

Drug Enforcement Administration

BREAKOUT SESSION



**Import/Export Drugs
and Chemicals**

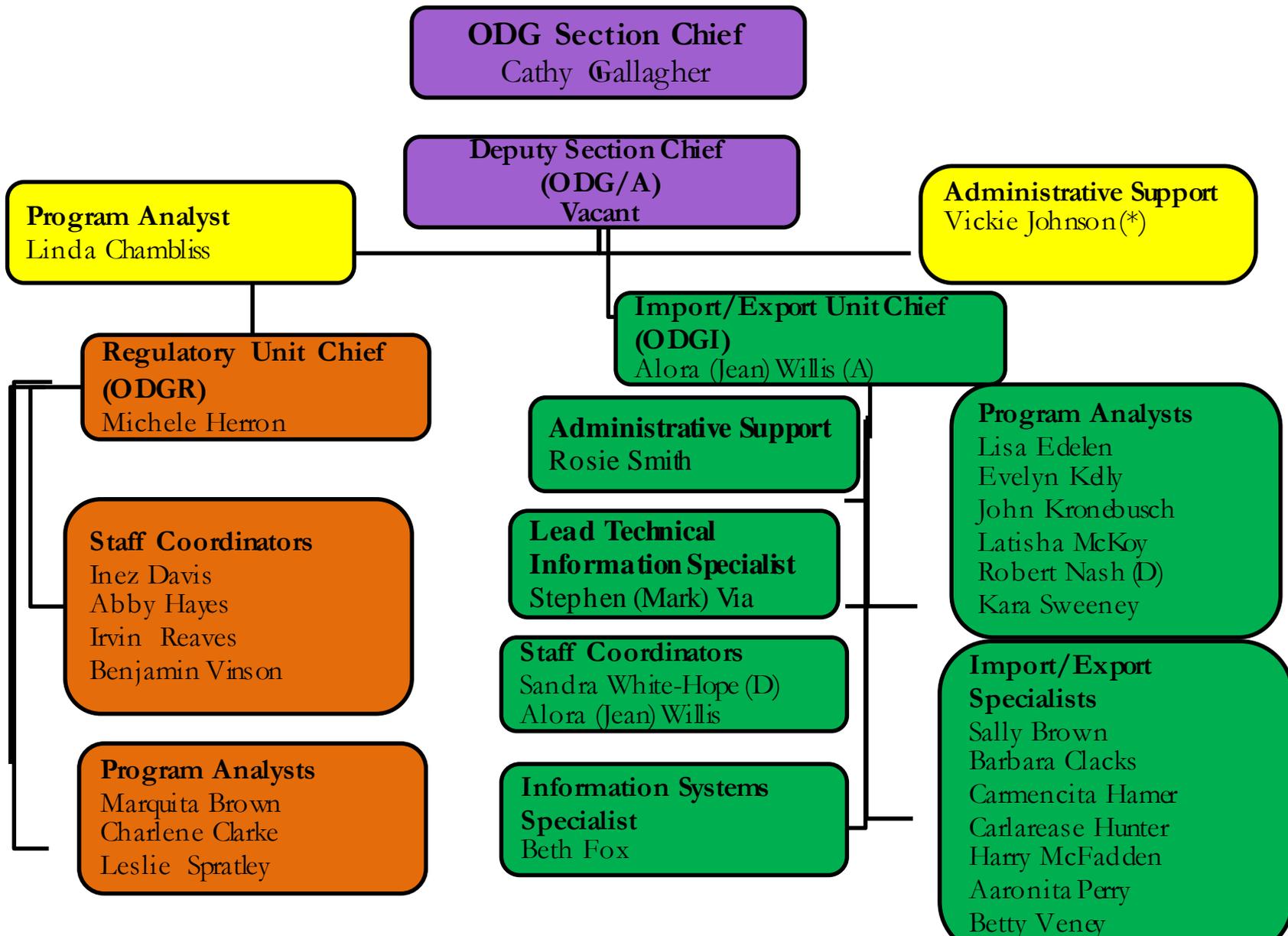
September 24, 2015

Regulatory Section

Cathy Gallagher
Section Chief

Michele Herron
Unit Chief, Regulatory Unit/ODGR

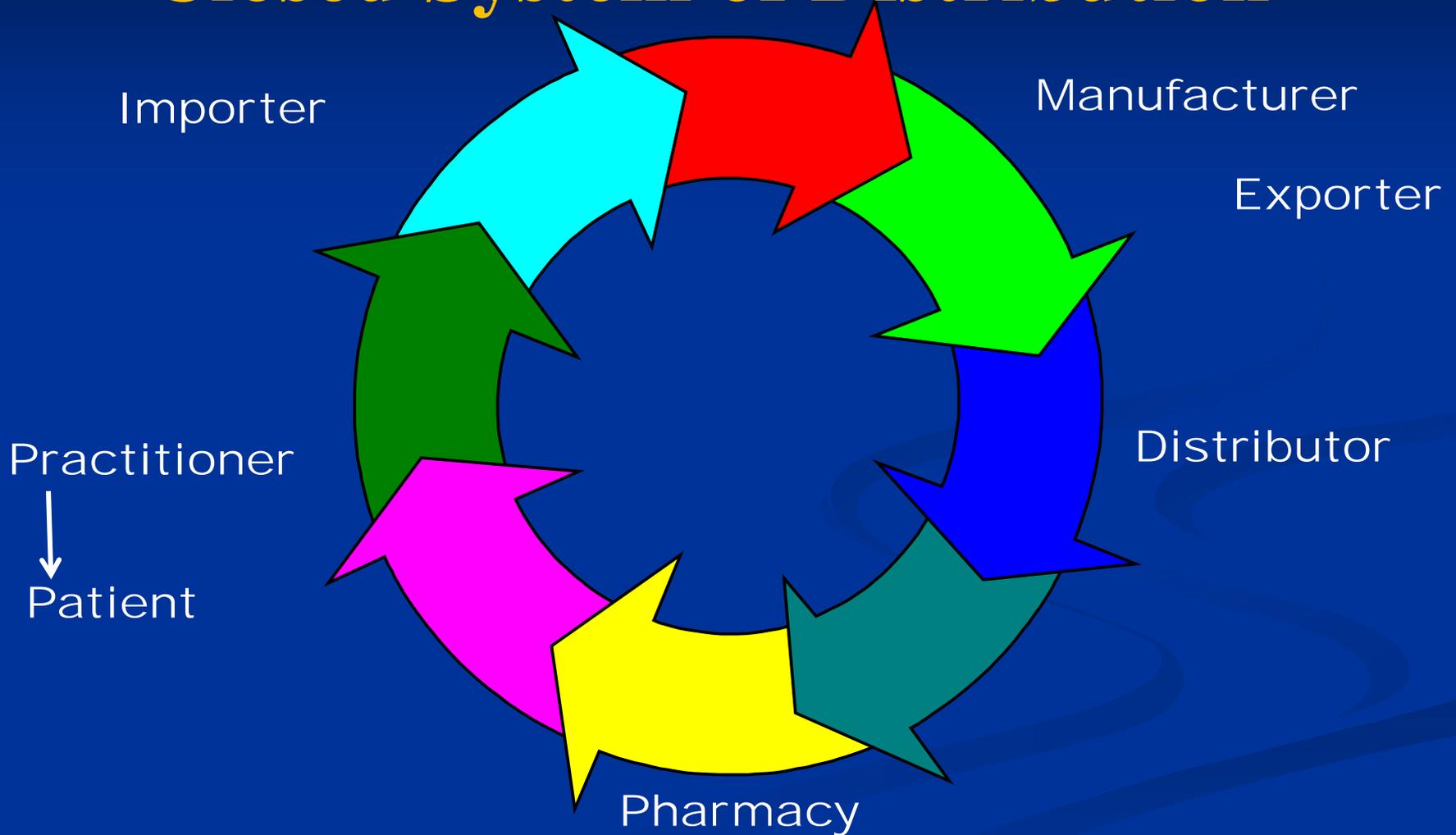
Alora (Jean) Willis
Acting Unit Chief, Import/Export/ODGI
Molly Callahan – Reports November 2015



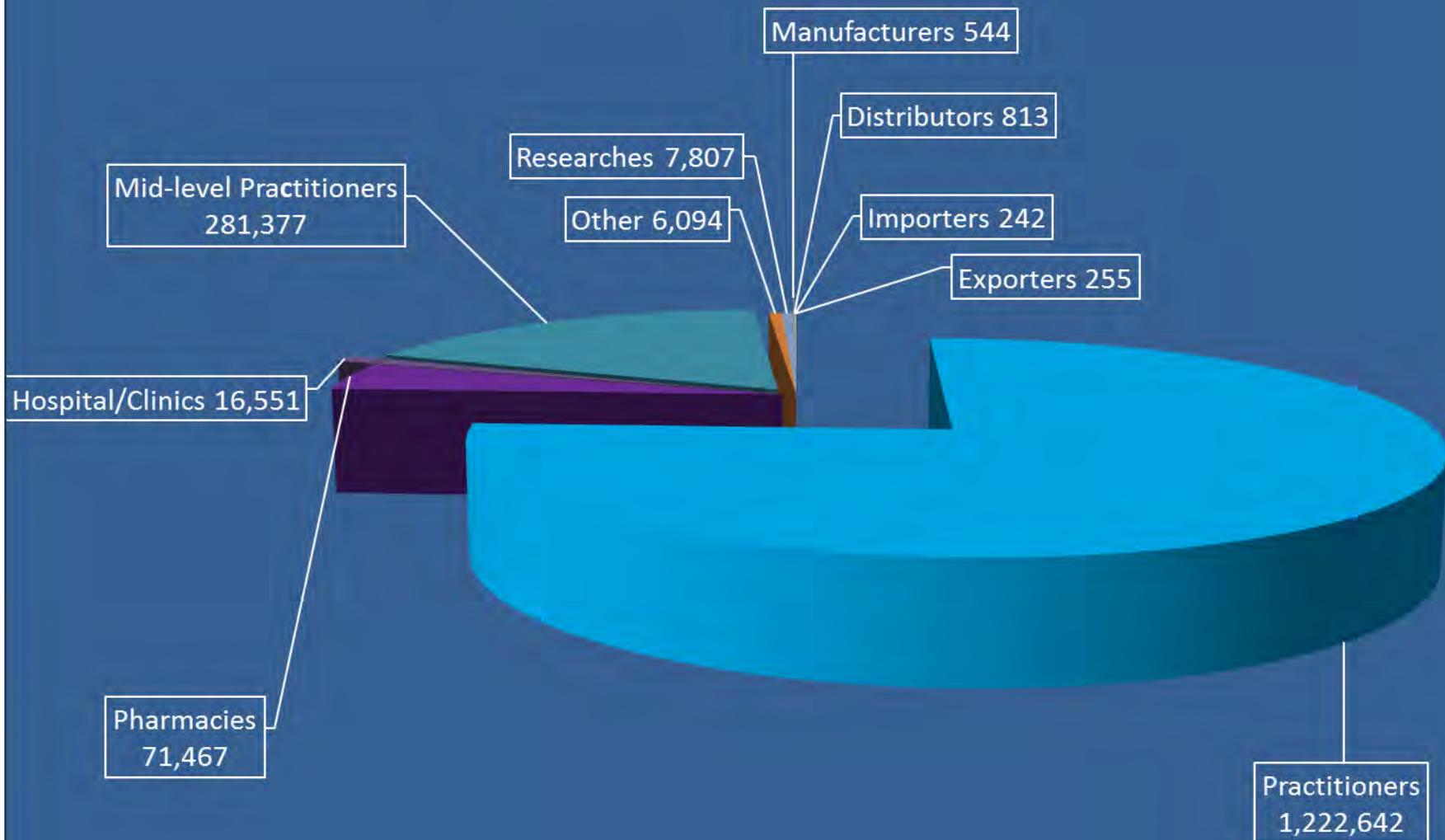
Discussion Points

- Legal Foundation
- Applications/Permits and Declarations
- ITDS
- Q & A

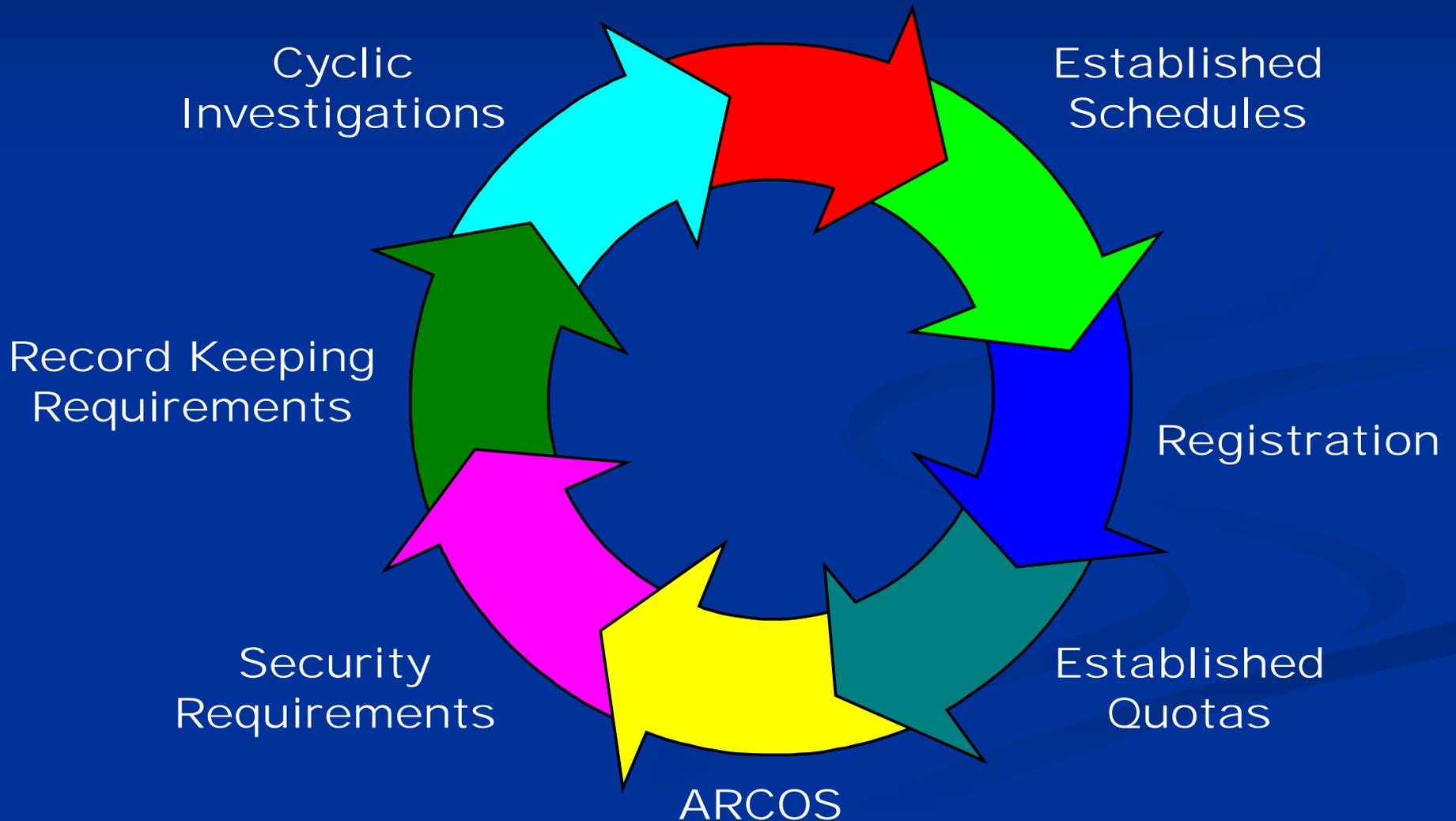
The CSA's Closed System of Distribution



Active Registrants 1,605,785 total (09-22-2015)



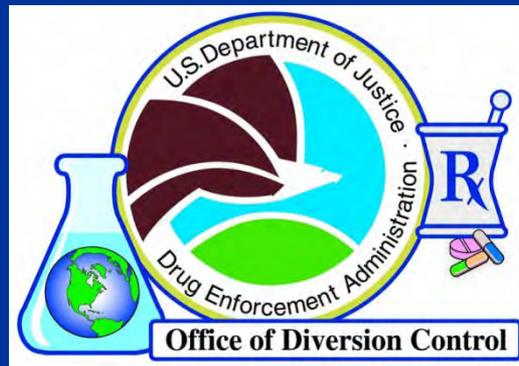
Closed System of Distribution



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

Registration

21 U.S.C. § 957(a)(1)

- 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

21 U.S.C. § 957(a)(1):

(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.

Re-exportation Statute Conditions

- 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.

Re-exportation Statute Conditions

- 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

Re-exportation Regulations

21 C.F.R. § 1312.22-23 & 1313.27

- 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.

Re-exportation Regulations

- (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.

Re-exportation Regulations

- 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

	161 & 161R Export Application Online	357 Import Application Online	236 Exports Declaration Online	236 Imports Declaration Online	486 & 486A Import/Export Declaration Online
Schedule I & II	✓	✓			
Schedule III Narcotic	✓	✓			
Schedule III Non-narcotic 7369 = Permit			✓	✓	
Schedule IV Narcotic	✓	✓			
Schedule IV Non-narcotic			✓	✓	
Schedule V Narcotic		✓	✓		
Schedule V Non-narcotic			✓	✓	
DEA Issues Permit	Dea-36	Dea-35			
Listed Chemicals					✓

DEA 357

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

Accounts/Access

- Passwords – **Expire every 60 day**
- 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

DEA SENSITIVE BUT UNCLASSIFIED

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http://www.deadiversion.usdoj.gov/

DEA Office of Diversion Co...
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U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION OFFICE OF DIVERSION CONTROL

Search

HOME REGISTRATION REPORTING RESOURCES ABOUT US

Report Illicit RX Abuse Online Reporting
Need to Obtain or Renew Your DEA Registration?
Save Time, Apply Online

- ARCOS
- BCM Online
- Chemical Import/Export Declarations
- CSOS (Controlled Substances Ordering System)
- Drug Theft/Loss
- Import/Export
- Registrant Record of Controlled Substances Destroyed
- Quotas
- Reports Required by 21 CFR
- Submit a Tip to DEA

Registration Support
Call: 1-800-882-9539 (8:30 am-6:00 pm EST)
Email: DEA.Registration.Help@usdoj.gov
Locate Field Registration Specialists
Applications
Registration Changes (Address, Drug Code, Name, Schedule)
Combat Meth Epidemic Act)
Application for Disposal of Controlled Substances
Certificate Request
Receipt of Registration
Form Validation

What's New

- Chung-Kuang Chen, M.D.; Dismissal of Proceeding (September 16, 2015)
- Final Adjusted Aggregate Production Quotas for Schedule I Controlled Substances and Assessment of Annual Needs for the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine for 2015 (September 16, 2015)
- Temporary Placement of the Synthetic Cannabinoid MAB-CHMINACA Into Schedule I (September 16, 2015)
- Masters Pharmaceuticals, Inc.; Decision and Order (September 15, 2015)
- Removal of [¹²³I]Ioflupane From Schedule II of the Controlled Substances Act (September 11, 2015)

DEA Forms & Applications

Publications & Manuals

Questions & Answers

Meetings & Events

In The News

- DEA Announces 10th National Prescription Drug Take-Back (July 28, 2015)
- Former Kentucky Physician Charged with Conspiracy to Dispense Controlled Substances (June 16, 2015)
- DEA Announces Largest-Ever Prescription Drug Operation (May 20, 2015)

Quick Links

- ARCOS (Automation of Reports & Consolidated Orders System)
- Cases Against Doctors
- Chemical Control Program
- CSOS (Controlled Substances Ordering System)
- EPSC (Electronic Prescriptions for Controlled Substances)
- DEA Form 106: Report Theft or Loss of Controlled Substances
- Find Your Local DEA Office
- Mailing Addresses for Topics Related to Title 21 CFR

http://www.deadiversion.usdoj.gov/quotas/index.html 100%

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Control Status Determination

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http://www.deadiversion.usdoj.gov/quotas/index.html

Reporting - Quotas

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U.S. DEPARTMENT OF JUSTICE ★ **DRUG ENFORCEMENT ADMINISTRATION**
OFFICE OF DIVERSION CONTROL

HOMEREGISTRATIONREPORTINGRESOURCESABOUT US



REPORTING > Quotas

Quotas

- [Quota Applications](#)
- [Year-End Reports](#)
- [Aggregate Production Quota History \(PDF\)](#)
- [List of Controlled Substances](#)
- [Conversion Factors for Controlled Substances](#)

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.

- [Federal Register Notices](#)
- [Pharmaceutical Training Seminars](#)

- ARCOS
- BCM Online
- Chemical Import/Export Declarations
- CSOS (Controlled Substances Ordering System)
- Drug Theft/Loss
- Import/Export
- Registrant Record of Controlled Substances Destroyed
- Quotas
- Reports Required by 21 CFR
- Submit a Tip to DEA
- Year-End Reports

Control Status Determination

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http://www.deadiversion.usdoj.gov/quotas/conv_factor/index.html

Quotas - Conversion Facto...

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Schedules I - V Controlled Substance Conversion Factors

[Download PDF](#)

Controlled Substance	Schedule	Drug Code	Conversion Factor
(+/-)-cis-4-Methylaminorex	I	1590	1.00
(+/-)-cis-4-Methylaminorex Hydrochloride	I	1590	0.83
1-(5-fluoropentyl)-1 <i>H</i> -indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201)	I	7024	1.00
1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201)	I	7201	1.00
1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694)	I	7694	1.00
1-[1-(2-thienyl)cyclohexyl]pyrrolidine (TCPy)	I	7473	1.00
1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200)	I	7200	1.00
1-butyl-3-(1-naphthoyl)indole (JWH-073)	I	7173	1.00
1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole 7008 (SR-18 and RCS-8)	I	7008	1.00
1-hexyl-3-(1-naphthoyl)indole (JWH-019)	I	7019	1.00
1-pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678)	I	7118	1.00
1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203)	I	7203	1.00
1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250)	I	6250	1.00
1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398)	I	7398	1.00
1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122)	I	7122	1.00
1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19 and RCS-4)	I	7104	1.00
1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081)	I	7081	1.00
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P)	I	7524	1.00
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine Hydrochloride (2C-P)	I	7524	0.86
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E)	I	7509	1.00
2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine Hydrochloride (2C-E)	I	7509	0.85
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D)	I	7508	1.00
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine Hydrochloride (2C-D)	I	7508	0.84
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N)	I	7521	1.00
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine Hydrochloride (2C-N)	I	7521	0.86
2-(2,5-Dimethoxyphenyl)ethanamine (2C-H)	I	7517	1.00
2-(2,5-Dimethoxyphenyl)ethanamine Hydrochloride (2C-H)	I	7517	0.83
2-(4-Bromo-2,5-dimethoxyphenyl)- <i>N</i> -(2-methoxybenzyl)ethanamine (25B-NBOMe)	I	7537	1.00
2-(4-Bromo-2,5-dimethoxyphenyl)- <i>N</i> -(2-methoxybenzyl)ethanamine Hydrochloride (25B-NBOMe)	I	7537	0.91
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C)	I	7519	1.00
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine Hydrochloride (2C-C)	I	7519	0.86
2-(4-Chloro-2,5-dimethoxyphenyl)- <i>N</i> -(2-methoxybenzyl)ethanamine (25C-NBOMe)	I	7537	1.00
2-(4-Chloro-2,5-dimethoxyphenyl)- <i>N</i> -(2-methoxybenzyl)ethanamine Hydrochloride (25C-NBOMe)	I	7537	0.90
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I)	I	7518	1.00
2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine Hydrochloride (2C-I)	I	7518	0.89
2-(4-Iodo-2,5-dimethoxyphenyl)- <i>N</i> -(2-methoxybenzyl)ethanamine (25I-NBOMe)	I	7538	1.00
2-(4-Iodo-2,5-dimethoxyphenyl)- <i>N</i> -(2-methoxybenzyl)ethanamine Hydrochloride (25I-NBOMe)	I	7538	0.92
2,5-Dimethoxy-4-ethylamphetamine (DOET)	I	7399	1.00
2,5-Dimethoxy-4-ethylamphetamine Hydrochloride (DOET)	I	7399	0.86
2,5-Dimethoxy-4- <i>N</i> -propylthiophenethylamine (2C-T-7)	I	7348	1.00
2,5-Dimethoxy-4- <i>N</i> -propylthiophenethylamine Hydrochloride	I	7348	0.88
2,5-Dimethoxyamphetamine	I	7396	1.00
2,5-Dimethoxyamphetamine Hydrochloride	I	7396	0.84
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2)	I	7385	1.00
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine Hydrochloride (2C-T-2)	I	7385	0.87
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4)	I	7532	1.00
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine Hydrochloride (2C-T-4)	I	7532	0.88
2,4,5-Trimethoxyamphetamine	I	7300	1.00

100%

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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.

List Foreign Permit

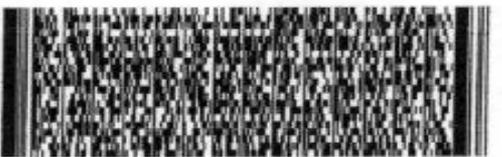
- Convention on Psychotropic Substances of 1971. Article 12. Provisions relating to international trade. Paragraph 1. (b):
- Such authorization shall state the international non-proprietary name, or, lacking such a name, the designation of the substance in the Schedule, the quantity to be exported or 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, profit, 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.

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.

<p>From: (202) 307- [REDACTED] Origin ID: [REDACTED] DEA HEADQUARTERS IMPORT&EXPORT UNIT 8701 MORRISSETTE DR. SPRINGFIELD, VA 22152</p>	<p>FedEx Express E J148214023003.v</p>	<p>Ship Date: 09/JUL/15 Act/Wgt: 0.1 LB MAN CAD: [REDACTED]</p>
<p>SHIP TO: [REDACTED] BILL SENDER [REDACTED] [REDACTED] [REDACTED]</p>	<p>Delivery Address Bar Code </p>	<p>Ref # RMA #: Return Reason:</p>
	<p>TRK# [REDACTED] 1551 0221</p> <p>RETURNS MON-FRI ** 2DAY **</p>   021C1/05966F03	

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

- Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971.

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
- ODGIOOnline161@usdoj.gov
- ODGI.Online.236's@usdoj.gov
- ODGI.Online.486's@usdoj.gov
- ODGIOOnline357@usdoj.gov

- Faxes:
 - Chemicals 202-307-4702
 - Controlled Substances 202-307-7503

Q & A

