



# **Supply Chain Conference**

**Orlando, Florida**



**April 1 – April 3, 2025**





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I have no financial relationship to disclose.







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# Online Quota System

Greg Kavanagh  
United Nations Reporting and Quota Section  
Diversion Control Division





- Quota Applications Must be Submitted Online
- Benefits
  - Provides secure web-based database system
  - Verifies registration as active and current
  - Preloads your available drug codes, historical data
  - Performs calculations
  - Provides confirmation of agency receipt and status
  - Expedites process





# Code of Federal Regulations Requirements for Submitting Quota Requests



- Procurement applications due by April 1
- Import applications due by April 1
- Manufacturing applications due by May 1
- Adjustments to any quota can be requested throughout the year
  - Avoiding duplicate entries is helpful
  - Can request withdrawal of erroneous entries via email
  - New requests for the same substance automatically supersede older requests
- Quantities should be expressed as:
  - Anhydrous acid, base or alkaloid
  - GRAMS, rounded to the nearest WHOLE gram





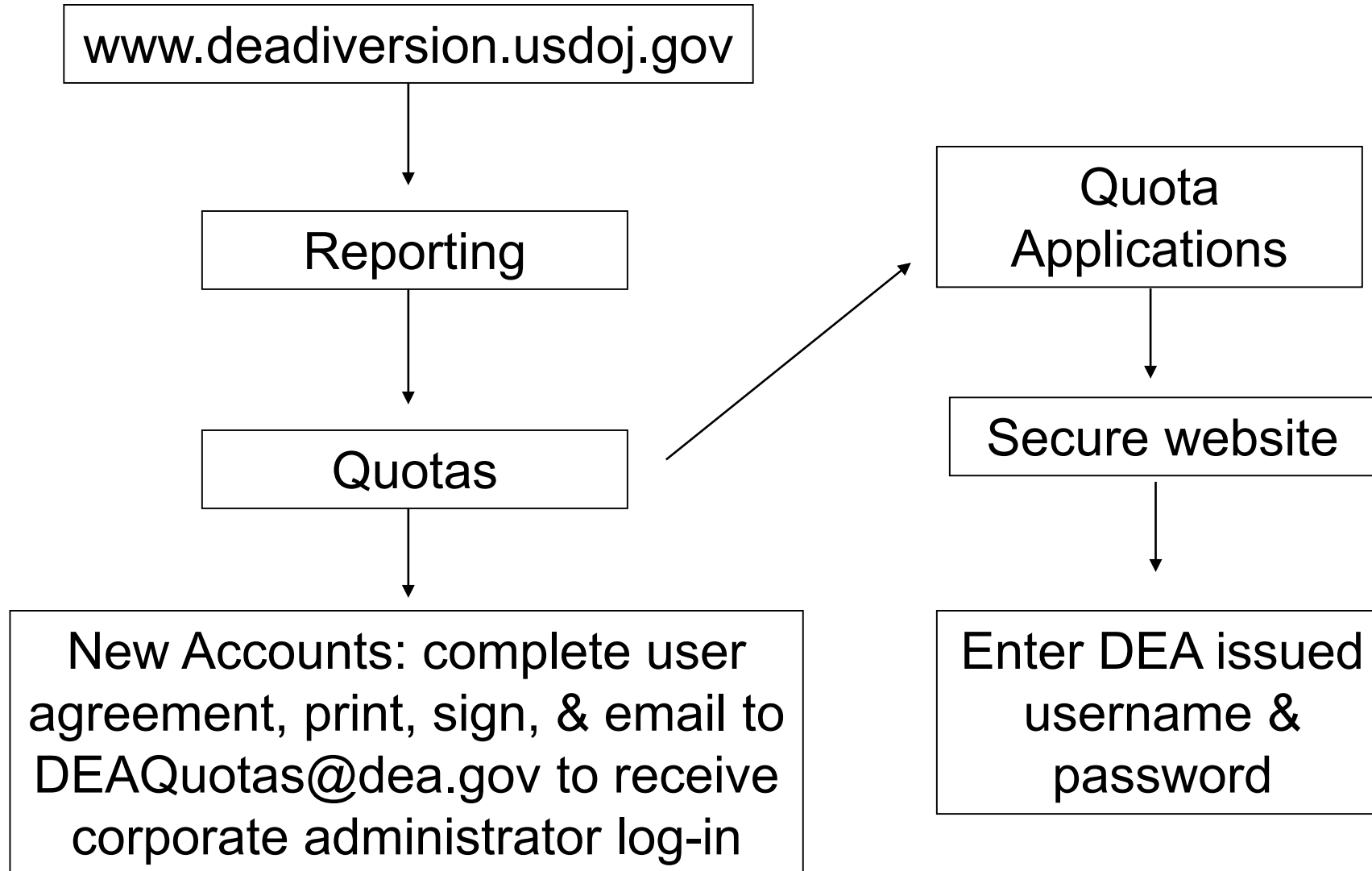


# Additional questions have been added to the application

1. Will alleviate the additional back and forth between DEA and registrants which had been delaying the review process
2. Will allow DEA to better understand the time required to bring products to market
3. Better predict when the results of the quota adjudications will be available to patients in need
4. Ultimately help to prevent and alleviate shortages














U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION

## OFFICE OF DIVERSION CONTROL

Application for Quota Allotment

### User Login

- If you are a corporate user, enter your user name, password and DEA Number.
- If you are a corporate administrator, enter your user name and password, and the DEA Number of the registrant for which you will be managing user accounts.
- If you are a DEA administrator, enter your user name and password, and the DEA Number of the registrant for which you will be managing user accounts.

DEA Number:

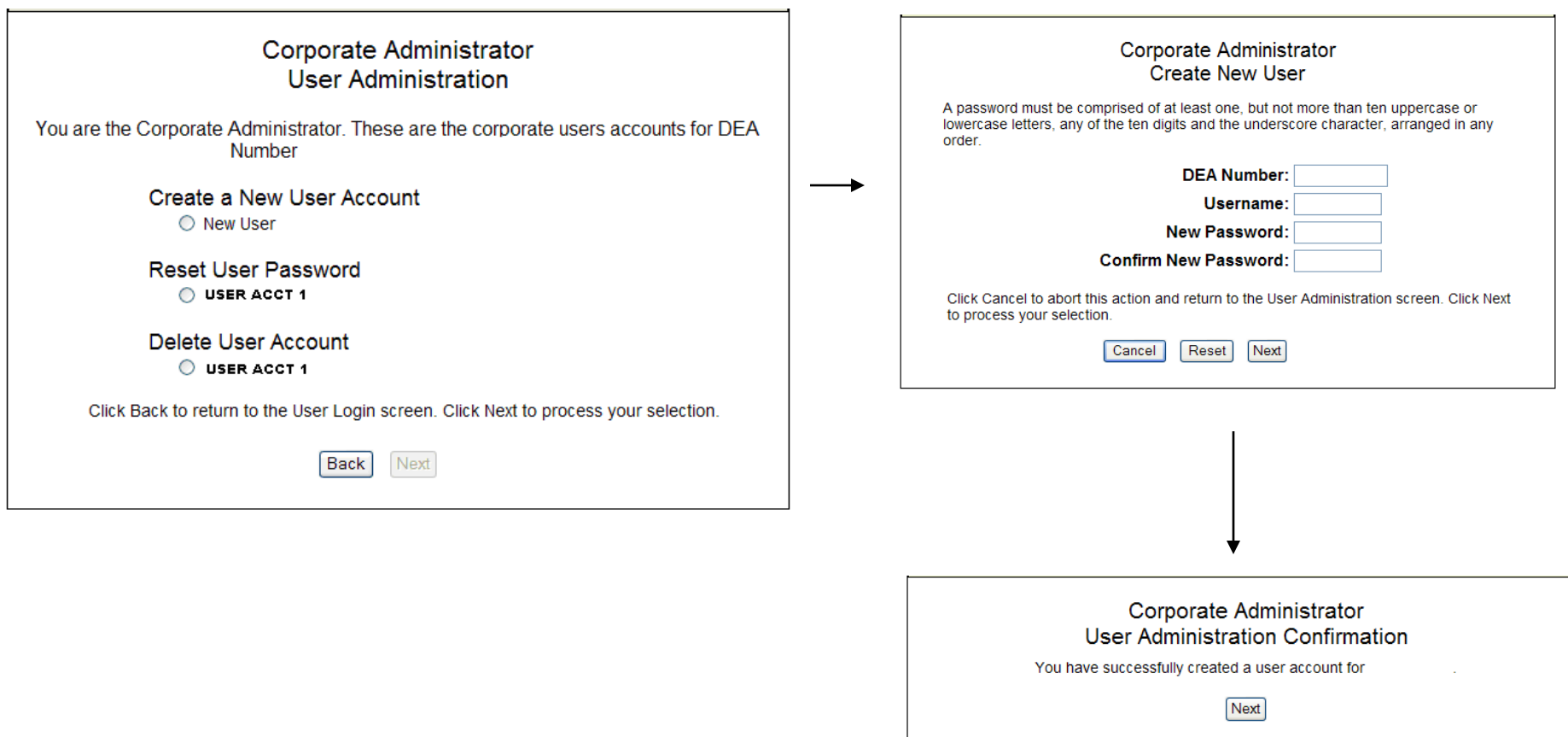
Username:

Password:

Change Password: ☐




# Create New Corporate User Account









U.S. Department of Justice Drug Enforcement Administration  
**Office of Diversion Control**

Application for Quota Allotment

### User Login

- If you are a corporate user, enter your user name, password and DEA Number.
- If you are a corporate administrator, enter your user name and password, and the DEA Number of the registrant for which you will be managing user accounts.
- If you are a DEA administrator, enter your user name and password, and the DEA Number of the registrant for which you will be managing user accounts.

DEA Number:

Username:


Password:

Change Password: ☐

To change your password, check the Change Password checkbox.  
To reset the form's text values to their original state, click Reset.  
To submit the form, click Next.



# Corporate User Login Confirmation



U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION

## OFFICE OF DIVERSION CONTROL

### Application for Quota Allotment

### Login Confirmation


- You are logged in as [REDACTED]
- As a Corporate User of the Quota Allotments system, you are authorized to submit requests for Quota Allotments for DEA Number [REDACTED] (DEA MANUFACTURER TEST ACCOUNT).
- If this information is not correct, please contact your administrator immediately.

[Return](#) [Next](#)

Click Return to return to the User Login screen. Click Next to advance to the next screen.







U.S. DEPARTMENT OF JUSTICE

★

DRUG ENFORCEMENT ADMINISTRATION

**DIVERSION CONTROL DIVISION**

Application for Quota Allotment

**Main Selection Menu**

**Quota Type**

- ☒ Procurement
- ☐ Manufacturer
- ☐ Import

Note: The list of controlled substances will only display drugs that are currently listed under your registration. If you do not see the drug you are seeking, please contact your local field office to have the drug added to your registration.

**Controlled Substance**

--- Listed in Alphabetical Order (Select One) --- ▼

**Quota Year**

- ☒ Current Year (2017)
- ☐ Next Year (2018)

To file a new request for quota allotment or revise an existing one, select Quota Type, Controlled Substance and Reporting Year, then click Next.

To see the status of any requests for quota allotment that you have previously submitted to DEA, click Status.

Exit

Status

Next





Must request specific isomers for:

- Amphetamine
  - d-amphetamine
  - l-amphetamine
  - d,l-amphetamine
- Methamphetamine
  - d-methamphetamine
  - l-methamphetamine
  - d,l-methamphetamine
- Tetrahydrocannabinols
  - Delta-9-THC
  - All Other Tetrahydrocannabinols
- **As of 2022, Methylphenidate and Dexmethylphenidate must be applied for separately**







### “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





## Examples of “For Sale” vs. “For Conversion”



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


- **Methylphenidate**
- Morphine
- Noroxymorphone
- Oxycodone
- Oxymorphone





# Procurement Quota Application





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**DIVERSION CONTROL DIVISION**

Application for Quota Allotment

Year-End Estimates  
for Reporting Year 2017

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2017	9193	HYDROCODONE (FOR SALE)		.000

DEA Form 250 -- Box 12  
Enter your estimated year-end report projections in the fields provided.  
Use the TAB and SHIFT-TAB keys to tab forward and backward among the fields.  
*All amounts are expressed as grams of anhydrous base or alkaloid, not as salt.*

Reporting Year	2015 (actual)	2016 (actual)	2017 (estimate)
<b>Inventory (as of Dec 31)</b>			
Bulk controlled substance (API)	0.000	0.000	0.000
In-process material (in all forms)	0.000	0.000	0.000
Finished dosage forms (bulk and/or packaged)	0.000	0.000	0.000
<b>Total</b>	0.000	0.000	0.000
<b>Dispositions</b>			
Domestic	0.000	0.000	0.000
Exports	0.000	0.000	0.000
<b>Total</b>	0.000	0.000	0.000
<b>Acquisitions</b>			
Domestic	0.000	0.000	0.000
Imports	0.000	0.000	0.000
<b>Total</b>	0.000	0.000	0.000

Click Next to advance to the next page.

ResetReturnNext






- **Commercial Manufacturing**
  - Conversion to other substances
  - Dosage form
- **Product Development**
  - All stages leading to FDA approval
  - Laboratory scale
  - Scale up
  - Exhibit/Submission/Registration
  - Validation
  - Stability
- **Packaging**
  - Packaging/Repackaging
  - Labeling/Relabeling
- **Replacement**
  - Case-by-case basis for commercial manufacturing
- **Transfer**
  - Bulk API
  - In-process material
  - Finished dosage units





# Quota Allotment Categories





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**DIVERSION CONTROL DIVISION**

Application for Quota Allotment

Quota Request  
for Reporting Year 2016

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2016	9801	FENTANYL	1,500.000	.000

Quota History  
(DEA Form 250 -- Box 11)

Enter the total value for your quota allotment request in the Total Requested for field.  
All amounts are expressed as grams of anhydrous base or alkaloid, not as salt.

--- History (Approved) ---			--- Total Requested for ---
2013	2014	2015	2016
0.000	0.000	0.000	1,500.000

Quota Allotment Request by Category

Sub-divide your total quota request by category.  
You must provide a value for at least one category, and the sum of the categories must equal the value of Total Requested for.  
Use the TAB and SHIFT-TAB keys to tab forward and backward among the fields.

Commercial Manufacturing-Domestic :	1,000.000	?
Commercial Manufacturing-Export :	100.000	?
Product Development :	100.000	?
Packaging/Labeling :	100.000	?
Replacement :	100.000	?
Transfer :	100.000	?
Total :	1,500.000	

☐ Check this box if the procured substance for this quota application will ONLY be used to produce exempt standards, reference standards, or diagnostic kits.


Click Next to advance to the next page.

Reset Back Next



# Quota Allotment Categories





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**DIVERSION CONTROL DIVISION**

Application for Quota Allotment

Report Selection Menu

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2016	9801	FENTANYL	1,500.000	.000

Sub-Reports Selection

In order to complete your application for quota allotment, you will need to provide additional information using the sub-reports below. To fill out a sub-report, click the Report Link to advance to the corresponding report form. If the color of the sub-report link is gray, it means there are sub-reports already on file. You may review and/or update these by clicking the link. You will not be able to advance to the next page until all required sub-reports have been completed.

Required / Optional	Status	Current Request	Report Link
Optional	Incomplete		Commercial Manufacturing <a href="#">Converted Substances</a> (DEA Form 250 -- Box 13)
Optional	Incomplete	1,100.000	Commercial Manufacturing <a href="#">Dosage Forms</a> (DEA Form 250 -- Box 14)
Required	Incomplete	100.000	<a href="#">Product Development</a> (DEA Form 250 -- Box 14)
Required	Incomplete	100.000	<a href="#">Packaging/Labeling</a> (DEA Form 250 -- Box 14)
Required	Incomplete	100.000	<a href="#">Replacement</a>
Required	Incomplete	100.000	<a href="#">Transfer</a>

If you have completed all required sub-reports, click Next to continue.


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# Commercial – Conversions





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**DIVERSION CONTROL DIVISION**

Application for Quota Allotment

Converted Substances

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2016	9143	OXYCODONE (FOR CONVERSION)	100.000	.000

Basic Class To Be Manufactured  
(DEA Form 250 -- Box 13)

To convert OXYCODONE (FOR CONVERSION) to another substance, select the substance from the list. If the target substance is not on the list, either contact DEA to have the substance added to your registration, or select "Users Choice" (the last entry).

--- Listed in Alphabetical Order (Select One) ---

7470 1-[1-(2-THIENYL)CYCLOHEXYL]PIPERIDINE

9273 DEXTROPROPOXYPHENE, BULK (NON-DOSAGE)FORMS

7379 NABILONE

9600 OPIUM, RAW

9143 OXYCODONE (FOR SALE)

Drug Name	Drug Code	2014 (actual)	2015 (actual)	2016 (estimated)	% Yield (estimated)

Fill in the fields above and click Submit.

Reset Submit

Summary


Remove	Drug Name	Drug Code	2014 (actual)	2015 (actual)	2016 (estimated)	% Yield (estimated)
Currently there are no Converted Substances.						

Next



# Commercial - Dosage Forms





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**DIVERSION CONTROL DIVISION**

Application for Quota Allotment

Commercial Manufacturing

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2016	9143	OXYCODONE (FOR SALE)	1,500.000	.000

Dosage Form Data  
(DEA Form 250 -- Box 14)  
Quota Requested: 1,100.000

If you intend to manufacture dosage forms from OXYCODONE (FOR SALE), fill out the fields below and click Submit. You may create as many individual dosage forms as necessary.

\* Name

Oxycodone HCL Tabs

\* Authority to Market ?

ANDA Number

\* Used 2014

Domestic: 100.000  
Export: 0.000

\* Used 2015

100.000  
0.000

\* Estimate 2016

500.000  
500.000

\* Strength

5 mg

\* FDA Shortage ?

☐

\* Days To Start Prod. ?

14

\* Days for Production ?

10

\* Days to Distribute ?

5

Remarks (maximum 1,000 characters :: characters remaining)

The \* symbol denotes a required field. Number fields must be a valid number between 0 and 999,999,999.999 inclusive.

Revert Submit





## Product Development

### Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement ( <input type="text"/> )	2016	<input type="text"/>	HYDROCODONE (FOR SALE)	3,067,338.000	1,878,465.000

### Dosage Form Data (DEA Form 250 -- Box 14) Quota Requested: .000

If you intend to manufacture HYDROCODONE (FOR SALE) into dosage forms, fill out the fields below and click Submit. You may create as many individual dosage forms as necessary.

* Name	* Strength ?	* Units/Batch	* # Batches	* Purpose ?	* Qty ?	* Completion Time
Sample	10	2	6	**Original: <input type="text"/> Domestic: <input type="text"/> Export: 1	** <input type="text"/> 1	1/29/2025

The \* symbol denotes a required field.

Units/Batch and # Batches must be a whole number (integer) between 0 and 9,999,999.

Qty must be a decimal number between 0 and 999,999,999.999.

Reset

Submit

The areas marked with a red asterisk (\*) must be filled out before the form can be submitted.. Once completed, the form will populate under **Summary** at the bottom of the page.

Edit	Sample	10	2	6	/ 1	/ 1.000	1/29/2025
Remove							

To remove an entry, click the Remove radio button.  
Click Next to return to the Report Selection Menu.





## Packaging / Labeling

### Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2016	9193		100,000.000	100,000.000

### Package/Label Form Data (DEA Form 250 -- Box 14) Quota Requested: .000

If you intend to segment HYDROCODONE (FOR SALE) into packages, fill out the fields below and click Submit. You may create as many individual package forms as necessary.

* Name	* Strength ?	* Units / Pkg	# Pkgs	* Purpose ?	* Qty ?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Domestic: <input type="text"/> Export: <input type="text"/>	<input type="text"/>
* Authority to Market ?	* <a href="#">FDA Shortage</a> ?	* Days To Start Prod. ?	* Days for Production ?	* Days to Distribute ?	
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	

Remarks (maximum 1,000  
characters :: characters  
remaining)

The \* symbol denotes a required field.

Units / Pkg must be a whole number (integer) between 0 and 9,999,999.  
Qty must be a decimal number between 0 and 999,999,999.999.


Clear

Submit



# Packaging and Labeling Continued





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**DIVERSION CONTROL DIVISION**


Application for Quota Allotment

**Packaging / Labeling**  
**Current Selection**

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2016	9143	OXYCODONE (FOR SALE)	1,500.000	.000

**Package/Label Form Data**  
(DEA Form 250 -- Box 14)  
Quota Requested: 100.000

List the DEA-registered manufacturer(s), importer(s) and distributor(s) who applicant will procure the controlled substance from, and how many days will it take to receive API once applicant receives DEAs quota response.

* DEA Number	DEA Number	Days Until API Receipt	Action
<input type="text"/>		7	<input type="button" value="Edit"/>
<input type="button" value="Clear"/> <input type="button" value="Submit Api Source"/>			<input type="button" value="Remove"/>

Provide year-to-date (YTD) domestic sales (in grams, expressed in terms of anhydrous base) and export sales from your manufacturing facility that will utilize the packaging/repackaging and labeling/relabeling quota.  
Provide manufacturing losses on year-to-date sales/production (in grams, expressed in terms of base)


* Domestic Sales	* Exports	* Manufacturing Losses
<input type="text" value="10.000"/>	<input type="text" value="0.000"/>	<input type="text" value="0.000"/>

The \* symbol denotes a required field. Number fields must be a valid number between 0 and 999,999,999.999 inclusive.



# Commercial Manufacturing (Secondary manufacturing)





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**DIVERSION CONTROL DIVISION**

Application for Quota Allotment

**Commercial Manufacturing**

**Current Selection**

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2016	9143	OXYCODONE (FOR SALE)	1,500.000	.000

**Dosage Form Data**  
(DEA Form 250 -- Box 14)  
Quota Requested: 1,100.000

List any other DEA-registered manufacturers who perform manufacturing activities for the products listed below (e.g. granulation, milling, packaging, etc)

**Summary**


Name	Action	Manufacturer(s)
Oxycodone HCL Tabs	<input type="button" value="Add Manufacturer"/>	<div><div><div>* DEA Number: <input type="text"/></div><div>* <input type="text" value="PACKAGING"/> <input type="button" value="v"/></div><div><input type="button" value="Submit Manufacturer"/></div></div><div><div>PACKAGING</div><div><input type="button" value="Remove Manufacturer"/></div></div></div>

Click Next to return to the Report Selection Menu.



# Commercial Manufacturing (Exporter/Distributor)





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**DIVERSION CONTROL DIVISION**

Application for Quota Allotment

Commercial Manufacturing

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2016	9143	OXYCODONE (FOR SALE)	1,500.000	.000

Dosage Form Data  
(DEA Form 250 -- Box 14)  
Quota Requested: 1,100.000

List the DEA registrant(s) who perform domestic distribution and export (if applicable) activities for the finished goods

Summary


Name	Action	DEA number : Exporter/Distributor
Oxycodone HCL Tabs	<input type="button" value="Add Activity"/>	<div><div>* DEA Number: <input type="text"/></div><div>* Domestic <input type="button" value="Submit Activity"/></div></div> <div><input type="button" value="Remove Activity"/></div>

Click Next to return to the Report Selection Menu.



# Commercial Manufacturing (Supplier)





U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION  
**DIVERSION CONTROL DIVISION**

Application for Quota Allotment


**Commercial Manufacturing**

**Current Selection**

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2016	9143	OXYCODONE (FOR SALE)	1,500.000	.000

**Dosage Form Data**  
(DEA Form 250 -- Box 14)  
Quota Requested: 1,100.000

List the DEA-registered bulk manufacturer (s) (i.e. producer of active pharmaceutical ingredient or API) or DEA-registered importer(s) who applicant will procure the controlled substance from, and how many days will it take to receive API once applicant receives DEAs quota response.

* DEA Number	DEA Number	Days Until API Receipt	Action
* Days Until API Receipt:		2	<input type="button" value="Edit"/>
<input type="button" value="Clear"/>	<input type="button" value="Submit Api Source"/>		<input type="button" value="Remove"/>

Provide year-to-date (YTD) domestic sales (in grams, expressed in terms of anhydrous base) and export sales from your manufacturing facility that will utilize commercial manufacturing quota. Provide YTD orders on hand which are un-filled (in grams, expressed in terms of base). Are any of these orders subject to a "failure to fill" penalty which would be imposed on your company if not filled. Provide manufacturing losses on year-to-date sales/production (in grams, expressed in terms of base)


* Domestic Sales	* Exports	* Unfilled Orders	* Unfilled Order Penalty	* Manufacturing Losses
<input type="text" value="800.000"/>	<input type="text" value="300.000"/>	<input type="text" value="10.000"/>	<input checked="" type="checkbox"/> ***	<input type="text" value="40.000"/>

\*\*\*Manufacturers should be wary of entering into these types of agreements without a guarantee of having adequate quota from DEA.

The \* symbol denotes a required field. Number fields must be a valid number between 0 and 999,999,999.999 inclusive.







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**DIVERSION CONTROL DIVISION**

Application for Quota Allotment

### Replacement

#### Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2017	9193	HYDROCODONE (FOR SALE)	1,000.000	.000

#### Replacement Data

**Quota Requested: 100.000**

Please provide an explanation of what was destroyed and why. You must submit appropriate documentation, including DEA Form 48 and DEA Form 522 (if a reverse distribution was used). Summarize what was destroyed (ie. commercial batches, product development samples and retains, bulk API, etc.) and the reason for disposal.

\* Date of Destruction

\* Explanation (maximum 270 characters :: 270 characters remaining)

The \* symbol denotes a required field. The Explanation field must be greater than 0 and less than 270 characters.

Reset

Submit

#### Summary

Remove	Date of Destruction	Explanation
<input type="radio"/>	Apr 10, 2017	Batch contamination

To remove an entry, click the Remove radio button.  
Click Next to return to the Report Selection Menu.

Next






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**DIVERSION CONTROL DIVISION**

**Application for Quota Allotment**

## Transfer

**Current Selection**

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2016	9143	OXYCODONE (FOR SALE)	1,500.000	.000

**Transfer Data**  
**Quota Requested: 100.000**

If you intend to transfer OXYCODONE (FOR SALE), fill out the fields below and click Submit. You may create as many individual Transfer forms as necessary.

**\* DEA Number**

**\* Explanation (maximum 270 characters :: 270 characters remaining)**

Please provide details of transfers, ie. what will be transferred, the purpose of the transfer, etc.


The \* symbol denotes a required field. Number fields must be a valid number greater than 0 and less than 1,000,000,000.000.

**Summary**

Remove	DEA Number	Explanation
<input type="radio"/>	[REDACTED]	Quota needed to receive 100 kg from sister facility.
To remove an entry, click the Remove radio button. Click Next to return to the Report Selection Menu.		







U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION  
**DIVERSION CONTROL DIVISION**

Application for Quota Allotment

Final Summary

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2016	9143	OXYCODONE (FOR SALE)	1,500.000	.000

Year-End Report Data

	2014 (actual)	2015 (actual)	2016 (estimate)
Inventory	0.000	0.000	430.000
Dispositions	0.000	0.000	1,100.000
Acquisitions	0.000	0.000	1,500.000

Quota Allotment Request by Category

Comm Man: Domestic	Comm Man: Export	Prod Dev	Packaging/Labeling	Replacements	Transfers	Total
1,000.000	100.000	100.000	100.000	100.000	100.000	1,500.000

Remarks

(maximum 1,024 characters :: 1017 characters remaining)

Remarks

Supporting Documents

You can optionally include a supporting document with your request. If so, click the Browse button and select a file from your local file system. The file must be a valid PDF file, must have a .pdf extension and must be free of any security restrictions.

Choose File No file chosen

Click Submit to transmit your data to the DEA.  
Click Return to go back to the Year-End Estimates page to modify any part of your request.

ReturnResetSubmit



# Summary Confirmation





U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION  
**DIVERSION CONTROL DIVISION**

Application for Quota Allotment

Summary Confirmation

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2016	9143	OXYCODONE (FOR SALE)	1,500.000	.000

Confirmation

The Quota Allotment request for the substance above has been submitted successfully.

**Reference Number: 154713**

Questions regarding this transaction may be emailed to DEA at [DEAQuotas@dea.gov](mailto:DEAQuotas@dea.gov). Please include your DEA registration number, the above reference number and your company name in the subject line of all correspondence regarding this request.

This request may be amended by selecting the same substance from the Main Selection Menu. All data entry fields will be loaded with the values from the latest completed request.

Printing Options


Click the Print button below to print the request or archive it as a PDF report.

Print

ReturnExit







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**DIVERSION CONTROL DIVISION**

Application for Quota Allotment

### Quota Request Status

The following table lists substances for which you have formally requested a quota allotment, and the status of your application. Multiple requests for the same substance are sorted sequentially by Drug Name within Quota Type.

A date in the Date Approved field indicates the date the request was approved. Requests that have not been approved yet show as "Pending."

Requests may be amended by returning to the Main Selection Menu and selecting the substance from the list.

To view the request as a PDF report, click the Request ID link.


Quota Type	Quota Year	Date Submitted	Drug Code	Drug Name	Quota	Date Approved	Request ID
PRO	2017	Mar 31, 2016	9200	HEROIN	50.000	Pending	<a href="#">121569</a>
PRO	2017	Apr 10, 2017	9193	HYDROCODONE (FOR SALE)	1,000.000	Pending	<a href="#">121583</a>

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Print







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**DIVERSION CONTROL DIVISION**

Application for Quota Allotment

### Quota Request Revision

**Notice**

You have previously filed a quota allotment request for the substance noted below. The request was filed on Apr 17, 2024 in the amount of 1,500.000 grams. The Reference Number is 154713.

In the pages that follow, your original data values for the request will be displayed. You may freely remove, append or revise this data. Once you complete this revised request, it will be filed with its own reference number and will become the new statement of record for the requested quota allotment for this substance.

**Current Selection**

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2016	9143	OXYCODONE (FOR SALE)	1,500.000	.000


Back

Next



## List 1 Import quota





U.S. Department of Justice Drug Enforcement Administration  
**Office of Diversion Control**

Application for Quota Allotment

**Worksheet-A**

**Current Selection**

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Import	2011	1225	PHENYLPROPANOLAMINE (FOR SALE)	6,879.000	.000

**Instructions**  
**(DEA Form 488 -- Worksheet-A)**

The Worksheet-A form is for you to document the subsequent disposition (sale) or utilization of PHENYLPROPANOLAMINE (FOR SALE). You may submit individual Worksheet-A forms using this web site. To do so, click the Next button below.

Alternatively, you may submit a Worksheet-A in Excel format via email. To email a Worksheet-A, first complete this request for an import quota, at the conclusion of which you will be given a reference number. Then prepare a Worksheet-A in Excel format and email it to [DEAQuotas@DEA.gov](mailto:DEAQuotas@DEA.gov). Include the reference number in the subject line of the email. Click the radio button below to indicate that Worksheet-A submission by email.

☒ Worksheet-A Email Submission



# List 1 Import quota – Worksheet A



**Worksheet-A**

**Current Selection**

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Import	2011	1225	PHENYLPROPANOLAMINE (FOR CONVERSION)	12.000	.000

**Worksheet-A Data**  
(DEA Form 488 -- Worksheet-A)

\* DEA Number :

\* Name of company

\* Address :

\* Phone :

\* Fax :

\* Email :

\* Contact Person :

\* Quantity to be sold (as grams of anhydrous base) :

\* Provide documentation for Quantity to be sold (purchase orders, supply agreements, etc) :

\* Intended Use :

☐ Sale / Product Launch

☐ Product Development / Research

☐ Other (explain)

The \* symbol denotes a required field. Number fields must be a valid number between 0 and 999,999,999.999 inclusive.

Fill in the fields above and click Submit.

Reset

Submit



## List 1 Import quota - Summary



### Summary

☐ Remove

DEA Num : #####

Company Name : dFGHFYT

Address : HFGGGYYJK,GYFJYYU CTGBD BGFSHDFJKSD

Phone : 256-515-4422

Fax : 121-142-4448

Email : NCBHXJH@GMAIL.COM

Contact : SHJAGYSG

Quantity to be sold : 5,226.000

Supporting docs : GJKEYU

Intended Use : Other

Intended Use Explain : FJDSIOUFRW

To remove an entry, click the Remove radio button.  
To return to the Worksheet-A Selection Menu, click Return.

Next





- Provide YTD sales in grams base when applying for commercial quota
- If requested, provide your Customer List with year to date (YTD) sales aggregated by DEA number (in excel format). The customer lists should have the DEA registration shown ONCE in the entire document and the aggregated total sold to that DEA Number.
- Provide product development in the following format: batch purpose, strength (mg) x Units x batches x conversion factor = total grams base. Please note amounts for overages, stability, retains, and waste.
- Include DEA#, application# on all correspondence
  - POC/direct phone line/extension if different than registration
- Too much or too little information will slow your quota review down
- If you're going to submit a large amount of information, please provide a summary page that provides a synopsis of your activity and the calculations you used to determine your quota requirements
- Do not submit a copy of this/past applications, registration certificate, past quota letters with your supporting documentation







- Please separate how much quota is required for commercial sale (CM) vs validation (PD)
  - Validation material can be sold once the FDA approves the product
- Ensure the names and DEA numbers of suppliers and customers are correct
- CMO's should request that their customer provide information directly to DEA or through you (if possible) regarding any other manufacturer's involved in manufacturing the same products and the allocation of quota between them.
- Relinquishment Procedure
  - Using the online quota system submit a request for the amount you require for the year
  - When it is smaller than the amount you currently have, we know you mean to relinquish quota
  - If you want to relinquish all of your quota because you don't need any of it, enter 0.001 g in the amount requested field. The system will not accept zero; however, we will grant you zero quota on your letter.







- **Authority to Market** – Enter the authority to market the product (NDA#, ANDA#, OTC Monograph, etc.)
- **FDA Shortage** – Check the box if this product is currently listed on FDA's Drug Shortage List
- **Days to Start Production** – How many days will it take to begin production (from the time of receipt of the substance for which you are applying?)
- **Days for Production** – How many days will it take to perform production cycle (milling, granulation, coating, pressing, etc.)?
- **Days to Distribute** – How many days will it take to distribute finished goods to customers?







Thank you!

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

United Nations Reporting and Quota Section (DRQ)

[DEAQuotas@dea.gov](mailto:DEAQuotas@dea.gov)

(571) 362-3248

