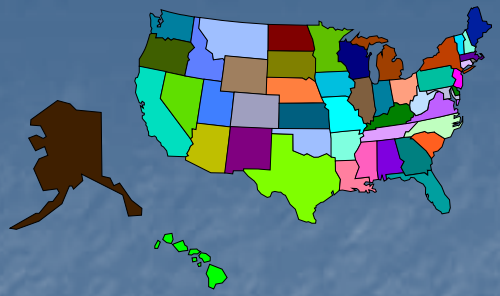
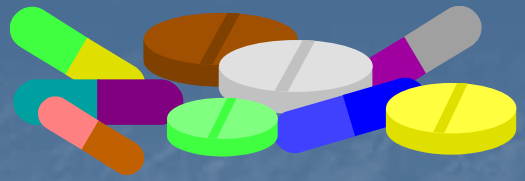
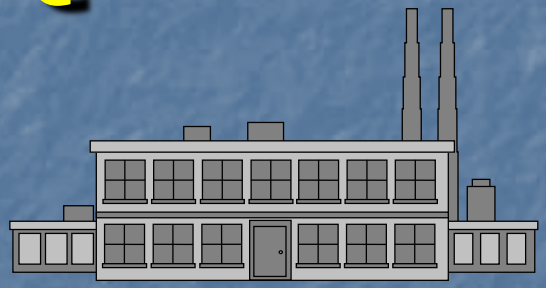




QUOTAS



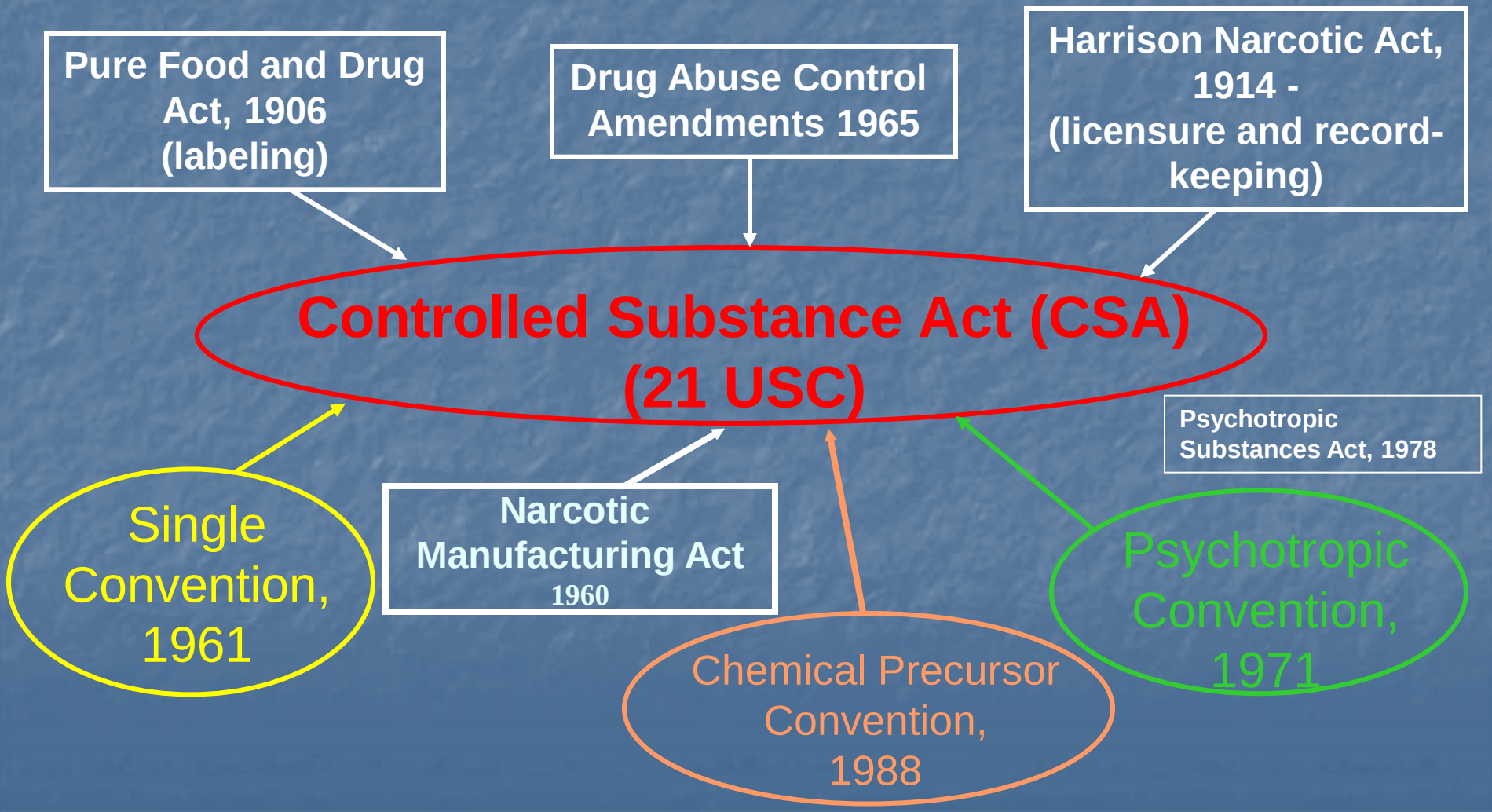
Drug Enforcement Administration

Office of Diversion Control

UN Reporting and Quota Section

Pharmaceutical Training Seminars

CSA - Historical Perspective:



Levels of Drug Control

- Schedule I (CI) – NEED QUOTA (MFG)
  - Substances with high abuse potential and no medical utility (most restrictive)
- Schedule II (CII)- NEED QUOTA (MFG)
  - Substances with high abuse potential and medical utility
- Schedule III, IV and V (CIII, CIV, CV)–
  - Substances with medical utility in the U.S. and high (CIII) to progressively lower levels of abuse potential, dependence profile and regulatory controls
- Ephed, Pseudo & PPA (List 1)- NEED QUOTA (MFG/IMPORT)
  Substances used for manufacture of cough & cold medicines and vet products. Can also be used for illicit manufacture of methamphetamine & amphetamine

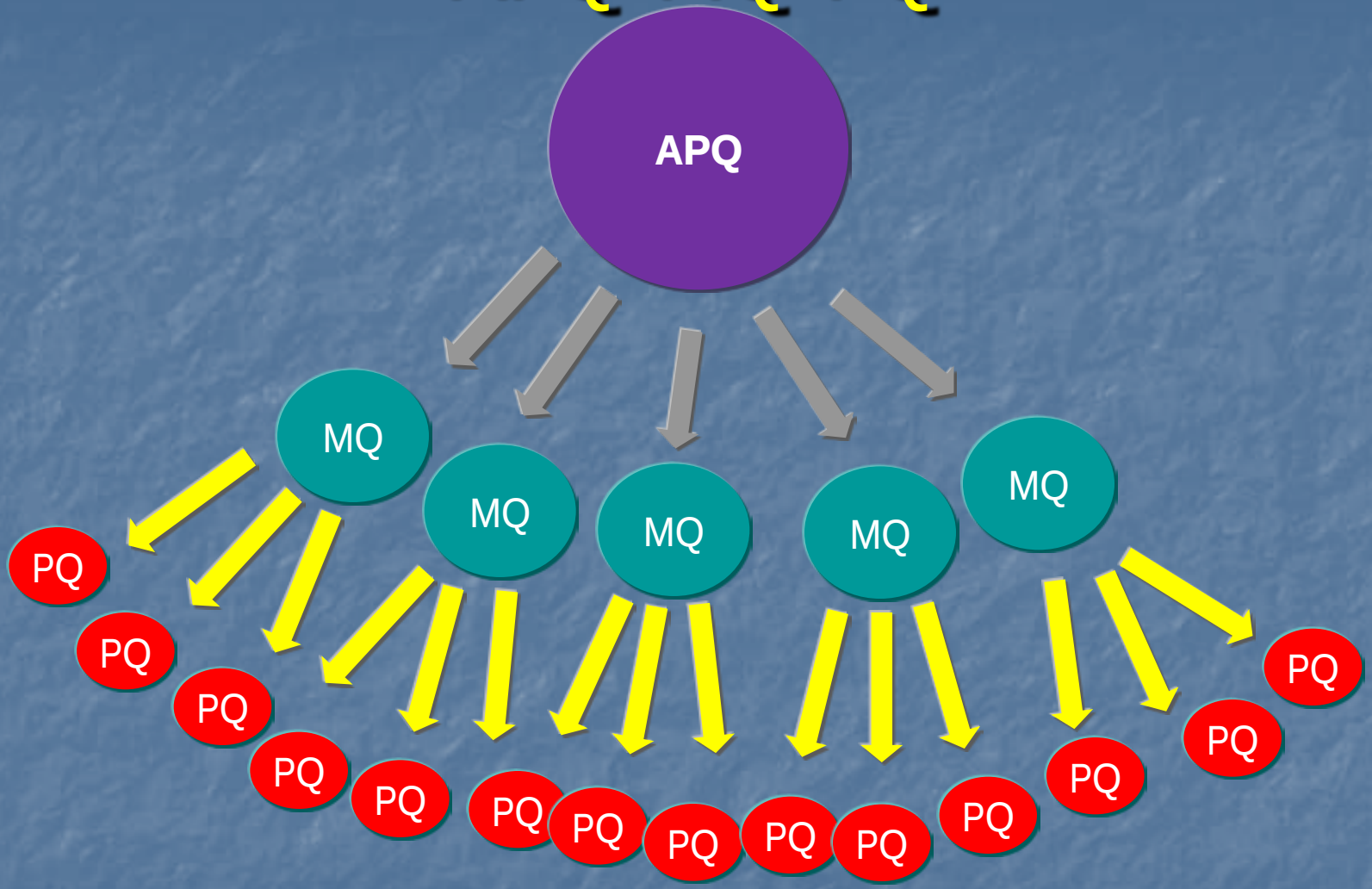
Purpose of Quotas

- Provide for legitimate need of Schedule I and II controlled substances and three list 1 chemicals (E, PE, and PPA)
- Restrict the manufacture and procurement to those manufacturers registered by DEA
- Limit the quantity of drugs in Schedule I and II, and three list 1 chemicals (E, PE, PPA) which may be manufactured or produced in U.S.
- Provide adequate inventories

Quota Requirements Schedule I and II Controlled Substances

- Aggregate Production Quotas (21 CFR 1303.11 and 1303.13)
- Individual Manufacturing Quotas (21 CFR 1303.21 through 1303.27)
- Procurement Quotas (21 CFR 1303.12)

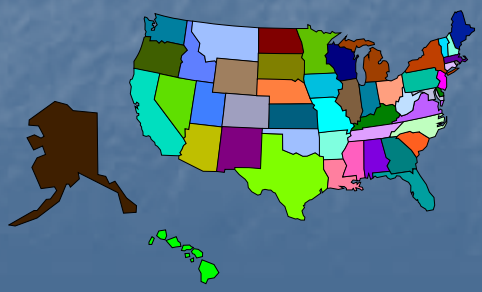
APQ-MQ-PQ



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

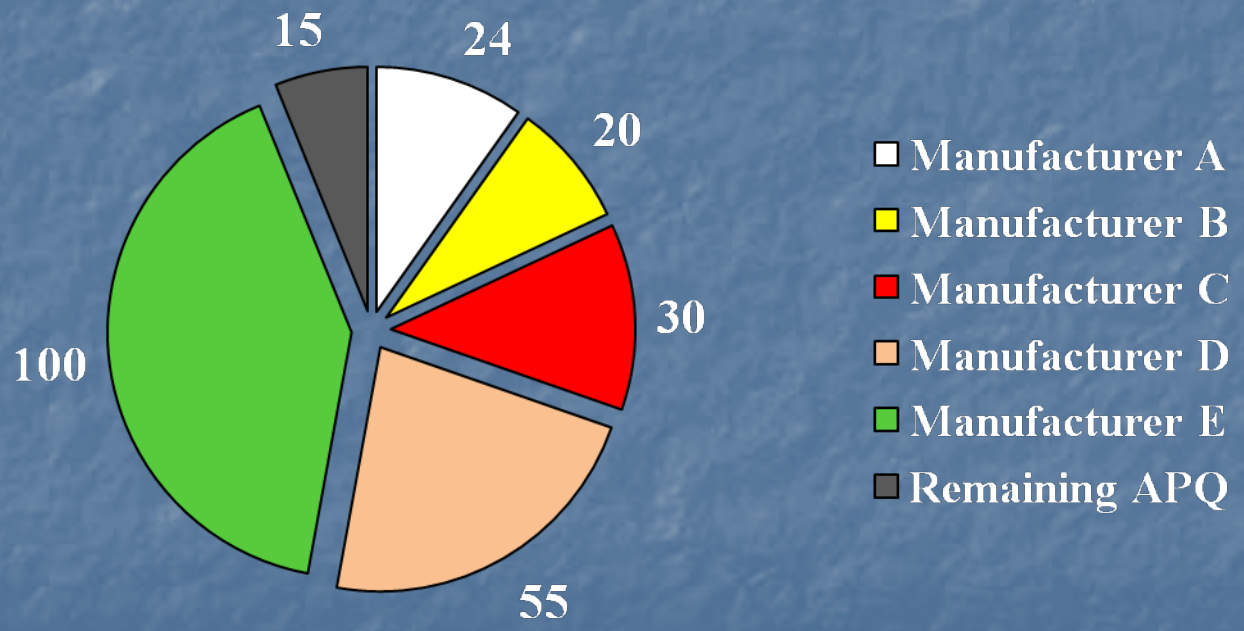
Aggregate Production Quotas

- Upper limit of national production
- Established annually with one revision
- Federal Register notices required
- Schedules I and II controlled substances (basic classes)

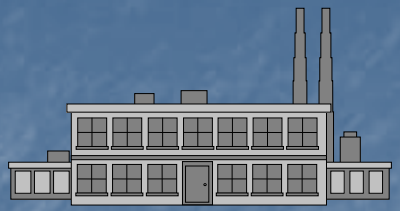


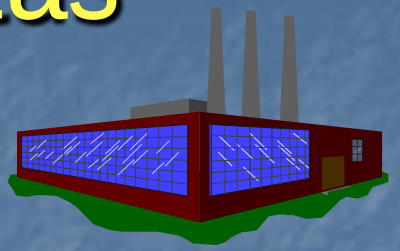
Relationship Between Aggregate and Manufacturing Quotas

APQ = 244 kg



Manufacturing Quotas

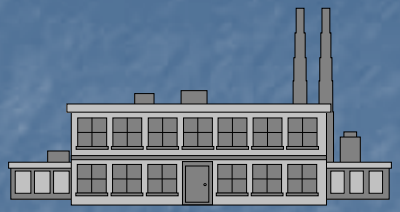


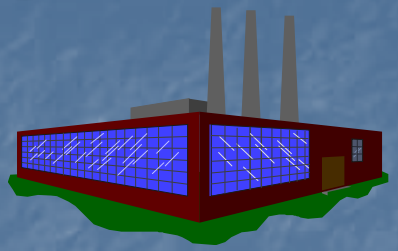


Bulk manufacturers of Schedules I and II controlled substances whose methods include:

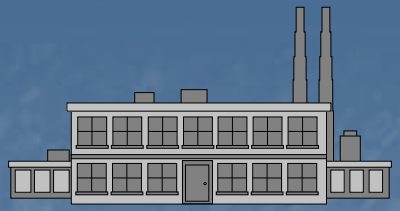
- Extraction from plant material i.e. coca leaf, opium, poppy straw concentrate
- Synthetic routes i.e.
  - hydrocodone from codeine
  - Controlled from non-controlled substance/chemical

Manufacturing Quotas

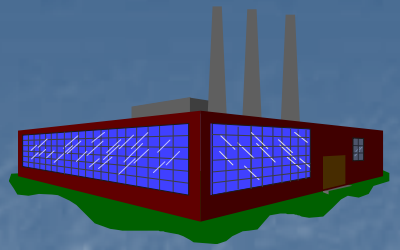




- Establish maximum amount which may be manufactured in a calendar year
- DEA registered bulk manufacturers cannot exceed manufacturing quota
- Establish guidelines for inventory allowances

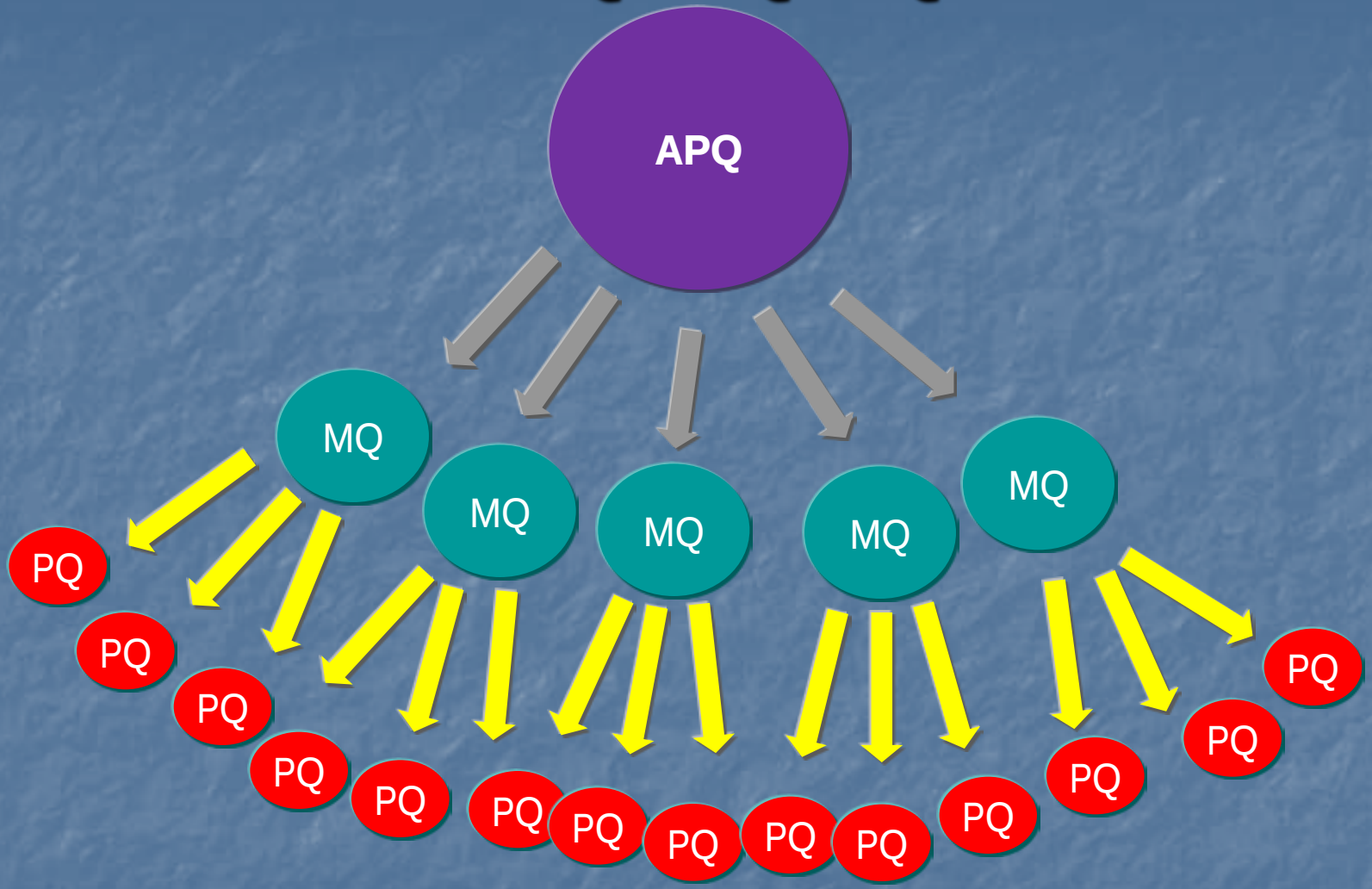


Manufacturing Quota Inventory Allowance



- 21 CFR 1303.24
- 50% of average net disposals for current and preceding year for current manufacturers
- 50% of reasonably estimated net disposal for current year for new manufacturers
- During calendar year may not exceed 65% of estimated net disposal
- Exceeding 65% will suspend quota until inventory is less than 60% of net disposals

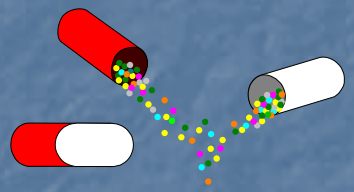
APQ-MQ-PQ



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

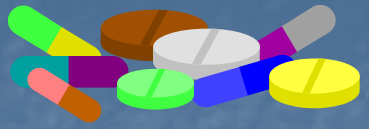
Procurement Quotas

- Manufacturers who procure a Schedule I or II controlled substance, or List 1 chemical for the purposes of:
  - Converting bulk API into finished dosage forms
  - Formulating products such as
    - FDA approved pharmaceuticals
    - Exempt chemical preparations
    - Reference standards

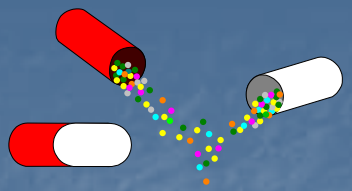


  - Packaging, repackaging, labeling or re-labeling a commercial container or dosage form

PQ always received for these activities

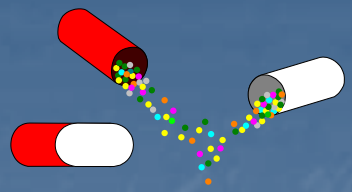


Procurement Quotas



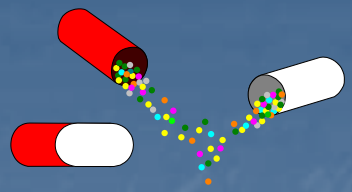
- DEA registered manufacturers
- Establishes maximum amount which may be acquired in a calendar year
- Certification of adequate quota needed to place order (21 CFR 1303.12(f))
- Cannot exceed procurement quota
- Sum of procurement quotas determines amount of bulk material to be produced

Procurement Quota Frequently Asked Questions



- Registration number changed
  - New Quota is needed to receive inventory of old registration
  - New Quota is needed to continue activity under new registration
  - Must submit new quota applications online once all necessary drug codes have been added to registration
  - QUOTA DOES NOT TRANSFER

Procurement Quota Frequently Asked Questions

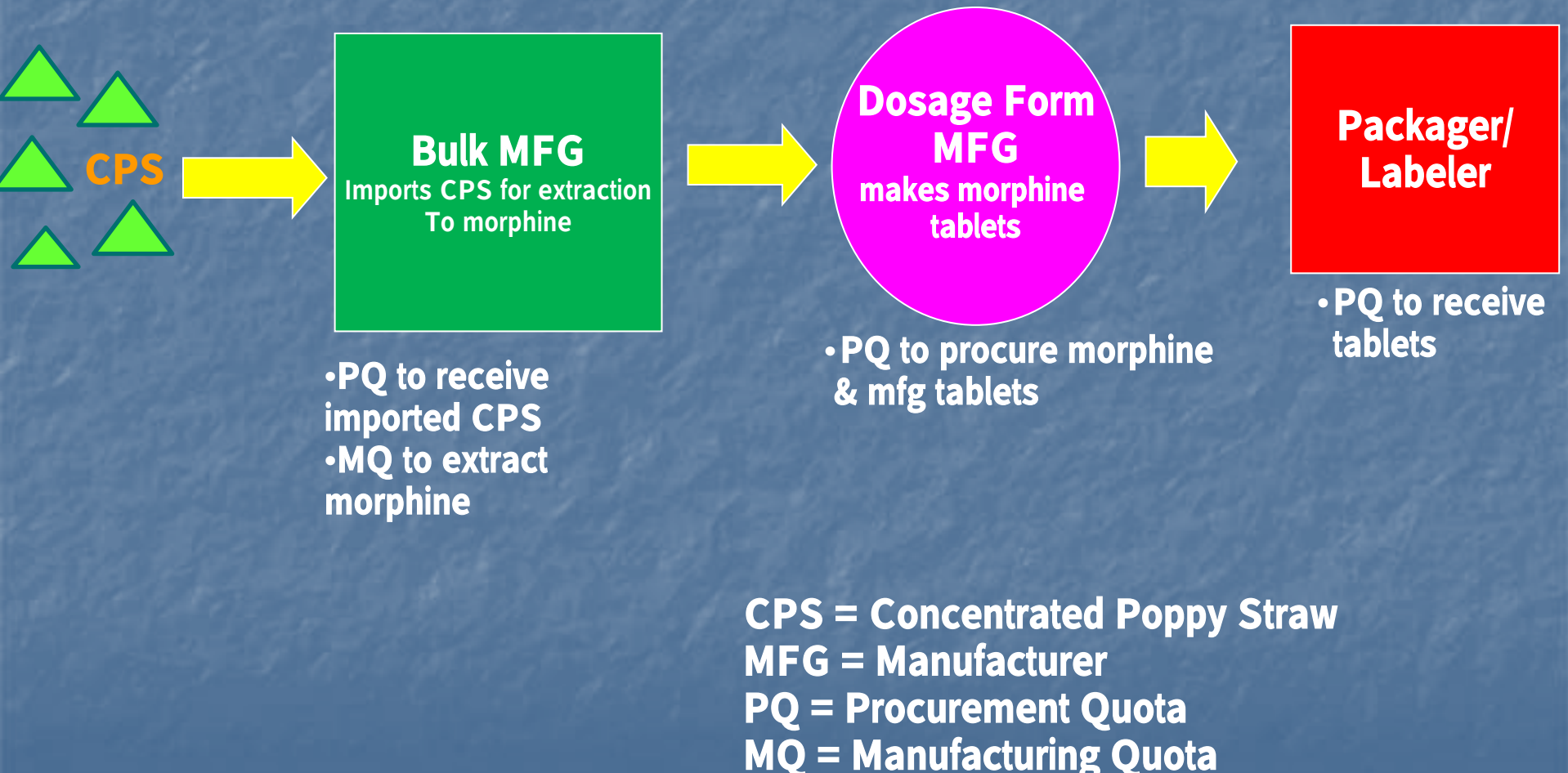


- Analytical exempted Standards
  - No quota is needed as per 21 CFR 1303.12(e)(2).
- Research
  - No quota needed for research registration per 21 CFR 1303.12(e)(3)
  - Be aware of what is considered research versus manufacturing

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



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

Who Needs Quota Answers:

- Bulk manufacturer
  - Procurement quota (CPS) is required to transfer the imported material to their manufacturing registration.
  - Manufacturing Quota (morphine) is required to extract morphine from the poppy straw.
- Company A – dosage form manufacturer
  - Procurement Quota (morphine) is required to procure bulk morphine for dosage form manufacturing.
- Company B – relabeler/repackager manufacturer
  - Procurement Quota (morphine) is required to acquire the finished dosage units for packaging and product labeling.

Combat Methamphetamine Epidemic Act 2005 (CMEA)

Enacted on March 9, 2006

Pseudoephedrine, Ephedrine, and Phenylpropanolamine

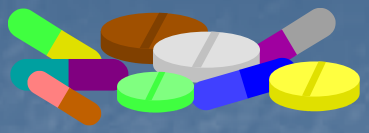
- Additional legislative and regulatory controls on the manufacture, distribution, importation, and exportation of these List 1 chemicals
- Registration now required for each physical location (manufacturer, distributor, importer or exporter)

Quota Provisions of CMEA

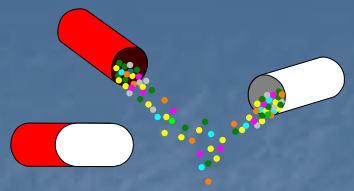
- Interim Final Rule - July 10, 2007 (71 FR 56008)
- Bulk manufacturers who synthesize EPH, PSE and PPA must obtain a manufacturing quota (DEA-189).
- Manufacturers who purchase EPH, PSE and PPA must obtain a procurement quota (DEA-250).
  - Dosage form manufacturers, packagers, labelers, repackagers and relabelers
- Importers who import EPH, PSE and PPA (or products containing EPH, PSE, and PPA) must obtain an import quota (DEA-488).

CMEA Quota Requirements
Pursuant to 21 CFR Part 1315

- 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 and 1315.32)
- Import Quotas
  (21 CFR 1315.34 and 1315.36)

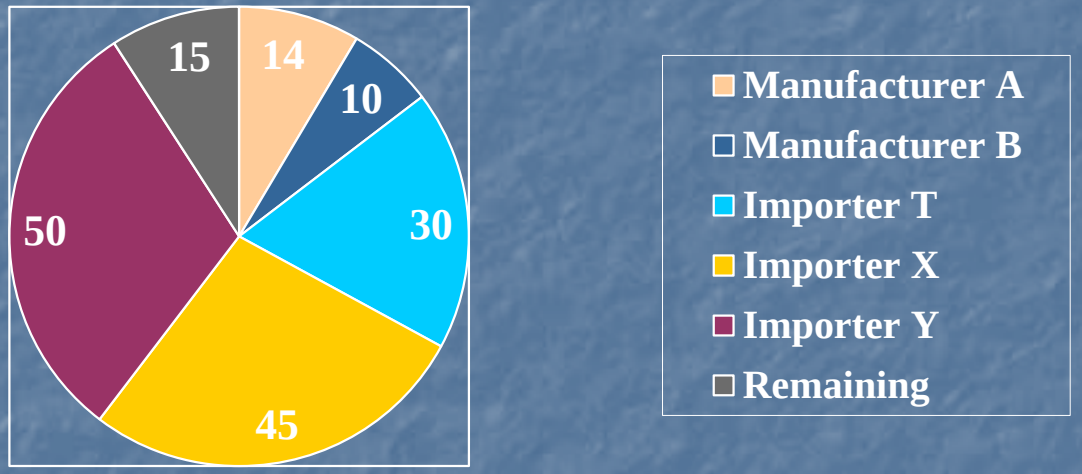


Import Quotas



- DEA registered importer
- Only applies to E, PE, PPA
- Established maximum amount which may be imported in a calendar year
- Quota adjustments may be requested at any time during the calendar year

Relationship Between Assessment of Annual Needs and Quotas



AAN = 164 kg

Frequently Asked List I Quota Questions

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

- No. Only DEA registered importers may import List I chemicals. Analytical labs may import *controlled substances* as a coincident activity only.

Frequently Asked List I Quota Questions
(Cont)

Does a manufacturer who consumes all of a list I chemical internally qualify as an “end user”?

- No. All DEA registered manufacturers who procure List I chemicals for a manufacturing activity must have quota, including those who do not distribute these list I chemicals.
- The absence of this information would prevent DEA from considering all relevant information required by law when establishing the assessment of annual needs.

Frequently Asked List I Quota Questions (Cont)

Can an importer of list I chemicals accept returns?

- No. Returns to an Importer are not allowed under the current statute and regulations. However, if the material is “not usable” and returned to the importer then this will be allowable as an “incomplete transaction”

Frequently Asked List I Quota Questions (Cont)

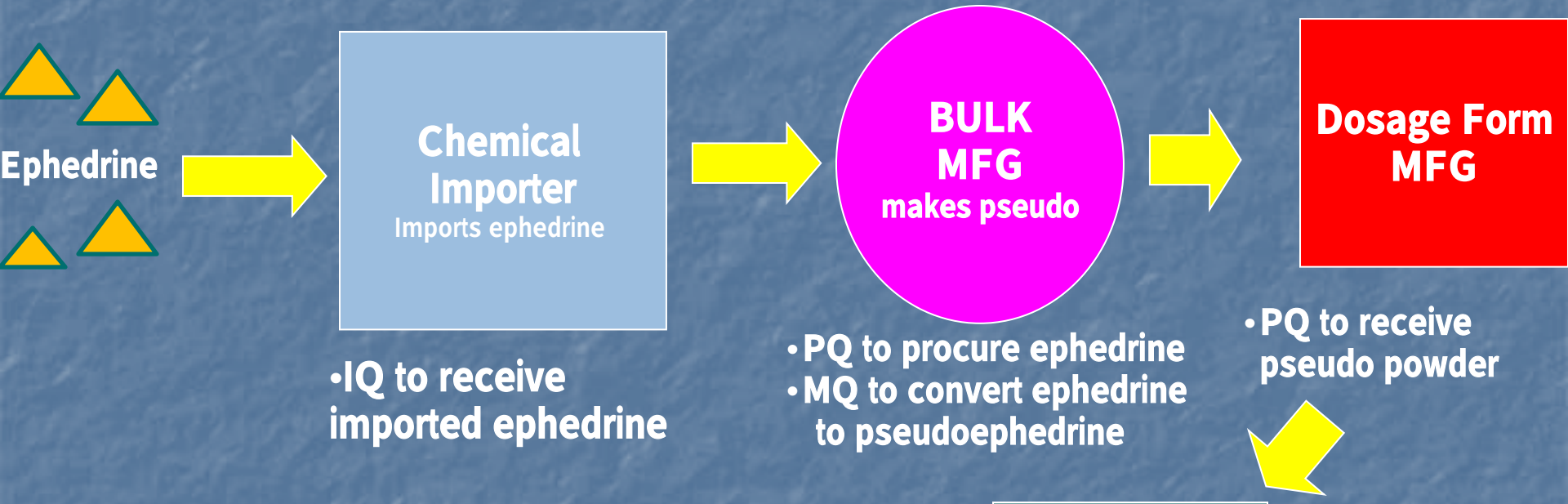
I am an importer and have a new customer can I supply the List I chemical to them?

- You may import to the extent of your firms import quota and may supply API to your customers who can supply certification that they have quota to receive this material. You may request an adjustment to your firm's import quota at anytime.

Who Needs Quota? Following a Product From Start To Finish

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

Who need Quotas - import ephedrine to pseudo



MFG = Manufacturer
PQ = Procurement Quota
MQ = Manufacturing Quota

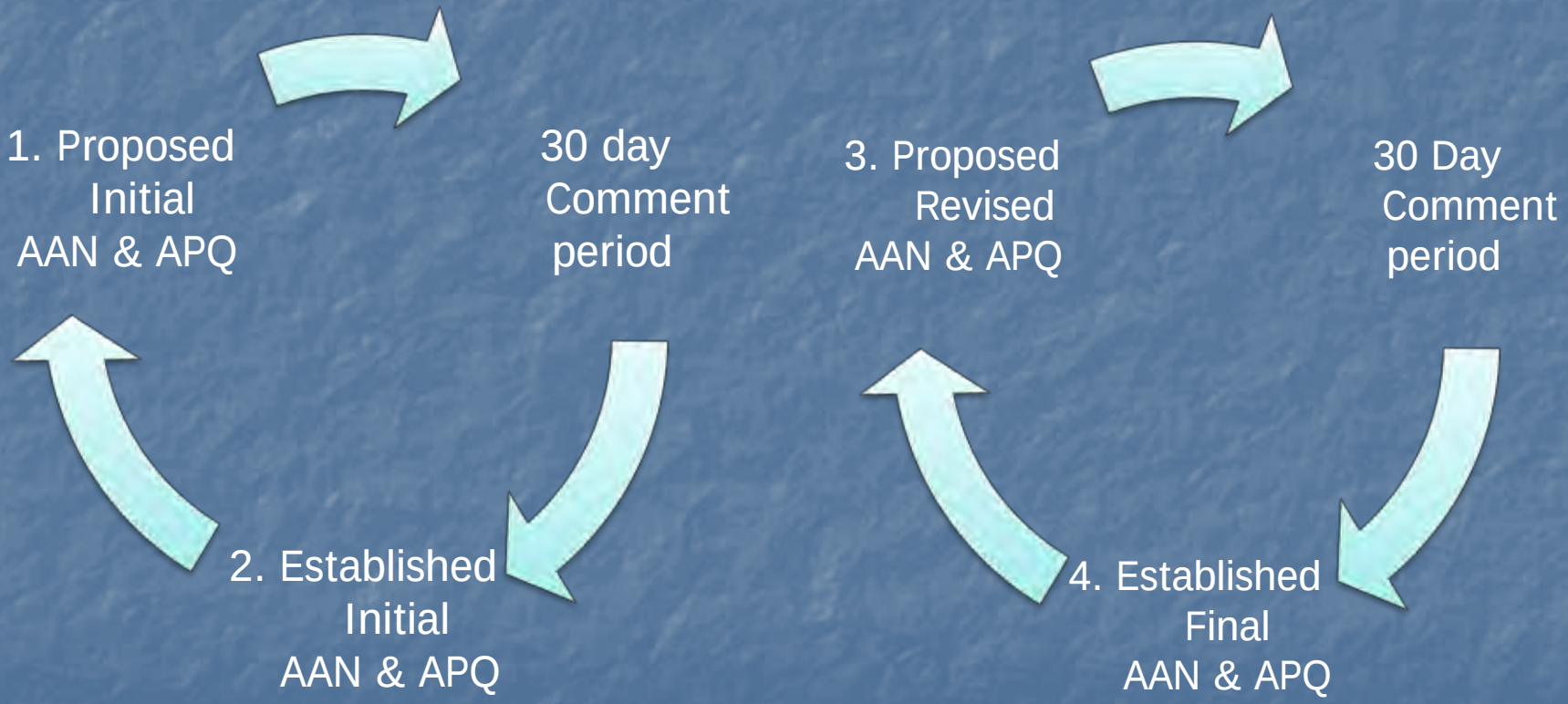
Who Needs Quota Answers:

- Importer
  - Import quota (ephedrine) is required to import the ephedrine into the U.S. under an importer registration.
- Bulk manufacturer
  - Procurement quota (ephedrine) is required to transfer the ephedrine from their importer registration to their manufacturing registration.
  - Manufacturing Quota (pseudoephedrine) is required to manufacture pseudoephedrine from the ephedrine.

Who Needs Quota Answers:
(cont)

- Company A – dosage form manufacturer
  - Procurement Quota (pseudoephedrine) is required to procure bulk pseudoephedrine for dosage form manufacturing
- Company B – repackager / relabeler
  - Procurement Quota (pseudoephedrine) is required to procure bulk dosage form for packaging/ labeling activities

Federal Registers Cycle



Overview of Procedure for Setting the Aggregate Production Quota

- To develop the APQ for the United States, DEA considers:
  - Applications for manufacturing and procurement quotas from DEA registered manufacturers
  - FDA Estimates
  - Other Considerations

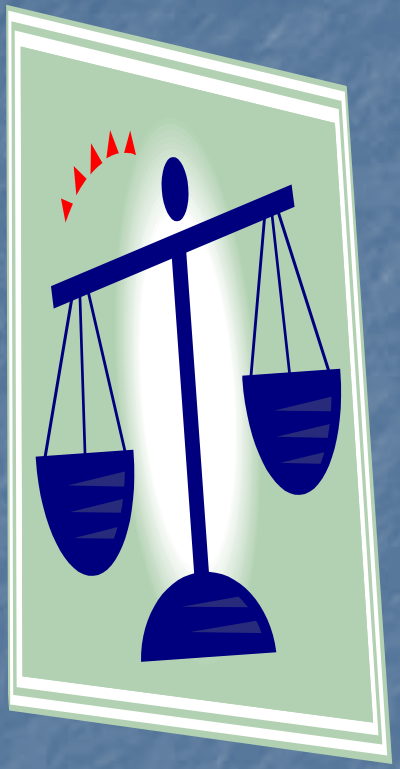
Data Used to Establish Quotas: Company Data Includes

- Inventory
- Dispositions
- Acquisitions
- Other factors such as yields, product development needs, etc.

Data Used to Establish Quotas: FDA Information Includes

- New, discontinued, and recalled drug products
- New indications for previously approved dosage forms
- New dosage forms

Other Considerations



Abuse Data

Consumption Data

Trafficking Data

Investigational Studies

Diversion Data

Overview of Procedure for Setting the Assessment of Annual Needs

- To develop the assessment of annual needs for the United States, DEA considers:
  - Applications for import, manufacturing and procurement quotas from DEA registered manufacturers and importers.
  - FDA Information
  - Trends in the national rate of disposals (sales/utilization).
  - Actual and estimated inventories.
  - Projected demand for the list I chemicals PE, E, PPA
  - Other factors

Quota Types Summary

PROCUREMENT

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

MANUFACTURING

- DEA Form189
- Bulk Manufacturers

IMPORT

- DEA 488 & Form A
- Importers of List I chemicals

Contact

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