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Quotas for List I Chemicals

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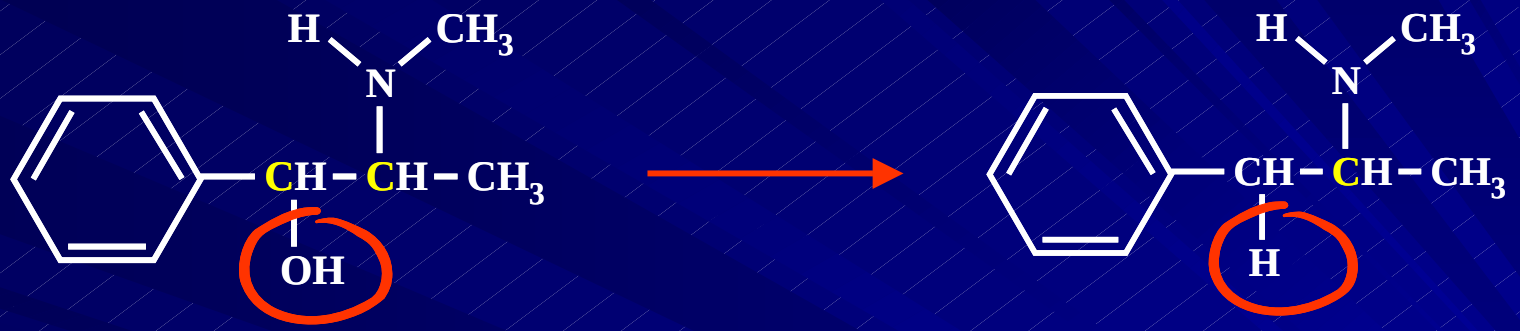
Combat Methamphetamine Epidemic Act (CMEA)

- Enacted on March 9, 2006.
- To prevent the illicit use of pseudoephedrine, ephedrine, and phenylpropanolamine in the clandestine synthesis of methamphetamine.
- CMEA places additional legislative and regulatory controls upon the manufacture, distribution, importation, and exportation of these List I chemicals.

METHAMPHETAMINE PRODUCTION

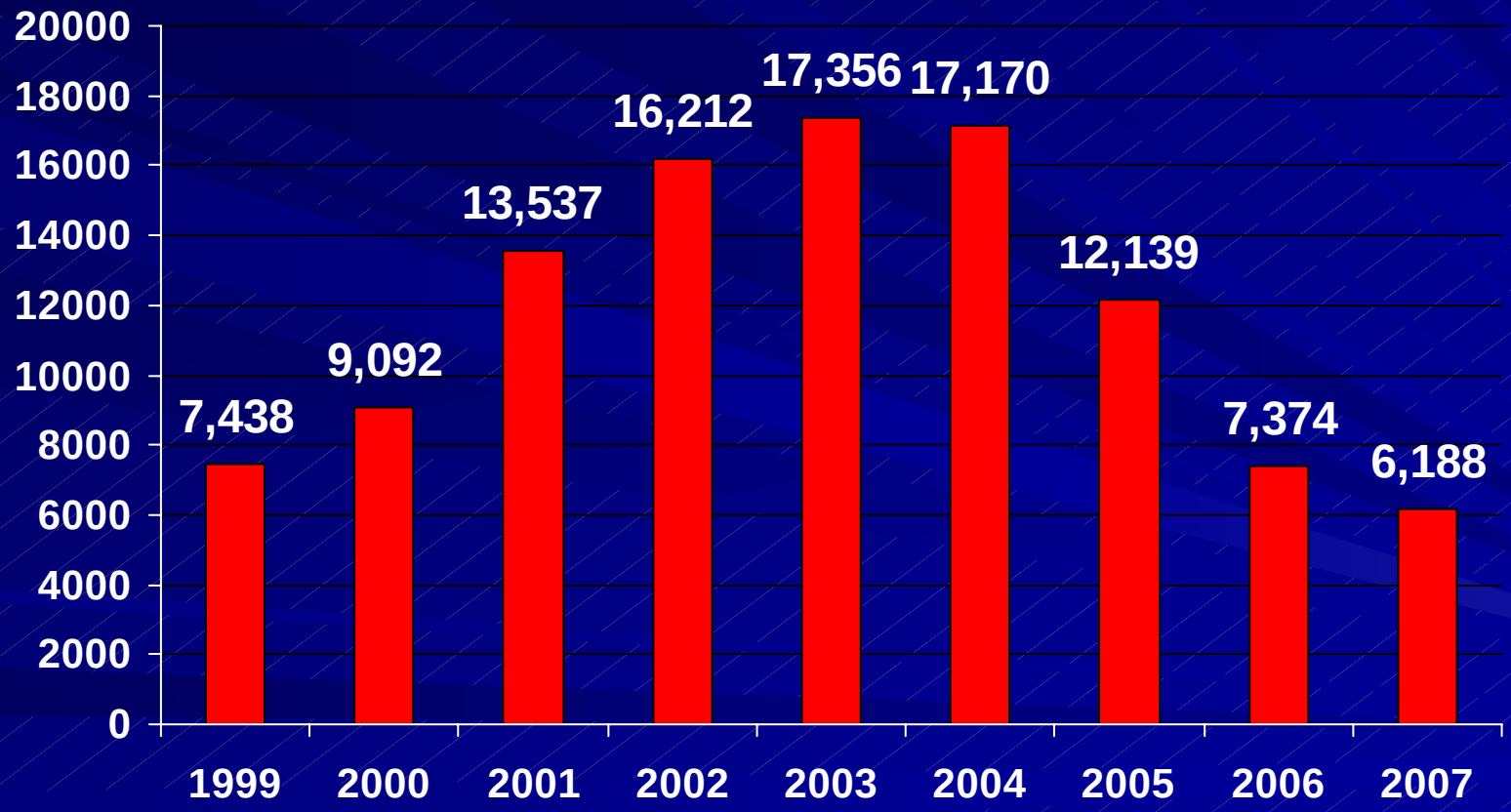


EPHEDRINE OR PSEUDOEPHEDRINE

METHAMPHETAMINE

Typical clandestine methamphetamine laboratory

DEA and State and Local Law Enforcement Methamphetamine Seizures (Includes Labs, dump sites, glassware and equipment seizures) Calendar Years 1999 – 2007



DEA Requirements Under CMEA

- CMEA mandates that DEA
  - Establish Assessment of Annual Need (AAN) for the List I chemicals ephedrine, pseudoephedrine and PPA.
  - Establish procedures for the administration of the import, manufacturing and procurement quotas for the List I chemicals ephedrine, pseudoephedrine and PPA.

Assessment of Annual Needs (AAN)- Provides for

- Assessment of Annual Need (AAN): The maximum quantity of pseudoephedrine, ephedrine and PPA that may be produced or imported annually

  - For the medical, scientific, research, and industrial needs of the United States
  - For lawful export and for reserve stocks

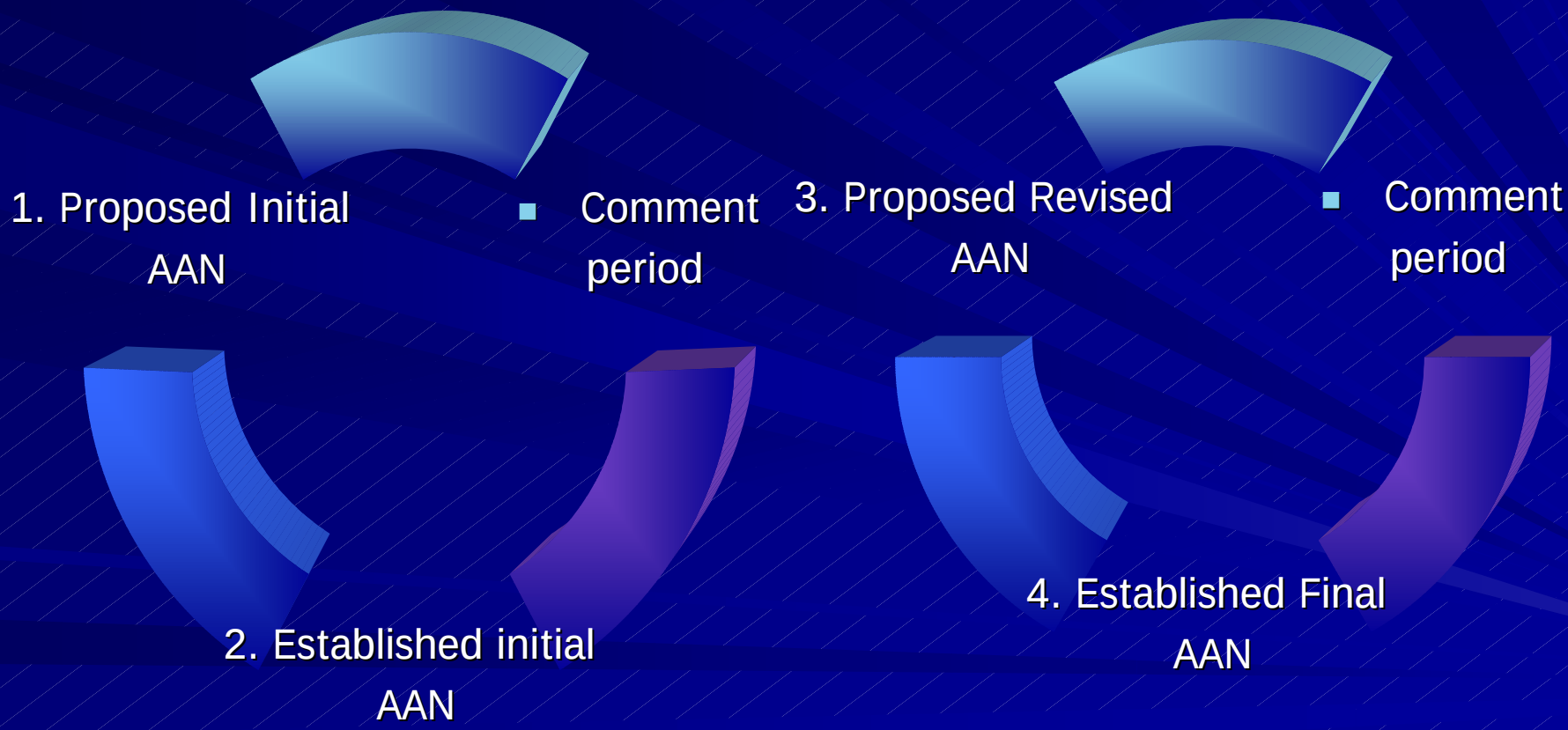
Assessment of Annual Needs (AAN) Considerations

- 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

2008 AAN Summary

- 2008 Proposed AAN – published Sept. 20, 2007
- 2008 AAN Established– published Dec. 27, 2007
- 2008 Revised AAN – published June 23, 2008

Federal Registers and the Assessment of Annual Needs (AAN)



2008 Assessment of Annual Needs

Established

PSEUDOEPHEDRINE	511,100	kg
EPHEDRINE (for sale)	11,500	kg
EPHEDRINE (conversion)	128,760	kg
PPA (for sale)	5,545	kg
PPA (conversion)	85,470	kg

Purpose of Quotas

- Provide for legitimate need of List I Chemicals
- Regulate the import, manufacture and procurement to those manufacturers/importers registered by DEA
- Regulate the quantity of List I chemicals which may be imported, manufactured or produced
- Provide adequate inventories

List I Quota: Types

Three types of Quotas for ephedrine, pseudoephedrine & PPA:

Procurement

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

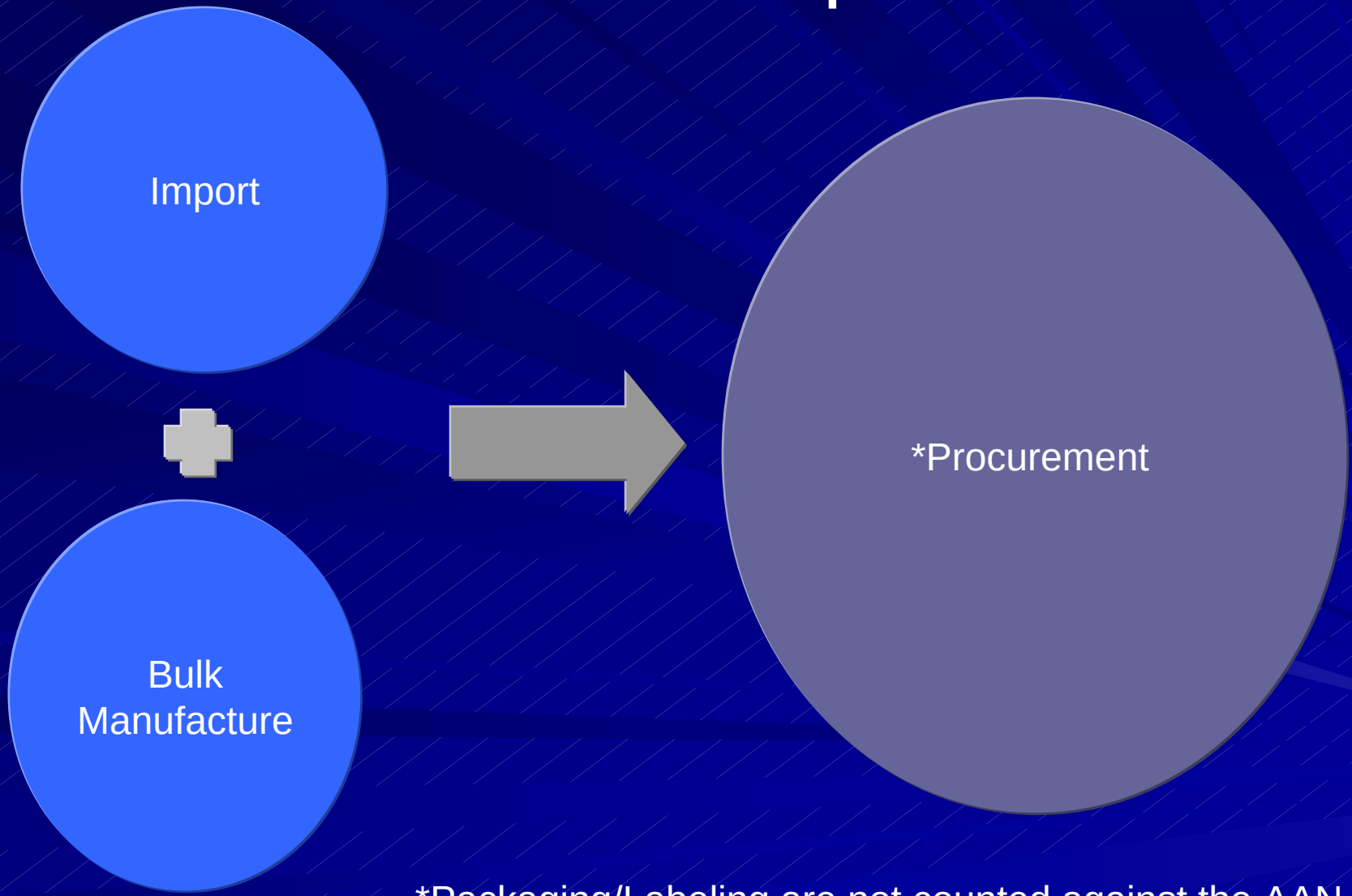
Import

- DEA 488 & Form A
- Applies to:
  - Importers

Manufacturing

- DEA 189
- Applies to:
  - Bulk Manufacturer

Import/Manufacture/Procurement - Relationship



*Packaging/Labeling are not counted against the AAN

Import Procedures

- Step 1: Must be a DEA registered importer registered to import each List I chemical
- Step 2: Apply for importation quota (DEA 488) due April 1 of the year preceding the year imports are to be applied.
- Step 3: In the year for which quota was granted, submit declaration to import (DEA-486).
- Step 4: Within 30 days of import, submit a return declaration to DEA (from DEA-486).
- Step 5: Certifications – an importer must receive certification in writing the quantity (as base) being ordered dos not exceed their customers procurement quota

Manufacturing (Bulk) Procedures

- Step 1: Must be a DEA registered manufacturer registered for each List I chemical

- Step 2: Apply for a manufacturing quota (DEA-189) due May 1 of the year preceding the year quotas are to be applied.

Procurement Procedures

- Step 1: Must be a DEA registered manufacturer registered for each List I chemical

- Step 2: Apply for procurement quota (DEA-250) due April 1 of the year preceding the year quotas are to be applied.

- Step 3: Certification – when ordering these list I chemicals your firm must provide certification that the quantity (as base) does not exceed quota.

Quota Applications- Information Required -

- Inventory
  - As of December 31st for the current and preceding 2 years
- Acquisition/Production
  - Domestic Purchases and Imports (both acquired against quotas)
- Disposition/Utilization
  - Domestic sales, transfer, or usage
  - Exports
- A statement about the purpose(s).
  - Official/chemical/brand name of the dosage form and the strength(s) required. Specific FDA authority to market product.
  - Type of activity intended: product development, repackaging, relabeling, manufacturing OTC finished product, manufacturing prescription finished product.
  - If the purpose is to manufacture a controlled substance listed in Schedule I or II or another List I chemical, the applicant must state the quantity of the other substance or chemical that the applicant has applied to manufacture under § 1303.22 and the quantity of the first chemical needed to manufacture a specified unit of the second chemical.

Registration

- DEA can ONLY issue quotas to DEA-registered importers and manufacturers that have the drug codes specifically listed on their registration.

- Manufacturers and importers of ephedrine, pseudoephedrine, and phenylpropanolamine are **required to register with the DEA**
  - Registration must be obtained for each chemical for each physical location where these List I chemicals are manufactured, distributed, imported, or exported.

- Registered controlled substances manufacturers at the same location where these List I chemicals are also manufactured must
  - Have each List I chemical added to their registrations

Registration (continued)

- NPRM: Registration Requirements for Importers and Manufacturers of Prescription Drug Products Containing List I Chemicals
  - On Jan 18, 2008 DEA published a notice of proposed rulemaking entitled "Registration Requirements for importers and manufacturers of Prescription Drug Products containing Ephedrine, Pseudoephedrine or Phenylpropanolamine.
  - Proposal seeks to amend the registration regulations to ensure that every location that manufactures or imports List I chemicals is a DEA registered manufacturer or importer in accordance with the CMEA.
  - Note: Only DEA registered manufactures and importers may be issued quotas

Status of the Annual Assessment of Needs

As of September 15, 2008, DEA has processed **250** of **276** quota applications.

No quotas have be reduced due to limitations in the available AAN.

Chemical	2008 AAN	2008 PQ's* (June 2008)
PSEUDOEPHEDRINE	511,100	226,000
EPHEDRINE (for sale)	11,500	1,288
EPHEDRINE (conversion)	128,760	69,576
PPA (for sale)	5,545	2,401
PPA (conversion)	85,470	16,923

***PQ=Procurement Quotas not including packagers/relabelers**

Frequently Asked Questions

- Question: May I request an adjustment to my quota?
- Answer: Yes. You may request an adjustment to your quota(s) at anytime.
  - Request must be in writing DEA may request additional information to support request.
  - Providing the following information may decrease the time necessary to process your request:
    - Reason for increase – sales, product development, etc.
    - Product to be manufactured, procured or imported
    - Information relating to the utilization of the proposed quota increase.
    - Year-to-date (YTD) sales
    - Purchase orders, letters of intent, delivery schedules.

Frequently Asked Questions

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

- Answer: No. Analytical labs may import controlled substances as a coincident activity only.
- DEA registered importers are the only registrant category that can import List I chemicals.

Frequently Asked Questions

- Question: What business activities are allowed with List I chemicals as "coincident" activities under a manufacturer registration?
- Answer: None. Neither a DEA-registered chemical manufacturer nor DEA-registered controlled substance manufacturer may perform coincident activities with List I chemicals.
- However, a DEA-registered controlled substance manufacturer may distribute and conduct chemical analysis and preclinical research (including quality control analysis) with the controlled substance for which the manufacturer is registered.

Frequently Asked Questions

- Question: I have received List I chemicals from an importer. The materials failed specifications. May I return the materials to the importer?
- Answer: No. DEA registered importers are only authorized to import listed chemicals, they cannot procure List I chemicals domestically.
- Your firm may request a procurement quota to replace the unusable material.

Useful Websites

- DEA Office of Diversion Control
  - www.deadiversion.usdoj.gov
- Government Printing Office
  - www.gpoaccess.gov