



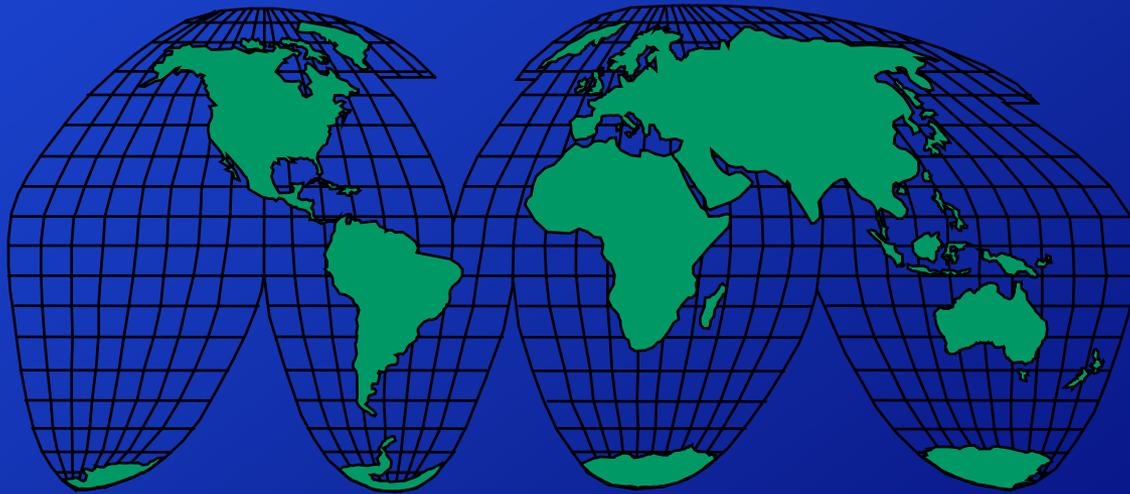
IMPORT/EXPORT UNIT

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

DEA Chemical Conference

Denver, Colorado

2010





IMPORT/EXPORT UNIT

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section



U.S. Department of Justice
Drug Enforcement Administration
Office of Diversion Control

Daniel J. Gillen
Chief

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Import/Export Unit (ODGI)
Regulatory Section

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PRESENTATION TOPICS

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

WHO YA GONNA CALL

PRACTICE, PRACTICE, PRACTICE

ON THE SAME PAGE

THE RIGHT HOOK

NOT ELTON JOHN'S SONG



POINTS OF CONTACT

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

DEA Form-486 (Exports)

Ms. Carmencita Hamer (202) 307-0545

DEA Form-486 & 486A (Imports & International)

Mr. Harry McFadden (202) 307-4761

Another Important Telephone Number

Mr. Fac Simile (202) 307-4702
and his son (202) 307-7968



BEST PRACTICES REVISITED

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

Use Upper Case for all Information

Enter your DEA Registration Number if you are Registered with DEA as an Importer or Exporter of Listed Chemicals

Enter Only Necessary Address Information for the Foreign Company; The Foreign Fax Number is not Necessary

Provide a Purchase/Invoice No. to Assist DEA with Identifying a Specific Transaction you Inquire about



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Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

THE **BIG** ONE

For US Exports, Ask your Customer if their Competent Authority has issued a Permit or Authorization Number for the Import ... If Yes, Enter it on the DEA Form-486

Why? See 21 CFR

- § 1310.07 (a) to (f);
- § 1313.21 (g); and
- § 1313.25

Notification to DEA does NOT Mean it's been Approved!



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Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

U.S. Department of Justice

Import / Export Declaration for List I and List II Chemicals

Drug Enforcement Administration

SEE REVERSE INSTRUCTIONS FOR PRIVACY ACT

OMB Approval No. 1117-0023

1a. Type of Transaction: IMPORT EXPORT INTERNATIONAL

1b. Type of Submission: ORIGINAL AMENDED WITHDRAWAL

1c. **WARNING!** 15-day advance notice required for initial shipment or for company that has lost regular importer or regular customer status. See 21 C.F.R. Part 1313 for further details.
 I certify I have met the conditions for the waiver of 15-day advance notice requirement.

DEA Control Number

2a. U.S. IMPORTER/ U.S. EXPORTER / U.S. BROKER
(Name, address, telephone, and fax no.)

CAVERLY CHEMICAL COMPANY
600 ARMY LOSSES TO NAVY DRIVE
ARLINGTON, VA 22202
703-555-1212 (T) 703-444-1111 (F)

DEA Registration Number (for List I only): 052458CPX

Purchase/Invoice no. (optional) 2009-0524

2b. IF IMPORT, LIST FOREIGN CONSIGNOR; IF EXPORT OR INTERNATIONAL TRANSACTION, LIST FOREIGN TRANSFEREE.
(Name, address, telephone, and fax no.)

FERRITTO FINE FRAGRANCES
AV VICTOR HUGO
75116 PARIS, FRANCE
(33) 1-558-8-9339

Foreign permit no. (if applicable) P/2009/08/1440



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Office of Diversion Control, Regulatory Section

Only use List I & II Chemical Names in Block 3b per § 1310.02; Exception, use CP with List I Chemical Name for Drug Products

For Drug Products, Calculate the Net Weight of the Active Ingredient (i.e. Use the Conversion Factor)

The Net Weight in Block 3c must be in Kilograms

Do Not provide "Return Information" in Block 3d on initial DEA Form-486 submissions



BEST PRACTICES REVISITED

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

Provide "Return Information" (Actual Date and Actual Quantity) in Block 3d within 30 Days after the Transaction has Occurred

If the Amended Box is not already Checked do not Check it for Return Information; Providing Return Information is not an Amendment

Do Not Change any Original or Amended Information when you File the Return Information



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Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

THE **BIG** TWO

Indicate if Substance is a Raw Material or Mixture in Block 3a of the DEA Form-486 and Block 6a of the DEA Form-486A

On Return Information for Exports, Sign and Date at the Bottom of Block 3d with "per block 6" ... Do not Submit the 2nd Page of the DEA Form-486



BEST PRACTICES REVISITED

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

3. Listed Chemicals to be Imported / Exported / Brokered

3a. Name and Description of chemical appearing on label or container. For drug products, show dosage strength and dosage size.	3b. Name of chemicals as designated by Title 21 C.F.R. 1310.02	3c. Number of containers, size, net weight of each chemical (kg). For drug products, show number of dosage units. Show net total weight per chemical.	3d. DATE OF ACTUAL IMPORT/EXPORT AND ACTUAL QUANTITY (To be completed by person named in (2a).) If same as 3c, write "same as 3c."
DAYTIME COUGH & COLD (CONTAINS PSE HCL) M	CP PSEUDOEPHEDRINE	50,000 BOTTLES X 100 TABS/BOTTLE X 37.5 MG/TAB = 187,500,000 MG/ 1,000,000 = 187.5 KG X 0.8192 = 153.6 KG	153.6 KG
PSEUDOEPHEDRINE R	PSEUDOEPHEDRINE	1 DRUM X 40 KG/DRUM = 40 KG	40 KG EXPORTED 8/25/2009 <i>Stephen M. Via - 8/26/09 Per block 6</i>



BEST PRACTICES REVISITED

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

Do Not list any Substances on the DEA Form-486 that are not List I or II Chemicals

Include the Concentration/Percentage Amounts for each Listed Chemical in a Mixture

Do the Math in block 3c for each Listed Chemical on the DEA Form-486



BEST PRACTICES REVISITED

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3. Listed Chemicals to be Imported / Exported / Brokered

3a. Name and Description of chemical appearing on label or container. For drug products, show dosage strength and dosage size.	3b. Name of chemicals as designated by Title 21 C.F.R. 1310.02	3c. Number of containers, size, net weight of each chemical (kg). For drug products, show number of dosage units. Show net total weight per chemical.	3d. DATE OF ACTUAL IMPORT/EXPORT AND ACTUAL QUANTITY (To be completed by person named in (2a).) If same as 3c, write "same as 3c."
<p>BOGGS REDUCER V11 M</p> <p>ACETONE (23%)</p> <p>TOLUENE (15%)</p>	<p>ACETONE</p> <p>TOLUENE</p>	<p>1 TANKER</p> <p>10,000 KG/TANKER X 23% = 2,300 KG</p> <p>10,000 KG/TANKER X 15% = 1,500 KG</p>	



BEST PRACTICES REVISITED

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

Provide Complete Information for all Fields; All Field Values are Required for Processing a DEA Form-486

A NULL Value is not a Valid Field Entry, Neither is TBD

Print and Sign your Name Clearly in the Signature Block and Include your Telephone number

Provide your E-mail Address or your Company's E-mail Address; Used for Sending the Transaction ID (Previously Known as Control Number) to you



BEST PRACTICES REVISITED

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

4a. FOREIGN DOMESTIC

PORT OF EXPORTATION: WASHINGTON, DC

APPROX. DEPARTURE DATE: 9/17/2009

4b. FOREIGN DOMESTIC

PORT OF IMPORTATION: PARIS, FRANCE

APPROX. ARRIVAL DATE: 9/19/2009

5. MODE OF TRANSPORTATION, NAME OF VESSEL, OR NAME OF CARRIER:

AIR FREIGHT

FEDEX EXPRESS

SIGNATURE OF AUTHORIZED INDIVIDUAL (Print or Type Name below
Signature)

STEPHEN M. VIA

Print Name: STEPHEN M. VIA 202-307-8294

DATE:

9/1/2009

stephen.m.via@usdoj.gov

DEA form - 486 (Previous version obsolete.)
September 2006

Copy 1



DEA FORM-486A QUOTA

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

In Block 6b the "Quota Used to Date for Current Year" should only Reflect that which has Actually been Imported into the United States

Listed Chemicals Imported into the United States Count in the Year they were Actually Imported not the Year they were Declared



DEA FORM-486A QUOTA

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

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, size, 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).
PSEUDOEPHEDRINE	Current year Quota [2010] 1200	10 DRUMS X 50 KG/DRUG = 500 KG	
	Quota used to date for current year 0		
	Amount of Quota remaining 1200		

7a. FOREIGN PORT OF EXPORTATION:

APPROX. DEPARTURE DATE:



DEA FORM-486A QUOTA

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

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, size, 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).
PSEUDOEPHEDRINE	Current year Quota [2010] 1200	8 DRUMS X 50 KG/DRUG = 400 KG	
	Quota used to date for current year 500		
	Amount of Quota remaining 700		

7a. FOREIGN PORT OF EXPORTATION:

APPROX. DEPARTURE DATE:



REGULAR CUSTOMER STATUS

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

DEA cannot waive the 15-Day Advance Notice because
IT'S THE LAW under 21 USC § 971 (a) and (b).

Therefore,

If your Company has not Conducted Business with a Foreign Customer at least once in the past 6 months or twice in the past 12 months Regarding Listed Chemicals you must give DEA a 15-Day Advance Notice

If your Foreign Customer has a Change of Address, you must give DEA a 15-Day Advance Notice the First Time you Ship to their New Address



REGULAR CUSTOMER STATUS

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

If your Address Changes, you must give DEA a 15-Day Advance Notice for all of your Customers from your Previous Address the First Time you Ship to them from your New Address to Re-establish Regular Customer Status

If your Customer has had its Regular Customer Status Denied or Revoked you must give DEA a 15-Day Advance Notice Prior to Shipping to them



DANIEL

Drug Enforcement Administration
Office of Diversion Control, Regulatory Section

DANIEL is the DEA's Application for New Import and Export Licenses. This System will allow US Chemical and Pharmaceutical Companies to Submit DEA Forms for the Import and Export of Listed Chemicals and Controlled Substances to DEA through the Internet.

DANIEL will be Online in the Fall of 2011.



IMPORT/EXPORT UNIT

Drug Enforcement Administration
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Questions?
