

# Quota Applications

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# Applications

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



# Quota Tips

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

# Helpful Information

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- ❑ 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

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- ❑ 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

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## Information Needed:

- ❑ Amount requested
- ❑ Domestic sales to-date and forecasts (kg as base)
- ❑ Exports to-date and forecasts (kg as base)
- ❑ Purchase orders/letters of intent

# Quota Adjustment Calculations

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Helpful information:

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

# Bulk Manufacturers

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## Summarize:

- ❑ Customers (include registration number)
- ❑ Sales to date (kg base)
- ❑ Forecasted sales for remainder of the year (kg base)
- ❑ Exportation to date (kg base)
- ❑ Forecasted exportation (kg base)

The following equation  
is generally used to  
calculate a revised  
quota:

Year-to-date sales  $\times$  365 / Day of the year  
 $\times$  Inventory allowance - Year-end inventory  
 $+$  Exports  $+$  Other factors = Total Quota

# 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

- ❑ Previously had been extended to procurement quotas
- ❑ “Double dipping” was observed
- ❑ DEA reviews all replacement quota requests on a case by case basis



# 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



# 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
- Contract Manufacturing
  - Quota is needed

# Frequently Asked Questions (continued)

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

# Frequently Asked Questions (continued)

- 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 DEA form 250s and 189s with original signatures

# Questions?

