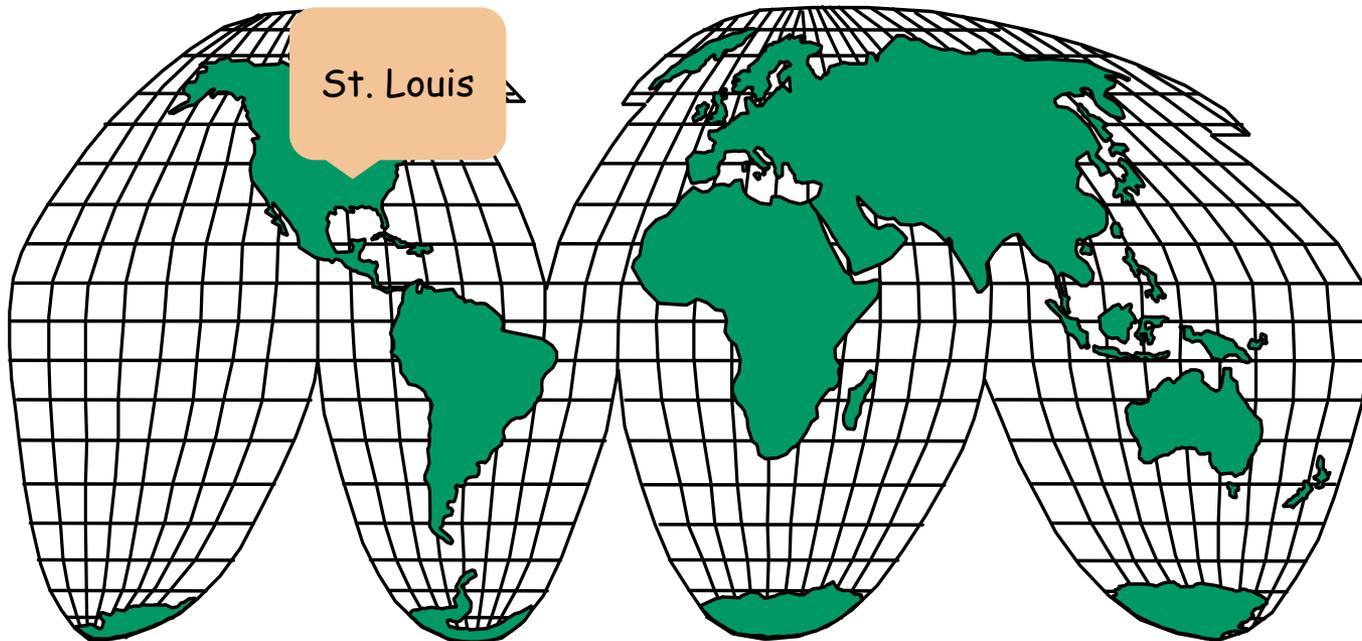




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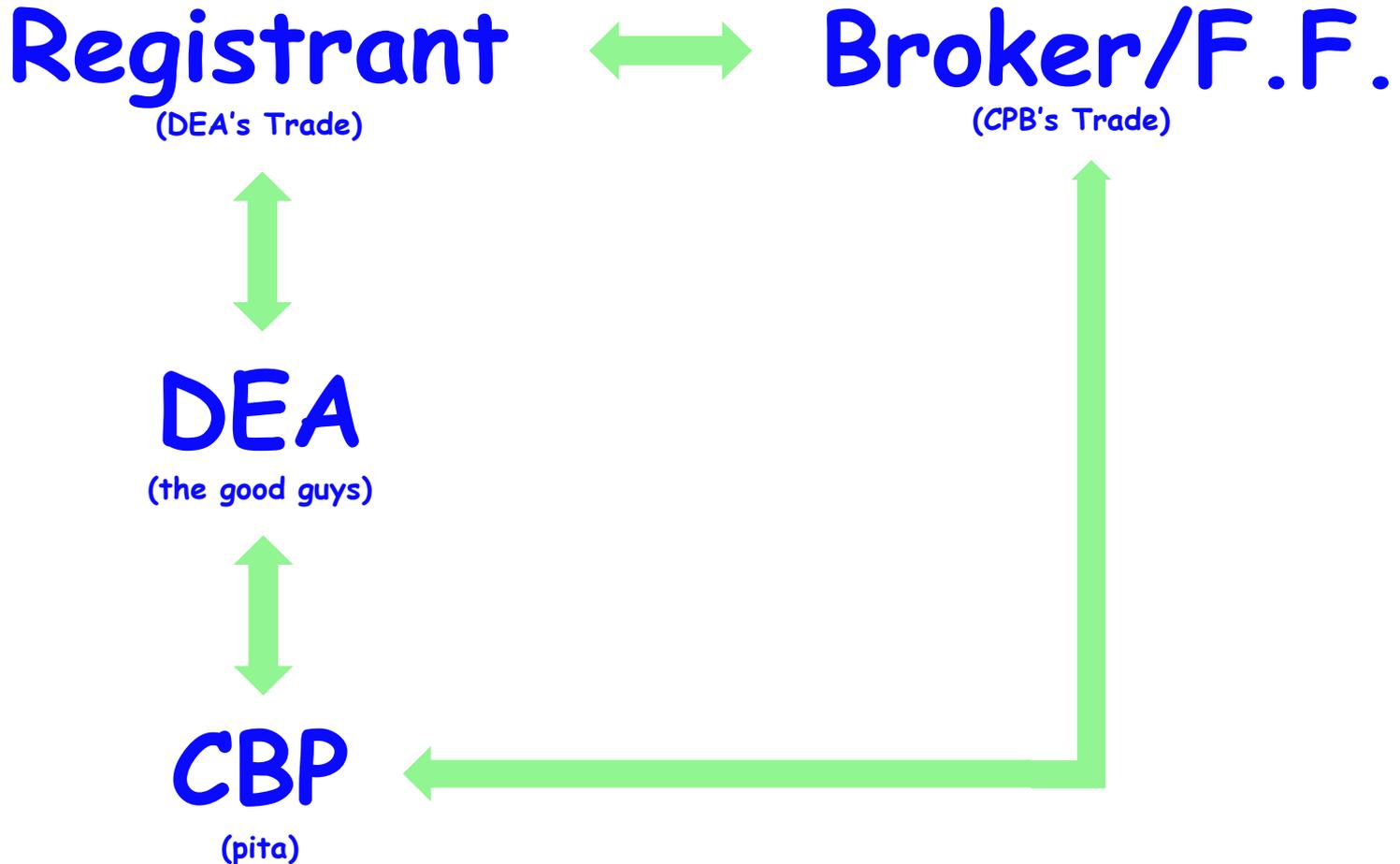
Drug Enforcement Administration Importer & Exporter Conference March 14, 2017





DEA * CBP * ITDS * ACE * AES

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Controlled Substances



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- **Mandatory Electronic Filing (to DEA) of the DEA-357 & DEA-161, DEA-161R, and DEA-161R-EEA Applications, and DEA-236 forms**
 - **Permits & DEA-236 forms ... Valid for 180 days ... there are Exceptions for certain Controlled Substances**
-



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- **Not Amendable: Adding or changing a controlled substance; Foreign Permit number and their dates**
 - **Drug Codes v. HTS & Schedule B codes - Limited to the same Drug Code for Controlled Substances (same situation with List I Chemicals)**
-



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CBP HTS Classification	Disclaim Import	Schedule B	Disclaim Export	DEA Drug Code	DEA Name of Controlled Substance or Listed Chemical	DEA Schedule	Narcotic
2921.46.0000	Yes (DE1)	2921.46.0000	Yes	1100	Amphetamine	II	N
2939.91.0000	Yes (DE1)	2939.91.0000	Yes	1105	Methamphetamine	II	N
2924.29.6250	Yes (DE1)	2924.29	Yes	1205	Lisdexamfetamine	II	N
2921.46.0000	Yes (DE1)	2921.46.0000	Yes	1228	Benzphetamine	III	N
2939.11.0000	Yes (DE1)			9050	Codeine	II	Y
2939.11.0000	Yes (DE1)			9064	Buprenorphine	III	Y
2939.11.0000	Yes (DE1)			9143	Oxycodone	II	Y
2939.19; 2939.11.00	Yes (DE1)	2939.19; 2939.11.00	Yes	9145	Dihydromorphine	I	Y
2939.11.0000	Yes (DE1)			9150	Hydromorphone	II	Y
2933.33.0000	Yes (DE1)	2933.33.0000	Yes	9801	Fentanyl	II	Y



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- DEA-236 forms still require a 15-Day Advance filing (to DEA) but remaining days are waived when the Transaction ID Number is issued
 - CBP will not Release an Import or Export until they have received the Authorized Permit or DEA-236 data from DEA
-



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- **If you Amend a Permit or DEA-236 form you must use the amended document for the shipment**
 - **Do not enter Return Information until you know that no further Amendments will be needed**
-



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- **Permits & DEA-236 forms must accompany the shipment to its final destination but they do not have to be uploaded to CBP**
 - **Controlled Substances must arrive at the registered location of the Importer (drop shipments are prohibited)**
-



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- **Dump your FedEx stock ... Registrants to print their Permits; Color v. Black & White re: CNAs**
 - **Denied Release for any reason at the Port of Release = Reason for Denial + Cancel + New Submission**
-



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- **Return Information added to 21 CFR § 1312 - Date Arrived or Departed registered location & Actual Quantity and Date & Actual Quantity Released by CBP**



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Listed Chemicals



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- **Mandatory Electronic Filing (to DEA) of the DEA-486 & DEA-486A forms**
 - **DEA-486 & DEA-486A forms ... Valid for 180 days**
-



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- **DEA-486 forms must be filed (to DEA)
15-days prior to Release by CBP or
3-days prior to Release by CBP with
Regular Importer/Customer Status**
 - **DEA-486A forms must be filed (to DEA)
15-days prior to Release by CBP**
-



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- **CBP will not Release an Import or Export until they have received the Authorized DEA-486 or DEA-486A data from DEA**



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- **Do not enter Return Information until you know that no further Amendments will be needed ... The Exception, which is being developed, the Transferee (downstream customer) information for the DEA-486 (imports) & DEA-486A**



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- List I Chemicals must arrive at the registered location of the Importer (drop shipments are prohibited)
 - DEA-486 forms for exports require the submission of a Foreign Permit, License or Registration issued by the CNA of the Consignee
-



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- Denied Release for any reason at the Port of Release = Reason for Denial + Cancel + New Submission
 - Return Information - Date Arrived or Departed Registered Location & Actual Quantity and Date & Actual Quantity Released by CBP
-



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Re-Exports of Controlled Substances



DEA-161R

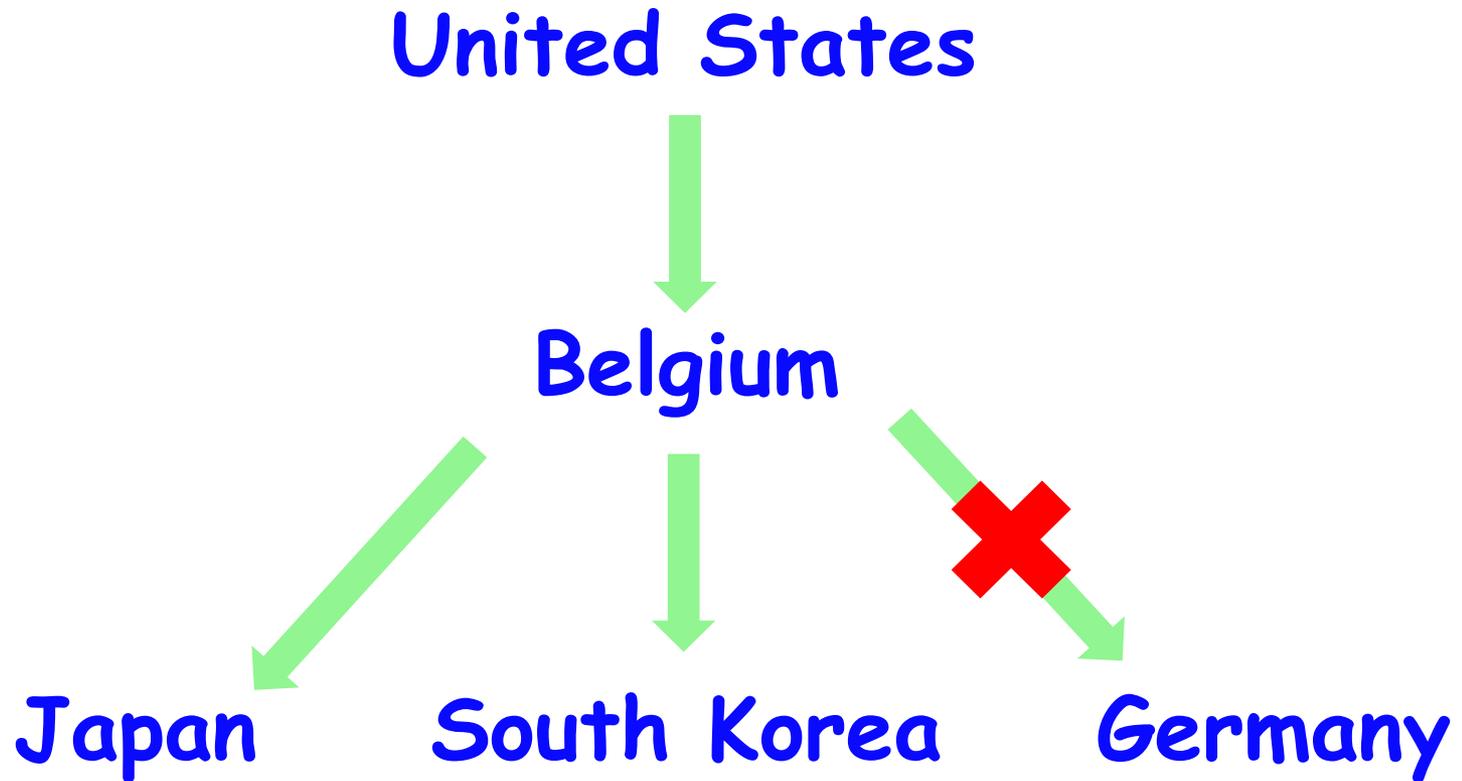
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- The DEA-161R is used for Re-Exports when the 2nd Country(ies) are not Members of the European Economic Area (EEA) unless the 1st Country is outside of the EEA; Re-Exports cannot occur from the 2nd Country(ies)



DEA-161R

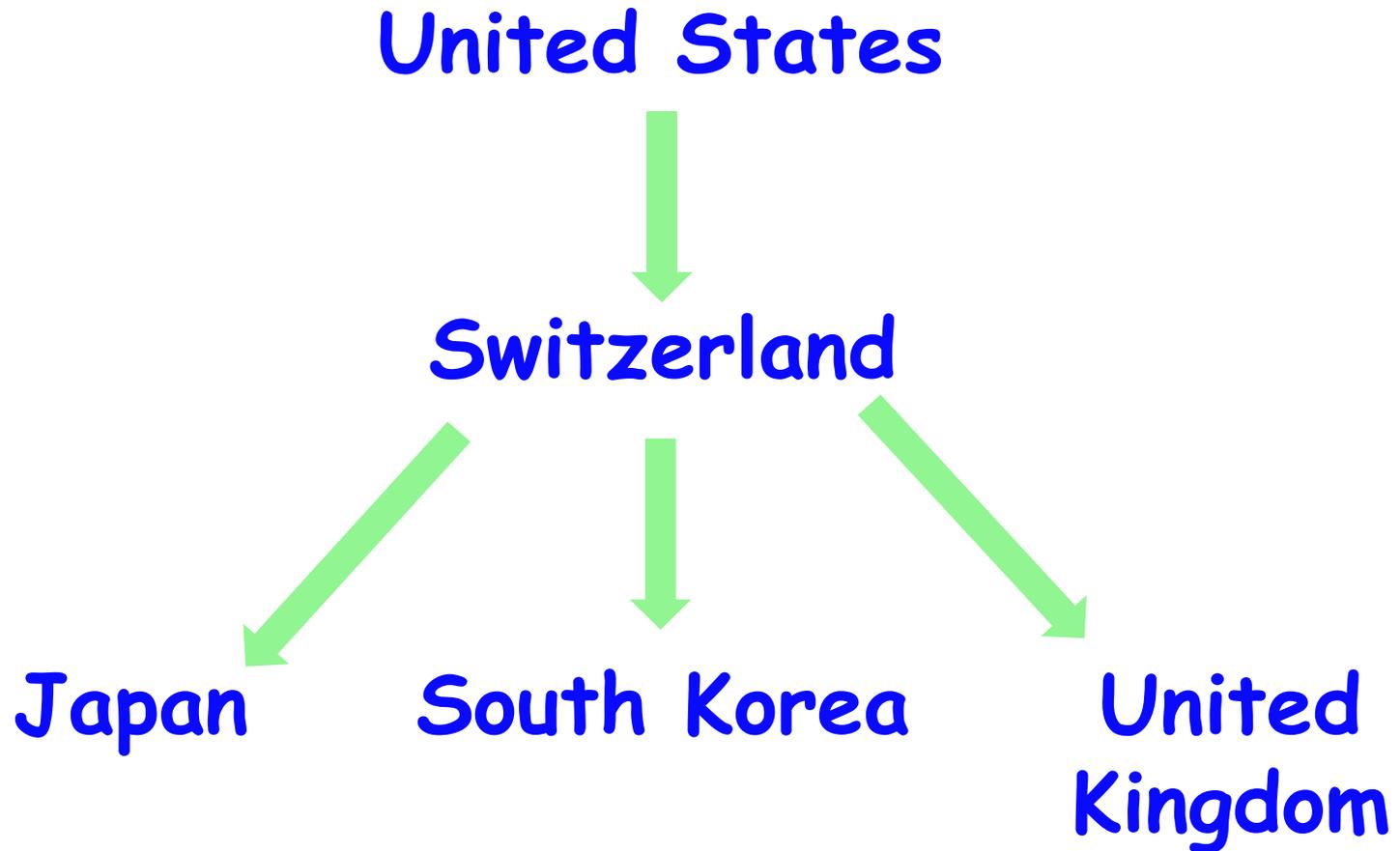
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DEA-161R





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DEA-161R-EEA

- The DEA-161R-EEA will be used for Re-Exports when the 1st Country and the Countries of Re-Export are Members of the European Economic Area (EEA); Re-Exports can continue to occur within the EEA



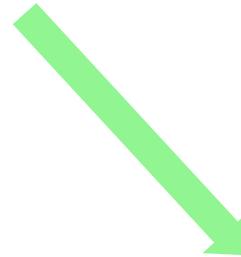
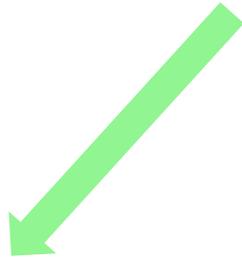
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DEA-161R-EEA

United States



Belgium



France

Switzerland

Italy



Unlimited Re-Exports among EEA Countries



DEA-161R & DEA-161R-EEA

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- **The Applications for Re-Export require / will require information re: the Importer's Name/Address, ports and dates, foreign import permit # and dates, including a copy of the permit, Controlled Substance Information and Registrant Information**
-



DEA-161R

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- The DEA-161R requires at the time of submission the Name/Address of the Importers in the 2nd Country(ies), quantity(ies) of the Controlled Substances to be Re-Exported, and the Affidavit the Controlled Substances will not be Re-Exported from the 2nd Country(ies)



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DEA-161R-EEA

- The DEA-161R-EEA requires at the time of submission the quantity of Controlled Substances to be Re-Exported (to check Estimates/Assessments if any Controlled Substance is remaining in the 1st Country)



DEA-161R

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- The DEA-161R subsequently requires the Return Information for the Export from the United States and the Re-Exports within 30 days after each occurs
 - The 180 days is still Applicable for the DEA-161R
-



DEA-161R-EEA

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- The DEA-161R-EEA subsequently requires Return Information for the Export from the United States and the information concerning the consignee, country, and product within 30-days after each re-exportation per 21 U.S.C. § 953(f)(6)(B)
-



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DEA-161R-EEA

- The bulk substance requirement is not Applicable to the DEA-161R-EEA
- The 180 days is not Applicable to the DEA-161R-EEA



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- The DEA-236 will function in the same manner as the DEA-161R & DEA-161R-EEA for Re-Exports of Non-Narcotic Controlled Substances in Schedules III, and IV and Controlled Substances in Schedule V



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Questions?