Regulatory Section

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Molly Callahan – Reports November 2015
Discussion Points

- Legal Foundation
- Applications/Permits and Declarations
- ITDS
- Q & A
The CSA’s Closed System of Distribution

Importer

Manufacturer

Exporter

Distributor

Practitioner

Patient

Pharmacy
Closed System of Distribution

- Cyclic Investigations
- Established Schedules
- Record Keeping Requirements
- Registration
- Security Requirements
- Established Quotas
- ARCOS
Closed System of Distribution

The DEA is responsible for:

- the **oversight** of the system
- the **integrity** of the system
- the **protection** of the public health and safety
Legal Foundation

- Controlled Substances Act
- Code of Federal Regulations
  - Registrations
  - Recordkeeping
  - Authorization of imports and exports
  - Re-exportation
Persons Required to Register:

No person may

(1) import into the customs territory of the United States from any place outside thereof

..., or import into the United States from any place outside thereof, any controlled substance or list I chemical, or
Registration


(2) export from the United States any controlled substance or list I chemical, unless there is in effect with respect to such person a registration issued by the Attorney General under Section 958 of this title, or unless such person is exempt from registration under subsection (b) of this section.
Registration
21 C.F.R. § 1301.11(a)

“Every person who manufactures, distributes, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation, or exportation of any controlled substance shall obtain a registration…”
Registration
21 C.F.R. § 1312.21(b)

“No person shall in any manner export or cause to be exported from the United States any non-narcotic controlled substance listed in Schedule III, IV, or V, …until such person is properly registered under the Act (or exempted from registration) and has furnished a special controlled substance export invoice as provided by...”
Re-exportation Statute
21 U.S.C. § 957(f)

- DEA may authorize any controlled substances in CI or CII or a CIII or CIV narcotic to be exported from the U.S. to a country for subsequent export from that country to another country.
Both the country to which the CS is exported from the U.S. (first country) and the country to which the CS is exported from the first country (second country) are parties to the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971.
Re-exportation Statute Conditions

- The first country and the second country have each instituted and maintain, in conformity with such Conventions, a system of controls of imports of controlled substances which the Attorney General deems adequate.

- With respect to the first country, the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance has been issued by the country.
Re-exportation Statute Conditions

- With respect to the second country, substantial evidence is furnished to the Attorney General by the person who will export the controlled substance from the United States that—

- (A) the controlled substance is to be consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance is to be issued by the country; and
Re-exportation Statute Conditions

- (B) the controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country.

- The controlled substance will not be exported from the second country.
Within 30 days after the controlled substance is exported from the first country to the second country, the person who exported the controlled substance from the United States delivers to the Attorney General documentation certifying that such export from the first country has occurred.

- (i) Name of second country;
- (ii) Actual quantity shipped;
- (iii) Actual date shipped; and
- (iv) DEA export permit number for the original export.
Where a person is seeking to export a controlled substance for re-export in accordance with paragraph (c) of this section, the following requirements shall apply in addition to (and not in lieu of) the requirements of paragraphs (a) and (b) of this section:
Re-exportation Regulations

- Bulk substances will not be reexported in the same form as exported from the United States, i.e., the material must undergo further manufacturing process. This further manufactured material may only be reexported to a second country.

- Finished dosage units, if reexported, must be in a commercial package, properly sealed and labeled for legitimate medical use in the second country.
(3) Any proposed reexportation must be made known to the Administration at the time the initial DEA Form 161R is submitted. In addition, the following information must also be provided where indicated on the form:

(i) Whether the drug or preparation will be reexported in bulk or finished dosage units;

(ii) The product name, dosage strength, commercial package size, and quantity;

(iii) The name of consignee, complete address, and expected shipment date, as well as the name and address of the ultimate consignee in the second country.
The controlled substance will be reexported from the first country to the second country (or second countries) no later than 180 days after the controlled substance was exported from the United States.
Re-export Statement

- Re-export Statement
  - Must state that the product will not be re-exported and not that your company will not re-export it.
Re-export Affidavit

- (1) both the first country to which the controlled substances(s) are exported from the United States and the second the country to which the controlled substances are exported are parties to the Single Convention on Narcotic Drugs, 1961 and the Convention of Psychotropic Substances, 1971;

- (2) the first and second countries have each instituted and maintain a system for the control of these substances;

- (3) the drugs will be consigned to a holder of such permits or licenses as may be reburied in the country of import and that a permit or license for importation will be issued for such import into the second country;
Re-export Affidavit

- (4) that the controlled substances will be reexported from the first country to the second country no later than 180 days after exportation from the United States;
- (5) the packages are labeled in conformance with the Single Convention on Narcotic Drugs, and the Convention of Psychotropic Substances, 1971; and any amendments to these treaties;
- (6) the controlled substances are to be applied exclusively to medical, scientific, or other legitimate uses within the second country; and
- (7) the controlled substances will not be exported from the second country.
Operation Efficiency
aka “Fast and Furious”

Help Us Be More Efficient
Let’s Talk Forms
IMPORT/EXPORT

Forms

- DEA-161 (Export Application)
- DEA-161R
- DEA-236 (Import & Export Declarations)
- DEA-357 (Import Application)
- DEA-486 (Import & Export Declarations)
- DEA-486A
# IMPORT/EXPORT FORM GUIDE

<table>
<thead>
<tr>
<th></th>
<th>161 &amp; 161R Export Application Online</th>
<th>357 Import Application Online</th>
<th>236 Exports Declaration Online</th>
<th>236 Imports Declaration Online</th>
<th>486 &amp; 486A Import/Export Declaration Online</th>
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<tr>
<td>Schedule I &amp; II</td>
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<td>DEA Issues Permit</td>
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<td>Dea-36</td>
<td>Dea-35</td>
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<td>Listed Chemicals</td>
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</table>
DEA 357

- Application for Permit to Export Controlled Substances
- Import Application in Online
- Join the party
Accounts/Access

- Passwords – Expire every 60 days
- Corporate Administrators should be resetting account passwords within 55-60 days
- Company Users should be contacting the Corporate Administrators to have the PW reset and for any other issues
Control Status Determination

- DEA Website
  - Resources
  - Quotas
  - Conversion Factors
Control Status Determination

An alphabetical listing of many Schedules I - V controlled substances are found in Title 21 Code of Federal Regulations, and their corresponding DEA code numbers and conversion factors.
### Schedules I - V Controlled Substance Conversion Factors

<table>
<thead>
<tr>
<th>Controlled Substance</th>
<th>Schedule</th>
<th>Drug Code</th>
<th>Conversion Factor</th>
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<tbody>
<tr>
<td>(±)-cis-4-Methylaminorex Hydrochloride</td>
<td>I, II</td>
<td>1590</td>
<td>1.00</td>
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<tr>
<td>(±)-trans-4-Methylaminorex Hydrochloride</td>
<td>I, II</td>
<td>1590</td>
<td>1.00</td>
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<tr>
<td>1,3-Dimethyl-1-indazol-3-yl-naphthalen-1-yl)methanone (THI-2201)</td>
<td>I</td>
<td>7032</td>
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<tr>
<td>1-(5-Fluoropropyl)-3-(1-naphthyl)indole (AM2201)</td>
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<tr>
<td>1-(5-Fluoropropyl)-3-(2-nitrobenzoyl)indole (AM208)</td>
<td>I</td>
<td>7034</td>
<td>1.00</td>
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<tr>
<td>1-(2-6-Thienyl)pyrroolidine (TC-P)</td>
<td>I</td>
<td>7025</td>
<td>1.00</td>
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<tr>
<td>1-[2-(4-Morpholinyl)ethyl]-3-(1-naphthyl)indole (WH-200)</td>
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<td>7033</td>
<td>1.00</td>
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<tr>
<td>1-[2-[2-(4-Morpholinyl)ethyl]-1-naphthyl]indole (WH-200)</td>
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<tr>
<td>1-cyclohexyl-2-ethyl-3-(2-methoxyphenyl)acetyl)indole (7008 SR-18 and RCS-8)</td>
<td>I</td>
<td>7008</td>
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<td>1-cyclohexyl-3-(1-naphthyl)indole (DHI-01)</td>
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<td>7019</td>
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<td>5-pentyl-3-(1-naphthyl)indole (OH-018 and AM478)</td>
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<td>7118</td>
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<tr>
<td>5-ethyl-3-(2-chlorophenyl)acetyl)indole (WH-203)</td>
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<td>7203</td>
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<td>5-ethyl-3-(2-methoxyphenyl)acetyl)indole (WH-250)</td>
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<td>6250</td>
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<tr>
<td>5-ethyl-4-phenyl-1-naphthylindole (WH-392)</td>
<td>I</td>
<td>7395</td>
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<tr>
<td>5-pentyl-3-(4-methyl)benzoyl)indole (NH-013)</td>
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<tr>
<td>5-ethyl-3-(4-methyl)benzoyl)indole (SR-19 and RCS-4)</td>
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<td>7040</td>
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<tr>
<td>5-pentyl-3-[4-(methoxy)methyl]indole (WH-981)</td>
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<td>7081</td>
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<tr>
<td>2,2,5-Dimethoxy-4-(n-propylfenyl)ethanamine (2C-E)</td>
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<td>2,2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-C)</td>
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<td>2,2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)</td>
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<td>2,2,5-Dimethoxy-4-nitrophenyl)ethanamine (2C-N)</td>
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<td>7521</td>
<td>1.00</td>
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<tr>
<td>2,2,5-Dimethoxy-4-nitrophenyl)ethanamine (2C-D)</td>
<td>I</td>
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<tr>
<td>2,2,5-Dimethoxy-4-nitrophenyl)ethanamine (2C-H)</td>
<td>I</td>
<td>7517</td>
<td>0.83</td>
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<tr>
<td>2,2,5-Dimethoxy-4-nitrophenyl)ethanamine (2C-M)</td>
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<td>2,2,5-Dimethoxy-4-nitrophenyl)ethanamine (2C-N)</td>
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<td>7521</td>
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Control Status Determination (for derivatives)

- Need Registrant to request ahead of application submission
- Letter to Drug and Chemical Evaluation Section with chemical structure (ODE@usdoj.gov)
  - Request control status determination
  - Base Code
  - Conversion Factor
- Submit result with application
Clean Copies of Documents

- Forms 161/236
  - Clean copies of document (Foreign permits)
DEA 161, 236 and 357 Issues

- Form not signed.
- CSA drug code number not listed.
- NDC number not listed.
- Translation not furnished when foreign import certificate is in a language other than English.
- Statement of non-reexport not furnished.
DEA 161, 236 and 357 Issues

- Incomplete description of drug preparation; specifically, how it is packaged--carton, box, bottle.
- Estimated dates of departure or arrival not entered.
- Base amount of controlled substance not computed or not entered.
- Boxes on DEA-236 form not marked.
DEA 236 Issues

- Incomplete or Incorrect DEA Registration #
- Lack of Reference/Tracking #
- Failing to Calculation Drug Amount In Grams (Box 2b)
- Supporting Documents for Re-exports – Import Permit or No Objection Letters or Statements, No Re-export Statements, Expected Quantity and Ship Dates
List Foreign Permit #

- Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol. Article 31. Special provisions relating to international trade. Paragraph 4. (c) The export authorization shall also state the number and date of the import certificate and the authority by whom it has been issued.

Such authorization shall state the international non-proprietary name, or, lacking such a name, the designation of the substance in the Schedule, the quantity to be exported or imported, the pharmaceutical form, the name and address of the exporter and importer, and the period within which the export or import must be effected.

If the substance is exported or imported in the form of a preparation, the name of the preparation, if any, shall additionally be furnished.

The export authorization shall also state the number and date of the import authorization and the authority by whom it has been issued.
Electronic Air Waybill

- Prefer that you supply already prepared labels.
Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of $100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profits, attorney’s fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of $100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is $1,000, e.g. jewelry, precious metals, negotiable Instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.

```plaintext
After printing this label:
CONSIGNEE COPY - PLEASE PLACE IN FRONT OF POUCH
1. Fold the printed page along the horizontal line.
2. Place label in shipping pouch and affix it to your shipment.

From: (202) 307____
DIA HEADQUARTERS IMPORT\EXPORT UNIT
8701 MORRISSETTE DR.
SPRINGFIELD, VA 22152

Ship To:____

BILL SENDER

Ship Date: 09/UL 15
Act/Id: 0.1 lb MAN

RETURN MON-FRI
** 2DAY **

TRK# 0721
1551
```

```plaintext
Delivery Address Bar Code

Ref #:____

RMA #:____
Return Reason:

US
```
Record Keeping Requirement

- Maintain on a Current Basis...
- Complete and Accurate Record of each substance manufactured, imported, exported, received, sold, delivered, or otherwise disposed of ...
- Except no registrant is required to maintain a perpetual inventory

21 C.F.R. § 1304.21(a)
Importer Records

- Import Permit: DEA 35
- Application for Permit: DEA 357
- Declaration: DEA 236
  - Filed 15 Days in advance
- Declaration: DEA 486
  - Filed 15 Days in advance

- 21 C.F.R. §1312.11(a)-(b), 1313
Exporter Records

- Export Permit: DEA 236
- Application for Permit: DEA 161
- Declaration: DEA 486
  - Filed 15 Days in advance

21 C.F.R. § 1312.23 & 1313.12
Returns & INCB

ITDS

- International Trade Data Systems
  - All Forms Electronic Submission
  - Drafting Notice of Proposed Rulemaking
  - TSN Working Group
  - Piloting 2016
Split Shipments

- One container - One Time Use of Permit
  - Ship – Multiple container – OK
  - Two Planes – Not OK
Reference Standards

- It shall be unlawful to import …
  - Such amounts of any CS … that AG finds to be necessary to provide for medical, scientific, or other legitimate needs of the U.S. –
    - Emergency
    - Lack of competition among domestic manufacturers is inadequate or
    - CS is in limited quantities for scientific, analytical, or research uses.

- Come to Regulatory Breakout Session
Who You Gonna Call?
Contact Information:

- Import/Export Permits and Declarations
  - Controlled Substances: CSIMEX@usdoj.gov
  - Chemical: Chemical.IMEX@usdoj.gov

- Faxes:
  - Chemicals: 202-307-4702
  - Controlled Substances: 202-307-7503
Q & A