

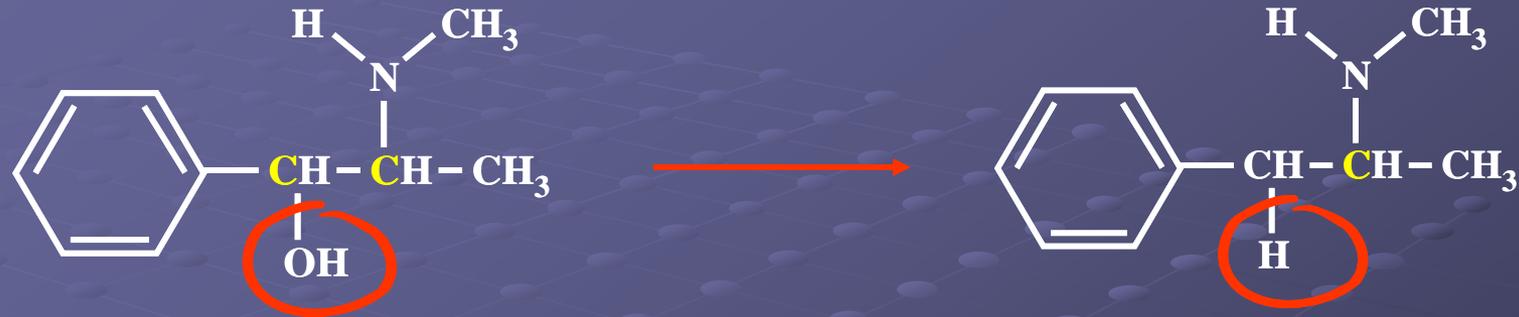
# Drug & Chemical Evaluation Section Office of Diversion Control

14<sup>th</sup> DEA Pharmaceutical Industry  
Conference  
Portland, OR  
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# METHAMPHETAMINE PRODUCTION



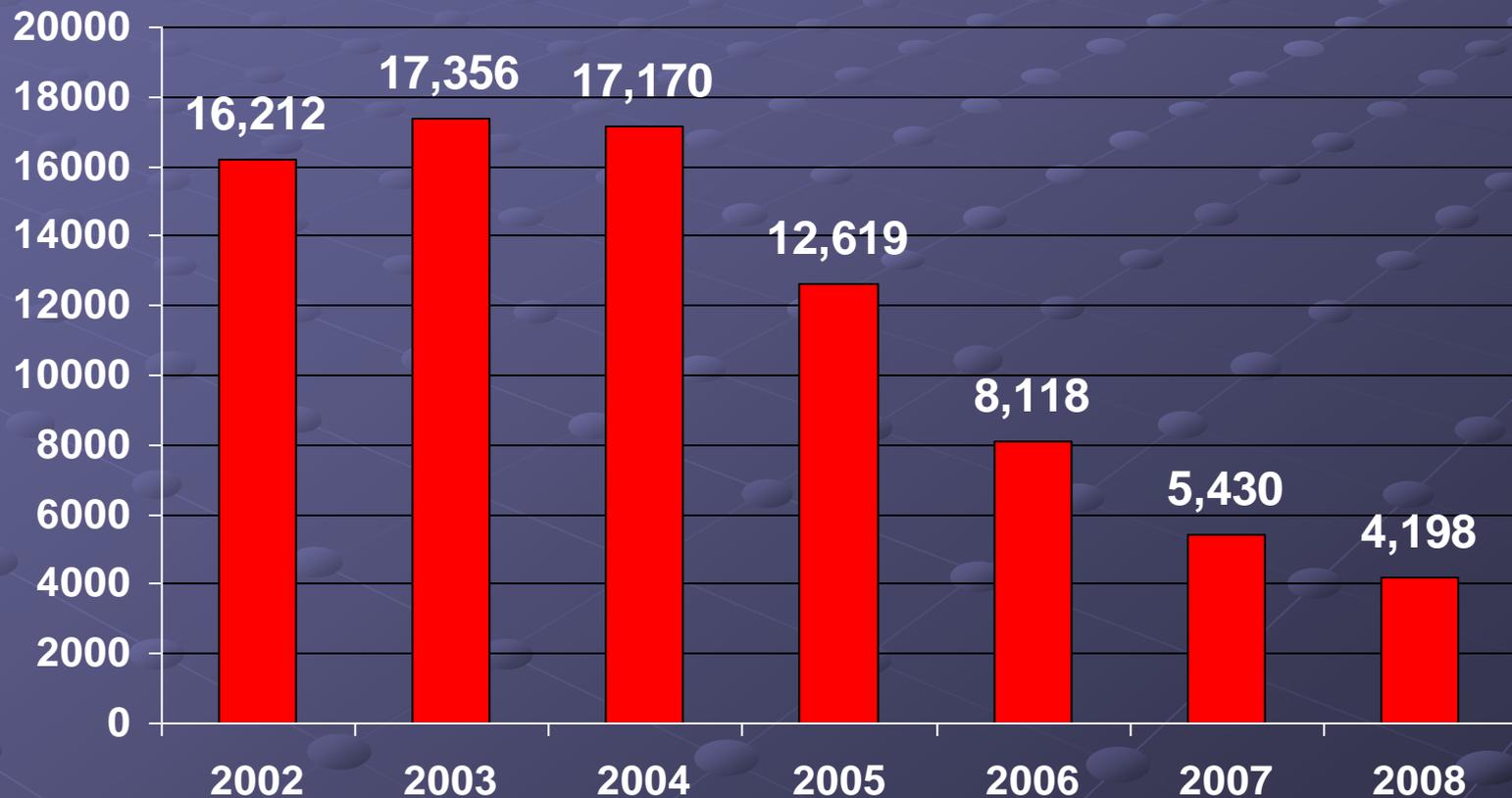
**EPHEDRINE OR PSEUDOEPHEDRINE**

**METHAMPHETAMINE**



Typical clandestine  
methamphetamine  
laboratory

**DEA and State and Local Law Enforcement Methamphetamine Seizures  
(Includes Labs, dump sites, glassware and equipment seizures)  
Calendar Years 2002 – 2008**



Drug and Chemical Evaluation (ODE) **As of: May 2009**

# 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**

# 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

# Registration

- 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**

# Who Needs Quota? Following a Product From Start To Finish

- A bulk manufacturer imports bulk ephedrine for conversion into pseudoephedrine. They sell pseudoephedrine to company “A” which converts the bulk pseudoephedrine into dosage forms.

# Who Needs Quota Answers:

- Bulk manufacturer and importer
  - **Import Quota (ephedrine)** is required to import the ephedrine into the U.S. under an importer registration
  - **Procurement Quota (ephedrine)** is required to move the ephedrine from their importer registration to their manufacturing registration.
  - **Manufacturing Quota (pseudoephedrine)** is required to manufacture pseudoephedrine from the ephedrine.
- Company A – dosage form manufacturer
  - **Procurement Quota (pseudoephedrine)** is required to procure bulk pseudoephedrine for dosage form manufacturing.

# 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

- **Question:** 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

- **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:** 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” then a return be allowable as an “incomplete transaction”

# Frequently Asked Questions

- Does a manufacturer who consumes all of a list I chemical internally qualify as an “end user”?
  - Answer: No. All manufactures who perform a manufacturing activity who procure List I chemicals must have quota, including those who do not distribute these list I chemicals and would otherwise be considered an “end user.”
  - The absence of this information would prevent DEA from considering all relevant information required by law when establishing the assessment of annual needs.

# Useful Websites

- This link contains detailed information including FAQ's regarding quotas and the annual assessment of needs.

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