Drug Enforcement Administration

Year-End Reporting and Quota Management System

Quotas
User Manual

Version 1.5
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DIVERSION CONTROL DIVISION
TECHNOLOGY SECTION

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1.0 Introduction

1.1 Overview

The Drug Enforcement Administration (DEA) is the United States (US) competent body charged with the management of controlled substances and chemicals for scientific, medical, research, and industrial applications while preventing diversion of these same substances and chemicals. To manage this complex system, DEA requires that manufacturers of Schedule I and II controlled substances and the importers and manufacturers of ephedrine, pseudoephedrine, and phenylpropanolamine (Combat Methamphetamine Epidemic Act [CMEA] List I chemicals) apply for quotas to control the quantity of material produced or procured per calendar year for US requirements. These individual import and procurement requests are aggregated to determine bulk manufacturer requirements, aggregate production quotas (APQ), annual assessment of needs (AAN), and generate reports to the United Nations regarding the consumption and manufacturing of Schedule I and II controlled substances and CMEA List I chemicals.

These specific individual importers and manufacturers apply for yearly importation and manufacturing quota allowances based on historical sales data and forecasted trends in their market. This information is transmitted to DEA through quota application forms DEA 189, DEA 250, and DEA 488. The individual manufacturing quota form DEA 189 is for use by individual manufacturers that extract or synthesize a Schedule I or II substance from plant material or other controlled substances. The procurement quota form DEA 250 is required for dosage form manufacturers, compound pharmacies, labelers/re-labelers, and packagers/re-packagers. The importation form DEA 488 is for use by the CMEA List I chemical importers.

1.2 Basic Navigation

Use the buttons at the bottom of the page to navigate the Quotas application. Button functionality is 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.

Exit : exit the Quotas application.

Do *not* use the browser's navigation buttons.

1.3 Login

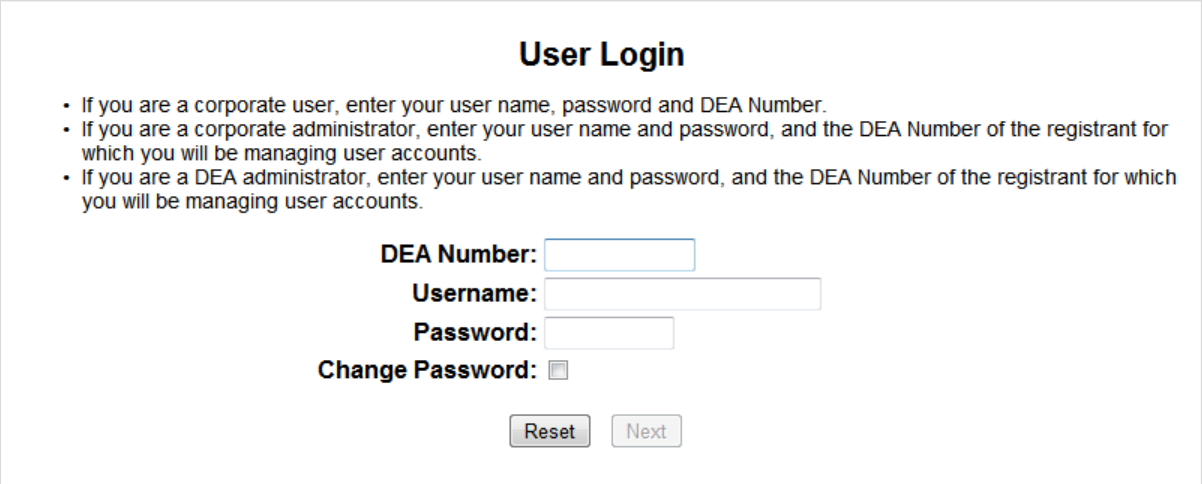


Figure 1: Login

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.

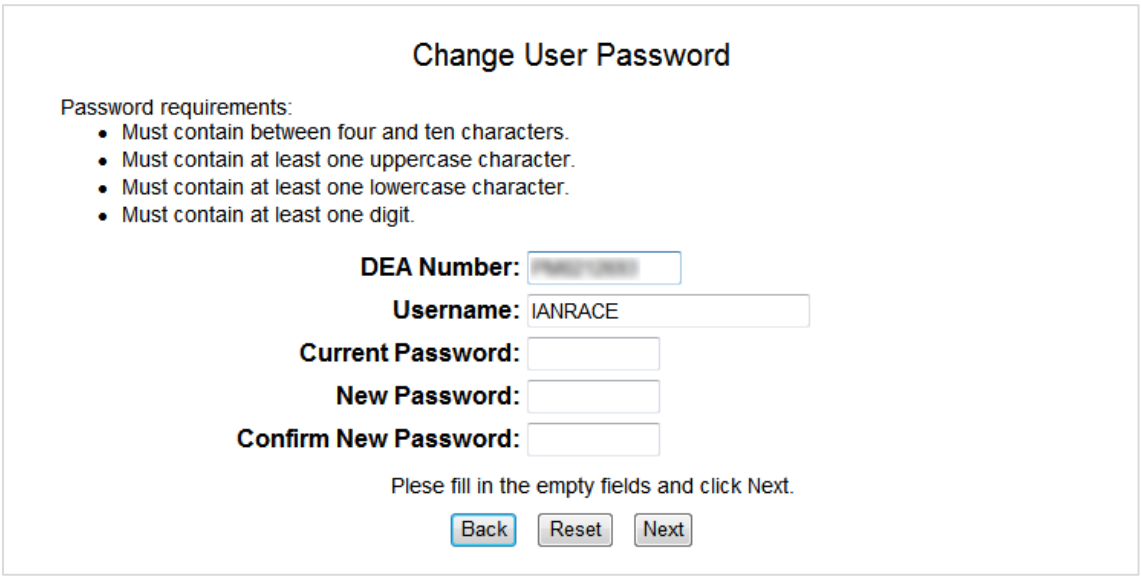


Figure 2: Change Password

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. Quotas 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.

2.0 Quota Application

2.1 Manufacturers and Types of Quota

Manufacturers can apply for three (3) different types of quota based on the business activities permitted by their DEA registration(s). The table below specifies the distinction between manufacturers, quotas, and controlled substances/CMEA List I chemicals.

Type of Account	Type of Quota	Substance/Chemical
Manufacturer	Procurement	Substance
Bulk Manufacturer	Procurement, Manufacturer	Substance
Chemical Manufacturer	Procurement, Manufacturer	Chemical
List I Chemical Importer	Import	Chemical

2.2 Quota Application

After confirming the account login, Quotas will load the **Main Selection Menu**. An initial quota may be requested or an already granted quota may be revised. From this page, users may check the status of existing quota requests (see Section 2.3) or file a new or amendment request.

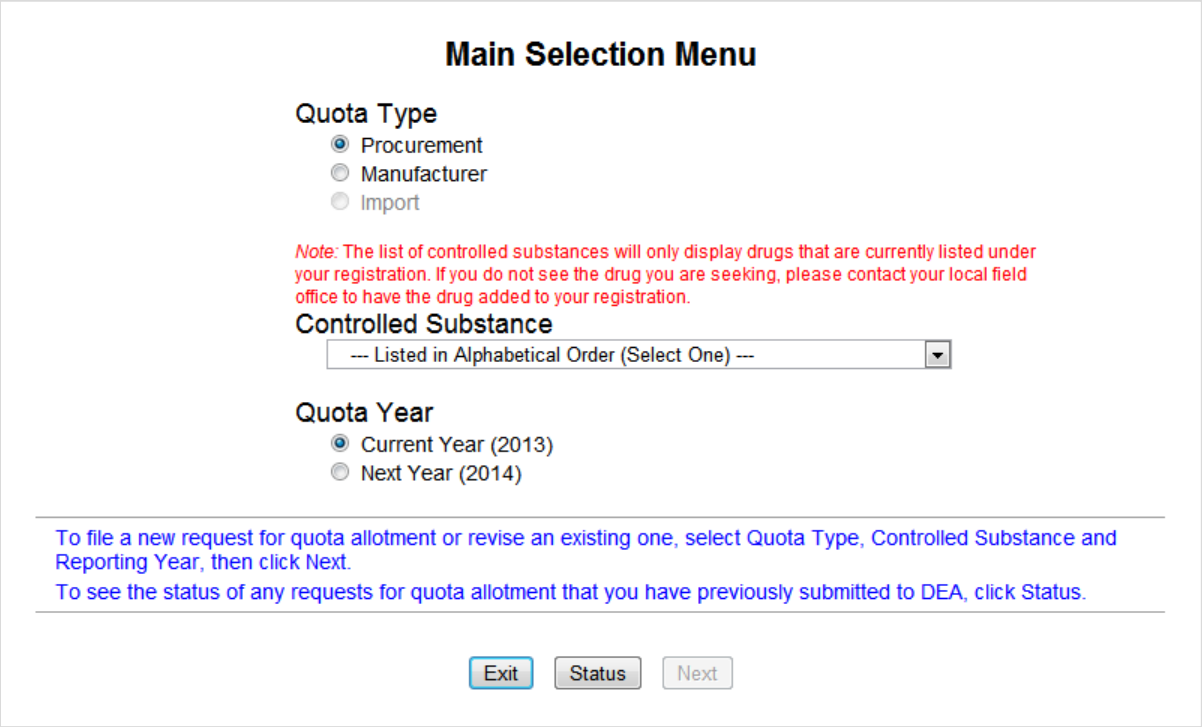


Figure 3: Main Selection Menu

The following information must be selected before the application process may continue.

- **Quota Type**: the type of quota being requested.
- **Controlled Substance**: the controlled substance for which a quota is being requested. List I chemical manufacturers and importers will only see the chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. No substance or chemical will be listed in the drop-down menu if it hasn't first been registered to the requesting manufacturer.
- **Quota Year**: the year during which the quota will be applied.

After all selections have been made, click the Next button. Following this page, the current or future year-end inventory, acquisitions, and dispositions are estimated and the quota amount is requested.

2.2.1 Current Selection

Once through the Main Selection Menu, every subsequent page in the Quota application process will display the following information.

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2014	9120	DIHYDROCODEINE		.000

Figure 4: Current Selection

2.2.2 Quota Revision

Note that the screen below will only be displayed if a request for the selected substance or chemical has already been submitted.

Quota Request Amendment

Notice

You have previously filed a quota allotment request for the substance noted below. The request was filed on Oct 26, 2012 in the amount of 100.000 grams. The Reference Number is 113654.

In the pages that follow, your original data values for the request will be displayed. You may freely remove, append or amend this data. Once you complete this amended 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	2013	9150	HYDROMORPHONE	100.000	.000

Back Next

Figure 5: Quota Amendment Notice

Click the Next button to proceed to the Year-End Estimates screen.

2.2.3 Year-End Estimates for Report Year

Note that the fields, as displayed in the image below, will already contain values if this is an amendment to an already submitted quota.

Enter the estimated amounts of the controlled substance or listed chemical expected to be held in inventory, disposed/sold to other entities, and acquired from other entities by the end of the selected year. At least one field must contain a value other than zero (0) before the quota application process may proceed.

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	2011 (actual)	2012 (actual)	2013 (estimate)	2014 (estimate)
Inventory (as of Dec 31)				
Bulk controlled substance (API)	0.000	0.000	10.000	0.000
In-process material (in all forms)	0.000	500.000	0.000	0.000
Finished dosage forms (bulk and/or packaged)	0.000	0.000	0.000	0.000
Total	0.000	500.000	10.000	0.000
Dispositions				
Domestic	0.000	0.000	0.000	0.000
Exports	0.000	0.000	0.000	0.000
Total	0.000	0.000	0.000	0.000
Acquisitions				
Domestic	0.000	0.000	0.000	0.000
Imports	0.000	0.000	0.000	0.000
Total	0.000	0.000	0.000	0.000

Click Next to advance to the next page.

Reset Return Next

Figure 6: Year-End Estimates

All entered values must be expressed as grams of anhydrous base or alkaloid, not as salt.

- **Bulk controlled substance (API [Active Pharmaceutical Ingredient])**: the quantity of bulk (non-packaged) substances or chemicals held in inventory.
- **In-process material (in all forms)**: the quantity of substances or chemicals in process for conversion, formulation, blending, tableting, encapsulation, etc.
- **Finished dosage forms (bulk and/or packaged)**: the quantity of substances or chemicals to have completed processing.
- **Domestic**: the quantity of substances or chemicals to have either been disposed or acquired within the United States.
- **Exports/Imports**: the quantity of substances or chemicals to have either been disposed or acquired internationally.

*Note that a fourth column will be displayed only if the **Next Year** option is selected on the **Main Selection Menu** screen (see* Figure 3*). The current year column will be unavailable for editing.*

Note that any values entered for an amended quota request will overwrite any values previously requested. New submissions for revising quota requests are not added to or subtracted from existing quota values.

Click the Next button to proceed to the **Quota Request** screen.

2.2.4 Quota Request

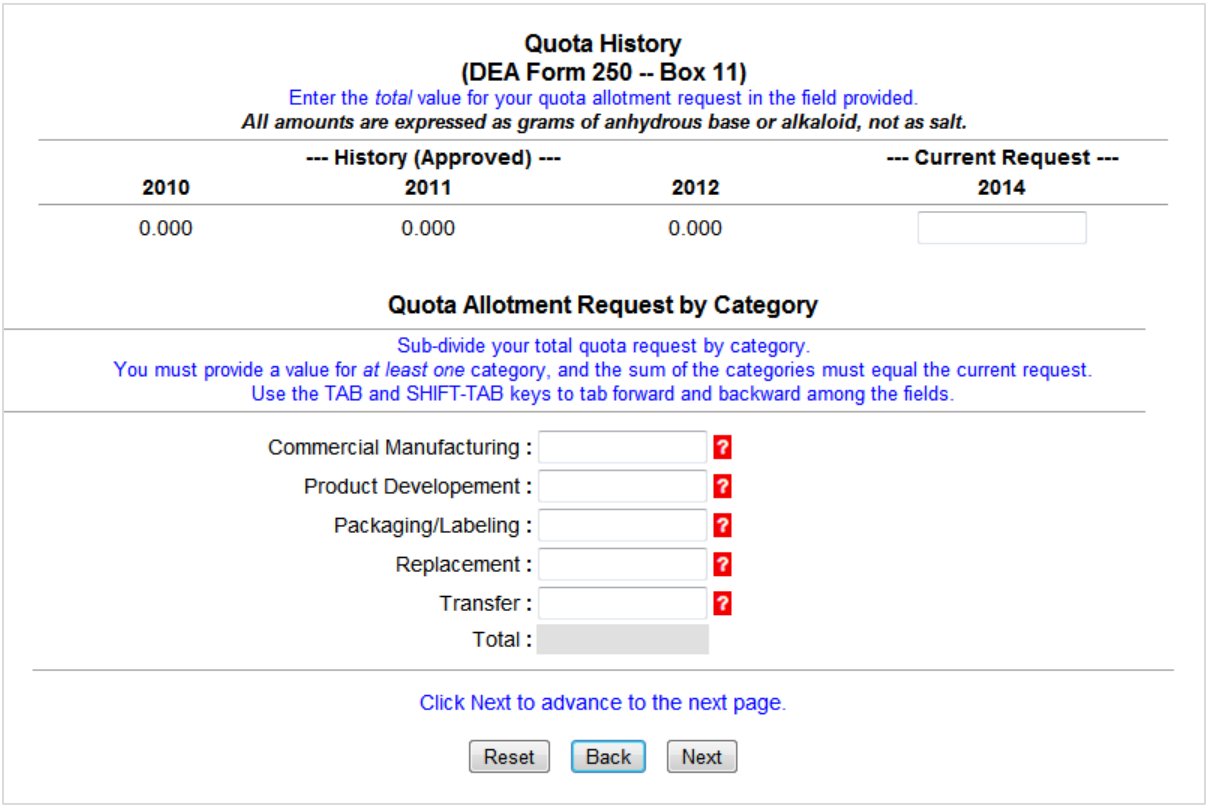


Figure 7: Quota Request

Enter the total value of the Quota reqest in the Total Requested for calendar year field.

separate the total of the current request into the fields of the **Quota Allotment Request by Category**. All fields must be filled; if no quota will be used in a particualr category, enter (0) for that field. Click the Reset button to clear the fields.

The total value of the **Quota Allotment Request by Category fields** must equal the value entered in the Current Request field. Hover the pointer over a ? icon to display a tooltip with specific information about the request categories.

List I chemical importers will see the **Product Type** section rather than the **Quota Allotment Request by Category** section. List I chemical importers must select the type of List I chemical product being imported.

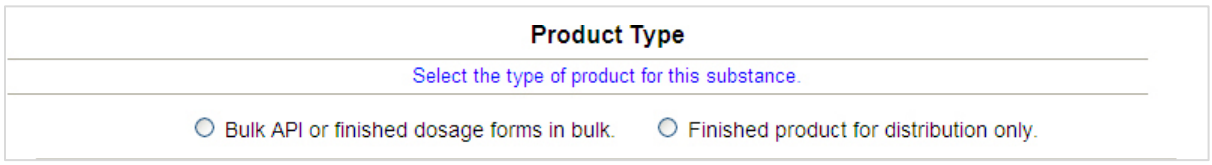


Figure 8: Import Product Type

After the fields have been filled and selection been made, click the Next button.

The following message shall appear for quota revision requests where the new value is lower than that already approved by DEA.

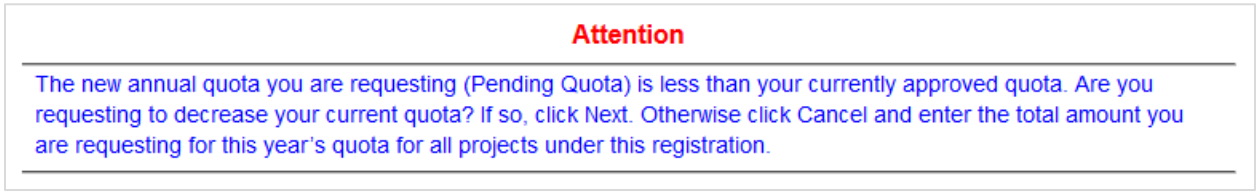


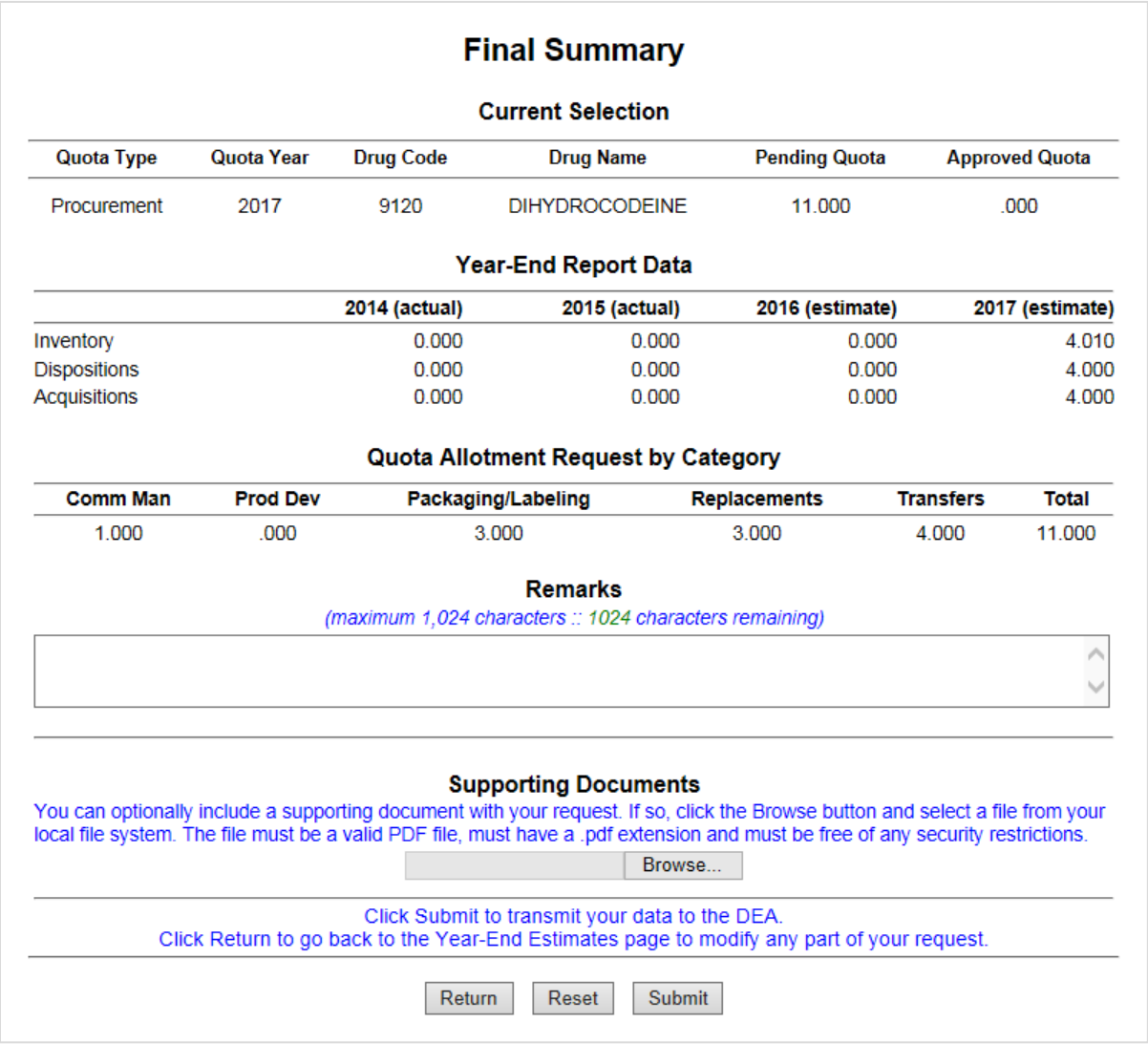
Figure 9: Attention

Click the Next button to display the **Sub-Report Selection Menu**.

Figure 10: Sub-Report Selection Menu

Refer to Section 3.0 for information about the Quota sub-category forms. When finished, click the Next button.

2.2.5 Final Summary



Final Summary

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2017	9120	DIHYDROCODEINE	11.000	.000

Year-End Report Data

	2014 (actual)	2015 (actual)	2016 (estimate)	2017 (estimate)
Inventory	0.000	0.000	0.000	4.010
Dispositions	0.000	0.000	0.000	4.000
Acquisitions	0.000	0.000	0.000	4.000

Quota Allotment Request by Category

Comm Man	Prod Dev	Packaging/Labeling	Replacements	Transfers	Total
1.000	.000	3.000	3.000	4.000	11.000

Remarks

(maximum 1,024 characters :: 1024 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.

Browse...

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.

Return Reset Submit

Figure 11: Final Summary

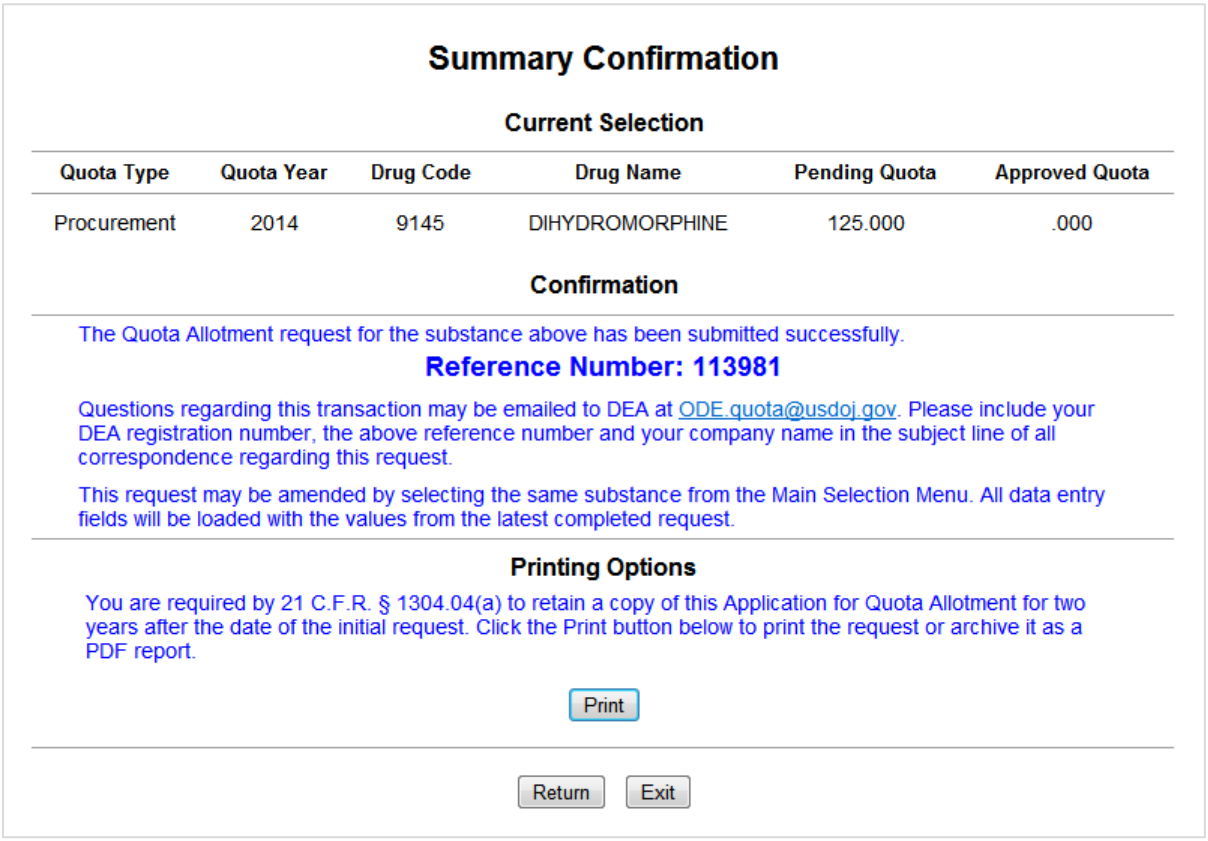
Review the summary of the quota request. Any additional remarks should be placed in the **Remarks** field.

Optionally, a Portable Document Format (PDF) file supporting the Quota request may be uploaded. Click the Browse... button to choose the file. *Note that PDF files may not take the place of a submitted quota request.*

If a mistake was made, click the Return button to return to the **Main Selection Menu**.

Click the Submit button to complete the Quota request.

A reference number will be assigned to the quota request. Reference this number in any emails to the UN Reporting and Quota Section (DRQ) concerning this quota request.



Summary Confirmation

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2014	9145	DIHYDROMORPHINE	125.000	.000

Confirmation

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

Reference Number: 113981

Questions regarding this transaction may be emailed to DEA at ODE.quota@usdoj.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

You are required by 21 C.F.R. § 1304.04(a) to retain a copy of this Application for Quota Allotment for two years after the date of the initial request. Click the Print button below to print the request or archive it as a PDF report.

Print

Return Exit

Figure 12: Summary Confirmation

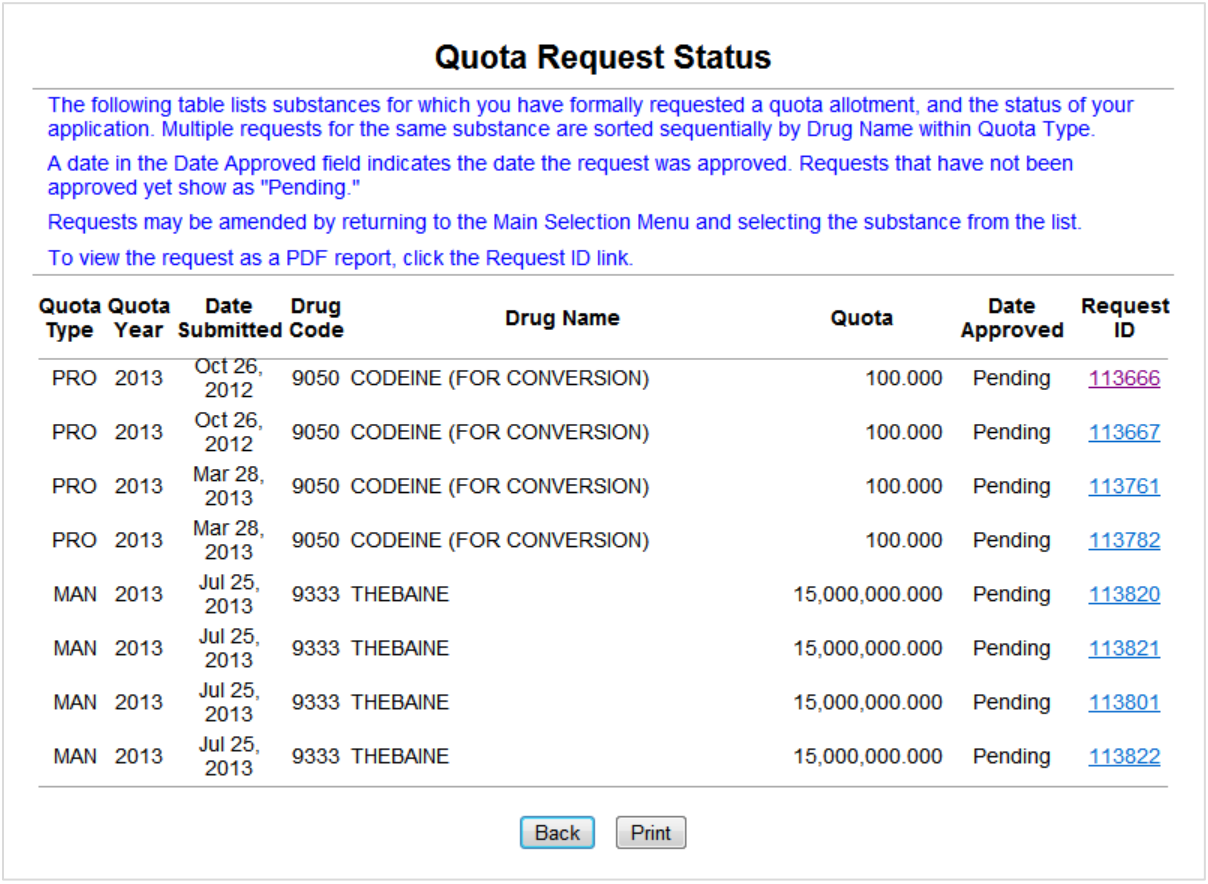
A PDF copy of the Quota request application may be saved to a local computer for printing. Click the Print button to create the PDF copy.

Click the Return button to return to the **Main Selection Menu** (Figure 3) to submit another Quota request.

Click the Exit button to return to the Office of Diversion Control website and exit the application.

2.3 Checking the Application Status

To check the current status of a pending quota application, click the Status button from the **Main Selection Menu**.



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	2013	Oct 26, 2012	9050	CODEINE (FOR CONVERSION)	100.000	Pending	113666
PRO	2013	Oct 26, 2012	9050	CODEINE (FOR CONVERSION)	100.000	Pending	113667
PRO	2013	Mar 28, 2013	9050	CODEINE (FOR CONVERSION)	100.000	Pending	113761
PRO	2013	Mar 28, 2013	9050	CODEINE (FOR CONVERSION)	100.000	Pending	113782
MAN	2013	Jul 25, 2013	9333	THEBAINE	15,000,000.000	Pending	113820
MAN	2013	Jul 25, 2013	9333	THEBAINE	15,000,000.000	Pending	113821
MAN	2013	Jul 25, 2013	9333	THEBAINE	15,000,000.000	Pending	113801
MAN	2013	Jul 25, 2013	9333	THEBAINE	15,000,000.000	Pending	113822

Back Print

Figure 13: Quota Request Status

The following information is available:

- **Quota Type**: the type of quota for which the application has been submitted (procurement, manufacturer, import).
- **Quota Year**: they year for which the quota will be applied.
- **Date Submitted**: the date on which the request was submitted.
- **Drug Code**: the code given to the controlled substance or listed chemical for which a quota was requested.
- **Drug Name**: the name of the controlled substance or listed chemical for which a quota was requested.
- **Quota**: the quota amount requested for the applicable year.
- **Date Approved**: the date on which the quota request was approved. Note: Approval date does **not** indicate the quota amount requested is the amount granted. DEA will still send a letter (by email and post) indicating the amount of quota granted for the request.
    - Pending indicates that the request is still awaiting final determination by DRQ.

  - Withdrawn indicates that the request has been withdrawn either by registrant's written request to DRQ or that DRQ has combined the application with the registrant's additional pending request for the same drug code. Withdrawn requests may be resubmitted.
- **Request ID**: every quota request is assigned a unique six (6)-digit number. This number should be referenced with inquiries concerning the quota request. Click on the Request ID to display and/or print the details of that specific request.

Clicking the Print button will create a PDF copy of the status page information suitable for printing. A letter addressed to the registrant from the Deputy Assistant Administrator of DC will be displayed on the final page of the summary.

To return to the **Main Selection Menu**, click the Back button.

3.0 Quota Sub-Category Forms

3.1 Commercial Manufacturing (Converted Substances)

The **Converted Substances** sub-category form is only available for substances and List I chemicals specifically marked for conversion. Filing the **Converted Substances** sub-category form is an optional activity for bulk manufacturers.

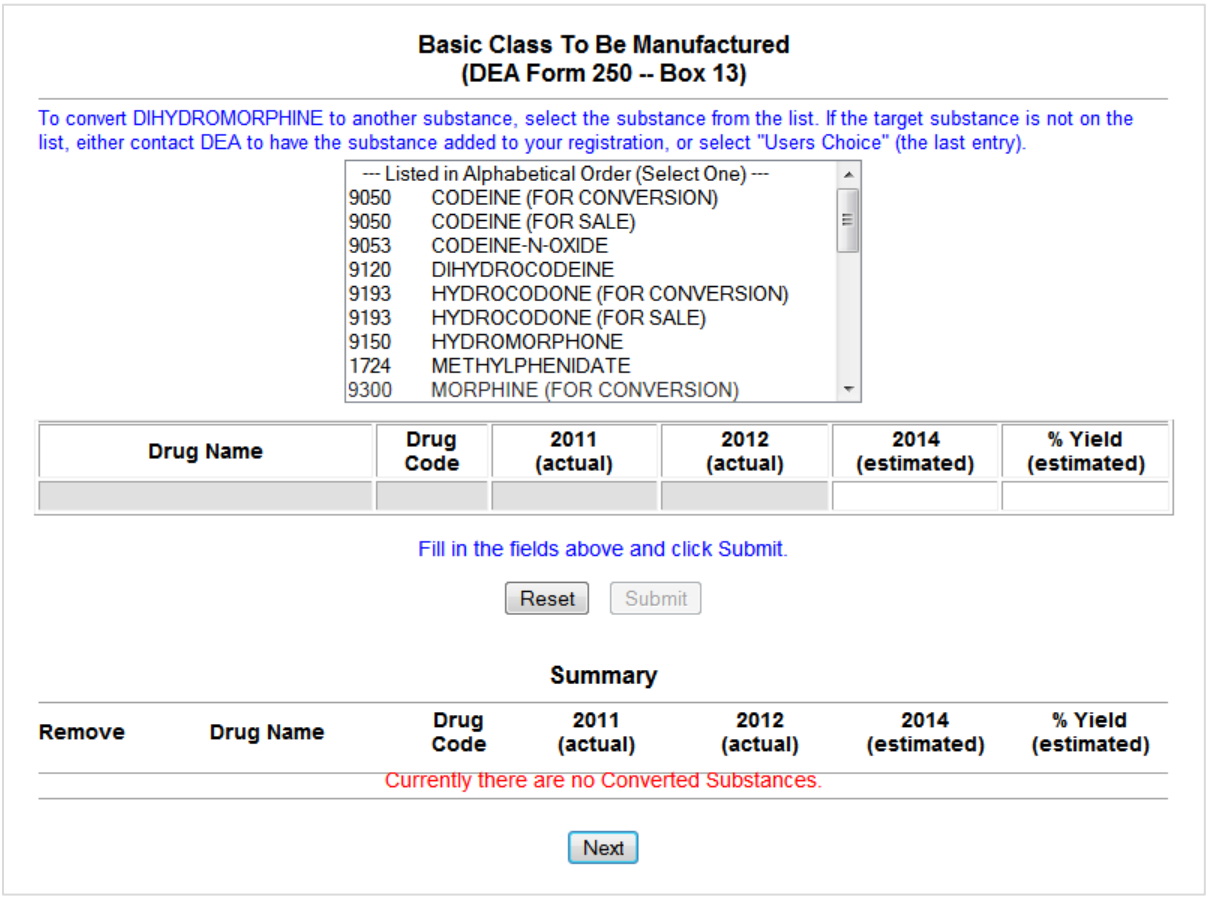


Figure 14: Converted Substances

Select a drug from the drop down menu.

Note that substances will only be listed if they can be products of the selected base substance.

Any selections will be added to the **Basic Class to be Manufactured** table. If User Choice is selected, the name of the drug must be manually entered into the **Drug Name** column.

Fill in the estimated year and percentage yield fields and click the Submit button. The information will be added to the **Summary** table.

To remove a drug from the **Summary** table, select the **Remove** radio button.

Click the Next button to return to the **Report Selection Menu** (see Figure 10).

3.2 Commercial Manufacturing (Dosage Form)

The **Commercial Manufacturing** sub-category form is only available for procurement manufacturers and importers. Filing the **Commercial Manufacturing** sub-category form is optional.

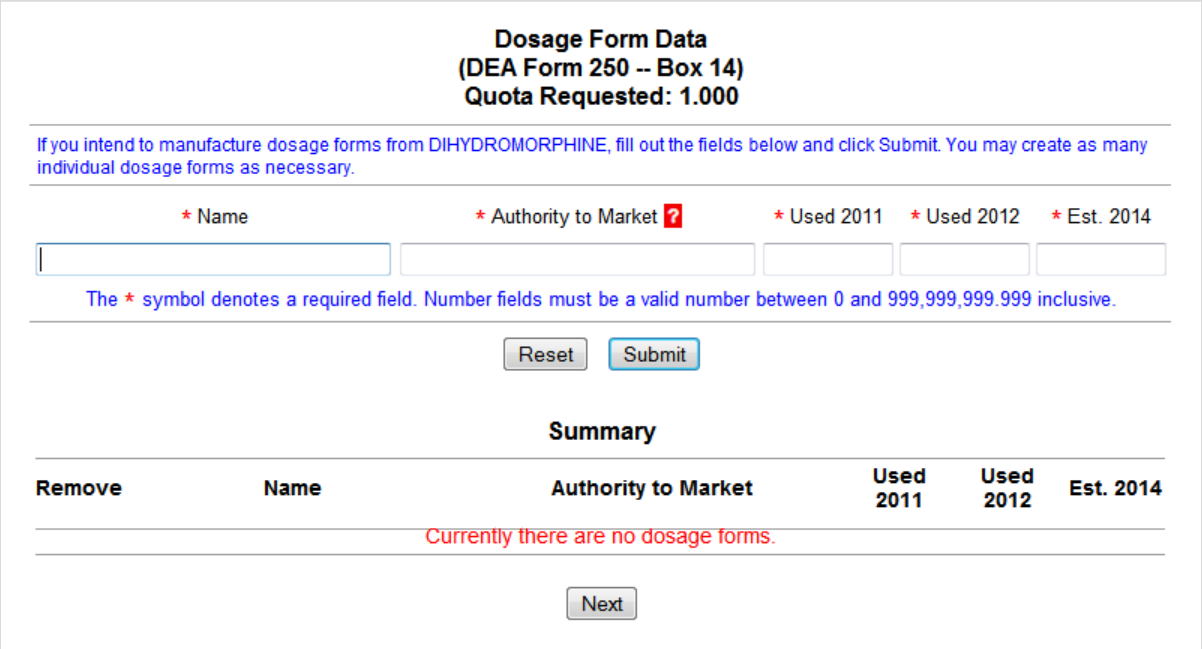


Figure 15: Commercial Manufacturing

Complete the following fields:

- **Name**: the name of the manufactured dosage form.
- **Authority to Market**: the authority with which the indicated dosage form is marketed. Click on a ? icon to display a popup with specific information about the request categories.
- **Used <2 years prior>**: the quantity used two (2) years prior to the current year.
- **Used <1 years prior>**: the quantity used one (1) year prior to the current year.
- **Est. <quota year>**: the estimated quantity to be used during the requested year.

Click the Submit button. The information will be added to the **Summary** table.

To remove a drug from the **Summary** table, select the **Remove** radio button.

Click the Next button to return to the **Report Selection Menu** (see Figure 10).

3.3 Product Development

The **Product Development** sub-category form is only available for those requesting procurement and manufacturer quotas. Filing the **Product Development** sub-category form is mandatory if the registrant placed a numerical value in the quota allotment by category (see Figure 7, page 6).

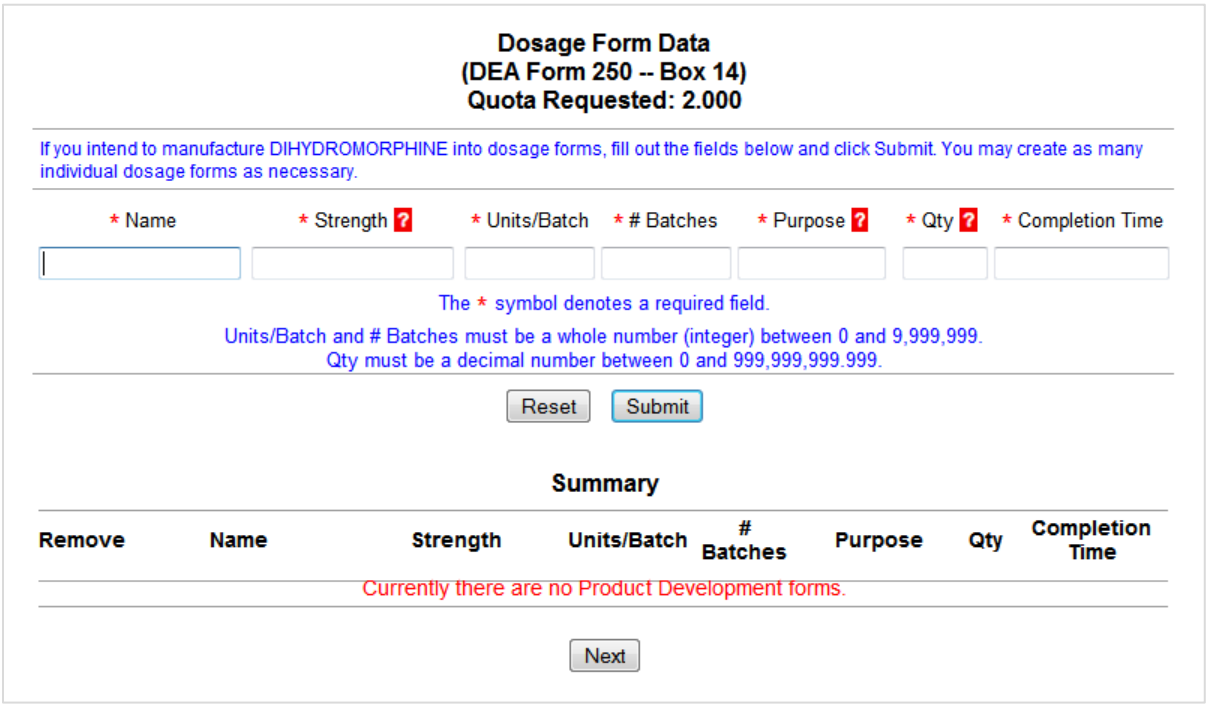


Figure 16: Product Development

Complete the following fields:

- **Name**: the name of the substance required for product development.
- **Strength**: the strength of the dosage required for product development. Click on a ? icon to display a tooltip with specific information about the request categories.
- **Units/Batch**: the number of units allotted per batch required for product development.
- **# Batches**: the number of batches of the substance required for product development.
- **Purpose**: the purpose of the substance's use in product development. Click on a ? icon to display a tooltip with specific information about the request categories.
- **Qty**: the total quantity expected to be utilized through product development. Click on a icon ? display a tooltip with specific information about the request categories.
- **Completion Time**: the time required to complete product development.

Click the Submit button. The information will be added to the **Summary** table.

To remove a drug from the **Summary** table, select the **Remove** radio button.

Click the Next button to return to the **Report Selection Menu** (see Figure 10).

3.4 Packaging/Labeling

The **Packaging** sub-category form is only available for those requesting procurement and manufacturer quotas. Filing the **Packaging** sub-category form is mandatory if the registrant placed a numerical value in the quota allotment by category (see Figure 7, page 6).

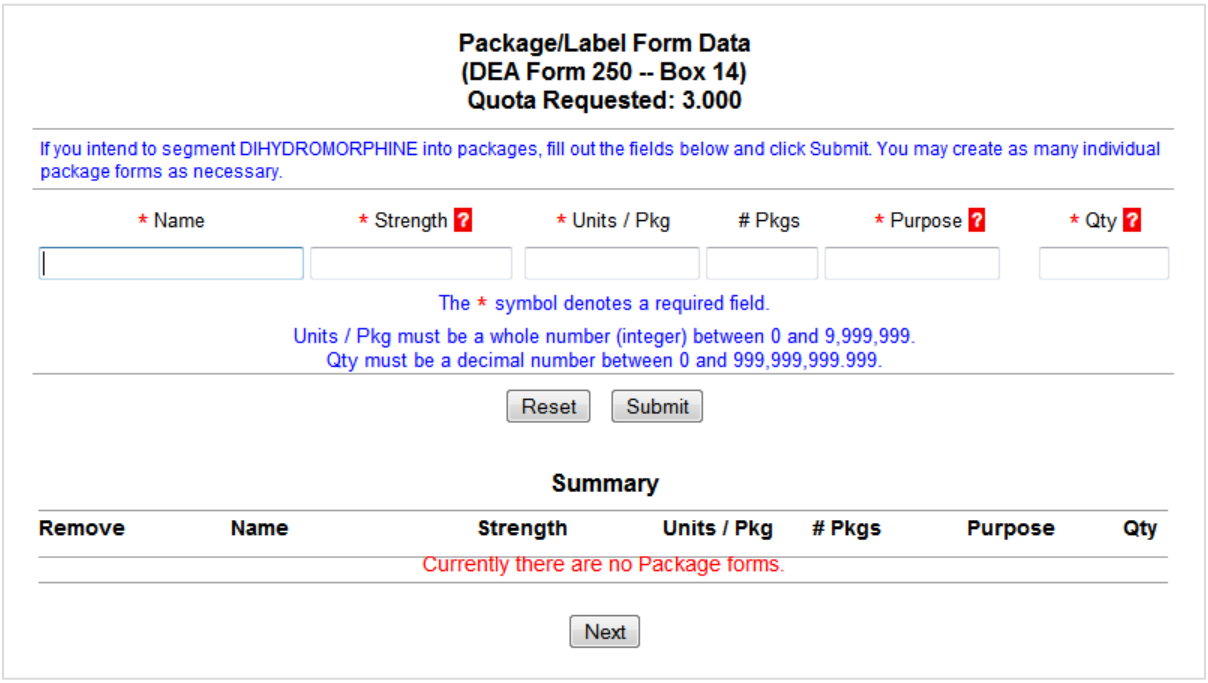


Figure 17: Packaging

Complete the following fields:

- **Name**: the name of the package into which the substance will be segmented.
- **Strength**: the strength of the packaged segments. Click on a ? icon to display a tooltip with specific information about the request categories.
- **Units/Pkg**: the number of units allotted per package.
- **# Pkgs**: the number of segments the package will comprise.
- **Purpose**: the purpose of segmenting the substance into packages. Click on a ? icon to display a tooltip with specific information about the request categories.
- **Qty**: the quantity of total packages required. Click on a ? icon to display a tooltip with specific information about the request categories.

Click the Submit button. The information will be added to the **Summary** table.

To remove a drug from the **Summary** table, select the **Remove** radio button.

Click the Next button to return to the **Report Selection Menu** (see Figure 10).

3.5 Replacement

The **Replacement** sub-category form is only available for those requesting procurement and manufacturer quotas. Filing the **Replacement** sub-category form is mandatory if a numerical value was typed in the quota allotment section (see Figure 7, page 11).

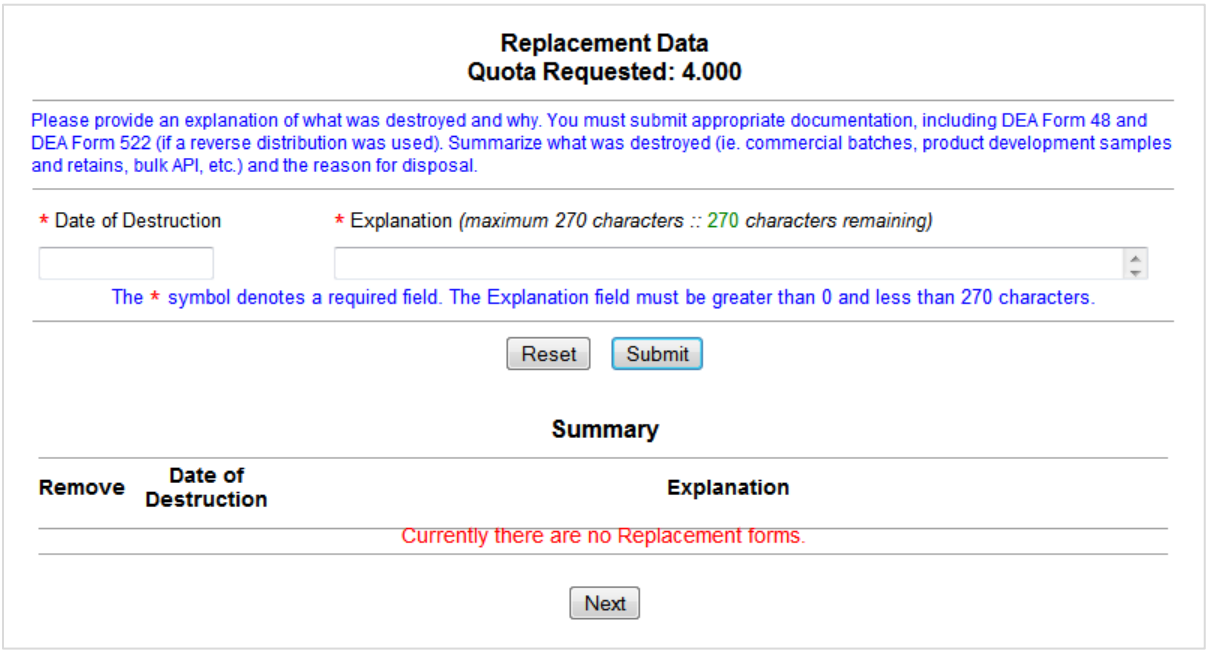


Figure 18: Replacement

Enter the following information:

- **Destruction Date**: the date the original substance was or will be destroyed. Click this field to display a calendar from which the date of destruction may be chosen.
- **Explanation**: the reason for the destruction of the original substance or chemical.

Click the Submit button. The information will be added to the **Summary** table.

To remove a drug from the **Summary** table, select the **Remove** radio button.

Click the Next button to return to the **Report Selection Menu** (see Figure 10).

3.6 Transfer

The **Transfer** sub-category form is only available for those requesting procurement and manufacturer quotas. Filing the **Transfer** sub-category form is mandatory if a numerical value was typed in to the quota allotment (see Figure 7, page 11).

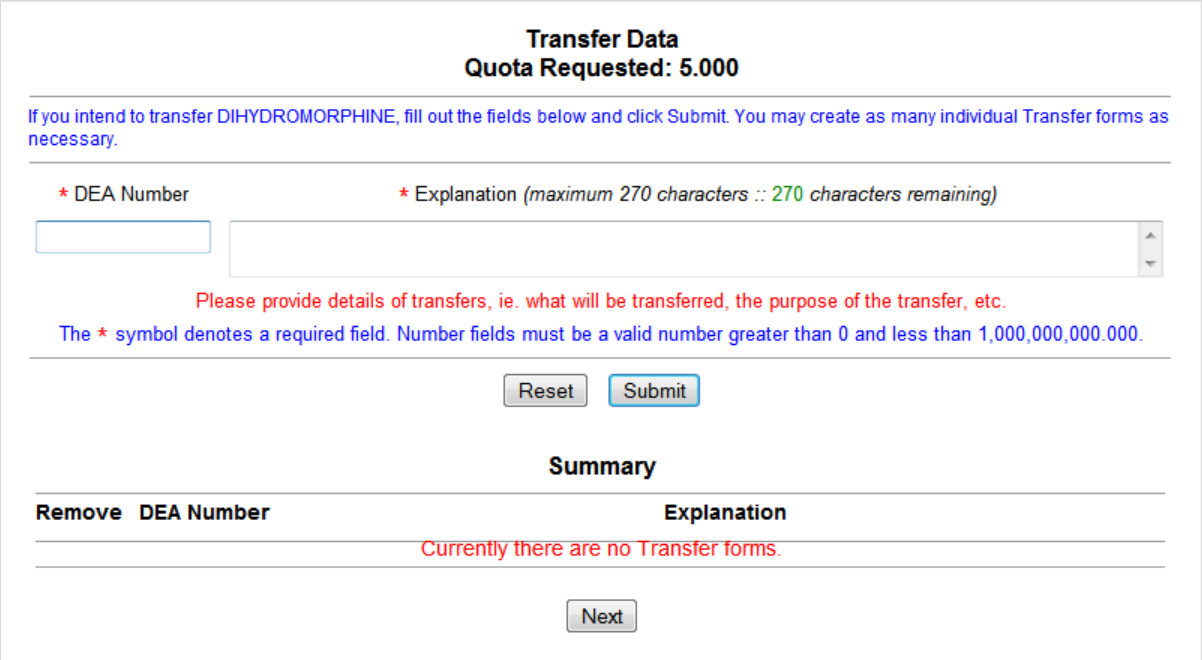


Figure 19: Transfer

Enter the DEA number of the manufacturer to whom the substance was transferred, as well as the reason for the transfer.

Click the Submit button. The information will be added to the **Summary** table.

To remove a drug from the **Summary** table, select the **Remove** radio button.

Click the Next button to return to the **Report Selection Menu** (see Figure 10).

3.7 Worksheet A

The **Worksheet A** sub-report form is only available for List I chemical importers. Filing the **Worksheet A** sub-report form is mandatory unless the form is submitted via email with the reference number of this request displayed in the subject line.

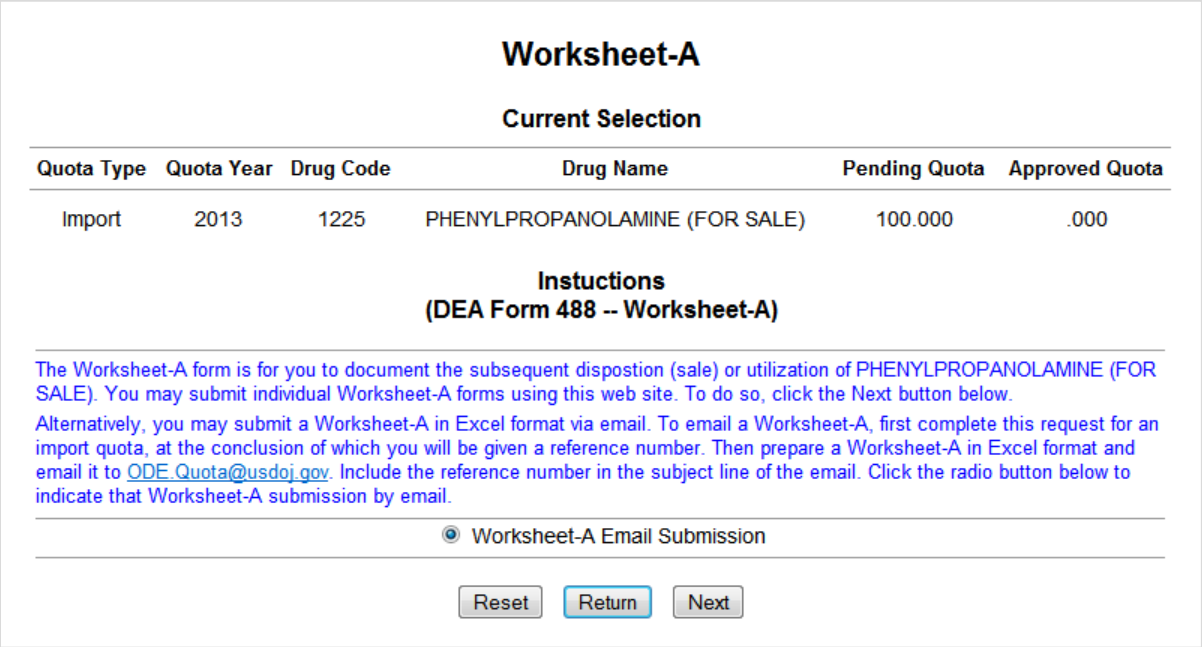


Figure 20: Worksheet-A Introduction

Click the Next button.

If the Worksheet-A Email Submission radio button has been selected, Quotas will return to the **Report Selection Menu** (Figure 10). Otherwise, Quotas will display **Worksheet-A** (Figure 21, next page).

If **Worksheet-A** appears, enter the following information:

- **DEA Number (if applicable)**: the registration number assigned by the DEA.
- **Name of Company**: the name of the company or manufacturer purchasing drugs from the importer.
- **Address**: the mailing address of the company or manufacturer listed above.
- **Phone**: the telephone number where the corporate user or administrator may be reached.
- **Fax**: the fax number where the corporate user or administrator may be reached.
- **Email**: the email address where the corporate user or administrator may be reached.
- **Contact Person**: the name of the designated representative of the company or manufacturer.
- **Quantity to be Sold (as grams of anhydrous base)**: the estimated quantity of chemicals expected to be sold to the listed company during the requested year.
- **Provide documentation for Quantity to be sold (purchase order, supply agreements, etc.)**: list details supporting the Quantity to be Sold estimate.

- **Intended Use**: select one of the three options provided. If "Other" is selected, provide an explanation for the intended use of the chemical.

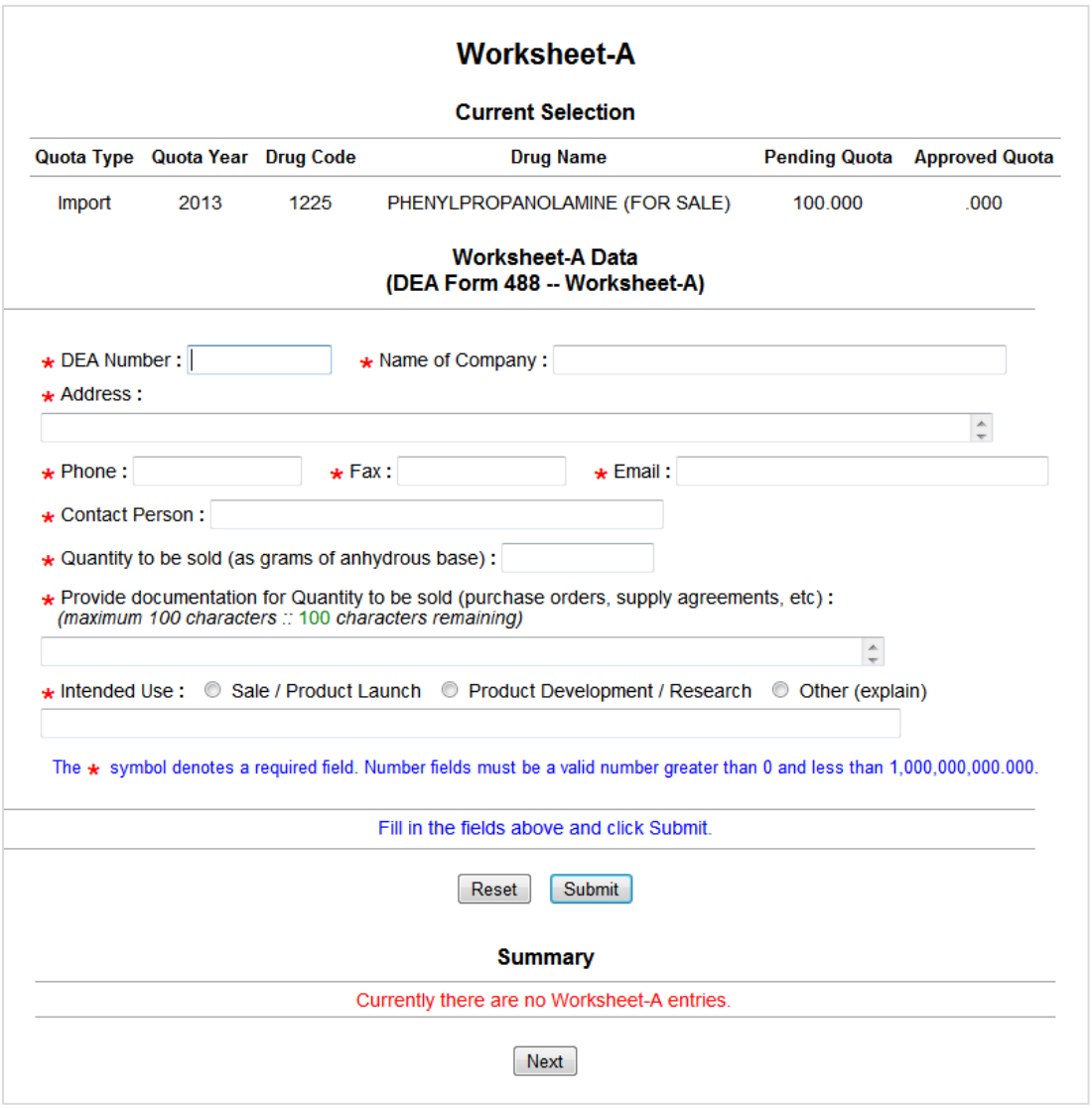


Figure 21: Worksheet A

When all fields have been completed, click the Submit button. Quotas will save the sub-report form and display a summary of the completed worksheet.

A worksheet may be removed from the **Summary** page by selecting the "Remove" radio button.

Click Next to return to return to the **Report Selection Menu** (see Figure 10, page 12).

Appendices

A.0 Glossary

Term	Definition
Acquisition	Acquiring any Schedule I or II controlled substance or CMEA List I chemical 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.
Aggregate Production Quota	The total quantity of a basic class of controlled substances listed in Schedule I or II necessary to be manufactured during the calendar year to provide for the estimated medical, scientific, research, and industrial needs of the US , for lawful export requirements, and the establishment and maintenance of reserve stock.
Annual Assessment of Needs	Total quantity of ephedrine, pseudoephedrine, and phenylpropanolamine, including products containing such, necessary to be manufactured and/ or imported during the calendar year to provide for the estimated medical, scientific, research, and industrial needs of the US, for lawful export requirements, and for the establishment and maintenance of reserve stocks.
Authority to Market	Approval number from the Food and Drug Administration demonstrating the ability to lawfully market specified dosage form(s) in the US .
Bulk Controlled Substances	Any controlled substance manufactured in bulk quantities.
Bulk Manufacturer	Manufacturers of Schedules I and II controlled substances whose production methods include extraction from plant material, propagation, or synthesis from other controlled or non-controlled substances or chemicals
Chemical Manufacturer	Manufacturers of CMEA List I chemicals who product ephedrine, pseudoephedrine, or phenylpropanolamine (PPA) from controlled or non-controlled substances or chemicals
CMEA List I Chemicals	Ephedrine, pseudoephedrine, PPA
Commercial Manufacturing	Production, compounding, or processing of a controlled substance for retail sale
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 (CSA). 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.
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

Term	Definition
	course of a calendar year.
Domestic	Any substance or chemical manufactured or produced within the United States.
Finished Dosage Forms	Substances or chemicals classified as having completed processing.
Import	Any bringing in or introduction of any article into either the jurisdiction of the United States or the customs territory of the united States, and from the jurisdiction of the United States into the customs territory of the United States (whether or not such bringing in or introduction constitutes an importation within the meaning of the tariff laws of the United States.
Importer	Every person who imports, or who acts as an import broker for importation of, controlled substances listed in a schedule and or/ listed chemicals.
Initial Quota Request	First quota request submitted for a calendar year
In-Process Material	Substances or chemicals classified as in process for conversion.
Inventory	All factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor.
Labeling	All labels and other written, printed, or graphic matter either placed upon any controlled substance or any of its commercial containers or wrappers of any controlled substance by any manufacturer of such substance or accompanying such controlled substance.
Listed Chemical	Any chemical specifically designated by the Administrator that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the CSA and is important to the manufacture of a controlled substance; and any chemical other than that described above specifically designated by the Administrator that, in addition to the legitimate uses, is used in manufacturing a controlled substance in violation of the CSA.
Manufacturer	A person who manufacturers a drug or other substance, whether under registration as a manufacturer or under authority of registration as a researcher or chemical analyst.
Password	The unique identifying set of characters comprised of alphanumerical and special characters used to access an account. User passwords are provided by the corporate administrator.
Pending	A quota request that has been submitted, but has not yet been approved.
Procurement	The act of obtaining a controlled substance for the purpose of producing reference standards, exempt preparations, dosage forms or manufacturing another

Term	Definition
	controlled substance.
Product Development	Manufacturing of dosage forms for testing, FDA approval, clinical trials
Quota Revision Request	Any submitted request that occurs after the initial quota request for the calendar year has been submitted and/or granted.
Quota Type	Bulk manufacturing, procurement, or importation
Quota Year	Calendar year for which the requested and/or granted quota is valid
Reference Number	Unique identification number generated when a request is submitted
Strength	The dosage of controlled substance per unit
Substance Conversion	The process by which two (2) or more controlled substances and/or listed chemicals are combined to manufacture a different substance. The new substance may or may not be itself subject to control by the DEA.
Supporting Document	A document submitted in support of a quota application.
Username	The user account name used to differentiate between one user account and another, provided by the corporate administrator.

B.0 Acronyms

Acronym	Definition
AAN	Assessment of Annual Needs
API	Active Pharmaceutical Ingredient
APQ	Aggregate Production Quota
CMEA	Combat Methamphetamine Epidemic Act
CSA	Controlled Substances Act
DEA	Drug Enforcement Administration
DRQ	UN Reporting and Quota Section
PDF	Portable Document Format
US	United States