Drug Enforcement Administration

Year-End Reporting and Quota Management System

YERS Online User Manual

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DIVERSION CONTROL DIVISION TECHNOLOGY SECTION

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1.0 Introduction

1.1 Overview

The United Nations (UN) has in place a global mechanism designed to limit the supply of Schedule I and II controlled substances and the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine available for legitimate international use, thereby preventing the accumulation of surplus substance stockpiles. UN treaty agreements obligate the United States (US) to keep its production of controlled substances within a predetermined annual quota to help ensure this limited stockpile.

Section 306 of the Controlled Substances Act (CSA) gives the Drug Enforcement Administration (DEA) – through the Diversion Control Division (DC) – the authority to establish quotas for each basic class of Schedule I and II controlled substance and the 3 List 1 Chemicals manufactured each year.

There are two types of quota assigned to Schedule I and II controlled substance manufacturers: procurement and manufacturing. There are three types of quota given to DEA-registered importers and manufacturers of ephedrine, pseudoephedrine, and phenylpropanolamine: procurement, manufacturing, and import. Procurement quotas determine the amount of selected substances a manufacturer will require in order to produce another substance (example: a manufacturer would require a quota for morphine to later produce the drug codeine). Manufacturing quotas limit the amount of substances or chemicals a manufacturer is allowed to produce in a given year. Import quotas affect the amount of chemicals a manufacturer is allowed to import into the United States for the purposes of later manufacture or distribution.

The UN Reporting and Quota Section (DRQ) ascertains such quotas, in part, by projecting requirements based upon a manufacturer's reported inventory, procurement, and disposition activity. Year-End Reporting and Quota System (YERS) is an online resource for manufacturers to securely submit their year-end sales and inventory reports.

1.2 Basic Navigation

All navigation in the online YERS application should be completed with the buttons found at the bottom of the pages. Generally, the buttons function as follows:

Next : continue to the next page in sequence.

Back : return to the previous page.

Reset : clear any fields, drop down menus, and radio buttons with enterable data.

Return : similar to the Back button. This usually appears when beginning a new form or sub-form and will return the user to a main menu.

Exit : exit the Quotas application.

Do not use the browser's navigation buttons unless specifically directed by this manual.

1.3 Login

User	Login
the registrant for which you will be managing us	user name and password, and the DEA Number of ser accounts. name and password, and the DEA Number of the
DEA Number:	
Username:	
Password:	
Change Password:	
Reset	Next

Figure 1: Login

Enter the following:

- **DEA Number**: the unique identifying number issued to each registrant upon enrolling with the DEA.
- **Username**: the user account name used to differentiate between one user account and another, provided by the corporate administrator.
- **Password**: the unique identifying set of characters comprised of alphanumerical and special characters used to access an account, initially provided by the corporate administrator.

To clear the fields, click the Reset button.

Click the Next button on this page to proceed. An error will be displayed if any of the entered information is incorrect.

On the Login Confirmation screen (not pictured), click the Next button to continue. The Return button will return users to the Login screen.

1.4 Changing the Password

To change the current password, check the **Change Password** checkbox on the Login screen before clicking the Next button.

Change User Password
 Password requirements: Must contain between four and ten characters. Must contain at least one uppercase character. Must contain at least one lowercase character. Must contain at least one digit.
DEA Number:
Username: IANRACE
Current Password:
New Password:
Confirm New Password:
Plese fill in the empty fields and click Next.
Back Reset Next

Figure 2: Change Password

New passwords must be between 4 – 10 characters in length and contain at least one of the following:

- One (1) uppercase letter
- One (1) lowercase letter
- One (1) number

Enter the current password into the field provided. The new password must be entered twice to ensure accuracy.

When the fields have been filled, click the Next button. YERS passwords will not expire.

To return to the previous screen without making any changes, click the Back button.

To clear any entered text from the Password fields, click the Reset button.

1.5 Selecting YERS or NRM

The YERS/NRM Selection Menu is only available to E1 manufacturers who have registered for one or more of the following drug codes: 9670, 9600, and 9040.

YERS / NRM Selection Menu	
 Select One Year-End Reports Narcotic Raw Materials Quarterly Reports 	
Make a selection and click Next to continue.	
Exit Next	

Figure 3: YERS/NRM Selection Menu

Click the Next button to advance to the either the YERS or NRM application.

If filing a year-end report, refer to section 2.0: Year-End Reports, on page 6.

If filing a narcotic raw materials report, refer to section 3.0: Narcotic Raw Materials, on page 36.

Click the **Exit** button to leave the YERS application.

2.0 Year-End Reports

2.1 Report Selection Menu

Users select the type of report to file from the **Report Selection Menu** (Figure 3, following page). Consult the list below for a description of each option. Note that not every user will see the Manufactured or Imported sections.

Registered Substances With Quotas and / or Outstanding Inventory

• Select this option to file a normal year-end report for every substance and chemical in which a quota was granted and/ or the previous calendar year's inventory was carried over.

Other registered substances

• Select this option to file a year-end report for substances or chemicals which became controlled in schedule 1 or 2 of the CSA and the registrant held inventory for the reporting year. Null reports may be filed with this option (see section 2.3 for further information).

View Null Reports

• Select this option to view a list of substances or chemicals in the manufacturer's registration in which no quota was granted and no inventory held. Substances and chemicals may be removed from the list.

Drugs Converted to Other Substances

• This function outputs a Portable Document Format (PDF) document that details which drugs the registrant has reported as having been converted to other substances.

Psychotropic Drugs

• Select this option to file a report for any Schedule III psychotropic substance which may have been manufactured or held in inventory at the end of the reporting year (see section 2.2.2 for further information).

	Report Selection Menu
Year-End Report	t for Procured Substances
Registered Su	ibstances With Quotas and / or Outstanding Inventory
Other register	ed substances
View Null Rep	orts
O Drugs Conver	ted to Other Substances
Year-End Report	t for Manufactured Substances
Registered Su	ibstances With Quotas and / or Outstanding Inventory
Other register	ed substances
View Null Rep	orts
O Drugs Conver	ted to Other Substances
Year-End Report	t for Imported Substances
Registered Su	ibstances With Quotas and / or Outstanding Inventory
O Other register	red substances
O View Null Rep	orts
O Drugs Conver	ted to Other Substances
Year-End Report	t for Psychotropic Substances
O Psychotropic I	
	Return

Figure 4: Report Selection Menu

2.2 Report Actions

2.2.1 Filing or Updating a Procurement, Import, or Manufacturer Report

2.2.1.1 Select a Substance or Chemical

After selecting a reporting option, YERS will load the Pending/Completed Reports screen. This begins a four (4) page cycle whereby inventory, acquisition, and disposition information is entered about a selected substance or chemical.

File	Drug (Code		Drug Name C	Quota Granted <i>(grams)</i>
0	737	0	DELTA-9-TE	TRAHYDROCANNABINOL	9,300.00
				Completed Reports	
	Click the			ports (listed in drug code order) that you have alrea to review or make changes to the report. Click the <i>L</i>	
the re					
		Print	Drug Code	Drug Name	Quota Granted (grams)
		Print	Drug Code	Drug Name CODEINE (FOR SALE)	Quota Granted (grams) 59,200.00
Update	Delete	-			59,200.00
Update	Delete	0	9050	CODEINE (FOR SALE)	59,200.00 270,000.00
Update	Delete	000	9050 9143	CODEINE (FOR SALE) OXYCODONE (FOR SALE)	59,200.00 270,000.00 992.00
Update	Delete	000	9050 9143 9273	CODEINE (FOR SALE) OXYCODONE (FOR SALE) DEXTROPROPOXYPHENE, BULK (NON-DOSAGE)RMS)	

Figure 5: Pending/Completed Reports

The **Pending/Completed Reports** page lists every substance or chemical for which a quota was granted during the reporting year. Reports that have not yet been filed will appear in the **Pending Reports** section, while those that have been completed will appear in the **Completed Reports** section.

Note that any values entered while updating a submitted year-end report will overwrite any previously saved values previously. Updated year-end reports are not added to or subtracted from existing reported values.

Both Report sections hold five (5) records at a time. Use the <u><< Back</u> and <u>Forward >></u> navigation links to see other available records.

The Back button will return users to the **Report Selection Menu**.

Select a record by clicking the radio button in the File or Update sections, respectively. When ready, click the Next button to proceed to a **Confirmation** screen.

Current Selection							
Reporting Year	Drug Code	Drug Name	Quota Granted (grams)				
2010	7370	DELTA-9-TETRAHYDROCANNABINOL	9,300.000				
		pressed as grams of anhydrous base or all					
	ine and phenyl	lue for this controlled substance or list propanolamine) reflects your establish pat include any granted replacement					

Figure 6: Confirmation to File a New Report

From this point forward, YERS will display the currently selected substance or chemical in a table near the top of the screen.

- **Reporting Year**: the year for which the substance is being reported.
- **Drug Code**: the code assigned to the substance or chemical upon its scheduling or listing into the CSA.
- **Drug Name**: the name of the substance or chemical as it appears in the CSA catalogue.
- **Quota Granted**: the value of the granted drug quota for the reporting year.

Click the Next button again to continue to the **Inventory** screen.

2.2.1.2 Inventory

The **Inventory** screen is used to report any inventory held by manufacturers at the end of the reporting year. The Bulk controlled substance field, In-Process Material, and Finished Dosage Forms field will be auto-populated with the value for any Quotas granted for the reporting year.

Grayed fields may not be edited. Click the Return button to go back to the **Pending/Completed Reports** screen, (Figure 4).

Complete the following fields (Figure 6, next page). Non-applicable fields should be left at zero (0).

- **Bulk controlled substance (API [Active Pharmaceutical Ingredient])**: the measure of bulk (non-packaged) substances or chemicals held in inventory.
- **In-process material (in all forms)**: the measure of substances or chemicals in process for conversion.
- **Finished dosage forms (bulk and/or packaged)**: the measure of substances or chemicals to have completed processing.
- Non-salable material: the following categories refer to inventory that cannot be sold.
 - Retains/stability samples
 - Product development material
 - o Pending destruction
 - Other (specify)

Note that any numeric value placed in the Other field must be accompanied by explanatory text entered in the *(specify)* field.

The total value of the entered fields may be viewed by clicking the **Sum** button.

When finished, click the Next button to continue to the **Acquisitions** screen.

		Inventory			
		Current Selection			
Reporting Year	Drug Code	Drug Name		Quota Granted (gr	ams)
2010	1225	PHENYLPROPANOLAMINE (FOR CONVERSION)		N/A
nventory (as of De		e expressed as grams of anhydrous base o Use the Tab key to navigate between fie		t as salt.	
Bulk controlled sub			.000	1,100.000	
In-process material	(in all forms)		.000	2,200.000	
Finished dosage fo	rms (in bulk an	id/or packaged)	.000	3,300.000	
Non-saleable mate	rial		·		
retains / stabil	ity samples		.000	.000	
product develo	pment material		.000	.000	
pending destru	iction		.000	.000	
other (specify)			.000	.000	
	material		.000	.000	
Total non-saleable			.000	6,600.000	Sum

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

Return Next

Figure 7: Inventory

2.2.1.3 Acquisitions

The **Acquisitions** screen is used to report the amount of the selected substance acquired by manufacturers during the course of the reporting year.

Click the Back button to return to the **Inventory** screen (Figure 6).

Note that any numeric value placed in the Other field must be accompanied by explanatory text entered in the *(specify)* field.

The total value of the entered fields may be viewed by clicking the **Sum** button.

When finished, click the Next button to continue to the **Dispositions** screen.

Continue to section 2.2.1.3.1 for procurement reports. Turn to section 2.2.1.3.2 on page 15 for manufacturing reports.

2.2.1.3.1 Procurement

Non-applicable fields should be left at zero (0). Grayed fields may not be edited. See Figure 7 on the following page.

- **Domestic procurements, acquisitions, transfers, etc.**: the quantity of the selected substance acquired domestically during the reporting year.
 - o Bulk API
 - Non bulk API material (in process, blends, beads, dosage forms, etc.)
- **Imports**: the quantity of the selected substance acquired through importation during the reporting year.
 - o Bulk API
 - Non bulk API material (in process, blends, beads, dosage forms, etc.)
- **Returns by customer for credit, salvage, rework, etc. (bulk API)**: the quantity of the selected substance acquired through returns by customer.
 - o Bulk API
 - Non bulk API material (in process, blends, beads, dosage forms, etc.)
- **Other acquisitions**: the following categories refer to inventory that cannot be sold.
 - Replacement quota
 - Other (specify)

		Current Selection			
Reporting Year	Drug Code	Drug Name	Quota Granted (gr	Quota Granted (grams)	
2010	1225	PHENYLPROPANOLAMINE (FOR CONVERSION)		N/A	
	All amounts ar	e expressed as grams of anhydrous base or alkalo Use the Tab key to navigate between fields.	oid, not as salt.		
cquisitions (durin	ng the year)		2010		
Domestic procuren	nents, acquisit	ions, transfers, etc			
bulk API			000		
non-bulk API n	naterial (in pro	cess, blends, beads, dosage forms, etc.)	.000		
Total domestic proc	curements		.000		
Imports					
bulk API	.000				
non-bulk API n	naterial (in pro	cess, blends, beads, dosage forms, etc.)	.000		
Total imports .0					
Returns by custom	er for credit, s	alvage, rework, etc.			
bulk API			.000		
non-bulk API n	naterial (in pro	cess, blends, beads, dosage forms, etc.)	.000		
Total returns			.000		
Other acquisitions					
Replacement of	quota		.000		
other (specify).			.000		
Total other acquisit	ions		.000		
otal acquisitions	(grams)		.000	Sum	
			p		

Figure 8: Procurement Acquisitions

2.2.1.3.2 Manufacturer

Non-applicable fields should be left at zero (0). Grayed fields may not be edited.

- **Qty manufactured, produced, synthesized, extracted**: the quantity of the substance acquired for the purposes of manufacture, production, synthesis, or extraction.
- **Qty realized from conversion of another controlled substance**: the quantity of the selected substance acquired for conversion into another controlled substance.
- **Returns by customer for credit, salvage, rework, etc. (bulk API)**: the quantity of the selected substance acquired through returns by customer.
- **Other acquisitions**: the following categories refer to inventory that cannot be sold.
 - o Replacement quota
 - Other (specify)

		Current Selection		
Reporting Year	Drug Code	Drug Name	Quota Granted (gram	s)
2010	9143	OXYCODONE (FOR SALE)	34,714	4,000.00
All a	Use	ssed as grams of anhydrous base or the Tab key to navigate between field		
Qty manufactured, syn	.000			
Qty realized from conve	.000			
Returns by customer for	.000			
Other acquisitions	n creuit, salvaye,	Tework, etc. (buik AFT)	.000	
Replacement quot	a		.000	
other (specify):			.000	
Total other acquisitions			.000	
lotal acquisitions (gra	ims)		.000	Sum

Figure 9: Manufacturer Acquisitions

2.2.1.4 Dispositions

The **Dispositions** screen is used to report the amount of the selected substance disposed of by manufacturers during the course of the reporting year.

Click the Back button to return to the Acquisitions screen (Figure 7).

Note that any numeric value placed in the Losses or Other fields must be accompanied by explanatory text entered in the *(specify)* field.

The total value of the entered fields may be viewed by clicking the **Sum** button.

Click the Next button. If a value was placed into the Put in process for conversion to bulk substances field, the **Converted Substances** screen will appear (see section 2.2.1.5). Otherwise, the **Summary** screen will appear (see section 0).

Continue to section 2.2.1.4.1 for procurement reports. Turn to section 2.2.1.4.2 on page 19 for manufacturing reports.

2.2.1.4.1 Procurement

Non-applicable fields should be left at zero (0). Grayed fields may not be edited. See Figure 9 on the following page.

- **Domestic Sales or Transfers to**: the quantity of the selected substance disposed of domestically during the reporting year.
 - Pharmacies, Doctors, Hospitals, Clinics
 - o Other manufacturers
 - o Distributors for commercial sale
 - Distributors for destruction
 - Researchers, analytical labs
 - Other federal, state, or county agencies
- **Put in process for conversion to bulk substances**: determines whether or not the selected substance will be converted into another controlled substance. Note that this option will be unavailable if reporting a Concentrate of Poppy Straw (CPS) alkaloid. See section 2.2.1.5 for further information.
- **Exports**: the quantity of the selected substance disposed of through exportation during the reporting year.
- **Returns from you to your suppliers (specify)**: the quantity of the selected substance disposed of through returns to suppliers.
- **Quantity used to make exempted or excluded products**: the quantity of the selected substance used to make products exempted or excluded from CSA.
- **Losses (specify)**: the quantity of the selected substance to become missing from inventory.
- Authorized destructions via DEA Form 41: the quantity of the selected substance destroyed and documented with submitted DEA Form 41.
- **Other dispositions (specify)**: the quantity of the selected substance disposed of via any form not listed on the Dispositions screen.

		Dispositions		
		Current Selection		
Reporting Year	Drug Code	Drug Name	Quota Granted (gr	ams)
2010	1225 PHENYL	PROPANOLAMINE (FOR CONVERSION)		N//
		ssed as grams of anhydrous base or alka the Tab key to navigate between fields.	loid, not as salt.	
spositions (durii	ng the year)		2010	
Domestic Sales or	Transfers to:			
Pharmacies, D	Doctors, Hospitals, Clir	nics	.000	
Other manufac	cturers		.000	
Distributors for	r commercial sale		.000	
Distributors for	r destruction		.000	
Researchers,	analytical labs		.000	
Other federal,	state or county agenci	es	.000	
Total domestic sale	es or transfers		.000	
Put in process for	conversion to bulk sub	stances. Yes 🔿 No 💿	.000	
Exports			.000	
Returns from you t	o your suppliers <i>(spec</i>	ify):	.000	
Quantity used to m	nake exempted or excl	uded products	.000	
Losses (specify):			.000	
Authorized destruc	tions via DEA Form 41		.000	
Other dispositions	(specify):		.000	
tal 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, click Yes, enter an amount in to textbox, and click Next.



Figure 10: Procurement Dispositions

2.2.1.4.2 Manufacturer

Non-applicable fields should be left at zero (0) (Figure 10, next page). Grayed fields may not be edited.

- **Domestic Sales or Transfers to**: the quantity of the selected substance disposed of domestically during the reporting year.
 - o Dosage form manufacturers
 - Distribution for destruction
 - Researchers, analytical labs
 - Finished dosage forms for commercial sale
- **Put in process for conversion to bulk substances**: determines whether or not the selected substance will be converted into another controlled substance. Note that this option will be unavailable if reporting a CPS alkaloid. See section 2.2.1.5 for further information.
- **Exports**: the quantity of the selected substance disposed of through exportation during the reporting year.
- **Qty used to make exempted or excluded products**: the quantity of the selected substance used to make products exempted or excluded from CSA.
- **Losses (specify)**: the quantity of the selected substance to become missing from inventory.
- Authorized destructions via DEA Form 41: the quantity of the selected substance destroyed and documented with submitted DEA Form 41.
- **Other dispositions (specify)**: the quantity of the selected substance disposed of via any form not listed on the Dispositions screen.

		Current Selection			
Reporting Year	Drug Code	Drug Name	Quota Granted (gran	ns)	
2010	9143	OXYCODONE (FOR SALE)	34,7	14,000.000	
All a		sed as grams of anhydrous base or a ne Tab key to navigate between field			
Dispositions <i>(during ti</i>	he year)		2010		
Domestic Sales or Tran	nsfers to:				
Dosage form manu	facturers		.000		
Distribution for des	.000				
Researchers, analy	.000				
Finished dosage fo	.000				
Total domestic sales or	Total domestic sales or transfers				
Put in process for conv	ersion to bulk subs	tances Yes 🔿 No 💿	.000		
Exports			.000		
Qty used to make exer	mpted or excluded	products	.000		
Losses (specify):			.000		
Authorized destructions	s via DEA Form 41		.000		
Other dispositions (spe	cify):		.000		
Total dispositions (gra	ms)		.000	Sum	

Back Next

Figure 11: Manufacturer Dispositions

2.2.1.5 Converted Substances

Manufacturers who enter a quantity in the Put in process for conversion to bulk substances field will see the Converted Substances screen (Figure 11, following page).

Non-Controlled Substance: select Non-Controlled Substance from the drop-down menu. Replace the phrase "Non-Controlled Substance" with the non-controlled substance produced by the conversion. Enter the quantities converted and produced in the available fields.

Note that text in the field must be removed before entering new information.

Controlled Substance: select any listed substance from the drop-down menu. Enter the quantities converted and produced in the available fields.

Note that there are only ten (10) substances into which CPS substances may be converted. Of these, only those substances registered to the current **registrant** will be listed.

Click the **Submit** button to add the conversion to the year-end report.

If necessary, enter another drug conversion. Otherwise, click the Next button to continue to the **Summary** screen (0).

Note that the value of the quantities converted may not total more than the quantity entered for the substance put into process for conversion. If a substance conversion (or conversions) exceeds the quantity allotted, one or more substances must be removed.

Remove converted substances by selecting their respective radio buttons and clicking the **Remove** radio button for that substance.

	Substance Put In Process For Conversion						
Drug Code	D	rug Name	Quan	uantity (grams)			
9050	CODE	INE (FOR SALE)	200.000				
	Bulk	Substances Sel	ection				
	Back buttton to return to		o one or more other bulk s and set the value for the				
ubstance you want to c alues for Qty Converted ubstance) then overwrit	onvert to is in the Drug N and Qty Produced. If the Non Controlled Substa	lame drop-down list, s substance is <i>not</i> in t nce with the name of y	elect the substance from he list, click the first entry your substance and fill in	the list and fill in the (Non Controlled the values for Qty			
ubstance you want to c alues for Qty Converted ubstance) then overwrit onverted and Qty Produ opear in the Summary b	onvert to is in the Drug N and Qty Produced. If the te Non Controlled Substa uced. When you are satis below. You may enter as ntity Put in Process for C	lame drop-down list, s e substance is <i>not</i> in the nce with the name of sfied with your entry, or many conversions as	elect the substance from he list, click the first entry your substance and fill in tlick Submit and the newly you like as long as the T re finished with conversion	the list and fill in the v (Non Controlled the values for Qty y created conversion w otal Qty Converted is r ns, click Next.			
ubstance you want to c alues for Qty Converted substance) then overwrit converted and Qty Produ ppear in the Summary b reater than original quar	envert <i>to</i> is in the Drug N and Qty Produced. If the te Non Controlled Substa uced. When you are satis below. You may enter as ntity Put in Process for C Drug Name	lame drop-down list, s e substance is <i>not</i> in the nce with the name of sfied with your entry, or many conversions as	elect the substance from he list, click the first entry your substance and fill in click Submit and the newly you like as long as the T	the list and fill in the (Non Controlled the values for Qty y created conversion w otal Qty Converted is r			
ubstance you want to c alues for Qty Converted ubstance) then overwrit onverted and Qty Produ ppear in the Summary b reater than original quar	envert <i>to</i> is in the Drug N and Qty Produced. If the te Non Controlled Substa uced. When you are satist below. You may enter as ntity Put in Process for C Drug Name	lame drop-down list, s e substance is <i>not</i> in the nce with the name of sfied with your entry, c many conversions as conversion. When you e fields above and cl Reset Submit	elect the substance from he list, click the first entry your substance and fill in click Submit and the newly you like as long as the T re finished with conversion Qty Converted	the list and fill in the v (Non Controlled the values for Qty y created conversion w otal Qty Converted is r ns, click Next.			
alues for Qty Converted Substance) then overwrit converted and Qty Produ ppear in the Summary b reater than original quar	envert <i>to</i> is in the Drug N and Qty Produced. If the te Non Controlled Substa uced. When you are satis below. You may enter as ntity Put in Process for C Drug Name nce - Fill in the	lame drop-down list, s e substance is <i>not</i> in the nce with the name of sfied with your entry, c many conversions as conversion. When your e fields above and cl Reset Submit Summary	elect the substance from he list, click the first entry your substance and fill in click Submit and the newly you like as long as the T re finished with conversion Qty Converted click Submit.	the list and fill in the v (Non Controlled the values for Qty y created conversion w otal Qty Converted is n ns, click Next. Qty Produced			
ubstance you want to c alues for Qty Converted ubstance) then overwrit onverted and Qty Produ ppear in the Summary b reater than original quar	envert <i>to</i> is in the Drug N and Qty Produced. If the te Non Controlled Substa uced. When you are satist below. You may enter as ntity Put in Process for C Drug Name	lame drop-down list, s e substance is <i>not</i> in the nce with the name of sfied with your entry, c many conversions as conversion. When your e fields above and cl Reset Submit Summary	elect the substance from he list, click the first entry your substance and fill in click Submit and the newly you like as long as the T re finished with conversion Qty Converted	the list and fill in the v (Non Controlled the values for Qty y created conversion w otal Qty Converted is n ns, click Next.			

Figure 12: Converted Substances

2.2.1.6 Summary

The inventory and acquisitions of the previous year must balance with the inventory and dispositions of the reporting year. Any difference between the two sums must be explained.

If necessary provide the reason for any differences between the **Total to be Accounted For** and **Total Accounted For** fields. A maximum of 1024 characters are permitted.

Include any comments in the **Remarks** field. A maximum of 1024 characters are permitted.

Click the Back button to load to the **Inventory** screen (Figure 6) to make further changes.

Click the **Return** button to return to the **Pending/Completed Reports** screen without filing the report. Note that any changes to the **Inventory**, **Acquisitions**, **Dispositions**, and **Converted Substances** screen will be lost.

Click the Submit button to file the year-end report. YERS will confirm that the report's filing.

Current Selection						
Reporting Year	ear Drug Code Drug Name		Quota Granted (grams)			
2011	9050 0	CODEINE (FOR SALE)	3,000.000			
All ar		as grams of anhydrous base o ab key to navigate between fie				
Total Ending Inventory	for 2010		.0			
Total Ending Inventory	1,900,240.8					
Total Acquisitions for 2	.00					
Total To Be Accounted (Total Ending Inventory	.0					
Total Dispositions for 2	.0					
Total Accounted For (Total Ending Inventory	1,900,240.8					
Difference (Total To Be Accounted						
Please provide an exp (maximum 1,024 charac						
(maximum 1,02 Fondrad		no remainingy	1			
			3			
Remarks:	toro :: 400 toborooto					
(maximum 1,024 charac	lers 1024characle	ers remaining)	1			
			۰ ۱			
To return to th	e beginning of this rep	port to permanent storage, clic ort in order to review or chang e Report Selection List, click R	e the entered data, click Back.			

Figure 13: Summary

Summary Confirmation					
Current Selection					
Reporting Year	Drug Code	Drug Name	Quota Granted (grams)		
2010	9143	OXYCODONE (FOR SALE)	270,000.00		
		e year-end report for the contro oved to the Completed Reports			
			Main		
	To retur	rn to the Report Selection Menu, click n to the Report Selection List, click <i>R</i> To exit this application, click <i>Exit</i> .			

Figure 14: Summary Confirmation

Click the Main button to return to the **Report Selection Menu**.

To load the **Pending/Completed Reports** screen, click the **Return** button.

Clicking the Exit button will load the DC website.

2.2.2 Filing or Updating a Psychotropic Report

2.2.2.1 Selecting a Psychotropic Substance

After selecting Psychotropic Drugs from the **Reporting Selection Menu**, YERS will load the Pending/Completed Reports screen (Figure 14, next page).

The **Pending/Completed Reports** page lists every psychotropic substance registered to the current user account. Reports that have not yet been filed will appear in the **Pending Reports** section, while those that have been completed will appear in the **Completed Reports** section.

The Back button will return users to the **Report Selection Menu**.

Select a record by clicking the radio button in the File or Update sections, respectively. When ready, click the Next button to proceed to a **Confirmation** screen.

ile	Drug Code	Drug Name				
0	1228	BENZPHETAMINE				
0	1230	CATHINE				
0	1485	PYROVALERONE	PYROVALERONE			
0	1530	PEMOLINE				
0	1575	FENPROPOREX				
0	1580	MEFENOREX				
0	1605	MAZINDOL	MAZINDOL			
0	1610	DIETHYLPROPION				
0	1615	PHENDIMETRAZINE	PHENDIMETRAZINE			
0	9709	PENTAZOCINE				
		Complet	ed Reports			
	Click the Update ra	pic drug reports (listed in a	drug code order) that you	have already filed for reporting Click the <i>Delete</i> radio button to		
Update	Dele	te Print	Drug Code	Drug Name		
0	0	0	2765	DIAZEPAM		
	To make To subn	I the list backward or forw: a a selection, click a radio nit your selection for proce n to the previous page, clic	button in one of the the li ssing, click the Next butt	sts. on below.		



2.2.2.2 Completing the Report

The **Psychotropic Report** screen (Figure 15, following page) is used to report any manufacturing, inventory, and dispositions conducted by manufacturers during the course of the reporting year. Users will also be expected to estimate future usage of dosage forms

Click the Return button to go back to the Pending/Completed Reports screen, (Figure 14).

Complete the following fields (Figure 15, next page). Non-applicable fields should be left at zero (0). Grayed fields may not be edited.

- **Inventory**: the amount of psychotropic substances in held in inventory during the reporting year. The left-most year column may not be edited.
- **Bulk Manufactured**: the quantity psychotropic substances that have been bulk manufactured.
- **Dispositions:** the following categories include all forms of disposition available to psychotropic substances.
 - o Quantity Sold as Finished Dosage Forms
 - o Quantity used to Manufacturer Non-Psychotropic Substances
 - o Quantity Used to Manufacturer Excluded, Excepted, or Exempted Substances
- **Estimates for Future Usage (Sale) of Finished Dosage Forms**: the estimated measure of psychotropic substances to have completed processing.
- **Remarks**: include any additional remarks appropriate to the report.

The total value of the entered disposition fields may be viewed by clicking the sum button.

Current	Selection				
Reporting Year	Drug Code		Drug Name		
2010	1230	CATHINE			
All amounts are expressed as grams	of anhydrous bas	e or alkaloid, not as	salt.		
		2009	2010		
Inventory (as of December 31)		.000	000		
Bulk Manufactured			.000		
Dispositions (during 2010)					
Quantity Sold as Finished Dosage Forms			.000		
Quantity Used to Manufacture Non-Psychotropic Substa	ances		.000		
Quantity Used to Manufacture Excluded, Excepted or Ex Substances	xempted		.000		
Total Dispositions			.000	Sum	
Estimates for Future Usage		2011	2012		
Expected Future Usage (Sale) of Finished Dosage Form	IS	.000	.000		
Remarks: To save this report to perm To abandon this report and return to			rn.		

Figure 16: Psychotropic Report

When finished, click the Submit button to display the Summary Confirmation screen (next page).

Current Selection				
Reporting Year	Drug Code	Drug Name		
2010	2145	BARBITAL		
You have successfully filed the year report selection has been moved to Selection List.				
To return to	o the Report Selection Menu, clic o the Report Selection List, click / exit this application, click Exit.			

Figure 17: Psychotropic Summary Confirmation

Click the Main button to return to the **Report Selection Menu**.

To load the **Pending/Completed Reports** screen, click the Return button.

Clicking the Exit button will load the DC website.

2.2.3 Printing a Completed Report

Reports may be printed from the **Pending/Completed Report** screen. Select the section in which a report was originally filed (i.e. *Drugs for which a quota was granted during the reporting year, Other registered substances,* etc.).

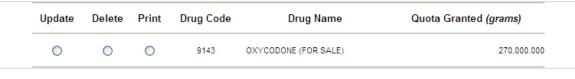


Figure 18: Print/Delete Report

Select the Print radio button and click Next.

Current Selection					
Reporting Year	Drug Code	Drug Name	Quota Granted (grams)		
2010	9143	OXYCODONE (FOR SALE)	270,000.000		
substance noted on your compute report to a file (us	above. You mus r. A separate Act sing the commar		dobe Acrobat Reader installed where you can print or save the u). After you have completed		

Figure 19: Print Confirmation

Clicking the Next button will create a PDF copy of the YERS report form. This may then be saved to a local hard drive, or sent to a local printer.

2.2.4 Deleting a Completed Report

Reports may be deleted from the **Pending/Completed Report** screen. Select the section in which a report was originally filed (i.e. *Drugs for which a quota was granted during the reporting year, other registered substances*, etc.).

Current Selection					
Reporting Year	Drug Code	Drug Name	Quota Granted (grams)		
2010	9143	OXYCODONE (FOR SALE)	270,000.00		
All an	nounts are express	ed as grams of anhydrous base o	r alkaloid, not as salt.		
		t to delete this Procurement rep I move to the Pending Reports			

Select the Delete radio button (Figure 17, previous page) and click Next.

Figure 20: Delete Confirmation

Clicking the Next button will delete the complete report. YERS will not delete report if the selected substance was used in the conversion of another substance. The substance will again be listed in the Pending section of the **Pending/Completed Reports** screen.

2.3 Other Actions

2.3.1 Null Reports

All controlled substances and listed chemicals registered to a manufacturer must be accounted for, regardless of whether or not it was used. Substances and chemicals for which no quota is granted and no inventory held for the reporting year is considered null. Null reports should be filed for such substances where the manufacturer previously had activity to indicate that the manufacturer conducted no activity for the reporting year. A null report does not need to be filed the second consecutive year after no further manufacturing activity or inventory has occurred for the substance.

2.3.1.1 Filing Null Reports

Select Other Registered Substances to view a list of substances registered to the manufacturer, but not granted quota. Substances in this list that have been held in inventory must be reported normally. Select the File radio button for the appropriate substance and click the Next button. See section 2.2 on page 9 for more information.

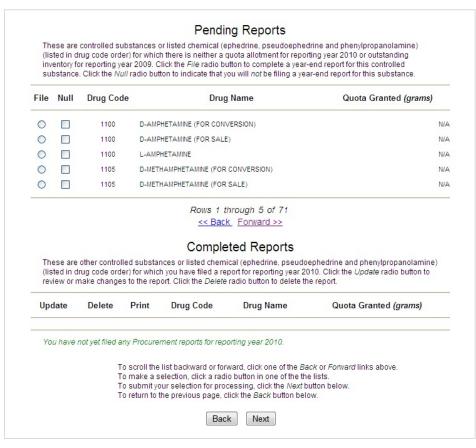


Figure 21: Other Registered Substances

To file a Null report, click any number of checkboxes in the Null column for substances that have not been granted quota, nor held in inventory for the reporting year. When finished, click the Next button. A confirmation screen will be displayed.

Current Selection					
Reporting Year	Drug Code	Drug Name	Quota Granted (grams)		
2010	1100	D-AMPHETAMINE (FOR SALE)			
All an	mounts are expres	ssed as grams of anhydrous base o	r alkaloid, not as salt.		
or listed chemica	al (ephedrine, pa	I not be filing a Procurement repo seudoephedrine and phenylpropa port entry will move to the Null Re	anolamine) for reporting year		

Figure 22: Null Confirmation

Click the Next button again to confirm the Null report. The **Summary Confirmation** screen will be displayed. The Back button will return users to the **Pending/Completed Reports** screen for other registered substances.

Current Selection					
Reporting Year	Drug Code	Drug Name	Quota Granted (grams)		
2010	1100	D-AMPHETAMINE (FOR SALE)	N/		
	above. The rep	that you will not be filing the year port selection has been moved to ion List.			
	To ret	urn to the Report Selection Menu, click Irn to the Report Selection List, click Re			

Figure 23: Null Summary Confirmation

Click the Main button to return to the **Report Selection Menu**.

To load the **Pending/Completed Reports** screen, click the **Return** button.

Clicking the Exit button will load the DC website.

2.3.1.2 Deleting Null Reports

Select View Null Reports from the **Report Selection Menu**.

Null Reports These are controlled substances or listed chemical (ephedrine, pseudoephedrine and phenylpropanolamine) (listed in drug code order) for which you have indicated that you will not be filing a year-end report. Click the <i>Remove</i> radio button to return this controlled substance to active status.					
Remove	Drug Code	Drug Name	Quota Granted (grams)		
0	1100	D,L-AMPHETAMINE	N/A		
0	1100	D-AMPHETAMINE (FOR SALE)	N/A		
	To make To subm	the list backward or forward, click one of th a selection, click a radio button in one of th it your selection for processing, click the <i>N</i> to the previous page, click the <i>Back</i> buttor Back Next	ne the lists. ext button below.		

Figure 24: View Null Reports

Select the radio button of the appropriate null report and click the Next button.

Current Selection						
Reporting Year	Drug Code	Drug Name	Quota Granted (grams)			
2010	1100	D,L-AMPHETAMINE				
All amo	unts are expressed a	as grams of anhydrous base	or alkaloid, not as salt.			
		remove this report entry fro vill move to the Registered	om the Null Reports selection Substances selection list.			

Figure 25: Null Delete Confirmation

Click the Next button again to delete the report.

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	Sum	mary Confirmation	n	
		Current Selection		
Reporting Year	Drug Code	Drug Name	Quota Granted (grams)	
2010	1100	D,L-AMPHETAMINE		N/
	oove. The report s		port for the controlled o the Pending Reports section	
of the Registered S	substances Select	IOH LISU		
	To return to To return to) the Report Selection Menu, clic the Report Selection List, click / exit this application, click <i>Exit</i> .		

Figure 26: Null Report Removed

Click the Main button to return to the **Report Selection Menu**.

To load the **Pending/Completed Reports** screen, click the **Return** button.

Clicking the Exit button will load the DC website.

2.3.2 Viewing Converted Substance Reports

Select Drugs Converted to Other Substances to view a PDF copy of the converted substances report. This may then be saved to hard drive or printed to a local printer.

3.0 Narcotic Raw Materials

3.1 NRM Main Selection Menu

NRM Main Selection Menu
Select One File a New Report for the Current Quarter View, Print, Update or Delete a Report for the Current Quarter Amend a Report from a Previous Quarter
Make a selection and click Next to continue. Click Return to return to the NRM-YERS Choice Selection Menu.
Return

Figure 27: NRM Main Selection Menu

Users select the type of report to file from the **NRM Main Selection Menu** (Figure 26, above). Consult the list below for a description of each option.

File a New Report for the Current Quarter

• Select this option to file a new NRM report for the current quarter (see section 3.2, page 38).

View, Print, Update, or Delete a Report for the Current Quarter

• Select this option to view, update, print, or delete reports for the current quarter (see section 0, page 43).

Amend a Report from the Previous Quarter

• Select this option to amend a report from the previous quarter. Not only reports from the current or previous quarter may be amended (see section 3.4, page 43).

3.2 File a New Report for the Current Quarter

3.2.1 NRM Quarter Selection Menu

After selecting File a New Report for the Current Quarter from the **Main Selection Menu**, NRM will load the Quarter Selection Menu.

NRM Quarter Selection Menu for Reporting Year 2014
 Second Quarter (Apr 1 through Jun 30) Third Quarter (Jul 1 through Sep 30)
Notice: Today is Jul 7, 2014. Per 21 CFR 1304.31 you have a 15 day grace period after the end of a quarter in which to file a report. If todays date falls within the grace period of the previous quarter, you may select it instead of the current quarter. To determine the quarter for which you will file, use the date you received the raw materials.
Make a selection and click Next to continue. Click Back to return to the NRM Main Selection Menu.
Back

Figure 28: Quarter Selection Menu

File a report for either the current quarter or the previous quarter. Note that previous quarter reports may only be filed if the current date is within the 15-day allowable grace period.

The Back button will return users to the Main Selection Menu.

Select a record by clicking the radio button in the File or Update sections, respectively. When ready, click the Next button to proceed to a **Substance Selection Menu**.

3.2.2 NRM Substance Selection Menu

	NRM Substance Selection Menu Quarterly Report for 2014, Third Quarter
5	Select One:
	Concentrate of Poppy Straw (High Morphine)
	Concentrate of Poppy Straw (High Oripavine)
	Concentrate of Poppy Straw (High Thebaine)
	Concentrate of Poppy Straw (High Codeine)
	Opium, Raw
	Coca Leaves
Ма	ke a selection and click Next to continue. Click Back to return to the NRM Quarter Selection Menu.
	Back

Figure 29: Substance Selection Menu

Select a listed substance. Any substance unavailable for selection will be marked in gray.

The Back button will return users to the **Quarter Selection Menu**.

Select a record by clicking the radio button in the File or Update sections, respectively. When ready, click the Next button to proceed to a **File a New Report** screen.

3.2.3 Filing the New Report

Enter values into every required field. The following fields are required: **Country of Origin**, **Permit No.**, **Date Received**, **Gross Weight (g)**, and **dominant alkaloid**.

- The dominant alkaloid varies with the selected drug code. The table in appendix A.0 defines the dominate alkaloid per selected drug code.
- The value for the dominant alkaloid must be greater than the other alkaloids.
- The gross weight and alkaloid values must be between 0 and 999,999,999.999.
- The sum of the alkaloids must not be greater than the gross weight. However, the gross weight does not have to equal the total of the alkaloids.

Reporti	ng Year / Quarter	Drug Code		Drug Name		Quota Granted (grams)
	2014/Q3	9670 - A	Concentrate of	Poppy Straw (High I	Morphine)	.000	
* Country of Origin	* Permit No.		ate of Poppy St (Jul 1 through * Gross Weight (g)		ATA (g)	ACA (g)	AOA (g
	 ▼ 				(9)		
Th	e * symbol denotes a	required field. All v	veights are express	ed in grams in the	range 0 to 999,99	9,999.999 (inclusive)	

Figure 30: File a New Report

Click Return to go back to the Main Selection Menu.

Press the Reset button to clears the fields.

Click Preview to temporarily save the report (see Figure 30: Report Preview, page 41).

			F	Preview			
Remo	ove	Country of Origin France		i it No. 946	Date Received Jul 9, 2014		o <mark>ss Weight</mark> 100.000
AMA (g) 2.000	AMA (%) 2.00	ATA (g) 10.000	ATA (%) 10.00	ACA (g) 2.000	ACA (%) 2.00	AOA (g) 5.000	AOA (%) 5.00
from the Pre	eview list, click	ny number of quarterly the red Remove button. to discard all reports an	When finished, o	lick the Submit b	utton to submit and sa		
				Submit			

Figure 31: Report Preview

Multiple reports for the selected drug code may be previewed simultaneously without leaving the File a New Report screen. Data is not required to change before previewing another report.

To remove a report from the Preview list, click the report's **Remove** radio button

Click the Submit button to save the reports. *Note that all previewed reports, not just the latest, will be saved to the database.*

3.2.4 Confirmation

Once the report has been saved to the database, the following options are available:

- Click the **Pint** button to generate a PDF copy of the report. This may then be saved to hard drive or printed. *Note that if the PDF opens in the same window as the application, it is possible to return to the application using the browser's* **Back** *button.*
- Click the Return button to go back to the Main Selection Menu.
- Click the Exit button to leave the application

		Current Selection		
Reporting Year / Quarter	Drug Code	Drug Name		Quota Granted (grams)
2014/Q3	9670 - A	Concentrate of Poppy Straw (Hig	h Morphine)	.000
		Confirmation		
You have	e successfully sub	mitted the quarterly report(s) for	the Narcotic Raw M	laterial noted below.
Reference No.	Count	try of Origin [ate Received	Gross Weight
-		ustralia	Jul 7, 2014	6.000
		amplied to DEA at ODE swate Or	sdoj.gov. Please ir	Include your DEA registration number
he reference number and	your company nar			ing this transaction. Also include you
he reference number and	your company nar		spondence regard	ng this transaction. Also include you
	your company nar	ne in the subject line for all corre	spondence regard	ng this transaction. Also include you

Figure 32: File New Report Confirmation

3.3 View, Print, Update, or Delete a Report for the Current Quarter

Selecting the option to view reports will load a screen like the one below.

		·	<	of 7 (total) Quart	2		
	Click	the directional (arr Sort order is Dat					
Select	Reference No.	Drug Name	Country of C	Drigin Perm	it No.	Date Received	Gross Weight
	1987	CPS (HIGH ORIPAVINE)	India			Jul 24, 2014	77.000
AMA (g)	AMA (%)	ATA (g)	ATA (%)	ACA (g)	ACA (%)	AOA (g)	AOA (%)
4.000	5.19	4.000	5.19	4.000	5.19	8.000	10.39
	Notice the	directional (arrow) buttons above	e to advance to th	ne the next or	r previous data pao	Ie.

Figure 33: View Reports

The following options are available:

- Click Return to go back to the Main Selection Menu.
- Click the **Print** button to generate a PDF copy of the report. This may then be saved to hard drive or printed. *Note that if the PDF opens in the same window as the application, it is possible to return to the application using the browser's* **Back** *button.*
- Click the Update button to make changes to the submitted report. See section 3.2, File a New Report for the Current Quarter for further information.
- Click the Delete button to delete the selected record. *Note that clicking this button will instantly delete the record. The application will not ask for confirmation before deleting the record.*

3.4 Amend a Report from a Previous Quarter

Only the current quarter and the one immediately prior may be amended. See section 3.2, File a New Report for the Current Quarter for further information.

Appendices

A.0 Drug Code Dominant Alkaloids

The following table lists the selectable drug codes and their associated dominant alkaloid.

Drug Code	Dominant Alkaloid
9040	No dominant alkaloid
9600	Anhydrous Morphine Alkaloid (AMA)
9670-A	Anhydrous Morphine Alkaloid (AMA)
9670-B	Anhdrous Oripavine Alkaloid (AOA)
9670-C	Anhdrous Thebaine Alkaloid (ATA)
9670-D	Anhdrous Codeine Alkaloid (ACA)

B.0 Glossary

Term	Definitions
Acquisition	Acquiring any controlled substance by means that include domestic procurements, acquisitions, and transfers; imports, returns by customers for salvage, rework, etc.; and those acquired from manufacture or conversion during the course of a calendar year.
Authorized Destruction	Any substance or chemical that has been destroyed with express permission from the DEA.
Bulk Substance	Any controlled substance manufactured in bulk quantities.
Controlled Substance	A drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of the Controlled Substances Act. The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986. It is a substance determined potentially harmful for human consumption and therefore limited by the DEA. Controlled substances may or may not have beneficial properties.
Conversion	The process by which a controlled substance or listed chemical undergoes processing in such a manner as to manufacture a different substance. The new substance may or may not be itself subject to control by the DEA.
DEA Number	A valid registration number assigned to the registrant by CSA.
Disposition	Removing from inventory any controlled substance by means that include domestic sales and transfers, conversion, exportation, returns, the manufacture of exempted or excluded products, losses, and authorized destruction during the course of a calendar year.
Domestic	Any substance or chemical manufactured or produced within the United States.
Drug Code	The number assigned to a substance controlled by CSA. Drug codes are cataloged into drug schedules.
Excluded Product	A substance or chemical excluded from the application of CSA
Exempted Product	A substance or chemical exempt from the application of CSA based on a finding that the mixture is formulated in such a way that it cannot be easily used in the illicit production of a controlled substance and that the listed chemical or chemicals contained in the mixture cannot be readily recovered
Export	Taking out or removing any article into either the jurisdiction of the United States or the custom territory of the United States.
Finished Dosage Forms	Substances or chemicals classified as having completed processing.
Import	The bringing in or introducing any article into either the jurisdiction of the United

Term	Definitions
	States or the custom territory of the United States.
In-Process Material	Substances or chemicals classified as in process for conversion.
Inventory	All factory and branch stocks of a basic class of controlled substance manufactured or otherwise in the possession of the registrant , whether as bulk material commercial containers, in-process materials, or contained in pharmaceutical preparations.
Listed Chemical	Any List I or II chemical, in addition to legitimate uses, is used in manufacturing controlled substances in violation of the Controlled Substances Act.
Lost	A substance or chemical cannot be accounted for in inventory and no record exists of its proper disposition.
Manufacture	The producing, preparation, propagation, compounding, or processing of a drug or other substance or the packaging or repackaging such substance, or the labeling or relabeling of the commercial container of such substance.
Non-Saleable Material	Substances or chemicals classified as not eligible for sale.
Null Report	A year-end report that states that no quota was granted for selected substances and chemicals and no inventory was held for those substances during the reporting year.
Outstanding Inventory	Inventory held by a manufacturer that is greater than that allocated in the quota for the reporting calendar year.
Procurement	The act of obtaining a controlled substance for the purpose of producing or manufacturing another controlled substance or a finished dosage form.
Psychotropic Substance	Any substance included in the laws executing the international treaty entitled Convention on Psychotropic Substances and signed in Vienna, Austria, on February 21, 1971.
Quota	A predetermined limit on the total amount of controlled substances and listed chemicals that individual manufacturers may procure or manufacture during a single calendar year.
Registrant	Any person with a registered account in CSA.
Reporting Year	The year for which a year-end report is filed.
Return	A substance or chemical that is returned to a manufacturer's suppliers.
Transfer	To deliver control of a substance or chemical from one CSA registrant to another.
Year-End Report	A detailed report filed by manufacturers at the conclusion of a calendar year detailing the amount of inventory, acquisitions, and dispositions made during the course of the same calendar year. This number is compared the assigned quota allotment and discrepancies reconciled.

C.0 Acronyms

Acronym	Definition
API	Active Pharmaceutical Ingredient
CPS	Concentrate of Poppy Straw
CSA	Controlled Substances Act
DEA	Drug Enforcement Administration
DC	Diversion Control Division
DRQ	UN Reporting and Quota Section
PDF	Portable Document Format
UN	United Nations
US	United States
YERS	Year-End Reporting and Quota System