Pharmaceutical Training Seminar Year-End Reports

UN Reporting and Quota Section
DEAQuotas@usdoj.gov
(202) 307-7184

Pre-YERS History

- **ARCOS system was developed to track the distribution of controlled substances.**

Manufacturer >> Distributor >> Various Retail Outlets

- **Timeliness of registrants completing reports makes it less suitable for certain DEA functions.**

It was decided that ARCOS data could not be used to comply with UN mandates

YERS History

- **In the early 90's, the DEA created year-end reports to facilitate:**
  - Establishment & Revision of
    - Aggregate Production Quotas (APQ) – CI, CII
    - Assessment of Annual Needs (AAN) – List 1
    - Individual registrant quotas (IQ,MQ,PQ)
  - Monitoring the "80/20" NRM import rule
  - UN-treaty mandated reporting

Year-end Reporting Benefits

- Provides secure web-based database system
- Preloads your available drug codes, historical data
- Performs calculations
- Generates error messages for possible incorrect entries or when “specify” fields are not completed
- Moves submitted reports to completed list

Year-end Reporting

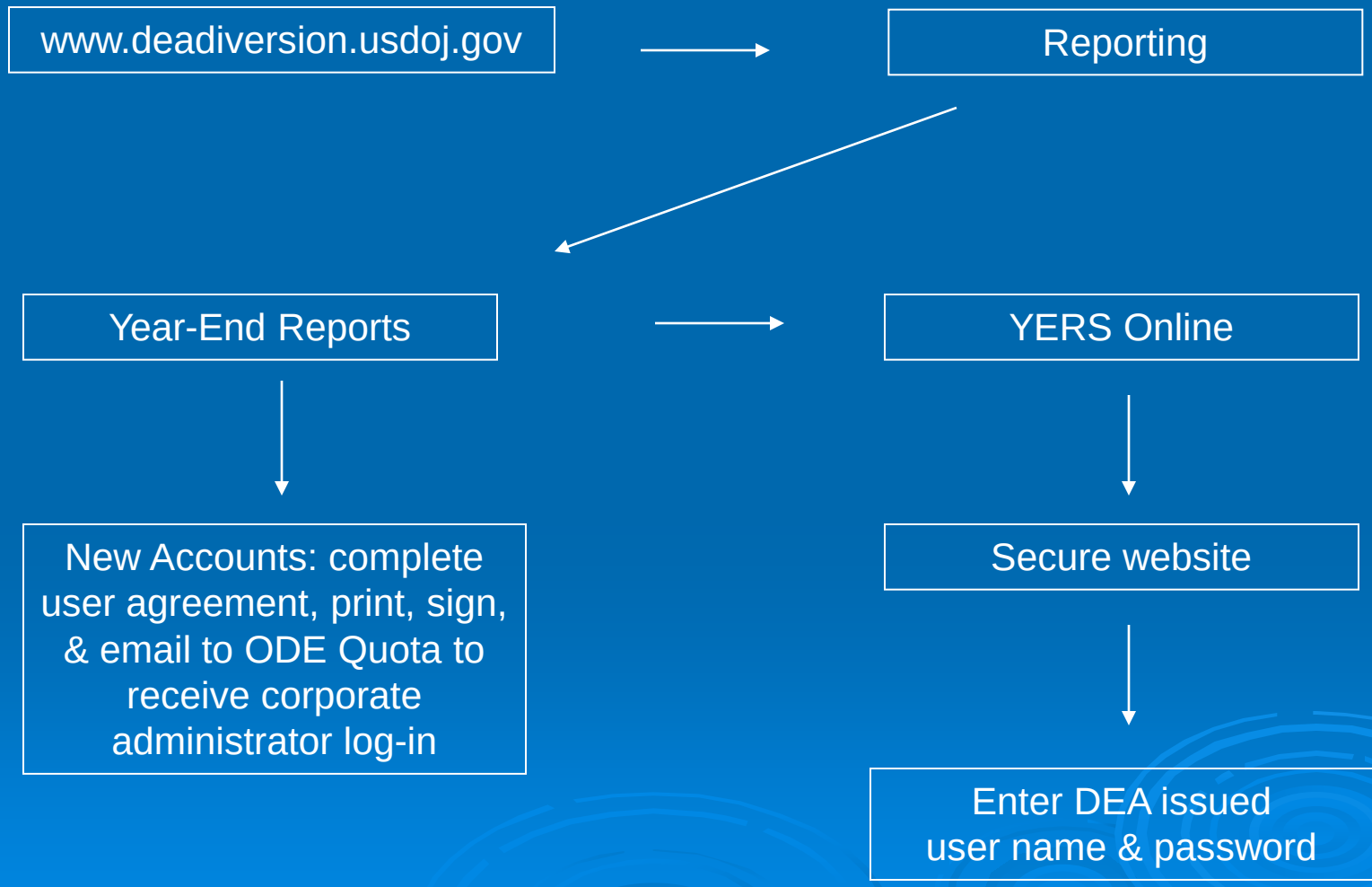
Reports need to be completed by:

- DEA REGISTERED MANUFACTURERS
  - Schedule I and II controlled substances
  - Psychotropic drugs on UN's "green list"
- DEA REGISTERED LIST 1 IMPORTERS
  - Ephedrine
  - Pseudoephedrine
  - Phenylpropanolamine

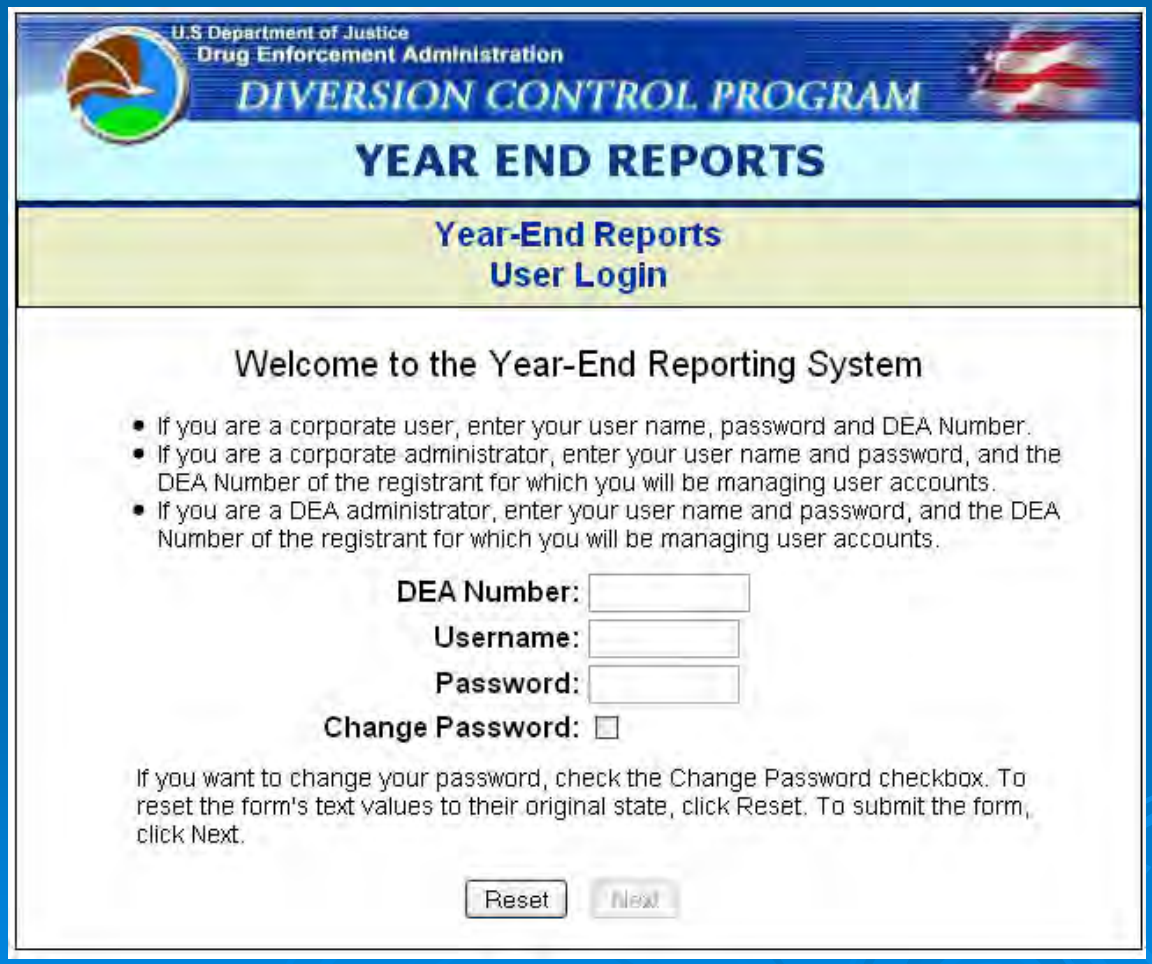
Please Note

- Due by January 31 after end of reporting CY
- Separate report required for each substance if
  - Quota was issued for that reporting CY
  - Inventory processed or carried over from an earlier CY
  - Psychotropic drug on UN's 'green list'
  - Newly scheduled CI or CII drugs
- Quantities reported should expressed as:
  - Anhydrous acid, base or alkaloid
  - GRAMS

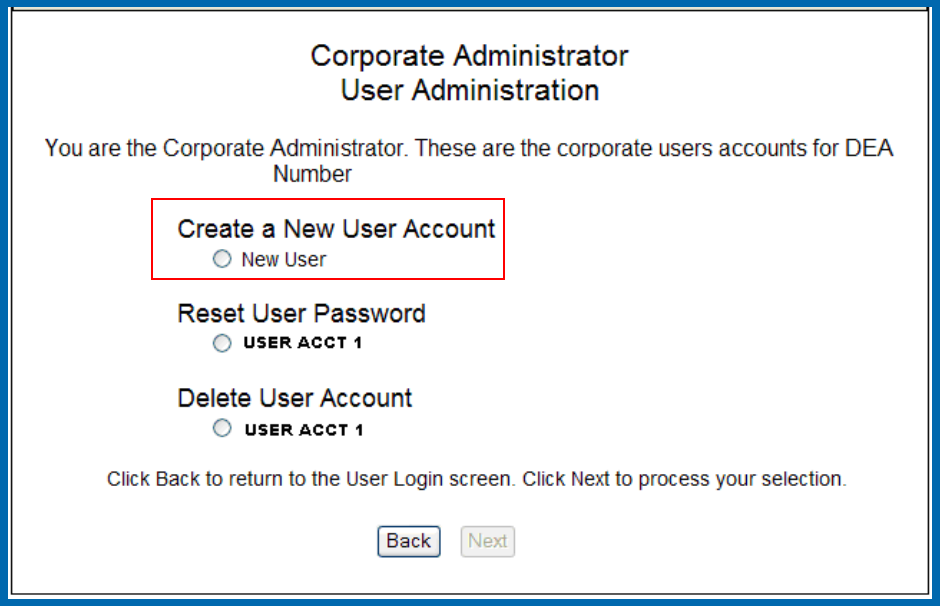
Accessing YERS Online

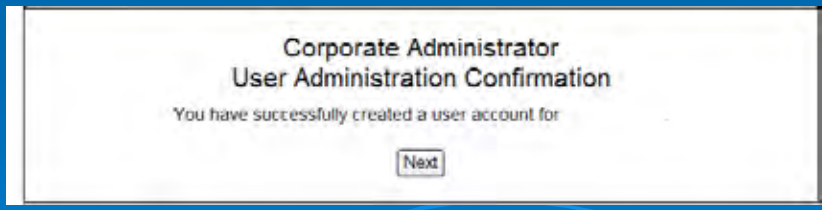


Corporate Administrator Login



Create New Corporate User Account



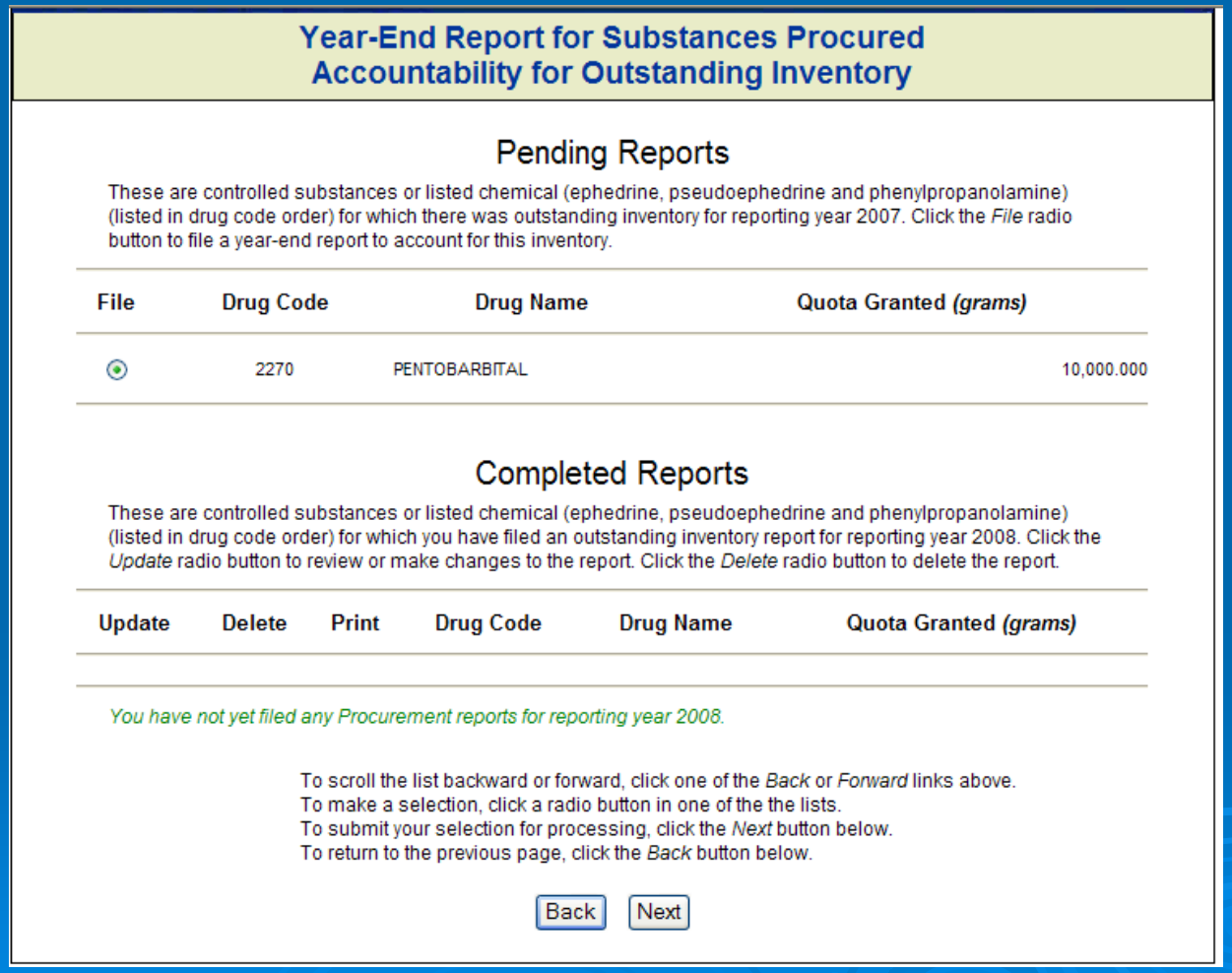


Corporate User Login

Corporate User Login Confirmation

Report Selection Menu

Report Selection



Year-End Report for Substances Procured
Accountability for Outstanding Inventory

Pending Reports

These are controlled substances or listed chemical (ephedrine, pseudoephedrine and phenylpropanolamine) (listed in drug code order) for which there was outstanding inventory for reporting year 2007. Click the *File* radio button to file a year-end report to account for this inventory.

File	Drug Code	Drug Name	Quota Granted *(grams)*
◉	2270	PENTOBARBITAL	10,000.000

Completed Reports

These are controlled substances or listed chemical (ephedrine, pseudoephedrine and phenylpropanolamine) (listed in drug code order) for which you have filed an outstanding inventory report for reporting year 2008. Click the *Update* radio button to review or make changes to the report. Click the *Delete* radio button to delete the report.

Update	Delete	Print	Drug Code	Drug Name	Quota Granted *(grams)*

You have not yet filed any Procurement reports for reporting year 2008.

To scroll the list backward or forward, click one of the *Back* or *Forward* links above.
To make a selection, click a radio button in one of the the lists.
To submit your selection for processing, click the *Next* button below.
To return to the previous page, click the *Back* button below.

Back Next

Year-end Reporting

UN mandated individual reports for the following optical isomers:

- Amphetamine
  - d-amphetamine
  - l-amphetamine
  - d,l-amphetamine
- Methamphetamine
  - d-methamphetamine
  - l-methamphetamine
  - d,l-methamphetamine
- Tetrahydrocannabinols
  - Delta-9-THC
  - All Other Tetrahydrocannabinols

“For Sale” vs. “For Conversion”

- Codeine
- D-Amphetamine
- D-Methamphetamine
- Diphenoxylate
- Hydrocodone
- Morphine
- Noroxymorphone
- Oxycodone
- Oxymorphone

"For Sale" vs. "For Conversion"

For Sale: substance used to manufacture products containing same basic class which is bought from the bulk manufacturer.

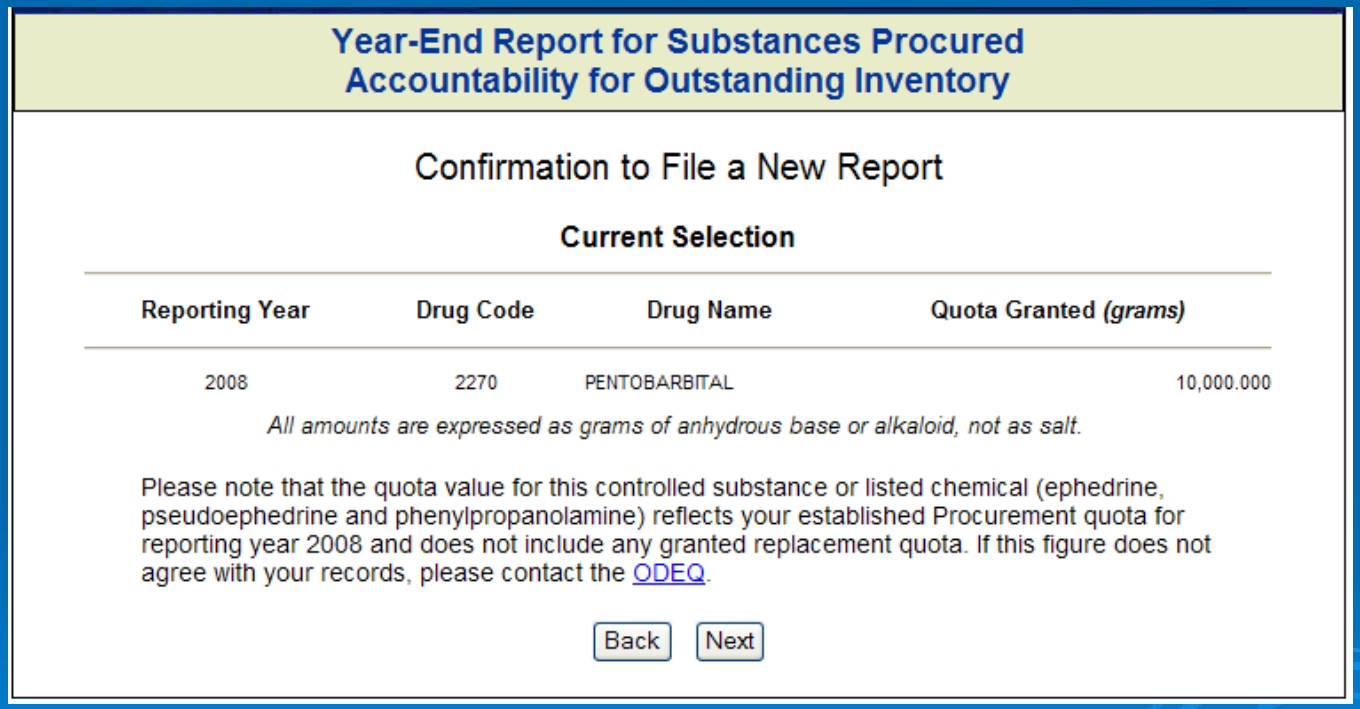
- involves ~95% of the quota applications

ex: Codeine (for sale) ⟶ codeine/APAP

For Conversion: substance used to synthesize a different basic class.

ex: Codeine (for conversion) ⟶ hydrocodone

Report Selection Confirmation



Year-End Report for Substances Procured
Accountability for Outstanding Inventory

Confirmation to File a New Report

Current Selection

Reporting Year	Drug Code	Drug Name	Quota Granted *(grams)*
2008	2270	PENTOBARBITAL	10,000.000

All amounts are expressed as grams of anhydrous base or alkaloid, not as salt.

Please note that the quota value for this controlled substance or listed chemical (ephedrine, pseudoephedrine and phenylpropanolamine) reflects your established Procurement quota for reporting year 2008 and does not include any granted replacement quota. If this figure does not agree with your records, please contact the ODEQ.

Back Next

Year-end Reporting: Inventory

- Inventories include amounts held by the registrant under manufacturer, importer, exporter or distributor registrations at that physical location
- “Bulk Controlled Substance” is the amount of raw material in inventory
- “In-process” - i.e. beads not yet encapsulated
- “Non-saleable Materials” includes any non-saleable inventory - i.e. retains, product development, pending destructions

Inventory

Year-End Report for Substances Procured
Accountability for Outstanding Inventory

Inventory

Current Selection

Reporting Year	Drug Code	Drug Name	Quota Granted *(grams)*
2008	2270	PENTOBARBITAL	10,000.000

All amounts are expressed as grams of anhydrous base or alkaloid, not as salt.
Use the Tab key to navigate between fields.

Inventory *(as of December 31)*	**2007**	**2008**	
Bulk controlled substance (API)	52.439		
In-process material (in all forms)	125.055		
Finished dosage forms (in bulk and/or packaged)	.000		
Non-saleable material ...			
retains / stability samples	.000		
product development material	.000		
pending destruction	.000		
other *(specify)*:	.000		
Total non-saleable material	.000		
Total Ending Inventory *(grams)*	177.494		Sum

Click *Return* to abandon this report and start over with a new selection.
Click *Next* to advance to the Acquisitions page.

Return Next

Year-end Reporting: Acquisitions

- Only material which was obtained against a quota should be reported under “Domestic Procurement” or “Manufactured/ Produced/ Synthesized/ Extracted”

- Material acquired through authorized replacement of destroyed material is reported under “Other Acquisitions to be Accounted For”

Acquisitions

Year-End Report for Substances Procured
Accountability for Outstanding Inventory

Acquisitions

Current Selection

Reporting Year	Drug Code	Drug Name	Quota Granted *(grams)*
2008	2270	PENTOBARBITAL	10,000.000

All amounts are expressed as grams of anhydrous base or alkaloid, not as salt.
Use the Tab key to navigate between fields.

Acquisitions *(during the year)*	**2008**	
Domestic procurements, acquisitions, transfers, etc ...		
bulk API		
non-bulk API material (in process, blends, beads, dosage forms, etc.)		
Total domestic procurements	.000	
Imports ...		
bulk API		
non-bulk API material (in process, blends, beads, dosage forms, etc.)		
Total imports	.000	
Returns by customer for credit, salvage, rework, etc.		
bulk API		
non-bulk API material (in process, blends, beads, dosage forms, etc.)		
Total returns	.000	
Other acquisitions ...		
Replacement quota		
other *(specify)*:		
Total other acquisitions	.000	
Total acquisitions *(grams)*	.000	Sum

Click *Back* to return to the Inventory page.
Click *Next* to advance to the Dispositions page.

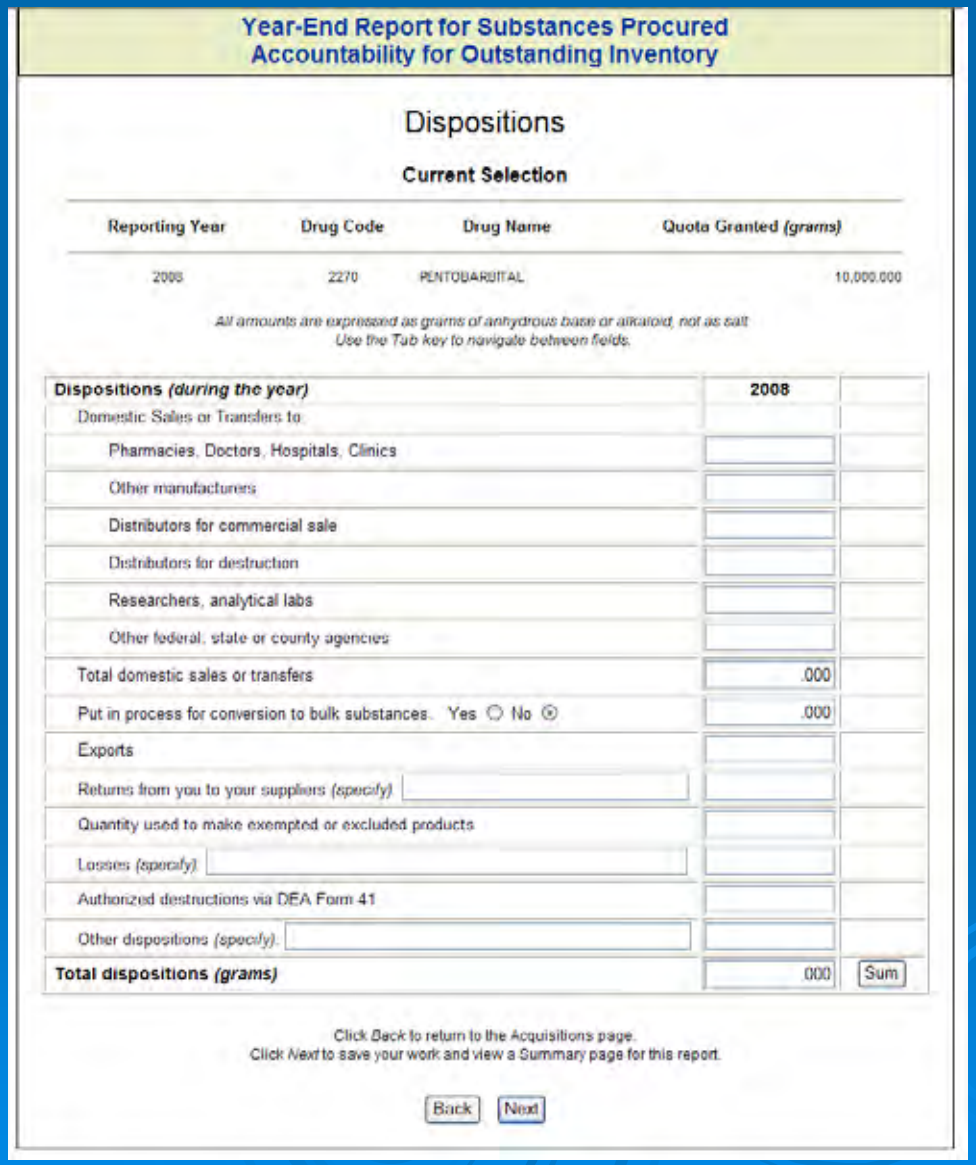
Back Next

Year-end Reporting: Dispositions

- Material acquired with current year's quota
- Material from previous year's inventory

  - Domestic sales / transfers
  - Exempted products
  - Exports
  - Returns
  - Authorized destructions

Dispositions



Year-End Report for Substances Procured
Accountability for Outstanding Inventory

Dispositions

Current Selection

Reporting Year	Drug Code	Drug Name	Quota Granted *(grams)*
2008	2270	PENTOBARBITAL	10,000.000

All amounts are expressed as grams of anhydrous base or alkaloid, not as salt
Use the Tab key to navigate between fields.

Dispositions *(during the year)*	**2008**	
Domestic Sales or Transfers to:		
Pharmacies, Doctors, Hospitals, Clinics		
Other manufacturers		
Distributors for commercial sale		
Distributors for destruction		
Researchers, analytical labs		
Other federal, state or county agencies		
Total domestic sales or transfers	.000	
Put in process for conversion to bulk substances. Yes ○ No ◉	.000	
Exports		
Returns from you to your suppliers *(specify)*		
Quantity used to make exempted or excluded products		
Losses *(specify)*		
Authorized destructions via DEA Form 41		
Other dispositions *(specify)*		
Total dispositions *(grams)*	.000	Sum

Click *Back* to return to the Acquisitions page.
Click *Next* to save your work and view a Summary page for this report.

Back Next

Summary Totals

Year-End Report for Substances Procured
Accountability for Outstanding Inventory

Summary Totals

Current Selection

Reporting Year	Drug Code	Drug Name	Quota Granted *(grams)*
2008	2270	PENTOBARBITAL	10,000.000

All amounts are expressed as grams of anhydrous base or alkaloid, not as salt.
Use the Tab key to navigate between fields.

Total Ending Inventory for 2007	**177.494**
Total Ending Inventory for 2008	**.000**
Total Acquisitions for 2008	**.000**
Total To Be Accounted For *(Total Ending Inventory For 2007 plus Total Acquisitions For 2008)*	**177.494**
Total Dispositions for 2008	**.000**
Total Accounted For *(Total Ending Inventory For 2008 plus Total Dispositions For 2008)*	**.000**
Difference *(Total To Be Accounted For minus Total Accounted For)*	**177.494**

Please provide an explanation for any difference:

Remarks:

To save this report to permanent storage, click Submit.
To return to the beginning of this report in order to review or change the entered data, click *Back*.
To return to the Report Selection List, click *Return*.

Return | Back | Submit

Confirmation

Year-End Report for Substances Procured
Accountability for Outstanding Inventory

Summary Confirmation

Current Selection

Reporting Year	Drug Code	Drug Name	Quota Granted *(grams)*
2008	2270	PENTOBARBITAL	10,000.000

You have successfully created the year-end report for the controlled substance noted above. The report selection has been moved to the Completed Reports section of the Outstnading Inventory Selection List.

To return to the Report Selection Menu, click *Main*.
To return to the Report Selection List, click *Return*.
To exit this application, click *Exit*.

Main | Return | Exit

Completed Reports

Year-End Report for Substances Procured
Accountability for Outstanding Inventory

Pending Reports

These are controlled substances or listed chemical (ephedrine, pseudoephedrine and phenylpropanolamine) (listed in drug code order) for which there was outstanding inventory for reporting year 2007. Click the *File* radio button to file a year-end report to account for this inventory.

File	Drug Code	Drug Name	Quota Granted *(grams)*

There are no qualifying pending Procurement report selections for reporting year 2007. Either you have filed all qualifying reports, or there were no qualifying substances to begin with.

Completed Reports

These are controlled substances or listed chemical (ephedrine, pseudoephedrine and phenylpropanolamine) (listed in drug code order) for which you have filed an outstanding inventory report for reporting year 2008. Click the *Update* radio button to review or make changes to the report. Click the *Delete* radio button to delete the report.

Update	Delete	Print	Drug Code	Drug Name	Quota Granted *(grams)*
○	○	○	2270	PENTOBARBITAL	10,000.000

To scroll the list backward or forward, click one of the *Back* or *Forward* links above.
To make a selection, click a radio button in one of the the lists.
To submit your selection for processing, click the *Next* button below.
To return to the previous page, click the *Back* button below.

Back Next

Year End Report Manufacturing Selection Menu

Year-end Reporting

- Narcotic Raw Materials reporting is required by 1961 Single Convention on Narcotic Drugs:
  - Opium
  - Concentrated poppy straw (CPS)

- Alkaloids in CPS which are reported:
  - Codeine
  - Morphine
  - Oripavine
  - Thebaine

Year-end Report for Bulk Manufacturers

- To be completed by a manufacturer who manufactures, produces, synthesizes or extracts a bulk Schedule I or II controlled substance

- In-process inventories are to be reported as end-product inventories, not as precursor inventories
  - based on actual assay of in-process material, or
  - based on historical yields

Conversion Reporting

- To be completed by a manufacturer who utilized a basic class for conversion to another controlled or non-controlled substance
  - Example 1 - If a manufacturer used phenylacetone to synthesize amphetamine, the amount of phenylacetone used and the amount of amphetamine synthesized would be reported on this worksheet
  - Example 2 - Manufacturer received a “codeine (for conversion)” manufacturing quota and utilized it for purposes of making “hydrocodone (for sale)”.
- This is NOT to be used to report:
  - the manufacture of dosage forms
  - the manufacture of exempt or excluded products
  - the “conversion” of a basic class to a different schedule (i.e. II to a III, IV or V)

Dispositions – Bulk Conversions

Dispositions

Current Selection

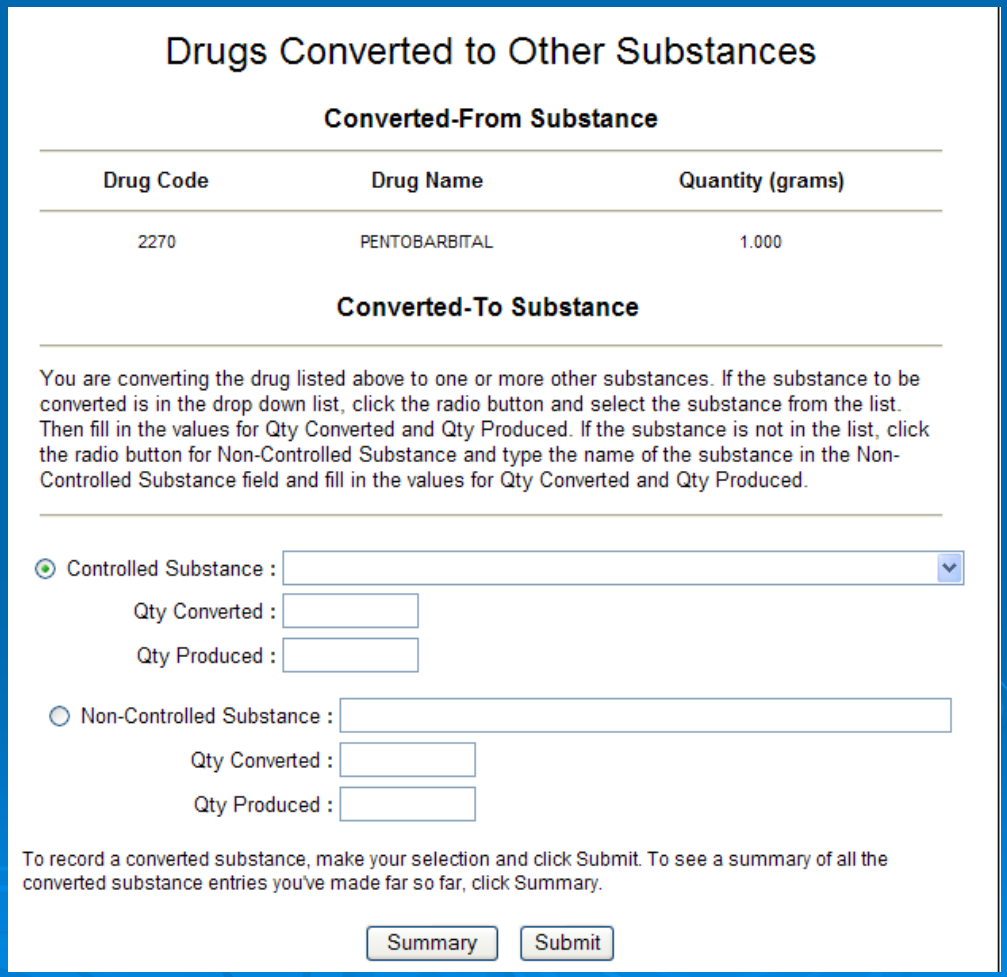
Reporting Year	Drug Code	Drug Name	Quota Granted (grams)
2007	2270	PENTOBARBITAL	15,000.000

All amounts are expressed as grams of anhydrous base or alkaloid, not as salt.
Use the Tab key to navigate between fields

Dispositions (during the year)	2007	
Domestic Sales or Transfers to:		
Pharmacies, Doctors, Hospitals, Clinics	1.000	
Other manufacturers	1.000	
Distributors for commercial sale	1.000	
Distributors for destruction	1.000	
Researchers, analytical labs	1.000	
Other federal, state or county agencies	1.000	
Total domestic sales or transfers	6.000	
Put in process for conversion to bulk substances. Yes ◉ No ○	.000	
Exports	1.000	
Returns from you to your suppliers (specify): TEST	1.000	
Quantity used to make exempted or excluded products	1.000	
Losses (specify): TEST2	1.000	
Authorized destructions via DEA Form 41	1.000	
Other dispositions (specify): TEST3	1.000	
Total dispositions (grams)	12.000	Sum

Click Back to return to the Acquisitions page.
Click Next to save your work and view a Summary page for this report.

Back Next



Drugs Converted to Other Substances

Converted-From Substance

Drug Code	Drug Name	Quantity (grams)
2270	PENTOBARBITAL	1.000

Converted-To Substance

You are converting the drug listed above to one or more other substances. If the substance to be converted is in the drop down list, click the radio button and select the substance from the list. Then fill in the values for Qty Converted and Qty Produced. If the substance is not in the list, click the radio button for Non-Controlled Substance and type the name of the substance in the Non-Controlled Substance field and fill in the values for Qty Converted and Qty Produced.

◉ Controlled Substance :

Qty Converted :

Qty Produced :

○ Non-Controlled Substance :

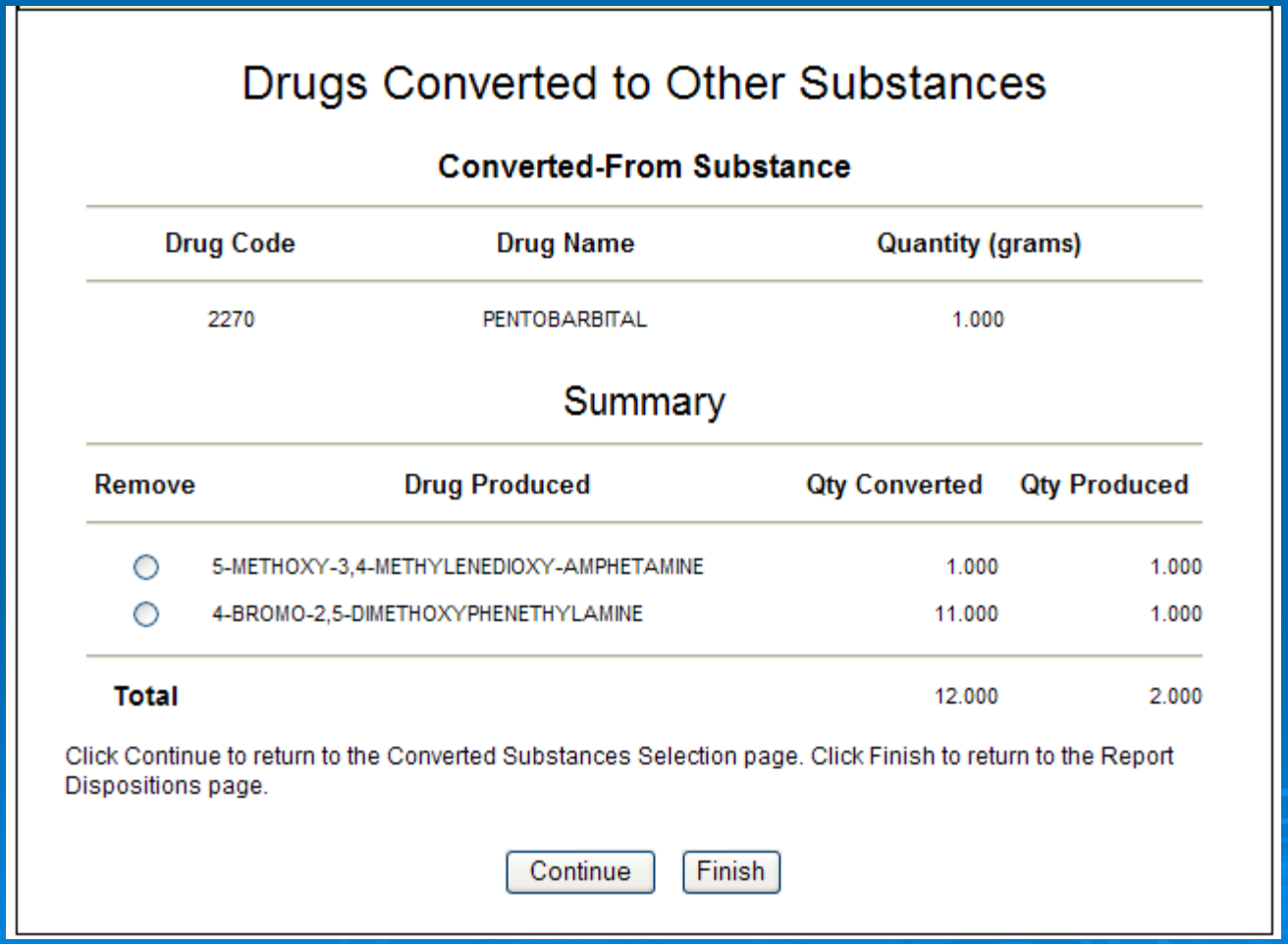
Qty Converted :

Qty Produced :

To record a converted substance, make your selection and click Submit. To see a summary of all the converted substance entries you've made far so far, click Summary.

Summary Submit

Dispositions– Bulk Conversions Summary



Drugs Converted to Other Substances

Converted-From Substance

Drug Code	Drug Name	Quantity (grams)
2270	PENTOBARBITAL	1.000

Summary

Remove	Drug Produced	Qty Converted	Qty Produced
○	5-METHOXY-3,4-METHYLENEDIOXY-AMPHETAMINE	1.000	1.000
○	4-BROMO-2,5-DIMETHOXYPHENETHYLAMINE	11.000	1.000
Total		12.000	2.000

Click Continue to return to the Converted Substances Selection page. Click Finish to return to the Report Dispositions page.

Continue Finish

Summary Totals

Year-End Report for Substances Procured
Accountability for Outstanding Inventory

Summary Totals

Current Selection

Reporting Year	Drug Code	Drug Name	Quota Granted *(grams)*
2008	2270	PENTOBARBITAL	10,000.000

All amounts are expressed as grams of anhydrous base or alkaloid, not as salt.
Use the Tab key to navigate between fields.

Total Ending Inventory for 2007	**177.494**
Total Ending Inventory for 2008	**.000**
Total Acquisitions for 2008	**.000**
Total To Be Accounted For *(Total Ending Inventory For 2007 plus Total Acquisitions For 2008)*	**177.494**
Total Dispositions for 2008	**.000**
Total Accounted For *(Total Ending Inventory For 2008 plus Total Dispositions For 2008)*	**.000**
Difference *(Total To Be Accounted For minus Total Accounted For)*	**177.494**

Please provide an explanation for any difference:

Remarks:

To save this report to permanent storage, click Submit.
To return to the beginning of this report in order to review or change the entered data, click *Back*.
To return to the Report Selection List, click *Return*.

Return | Back | Submit

Confirmation

Year-End Report for Substances Procured
Accountability for Outstanding Inventory

Summary Confirmation

Current Selection

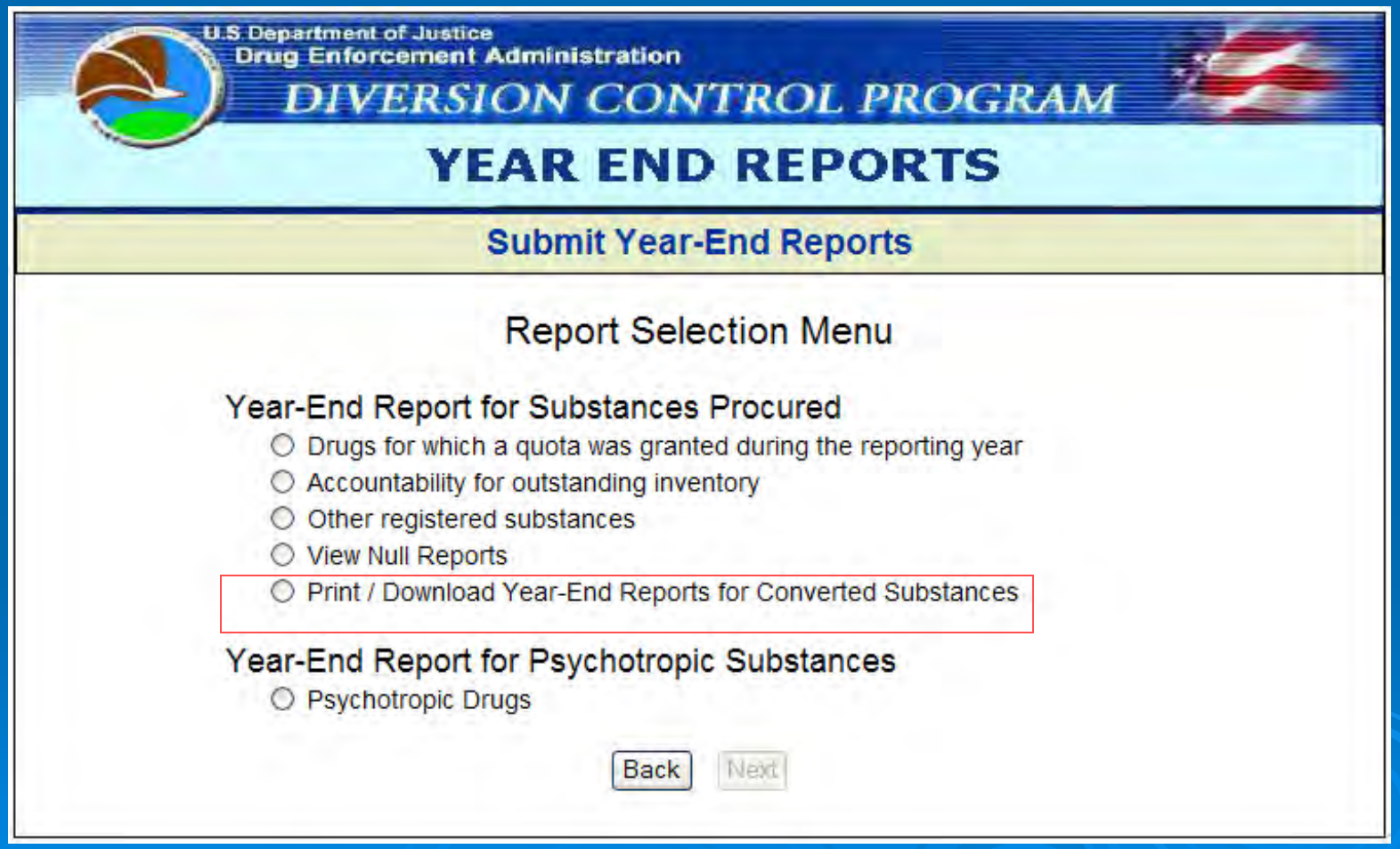
Reporting Year	Drug Code	Drug Name	Quota Granted *(grams)*
2008	2270	PENTOBARBITAL	10,000.000

You have successfully created the year-end report for the controlled substance noted above. The report selection has been moved to the Completed Reports section of the Outstnading Inventory Selection List.

To return to the Report Selection Menu, click *Main*.
To return to the Report Selection List, click *Return*.
To exit this application, click *Exit*.

Main Return Exit

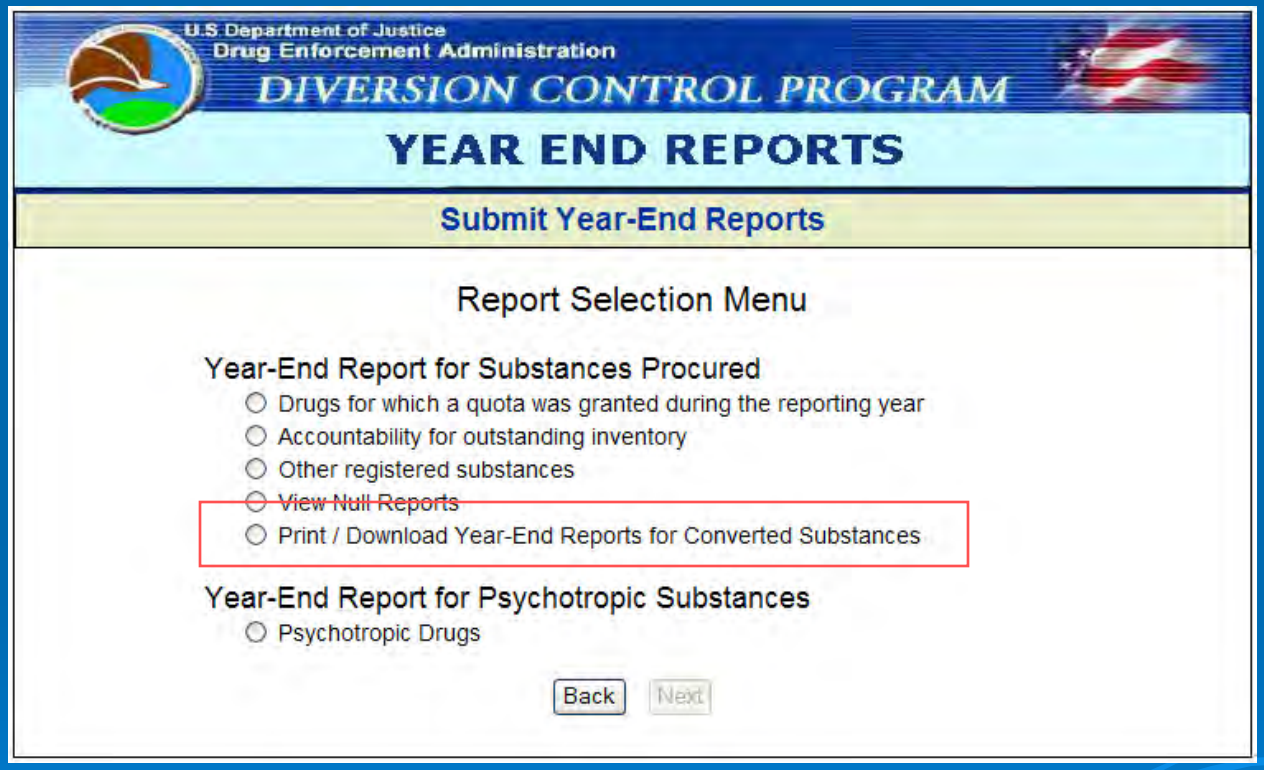
Year End Report Procurement Selection Menu



UN Psychotropic Substance Report

- Specified psychotropic substances in UN Schedules III and IV, member countries voluntarily submit statistics to UN
  - Check the DEA Diversion web site (www.deadiversion.usdoj.gov)
  - Check the INCB web site (www.incb.org)
  - Check the “green list” - attached
- Bulk and non-bulk manufacturers should report.
- DEA attempted to codify a regulation which would have required such reporting (circa 1992), however never promulgated the rule.

Year End Report Psychotropic Selection Menu



Psychotropic Substances to be Reported

71 Schedule III:

- Buprenorphine
- Butalbital
- Cathine
- Cyclobarbital
- Flunitrazepam
- Pentazocine

71 Schedule IV:

- Allobarbital
- Alprazolam
- Barbital
- Benzphetamine
- Bromazepam
- Brotizolam
- Camazepam
- Chlordiazepoxide
- Clobazam
- Clonazepam
- Clorazepate
- Clotiazepam
- Cloxazolaml
- Delorazepam
- Diazepam
- Diethylpropion
- Estazolam
- Ethchlorvynol
- Ethinamate
- Ethyl loflazepate
- Fencamfamin
- Fenproporex
- Fludiazepam
- Flurazepam
- Halazepam
- Haloxazolam
- Ketazolam
- Loprazolam
- Lorazepam
- Lormetazepam
- Mazindol
- Medazepam
- Mefenorex
- Meprobamate
- Mesocarb
- Methylphenobarbital
- Methyprylon
- Midazolam
- Nimetazepam
- Nitrazepam
- Nordazepam
- Oxazepam
- Oxazolam
- Pemoline
- Phendimetrazine
- Phenobarbital
- Phentermine
- Pinazepam
- Pipradrol
- Prazepam
- Pyrovalerone
- Secbutabarbital
- SPA (lefetamine)
- Temazepam
- Tetrazepam
- Triazolam
- Vinylbital
- Zolpidem

Psychotropic Report

UN PSYCHOTROPIC SUBSTANCE REPORT		
Registrant Name:		
DEA Registration Number:	Date Submitted:	Reporting Year:
Drug Code: 2885	Drug Schedule: 4	Quota Allotment *(grams)*: N/A
Registrant Address:		
Mailing Address:		
User ID:	Phone:	Fax:
Email:		

All amounts are expressed as grams of anhydrous base or alkaloid, not as salt.

	2007	2008
Inventory *(as of December 31)*	.000	.000
Bulk Manufactured		.000
Dispositions (during 2008)		
Quantity sold as finished dosage forms		.000
Quantity used to manufacture non-psychotropic substances		.000
Quantity used to manufacture excluded, excepted or exempted substances		.000
Total Dispositions		.000
Estimates for future usage	2009	2010
Expected future usage (sale) of finished dosage forms	.000	.000
Remarks:		

Questions?

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