION and NAME OF VESSEL or NAME OF CARRIER. MARY POPPINS AIRWAYS				
9. RETURN DECLARATION FOR IMPORTER. MUST be returned within 30 days from actual date of import (6d).				
SIGNATURE: STEPHEN VIUGG			DATE: 09/17/2015	
DEA FORM - 486A (Previous version obsolete.)		<b>PG22 - Document Type "923"</b>	Page 1	Copy 1

**Example DEA 35 Form** - Import permit for the import of any controlled substance listed in schedule I or II or any narcotic controlled substance listed in schedule III, IV, or V

DEA 35 copies must be attached/accompany the shipment to the registered location. Separate permit for each submission encouraged in case goods get split.

U.S. Department of Justice  
Drug Enforcement Administration

## PERMIT TO IMPORT

The Administrator of the Drug Enforcement Administration, being the official charged with the administration of the laws relating to the importation of the dangerous drugs to which the Controlled Substances Import and Export Act and the several international treaties apply, authorizes and permits the following importation of controlled substances from the United States.

DATE OF ISSUE SEPTEMBER 10, 2014	EXPIRATION DATE DECEMBER 31, 2014	PERMIT NO. <b>FU77R3A-0</b> <span style="float: right;">PG14</span>
IMPORTER U.S. IMPORTER 100 PINE STREET ARLINGTON, VA 22202		
CONSIGNOR FOREIGN SUPPLIER 25 CANDY LANE EDINBURGH, SCOTLAND, U.K.		
PORT OF IMPORT PHILADELPHIA, PENNSYLVANIA	FOREIGN PORT OF EXPORT EDINBURGH, SCOTLAND, UNITED KINGDOM <span style="float: right;">PG06</span>	

Importer is hereby permitted under the provision of the Controlled Substance Import and Export Act to import items below.

Item No.	Number and Size of Packages	Name of Substance or Preparation	Controlled Substances Content
1	2 CONTAINERS 25,000 GRAMS/CONTAINER	BUPRENORPHINE HYDROCHLORIDE	50,000 GM BUPRENORPHINE HCL (48,500 GM BASE)
2	1 CONTAINER 13,000 GRAMS/CONTAINER	BUPRENORPHINE HYDROCHLORIDE	13,000 GM BUPRENORPHINE HCL (12,090 GM BASE)
****		NOTHING FOLLOWS	****

Obtain Drug Code from Importer if not listed

Total Number of Items TWO

The consignment proposed to be imported is required for legitimate purposes.

NOTES:

**Endorsement by U.S. Customs (Original)** This is to certify that the controlled substance is different than permitted, please indicate

**Form is to be Amended- No endorsement or submission of form is required per new Regulations Dec 31, 2016**

For the Administrator:  
 Chief Import and Export Unit Address:  
Drug Enforcement Administration  
Import/Export Unit (ODGI)  
8701 Morrisette Drive  
Springfield, VA 22152

DEA Form 35 (10/10) (Signature)

PG22 - Document Identifier "911"

ORIGINAL — TO ACCOMPANY SHIPMENT AND AFTER ENDORSEMENT BY U.S. CUSTOMS FORWARD TO DEA

## DEA ACE Cargo Release Messages:

- Successful Filing of DEA PGA Message sets:
  - DEA Message set will generate an auto MAY PROCEED for a successful filing
  - There are some rules that will trigger a warning i.e. the declared base quantity exceeds the permitted quantity, or Anticipated Arrival Date conflict.
  - Even if a filer receives a warning, filer will still get an auto may proceed.
- Unsuccessful filing: 'Reject' (Bucket 1, did not pass CBP edits, full Cargo Release rejection)

## HTS Flagging

Tariff Flag Code	Agency Code	R= Required M = May be Required	Program Code	Tariff Flag Code Definition
DE1	DEA	M	DEA	U.S. Drug Enforcement Administration data may be required

- The importer is responsible for filing DEA PGA message set if goods are regulated *whether or not an HTS code has been flagged or not.*

## Disclaimer:

- Disclaimer is files if not a controlled substance or listed chemical, or it is an Excluded Transaction <sup>1</sup> (21 CFR § 1310.08), or where advance notification is waived <sup>2</sup> (21 CFR § 1313.12)
- If the substance is disclaimed an "A" – Product not regulated by the agency, must be entered as Disclaimer Type.
  - <sup>1</sup> U.S. imports of hydrochloric and sulfuric acids, Methyl Isobutyl Ketone (MIBK), anhydrous hydrogen chloride, chemical mixtures that contain acetone, ethyl ether, 2-butanone, and/or toluene, unless regulated because of being formulated with other List I or List II chemical(s) above the concentration limit.
  - <sup>2</sup> U.S. imports of the following listed chemicals- Acetone, 2-Butanone (or Methyl Ethyl Ketone or MEK), Toluene -do not require a DEA-486 form. The registrant or regulated person must submit a quarterly report for the import of these substances to the DEA no later than the 15th day of the month following the end of each quarter.
- Flagged HTS may have both a DEA controlled and non-controlled substance.

## Resources:

DEA Implementation Guide for ACE:

<https://www.cbp.gov/document/guidance/dea-implementation-guide-ace>

*This material is provided for general informational purposes only. It is not offered as and does not constitute legal advice*