To: Cc: Boockholdt, Barbara J. (B)(6)(b)(7)(C) Subject: Quota Increase Request Received on February 12, 2014  Importance: High  Bi(b)(6)(b)(7)(C) Chris, On Wednesday, February 12, 2014 this section ODGR received your request to review one (1) quota increase application from Manufacturer KVK Tech (B)(4)(b)(7)(E) who distribute to (B)(4) registered distributors, manufacturers, and mail order pharmacies, to determine if there are any pending administrative/legal actions against this applicant and to advise ODQ of the findings.  ODGR conducted reviews (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input and recommendation on KVK Tech, Inc. Provided below are the results and recommendations.  QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION  KVK Tech, Inc.  (b)(4)(b)(7)(E)  Based on the above findings, it is recommended that the increased amounts be reviewed to determine if they are warranted.	(b)(6);(b)(7)(C)	
On Wednesday, February 12, 2014 this section ODGR received your request to review one (1) quota increase application from Manufacturer KVK Tech (D)(4),(D)(7)(E) who distribute to (D)(4) registered distributors, manufacturers, and mail order pharmacies, to determine if there are any pending administrative/legal actions against this applicant and to advise ODQ of the findings.  ODGR conducted reviews (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input and recommendation on KVK Tech, Inc. Provided below are the results and recommendations.  QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION  KVK Tech, Inc.  (b)(4);(b)(7)(E)  Based on the above	To: Cc:	Boockholdt, Barbara J. (b)(6);(b)(7)(C)
On Wednesday, February 12, 2014 this section ODGR received your request to review one (1) quota increase application from Manufacturer KVK Tech (b)(4)(b)(7)(E) who distribute to (b)(4) registered distributors, manufacturers, and mail order pharmacies, to determine if there are any pending administrative/legal actions against this applicant and to advise ODQ of the findings.  ODGR conducted reviews (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input and recommendation on KVK Tech, Inc. Provided below are the results and recommendations.  QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION  KVK Tech, Inc.  (b)(4);(b)(7)(E)  Based on the above	Importance:	High
application from Manufacturer KVK Tech (b)(4),(b)(7)(E) who distribute to (b)(4) registered distributors, manufacturers, and mail order pharmacies, to determine if there are any pending administrative/legal actions against this applicant and to advise ODQ of the findings.  ODGR conducted reviews (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input and recommendation on KVK Tech, Inc. Provided below are the results and recommendations.  QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION  KVK Tech, Inc.  (b)(4),(b)(7)(E)  Based on the above	<sup>3);(b)(7)(</sup> Chris,	
and recommendation on KVK Tech, Inc. Provided below are the results and recommendations.  QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION  KVK Tech, Inc.  (b)(4);(b)(7)(E)  Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for KVK Tech, Inc.  (b)(4);(b)(7)(E)  Based on the above	application from Man registered distributors	nufacturer KVK Tech (b)(4);(b)(7)(E) who distribute to (b)(4) s, manufacturers, and mail order pharmacies, to determine if there are any pending
KVK Tech, Inc.    Discrete   Description		
Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for KVK  Tech, Inc.  (b)(4);(b)(7)(E)  Based on the above	QUOTA APPLICA:	NT WITH NO ADVERSE OR DEROGATORY INFORMATION
Tech, Inc.  (b)(4);(b)(7)(E)  Based on the above	KVK Tech, Inc.	(b)(4);(b)(7)(E)
(b)(4);(b)(7)(E)  Based on the above		the field offices, DEA does not have sufficient grounds to deny a quota increase for KVK
findings, it is recommended that the increased amounts be reviewed to determine if they are warranted.		Based on the above
b)(4);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)		

(b)(4);(b)(5);(b)(7)(E)
On February 12, 2014, Program Analyst (PA) emailed Group Supervisor (GS) (b)(6);(b)(7)(C);(b)(7)(F)
Philadelphia Field Division who responded that there are no investigative actions pending that would prevent
KVK Tech, Inc. from receiving an increase in quota for Oxycodone.
(b)(4);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)
N-W-W-W-W-W-W-W-W-W-W
The Control Sheet will be returned to ODQ, with copies of PA (c) findings. Based on this information,
ODG suggests that the increased quota be reviewed, and possibly reduced (b)(4);(b)(7)(E)
Based on the fields response, you can proceed with the completion or denial of the increase quota request.

(b)(6);(b)(7)(C)

## Frogram Analyst/ODGR

Regulatory Unit



(b)(6);(b)(7)(C)

@usdoj.gov

(b)(6);(b)(7)(C)		
From: Sent: To: Cc: Subject:	(b)(6);(b)(7)(C)  Wednesday, February (b)(6);(b)(7)(C);(b)(7)(F)  FW: 2014 Procureme	nt Quota INCREASE (for Oxycodone) for KVK Tech (b)(4);(b)(7)(E)
Importance:	High	(b)(4);(b)(6);(b)(7)(C);( b)(7)(E);(b)(7)(F)
	nt has no pending, active or or ation if necessary. Thank you.	please contact  (b)(6);(b) (7)(C)
(b)(6);(b)(7)(C)  Registration Program Spong Enforcement Admir Phone: (b)(6);(b)(7)(C)  Fax: (b)(6);(b)(7)(C)		
From: (b)(6),(b)(7)(C),(b)(7)(F)  Sent: Wednesday, Febru  To: (b)(6),(b)(7)(C)  Subject: Fw: 2014 Proc  Importance: High	Jary 12, 2014 5:12 PM	Oxycodone) for KVK Tech (b)(4);(b)(7)(E)
Please take Care of this.	Thanks.	
From: (b)(6);(b)(7)(C)  Sent: Wednesday, Febru  To: (b)(6);(b)(7)(C);(b)(7)(F)  Subject: 2014 Procurent	, ·	codone) for KVK Tech (b)(4);(b)(7)(E)
Good Afternoo	n (b)(6);(b)(7)(C);(b)(7)(F)	
	T allow us to issue a 2014 P	y pending, active, or ongoing investigations in your division rocurement Quota INCREASE (for Oxycodone) to the
VVV Tooh	(b)(4);(b)(7)(E)	

SINCE THE FRONT OFFICE HAS GIVEN US A FIVE (5) DAY TURN AROUND ON QUOTAS, A QUICK RESPONSE WOULD BE GREATLY APPRECIATED.

Thank you for your assistance in this matter.

(b)(6);(b)(7)(C)

## Frogram Analyst/VDGR Regulatory Unit



(b)(6);(b)(7)(C)

@usdoj.gov



Subject Date

KVK Tech (b)(4);(b)(7)(E)

201 Procurement Quota Increase Request

Oxycodone

(DFN: 630-08.2)

FEB 1 2 2014

ſο

Barbara Boockholdt

Chief

Regulatory Section

Office of Diversion Control

romy

Christine A. Sannyrug, Ph.I

Chief

UN Reporting and Quota Section Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2014 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when revising the applicant's quota allocation for oxycodone.

Folder ID: 131411

Reg No:

(b)(7)(E)

Author: Ms (b)(6),(b)(7)(C)

Addressed To:

ODĒ

Location:

ODEQ

Due:

02/22/2014

Received:

2/12/2014

Date Sent:

Security:

A-AES

Response:

Abstract:

KVK-Tech 2014 procurement quota increase request oxycodone (b)(4);(b)(7)(E)

Signature:

C. Sannerud

Doc Categories:

Doc Types:

(b)(6);(b)(7)(C)

ODG

02/19/2014

Action:

Recommendation and Comments

Requested Activity: Response Notes:

(b)(6);(b)(7)(C)	
To: Cc: Subject:	Sannerud, Christine A.  Boockholdt, Barbara J.; (b)(6); (b)(7)(C)  2014 Procurement Quota Increase (Hydrocodone) Request for - Vintage Pharma (b)(4); (b)(7)(E)
Hello (b)(6);(b) (Chris	
application from Vintage distributors, manufacture	9, 2014 this section ODGR received your request to review one (1) quota increase Pharma (b)(4);(b)(7)(E) who distributes to (b)(4) registered er, and retails pharmacies, to determine if there are any pending administrative/legal cant and to advise ODQ of the findings.
	ew (NADDIS, CSA, etc.), as well as surveyed the responsible field office for their input Provided below are the results and recommendations.
QUOTA APPLICANT	WITH NO ADVERSE OR DEROGATORY INFORMATION
Vintage Pharma (b)(4);(b)(7)	(E)
Per consultation with the Vintage Pharma.	field offices, DEA does not have sufficient grounds to deny a quota increase for
	(b)(4);(b)(7)(E)  Based on the
(b)(4);(b)(6);(b)(7)(C);(b)(7)(E	mmended that the increased amounts be reviewed to determine if they are warranted.

(b)(4);(b)(5);(b)(6);(b)(7)(	C);(b)(7)(E);(b)(7)(F)
On March 26, 2014,	Program Analyst (PA) emailed DI (b)(6);(b)(7)(C);(b)(1)(C) of the Birmingham
District Office who re	esponded that there are no investigative actions pending that would prevent from receiving
an increase in quota f	for Hydrocodone. (b)(4);(b)(7)(E)
	(0)(4),(0)(1)(2)
The Control Sheet wi	ill be returned to ODQ, with copies of PA <sub>C</sub> findings. Based on this information,
ODG suggests that th	the increased quota be reviewed, and possibly reduced (b)(4);(b)(7)(E)
Based on the fields re	esponse, you can proceed with the completion or denial of the increase quota request.
(b)(6);(b)(7)(C)	
Irogram Analy	st/ODGR
Regulatory Uni	$oldsymbol{t}$
(b)(6);(b)(7)(C)	
18 Ceparonent de	
US Cepartment of	
EMorcoment !	
	- -
(b)(6);(b)(7)(C)	@usdoj.gov



Subject

Vintage Pharma (b)(4);(b)(7)(E)

2014 Procurement Quota Increase Request

Hydrocodone (DFN: 630-08.2)

Date

MAR 1 8 2013

To

Barbara Boockholdt

Chief

Regulatory Section

Office of Diversion Control

From

Christine A. Sannerud, Ph.D.

Chief

UN Reporting and Quota Section

Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of hydrocodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2014 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when revising the applicant's quota allocation for hydrocodone.

(b)(6);(b)(7)(C)

### SBF-CM **Folder Details**

Folder ID: 131887

Reg No:

(b)(7)(E)

Author: Ms. (b)(6);(b)(7)(C)

Addressed To:

ODE

Location:

ODEQ

Due:

03/28/2014

Received:

3/18/2014

**Date Sent:** 

Security:

A-AES

Response:

Abstract:

Vintage Pharma (b)(4);(b)(7)(E)

2014 Procurement Quota Increase Request for hydrocodone

Signature:

(b)(6);(b)(7)(C)

Doc Categories:

Doc Types:

(b)(6);(b)(7)(C)

**ODG** 

03/25/2014

Action:

Recommendation and Comments

Requested Activity: **Response Notes:** 

(b)(6);(b)(7)(C)	
To: Cc: Subject:	(b)(6);(b)(7)(C)  Sannerud, Christine A.  Boockholdt, Barbara J.; (b)(6);(b)(7)(C)  Procurement Quota Increase Request dated 4/9/2014 for Vintage Pharmaceuticals, LLC (b)(4);(b)(7)(E)
Hello (7)(C) Chris,	
application from Vinta  (b)(4) registered distrib	0, 2014 this section ODGR received your request to review one (1) quota increase age Pharmaceuticals, LLC (b)(4);(b)(7)(E) who distributes to (b)(4) putors, manufacturer, and retails pharmacies, to determine if there are any pending ctions against this applicant and to advise ODQ of the findings.
ODGR conducted a re and recommendations.	view (NADDIS, CSA, etc.), as well as surveyed the responsible field office for their input. Provided below are the results and recommendations.
QUOTA APPLICAN	T WITH NO ADVERSE OR DEROGATORY INFORMATION
Vintage Pharmaceutic	als, LLC (b)(4);(b)(7)(E)
Per consultation with t	the field offices, DEA does not have sufficient grounds to deny a quota increase for als.
	(b)(4);(b)(7)(E)
Based or determine if they are v	the above findings, it is recommended that the increased amounts be reviewed to varranted.
(b)(4);(b)(6);(b)(7)(C);(b)(7	()(E);(b)(7)(F)

(b)(4);(b)(5);(b)(6);(b)(7)(C);(b)(7)(E	i);(b)(7)(F)
	ere are no investigative actions pending that would prevent from receiving an
increase in quota for Hydroco	(b)(4);(b)(7)(E)
	urned to ODQ, with copies of $PA_{C}^{(b)(6);(b)(7)()}$ findings. Based on this information, sed quota be reviewed, and possibly reduced $(b)(4);(b)(7)(E)$
Based on the fields response,	you can proceed with the completion or denial of the increase quota request.
(b)(6);(b)(7)(C)	
Trogram Analyst/OD(	$\mathcal{GR}$
Trogram Analyst/OD Regulatory Unit	



Subject

Vintage (b)(4),(b)(7)(E)

2014 Procurement Quota Increase Request
Hydrocodone
(DFN: 630-08.2)

To

Barbara Boockholdt
Chief
Regulatory Section
Office of Diversion Control

Date

Date

Date

Date

Date

#### Background:

As a result of the recent increase in the diversion and abuse of hydrocodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2014 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when establishing/revising the applicant's quota allocation for hydrocodone.



Folder ID: 132232

Reg No:

(b)(7)(E)

Author: (b)(6);(b)(7)(C)

Addressed To:

Location:

**ODEQ** 

Due:

04/19/2014

Received:

4/9/2014

Date Sent:

Security:

A-AES

Response:

Abstract:

Vintage

(b)(4);(b)(7)(E)

2014 PQ Increase Request for hydrocodone

Signature:

Doc Categories:

Doc Types:

(b)(6);(b)(7)(C)

ODG

04/16/2014

Action:

Recommendation and Comments

Requested Activity:

Response Notes: Memo

Boockholdt, Barbara J.; (b)(6); (b)(7)(C)  Subject: Procurement Quota Increase Request dated 4/9/2014 for (Oxycodone) Amerisource Health Servs Corp. (b)(4); (b)(7)(E)  Importance: High	b)(6);(b)(7)(C)	
Hello (7)(C) Chris,  On Thursday, April 10, 2014 this section ODGR received your request to review one (1) quota increase application from AmeriSource Health Servs Corp. (b)(4),(b)(7)(E) who distributes to (b)(4) registered distributors to determine if there are any pending administrative/legal actions against this applicant and to advise ODQ of the findings.  ODGR conducted a review (NADDIS, CSA, etc.), as well as surveyed the responsible field office for their input and recommendations. Provided below are the results and recommendations.  QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION  AmeriSource Health Servs Corp. (b)(4),(b)(7)(E)  Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for AmeriSource Health Servs Corp. (b)(4);(b)(7)(E)  Based on the above findings, it is	To: Cc: Subject:	Boockholdt, Barbara J.; (b)(6);(b)(7)(C)  Procurement Quota Increase Request dated 4/9/2014 for (Oxycodone) Amerisource
On Thursday, April 10, 2014 this section ODGR received your request to review one (1) quota increase application from AmeriSource Health Servs Corp. (b)(4).(b)(7)(E) who distributes to (b)(4) registered distributors to determine if there are any pending administrative/legal actions against this applicant and to advise ODQ of the findings.  ODGR conducted a review (NADDIS, CSA, etc.), as well as surveyed the responsible field office for their input and recommendations. Provided below are the results and recommendations.  QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION  AmeriSource Health Servs Corp. (b)(4);(b)(7)(E)  Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for AmeriSource Health Servs Corp.  (b)(4);(b)(7)(E)  Based on the above findings, it is	Importance:	High
application from AmeriSource Health Servs Corp. (b)(4);(b)(7)(E) who distributes to (c)(4) registered distributors to determine if there are any pending administrative/legal actions against this applicant and to advise ODQ of the findings.  ODGR conducted a review (NADDIS, CSA, etc.), as well as surveyed the responsible field office for their input and recommendations. Provided below are the results and recommendations.  QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION  AmeriSource Health Servs Corp. (b)(4);(b)(7)(E)  Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for AmeriSource Health Servs Corp.  (b)(4);(b)(7)(E)  Based on the above findings, it is	Hello $(7)(0)$ Chris,	
and recommendations. Provided below are the results and recommendations.  QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION  AmeriSource Health Servs Corp. (b)(4),(b)(7)(E)  Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for AmeriSource Health Servs Corp.  (b)(4);(b)(7)(E)  Based on the above findings, it is	application from Ame registered distributors	eriSource Health Servs Corp. (b)(4);(b)(7)(E) who distributes to (b)(4) to determine if there are any pending administrative/legal actions against this applicant
AmeriSource Health Servs Corp. (b)(4);(b)(7)(E)  Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for AmeriSource Health Servs Corp.  (b)(4);(b)(7)(E)  Based on the above findings, it is	ODGR conducted a reand recommendations	eview (NADDIS, CSA, etc.), as well as surveyed the responsible field office for their input s. Provided below are the results and recommendations.
Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for  AmeriSource Health Servs Corp.  (b)(4);(b)(7)(E)  Based on the above findings, it is	QUOTA APPLICA!	NT WITH NO ADVERSE OR DEROGATORY INFORMATION
AmeriSource Health Servs Corp./  (b)(4);(b)(7)(E)  Based on the above findings, it is	AmeriSource Health	Servs Corp. (b)(4);(b)(7)(E)
(b)(4);(b)(7)(E)  Based on the above findings, it is		
recommended that the increased amounts be reviewed to determine if they are warranted.	AmeriSource Health	(b)(4);(b)(7)(E)
	recommended that the	e increased amounts be reviewed to determine if they are warranted.

(b)(4);(b)(5);(b)(7)(E)
(b)(6);(b)(7)(C) (b)(6);(b)(7)(C);(b)(7)(F)
On April 15 2014 Program Analyst (PA)  lemailed DII bi the Columbus
District Office who responded that there are no investigative actions pending that would prevent from receiving
an increase in quota for Oxycodone.
The Control Sheet will be returned to ODQ, with copies of PA findings. Based on this information,
ODG suggests that the increased quota be reviewed, and possibly reduced (b)(4);(b)(7)(E)
Based on the fields response, you can proceed with the completion or denial of the increase quota request.
(b)(6);(b)(7)(C)
Irogram Analyst/ODGR
Trogram Analyst/ODGR Regulatory Unit
(b)(6);(b)(7)(C)



Subject Date

Oxycodone

(DFN: 630-08.2)

APR 9 2014

То

Barbara Boockholdt

Chief

Regulatory Section

Office of Diversion Control

Christine A. Sannerud, Ph.D.

Chief

UN Reporting and Quota Section

Office of Diversion Control

### Background:

As a result of the recent increase in the diversion and abuse of oxycodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2014 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when establishing/revising the applicant's quota allocation for hydrocodone.

GOMPLETED

4//8-2014
(b)(6):(
b)(7)(C)

# SBF-CM Folder Details

Folder ID: 132251

Reg No:

(b)(7)(E)

Author: Ms

Ms. (D)(D);(D)(7)(C)

Addressed To:

ODE

Location:

ODEQ

Due:

04/19/2014 4/9/2014

Received: Date Sent:

Security:

A-AES

Response:

Abstract:

AmriSource 2014 procurement quota increase request for oxycodone

(b)(4);(b)(7)(E)

Signature:

Christine Sannerud

Doc Categories:

Doc Types:

(b)(6);(b)(7)(C)

Boockholdt, Barbara

04/16/2014

Action:

Recommendation and Comments

Requested Activity:

Response Notes:

(b)(6);(b)(7)(C)	
To: Cc: Subject:	(b)(6);(b)(7)(C)  Sannerud, Christine A.  Boockholdt, Barbara J.; (b)(6);(b)(7)(C)  2014 Procurement Quota Increase request for (OXYCODONE) KVK Tech, Inc. (b)(4);(b)(7)(E)
Importance:	High
chris,	
from Manufacturer KV distributors, manufactur	114 this section ODGR received your request to review one (1) quota increase application K Tech (b)(4);(b)(7)(E) who distribute to (b)(4) registered rers, and mail order pharmacies, to determine if there are any pending ions against this applicant and to advise ODQ of the findings.
	ws (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input in KVK Tech, Inc. Provided below are the results and recommendations.
QUOTA APPLICANT	Γ WITH NO ADVERSE OR DEROGATORY INFORMATION
KVK Tech, Inc.	(b)(4);(b)(7)(E)
Per consultation with the Tech, Inc.	ne field offices, DEA does not have sufficient grounds to deny a quota increase for KVK
findings, it is recommen	(b)(4);(b)(7)(E)  Based on the above nded that the increased amounts be reviewed to determine if they are warranted.
b)(4);(b)(6);(b)(7)(C);(b)(7)	(E);(b)(7)(F)

(b)(4);(b)(7)(E)
On Tuesday, April 22, 2014, Program Analyst (PA) emailed Group Supervisor (GS) (b)(6);(b)(7)(C);(b)(7)(C);(c)(C)(C)(C)(C)(C)(C)(C)(C)(C)(C)(C)(C)(C)
Philadelphia Field Division who responded that there are no investigative actions pending that would
prevent KVK Tech, Inc. from receiving an increase in quota for Oxycodone.
(b)(4);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)
VIDURE VIDURAL
The Control Sheet will be returned to ODQ, with copies of PA (b)(6);(b)(7)(
ODG suggests that the increased quota be reviewed, and possibly reduced (b)(4);(b)(7)(E)
Based on the fields response, you can proceed with the completion or denial of the increase quota request.
Bused on the fields response, you can proceed with the completion of definal of the mercuse quota request.
(b)(6);(b)(7)(C)
Program Analyst/ODGR
Regulatory Unit (b)(6);(b)(7)(C)
(b)(6);(b)(7)(C) @usdoj.gov



Subject

KVK-Tech, Inc. (b)(4);(b)(7)(E)

2014 Procurement Quota Increase Request

Oxycodone

(DFN: 630-08.2)

Date

APR 1 1 2014

To

Barbara Boockholdt

Chief

Regulatory Section

Office of Diversion Control

Christine A. Sannerud, Ph.D.

Chief

UN Reporting and Quota Section

Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2014 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or arc the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when establishing/revising the applicant's quota allocation for hydrocodone.

Folder ID: 132291 Reg No: (b)(7)(E)

Author: Sannerud, Christine A Addressed To:

 Location:
 ODEQ

 Due:
 04/21/2014

 Received:
 4/11/2014

 Date Sent:
 4/29/2014

Security: A-AES Response:

Abstract: KVK-Tech, Inc. (b)(4);(b)(7)(E)

2014 Procurement Quota Increase Request

Oxycodone (DNF: 630-08.2)

Signature:

Doc Categories: Doc Types:

(b)(6);(b)(7)(C) ODG 04/18/2014 4/29/2014

Action: Recommendation and Comments

Requested Activity:

Response Notes: -Automatically closed by system when folder was closed

(b)(6);(b)(7)(C)	
To: Cc: Subject:	(b)(6);(b)(7)(C) Sannerud, Christine A. Boockholdt, Barbara J.; (b)(6);(b)(7)(C) 2014 Quota Increase for Fagron, Inc (b)(4);(b)(7)(E)
Importance:	High
Hello (b)(6);(b) (Chris,	
application from Fagror	2014, this section ODGR received your request to review one (1) quota increase in, Inc. (b)(4);(b)(7)(E) who distributes to (b)(4) registered retail pharmacies, to may pending administrative/legal actions against this applicant and to advise ODQ of the
	iew (NADDIS, CSA, etc.), as well as surveyed the responsible field office for their input Provided below are the results and recommendations.
QUOTA APPLICANT	WITH NO ADVERSE OR DEROGATORY INFORMATION
Fagron, Inc. (b)(4);(b)(7)(E)	
	a review of Fagron, Inc. customer list revealed no negative actions against the
Minneapolis District Of	2014, Program Analyst (PA) emailed GS (b)(6);(b)(7)(C) of the emailed GS (b)(6);(b)(7)(C);(b)(7)(F) of the emailed GS (b)(6);(b)(7)(C);(b)(7)(F) of the emailed GS (c)(6);(b)(7)(C);(b)(7)(F) of the emailed GS (c)(6);(b)(7)(C);(
	(b)(4)
	be returned to ODQ, with copies of PA <sup>(b)(6);(b)(7)(</sup> findings. Based on the fields response, ne completion or denial of the increase quota request.
(b)(6);(b)(7)(C)  Program Analyst O  Regulatory Unit	$\overline{\mathscr{DGR}}$
(b)(6);(b)(7)(C)	

@usdoj.gov

(b)(6);(b)(7)(C)



Subject

Fagron (b)(4);(b)(7)(E)

2014 Procurement Quota Increase Request

Oxycodone

(DFN: 630-08.2)

Date

APR 1 4 2014

Τo

Barbara Boockholdt Chief Regulatory Section

Office of Diversion Control

From

Christine A. Sannerud, Ph.D.

Chief

UN Reporting and Quota Section Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2014 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when establishing/revising the applicant's quota allocation for hydrocodone.

Folder JD: 132306 Reg No: (b)(7)(E)

Author: Ms. (b)(6);(b)(7)(C) Addressed To:

ODEQ

 Location:
 ODEQ

 Due:
 04/24/2014

 Received:
 4/14/2014

 Date Sent:
 4/9/2015

Security: A-AES Response:

Abstract: Fagron 2014 Procurement Quota Request oxycodone

(b)(4);(b)(7)(E)

Signature: Christine A. Sannerud

Doc Categories: Doc Types:

(b)(6);(b)(7)(C) Boockholdt, Barbara 04/21/2014 4/15/2014

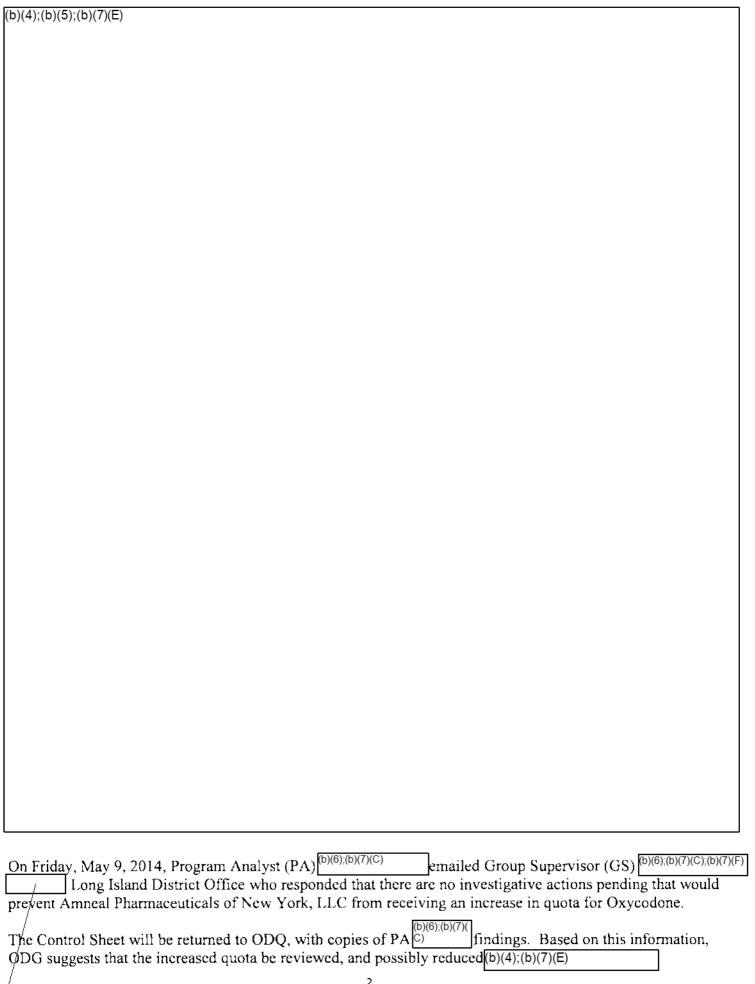
Action: Recommendation and Comments

Requested Activity: Received in the Office of Diversion Control (ODG) 04/14/2014

Response Notes: Enroute to ODGI-Automatically closed by system when folder

was closed

(b)(6);(b)(7)(C)	
From: Sent: To: Cc: Subject:	(b)(6);(b)(7)(C)  Thursday, May 15, 2014 1:56 PM (b)(6);(b)(7)(C)  Sannerud, Christine A.  Boockholdt, Barbara J.(b)(6);(b)(7)(C)  2014 Procurement Quota Increase (Oxycodone) for Amneal Pharmaceuticals of New York, LLC -(b)(4);(b)(7)(E)
Importance:	Hìgh
(b)(6);(b)(7)(Chris,	
application from Manufac	2014 this section ODGR received your request to review one (1) quota increase cturer Amneal Pharmaceuticals of New York, LLC (b)(4);(b)(7)(E) who distribute to d distributors, manufacturers, to determine if there are any pending ns against this applicant and to advise ODQ of the findings.
	s (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input Amneal Pharmaceuticals of New York, LLC Provided below are the results and
QUOTA APPLICANT	WITH NO ADVERSE OR DEROGATORY INFORMATION
Amneal Pharmaceuticals	of New York, LLC (b)(4);(b)(7)(E)
Per consultation with the Amneal Pharmaceuticals	field office, DEA does not have sufficient grounds to deny a quota increase for of New York, LLC.
	(b)(4);(b)(7)(E)
Based on the determine if they are warr	e above findings, it is recommended that the increased amounts be reviewed to ranted.
(b)(4);(b)(6);(b)(7)(C);(b)(7)(E	);(b)(7)(F)



(b)(6);(b)(7)( C);(b)(7)(F) Based on the fields response, you can proceed with the completion or denial of the increase quota request.

(b)(6);(b)(7)(C)	
Program An	alyst/ODGR
Regulatory	Unit
(b)(6);(b)(7)(C)	
(b)(6);(b)(7)(C)	@usdoj.gov



Subject

Amneal (b)(4);(b)(7)(E)

2014 Procurement Quota Increase Request

Oxycodone

(DFN: 630-08.2)

Date

MAY - 6 2014

To

Barbara Boockholdt

Chief

Regulatory Section

Office of Diversion Control

From

hristine A. Sannerud, Ph.D.

Chief

UN Reporting and Quota Section

Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2014 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when establishing/revising the applicant's quota allocation for hydrocodone.

Folder ID: 132663

Reg No:

(b)(7)(E)

Author: Ms (b)(6);(b)(7)(C)

ODE

Addressed To:

Location:

ODEQ

Due:

05/16/2014 5/6/2014

Received:

Date Sent:

Security:

A-AES

Response:

Abstract:

Amneal 2014 procurement quota increase request oxycodone

(b)(4);(b)(7)(E)

Signature:

J. Rannazzisi

Doc Categories:

Doc Types:

(b)(6);(b)(7)(C)

Boockholdt, Barbara

05/13/2014

Action:

Recommendation and Comments

Requested Activity: Response Notes:



Date Subject

KVK Tech (b)(4),(b)(7)(E)

201 Procurement Quota Increase Request

Oxycodone

(DFN: 630-08.2)

FEB 1 2 2014

ſο

Barbara Boockholdt

Chief

Regulatory Section

Office of Diversion Control

Chri

Chief

UN Reporting and Quota Section

Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2014 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when revising the applicant's quota allocation for oxycodone.

(b)(6);(b)(7)(C) (b)(6);(b)(7)(C) From: Thursday, May 08, 2014 2:58 PM Sent: (b)(6);(b)(7)(C) Sannerud, Christine A. To: (b)(6);(b)(7)(C) Boockholdt, Barbara J. Cc: 2014 Procurement Quota Increase (Oxycodone) for Metrics (b)(4);(b)(7)(E) Subject: High Importance: (b)(6);(b Hello)(7)(C) Chris. On Monday, May 5, 2014, this section ODGR received your request to review one (1) quota increase who distributes to (b)(4) application from Metrics (b)(4);(b)(7)(E) registered distributor, to determine if there are any pending administrative/legal actions against this applicant and to advise ODQ of the findings. ODGR conducted a review (NADDIS, CSA, etc.), as well as surveyed the responsible field office for their input and recommendations. Provided below are the results and recommendations. QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION  $Metrics^{(b)(4);(b)(7)(E)}$ Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for Metrics (b)(4);(b)(7)(E) However, a review of Metrics customer list revealed no negative actions against the registrants. On Wednesday, May 7, 2014, Program Analyst (PA) (b)(6);(b)(7)(C) emailed DI (b)(6);(b)(7)(C);(b)(7)(F) of the Greensboro District Office who responded that there are no investigative actions pending that would prevent from receiving an increase in quota for Oxycodone. findings. Based on the fields response, The Control Sheet will be returned to ODQ, with copies of PA[c) you can proceed with the completion or denial of the increase quota request. (b)(6);(b)(7)(C) Program Analyst/ODGR Regulatory Unit (b)(6);(b)(7)(C)

@usdoj.gov

(b)(6);(b)(7)(C)



Subject

Metries Ine (b)(4);(b)(7)(E)

2014 Procurement Quota Increase Request

Oxycodone

(DFN: 630-08.2)

Date

MAY - 2 2014

To

Barbara Boockholdt

Chief

Regulatory Section

Office of Diversion Control

Christine A. Sannerud, Ph.D.

Chief

UN Reporting and Quota Section

Office of Diversion Control

### Background:

As a result of the recent increase in the diversion and abuse of oxycodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2014 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when revising the applicant's quota allocation for oxycodone.

5

SBF-CM Folder Details

Folder ID: 132624 Reg No: (b)(7)(E)

Author: Ms. (b)(6);(b)(7)(C) Addressed To:

ODEQ

 Location:
 ODEQ

 Due:
 05/12/2014

 Received:
 5/2/2014

 Date Sent:
 7/21/2014

Security: A-AES Response:

Abstract: Metrics Inc 2014 procurement quota increase request oxycodone memo

(b)(4);(b)(7)(E)

Signature: Christine A. Sannerud

Doc Categories: Doc Types:

(b)(6);(b)(7)(C) Boockholdt, Barbara 05/09/2014 7/21/2014

Action: Recommendation and Comments

Requested Activity:

Response Notes: -Automatically closed by system when folder was closed

(b)(6);(b)(7)(C)	<u> </u>
From: Sent: To: Cc: Subject:	(b)(6);(b)(7)(C)  Wednesday, June 11, 2014 3:32 PM (b)(6);(b)(7)(C)  Sannerud, Christine A. (b)(6);(b)(7)(C)  Boockholdt, Barbara J.  2014 Procurement Quota Increase for Generics Bidco II, LLC (b)(4);(b)(7)(E)  Hydrocodone and Oxycodone
Importance:	High
application from Manufa	old this section ODGR received your request to review one (1) quota increase cturer Generics Bideo II, LLC (b)(4);(b)(7)(E) who distribute to (b)(4) stributors, manufacturers, to determine if there are any pending administrative/legal
actions against this applications against this application.  ODGR conducted review and recommendation on a recommendations.	cant and to advise ODQ of the findings.  (s (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input Generics Bidco II, LLC (b)(4);(b)(7)(E)  Provided below are the results and
Generics Bidco II, LLC	WITH NO ADVERSE OR DEROGATORY INFORMATION  (b)(4);(b)(7)(E)  field office, DEA does not have sufficient grounds to deny a quota increase for
Generics Bidco II, LLC	(b)(4);(b)(7)(E)  (b)(4);(b)(7)(E)  Based on
warranted.	ecommended that the increased amounts be reviewed to determine if they are
(b)(4);(b)(6);(b)(7)(C);(b)(7)	(E);(b)(7)(F)

(b)(4);(b)(5);(b)(7)(E)
On Tuesday, June 10, 2014, Program Analyst (PA) emailed Acting GS (b)(6);(b)(7)(C);(b) of Greensboro RO who responded that there are no investigative actions pending that would prevent Generics Bidco II, LLC (b)(7)(E) from receiving an increase in quota for Oxycodone.
The Control Sheet will be returned to ODQ, with copies of PA findings. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced (b)(4);(b)(7)(E)
Based on the fields response, you can proceed with the completion or denial of the increase quota request.
(b)(6);(b)(7)(C)

Program Analyst/ODGR Regulatory Unit

b)(6);(b)(7)(C) (b)(6);(b)(7)(C) From: Sent: Tuesday, June 10, 2014 4:26 PM (b)(6);(b)(7)(C);(b)(7)(F) To: Cc: Subject: RE: Procurement quota Increase for Generics Bidco II, LLC (b)(4);(b)(7)(E) for Hydrocodone and Oxycodone No issues that would prevent issuing quota. (b)(6);(b)(7)(C) **Drug Enforcement Administration** Greensboro Resident Office (b)(6);(b)(7)(C) From: (b)(6);(b)(7)(C)Sent: Tuesday, June 10, 2014 3:53 PM **To:** (b)(6);(b)(7)(C);(b)(7)(**Subject:** Procurement quota Increase for Generics Bidco II, LLC (b)(4);(b)(7)(E) for Hydrocodone and Oxycodone Importance: High Good Afternoon (b)(6);(b)(7)(C);(b)(7)(C) Please indicate whether or not you have any pending, active, or ongoing investigations in your division that WILL NOT allow us to issue a 2014 Procurement quota increase for Hydrocodone and Oxycodone to the following registrants: (b)(4);(b)(7)(E) Generics Bidco II, LLC SINCE THE FRONT OFFICE HAS GIVEN US A FIVE (5) DAY TURN AROUND ON QUOTAS, A QUICK RESPONSE WOULD BE GREATLY APPRECIATED. Thank you for your assistance in this matter. (b)(6);(b)(7)(C) Program Analyst/ODGR Regulatory Unit

(b)(6);(b)(7)(C)





Subject

Generics Bidco II, LLC (b)(4);(b)(7)(E)
2014 Procurement Quota Increase Request
Hydrocodone and Oxycodone

(DFN: 630-08.2)

Date

MAY 2 7 2014

To

Barbara Boockholdt Chief Regulatory Section Office of Diversion Control ron

Christine A. Sannerud, Ph.D.

Chief

Drug & Chemical Evaluation Section

Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of hydrocodone and oxycodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2014 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when establishing/revising the applicant's quota allocation for hydrocodone and oxycodone.

Folder ID: 132955

Reg No:

(b)(7)(E)

Author: Ms. (b)(6);(b)(7)(C)

ODEQ

Addressed To:

Location:

ODEQ

Due:

06/06/2014

Received:

5/27/2014

Date Sent:

Security:

A-AES

Response:

Abstract:

Generics Bidco II LLC 2014 Procurement quota increase request

hydrocodone and oxycodone

Signature:

(b)(4);(b)(7)(E)
Christine Sannerud

Doc Categories:

Doc Types:

(b)(6);(b)(7)(C)

Boockholdt, Barbara

06/03/2014

Action:

Recommendation and Comments

Requested Activity: Response Notes:

b)(6);(b)(7)(C)	
To: Cc: Subject:	(b)(6);(b)(7)(C)  (b)(6);(b)(7)(C)  Boockholdt, Barbara J.; Sannerud, Christine A.  2014 Procurement Quota Increase request for (OXYCODONE) Vintage Pharmaceuticals (b)(4);(b)(7)(E)
<sup>6);(b)(7)(</sup> Chris,	
application from Manuf registered distributors, r	2014 this section ODGR received your request to review one (1) quota increase facturer Vintage Pharmaceuticals (b)(4);(b)(7)(E) who distribute to (b)(4) manufacturers, to determine if there are any pending administrative/legal actions against vise ODQ of the findings.
ODGR conducted review and recommendation on recommendations.	ws (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input a Vintage Pharmaceuticals (b)(4);(b)(7)(E) Provided below are the results and
QUOTA APPLICANT	WITH NO ADVERSE OR DEROGATORY INFORMATION
Vintage Pharmaceutical	s ((b)(4);(b)(7)(E)
Per consultation with th Vintage Pharmaceutical	the field office, DEA does not have sufficient grounds to deny a quota increase for this (b)(4);(b)(7)(E)
<del></del>	(b)(4);(b)(7)(E)
Based on determine if they are wa	the above findings, it is recommended that the increased amounts be reviewed to arranted.
(b)(4);(b)(6);(b)(7)(C);(b)(7)	)(E);(b)(7)(F)

<u> </u>
(b)(4);(b)(5);(b)(7)(E)
On Wednesday, June 18, 2014, Program Analyst (PA) emailed Acting GS (7)(F) of
Birmingham RO who responded that there are no investigative actions pending that would prevent Vintage
Pharmaceuticals (b)(7)(E) from receiving an increase in quota for Oxycodone.
The Control Sheet will be returned to ODQ, with copies of PA (c) findings. Based on this information,
ODG suggests that the increased quota be reviewed, and possibly reduced(b)(4);(b)(7)(E)
Based on the fields response, you can proceed with the completion or denial of the increase quota request.
(b)(c)-(b)(7)(c)
(b)(6);(b)(7)(C)
Frogram Analyst/ODGR
Regulatory Unit

2



Subject Date

Vintage (b)(4);(b)(7)(E)

2014 Procurement Quota Increase Request

Oxycodone

(DFN: 630-08.2)

JUN 1 0 2014

To

Barbara Boockholdt

Chief

Regulatory Section

Office of Diversion Control

Christine A. Sannerud, Ph.D.

Chief

UN Reporting and Quota Section

Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains a list of customers for 2014 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when establishing/revising the applicant's quota allocation for hydrocodone.

Folder ID: 133180

Reg No:

(b)(7)(E)

Author: Ms. (b)(6);(b)(7)(C)

ODEQ

Addressed To:

Location:

ODEQ

Due:

06/20/2014

Received:

6/10/2014

Date Sent:

Security:

A-AES

Response:

Abstract:

Vintage

(b)(4);(b)(7)(E)

[0](4);(0)(7)(E) | 2014 Procurement Quota Increase Request for oxycodone.

Signature:

Christine A. Sannerud

Doc Categories:

Doc Types:

Memo

(b)(6);(b)(7)(C)

Boockholdt, Barbara

06/17/2014

Action:

Recommendation and Comments

Requested Activity: Response Notes:

From: Sent:	(b)(6);(b)(7)(C)  Wednesday, July 02, 2014 4:23 PM
To:	(b)(6);(b)(7)(C)
Cc: Subject:	Sannerud, Christine A.; Boockholdt, Barbara J.; (b)(6);(b)(7)(C)  2014 Procurement Quota Increase request for (Hydrocodone) for Vintage Pharmaceuticals (b)(4);(b)(7)(E)
(6);(b)(7) <b>Chris</b> ,	
application from Mai	12, 2014 this section ODGR received your request to review one (1) quota increase inufacturer Vintage Pharmaceuticals ((b)(4);(b)(7)(E) who distribute to (b)(4) ributors, manufacturers, to determine if there are any pending administrative/legal actions and to advise ODQ of the findings.
ODGR conducted reand recommendation recommendations.	eviews (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their in on Vintage Pharmaceuticals (b)(4);(b)(7)(E) Provided below are the results and
QUOTA APPLICA	ANT WITH NO ADVERSE OR DEROGATORY INFORMATION
Vintage Pharmaceuti	icals $(b)(4);(b)(7)(E)$
Per consultation with Vintage Pharmaceuti	h the field office, DEA does not have sufficient grounds to deny a quota increase for icals (b)(4);(b)(7)(E)
	(b)(4);(b)(7)(E)
Based of determine if they are	on the above findings, it is recommended that the increased amounts be reviewed to ewarranted.
b)(4);(b)(6);(b)(7)(C);(b)	)(7)(E);(b)(7)(F)

b)(4);(b)(6);(b)(7)(C);(b)(7)(E)
On Wednesday, June 18, 2014, Program Analyst (PA) emailed Acting GS (7)(F) of
Birmingham RO who responded that there are no investigative actions pending that would prevent Vintage
Pharmaceuticals (b)(7)(E) from receiving an increase in quota for Oxycodone.
The Control Sheet will be returned to ODQ, with copies of PA (b)(6);(b)(7)() findings. Based on this information,
ODG suggests that the increased quota be reviewed, and possibly reduced (b)(4);(b)(7)(E)
Based on the fields response, you can proceed with the completion or denial of the increase quota request.
(b)(6);(b)(7)(C)
Frogram Analyst   ODGR
Program Analyst ODGR Regulatory Unit
(b)(6);(b)(7)(C)



Subject

Vintage(b)(4);(b)(7)(E)

2014 Procurement Quota Increase Request

Hydrocodone

(DFN: 630-08.2)

Date

JUN 1 0 2014

Τo

Barbara Boockholdt

Chief

Regulatory Section

Office of Diversion Control

From

Christine A. Sannerúd, Ph.D.

Chief

UN Reporting and Quota Section

Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of hydrocodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains a list of customers for 2014 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when establishing/revising the applicant's quota allocation for hydrocodone.

# **Drug Enforcement Administration**

# **EXECUTIVE SECRETARIAT CONTROL SHEET**

OI	it Chief EQ	DATE RECEIVED:	6/10/2014	
		RECEIVED:		
O				
	DEQ			
LOCATION: OI	DEQ	DATE DUE:	06/20/2014	
TO:		DATE CLOSED:	7/3/2014	
SECURITY: A-A	AES	CREATED BY:	(b)(6);(b)(7)(C	6/10/2014
DOC ATEGORIES:		MODIFIED BY:	)	7/3/2014
DOC TYPE: Mo	mo			

SIGNATURE: Christine A. Sannerud

NOTES: FY1 - INFO COPIES:

FOLDER PRIORITY: High Priority

### **Assignments**

Action	Action Officer	Delegator	Status	Date Assigned	Date Due	Closed	Security
Recommendati on and Comments	Boockholdt, Barbara	(b)(6);(b)(7)(C)	Closed	6/10/2014	06/17/2014	7/3/2014	A-AES
Requested Ac	tivity:						
Handle as appropriate.	ODEQ		Closed	6/12/2014	06/26/2014	7/3/2014	A-AES

(b)(6);(b)(7)(C)
From:  Sent:  Tuesday, July 01, 2014 11:48 AM  To:  (b)(6);(b)(7)(C)  Sannerud, Christine A.  (b)(6);(b)(7)(C)  Boockholdt, Barbara J.  Subject:  2014 Procurement Quota Increase for (Oxycodone) for Norwich Pharmaceuticals, Inc.  (b)(4);(b)(7)(E)
Chris, Chris,
On Tuesday, June 17, 2014 this section ODGR received your request to review one (1) quota increase application from Manufacturer Norwich Pharmaceuticals, Inc. (b)(4);(b)(7)(E) who distribute to (b)(4) registered distributors, manufacturers, to determine if there are any pending administrative/legal actions against this applicant and to advise ODQ of the findings.
ODGR conducted reviews (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input and recommendation on Norwich Pharmaceuticals, Inc. (b)(4);(b)(7)(E) . Provided below are the results and recommendations.
QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION
Norwich Pharmaceuticals, Inc. (b)(4);(b)(7)(E)
Per consultation with the field office, DEA does not have sufficient grounds to deny a quota increase for Norwich Pharmaceuticals, Inc. (b)(4);(b)(7)(E) (b)(4);(b)(7)(E)
Based on the above findings, it is recommended that the increased amounts be reviewed to determine if they are warranted.
(b)(4);(b)(7)(E)
On Thursday, June 19, 2014, Program Analyst (PA) emailed GS (b)(6);(b)(7)(C) emailed GS (b)(6);(b)(7)(C);(b)(7)(F) of Syracuse RO who responded that there are no investigative actions pending that would prevent Norwich Pharmaceuticals Inc.(b)(4);(b)(7)(E) from receiving an increase in quota for Oxycodone.  The Control Sheet will be returned to ODQ, with copies of PA(C) findings. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced(b)(4);(b)(7)(E)
Based on the fields response, you can proceed with the completion or denial of the increase quota request.
(b)(6);(b)(7)(C)

1

Program Analyst/ODGR

Regulatory Unit
(b)(6)(b)(7)(C)



Subject

Norwich Pharma (b)(4);(b)(7)(E)

2014 Procurement Quota Increase Request

Oxycodone

(DFN: 630-08.2)

Date

JUN 1 3 2014

То

Barbara Boockholdt

Chief

Regulatory Section

Office of Diversion Control

Christine A. Sannerud, Ph.D.

Chief

UN Reporting and Quota Section Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2014 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when revising the applicant's quota allocation for oxycodone.

Folder ID: 133244 Reg No: (b)(7)(E)

Author: Ms. (b)(6);(b)(7)(C) Addressed To:

ODEQ

 Location:
 ODEQ

 Due:
 06/23/2014

 Received:
 6/13/2014

 Date Sent:
 7/1/2014

Security: A-AES Response:

Abstract: Norwich Pharma (b)(4);(b)(7)(E)

2014 PQ Increase Request for Oxycodone

Signature: Christine A. Sannerud

Doc Categories: Doc Types:

(b)(6);(b)(7)(C) Boockholdt, Barbara 06/20/2014 7/1/2014

Action: Recommendation and Comments

Requested Activity:

Response Notes: -Automatically closed by system when folder was closed

4/14/2015 2:19:51 PM

(b)(6);(b)(7)(C)	
From: Sent: To: Cc: Subject:	(b)(6);(b)(7)(C)  Thursday, July 03, 2014 1:21 PM (b)(6);(b)(7)(C)  Sannerud, Christine A. (b)(6);(b)(7)(C)  Boockholdt, Barbara J.  2014 Procurement Quota Increase for Oxycodone for Nesher Pharmaceuticals (USA) LLC (b)(4);(b)(7)(E)
Chris,	
application from Ma (4) registered distri	8, 2014 this section ODGR received your request to review one (1) quota increase nufacturer Nesher Pharmaceuticals (USA) LLC (b)(4),(b)(7)(E) who distribute to (b)(4) butors, manufacturers, to determine if there are any pending administrative/legal actions t and to advise ODQ of the findings.
ODGR conducted re and recommendation and recommendation	eviews (NADDIS, CSA, etc.), as well as surveyed the responsible field office for their input on Nesher Pharmaceuticals (USA) LLC (b)(4);(b)(7)(E) Provided below are the results as.
QUOTA APPLICA	ANT WITH NO ADVERSE OR DEROGATORY INFORMATION
Nesher Pharmaceutic	cals (USA) LLC (b)(4);(b)(7)(E)
Per consultation with Pharmaceuticals (US	th the field office, DEA does not have sufficient grounds to deny a quota increase for Nesher SA) LLC, (b)(4),(b)(7)(E)
	(b)(4);(b)(7)(E)
Based determine if they are	on the above findings, it is recommended that the increased amounts be reviewed to warranted.
(b)(4);(b)(5);(b)(6);(b)(7)	(C);(b)(7)(E);(b)(7)(F)

(b)(4);(b)(5);(b)(7)(E)
(b)(6);(b)(7)(C) (b)(6);(b)(7)(C);(b)(
On Thursday, July 3, 2014, Program Analyst (PA) emailed GS (7)(F) of St. Louis DO
who responded that there are no investigative actions pending that would prevent Nesher Pharmaceuticals (USA) LLC (D)(4),(D)(7)(E) from receiving an increase in quota for Oxycodone.
The Control Sheet will be returned to ODQ, with copies of PA findings. Based on this information,
ODG suggests that the increased quota be reviewed, and possibly reduced (b)(4):(b)(7)(E)
Based on the fields response, you can proceed with the completion or denial of the increase quota request.
(b)(6);(b)(7)(C)
Program Analyst ODGR
Regulatory Unit
(b)(6);(b)(7)(C)



Subject

Nesher Pharmaceuticals (USA) LLC (b)(4);(b)(7)(E)

2014 Procurement Quota Increase Request

Oxycodone

(DFN: 630-08,2)

Date

JUN 1 7 2014

To

Barbara Boockholdt

Chief

Regulatory Section

Office of Diversion Control

ron/

Christine A. Sannerud, Ph.D.

Chief

Drug & Chemical Evaluation Section

Office of Diversion Control

#### Background:

As a result of the recent increase in the diversion and abuse of oxycodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2014 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when establishing/revising the applicant's quota allocation for oxycodone.

Folder ID: 133295 Reg No: (b)(7)(E)

Author: Ms. (b)(6);(b)(7)(C) Addressed To:

ODEQ

 Location:
 ODEQ

 Due:
 06/27/2014

 Received:
 6/17/2014

 Date Sent:
 7/3/2014

Security: A-AES Response:

Abstract: Nesher Pharmaceuticals (USA) LLC (b)(4);(b)(7)(E)

2014 Procurement Quota Increase Request

Oxycodone

Signature: Christine A. Sannerud

Doc Categories: Doc Types:

(b)(6);(b)(7)(C) Boockholdt, Barbara 06/24/2014 7/3/2014

Action: Recommendation and Comments

Requested Activity: Received in the Office of Diversion Control (ODG) 06/20/2014

Response Notes: Enroute to ODG-Automatically closed by system when folder was

closed

(b)(6);(b)(7)(C)	
To: Cc: Subject:	(b)(6);(b)(7)(C)  Sannerud, Christine A.;(b)(6);(b)(7)(C)  Boockholdt, Barbara J.  2014 Procurement Quota Increase for (Hydrocodone) for Mikart (b)(4);(b)(7)(E)
Importance:	Hìgh
O(6);(b)(7)() Chris,	
On Tuesday, July 1, 20 application from Manuf determine if there are a findings.	old this section ODGR received your request to review one (1) quota increase facturer Mikart (b)(4);(b)(7)(E) who distribute to (b)(4) registered distributors to ny pending administrative/legal actions against this applicant and to advise ODQ of the
ODGR conducted revie	ews (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input in Mikart $(b)(4),(b)(7)(E)$ . Provided below are the results and recommendations.
QUOTA APPLICANT	T WITH NO ADVERSE OR DEROGATORY INFORMATION
Mikart (b)(4);(b)(7)(E)	
Per consultation with the Mikart (b)(4);(b)(7)(E)	ne field office, DEA does not have sufficient grounds to deny a quota increase for
	(b)(4);(b)(7)(E)  Based on the above findings, it is
recommended that the	increased amounts be reviewed to determine if they are warranted.
b)(4);(b)(7)(E)	
DO who responded that	2014, Program Analyst (PA) bi(6);(b)(7)(C) emailed GS F) of the Atlanta at there are no investigative actions pending that would prevent Mikart (b)(4);(b)(7)(E) ease in quota for Hydrocodone.
The Control Sheet will ODG suggests that the	be returned to ODQ, with copies of PA (c) findings. Based on this information, increased quota be reviewed, and possibly reduced (b)(4):(b)(7)(E)
Based on the fields resp	ponse, you can proceed with the completion or denial of the increase quota request.
b)(6);(b)(7)(C)	
Program Analyst Regulatory Unit	L <b>IODGR</b>



Subject Date

Mikart (b)(4);(b)(7)(E)

2014 Procurement Quota Increase Request

Hydrocodone (DFN: 630-08.2)

JUN 3 0 2014

To

Barbara Boockholdt

Chief

Regulatory Section

Office of Diversion Control

From

Christine A. Sannerud, Ph.D.

Chief

Drug & Chemical Evaluation Section

Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of hydrocodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2014 as provided by the registrant.

ODQ requests that ODG review and provide written comments to on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when establishing/revising the applicant's quota allocation for hydrocodone.

Folder ID: 133486 Reg No: (b)(7)(E)

Author: Ms. (b)(6);(b)(7)(C) Addressed To:

ODEQ

 Location:
 ODEQ

 Due:
 07/10/2014

 Received:
 6/30/2014

 Date Sent:
 7/10/2014

Security: A-AES Response:

Abstract: Mikart

(b)(4);(b)(7)(E)

2014 PQ Increase Request for hydrocodone

Signature: Christine A. Sannerud

Doc Categories: Doc Types:

(b)(6);(b)(7)(C) Boockholdt, Barbara 07/07/2014 7/10/2014

Action: Recommendation and Comments

Requested Activity:

Response Notes: -Automatically closed by system when folder was closed

(b)(6);(b)(7)(C)	<u></u>
To: Cc: Subject:	(b)(6);(b)(7)(C)  Sannerud, Christine A.  (b)(6);(b)(7)(C)  Procurement Quota Increase for (Oxycodone) Sun Pharmaceutical Industries (b)(4);(b)(7)(E)
(b)(6);(b)(7)( C) Chris,	
(b)(4) registered	distributors, manufacturers, to determine if there are any pending administrative/legal oplicant and to advise ODQ of the findings.
	on Sun Pharmaceutical Industries (b)(4);(b)(7)(E)  Provided below are the results and
QUOTA APPLICAN	NT WITH NO ADVERSE OR DEROGATORY INFORMATION
Sun Pharmaceutical In	ndustries (b)(4);(b)(7)(E)
Per consultation with Pharmaceutical Indus	the field office, DEA does not have sufficient grounds to deny a quota increase for Sun tries (b)(4);(b)(7)(E)
/Darida	(b)(4);(b)(7)(E)
determine if they are	n the above findings, it is recommended that the increased amounts be reviewed to warranted.
(b)(4);(b)(6);(b)(7)(C);(b)(7)	7)(E);(b)(7)(F)

On Tuesday, August 19, 2014, Program Analyst (PA) emailed GS F) of the New
Jersey DO who responded that there are no investigative actions pending that would prevent Sun
Pharmaceutical Industries (b)(4);(b)(7)(E) from receiving an increase in quota for Oxycodone.
The Control Sheet will be returned to ODQ, with copies of PA findings. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced (b)(4);(b)(7)(E)
Based on the fields response, you can proceed with the completion or denial of the increase quota request.
(b)(6);(b)(7)(C)
Frogram Analyst/ODGR
Regulatory Unit



Subject

Sun Pharmaceutical Industries, Inc. (b)(4);(b)(7)(E)

2014 Procurement Quota Increase Request

Oxycodone

(DFN: 630-08.2)

Date

AUG 1 3 2014

To

Barbara Boockholdt

Chief

Regulatory Section

Office of Diversion Control

From

Christine A. Sannerad, Ph.D.

Chief

UN Reporting and Quota Section

Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone, ODQ requests that ODG review the attached application and determine the legitimacy of the applicant's customers. The application enclosed contains year to date sales (broken out by customer) for 2014 as provided by the registrant.

ODQ requests that ODG review and provide written comments on the applicant's enclosed customer list. Specifically, ODQ requests information on whether the applicant's customers are currently under investigation or are the subject of an order to show cause or immediate suspension order. The sales made to such customers will be considered by ODQ when establishing/revising the applicant's quota allocation for hydrocodome.

Folder ID: 134119 Reg No: (b)(7)(E)

Author: Ms. (b)(6);(b)(7)(C) Addressed To:

ODEQ

 Location:
 ODEQ

 Due:
 08/24/2014

 Received:
 8/14/2014

 Date Sent:
 8/28/2014

Security:A-AESResponse:Abstract:Sun Pharmaceutical Industries, Inc.

(b)(4);(b)(7)(E)

2014 PQ Increase request for oxycodone

Signature: Christine A. Sunnerud

Doc Categories: Doc Types:

(b)(6);(b)(7)(C) Boockholdt, Barbara 08/21/2014 8/28/2014

Action: Recommendation and Comments

Requested Activity:

Response Notes: -Automatically closed by system when folder was closed

4/14/2015 2:25:22 PM