



QUOTAS

Minh T. Dang

United Nations Reporting & Quota Section

Office of Diversion Control

Drug Enforcement Administration

UN Reporting & Quota Section (ODQ)

Function

- Quotas & UN Reports & Other duties as assigned

Industry

- >400 registered manufacturers / manufacture or procure > 400 CI-CII & Chemicals
- Every registrant is unique
- 160,000 potential combinations of quotas

Staff

UN Reporting & Quota Section



Dr. Christine A. Sannerud

Section Chief

NY / MI / MD

Ph.D. Behavioral Pharmacology,

20+ Years DEA

Avid Reader



Stacy Harper-Avilla

Unit Chief

NY / FL / CA

MS Environmental Toxicology/ DB Design

Volunteer Tutor

UN Reporting & Quota Section



Dr. Gregory Kavanaugh
Hawaii/ PA/ Cincinnati
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MS Biology



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Ph.D. Biomedical Sciences
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UN Reporting & Quota Section

Erika Gehrman

Diversion Investigator DEA
30+ YEARS
Quota Reviewer
NY
Loves Dogs



Minh T. DANG

DEA 18+ YEARS
California
Beach Volleyball /
Watersports
Clandestine Lab Certified
MS Chemical Toxicology

- Analytical Chemistry
- Forensic Chemistry
- Biochemistry

ODQ Section

2 managers & 4 staff scientist

What do these folks have in common?

Controlled Substance Act (CSA)



Controlled Substance Act

Schedule I- QUOTAS

Substances with high abuse potential and no medical utility (most restrictive)

Schedule II- QUOTAS

Substances with high abuse potential and medical utility

Schedule III, IV and V—

Substances with medical utility in the U.S. and progressively lower levels of abuse potential



Combat Methamphetamine Epidemic Act (CMEA)

C

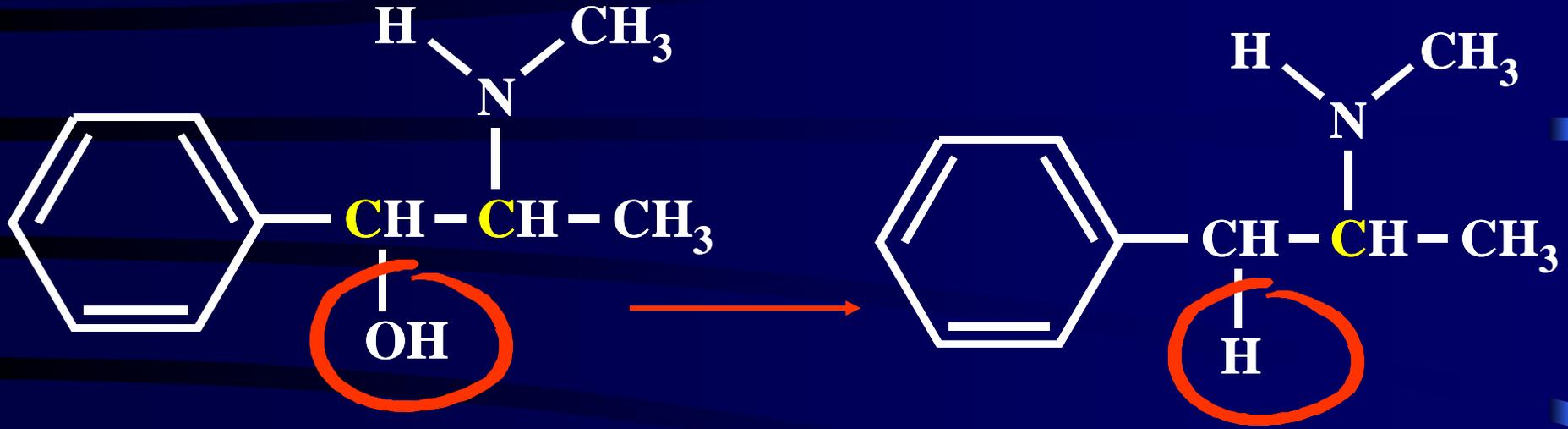
M

E

A

- ❖ Signed into law March 9, 2006
- ❖ Implemented January 1, 2008
- ❖ Added **quota** requirements to:
 - **Pseudoephedrine**
 - **Ephedrine**
 - **Phenylpropanolamine**
- ❖ Created Importation quota (PE, E, PPA)
- ❖ Amended 21 U.S.C. 826, 844, and 952

Ephedrine Reduction



**EPHEDRINE
OR PSEUDOEPHEDRINE**

METHAMPHETAMINE

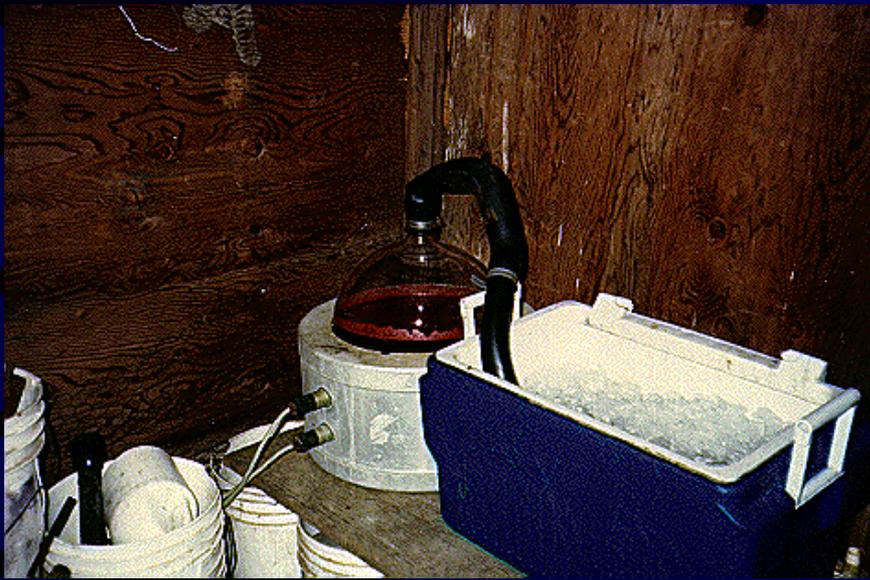
- Reduction of ephedrine/pseudoephedrine

Why CMEA?



Clandestine Drug Laboratories

Clandestine Laboratories



Clan Lab Dumpsites

Near water sources



Roadside



National Parks

Forests

CMEA Perspective

- Since CMEA precipitous declines in clandestine super labs
- **Q:** CMEA signed 2006 DEA implemented 2008. WHY?
- Seen non-registered manufactures leave the market
- Seen increase in production for legit manufactures

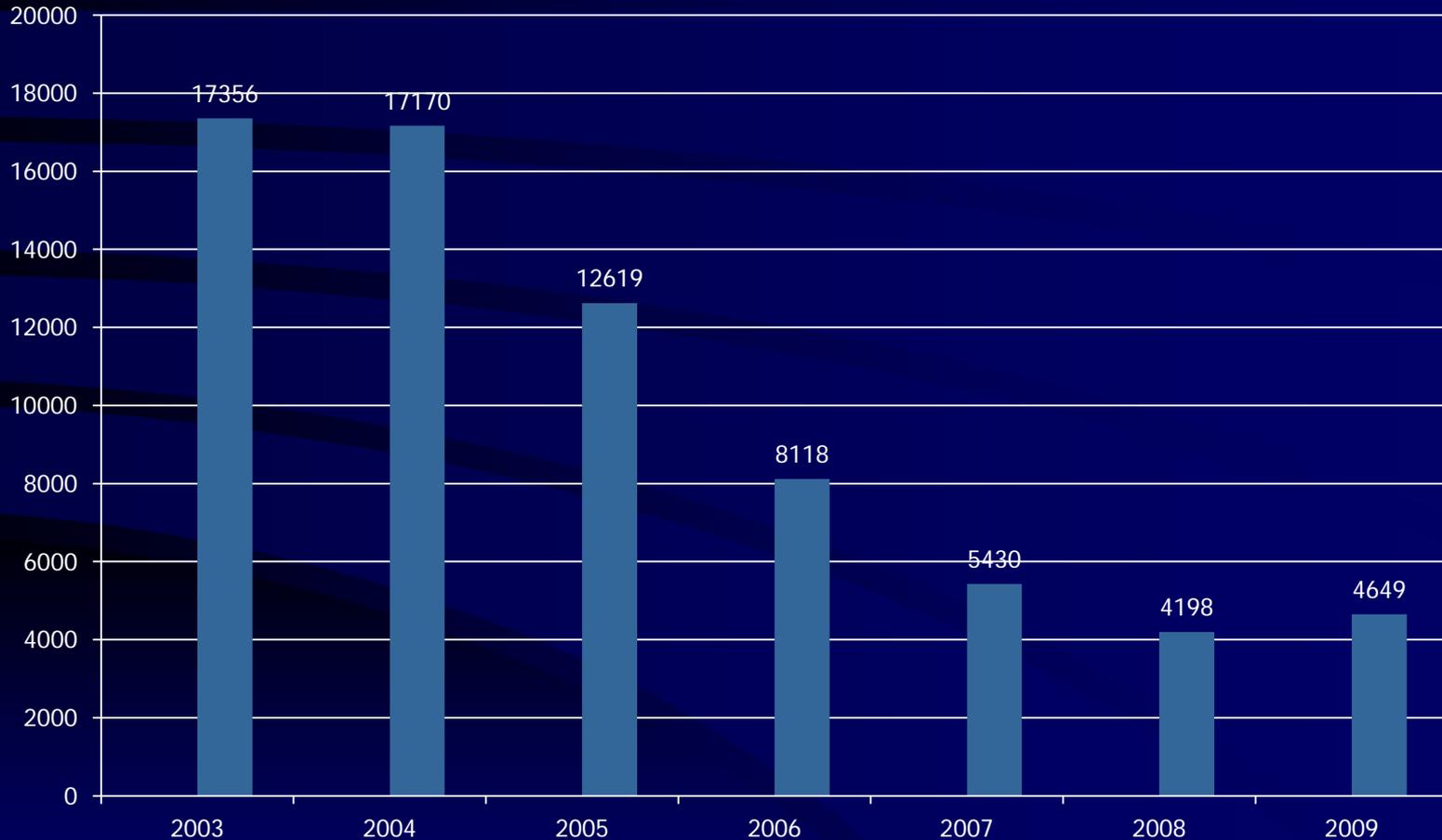
Q: How much pseudoephedrine would be required to provide every man/woman/child/baby (315 mil) in the US with one 30 mg tablet?

A: 7,749 kg

Q: What is the 2013 AAN for pseudoephedrine?

A: 225,000 kg

**DEA and State and Local Law Enforcement Methamphetamine Seizures
(Includes Labs, dump sites, glassware and equipment seizures)
Calendar Years 2002 – 2009**



As of: Feb 2010



Quota Regulations CSA & CMEA

Regulations pursuant to 21 CFR

- ✓ Part 1303 (Controlled Sub)
- ✓ Part 1315 (Chemicals)

Purpose of Quotas

- Provide for legitimate need for schedule I & II CS and for the three list I chemicals (PE, E, and PPA).
- Restrict the manufacture and procurement to those manufacturers registered by the DEA
- Provide for inventory allowance

Controlled Substances & Chemicals Lists

- * Controlled Substances Act (CSA)

- * Federal Register Notices

- * Diversion Website

www.deadiversion.usdoj.gov

- * Drug & Chemical Evaluation Section

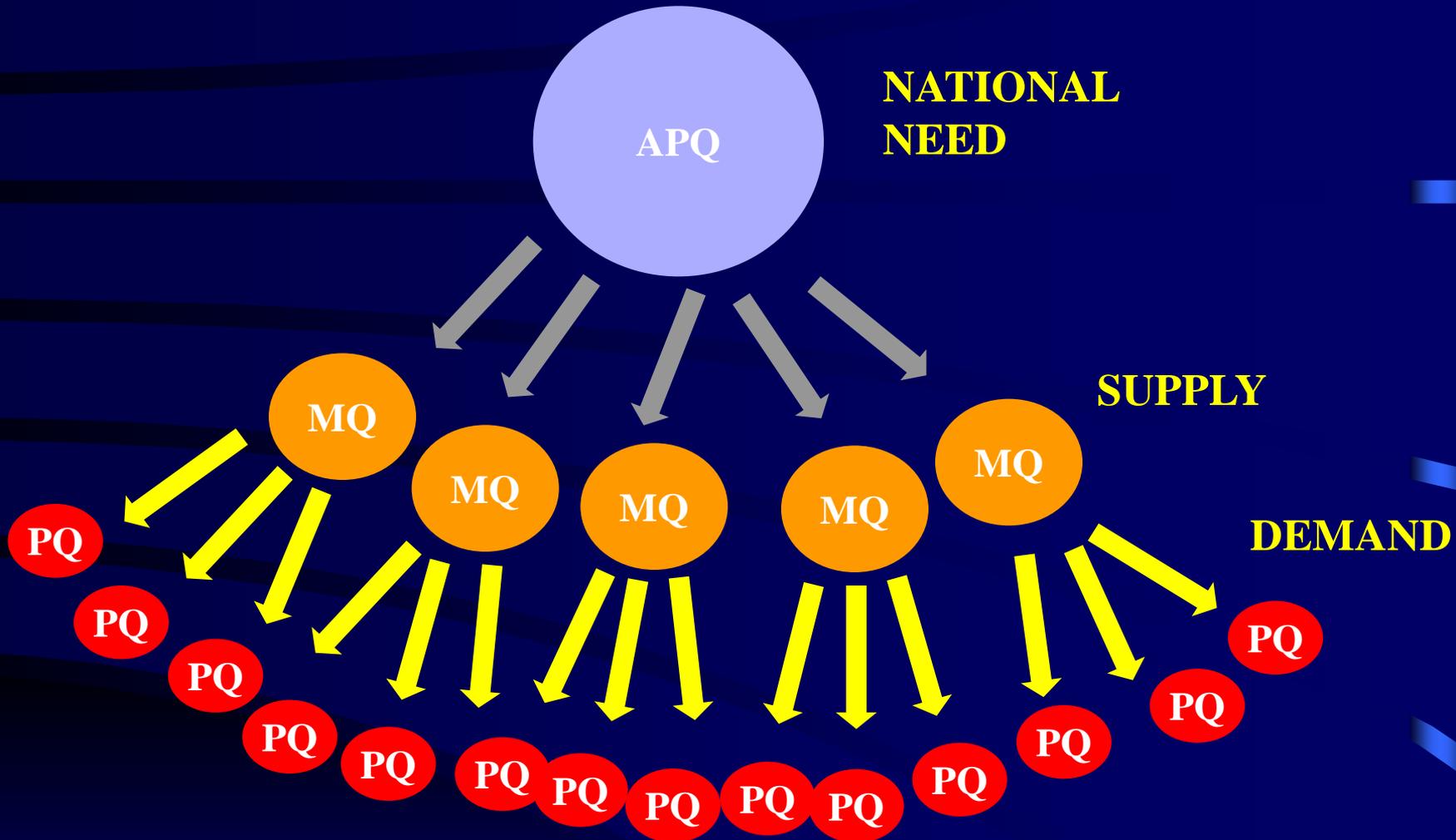
(202) 307-7183



Aggregate Production Quotas (APQ) & Annual Assessment of Needs (AAN)

- Upper limit of national production
- Established annually with one revision
- Federal Register notices required
- **APQ** - Schedules I and II CS
- **AAN** – Ephedrine, Pseudo, PPA

APQ-MQ-PQ



*Packaging/Labeling are not counted against the APQ/AAN

Quota Types

PROCUREMENT (PQ)

- DEA Form 250
- Dosage form MFG
- Packagers
- Labelers
- Repackager
- Relabelers

MANUFACTURING (MQ)

- DEA Form 189
- Bulk Manufacturers

IMPORT (IQ)

- DEA 488 & Form A
- Chemical Importers



“21 CFR”

Title 21 of the Code of Federal Regulations

Aggregate Production Quotas

(21 CFR 1303.11 and 1303.13)

Manufacturing Quotas

(21 CFR 1303.21 through 1303.27)

Procurement Quotas

(21 CFR 1303.12)

Schedule I and II Controlled Substances



“21 CFR”

Title 21 of the Code of Federal Regulations

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)

Import Quotas

(21 CFR 1315.34 and 1315.36)

List I Chemicals

Overview of Procedure for Setting Aggregate Production Quotas

❖ Procurement Quotas are Calculated

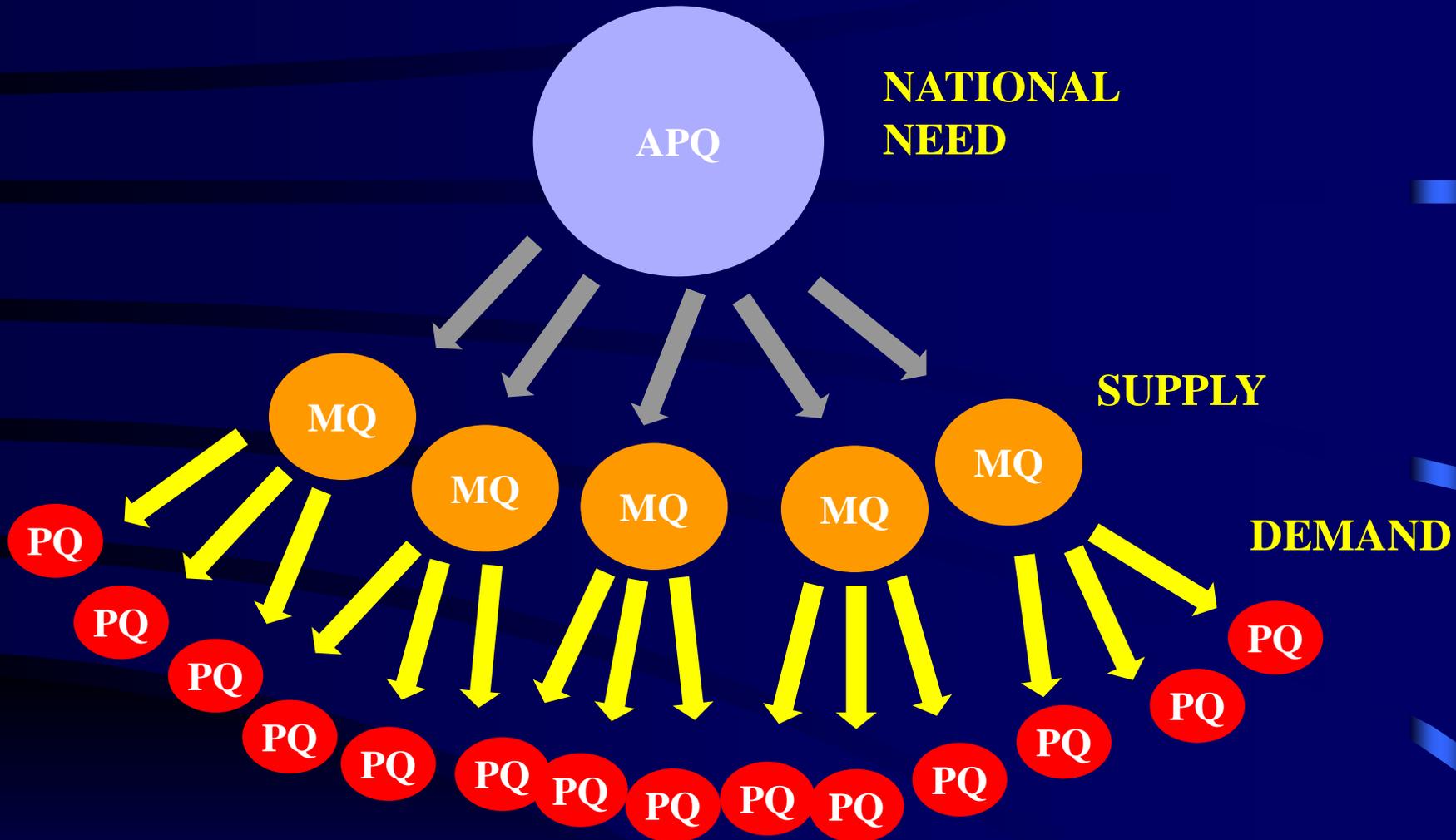
- Sales and inventory data
- Product development, yields, etc.

❖ Manufacturing Quotas are Calculated

- Procurement quotas
- Historical share of the market
- Inventory adjustments

Note Packager & Labelers Transfers are not included in Calc.

APQ-MQ-PQ



*Packaging/Labeling are not counted against the APQ/AAN

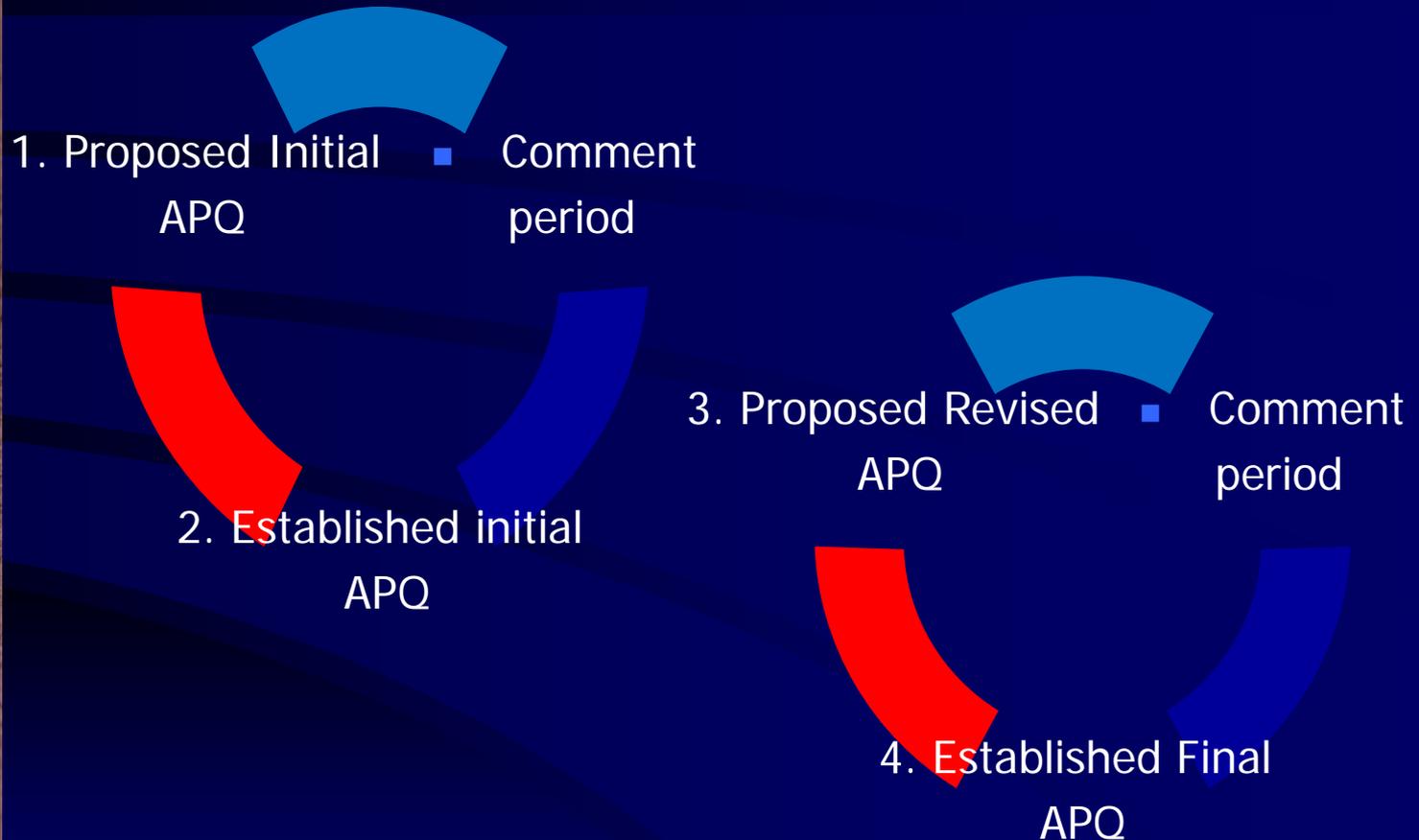
Overview for Setting APQ Continued

APQ's are Calculated

- Sum of the manufacturing quotas
- FDA Estimate
- Prescription Audit Data
- Other Considerations
- Federal Register notice

Revisions Mid-year

Federal Registers and the Aggregate Production Quotas (APQ)

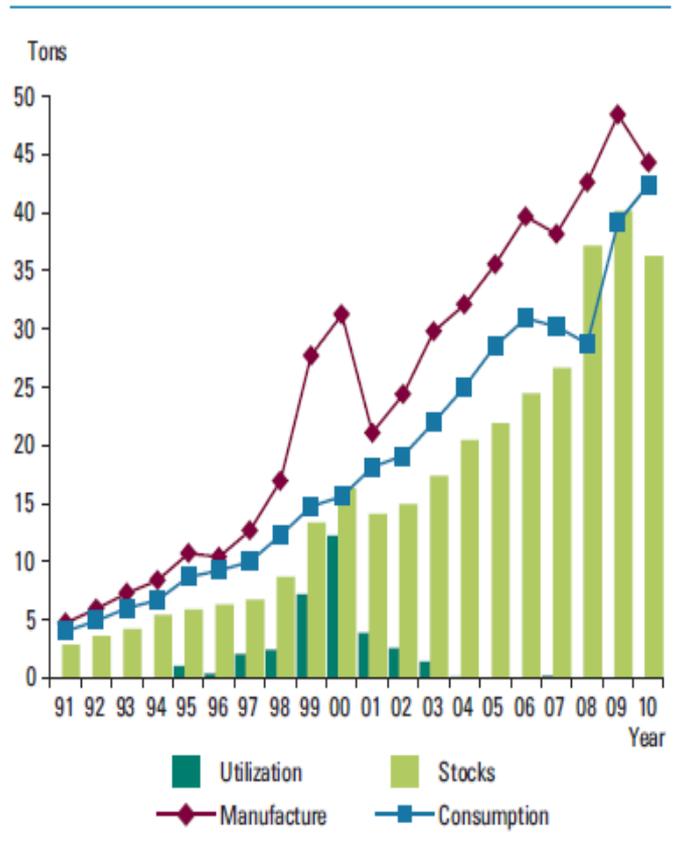


The Assessment of Annual Needs follows a similar cycle



Hydrocodone (2011 INCB)

Figure 22. Hydrocodone: global manufacture, consumption, utilization^a and stocks,^b 1991-2010



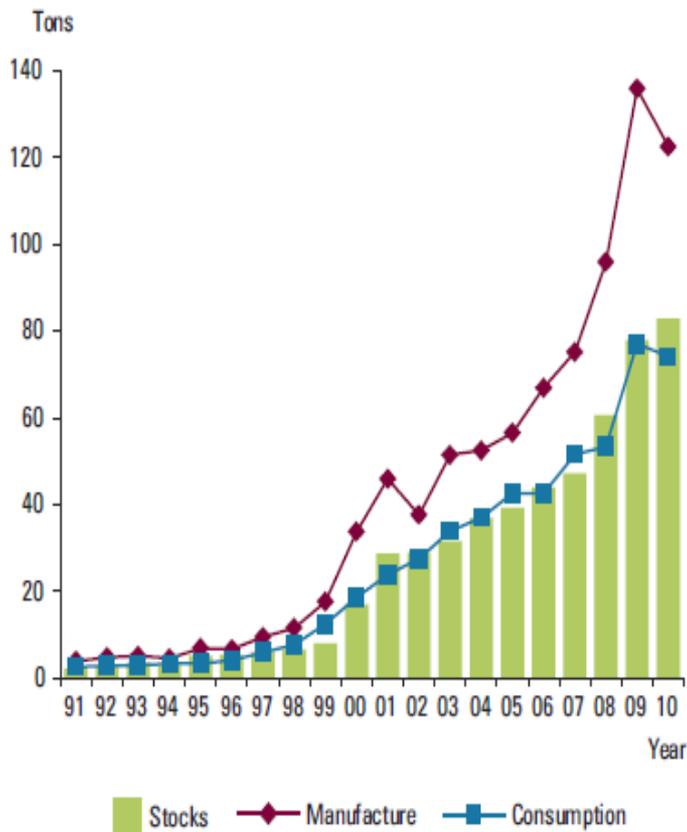
^aUtilization for the manufacture of other drugs.

^bStocks as at 31 December of each year.

- US MFG **100%** of world hydrocodone
- US **consumes 99%** of world hydrocodone
- From 1991 to 2010 US Increase manufacturing from 4,000 kg to 45,000 kg **1000% Increase**
- In 2010 US consumed **42,400 kg** Stocks (inventory) 35,000 kg
- **480 kg** base to supply 315 million people with 2.5 mg tablet
- 2013 Hydrocodone **APQ 99,625 kg**

Oxycodone (2011 INCB)

Figure 23. Oxycodone: global manufacture, consumption and stocks,^a 1991-2010



^aStocks as at 31 December of each year.

➤ US manufactures 80% of world supply of oxycodone

➤ US consumes 75% of world supply of oxycodone

➤ Increase mfg from 1,000 kg to 130,000 kg (1991-2010)

Over 1200% Increase

➤ **Q:** US population is 315 mil. how many kg would be needed to supply each person with 5 mg tablet **A: (1,291 kg base)**

➤ 2013 Oxycodone APQ **131,500 kg**



Assessment of Annual Needs (AAN)

- Upper limit of national production and importation requirements
- Established annually with one revision
- Federal Register notices required
- Three List I Chemicals (pseudoephedrine, ephedrine and phenylpropanolamine)

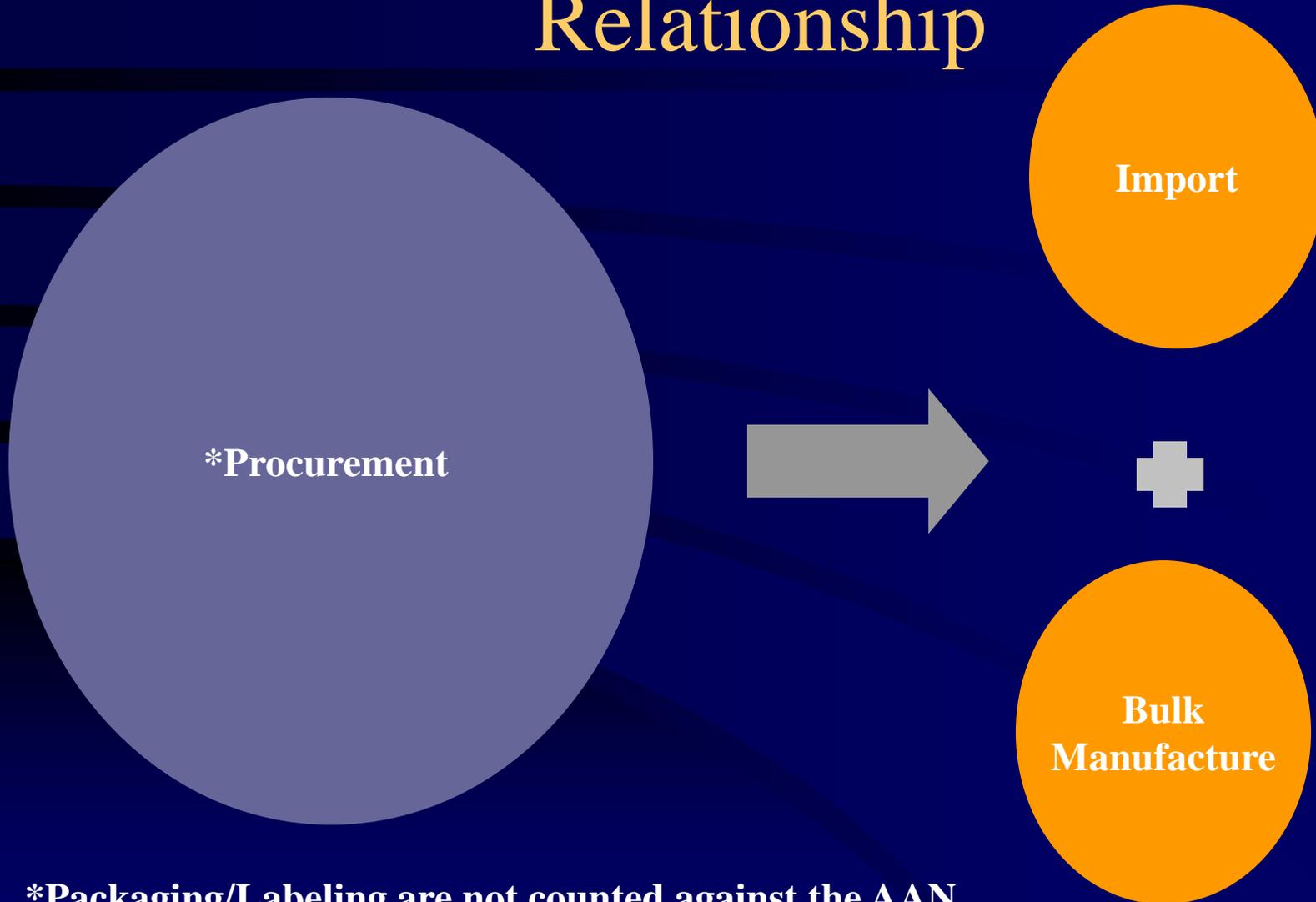


Overview of Procedure for Setting the AAN

• **To develop the AAN for the United States, DEA considered:**

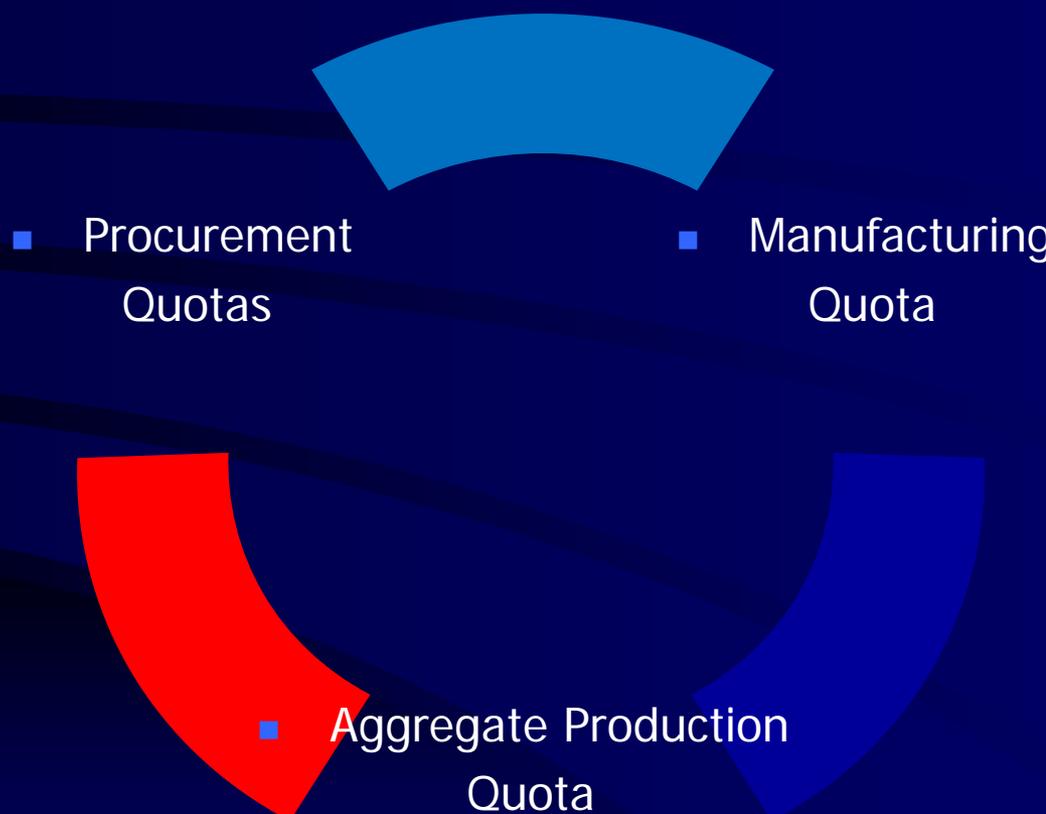
- Applications for import, manufacturing and procurement quotas from DEA Registered manufacturers and importers.
- The national rate of disposals (sales/utilization).
- Actual and estimated inventories.
- Projected demand for the list I chemicals

Import/Manufacture/Procurement - Relationship



***Packaging/Labeling are not counted against the AAN**

Quota Relationships



- Procurement Quotas

- Manufacturing Quota

- Aggregate Production Quota

Manufacturing (BULK) Quotas

- Applies to those who manufacture schedules I and II controlled substances or (PE, E & PPA) (bulk manufacturers) either from:

- Synthetic routes

- Morphine → Hydromorphone or
- Ephedrine → Pseudoephedrine

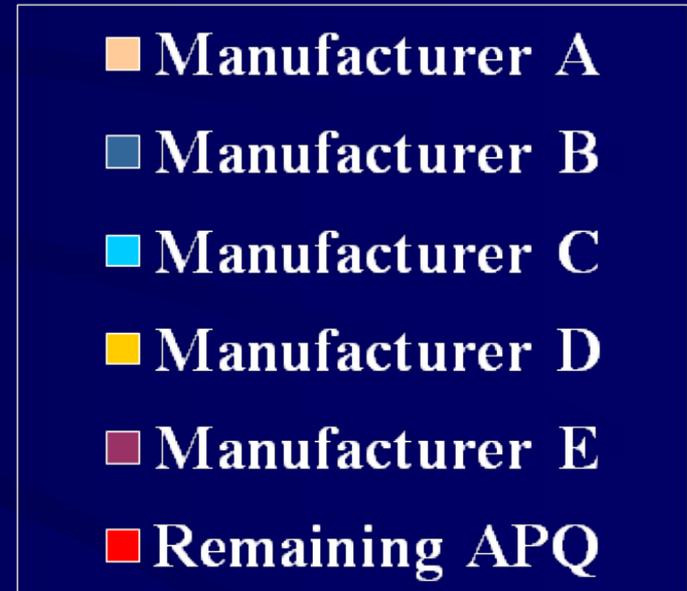
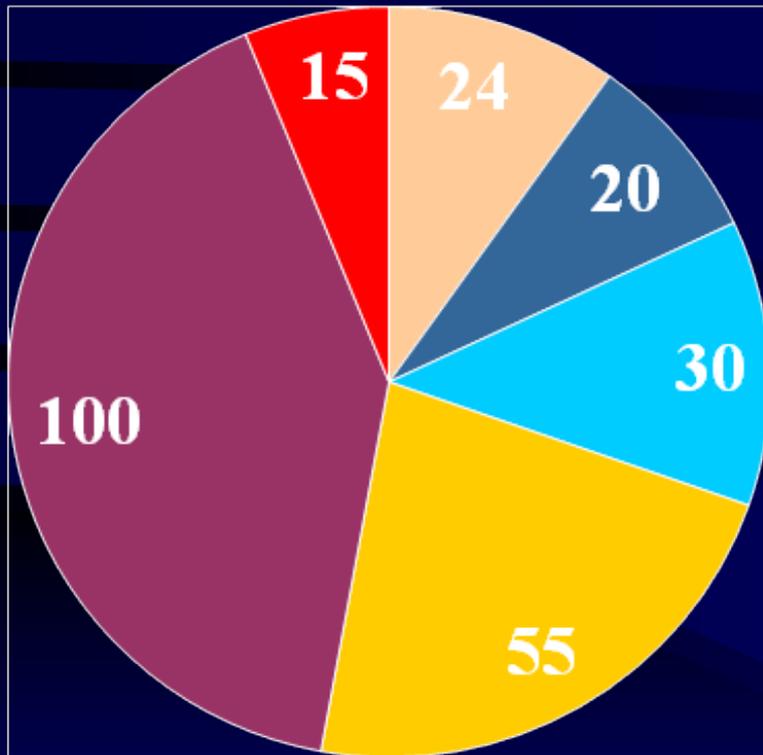
- Extraction from plant material

- Coca Leaf → Cocaine
- Concentrated Poppy Straw → Opium

Manufacturing Quotas

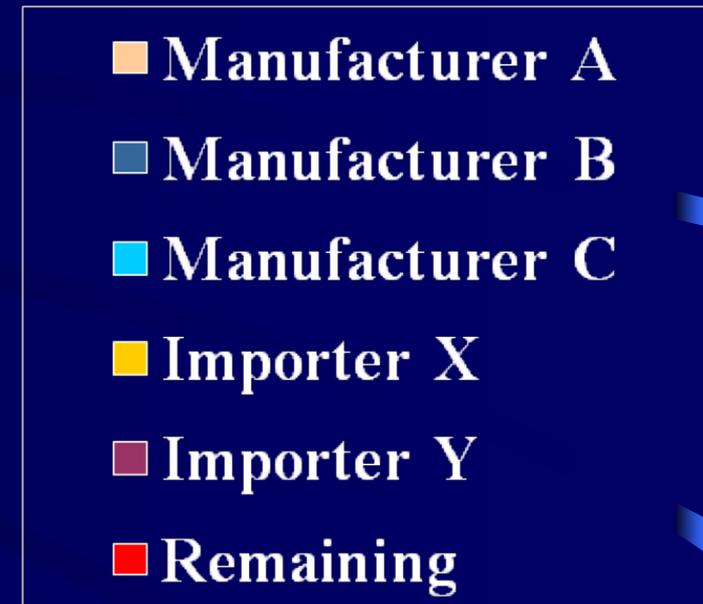
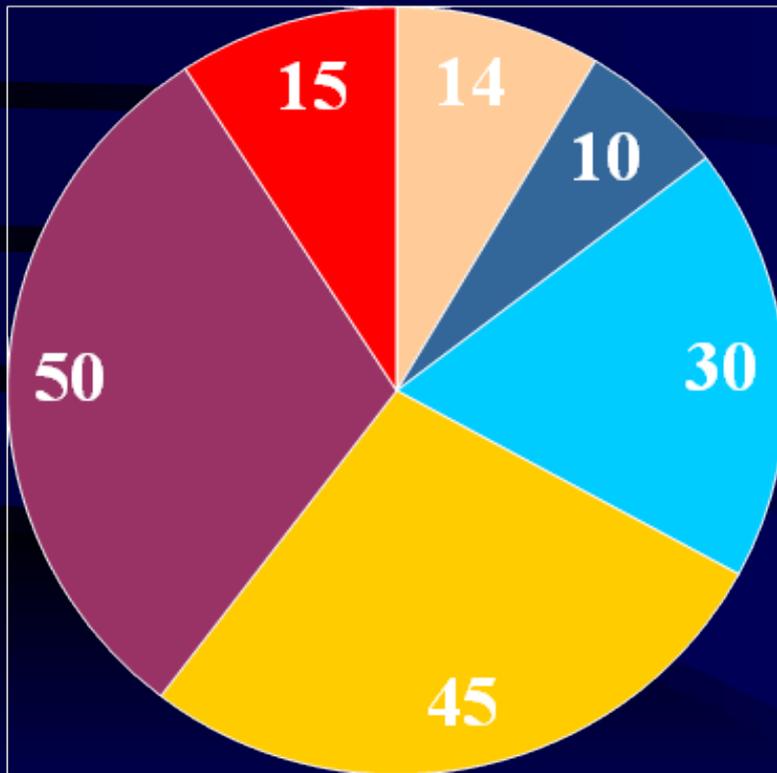
- DEA registered **bulk manufacturer**
- Established the maximum amount that may be manufactured during a particular calendar year
- Quota adjustments
- Sum of manufacturing quotas are equal to or less than the **aggregate production quotas (APQ)**

Aggregate Production Quota (APQ) and Manufacturing Quotas (MQ)



APQ

Assessment of Annual Needs (AAN) and Manufacturing + Import Quotas



AAN

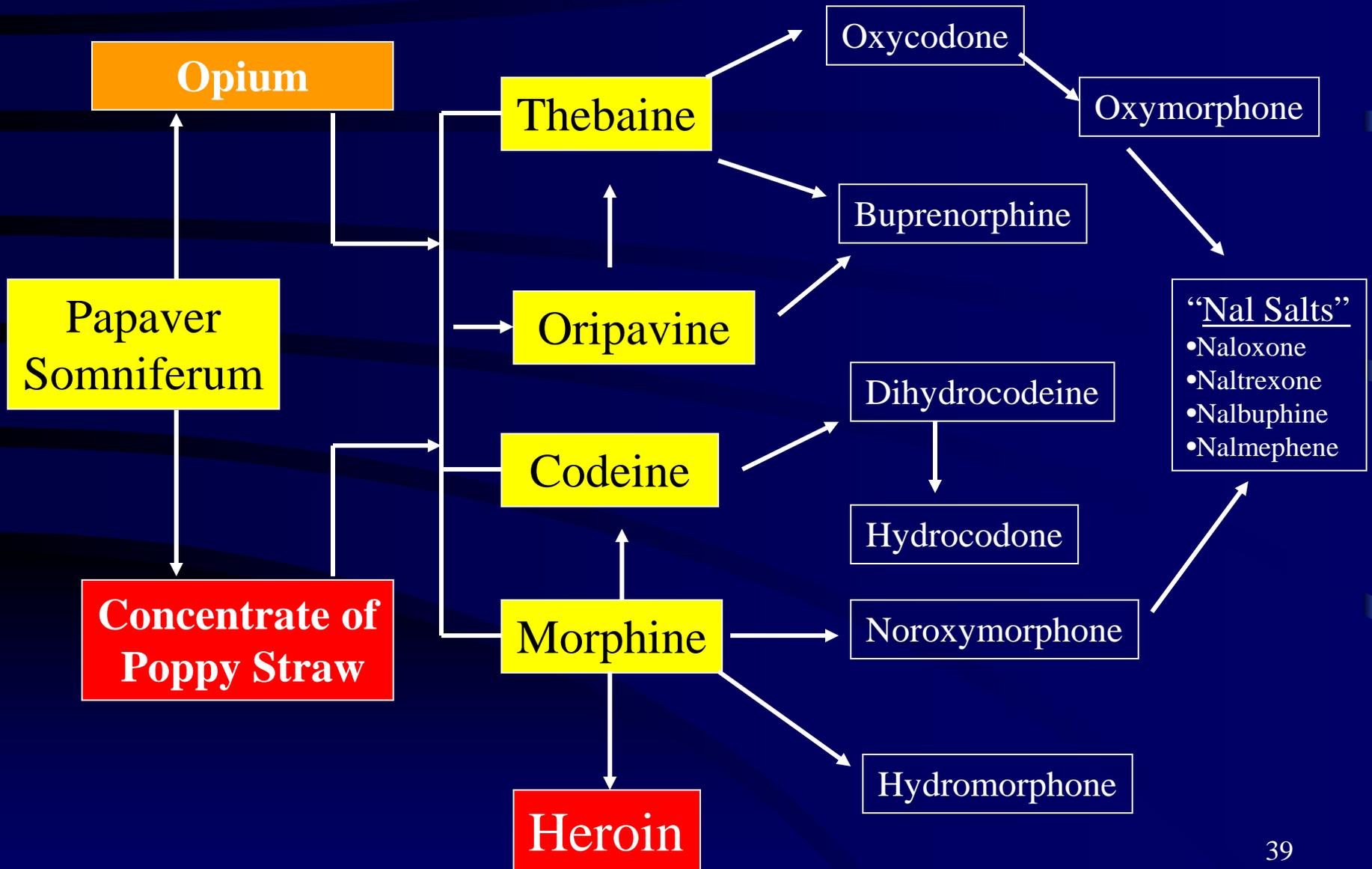
Procurement Quotas

- DEA registered **manufacturers**
- Establishes maximum amount which may be acquired in a calendar year
- Applies to dosage form manufacturers, packagers, repackagers, labelers and relabelers
- Certification of adequate quota
 - 21 CFR 1303.12(f) & 1315.32(h)
- Quota adjustments
- Sum of procurement quotas determines amount of bulk material to be produced

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
- DEA 488 (Import Quota)
 - Form A – Customer List
- DEA 486a - Import Declaration (E, PSE, PPA) to import into US for these substances

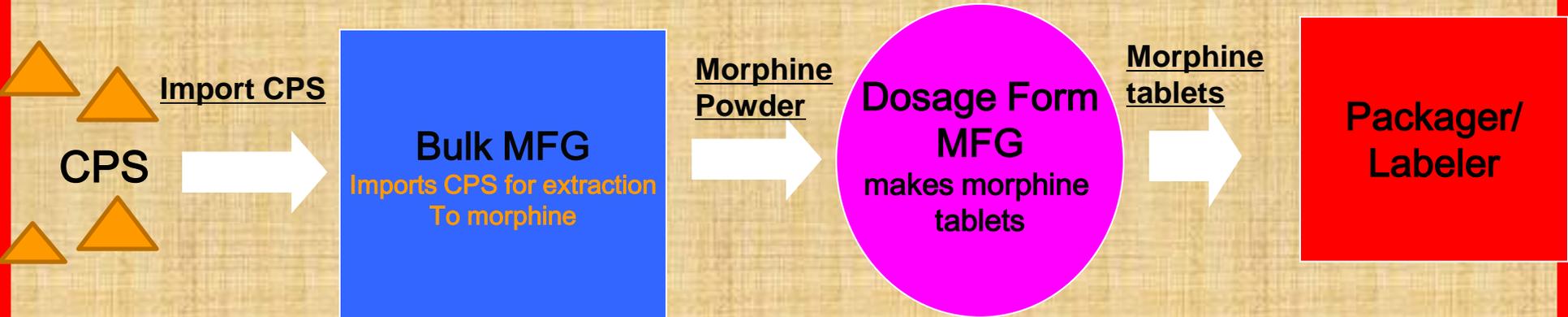
Narcotic Raw Material



Who needs Quota? Following a product from start to finish

- A bulk manufacturer imports poppy straw for morphine extraction. They sell the extracted morphine to company “A” which converts the bulk morphine into beads and encapsulates them.
- Company “A” sends the finished morphine capsules to their bottling and labeling company “B.”
- Company “B” bottles and labels the finished dosage units and sends them to a distributing company

Who need Quotas- Poppy Straw to Packager



- **NEED PQ** to receive imported CPS
- **MQ** to extract morphine

- **PQ** to procure morphine
- For mfg to tablets
- **PQ** to receive tablets

CPS = Concentrated Poppy Straw
MFG= Manufacturer
PQ= Procurement Quota
MQ= Manufacturing Quota

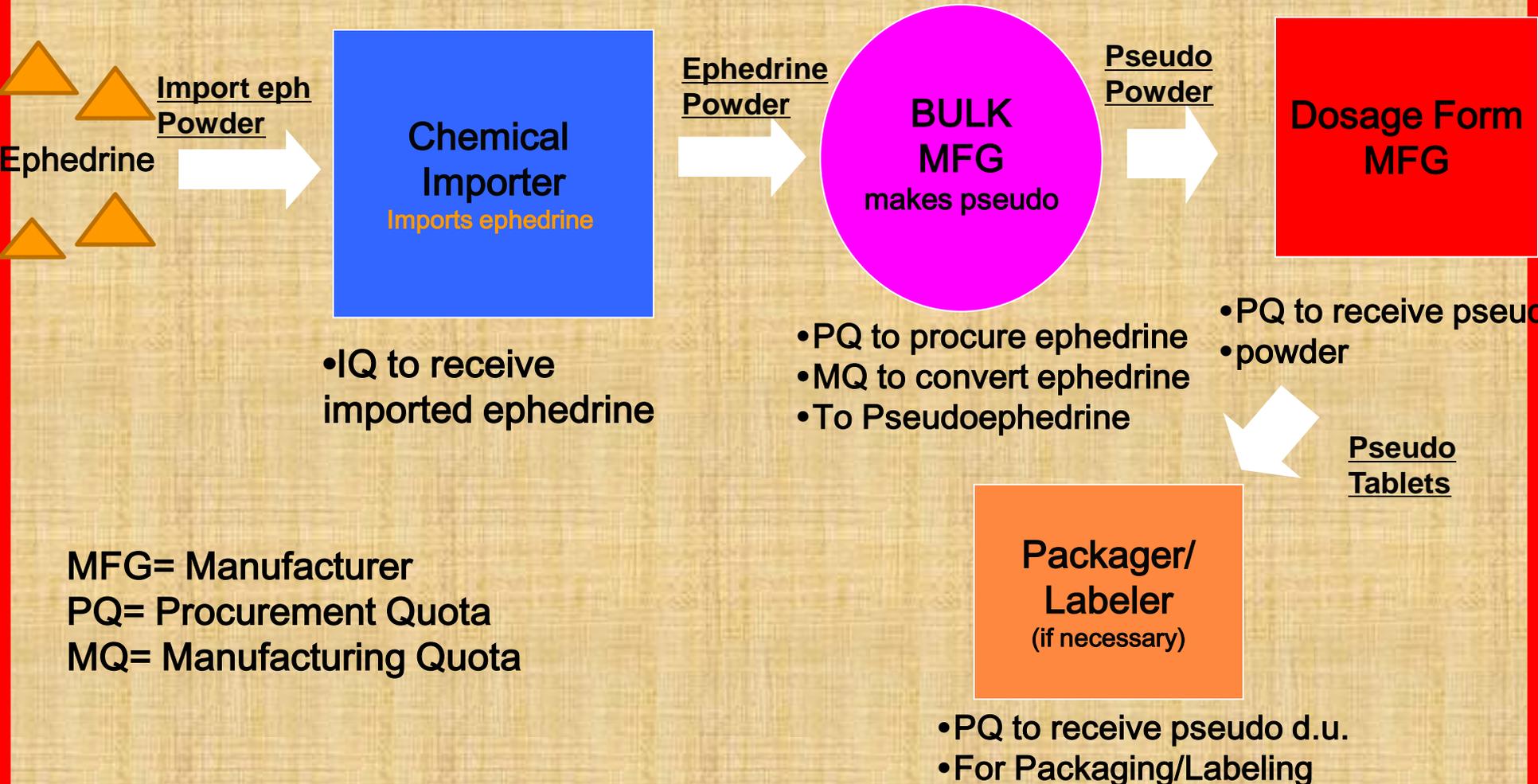


Who needs Quota?

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 need Quotas- import ephedrine to pseudo



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.

Data Used to Establish Quotas: Food & Drug Administration Estimates

- Yearly forecast of expected change in medical use
- Expressed in percent change in sales
- Data from prescription and hospital use
- New, discontinued and recalled products
- New indications or dosage forms

Other Considerations

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





Frequently Asked Questions

- Importation of schedules I and II controlled substances
 - No quota needed to import controlled substances
 - Quota is needed to transfer material from import registration to manufacturer registration
 - Quota is required to import three List I Chemicals (pseudoephedrine, ephedrine and phenylpropanolamine)

Frequently Asked Questions (continued)

❖ Contract Manufacturing

- quota is required

❖ Small quantities

- quota is required

Frequently Asked Questions (continued)

☐ Registration number change

- ✓ Quota is required to receive inventory from the old registration
- ✓ Quota is needed to continue manufacturing activities under new registration
- ✓ Must submit new DEA form 250s and 189s with original signatures
- **QUOTAS DO NOT TRANSFER**



Questions

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www.deadiversion.usdoj.gov

Drug Enforcement Administration
UN Reporting & Quota Section



Questions?

Total Quota Historic Snapshot

