



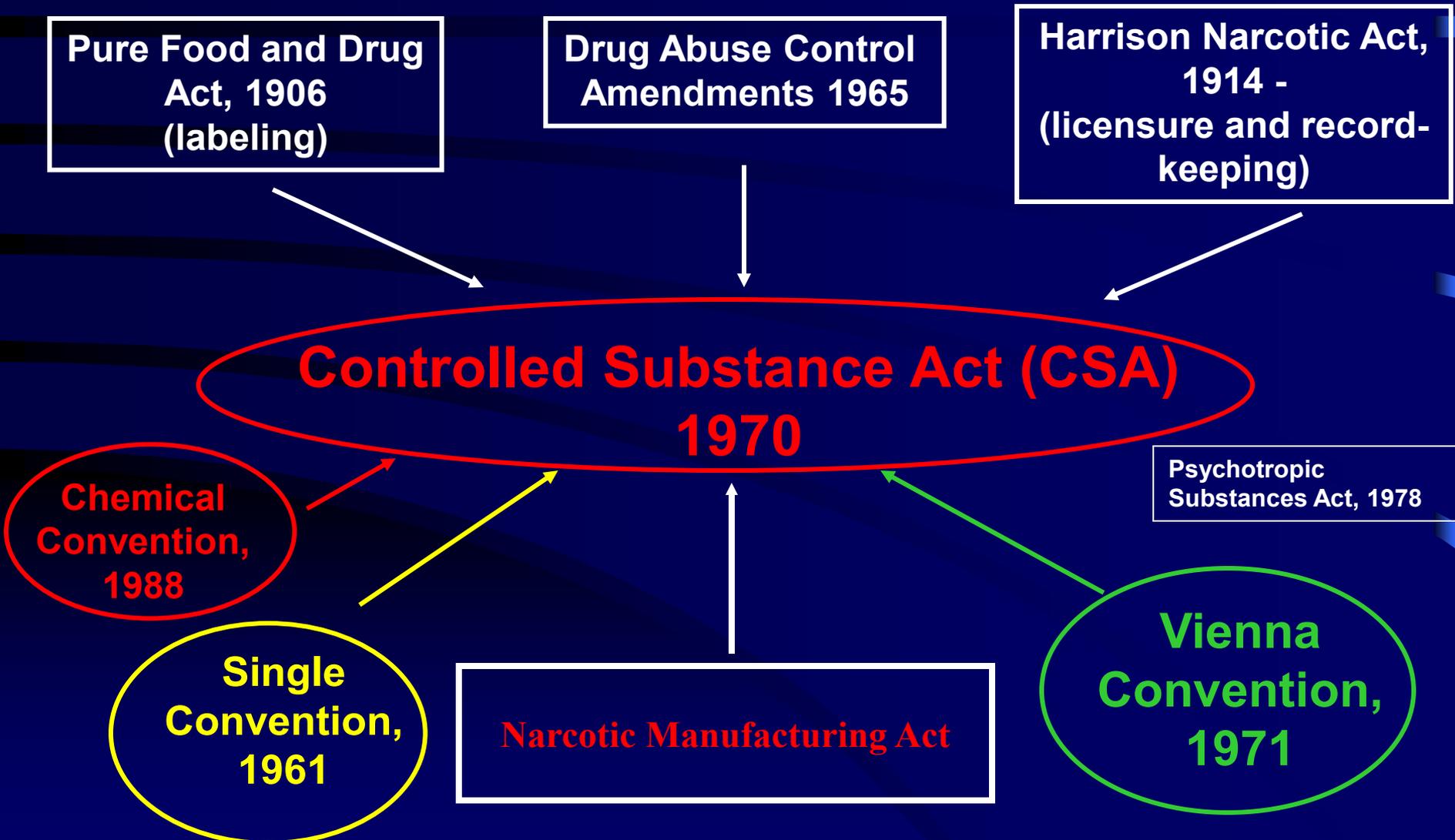
Drugs & Chemicals Quotas

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United Nations & Quota Section
Drug Enforcement Administration

United States CSA - Historical

Perspective:



Controlled Substance Act (CSA)

Schedule I- MDMA, LSD, Heroin, Bath Salts, Spice etc
Substances with high abuse potential and no medical utility (most restrictive)

Schedule II- oxycodone, hydrocodone, fentanyl etc
Substances with high abuse potential and medical utility

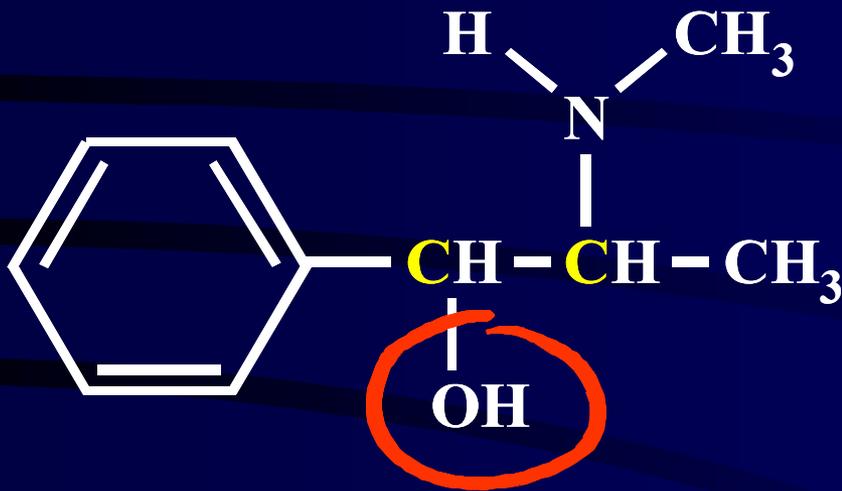
Schedule III, IV and V- codeine, barbiturates etc
Substances with medical utility in the U.S. and progressively lower levels of abuse potential

Regulated Chemicals- isosafrole, piperidine, ephedrine, pseudoephedrine, PPA etc.
Chemicals used to make drugs

Close System of Distribution



Ephedrine/Pseudoephedrine



**EPHEDRINE
OR PSEUDOEPHEDRINE**





Methamphetamine Epidemic





DRUG LABS

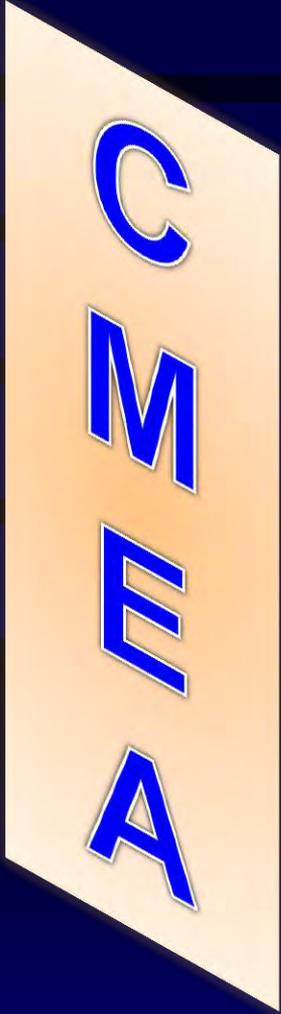


DANGERS

- Chemical hazards
- Explosive hazards
- Poisonous Gases
- Booby Traps



Combat Methamphetamine Epidemic Act (CMEA)



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



Which drugs require quotas?

Schedule I & II CS (CSA)

- substances with the highest abuse potential

3 List I Chemicals (CMEA)

- Ephedrine, Pseudoephedrine & PPA

substances which can be used to make methamphetamine



Purpose of Quotas

- Establishes the upper ceiling of production for Schedule I & II CS and PE, E, and PPA for the US.
- 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



Who Needs QUOTAS?

- Manufacturers

- Schedule I & II Controlled Substances & ephed, pseudo, PPA
 - Includes bulk manufacturers (manufacturers of API)
 - Manufacturers of dosage units
 - *Packagers*, repackagers, labelers & relabelers

- Importers

- ephedrine, pseudoephedrine & PPA
 - Includes importers of BULK and Dosage Units



Combat Meth Epidemic Act (CMEA)



US Quotas (AAN) in Kg

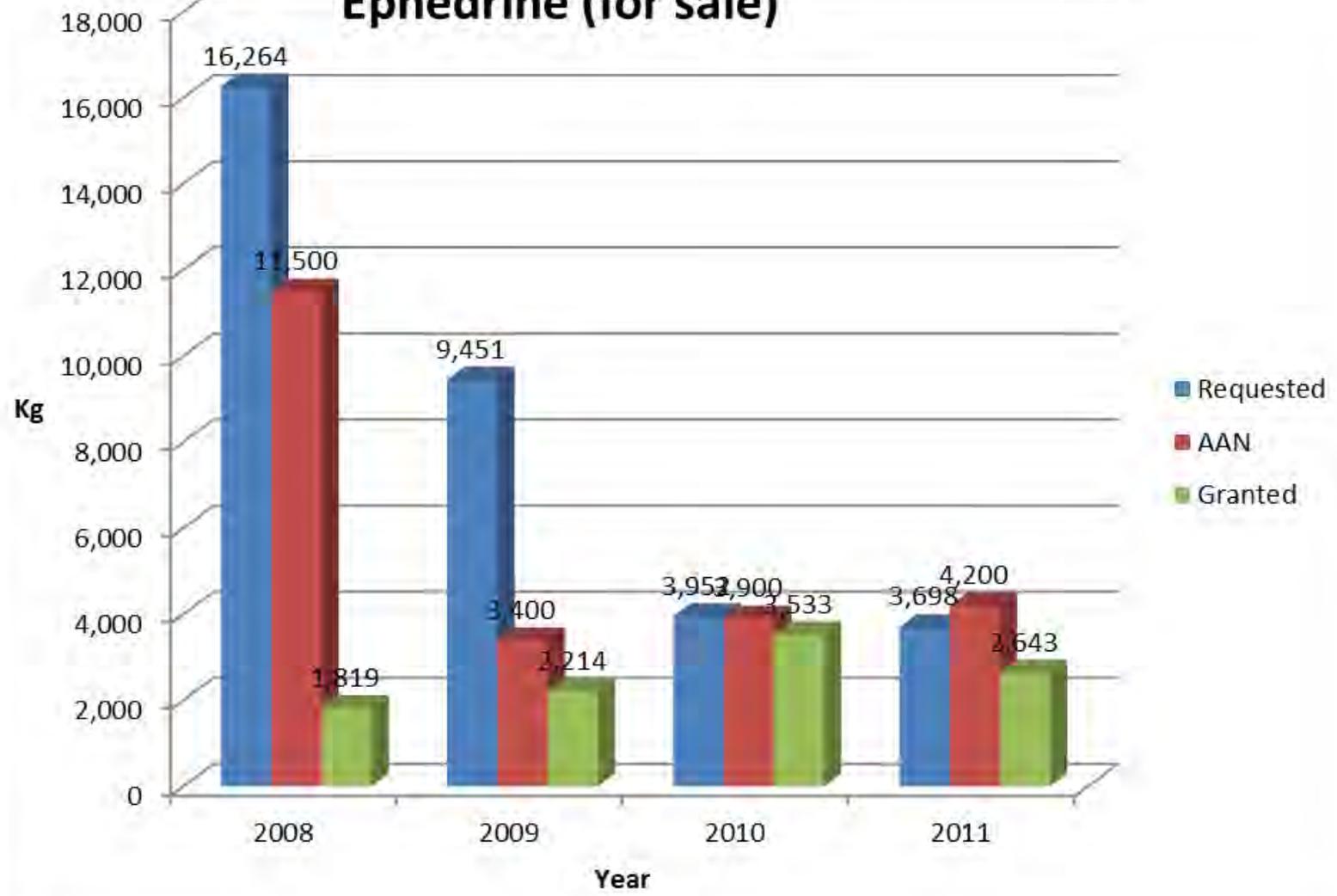
	2008	2009	2010	2011	2012	2013	% decrease 2008
Ephedrine (for sale)	11,500	3,400	3,900	4,200	4,300	3,500	-70%
Pseudoephedrine	511,100	390,000	404,000	280,000	278,000	225,000	-56%
PPA (for sale)	5,545	4,900	7,400	5,300	5,800	6,100	+10%
PPA (for conversion)	85,470	62,000	17,800	21,800	26,200	25,700	-70%
Ephedrine (for conversion)	128,760	120,000	75,000	18,600	12,000	15,100	-88%

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



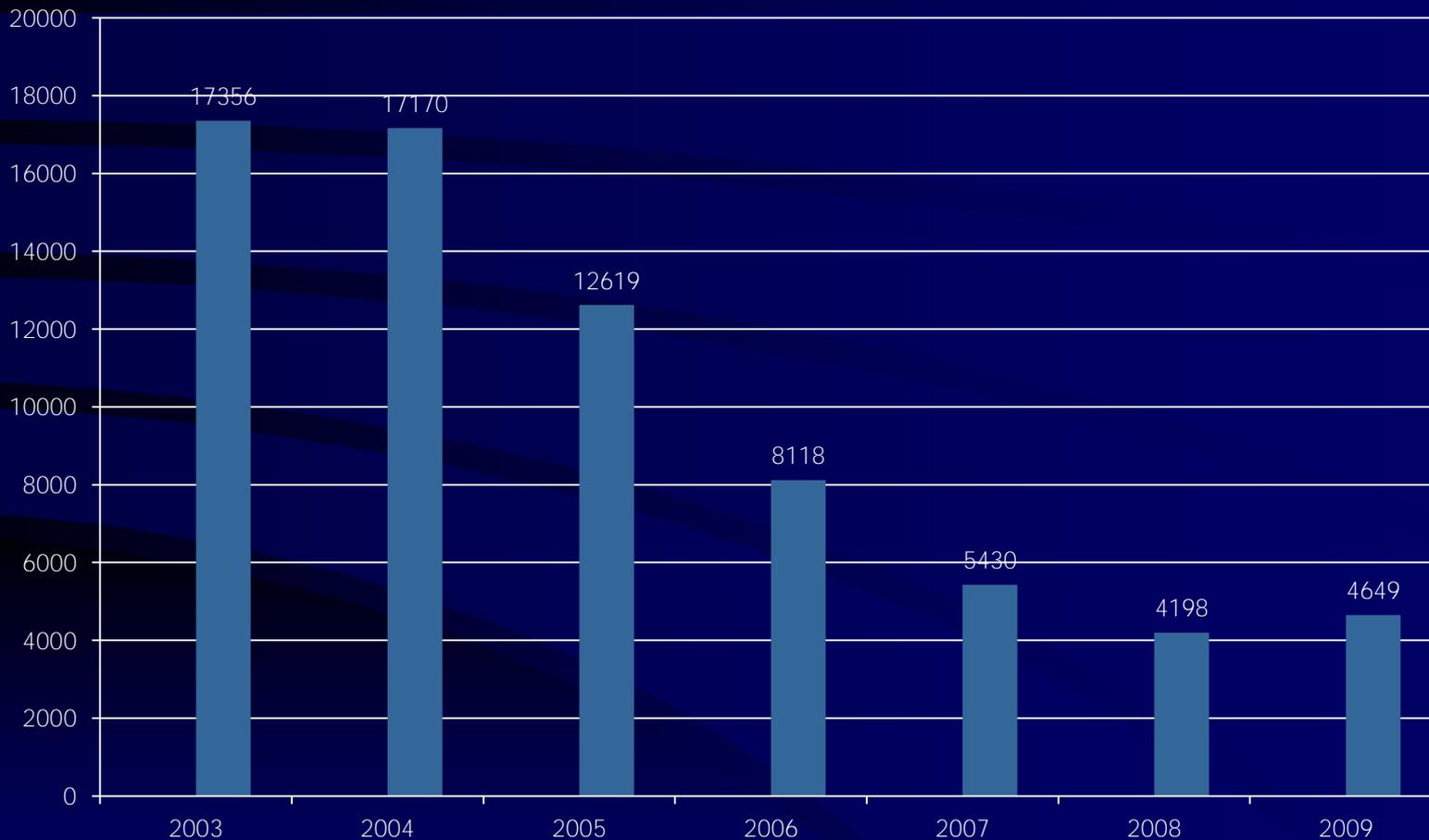
Ephedrine (for sale)





Methamphetamine Seizures

(Includes Labs, dump sites, glassware and equipment seizures)



Clandestine Laboratories



Heroin Lab - Afghanistan



Meth Labs – United States



Ecstasy Lab - Belgium

Other Labs DEA addresses-

- **Fentanyl**
- **MDMA**
- **Cocaine**
- **Heroin**
- **SPICE/Bath Salts**
- **PCP etc...**



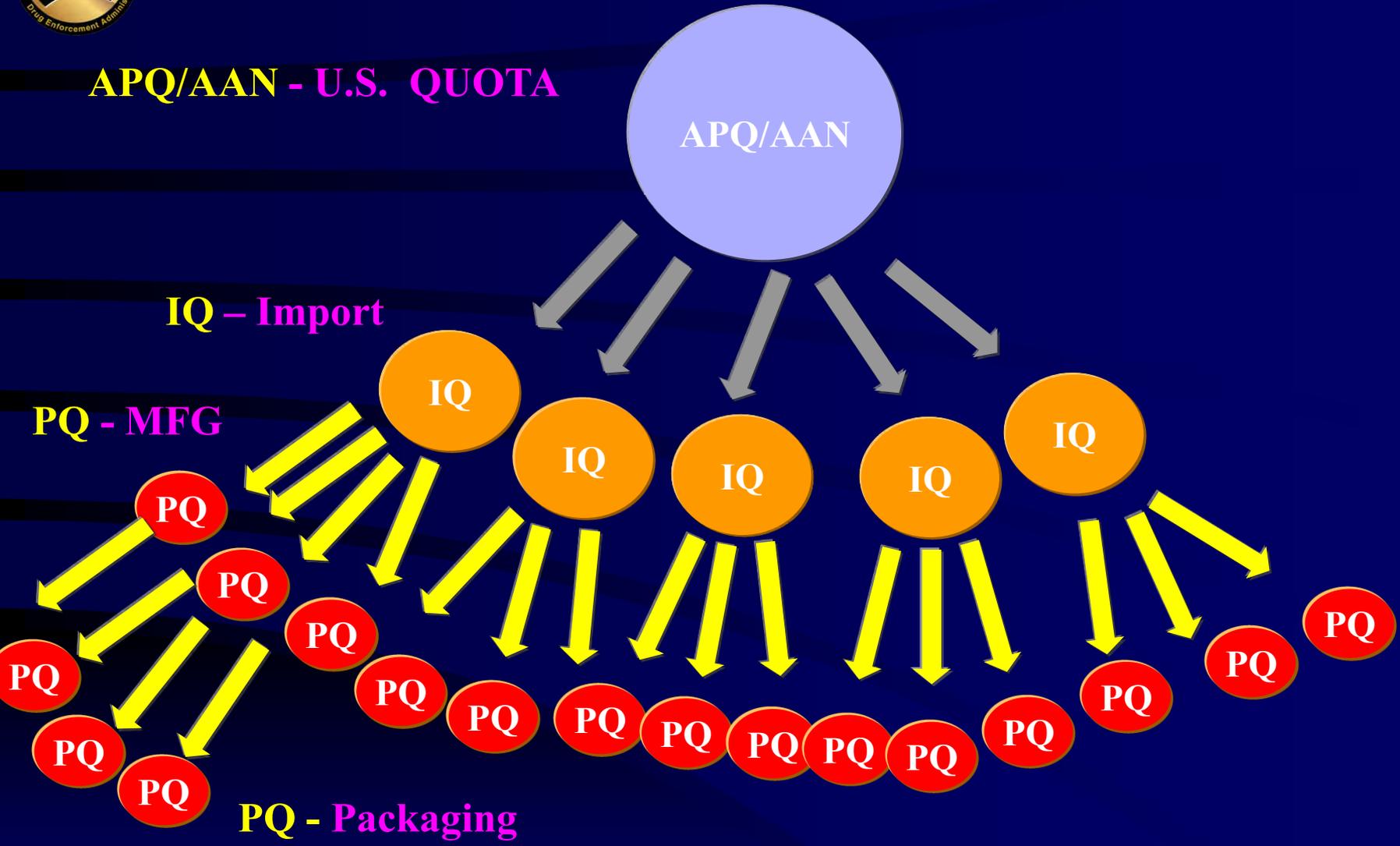
APQ/AAN

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



APQ/AAN

APQ/AAN - U.S. QUOTA





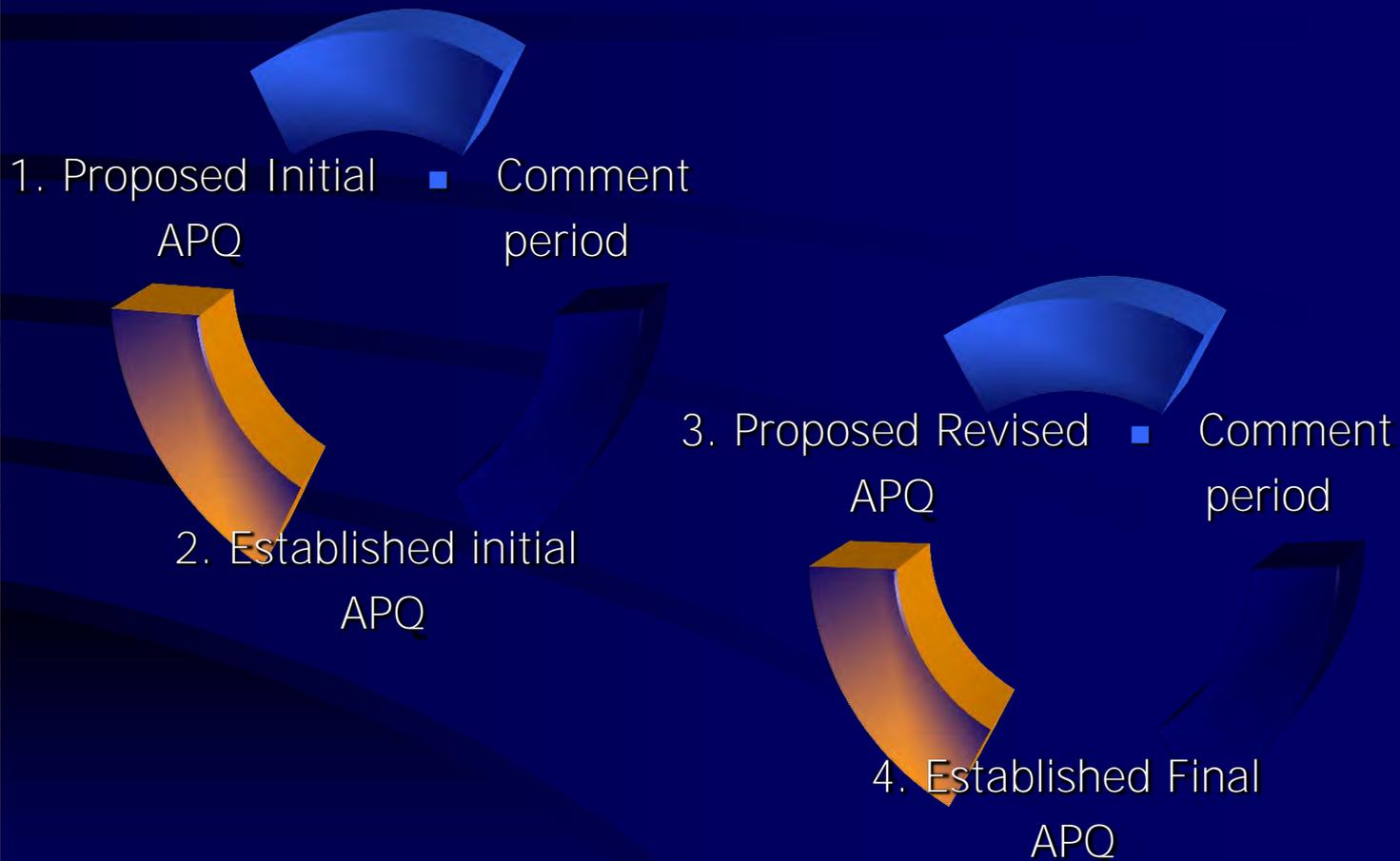
IQ/MQ/PQ



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



Federal Registers and the APQ/AAN





Overview of Procedure for Setting the APQ/AAN

- To develop the APQ/AAN :
 - Applications
 - Sales/Utilization
 - Inventory
 - Demand
 - FDA Estimates



Quota Types Summary

PROCUREMENT

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

MANUFACTURING

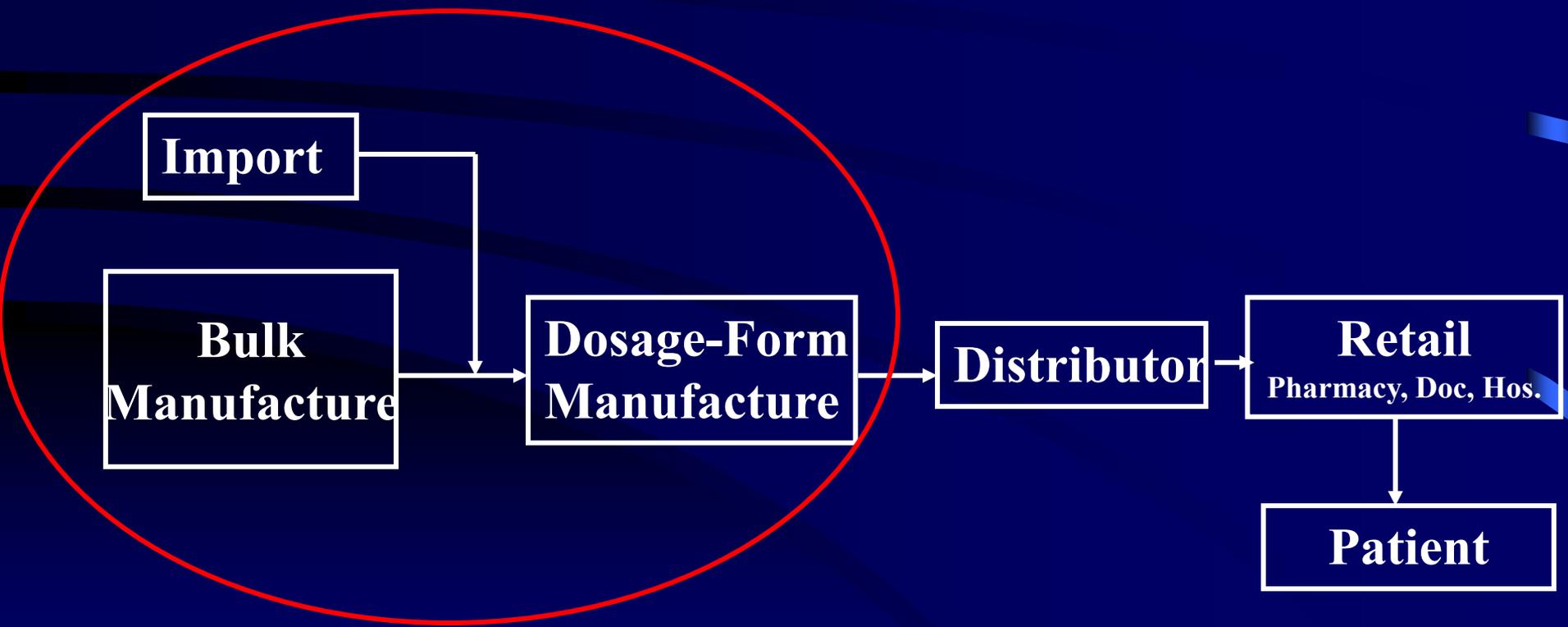
- DEA Form 189
- Bulk Manufacturers

IMPORT

- DEA 488 & Form A
- Chemical Importers



Drug Distributions





Manufacturing Quotas

- ❖ Registered bulk manufacturer
- ❖ Upper Ceiling of Production
- ❖ Quota adjustments



Procurement Quotas

- ✓ DEA registered manufacturers
- ✓ Establishes maximum amount which may be acquired in a calendar year
- ✓ Certification of adequate quota 21 CFR 1303.12(f) & 1315.32(h)
- ✓ Quota adjustments



Import Quotas

- DEA registered importer
- Only applies to pseudo, ephedrine and PPA
- Establishes maximum amount – for import
- Quota adjustments
- DEA 488 (Import Quota)
 - Form A – Customer List
- DEA 486a - Import Declaration (E, PSE, PPA) to import into US for these substances



Controlled Substances & Chemicals Lists

- * Controlled Substances Act (CSA)
- * Federal Register Notices
- * Diversion Website

www.deadiversion.usdoj.gov

- * Drug & Chemical Evaluation Section
analogues, salts, isomers (202) 307-7183



How to Apply

- DEA Registration
- Apply Online
- Adjustments
- Justifications



Questions

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