Supply Chain Conference Orlando, Florida



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Year-End Reporting System

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United Nations Reporting and Quota Section
Diversion Control Division

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) CMEA List I Chemicals
 - Individual registrant quotas (IQ,MQ,PQ)
- Monitoring the "80/20" Narcotic Raw Material import rule
- UN-treaty mandated reporting

YERS Benefits



- Provides a 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 CMEA LIST I CHEMICAL IMPORTERS
 - Ephedrine
 - Pseudoephedrine
 - Phenylpropanolamine

Important Things To Remember



- Due by January 31 after end of reporting calendar Year (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 be expressed as:
 - Anhydrous acid, base or alkaloid
 - -GRAMS

Accessing YERS Online



www.deadiversion.dea.gov Reporting

Year-End
Reports

Secure
New Accounts: Complete user

Reporting

agreement, print, sign, & email to DEAQuotas@dea.gov to receive corporate administrator log-in

Enter DEA issued username & password

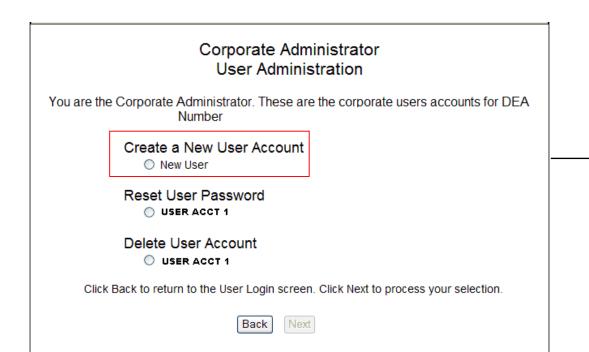
Corporate Administrator Login

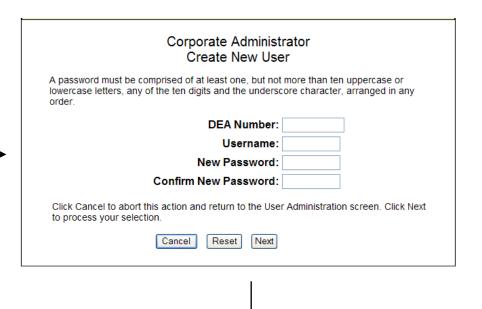




Create New Corporate User Account







Corporate Administrator User Administration Confirmation

You have successfully created a user account for

Next

Corporate User Login





Corporate User Login Confirmation





Year-End Reports Login Confirmation

Corporate User Login Confirmation

- You are logged in as
- You are authorized as a corporate user to submit Year-End Inventory Reports for DEA Number
- If this information is not correct, please contact your administrator immediately.

Click Back to return to the User Login screen. Click Next to advance to the Main Selection Menu screen.

Back

Next

Report Selection Menu





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OFFICE OF DIVERSION CONTROL

Year-End Reports

Report Selection Menu

Year-End Report for Procured Substances

- Registered Substances With Quotas and / or Outstanding Inventory
- Other registered substances
- View Null Reports
- Drugs Converted to Other Substances

Year-End Report for Manufactured Substances

- Registered Substances With Quotas and / or Outstanding Inventory
- Other registered substances
- View Null Reports
- Drugs Converted to Other Substances

Year-End Report for Psychotropic Substances

Psychotropic Drugs





Report Selection





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DIVERSION CONTROL DIVISION

Year-End Report for Procured Substances Drugs for Which a Quota Was Granted or Outstanding Inventory Exists

Pending Reports

These are controlled substances or listed chemicals (ephedrine, pseudoephedrine and phenylpropanolamine) (arranged in drug code order) for which you were granted a Procurement quota for reporting year 2016 and / or for which there was outstanding inventory for reporting year 2015. Click the *File* radio button to file a year-end report.

File	Drug Code	Drug Name	Quota Granted (grams)
•	1100	D,L-AMPHETAMINE	N/A
	1100	D-AMPHETAMINE (FOR SALE)	N/A
	1237	METHCATHINONE	N/A
	1724	METHYLPHENIDATE	N/A
	2125	AMOBARBITAL	N/A

Rows 1 through 5 of 6
Use the Back / Forward links to scroll the list. Use the Back / Next buttons below to advance the screen.

<< Back Scroll Forward >>

Completed Reports

These are year-end Procurement reports (arranged in drug code order) that meet the criteria above and that you have already filed for reporting year 2016. 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 2016.

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 Reports



UN mandated individual reports for the following optical isomers:

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

Substance Selection Identifiers



"For Sale" vs. "For Conversion"

<u>For Sale</u>: 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) \longrightarrow hydrocodone



Examples of "For Sale" vs. "For Conversion"

- Codeine
- D-amphetamine
- D-methamphetamine
- Dexmethylphenidate
- Diphenoxylate
- Hydrocodone

- Methylphenidate
- Morphine
- Noroxymorphone
- Oxycodone
- Oxymorphone

Report Selection Confirmation





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Year-End Report for Procured Substances Drugs for Which a Quota Was Granted or Outstanding Inventory Exists

Confirmation to File a New Report

Current Selection

Reporting Year	Drug Code	Drug Name	Quota Granted (grams)
2016	1100	D,L-AMPHETAMINE	N/A

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 2016 and does not include any granted replacement quota. If this figure does not agree with your records, please contact <u>ODEQ</u>.





Year-end Reporting: Inventory



- Inventories should include amounts held by the registrant and be reported for each manufacturer, importer, exporter or distributor registration at that registration's <u>physical location</u>
- "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. samples, product development

Inventory





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Year-End Report for Procured Substances Drugs for Which a Quota Was Granted or Outstanding Inventory Exists

Inventory

Current Selection

Reporting Year	Drug Code	Drug Name	Quota Granted (grams)
2016	1100	D,L-AMPHETAMINE	N/A

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)	2015	2016	
Bulk controlled substance (API)	600.000	.000	
In-process material (in all forms)	200.000	.000	
Finished dosage forms (in bulk and/or packaged)	300.000	.000	
Non-saleable material			
retains / stability samples	100.000	.000	
product development material	100.000	.000	
pending destruction	100.000	.000	
other (specify):	.000	.000	
Total non-saleable material	300.000	.000	
Total Ending Inventory (grams)	1,400.000	.000	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 <u>authorized replacement</u> of destroyed material is reported under "Other Acquisitions to be Accounted For"

Acquisitions



Year-End Report for Procured Substances Drugs for Which a Quota Was Granted or Outstanding Inventory Exists

Acquisitions

Current Selection

Reporting Year	Drug Code	Drug Name	Quota Granted (grams)
2016	1100	D,L-AMPHETAMINE	N/A

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)	2016	
Domestic procurements, acquisitions, transfers, etc		
bulk API	.000	
non-bulk API material (in process, blends, beads, dosage forms, etc.)	.000	
Total domestic procurements	.000	
Imports		
bulk API	.000	
non-bulk API material (in process, blends, beads, dosage forms, etc.)	.000	
Total imports	.000	
Returns by customer for credit, salvage, rework, etc.		
bulk API	.000	
non-bulk API material (in process, blends, beads, dosage forms, etc.)	.000	
Total returns	.000	
Other acquisitions		
Replacement quota	.000	
other (specify):	.000	
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 Procured Substances Drugs for Which a Quota Was Granted or Outstanding Inventory Exists

Dispositions

Current Selection

Reporting Year	Drug Code	Drug Name	Quota Granted (grams)
2016	1100	D,L-AMPHETAMINE	N/A

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)	2016	
Domestic Sales or Transfers to:		
Pharmacies, Doctors, Hospitals, Clinics	.000	
Other manufacturers	.000	
Distributors for commercial sale	.000	
Distributors for destruction	.000	
Researchers, analytical labs	.000	
Other federal, state or county agencies	.000	
Total domestic sales or transfers	.000	
Put in process for conversion to bulk substances	.000	
Exports	.000	
Returns from you to your suppliers (specify):	.000	
Quantity used to make exempted or excluded products	.000	
Losses (specify):	.000	
Authorized destructions via DEA Form 41	.000	
Other dispositions (specify):	.000	
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.

If you wish to put in process for conversion, enter an amount in to textbox and click Next.

Back

Next

Summary Totals





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Year-End Report for Procured Substances Drugs for Which a Quota Was Granted or Outstanding Inventory Exists

Summary Totals

Current Selection

Reporting Year	Drug Code	Drug Name	Quota Granted (grams)
2016	1100	D,L-AMPHETAMINE	N/A

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 2015	1,400.000
Total Ending Inventory for 2016	.000
Total Acquisitions for 2016	.000
Total To Be Accounted For (Total Ending Inventory For 2015 plus Total Acquisitions For 2016)	1,400.000
Total Dispositions for 2016	.000
Total Accounted For (Total Ending Inventory For 2016 plus Total Dispositions For 2016)	.000
Difference (Total To Be Accounted For minus Total Accounted For)	1,400.000
Please provide an explanation for any difference: (maximum 1,024 characters :: 1024 characters remaining)	
Remarks: (maximum 1,024 characters :: 1024 characters remaining)	

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





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Year-End Report for Procured Substances

Drugs for Which a Quota Was Granted or Outstanding Inventory Exists

Summary Confirmation

Current Selection

Reporting Year	Drug Code	Drug Name	Quota Granted (grams)
2016	1100	D,L-AMPHETAMINE	N/A

You have successfully created the year-end report for the substance noted above. The report selection has been moved to the Completed Reports section of the QA/OI 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 | F

Return

Exit

Completed Reports





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Year-End Report for Procured Substances Drugs for Which a Quota Was Granted or Outstanding Inventory Exists

Pending Reports

These are controlled substances or listed chemicals (ephedrine, pseudoephedrine and phenylpropanolamine) (arranged in drug code order) for which you were granted a Procurement quota for reporting year 2016 and / or for which there was outstanding inventory for reporting year 2015. Click the *File* radio button to file a year-end report.

File	Drug Code	Drug Name	Quota Granted (grams)
	1100	D-AMPHETAMINE (FOR SALE)	N/A
	1237	METHCATHINONE	N/A
	1724	METHYLPHENIDATE	N/A
	2125	AMOBARBITAL	N/A
	2270	PENTOBARBITAL	N/A

Completed Reports

These are year-end Procurement reports (arranged in drug code order) that meet the criteria above and that you have already filed for reporting year 2016. 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)
		•	1100	D,L-AMPHETAMINE	N/A

You no longer hold a valid registration for the substance outlined in red above. For that reason, your only option is to print a copy of the report.

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.

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Year-End Report Manufacturing Selection Menu





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Year-End Reports

Report Selection Menu

Year-End Report for Procured Substances

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- Other registered substances
- View Null Reports
- Drugs Converted to Other Substances

Year-End Report for Manufactured Substances

- Registered Substances With Quotas and / or Outstanding Inventory
- Other registered substances
- View Null Reports
- Drugs Converted to Other Substances

Year-End Report for Psychotropic Substances

Psychotropic Drugs





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
 - Noscapine

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 (II) to synthesize amphetamine (II), 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 schedule II to a III, IV or V

Dispositions – Bulk Conversions



Dispositions **Current Selection** Reporting Year **Drug Code** Drug Name Quota Granted (grams) 2007 PENTOBARBITAL 2270 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) 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 6.000 Total domestic sales or transfers Put in process for conversion to bulk substances. Yes No .000 1.000 Exports 1.000 Returns from you to your suppliers (specify): TEST 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 Click Back to return to the Acquisitions page. Click Next to save your work and view a Summary page for this report. Next Back

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 : Qtv 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. Submit Summary

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
0	5-METHOXY-3,4-METHYLENEDIOXY-AMPHETAMINE	1.000	1.000
\circ	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 Quota Granted (grams) Drug Name 2008 PENTOBARBITAL 10,000.000 2270 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 177.494 (Total Ending Inventory For 2007 plus Total Acquisitions For 2008) **Total Dispositions for 2008** .000 **Total Accounted For** .000 (Total Ending Inventory For 2008 plus Total Dispositions For 2008) Difference 177.494 (Total To Be Accounted For minus Total Accounted For) 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.

Back

Submit

Return

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.



Return



UN Psychotropic Substance Report



- Member countries must submit statistics to UN on specified psychotropic substances in UN Schedules III and IV,
 - Check the DEA Diversion web site (www.deadiversion.usdoj.gov)
 - Check the INCB web site (www.incb.org)
 - Check the "green list" attached

<u>Bulk</u> and <u>non-bulk</u> manufacturers should report

Year End Report Psychotropic Selection Menu





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DIVERSION CONTROL DIVISION

Year-End Reports

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Year-End Report for Procured Substances

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- Other registered substances
- View Null Reports
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Year-End Report for Manufactured Substances

- Registered Substances With Quotas and / or Outstanding Inventory
- Other registered substances
- View Null Reports
- Drugs Converted to Other Substances

Year-End Report for Psychotropic Substances

Psychotropic Drugs



Next

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





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UN Psychotropic Substances

Psychotropic Drugs

Psychotropic Drugs

Current Selection

Reporting Year	Drug Code	Drug Name	Quota Granted (grams)	
2016	2765	DIAZEPAM		N/A

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

	2015	2016		
Inventory (as of December 31)	.000	.000		
Bulk Manufactured		.000		
Dispositions (during 2016)				
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	Sum	
Estimates for Future Usage	2017	2018		
Expected Future Usage (Sale) of Finished Dosage Forms	.000	.000		
Remarks: (maximum 255 characters :: 255 characters remaining)				

To save this report to permanent storage, click *Submit*.

To abandon this report and return to the Report Selection List, click *Return*.

Return

Submit

Psychotropic Report





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UN Psychotropic Substances
Psychotropic Drugs

Summary Confirmation

Current Selection

Reporting Year	Drug Code	Drug Name	Quota Granted (grams)
2016	2765	DIAZEPAM	N/A

You have successfully filed the year-end report for the substance noted above. The report selection has been moved to the Completed Reports section of the Psychotropic Drugs 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.







Year-End Reporting



Thank you!

If you have questions we can be reached via email and phone.

United Nations Reporting and Quota Section (DRQ)

DEAQuotas@dea.gov

(571) 362-3248