13th Pharmaceutical Industry Conference Houston, Texas September 11-12, 2007

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Quotas and Related Topics

- Quotas for Schedule I and II Controlled Substances
- Quotas for Ephedrine, Pseudoephedrine and Phenylpropanolamine (List 1 Chemicals) Required for CMEA
- Quota Myths
- Freedom of Information (FOI)
- Questions

Quota Applications and Year-end Reports

Applications

- Procurement Quotas
  - DEA Form 250 (due April 1)
- Manufacturing Quotas
  - DEA Form 189 (due May 1)
- Two Forms are available on the Diversion Internet Site
- One application per basic drug class

Additional Reports

- All manufacturers
  - Year-End Inventory Worksheets due January 31
  - Working on making this an official form

Quota Tips

- Registration Number
- State request, i.e. amount and reason
- Show calculations, forecasts, estimates, etc.
- Submit different registration requests under separate letter

Helpful Information

- Amount of material used per batch
- Number of dosage units per batch
- Concentration of the dosage units
- Number of batches and their purpose
- Expected losses or yields
- Amounts needed for testing or retains
- Purchase orders or customer contracts

Quota Adjustments

- May request additional quota at any time
- Request must be in writing
- Include registration number
- Bulk manufacturers may be limited by the available Aggregate
- Bulk manufacturers should submit new DEA form 189

Quota Adjustment Calculations

Helpful information:

- Previous year-end inventory
- Batch size, losses etc.
- Product development requirements
- New products
- Summary of destroyed inventory/material
- Other factors

Product Development

- Objective: Ensure adequate quota availability
- Questions regarding new product development
- Describe product
- Describe proposed indications
- Product competition
- FDA approval status

Replacement Quota

- Not found in the CFR
- Created to allow bulk manufacturers to replace failed and subsequently destroyed batches/material
- Bulk manufacturers are limited by the aggregate production quotas
- Documentation
  - DEA Form 41
  - DEA Form 222

Replacement Quota

- Disposing of material is not an automatic approval and does not credit your quota
- DEA will take into consideration destroyed material and the impact it has on your inventory
- DEA may grant additional quota, issue a replacement quota, or deny request
- Replacement quota must be utilized by December 31

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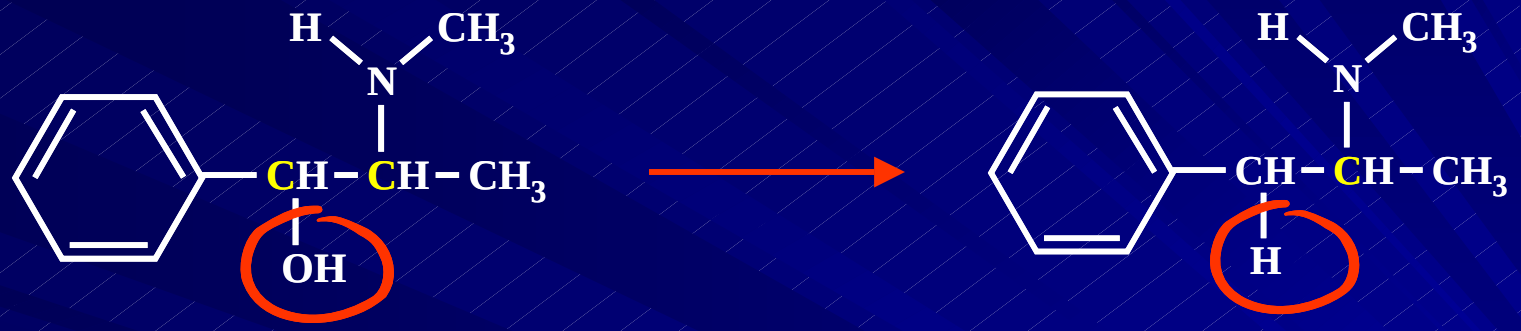
Quotas for List 1 Chemicals

- Ephedrine
- Pseudoephedrine
- Phenylpropanolamine

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

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.

List 1 Chemical Registration

- Manufacturers and importers of ephedrine, pseudoephedrine, and phenylpropanolamine (List 1 chemicals) are **required to register with the DEA**
  - Each physical location where List 1 chemicals are manufactured, distributed, imported, or exported.

List 1 Chemical Registration

- Controlled substances registrants that distribute, import, or export a scheduled listed chemical product (i.e., a drug product lawfully marketed or distributed under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug product, containing ephedrine, pseudoephedrine, or phenylpropanolamine) or another drug product containing a List I chemical, lawfully marketed or distributed under the Federal Food, Drug, and Cosmetic Act that is packaged and labeled in such a manner that the product is ready for sale on the retail shelf per FDA requirements, does NOT have to obtain a separate chemical registration as long as the controlled substances registrant is conducting the same activity for both controlled substances and the scheduled listed chemical product or other drug product containing a List I chemical.

- If, however, a controlled substances registrant distributes, exports, or imports a chemical in bulk form either as a powder, liquid, gas, or bulk tablets or capsules, then that registrant MUST get a separate chemical registration for the chemical activity they wish to pursue.

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:
  - Manufacturing quota (DEA-189) to produce any of the three chemicals.
  - Procurement quota (DEA-250) to purchase/acquire the bulk chemicals to produce products
- Importer Requirements Under CMEA:
  - Import quota (DEA 486) 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

CMEA – Import Quota Request Form

- Import Quotas
  - (ephedrine
  - Pseudoephrine
  - phenylpropanolamine)

- DEA Form 486 (due April 1)

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 AAN:

- 2005 medical and industrial needs x inventory allowance) + 2005 exports.
- Not issue quota for 2007

For 2008 AAN:

- Federal Register for Notice and Comment publish soon
- Issue quota for 2008

Quota Myths
CI or CII Controlled Substances
Ephedrine, Pseudoephedrine and
Phenylpropanolamine

- A product not approved yet by FDA does not need quota.
  - Yes, a registered manufacturer is required to have adequate quota.
- Procurement quota only applies to bulk controlled substances (API)
  - No, a registered manufacturer is required to have quota for bulk material, in process material, or finished dosage units.

Quota Myths

- Quota is not needed for gram or milligram quantities
  - Yes, a registered manufacturer is required to have adequate quota. The smallest amount of quota issued is one gram.
- I need to get import quota.
  - No, a registered importer or manufacturer of CI and CII do not need an import quota.
  - Yes, a registered importer of ephedrine, pseudoephedrine and phenylpropanolamine do need an import quota.

Quota Myths

- I don’t need a quota to procure dosage forms for comparability studies.
  - Yes, a quota is required for registered manufacturers no matter what form of the controlled substance or eph/pseudo/ppa.
- A labeler/relabeler contract manufacturer does not need a procurement quota
  - Yes, a quota is required, these activities are consistent with manufacturing activities.

Status: Implementing CMEA

- ✓ Assess “medical needs” of the US
- ✓ Assess “industrial needs” of the US
- ✓ Assess export requirements
- ✓ Consider inventory requirements
- ✓ Publish the Proposed Initial Annual Assessment of Needs (71 FR 61801)
  - Solicit Public Comments – published Oct. 19, 2006
  - Review Public Comments
- Final 2007 AAN after consideration of public comments (publish soon)

Freedom of Information (FOI)

- Requests for information come through DEA's FOI Office.
- Information and data from pharmaceutical companies' regarded as business/confidential.
- FOI Office requesting additional defense against release of confidential data.
- Contacting companies directly to obtain a statement of harm through release of confidential information.
- Add legal support for DEA's denial.
- Stamp all documents confidential, as necessary.

Questions