



# Drug Enforcement Agency (DEA): Instruction Letter

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".

<u>Controlled substances</u> 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.

The DEA must authorize all imports of controlled substances and listed chemicals prior to their arrival into the United States. This authorization is granted through the issuance of the DEA permit or declaration which applies to the product(s) being imported. Effective August 1, 2017, DEA PGA line data is required to be filed in ACE with the ACE Cargo Release for all products regulated by the DEA; paper or DIS filings will no longer be accepted. \*Please read the following information, complete the DEA Instruction Letter on page three of this document, and return to the undersigned Deringer contact.

### **DEA Permits/Declarations**

Permit applications and declarations must be filed directly with the DEA prior to their arrival into the United States and prior to the filing of the applicable PGA Message Set for imports of controlled substances and listed chemicals.

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

If your product is regulated by the DEA, one or more of the following permits/declarations is required. Please indicate the permits/declarations that apply to your products; where these permits/declarations are applicable, copies must be provided to your broker to transmit the required DEA data set. Where applicable you must also provide your registration or company identification number issued by the DEA identifying your company as an authorized party for the importation of controlled substances:

- DEA-35 (Permit to Import)
- DEA-236 (Controlled Substances Import/Export Declaration)
- DEA-486 (Import/Export Declaration for List I and List II Chemicals)
- DEA-486A (Import Declaration for Ephedrine, Pseudoephedrine and Phenylpropanolamine)



### **DEA Disclaimers**

A disclaimer is filed if the product is not a controlled substance or listed chemical and is not regulated by the DEA, or it is an Excluded Transaction 1 (21 CFR § 1310.08), or where advance notification is waived 2 (21 CFR § 1313.12)

In order for your product to be disclaimed with DEA, it must fall under one of three descriptions listed below:

- Product is not a controlled substance or listed chemical, and is not regulated by the DEA
- (1) 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.
- (2) 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.

### **DEA Toolkit:**



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

**DEA Implementation Guide for ACE:** 

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

**DEA Point of Contact:** 

Stephen Via: Stephen.m.via@usdoj.com

**DEA Compliance Date:** 

Mandatory Use Date: August 1, 2017

# **DEA Instruction Letter**

Product Name										
Product Item or Part Number										
DEA Regulated Y or N:	If "Y" check off the applicable permit/declaration:									
YES	DEA-35									
	DEA-236									
NO	DEA-486									
	DEA-486A									
	*Copies of applicable permits/declarations must be provided to your broker									
	If "N" indicate applicable disclaim category:									
	Not Regulated:			Exclusion 1: Exclusion 2:						
	Check here if blanket disclaimer									
Registration or Company ID*										
2 Alpha 7 Digit = 9 total characters										
*Applicable to importations of Controlled	Α	Α	D	D	D	D	D	D	D	
Substances only (Form DEA-35)										
Name of Person Completing Form										
Title										
Company Name										
Company Name  Date										

## Please return completed form to:

For questions, please contact your A.N. Deringer Representative or email Deringer's Compliance Department: <a href="mailto:compliance@anderinger.com">compliance@anderinger.com</a>



<sup>\*</sup>Please ensure A.N. Deringer is notified immediately if there are any changes to the above information.