

OPERATIONS DIVISION  
**DIVERSION**



**CONTROL**

# List 1 Chemical Quotas

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# Topic of Discussion

- ❖ Overview of Quota system
- ❖ CMEA Quota Requirements

# Quota Overview

- ❖ Provide for US legitimate need regarding scientific, medical and research utilization
- ❖ Restrict the manufacture and procurement to those manufacturers registered by DEA
- ❖ Limit the quantity of Schedule I and II, List I drugs which may be manufactured or produced
- ❖ Provide adequate inventories

# Three International Conventions

- ✓ Single Convention on Narcotic Drugs, 1961
- ✓ Convention on Psychotropic Substances, 1971
- ✓ Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988
  
- ✓ US is a party to all three treaties

Goal: limit the use of narcotic drugs and psychotropic substances and their precursors to legitimate medical and scientific purposes.

# Quota Overview

- International drug control system based on three UN treaties
- Treaties form the basis for the statutory framework of the CSA and much of our drug control policy.
- The CSA (and Congressional changes to the CSA) are implemented through the CFR, as communicated to the public in the FR.

# Code of Federal Regulations (CFR)

“Codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government.”

- The CFR is the “**how to**” guide for both the public and the Federal Government.
- Individual agencies make additions or changes to the code
- Updated once per year (total of 50 titles)
- [www.gpoaccess.gov/cfr/index.html](http://www.gpoaccess.gov/cfr/index.html)

# What is the Federal Register (FR)?

✓ “The Federal Register is the official publication for rules, proposed rules, and notices of Federal agencies and organizations, as well as executive orders and other presidential documents.”

✓ Communicated to the public

✓ Published daily

[www.gpoaccess.gov/fr/index.html](http://www.gpoaccess.gov/fr/index.html)

# Quota Overview

- ❖ Narcotics Manufacturing Act of 1960
- ❖ Single Convention on Narcotic Drugs, 1961
- ❖ Controlled Substances Act of 1970
- ❖ Combat Methamphetamine Epidemic Act, 2005

What is the average price of the hazardous waste disposal of a clandestine laboratory?

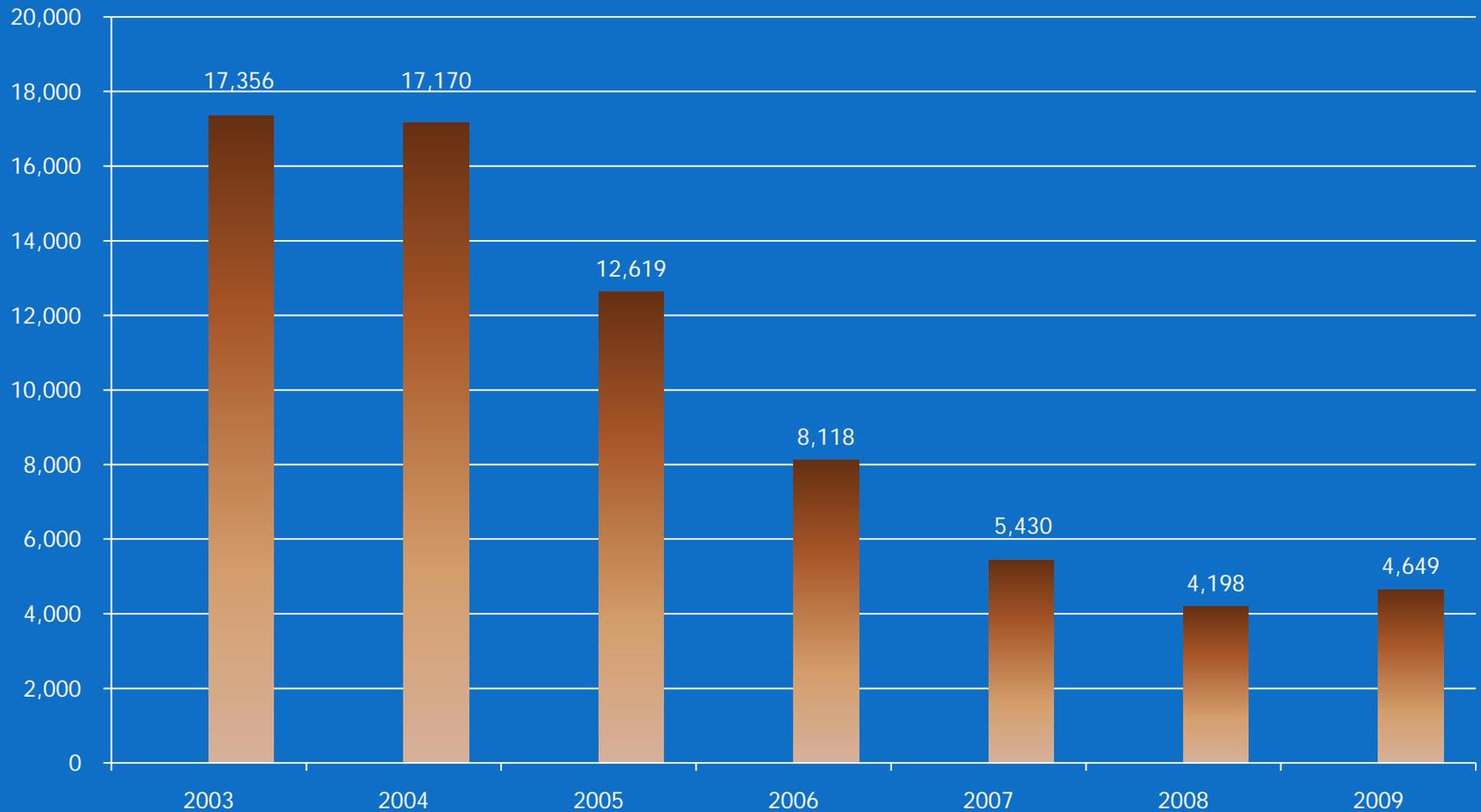


Average price of clandestine laboratory hazardous waste disposal = \$20,000



17,356 (2003) labs x \$20,000 = \$347 million

# DEA and State and Local Law Enforcement Methamphetamine Seizures (Includes Labs, dump sites, glassware and equipment seizures) Calendar Years 2003 – 2009



# Combat Methamphetamine Epidemic Act 2005 (CMEA)

Enacted on March 9, 2006

Pseudoephedrine, Ephedrine, & Phenylpropanolamine

- Additional legislative and regulatory controls on the manufacture, distribution, importation, and exportation of these List 1 chemicals
- Registration now required for each physical location (manufacturer, distributor, importer or exporter)

# Combat Methamphetamine Epidemic Act (CMEA) of 2005

- Amended 21 U.S.C. 826, 844, and 952
- Added quota requirements for (PE, E, PPA)
- Created Importation quota (PE, E, PPA)

# CMEA Quota Requirements

Pursuant to 21 CFR Part 1315

- **Assessment of Annual Needs**  
(21 CFR 1315.11 and 1315.13)
- Individual **Manufacturing** Quotas  
(21 CFR 1315.21 through 1315.27)
- **Procurement** Quotas  
(21 CFR 1315.30 and 1315.32)
- **Import** Quotas  
(21 CFR 1315.34 and 1315.36)

# Quota Provisions of CMEA

- Interim Final Rule - July 10, 2007 (71 FR 56008)
- Bulk manufacturers who synthesize EPH, PSE and PPA must obtain a manufacturing quota (DEA-189).
- Manufacturers who purchase EPH, PSE and PPA must obtain a procurement quota (DEA-250).
  - Dosage form manufacturers, packagers, labelers, repackagers and relabelers
- Importers who import EPH, PSE and PPA (or products containing EPH, PSE, and PPA) must obtain an import quota (DEA-488).

# Quota Provisions of CMEA

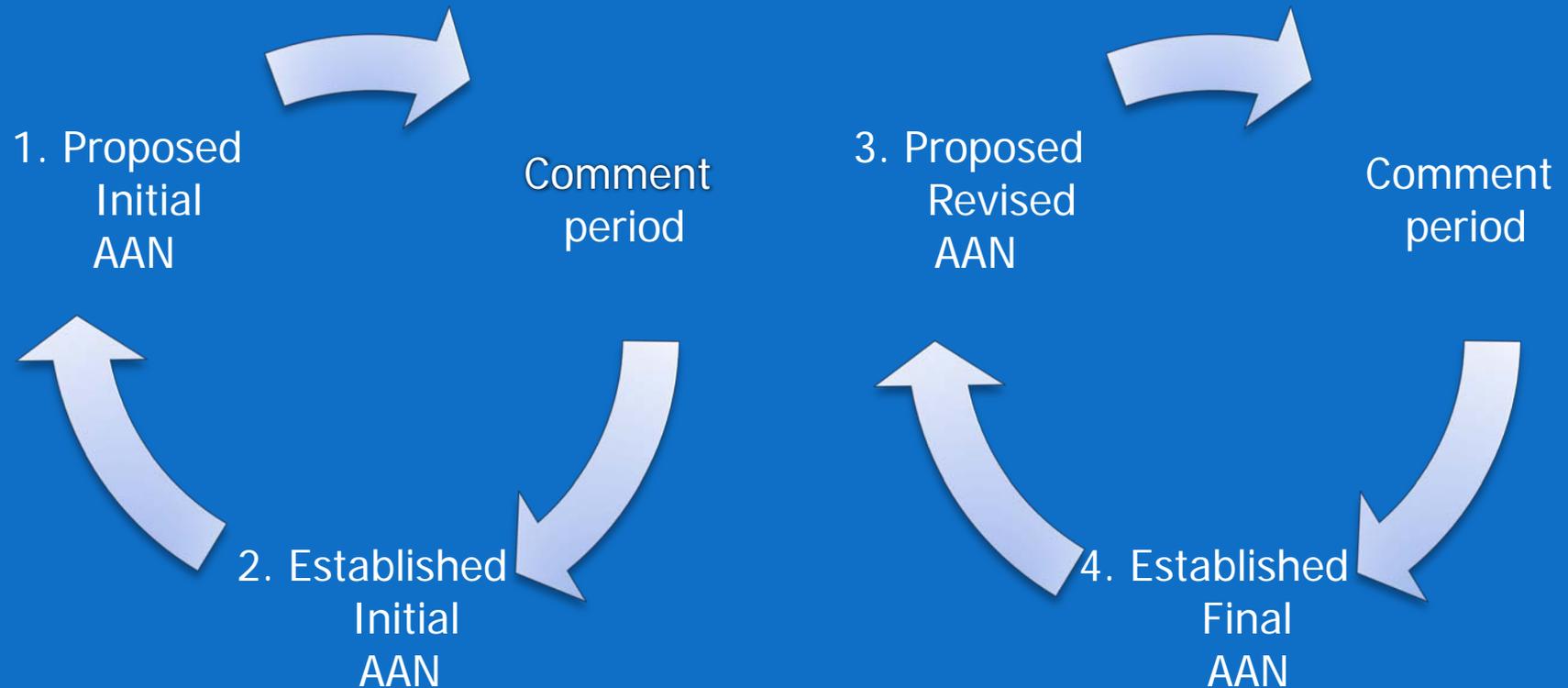
(con't)

- Before issuing individual quotas, DEA had to first establish the annual needs of the United States for EPH, PSE and PPA.
- The 2008 Assessment of Annual Needs (AAN) was published in the Federal Register on December 27, 2007.
- ODE began issuing individual quotas on December 30, 2007 for the calendar year 2008.

# Assessment of Annual Needs

- Upper limit of national production and importation requirements
- Established annually with one revision
- Federal Register notices required

# Assessment of Annual Needs (AAN) Federal Registers



# Overview of Procedure for Setting the Assessment of Annual Needs

- To develop the assessment of annual needs for the United States, DEA considered:
  - Applications for import, manufacturing and procurement quotas from DEA registered manufacturers and importers.
  - The national rate of disposals (sales/utilization)
  - Actual and estimated inventories
  - Projected demand for the list I chemicals ephedrine, pseudoephedrine and PPA

# AAN Evolution

- CS has 30 years of historical information
- Solicited industry, chem mfgs, public, physicians, statisticians, economist, data aggregators, politicians etc...
- 2008 AAN based on contract study
- Recent FDA determinations on PPA (human), ephedrine (dietary), pediatric products
- Movement of L1 to behind the counter / switch to phenylephrine
- Capturing legitimate sales
- **NO L1 QUOTAS HAVE EVER BEEN LIMITED BY THE AAN**

# Sample Calculation of Assessment of Annual Needs

Pseudoephedrine (for sale)	2007	2008	2009	2010 Request
Sales* (DEA 250)	238,608	223,196	286,516	225,116
Sales* (DEA 189)	100,300	64,781	33,600	32,760
Imports** (DEA 488)	232,822	170,995	267,808	233,569
Export Declarations (DEA 486)	42,132	47,194	25,526	n/a
Inventory* (DEA 250)	135,097	119,515	62,748	n/a
IMS *** (NSP)	180,204	149,159	n/a	n/a

DEA calculated the pseudoephedrine (for sale) assessment by the following methodology:  
2009 sales + reserve stock + export requirement – existing inventory = AAN

$286,516 + (50\% * 286,516) + 36,360 - 62,748 = 403,386$  kg pseudoephedrine (for sale) for 2010.

What is the US population?

A: Approx 309 million.

How much pseudoephedrine would be required to supply one 30 mg pseudoephedrine tablet for every man, woman, child and infant in the US?

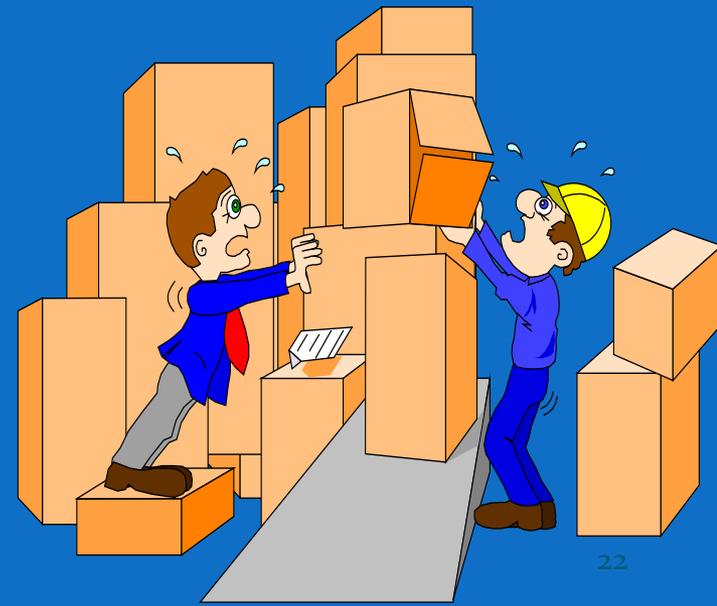
309 million x 30 mg = 9,270 kg HCL (7,601 kg base)

What was the 2010 AAN?

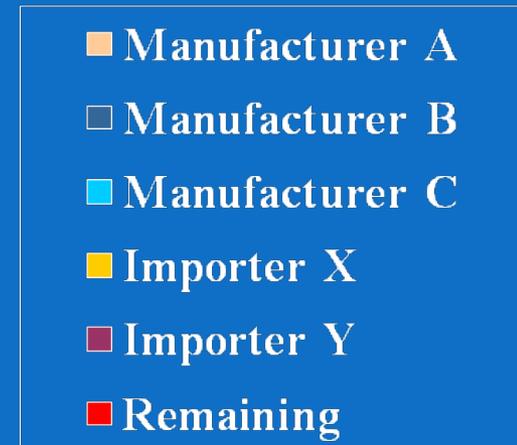
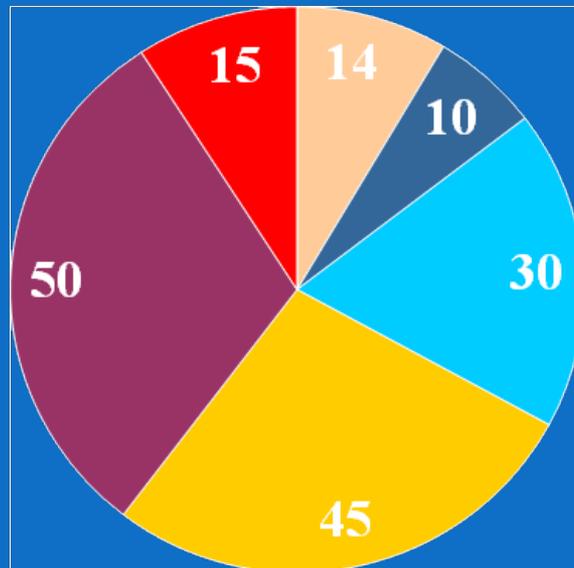
A: 404,000 kg (base)

\*note this will likely increase in the revised AAN

Why are application due dates important?

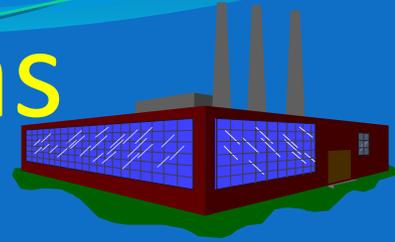
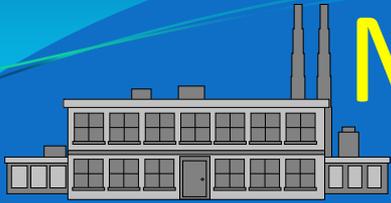


# Relationship Between Assessment of Annual Needs (AAN) and Manufacturing Quotas

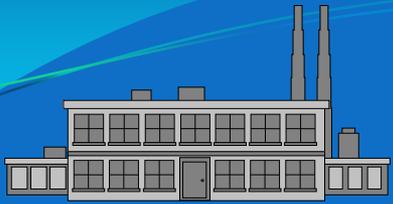


AAN = 164 kg

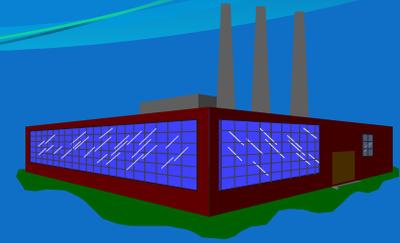
# Manufacturing Quotas



- Establish maximum amount which may be **manufactured** in a calendar year
- DEA registered bulk manufacturers cannot exceed manufacturing quota
- Sum of all issued manufacturing quotas is equal to / less than the Annual Assessment of Needs
- Establish guidelines for inventory allowances

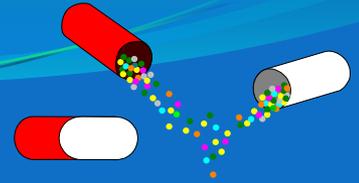


# Manufacturing Quota Inventory Allowance



- 21 CFR 1315.24
- Normally 50% of average net disposals for current and preceding year
- During calendar year may not exceed 65% of estimated net disposal
- Exceeding 65% will suspend quota until inventory is less than 60% of net disposals

# Procurement Quotas



- DEA registered manufacturers who procure a List 1 chemical for the purposes of:
  - ❖ Converting bulk API into finished dosage forms
  - ❖ Formulating products such as exempt chemical preparations or reference standards
  - ❖ Packaging, repackaging, labeling or re-labeling a commercial container or dosage form

PQ always received for these activities



# Procurement Quotas

- ❖ Establishes maximum amount which may be **acquired** in a calendar year
- ❖ Certification of adequate quota needed to place order (21 CFR 1315.32(h))
- ❖ Cannot exceed procurement quota
- ❖ Sum of procurement quotas determines amount of bulk material to be produced

# Data Used to Establish Quotas: Company Data

- ✓ Inventory including bulk, in-process and finished dosage forms
- ✓ Dispositions including both domestic sales and exports
- ✓ Acquisitions from both domestic manufacturers and importers
- ✓ Other factors: yields, product development needs, etc.

# Other Considerations

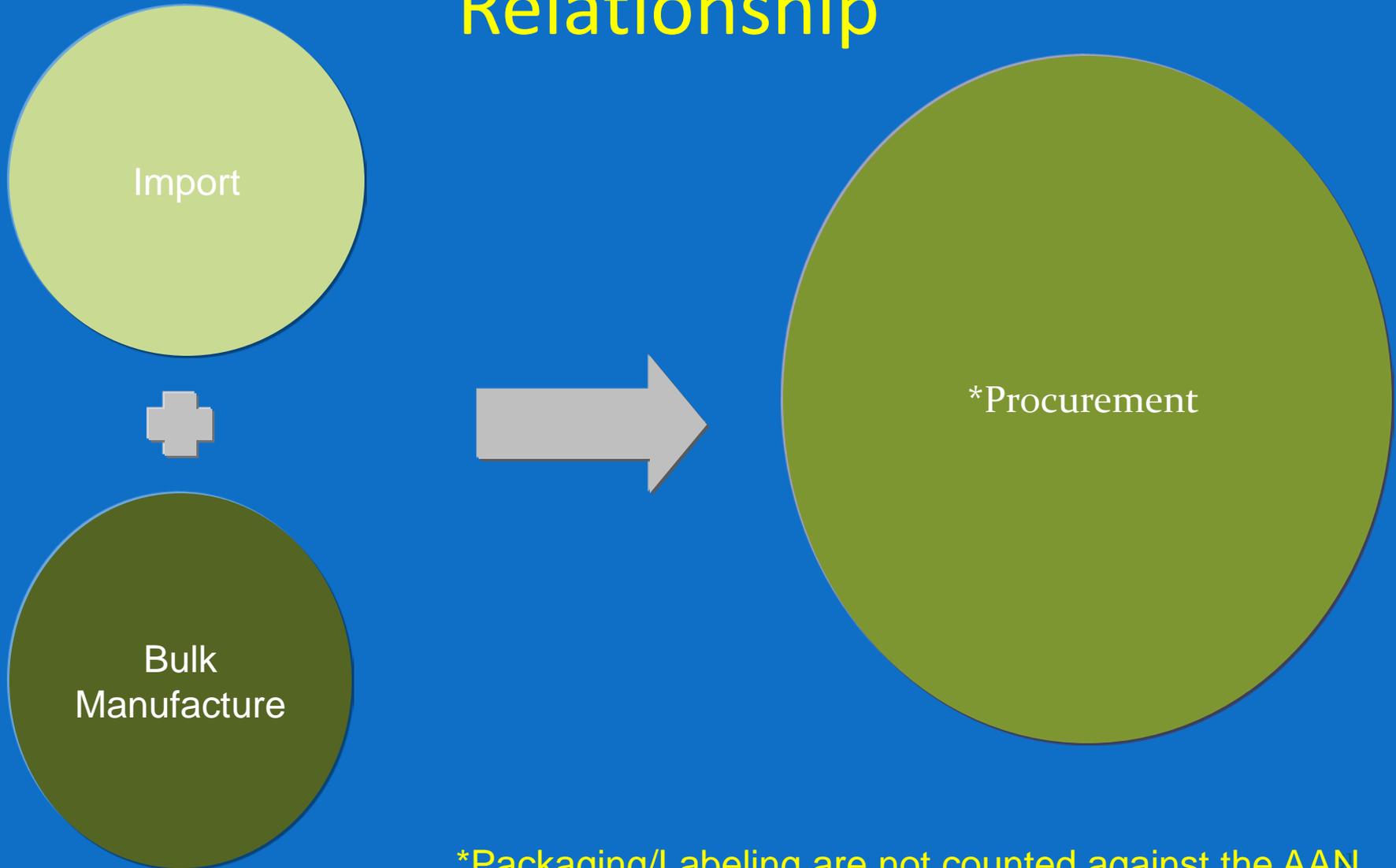
- Abuse Data
- Consumption Data
- Trafficking Data
- Investigational Studies
- Diversion Data



# Import Quotas

- DEA registered importer
- Only applies to pseudoephedrine, ephedrine and phenylpropanolamine
- Establishes maximum amount which may be imported in a calendar year
- Quota adjustments
- **NOTE:** an importer is also required to obtain an importation permit for these substances

# Import/Manufacture/Procurement - Relationship



\*Packaging/Labeling are not counted against the AAN

# Quota Types Summary

## Procurement

- DEA 250
- Applies to:
  - Dosage Manufacturers
  - Packagers
  - Labelers
  - Repackagers
  - Relabelers

## Import

- DEA 488 & Form A
- Applies to:
  - Importers of list I chemicals only

## Manufacturing

- DEA 189
- Applies to:
  - Bulk Manufacturers

# Frequently Asked Questions

Question: May registrants request an adjustment to their quotas?

Answer: Yes. Registrants may request an adjustment to quota(s) at anytime.

Request must be **in writing**

DEA may request additional information to support request.

# Frequently Asked Questions

What is the process when a DEA registrant has changed registration numbers?

Answer:

- 1) New Quota is needed to receive inventory from old registration
- 2) Additional new Quota is needed to continue activity under new registration

\*Must submit new DEA form 250s and 189s with original signatures

# Frequently Asked Questions

Can a DEA registered analytical lab import  
List I chemicals as a coincidental activity?

Answer: **No**. Only DEA registered importers may import  
List I chemicals.

Analytical labs may import controlled substances as a  
coincident activity only.

# Frequently Asked Questions

Does a manufacturer who consumes all of a list I chemical internally qualify as an “end user”?

Answer: **No.** All DEA registered manufactures who procure List I chemicals for a manufacturing activity must have quota, including those who do not distribute these list I chemicals.

The absence of this information would prevent DEA from considering all relevant information required by law when establishing the assessment of annual needs.

# Frequently Asked Questions

Can an importer of list I chemicals accept returns?

Answer: **No**. Returns to an Importer are not allowed under the current statute and regulations. However, if the material is “not usable” and returned to the importer then this will be allowable as an “incomplete transaction”

# Frequently Asked Questions

I am an importer and have a new customer can I supply the List I chemical to them?

Answer: You may import to the extent of your firms **import quota** and may supply API to your customers who can **supply certification** that they have quota to receive this material. You may request an adjustment to your firms import quota at anytime.

# Useful Websites

These links contain detailed information regarding controlled substances and the CMEA list 1 chemicals

[www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)

[www.deadiversion.usdoj.gov/meth/index.html](http://www.deadiversion.usdoj.gov/meth/index.html)