



Supply Chain Conference 2024

Online Quota System

UN Reporting and Quota Section

Diversion Control Division



April 30 - May 2, 2024

Little Rock, Arkansas



The contents of this document do not have the force and effect of law and are not meant to bind the public or DEA in any way.

This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

I have no financial relationship to disclose.





“The presentation is for educational purposes.

Materials, images, or sounds authored or created by parties other than DEA may be subject to copyright and are used herein in accordance with the fair use provision of Title 17 United States Code Section 107. DEA’s use of these materials does not authorize persons outside of DEA further distribute or use copyrighted materials.”





- 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

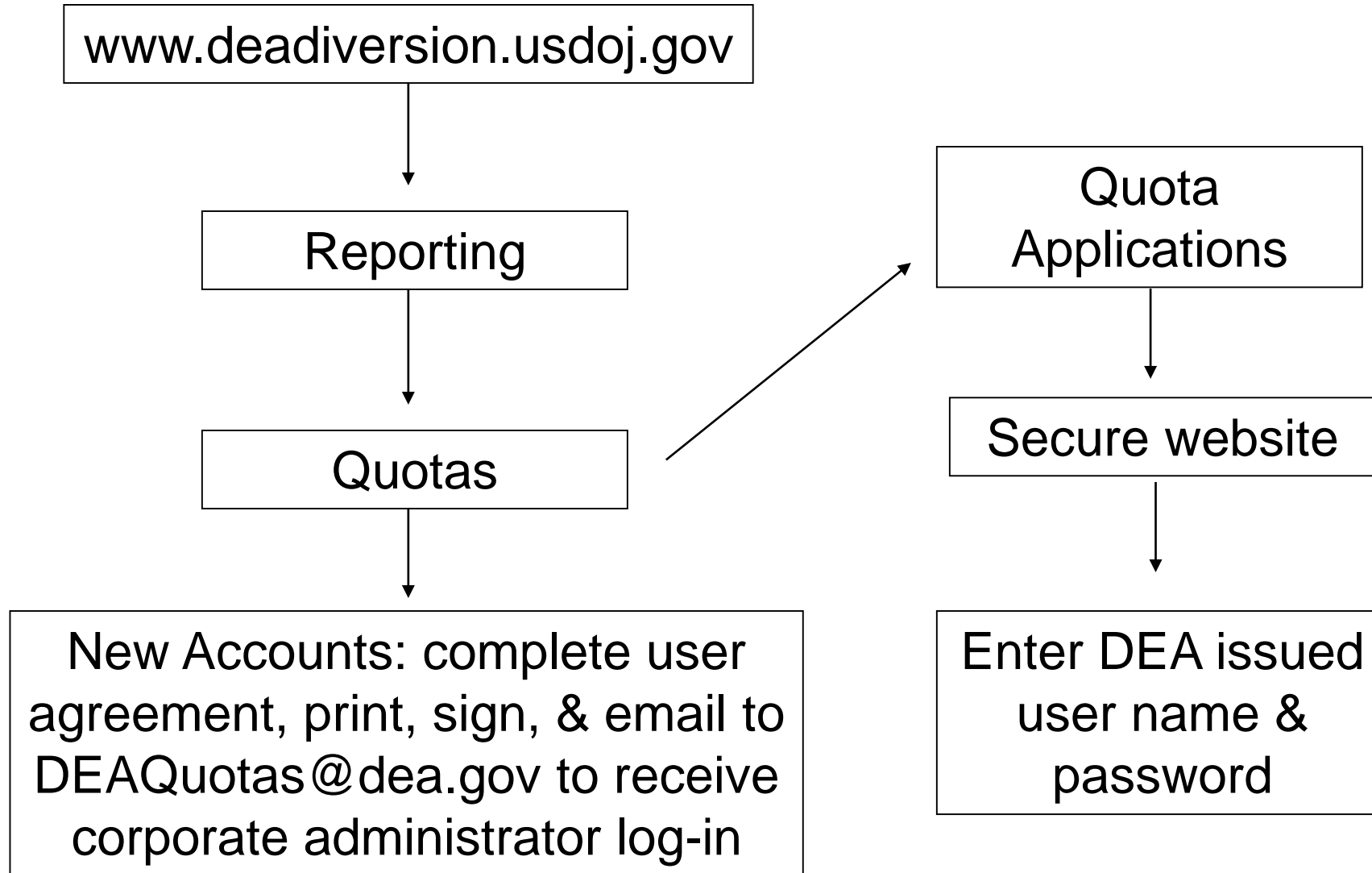




Additional questions have been added to the application

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



**Corporate Administrator
User Administration**

You are the Corporate Administrator. These are the corporate users accounts for DEA Number

Create a New User Account
 New User

Reset User Password
 USER ACCT 1

Delete User Account
 USER ACCT 1

Click Back to return to the User Login screen. Click Next to process your selection.



**Corporate Administrator
Create New User**

A password must be comprised of at least one, but not more than ten uppercase or lowercase letters, any of the ten digits and the underscore character, arranged in any order.

DEA Number:

Username:

New Password:

Confirm New Password:

Click Cancel to abort this action and return to the User Administration screen. Click Next to process your selection.



**Corporate Administrator
User Administration Confirmation**

You have successfully created a user account for





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.

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.



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) \longrightarrow 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







U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
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	.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)
Inventory (as of Dec 31)			
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
Total	0.000	0.000	0.000
Dispositions			
Domestic	0.000	0.000	0.000
Exports	0.000	0.000	0.000
Total	0.000	0.000	0.000
Acquisitions			
Domestic	0.000	0.000	0.000
Imports	0.000	0.000	0.000
Total	0.000	0.000	0.000

[Click Next to advance to the next page.](#)






- **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





U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
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.

Quota Allotment Categories



U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
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 Converted Substances (DEA Form 250 -- Box 13)
Optional	Incomplete	1,100.000	Commercial Manufacturing Dosage Forms (DEA Form 250 -- Box 14)
Required	Incomplete	100.000	Product Development (DEA Form 250 -- Box 14)
Required	Incomplete	100.000	Packaging/Labeling (DEA Form 250 -- Box 14)
Required	Incomplete	100.000	Replacement
Required	Incomplete	100.000	Transfer

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







U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
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.

Summary

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







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**

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	* Authority to Market ?	* Used 2014	* Used 2015	* Estimate 2016
Oxycodone HCL Tabs	ANDA Number	Domestic: 100.000 Export: 0.000	100.000 0.000	500.000 500.000
* Strength	* FDA Shortage ?	* Days To Start Prod. ?	* Days for Production ?	* Days to Distribute ?
5 mg	<input type="checkbox"/>	14	10	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.







U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION

DIVERSION CONTROL DIVISION

Application for Quota Allotment

Product Development

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: 100.000

If you intend to manufacture OXYCODONE (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
<input type="text" value="Oxycodone Tab"/>	<input type="text" value="10 mg"/>	<input type="text" value="5"/>	<input type="text" value="2"/>	<input type="text" value="R&D"/>	<input type="text" value="100.000"/>	<input type="text" value="2 weeks"/>

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.

Summary

Remove	Name	Strength	Units/Batch	# Batches	Purpose	Qty	Completion Time
Currently there are no Product Development forms.							







U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
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**

If you intend to segment OXYCODONE (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" value="Oxycodone tabs"/>	<input type="text" value="5 mg"/>	<input type="text" value="10"/>	<input type="text" value="2"/>	<input type="text" value="Packaging"/>	<input type="text" value="100.000"/>

* Authority to Market ?	* FDA Shortage ?	* Days To Start Prod. ?	* Days for Production ?	* Days to Distribute ?
<input type="text" value="ANDA Number"/>	<input type="checkbox"/>	<input type="text" value="7"/>	<input type="text" value="7"/>	<input type="text" value="3"/>

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.

Summary

Action	Name	Strength	Units / Pkg	# Pkgs	Purpose	Qty
Currently there are no Package forms.						

Packaging and Labeling Continued





U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
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"/>	[REDACTED]	7	<input type="button" value="Edit"/> <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 <input style="width: 100%;" type="text" value="10.000"/>	* Exports <input style="width: 100%;" type="text" value="0.000"/>	* Manufacturing Losses <input style="width: 100%;" 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)





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 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 style="border: 1px solid black; padding: 5px;"><p>* DEA Number: <input type="text"/></p><p>* PACKAGING <input type="button" value="v"/></p><p style="text-align: right;"><input type="button" value="Submit Manufacturer"/></p></div> <p style="text-align: center;">[REDACTED] PACKAGING <input type="button" value="Remove Manufacturer"/></p>

[Click Next to return to the Report Selection Menu.](#)

Commercial Manufacturing (Exporter/Distributor)





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 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"/>	<p>* DEA Number: <input type="text"/></p> <p>* Domestic <input type="button" value="Submit Activity"/></p> <p><input type="button" value="Remove Activity"/></p>

[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
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="button" value="Edit"/>
* Days Until API Receipt: <input type="text"/>	<input type="text" value="REDACTED"/>	2	<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.



 U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
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.


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.







U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
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.

<small>* DEA Number</small> <input type="text"/>	<small>* Explanation (maximum 270 characters :: 270 characters remaining)</small> <input type="text"/>
---	---

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)

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.

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.](#)



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. 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.



U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
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	121569
PRO	2017	Apr 10, 2017	9193	HYDROCODONE (FOR SALE)	1,000.000	Pending	121583

[Back](#)

[Print](#)



U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION
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. 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.



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.





- Provide YTD sales in grams base when applying for commercial quota
- If requested, provide customers' DEA#'s and the amount sold to each customer in grams base
- 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.





- **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

(571) 362-3248





BREAK