# Quotas for List I Chemicals

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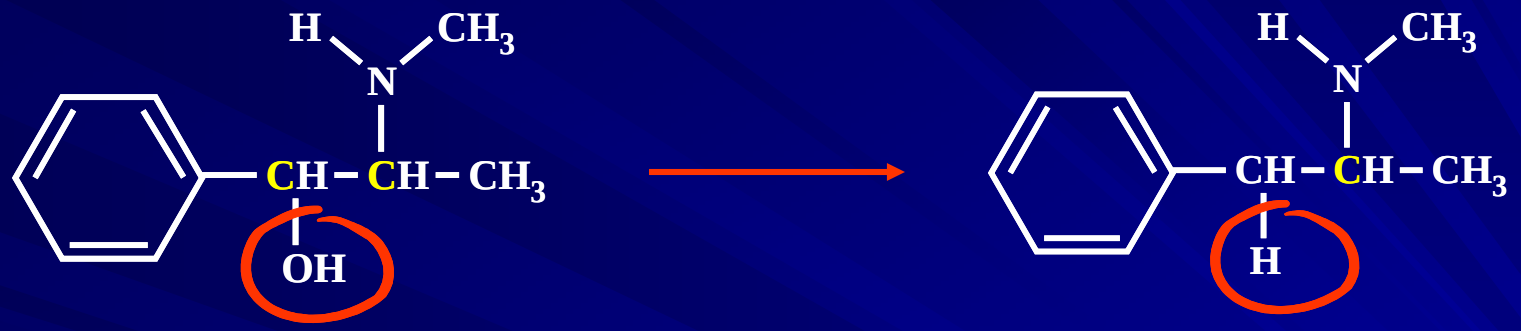
# Objective

- Problem: Clandestine manufacture of methamphetamine in the US.
- Solution: Combat Methamphetamine Epidemic Act of 2005 (CMEA)
  - Quota Requirements under CMEA
  - Status of DEA Implementation

# METHAMPHETAMINE PRODUCTION




**EPHEDRINE OR PSEUDOEPHEDRINE** **METHAMPHETAMINE**

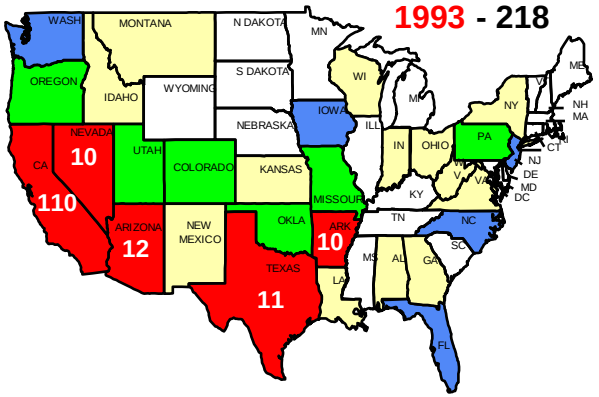
**REACT WITH IODINE AND RED PHOSPHORUS**

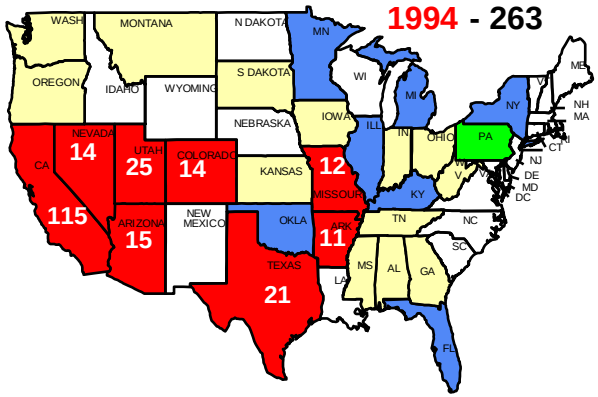
Typical clandestine methamphetamine laboratory

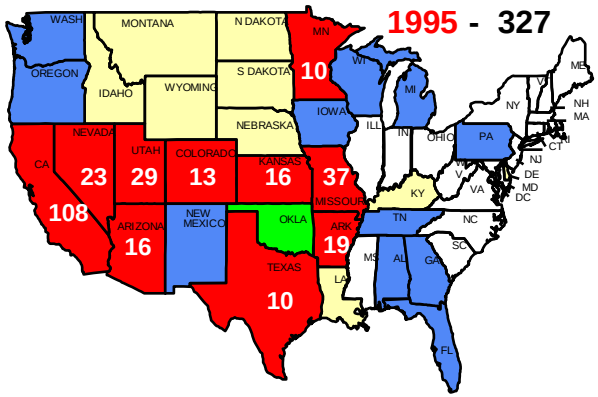
# “Mexican Crime Group Methamphetamine ‘SUPER LAB’ Seizure in California.”

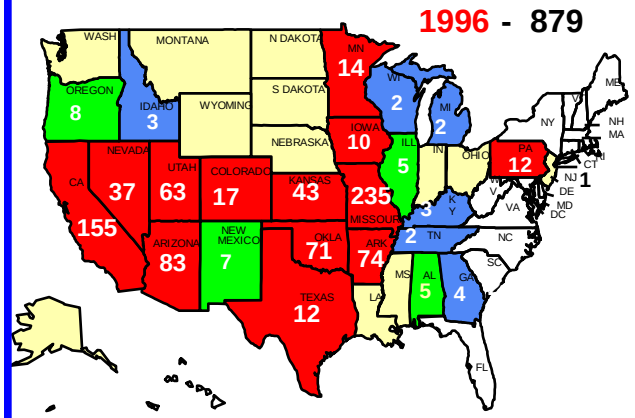
**U.S. Department of Justice**
Drug Enforcement Administration
*Office of Diversion Control*
*Chemical Investigations Section*

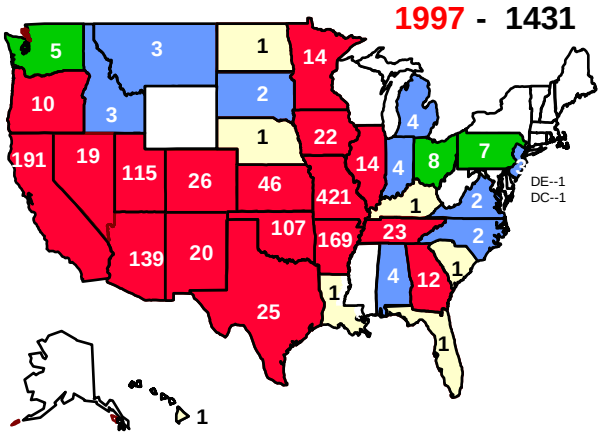
# Methamphetamine
# Clandestine Laboratory Seizures
***With DEA participation***

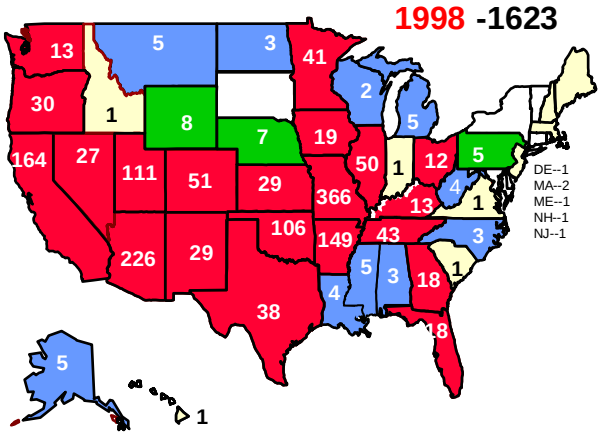
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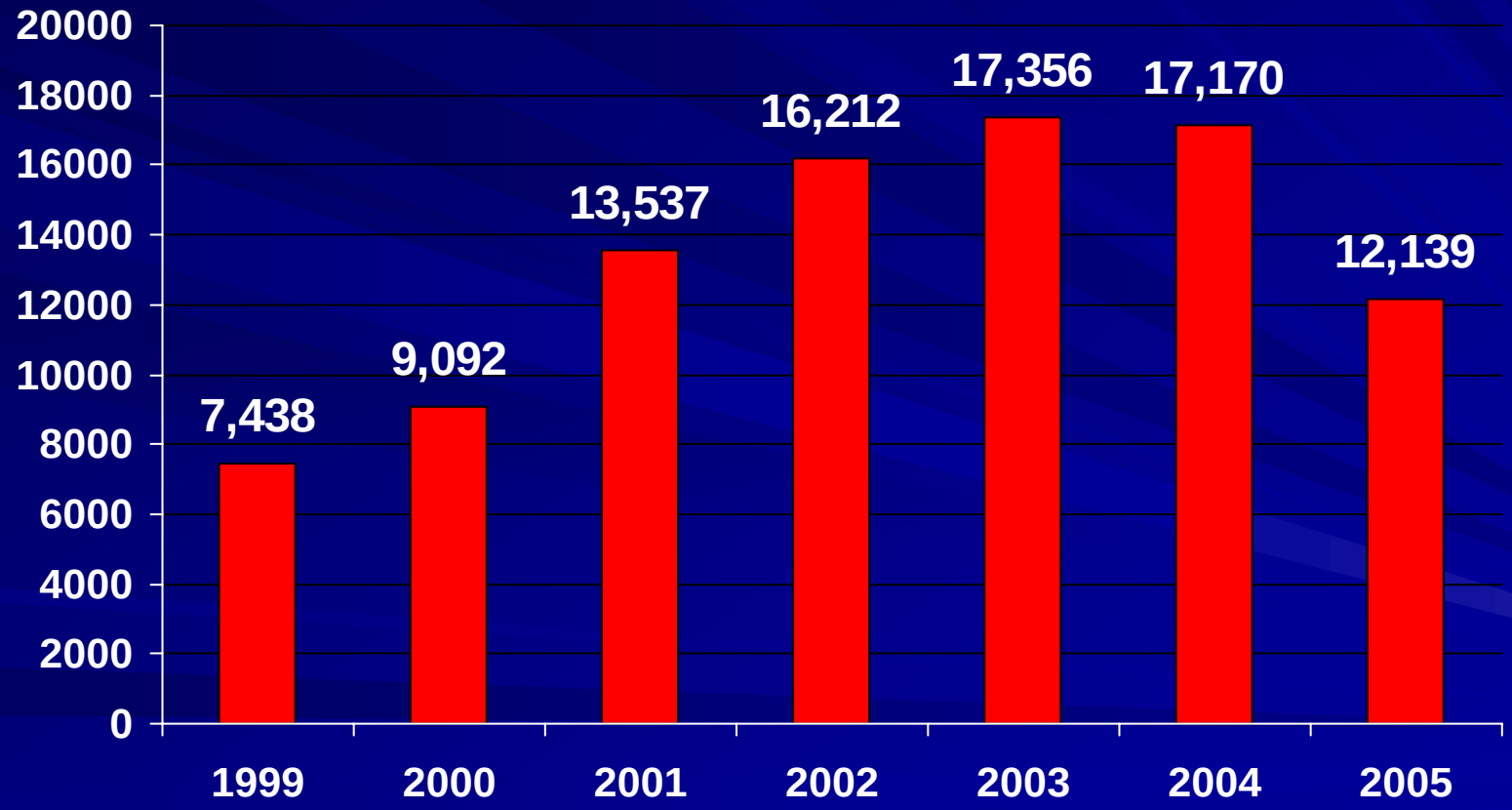
## DEA and State and Local Law Enforcement Methamphetamine Seizures (Includes Labs, dump sites, glassware and equipment seizures) Calendar Years 1999 – 2005 (Reported through June 2006)



# 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.

# Registration

- Manufacturers and importers of ephedrine, pseudoephedrine, and phenylpropanolamine are **required to register with the DEA**
  - Registration must be obtained 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 will not be required to register separately to conduct the same activity

# Registration (continued)

- Unless exempted by law or under §§ 1309.24 through 1309.26, the following persons must annually obtain a registration specific to the List I chemicals to be handled:
  - Each person who manufacturers or imports or proposes to manufacture or import a List I chemical or drug product containing ephedrine, pseudoephedrine, or phenylpropanolamine
  - Each person who distributes or exports or proposes to distribute or export any List I chemical, other than those List I chemicals contained in a product exempted under § 1300.02(b)(28)(i)(D) of this chapter

# Registration (continued)

- The following groups of activities are deemed to be independent of each other:
  1. Manufacturing List I chemicals or drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine.
  2. Importing List I chemicals or drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine.
  3. Distributing List I chemicals.
  4. Exporting List I chemicals.

# Quota Requirements Under CMEA

- DEA Requirements Under CMEA:
  - Establish an Annual Assessment of Need (AAN): The maximum quantity of each chemical that may be produced or imported annually to meet the estimated medical, scientific, research, and industrial needs of the United States, for lawful export, and for the maintenance of reserve stocks.
- Manufacturer Requirements Under CMEA:
  - Bulk manufacturers must obtain a manufacturing quota (DEA-189) to produce any of the three chemicals.
  - Manufacturers who purchase the bulk chemicals to produce products must obtain a procurement quota (DEA-250).
- Importer Requirements Under CMEA:
  - Importers must obtain a quota to import the chemicals in bulk or in drug products.
  - Importers and brokers and traders must provide additional information on the persons to whom they intend to sell the chemicals prior to the sale.
  - Importers must provide return declaration

# Quota for Manufacturers

- DEA Form 189
  - Manufacturing Quota Application
  - ONLY FOR **BULK MANUFACTURERS**
  - Due May 1st of the calendar year preceding the year for which the quota is being requested
- DEA Form 250
  - Procurement Quota Application
  - FOR ALL **"NON-BULK" MANUFACTURERS**
  - Needed in order to obtain the controlled substance or List I chemical to the physical location
  - Due April 1st of the calendar year preceding the year for which the quota is being requested

# Quota for Manufacturers

## - 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.
  - 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.

# Quotas for Importers

- CMEA amends 21 U.S.C. § 952 by adding a new paragraph (d) to cover the importation of the three chemicals:
  - Section 715 (conference report) extends Attorney General's (AG) authority to set quotas for controlled substances to imports of pseudoephedrine, ephedrine, and phenylpropanolamine.
  - Registered importers apply for temporary or permanent increases in a quota to meet legitimate needs.
  - The AG is required to act within 60 days.

# Quotas for Importers
## - Information Required -

- Application is under development.
- Importers will be required to submit an application that includes the following information:
  - The type of product (bulk, finished dosage forms to be transferred to a manufacturer, or product to be sold for distribution only).
  - The quantity of each type of product requested.
  - For the previous two years
    - the name, address, and DEA registration number of each customer and the amount sold;
    - inventory as of December 31 for each form of the product (i.e., bulk chemical, in-process material, or finished dosage form);
    - and acquisitions (imports).

# Three Step Process to Import

- Step 1: In the preceding year, request and obtain an import quota from DEA.
- Step 2: In the year for which quota was granted, request and obtain authorization to import (amended DEA-486).
- Step 3: Within 30 days of import, submit a return declaration to DEA.

# CMEA Quota Implementation

- Establish regulations in the Code of Federal Regulations.
- Establish the Assessment of Annual Need for ephedrine, pseudoephedrine and phenylpropanolamine

# CMEA Implementation

## - Assessment of Annual Need (AAN) -

For 2007:

**(2005 medical and industrial needs x inventory allowance) + 2005 exports.**

# CMEA Implementation

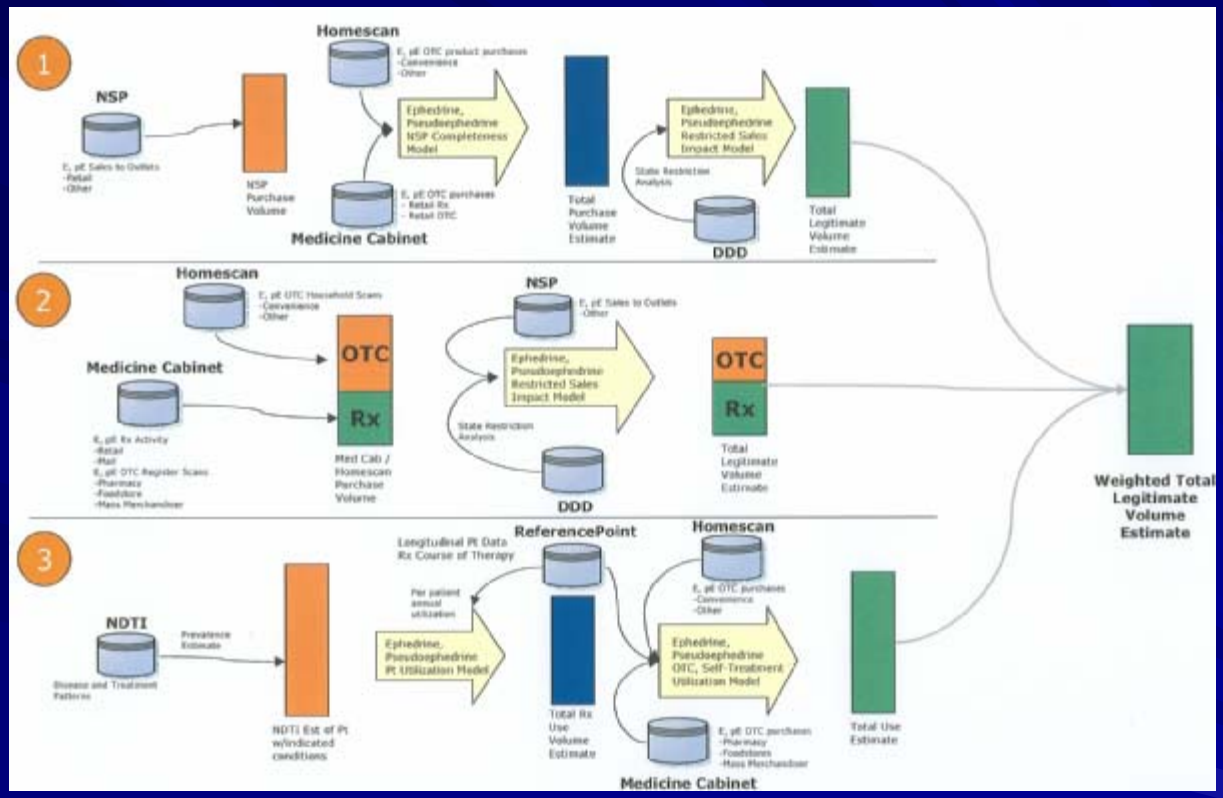
- On May 22, 2006, Office of Diversion Control (OD) sent a letter to all DEA registered importers and manufacturers of controlled substances and List I chemicals, soliciting applications for procurement and manufacturing quota.

# Medical Needs of the US

DEA contracted IMS Health (IMS), the industry leader in pharmaceutical sales data and data analysis, to develop an estimate of the “medical use” of ephedrine and pseudoephedrine for 2005.

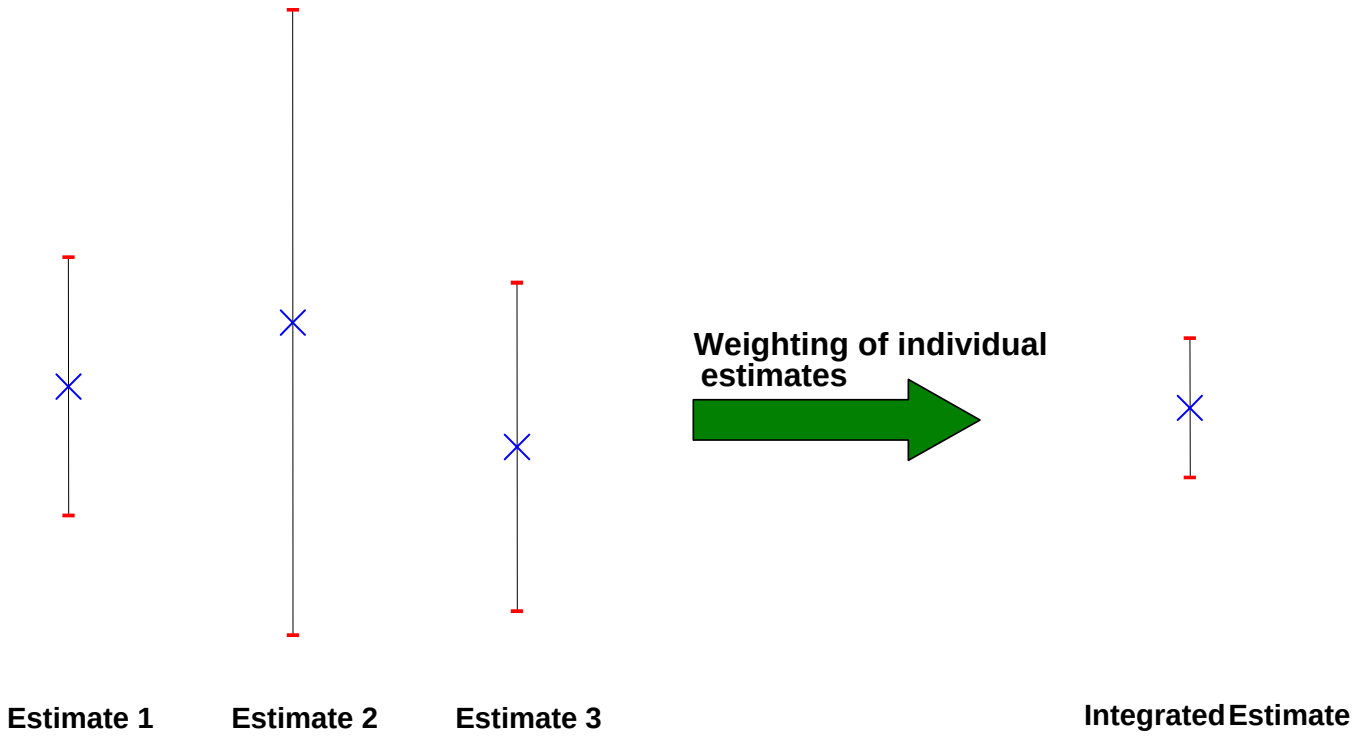
- Since PPA is used only for veterinary purposes in the U.S., the legitimate needs were not determined by IMS.

# IMS' 3 Independent Models




The generated estimates were based on the integration of data IMS currently has available; 1) retail sales; 2) patient distribution; and 3) medical claims.

# Illustration of IMS' Estimate Integration



# Status: Implementing CMEA

- ✓ Assess “medical needs” of the US
- ✓ Assess “industrial needs” of the US
- ✓ Assess export requirements
- ✓ Consider inventory requirements
- ✓ Publish the Initial Proposed Annual Assessment of Needs
  - Solicit Public Comments – December 4, 2006
  - Review Public Comments
- Draft Final AAN after consideration of public comments

# Status

- Notice of Proposed Rulemaking (NPRM) to implement regulations in Federal Register
  - DEA preparation
  - DOJ/OMB review
  - Solicit public comments
  - Review public comments
- Draft Final Rule after consideration of public comments

# Initial Proposed AAN
# - 71 FR 61801 -

## The Proposed Assessments of Annual Need

- PSE 511,100 kg
- EPH (for sale) 7,100 kg
- EPH (for conversion) 128,760 kg
- PPA (for sale) 5,545 kg
- PPA (for conversion) 6,240 kg

# Important Websites

- Diversion, www.deadiversion.usdoj.gov
- www.gpoaccess.gov (Updated FRs published daily)