Pharmaceutical Training Seminar – 2016
Online Quota Applications

UN Reporting and Quota Section
ODEquota@dea.usdoj.gov
(202) 307-7184

Why the Switch from Paper?

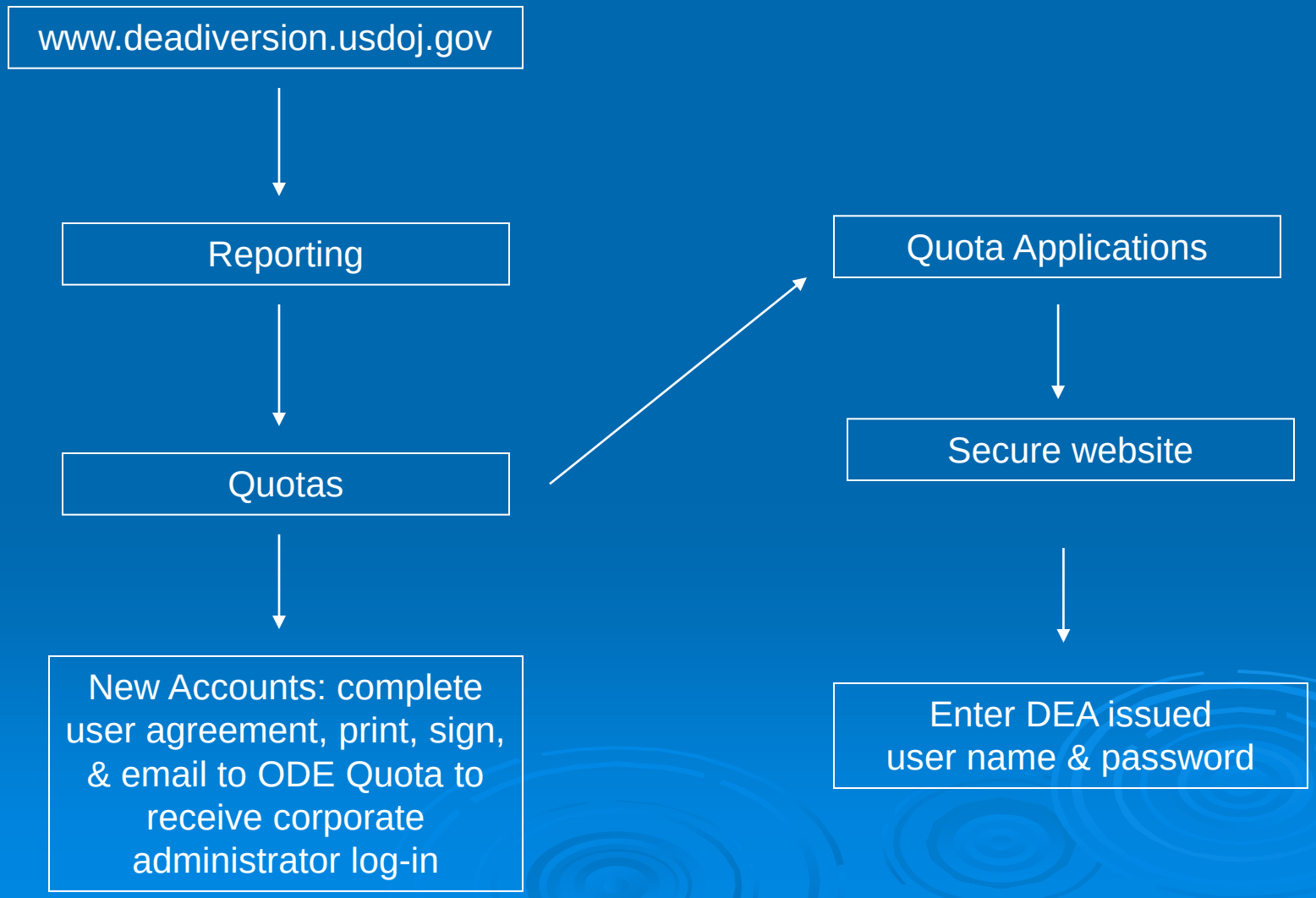
- OMB requested we go paperless by 2013

- 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 receipt and status
  - Expedites process

21 CFR 1303 & 1315 Compliance

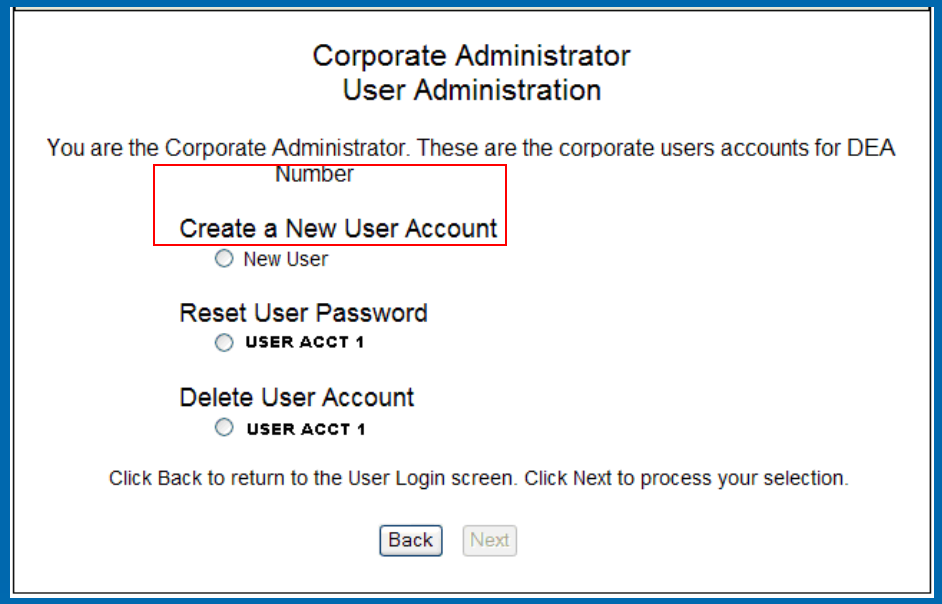
- Procurement applications due by April 1
- Import applications due by April 1
- Manufacturing applications due by May 1
- Adjustments to any quota can be requested throughout the year
- Quantities should expressed as:
  - Anhydrous acid, base or alkaloid
  - GRAMS

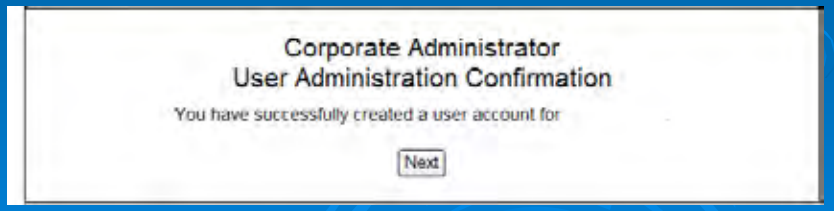
Accessing Quota Applications



Corporate Administrator Login

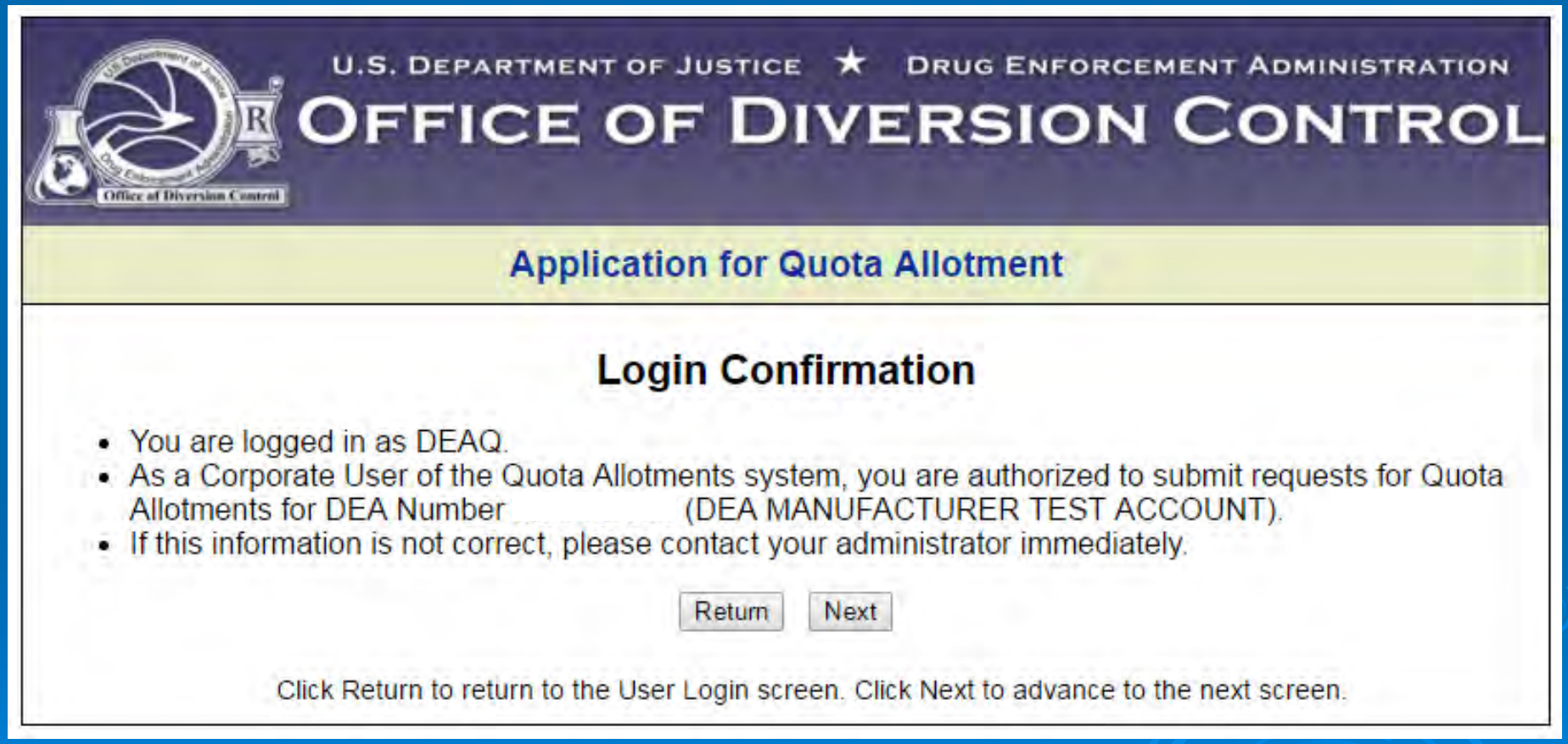
Create New Corporate User Account





Corporate User Login

Corporate User Login Confirmation



Report Selection Menu

‘71 Convention Compliance

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

Online Quota Application

"For Sale" vs. "For Conversion"

- Codeine
- D-Amphetamine
- D-Methamphetamine
- Diphenoxylate
- Hydrocodone
- Morphine
- Noroxymorphone
- Oxycodone
- Oxymorphone

Online Quota Application

For Sale: substance used to manufacture products containing same basic class which is bought from the bulk manufacturer.

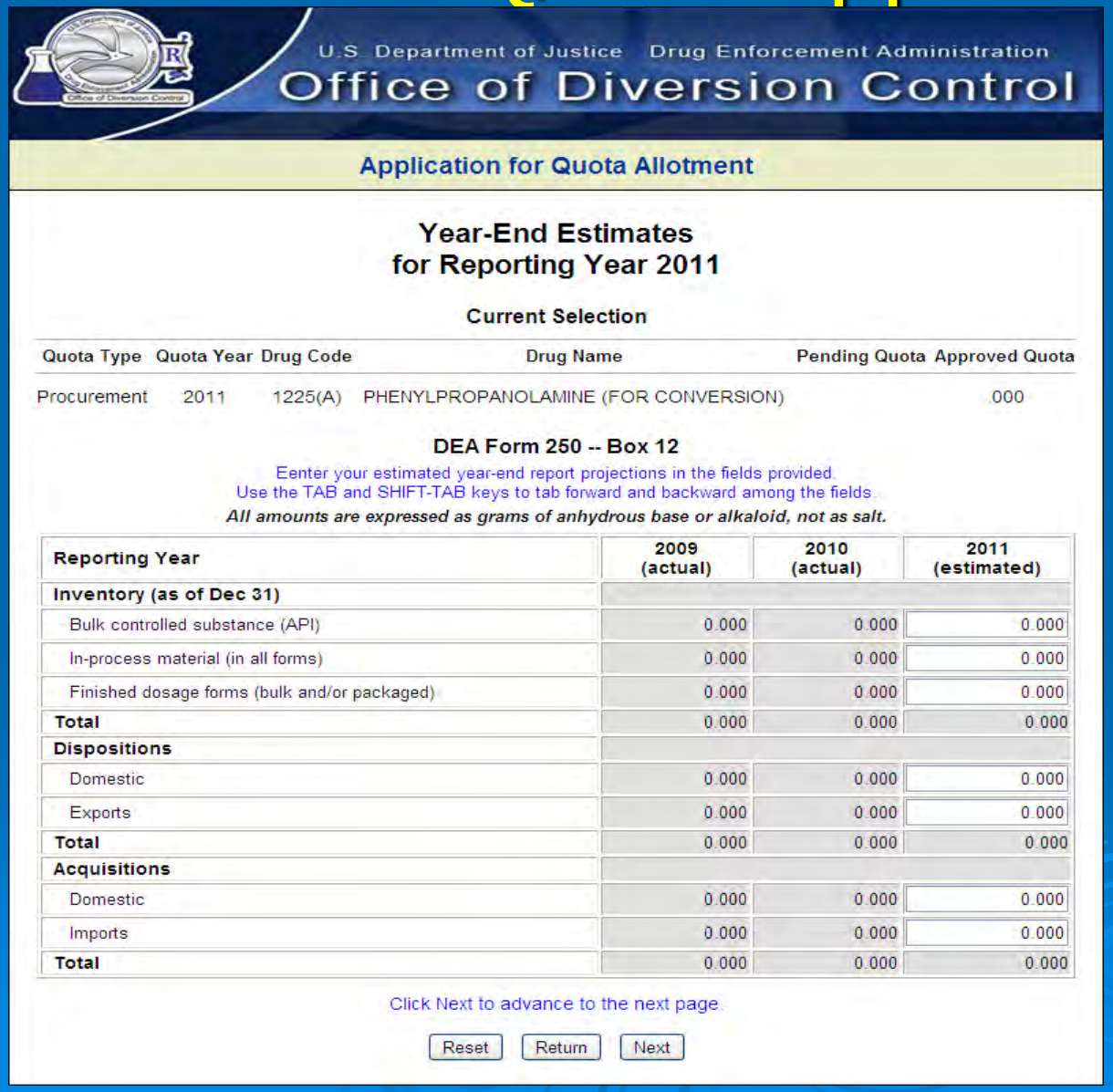
- involves ~95% of the quota applications

ex: Codeine (for sale) ⟶ codeine/APAP

For Conversion: substance used to synthesize a different basic class.

ex: Codeine (for conversion) ⟶ hydrocodone

Procurement Quota Application



U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

Application for Quota Allotment

Year-End Estimates for Reporting Year 2011

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2011	1225(A)	PHENYLPROPANOLAMINE (FOR CONVERSION)		000

DEA Form 250 -- Box 12

Eenter 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	2009 (actual)	2010 (actual)	2011 (estimated)
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.

Reset Return Next

Quota Allotment Categories

U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

Application for Quota Allotment

Quota Request for Reporting Year 2011

Current Selection

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

Quota History (DEA Form 250 -- Box 11)

Enter the *total* value for your quota allotment request in the field provided.

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

--- History (Approved) ---			--- Current Request ---
2008	2009	2010	2011
0.000	0.000	0.000	

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 total quota request.
Use the TAB and SHIFT-TAB keys to tab forward and backward among the fields.

Commercial Manufacturing :
Product Developement :
Packaging :
Replacement :
Transfer :
Total :

Click Next to advance to the next page.

Reset Back Next

Quota Allotment Categories

- Commercial Manufacturing
  - Conversion to other substances
  - Dosage form
- Product Development
  - All stages leading to FDA approval
    - Laboratory scale
    - Scale up
    - Exhibit
    - Stability

Quota Allotment Categories

- Packaging
  - Packaging/Repackaging
  - Labeling/Relabeling
- Replacement
  - Case-by-case basis for commercial mfg
- Transfer
  - Bulk API
  - In-process material
  - Finished dosage units

Quota Allotment Categories

U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

Application for Quota Allotment

Report Selection Menu

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2011	1225	PHENYLPROPANOLAMINE (FOR CONVERSION)	2,513.000	.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	Current Request	Report Link
Optional		Commercial Manufacturing Converted Substances (DEA Form 250 -- Box 13)
Optional	894.000	Commercial Manufacturing Dosage Forms (DEA Form 250 -- Box 14)
Required	984.000	Product Development (DEA Form 250 -- Box 14)
Required	543.000	Packaging (DEA Form 250 -- Box 14)
Required	151.000	Replacement
Required	484.000	Transfer

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

Back Next

Commercial – Conversions

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

To convert PHENYLPROPANOLAMINE (FOR CONVERSION) to another substance, select the substance from the list. If the target substances is not in 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) ---

Drug Name	Drug Code	2009 (actual)	2010 (actual)	2011 (estimated)	% Yield (estimated)

Fill in the fields above and click Submit.

Reset Submit

Summary

Remove	Drug Name	Drug Code	2009 (actual)	2010 (actual)	2011 (estimated)	% Yield (estimated)
○	Vraxoin	0000	.000	.000	2,524.002	252.24

To remove an entry, click the Remove radio button.

Next

Commercial - Dosage Forms

Dosage Form Data
(DEA Form 250 -- Box 14)
Quota Requested: 894.000

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

* Name	* Mkt Auth	* Used 2009	* Used 2010	* Est. 2011

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

Reset Submit

Summary

Remove	Name	Mkt Auth	Used 2009	Used 2010	Est. 2011
○	Traylopanifaphryn	Department of Agriculture	5121	1321	1231

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

Next

Product Development

Dosage Form Data
(DEA Form 250 -- Box 14)
Quota Requested: 984.000

If you intend to manufacture PHENYLPROPANOLAMINE (FOR CONVERSION) 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

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

Reset Submit

Summary

Remove	Name	Strength	Units/Batch	# Batches	Purpose	Qty	Completion Time
○	Calafrin	23 gm	125	521	Nausea	132	2 months

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

Next

Labeling & Packaging

Package Form Data
(DEA Form 250 -- Box 14)
Quota Requested: 543.000

If you intend to segment PSEUDOEPHEDRINE (FOR CONVERSION) 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

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

Reset Submit

Summary

Remove	Name	Strength	Units / Pkg	# Pkgs	Purpose	Qty
○	Protaxis	121	35	56	Resale	251

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

Next

Replacement

Replacement Data
Quota Requested: 151.000

If you intend to request Replacment quota for PHENYLPROPANOLAMINE (FOR CONVERSION), fill out the fields below and click Submit.

* Destruction Date

* Explanation

Please provide an explanation of what was destroyed and why. You must submit appropriate documentation including DEA Form 41 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.

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

Reset Submit

Summary

Remove	Destruction Date	Explanation
◉	Jan 21, 2011	Batch became contaminated.

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

Next

Transfer

Transfer Data
Quota Requested: 151.000

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

* DEA Number

* Explanation

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 between 0 and 999,999,999.999 inclusive.

Reset Submit

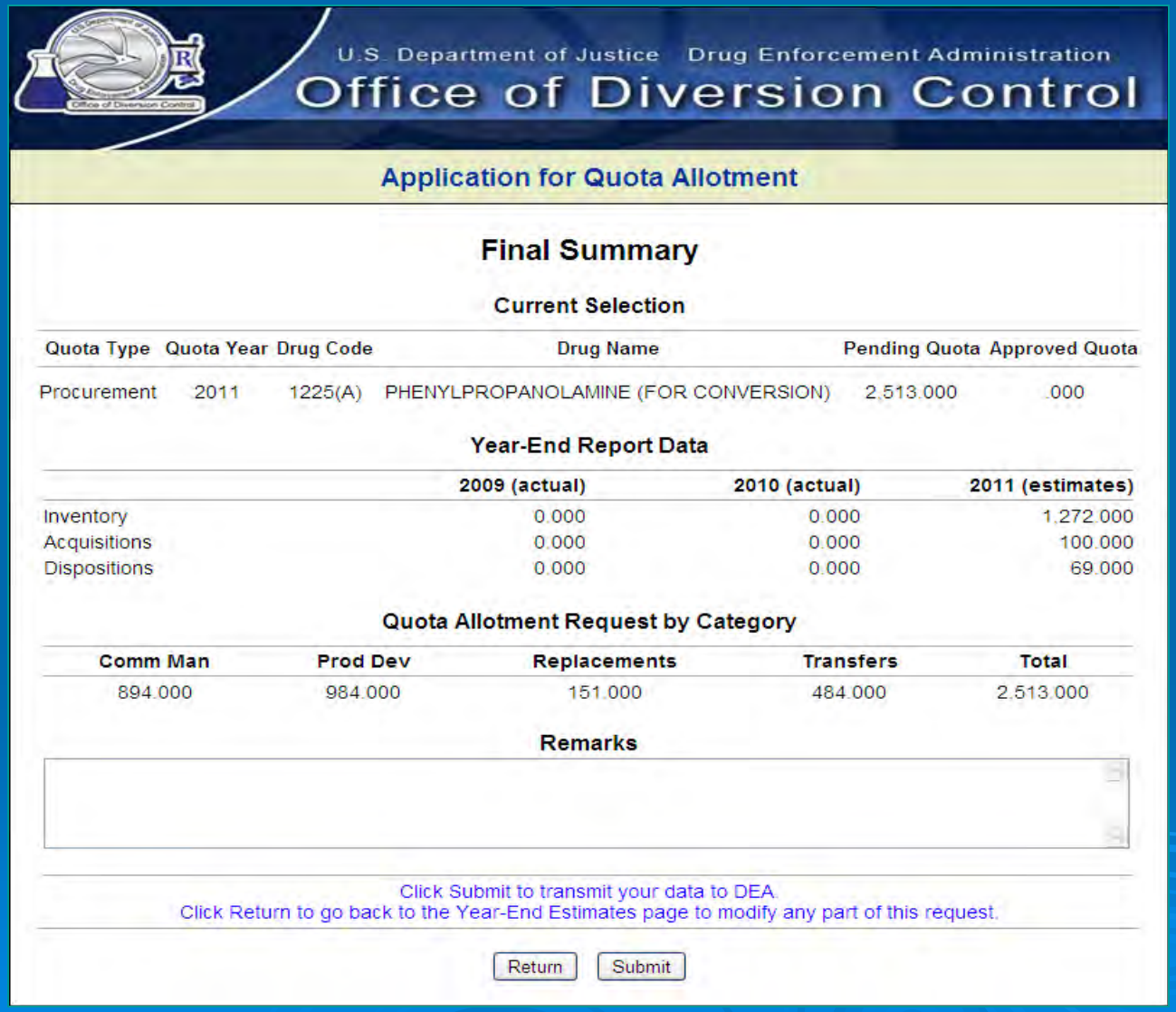
Summary

Remove	DEA Number	Explanation
○	RL0401187	Required the further analysis of product in outside independent study.

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

Next

Summary



U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

Application for Quota Allotment

Final Summary

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2011	1225(A)	PHENYLPROPANOLAMINE (FOR CONVERSION)	2,513.000	.000

Year-End Report Data

	2009 (actual)	2010 (actual)	2011 (estimates)
Inventory	0.000	0.000	1,272.000
Acquisitions	0.000	0.000	100.000
Dispositions	0.000	0.000	69.000

Quota Allotment Request by Category

Comm Man	Prod Dev	Replacements	Transfers	Total
894.000	984.000	151.000	484.000	2,513.000

Remarks

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

Return Submit

Summary

U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

Application for Quota Allotment

Summary Confirmation

Current Selection

Quota Type	Quota Year	Drug Code	Drug Name	Pending Quota	Approved Quota
Procurement	2011	1225(A)	PHENYLPROPANOLAMINE (FOR CONVERSION)	2,513.000	.000

Confirmation

You have successfully submitted a Quota Allotment Request for the substance noted above. Your reference number is:

108035

You may contact DEA via email at ODE.Quota@USDOJ.gov concerning this transaction. Be sure to include the reference number in the subject line of all such correspondence.

If you find a need to amend this request, you may do so by selecting this same substance from the Main Selection Menu. At that time all data entry fields will be pre-populated with values from your latest request.

Printing Options

You are required by law to retain a copy of this Request for Quota Allotment for a period of seven years after the date of the initial request. Click the Print button below and you will be able to print or archive the resultant PDF report.

Print

Return Exit

Status Report

U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

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	2011	Mar 2, 2011	1225	PHENYLPROPANOLAMINE (FOR CONVERSION)	2,513.000	Pending	108035
PRO	2011	Mar 30, 2011	1225	PHENYLPROPANOLAMINE (FOR CONVERSION)	2,513.000	Pending	108166
PRO	2011	Mar 4, 2011	1225	PHENYLPROPANOLAMINE (FOR SALE)	4,410.000	Pending	108076
PRO	2011	Mar 4, 2011	8112	PSEUDOEPHEDRINE (FOR CONVERSION)	5,545.000	Pending	108074

Back Print

Quota Amendments

U.S. Department of Justice Drug Enforcement Administration

Office of Diversion Control

Application for Quota Allotment

Quota Request Amendment

Notice

You have previously filed a quota allotment request for the substance noted above. The request was filed on Mar 02, 2011 in the amount of 585.000 grams. The Reference Number is 108019.

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	2011	8113(B)	EPHEDRINE (FOR SALE)	585.000	.000

Back Next

List 1 Import quota

List 1 Import quota

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)

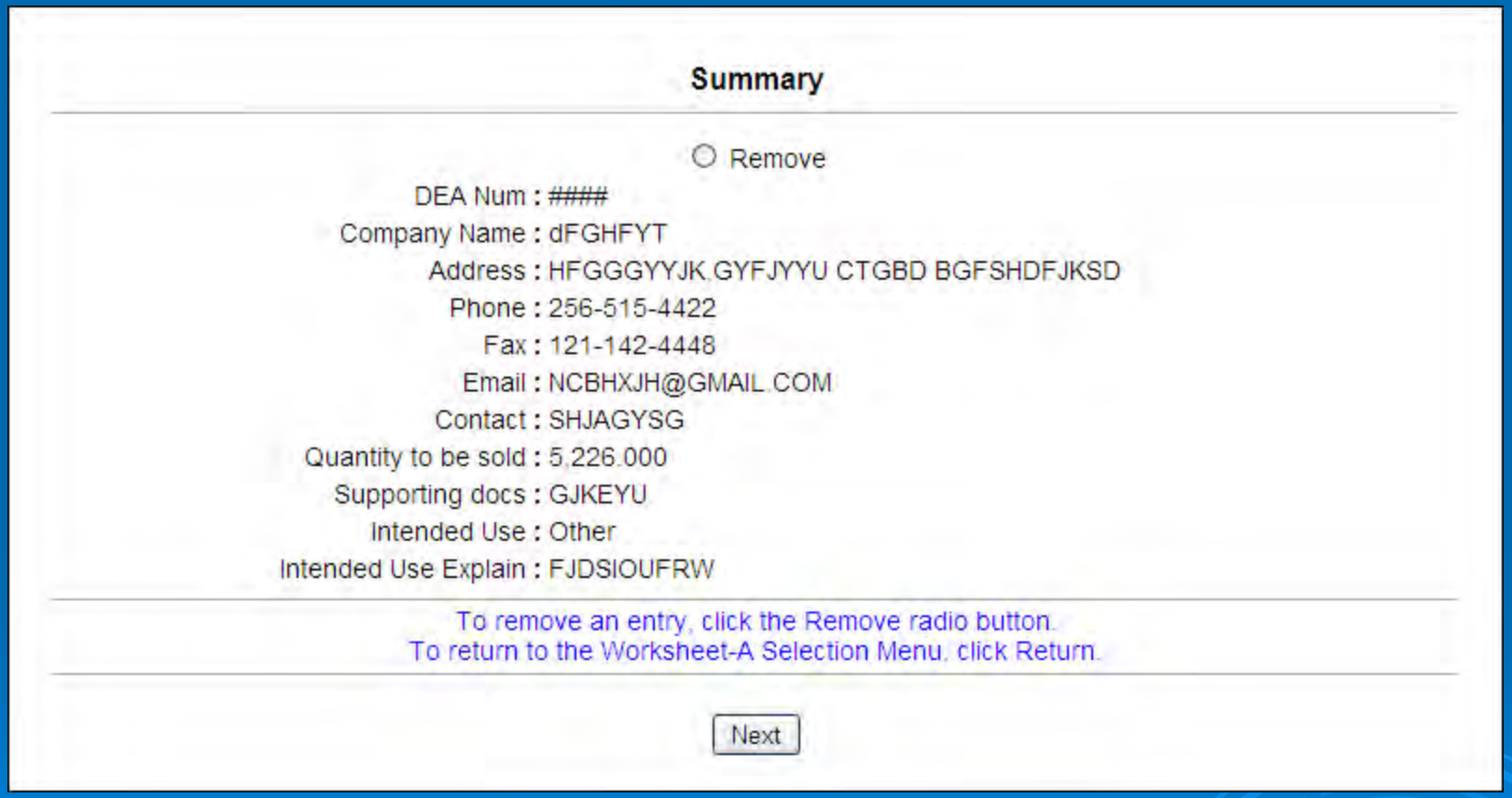
* DEA Number :
* Name of Comapany :
* Address :
* Phone :
* Fax :
* Email :
* Contact Person :
* Quantity to be sold (as grams of anhydrous base) :
* Provide documentation for Quantity to be sold (purchase orders, supply agreements, etc) :
* Intended Use : ○ Sale / Product Launch ○ Product Development / 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

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

Questions?

UN Reporting and Quota Section
ODEquota@dea.usdoj.gov
(202) 307-7184