∠ / ½ (b)(7)(E)

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		SBF-CM		
	F	older Details	i	
Folder 80: 127477		Reg No: (b)(7	7)(E)	
Author: Ms. (b)(6);(b)(7)(C)		Addressed To:		
ODEQ		Location:	ODEQ	
		Due:	06/01/2013	
		Received:	5/22/2013	
		Date Sent:	8/26/2013	
Security:	A-AES	Response:		
Abstract:	-			
Signature:	J. Rannazzisi			
Doc Categories:		Doc Types:	Memo	
(b)(c) (b)(7)(c)				
(b)(6);(b)(7)(C)	00	-	05/29/2013 8/26/2013	
Action:		ation and Comments		
Requested A	-			
Response N	otes: -Automatical	y closed by system w	vhen folder was closed	
nespense n	vice. Automatical	y closed by system w		

4/16/2015 2:26:07 PM

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From:	(b)(6);(b)(7)(C)
Sent:	Friday, May 31, 2013 1:48 PM
To:	(b)(6);(b)(7)(C) Sannerud, Christine A.
Cc:	Boockholdt, Barbara J.;(b)(6);(b)(7)(C)
Subject:	RE: Quota Increase Request Received on May 22, 2013
Importance:	High

On May 22, 2013 this section received your request to review one (1) quota increase application from one (1) registered manufacturer 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 recommendations. Provided below are the results and recommendations.

QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION

Watson Laboratories, Inc.

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

Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for Watson Laboratories.

(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.

On May 30, 2013, Staff Coordinator (SC) (^{b)(6),(b)(7)(C)} telephonically contacted Group Supervisor (GS) (^{b)(6),(b)(7)(C)} Riverside District Office, who stated that there are no investigative actions pending that would prevent Watson Laboratories from receiving an increase in quota for Oxycodone.

(b)(4);(b)(5);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)

The Control Sheet will be returned to ODQ, with copies of $SC^{(b)(6);(b)(7)(C)}$ findings. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced.

Based on the fields response, you can proceed with the completion or denial of the increase quota request.

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

Staff Coordínator Regulatory Unít - ODGR

(b)(6);(b)(7)(C)	
E-mail: (b)(6);(b)(7)(C)	<u>@usdoj.gov</u>

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Vol. II Page 517



Subject Watson ^{(b)(4);(b)(7)(E)} 2013 Procurement Quota Increase Request	Date
(DFN: 630-08.2)	MAY 2 2 2013
То	From Halfs /
Barbara Boockholdt	Christine A. Sannorug, Ph.D.
Chief	Chief
Regulatory Section	UN Reporting and Quota Section
Office of Diversion Control	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 2013 as provided by the registrant and as reported to ARCOS.

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 bydrocodone.

PEF LTR (b)(7)(E)

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		SBF-CM	
	F	older Details	6
Pokler (D: 127747		Rec No: (b)(7)(E)
Author: Ms (b)(6);(b))(7)(C)	Addressed To:	:
ODEQ			
		Location:	ODEQ
		Due:	06/16/2013
		Received:	6/6/2013
		Date Sent:	8/27/2013
Security:	A-AES	Response:	
Abstract:	Caraco Pharma Lal	os 2013 procurement	quota increase request oxycodone
Signature:	C. Sannerud		
Doc Categories:		Doc Types:	Memo
(b)(6);(b)(7)(C)	o	DG	06/13/2013 6/14/2013
Action:	Recomment	dation and Comments	3
Requested -	Activity:		
Response N	lotes: -Automatica	ily closed by system v	when folder was closed

IN SPECIM 4/16/2015 2:33:32 PM

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From:	(b)(6);(b)(7)(C)
Sent:	Thursday, June 13, 2013 8:49 AM
To:	(b)(6);(b)(7)(C) Sannerud, Christine A.
Cc:	Boockholdt, Barbara J.; (b)(6);(b)(7)(C)
Subject:	RE: Quota Increase Request Received on June 6, 2013

b)(6);(b)(7)(C)	Chris,

On June 6, 2013 this section received your request to review one (1) quota increase application from one (1) registered manufacturer 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, ctc.), as well as surveyed the responsible field offices for their input and recommendations. Provided below are the results and recommendations.

QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION

Caraco Pharma Labs

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

Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for Caraco Pharma Labs (Caraco).

(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.

On June 12, 2013, Staff Coordinator (SC)^{(b)(6),(b)(7)(C)} telephonically contacted Group Supervisor (GS) (b)(6),(b)(7)(C) New Jersey Field Division, who stated that there are no investigative actions pending that would prevent Caraco from receiving an increase in quota for Oxycodone.

(b)(4);(b)(5);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)

The Control Sheet will be returned to ODQ, with copies of $SC^{(b)(6);(b)(7)(C)}$ findings. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced.

Based on the fields response, you can proceed with the completion or denial of the increase quota request.

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

Staff Coordinator Regulatory Unit - ODGR

(b)(6);(b)(7)(C)]
E-mail: ^{(b)(6);(b)(7)(C)}	@usdoj.gov

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Subject	Date
Caraco Pharma Labs (DEA# ^{(b)(4);(b)(7)(E)}	
2013 Procurement Quota Increase Request	
Oxycodone (DFN: 630-08.2)	JUN 6 2013
(Dr.N. 030-08.2)	2010
То	From Hund la Un S.
Barbara Boockholdt	Christine A. Sannerud, Ph.D.
Chief	Chief
Regulatory Section	UN Reporting and Quota Section
Office of Diversion Control	Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone and the use of the internet to traffic oxycodone, ODE 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 eustomer) for 2013 as provided by the registrant and reported to ARCOS.

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 ODE when establishing/revising the applicant's quota allocation for hydrocodone.

LIR,

(b)(7)(E)

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SBF-CM Folder Details

Folder ID; 12/745		Reg No: (b)(7)((E)
Author: Ms. (b)(6);(b)(7)(C)	Addressed To	:
ODEQ		Location:	ODEQ
		Due:	06/16/2013
		Received:	6/6/2013
		Date Sent:	8/27/2013
Security:	A-AES	Response:	
Abstract:	Watson Laboratories oxycodone (b)(4);(b)(7)(E)	Inc 2013 procureme	ent quota increase request for
Signature:	C. Sannerud		
Doc Categories:		Doc Types:	Memo
(b)(6);(b)(7)(C)		G G	06/13/2013 6/14/2013
Action:	Recommenda	ation and Comments	3
Requested /	Activity:		
Response N	lotes: -Automaticall	y closed by system v	when folder was closed

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From:	(b)(6);(b)(7)(C)
Sent:	Thursday, June 13, 2013 1:18 PM
To:	(b)(6);(b)(7)(C) Sannerud, Christine A.
Cc:	Boockholdt, Barbara J.; (b)(6);(b)(7)(C)
Subject:	RE: Quota Increase Request Received on June 6, 2013

b)(6);(b)(7)(C)	Chris,

On June 6, 2013 this section received your request to review one (1) quota increase application from one (1) registered manufacturer 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 recommendations. Provided below are the results and recommendations.

QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION

Watson Laboratories Inc.

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

Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for Watson Laboratories Inc. (Watson).

(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.

On June 13, 2013, Staff Coordinator (SC) (^{(b)(6);(b)(7)(C)} telephonically contacted Group Supervisor (GS) (^{(b)(6);(b)(7)(C)} Riverside Resident Office, who stated that there are no investigative actions pending that would prevent Watson from receiving an increase in quota for Oxycodone.

(b)(4);(b)(5);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)

The Control Sheet will be returned to ODQ, with copies of $SC^{(b)(6);(b)(7)(C)}$ findings. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced.

Based on the fields response, you can proceed with the completion or denial of the increase quota request.

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

Staff Coordinator

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

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E-mail: (b)(6);(b)(7)(C) @usdoj.gov



Subject

Watson Laboratories, Inc. (b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)

To

Barbara Boockholdt Chief Regulatory Section Office of Diversion Control JUN 6 2013

Date

From

Christine A. Sarperud, 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 2013 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.

Full customer list sent electronically.

REF. LIK (b)(7)(E)

SBF-CM **Folder Details**

• Folder ID: 127808		keg No: (b)(7)	(E)
Author: Ms. (b)(6);(b)(7) ODEQ	7)(C)	Addressed To:	
		Location:	ODEQ
		Due:	06/24/2013
		Received:	6/14/2013
		Date Sent:	6/24/2013
Security:	A-AES	Response:	
Abstract:	Amneal Pharmaceuticals of New York LLC 2013 procurment quota increase request hydrocodone		
Signature:	Christine Sannerud		
Doc Categories:		Doc Types:	
(b)(6);(b)(7)(C)	ODG	n an steachtairte An Anailtean Martairtean An Anailtean Martairtean	06/21/2013 6/24/2013
Action:	Recommendation	and Comments	
Requested A	ctivity:		
Response No	tes: -Automatically clo	osed by system w	hen folder was closed

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Subject	Date
Amneal Pharmaceuticals of New York, LLC ^{(b)(4);(b)(7)(E} 2013 Procurement Quota Increase Request	
Hydrocodone (DFN: 630-08.2)	JUN 1 4 2013
	die lit C
То	From Villine (the
Barbara Boockholdt	Christine A. Sannerud, Ph.D.
Chief	Chief
Regulatory Section	Drug & Chemical Evaluation Section
Office of Diversion Control	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 2013 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.

From:	(b)(6);(b)(7)(C)	
Sent:	Friday, June 21, 2013 11:46 Al	M
To:	(b)(6);(b)(7)(C)	Sannerud, Christine A.
Cc:	Boockholdt, Barbara J. (b)(6);(b))(7)(C)
Subject:	RE: Quota Increase Request R	Received on June 14, 2013
Importance:	High	

On June 14, 2013 this section received your request to review one (1) quota increase application from one (1) registered manufacturer 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 recommendations. Provided below are the results and recommendations.

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

QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION

Amneal Pharmaceuticals of New York, LLC

Chris.

Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for Amneal Pharmaceuticals of New York, LLC (Amneal).

(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.

On June 20, 2013, Staff Coordinator (SC)^{(b)(6);(b)(7)(C)} telephonically contacted Group Supervisor (GS) (b)(6);(b)(7)(C) Long Island District Office, who stated that there are no investigative actions pending that would prevent Amneal from receiving an increase in quota for Oxycodone or Hydrocodone.

(b)(4);(b)(5);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)

The Control Sheet will be returned to ODQ, with copies of $SC^{(b)(6);(b)(7)(C)}$ indings. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced.

Based on the fields response, you can proceed with the completion or denial of the increase quota request.

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

Staff Coordinator

(b)(7)(E)

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		SBF-CM	
		Folder Details	S
Folder ID: 127884		Reg No: (b)	(7)(E)
Author: Ms ((b)(6),(b)	(7)(C)	Addressed To	n en en en geschieden eine het deutsche deutsche die deutsche deutsche deutsche deutsche deutsche deutsche deu Ne
ODEQ]		
		Location:	ODEQ
		Due:	06/24/2013
		Received:	6/14/2013
		Date Sent:	4/16/2015
Security:	A-AES	Response:	
Abstract:	Amneal Pharmac	euticals of New York L	LC
Signature:	2013 Procuremer Christine Sanner	nt quota increase for ox ud	ycodone
Doc Categories:		Doc Types:	
(b)(6);(b)(7)(C)		ODG	06/21/2013 6/2 6 /2013
Action:	Recomme	endation and Comment	s
Requested /	Activity:		
Response N	lotes: -Automati	cally closed by system	when folder was closed

4/16/2015 2:47:00 PM

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From:	(b)(6);(b)(7)(C)
Sent:	Friday, June 21, 2013 11:49 AM
То:	(b)(6);(b)(7)(C) Sannerud, Christine A.
Cc:	Boockholdt, Barbara J. (b)(6);(b)(7)(C)
Subject:	RE: Quota Increase Request Received on June 14, 2013
Importance:	High

On June 14, 2013 this section received your request to review one (1) quota increase application from one (1) registered manufacturer 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 recommendations. Provided below are the results and recommendations.

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

QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION

Amneal Pharmaceuticals of New York, LLC

Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for Amneal Pharmaceuticals of New York, LLC (Amneal).

(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.

On June 20, 2013, Staff Coordinator (SC)^{(b)(6);(b)(7)(C)} telephonically contacted Group Supervisor (GS) ^{(b)(6);(b)(7)(C)} Long Island District Office, who stated that there are no investigative actions pending that would prevent Amneal from receiving an increase in quota for Oxycodone or Hydrocodone.

(b)(4);(b)(5);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)

The Control Sheet will be returned to ODQ, with copies of $SC^{(b)(6);(b)(7)(C)}$ findings. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced.

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Based on the fields response, you can proceed with the completion or denial of the increase quota request.

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

Staff Coordinator



Subject	Date
Amneal Pharmaceuticals of New York, LLC ((b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request	
Oxycodone (DFN: 630-08.2)	JUN 1 4 2013
	in And
То	From June And
Barbara Boockholdt	Christine A. Sannerud, Ph.D.
Chief	Chief
Regulatory Section	Drug & Chemical Evaluation Section
Office of Diversion Control	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 2013 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.

(b)(6);(b)(7)(C)]	
From: Sent: To: Subject:	(b)(6);(b)(7)(C) Tuesday, June 11, 2013 8:30 AM (b)(6);(b)(7)(C) @amneal.com oxycodone and hydrocodone quota applications	

Mr. (b)(6);(b)(7)(C)

I originally sent this correspondence on 5/28/13. Please see the request for information below. I cannot process your applications without it. Thank you.

With regards to your recent applications requesting an increase to your 2013 procurement quotas for **oxycodone (for sale)**, under DEA Registration #(b)(4);(b)(7)(E) and **hydrocodone (for sale)** under DEA Registration #(b)(4);(b)(7)(E) [(b)(7)(E)] please provide me with the following information; a complete customer listing of your

oxycodone/hydrocodone sales for 2013 to date. Also, please provide them in the following format: <u>Customer Name</u>, <u>Customer DEA Registration #, Total Sales quantity to Customer as base in kg (not dosage quantities)</u>. Thank you.

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

Drug Science Specialist Office of Diversion Control UN Reporting and Quota Section (ODQ) Drug Enforcement Administration Phone:^{(b)(6);(b)(7)(C)} (b)(6);(b)(7)(C) @dea.usdoj.gov



(b)(7)(E) ZTR

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		0.01 0111	
	Fold	der Details	
		Reg No. (b)(7)(E)
Author: Ms. (b)(6);(b)(ODEQ	7)(C)	Addressed To:	
		Location:	ODEQ
		Due:	08/15/2013
		Received:	8/5/2013
		Date Sent:	4/16/2015
Security:	A-AES	Response:	
Abstract:	Amerisource Health Ser (b)(4);(b)(7)(E) 2013 PQ Increase Requ		9
Signature:	(b)(6);(b)(7)(C)		-
Doc Categories:		Doc Types:	Memo
(b)(6);(b)(7)(C)	ODG		08/12/2013 8/14/2013
Action:	Recommendatio	on and Comments	
Requested A	ctivity:		
Response N	otes: -Automatically c	losed by system w	when folder was closed

SBF-CM

4/16/2015 2:42:08 PM

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(b)(6);(b)(7)(C)		
To:	(b)(6);(b)(7)(C)	Sannerud, Christine A.
Cc: Subject:	Boockholdt, Barbara J.; RE: Quota Increase Req	(b)(6);(b)(7)(C) uest Received on August 7, 2013
Importance:	High	
^{6);(b)(7)(C)} Chris,		
registered manufactu	rer, who distribute to (^{D)(4)}	to review one (1) quota increase application from one (1) registered distributors, to determine if there are any icant and to advise ODQ of the findings.
ODGR conducted re- and recommendation	views (NADDIS, CSA, etc.), as s s. Provided below are the result	well as surveyed the responsible field offices for their inputs and recommendations.
QUOTA APPLICA	NT WITH NO ADVERSE OR	DEROGATORY INFORMATION
American Health Ser	vices Corporation (AHSC)	(b)(4);(b)(7)(E)
Per consultation with Amneal Pharmaceuti	the field offices, DEA does not cals of New York, LLC (Amnea	have sufficient grounds to deny a quota increase for 1).
	(b)(4));(b)(7)(E)
increased amounts be	Ba reviewed to determine if they a	used on the above findings, it is recommended that the
On August 9, 2013, 5 (GS) ^{(b)(6);(b)(7)(C)}	Staff Coordinator (SC) (b)(6);(b)(7)(Columbus District Office,	^{C)} telephonically contacted Group Supervisor , who stated that there are no investigative actions pending
that would prevent A	HSC from receiving an increase	in quota for Oxycodone or Hydrocodone.
	(b)(4);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)
The Control Sheet w ODG suggests that th	ill be returned to ODQ, with cop he increased quota be reviewed, a	ies of $SC_{(C)}^{(b)(6);(b)(7)()}$ findings. Based on this information, and possibly reduced.
Based on the fields re	esponse, you can proceed with th	e completion or denial of the increase quota request.
(b)(6);(b)(7)(C)		
	tor	
Staff Coordína Regulatory Un (b)(6);(b)(7)(C) E-mail: ^{(b)(6);(b)(7)(0}		

Vol. II Page 535



Subject	Date
Amerisource Health Service Cor (DEA# 2013 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)	AUG 5 2013
To	From Stand Stand
Barbara Boockholdt	Christine A. Sannerud, Ph.D.
Chief	Chief
Regulatory Section	UN Reporting and Quota Section
Office of Diversion Control	Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone and the use of the internet to traffic 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 2013 as provided by the registrant and reported to ARCOS.

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.

L78 (b)(7)(E)

		SBF-CM	
	Fol	der Details	5
Folder ID: 125559		Rec No: (b)(
Author: Ms.(b)(6);(b)(7 ODEQ	/)(C)	Addressed To	
		Location:	ODEQ
		Due:	08/15/2013
		Received:	8/5/2013
		Date Sent:	4/16/2015
Security:	A-AES	Response:	
Abstract:	Watson Labs (b)(4);(b)(7)(E) 2013 procurment quota	increase request	oxycdone
Signature:	(b)(6),(b)(7)(C)	, i	
Doc Categories:		Doc Types:	
(b)(6);(b)(7)(C)	ODG		08/12/2013 8/19/2013
Action:	Recommendation	on and Comments	5
Requested A	ctivity:		
Response No	tes: -Automatically c	losed by system	when folder was closed

4/16/2015 2:51:47 PM

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Subject Watson Labs (DEA# ^{(b)(4);(b)(7)(E)} 2013 Procurement Quota Increase Request	Date
Oxycodone (DFN: 630-08.2)	AUG 5 2013
	C
To	From the all the latter
Barbara Boockholdt	Christine A. Sannerud, Ph.D.
Chief	Chief
Regulatory Section	UN Reporting and Quota Section
Office of Diversion Control	Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone/hydrocodone and the use of the internet to traffic oxycodone/hydrocodone. ODE 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 2012 as provided by the registrant and reported to ARCOS.

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 ODE when establishing/revising the applicant's quota allocation for hydrocodone.

6);(b)(7)(C)	
Subject:	FW: Quota Increase Request Received on August 7, 2013
Importance:	High
From:(b)(6);(b)(7)(C) Sent: Friday, August 16 To:(b)(6);(b)(7)(C) Subject: RE: Quota Inc Importance: High	
^{δ);(b)(7)(C)} Chris,	
Watson Laboratories,	is section received your request to review one (1) quota increase application from Inc. who distribute to $^{(b)(4)}$ registered distributors, to determine if administrative/legal actions against this applicant and to advise ODQ of the findings.
ODGR conducted rev and recommendations	iews (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their inputs. Provided below are the results and recommendations.
QUOTA APPLICAN	NT WITH NO ADVERSE OR DEROGATORY INFORMATION
Watson Laboratories,	(b)(4);(b)(7)(E)
	the field offices, DEA does not have sufficient grounds to deny a quota increase for
Watson Laboratories,	
	(b)(4);(b)(7)(E) Based on the above findings, it is recommended that the increased amounts
be reviewed to determ	nine if they are warranted.
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Author: Ms. ^{(b)(6);(b} ODEQ	b)(7)(C)	Addressed To	
		Location:	ODEQ
		Due:	08/15/2013
		Received:	8/5/2013
		Date Sent:	8/26/2013
Security:	A-AES	Response:	
Abstract: Signature:	Amneal Pharma (b)(6);(b)(7)(C)	2013 procurement quot	a increase reugest oxycodone
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Subject Date Amncal Pharma (DEA# (b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Oxycodone AUG 5 2013 (DFN: 630-08.2) To From Barbara Boockholdt Christine A. Sannarud, Ph.D. Chief Chief Regulatory Section UN Reporting and Quota Section Office of Diversion Control Office of Diversion Control

Background:

As a result of the recent increase in the diversion and abuse of oxycodone and the use of the internet to traffic oxycodone. ODE 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 2012 as provided by the registrant and reported to ARCOS.

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 ODE when establishing/revising the applicant's quota allocation for oxycodone.

registered manufacturer 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 recommendations. Provided below are the results and recommendations. QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION Amneal Pharmaceuticals of New York, LLC [bi(4),(b)(7)(E) Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for Amneal Pharmaceuticals of New York, LLC (Amneal). (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. On August 9, 2013, Staff Coordinator (SC) ^{[bi(6),(b)(7)(C)} /C] telephonically contacted Group Supervisor (GS) ^{[bi(6),(b)(7)(C)} /C] Long Island District Office, who stated that there are no investigative actions pending that would prevent Amneal from receiving an increase in quota for Oxycodone or Hydrocodone. (b)(4);(b)(6);(b)(7)(C);(b)(7)(F) The Control Sheet will be returned to ODQ, with copies of SC ^{[bi(6),(b)(7)(C)} /C]. The Control Sheet will be returned to ODQ, with copies of SC ^{[bi(6),(b)(7)(C)} /C]. Based on the fields response, you can proceed with the completion or denial of the increase quota request. (b)(4);(b)(6);(b)(7)(C) Stuff Coordinator Regulatory Unit - ODGR bi(6);(b)(7)(C)	From: [b100].b107/RC] Sent: Wednesday, August 14, 2013 9 05 AM To: [b100].b107/RC] Subject: Boockholdt, Barbar J.;[b100].b07/RC] Subject: RE: Quota Increase Request Received on August 7, 2013 Importance: High 100(107/RC] Christine A. c: Boockholdt, Barbar J.;[b100].b07/RC] Christ, On August 7, 2013 this section received your request to review one (1) quota increase application from one (1) (R07/RC] Christ, On August 7, 2013 this section received your request to review one (1) quota increase application from one (1) (R07/RC] Christ, ODGR conducted reviews (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input and recommendations. QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION Anneel Pharmaceuticals of New York, LLC [b(4)(B)(7)(E)] (b)(4)(b)(7)(E) [based on the above findings, it is recommended that the increase amounts be reviewed to determine if they are warranted. On August 9, 2013, Staff Coordinator (SC) ^[D(0)(b)/RC] Lelephonically contacted Group Supervisor (GS) ^[D(0)(b)/RC] [G(3)[D(0)(M)/RC]) Long Island District Office, who stated that there are no investigative actions pending that would prevent Annueal from receiving an increase in quota for	•		
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Amneal Pharmaceuticals of New York, LLC Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for Amneal Pharmaceuticals of New York, LLC (Amneal). (b)(4);(b)(7)(E) (b)(4);(b)(7)(E) (b)(4);(b)(7)(E) (b)(4);(b)(7)(C) (c)(C)(C)(C)(C)(C)(C)(C)(C)(C)(C)(C)(C)(C)	Amneal Pharmaceuticals of New York, LLC Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for Amneal Pharmaceuticals of New York, LLC (Amneal). (b)(4);(b)(7)(E) (b)(4);(b)(7)(E) (b)(4);(b)(7)(E) (b)(4);(b)(7)(C) (b)(4);(b)(7)(C) (c)(6)(6)(7)(C) (c)(7)(C) (c)(6)(7)(C) (c)(7)(C) (c)(7)(C)			: input
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Amneal Pharmaceuticals of New York, LLC (Amneal). (b)(4);(b)(7)(E) /Based on the above findings, it is recommended that the ncreased amounts be reviewed to determine if they are warranted. On August 9, 2013, Staff Coordinator (SC) ^{(b)(6),(b)(7)(C)} // telephonically contacted Group Supervisor GS) ^{(b)(6),(b)(7)(C)} // Long Island District Office, who stated that there are no investigative actions bending that would prevent Amneal from receiving an increase in quota for Oxycodone or Hydrocodone. (b)(4);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F) The Control Sheet will be returned to ODQ, with copies of SC (b)(6),(b)(7)(C) The Control Sheet will be returned to ODQ, with copies of SC (b)(6),(b)(7)(C) Staff Coordínator Regulatory Unit - ODGR (b)(b)(7)(C)	Anneal Pharmaceuticals of New York, LLC (Amneal). (b)(4);(b)(7)(E) /Based on the above findings, it is recommended that the ncreased amounts be reviewed to determine if they are warranted. On August 9, 2013, Staff Coordinator (SC) ^{[b)(6),(b)(7)(C)} telephonically contacted Group Supervisor GS) ^{[b)(6),(b)(7)(C)} Long Island District Office, who stated that there are no investigative actions bending that would prevent Amneal from receiving an increase in quota for Oxycodone or Hydrocodone. (b)(4);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F) The Control Sheet will be returned to ODQ, with copies of SC DG suggests that the increased quota be reviewed, and possibly reduced. Based on the fields response, you can proceed with the completion or denial of the increase quota request. D(6)(b)(7)(C) Staff Coordínator Regulatory Unit - ODGR	Amneal Pharmaceuticals	(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. Dn August 9, 2013, Staff Coordinator (SC) ^{[b](6],(b)(7)(C)} telephonically contacted Group Supervisor (GS) ^{[b](6],(b)(7)(C)} Long Island District Office, who stated that there are no investigative actions bending that would prevent Amneal from receiving an increase in quota for Oxycodone or Hydrocodone. (b)(4);(b)(6);(b)(7)(C) (b)(7)(C);(b)(7)(C) (b)(7)(C) (b)(7)(C) (b)(7)(C) (c) (b)(6);(b)(7)(C) (c) (c) (c) (c) (c) (c) (c) (c) (c) (c	$\begin{tabular}{lllllllllllllllllllllllllllllllllll$			
Increased amounts be reviewed to determine if they are warranted. On August 9, 2013, Staff Coordinator (SC) ^{[D](6],(D](7)(C)} telephonically contacted Group Supervisor (GS) ^{[D](6],(D)(7)(C)} Long Island District Office, who stated that there are no investigative actions bending that would prevent Amneal from receiving an increase in quota for Oxycodone or Hydrocodone. (b)(4);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F) The Control Sheet will be returned to ODQ, with copies of SC DG suggests that the increased quota be reviewed, and possibly reduced. Based on the fields response, you can proceed with the completion or denial of the increase quota request. (b)(6);(b)(7)(C) Staff Coordinator Regulatory Unit - ODGR	Increased amounts be reviewed to determine if they are warranted. On August 9, 2013, Staff Coordinator (SC) ^{(b)(6),(b)(7)(C)} telephonically contacted Group Supervisor (GS) ^{(b)(6),(b)(7)(C)} Long Island District Office, who stated that there are no investigative actions bending that would prevent Amneal from receiving an increase in quota for Oxycodone or Hydrocodone. (b)(4);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F) (b)(4);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(C) Findings. Based on this information, DDG suggests that the increased quota be reviewed, and possibly reduced. Based on the fields response, you can proceed with the completion or denial of the increase quota request. (b)(6);(b)(7)(C) Staff Coordinator Regulatory Unit ~ ODGR		(b)(4);(b)(7)(E)	
Dn August 9, 2013, Staff Coordinator (SC) ^{(b)(6),(b)(7)(C)} telephonically contacted Group Supervisor GS) ^{(b)(6),(b)(7)(C)} Long Island District Office, who stated that there are no investigative actions bending that would prevent Amneal from receiving an increase in quota for Oxycodone or Hydrocodone. (b)(4);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F) The Control Sheet will be returned to ODQ, with copies of SC DG suggests that the increased quota be reviewed, and possibly reduced. Based on the fields response, you can proceed with the completion or denial of the increase quota request. (b)(6),(b)(7)(C) Staff Coordínator Regulatory Unít - ODGR	Dn August 9, 2013, Staff Coordinator (SC) ^{(b)(6),(b)(7)(C)} telephonically contacted Group Supervisor GS) ^{(b)(6),(b)(7)(C)} Long Island District Office, who stated that there are no investigative actions bending that would prevent Amneal from receiving an increase in quota for Oxycodone or Hydrocodone. (b)(4),(b)(6),(b)(7)(C);(b)(7)(E);(b)(7)(F) The Control Sheet will be returned to ODQ, with copies of SC (b)(6),(b)(7)(C) The Control Sheet will be returned to ODQ, with copies of SC (b)(6),(b)(7)(C) The Control Sheet will be returned to ODQ, with copies of SC (b)(6),(b)(7)(C) The Control Sheet will be returned to ODQ, with copies of SC (b)(6),(b)(7)(C) The Control Sheet will be returned to ODQ, with copies of SC (b)(6),(b)(7)(C) Staff Coordínator Regulatory Unit - ODGR			e
GS) (b)(6):(b)(7)(C) Long Island District Office, who stated that there are no investigative actions bending that would prevent Amneal from receiving an increase in quota for Oxycodone or Hydrocodone. (b)(4):(b)(6):(b)(7)(C):(b)(7)(E):(b)(7)(F) (b)(4):(b)(6):(b)(7)(C):(b)(7)(C):(b)(7)(C):(b)(7)(C):(b)(7)(C):(c):(c):(c):(c):(c):(c):(c):(c):(c):(c	GS) (b)(6):(b)(7)(C) Long Island District Office, who stated that there are no investigative actions bending that would prevent Amneal from receiving an increase in quota for Oxycodone or Hydrocodone. (b)(4):(b)(6):(b)(7)(C):(b)(7)(E):(b)(7)(F) (b)(4):(b)(6):(b)(7)(C):(b)(7)(C):(b)(7)(C) (b)(6):(b)(7)(C):(b)(7)(C) Findings. Based on this information, DDG suggests that the increased quota be reviewed, and possibly reduced. Based on the fields response, you can proceed with the completion or denial of the increase quota request. b)(6):(b)(7)(C) Staff Coordínator Regulatory Unit - ODGR ODGR	ncreased amounts be revi	ewed to determine if they are warranted.	
(b)(4);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F) The Control Sheet will be returned to ODQ, with copies of SC $^{(b)(6),(b)(7)(C)}$ findings. Based on this information, DDG suggests that the increased quota be reviewed, and possibly reduced. Based on the fields response, you can proceed with the completion or denial of the increase quota request. $^{(b)(6),(b)(7)(C)}$ Staff Coordínator Regulatory Unit ~ ODGR	(b)(4);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F) The Control Sheet will be returned to ODQ, with copies of SC $^{(b)(6);(b)(7)(C)}$ findings. Based on this information, DDG suggests that the increased quota be reviewed, and possibly reduced. Based on the fields response, you can proceed with the completion or denial of the increase quota request. $^{(b)(6);(b)(7)(C)}$ Staff Coordínator Regulatory Unit ~ ODGR	GS)(b)(6);(b)(7)(C)	Long Island District Office, who stated that there are no investigative actions)r
The Control Sheet will be returned to ODQ, with copies of SC $^{(b)(6);(b)(7)(C)}$ findings. Based on this information, DDG suggests that the increased quota be reviewed, and possibly reduced. Based on the fields response, you can proceed with the completion or denial of the increase quota request. $\overline{(b)(6);(b)(7)(C)}$ Staff Coordínator Regulatory Unít - ODGR	The Control Sheet will be returned to ODQ, with copies of SC $\begin{bmatrix} b)(6),(b)(7)(C) \\ 0 \end{bmatrix}$ Findings. Based on this information, DDG suggests that the increased quota be reviewed, and possibly reduced. Based on the fields response, you can proceed with the completion or denial of the increase quota request. b)(6),(b)(7)(C) Staff Coordínator Regulatory Unit - ODGR	bending that would preve		
The Control Sheet will be returned to ODQ, with copies of SC findings. Based on this information, DDG suggests that the increased quota be reviewed, and possibly reduced. Based on the fields response, you can proceed with the completion or denial of the increase quota request. D(6);(b)(7)(C) Staff Coordínator Regulatory Unít - ODGR D(6);(b)(7)(C)	The Control Sheet will be returned to ODQ, with copies of SC findings. Based on this information, DDG suggests that the increased quota be reviewed, and possibly reduced. Based on the fields response, you can proceed with the completion or denial of the increase quota request. D(6);(b)(7)(C) Staff Coordínator Regulatory Unít - ODGR D(6);(b)(7)(C)		(b)(4);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)	
b)(6);(b)(7)(C) Staff Coordinator Regulatory Unit ~ ODGR b)(6);(b)(7)(C)	b)(6);(b)(7)(C) Staff Coordinator Regulatory Unit - ODGR b)(6);(b)(7)(C)		returned to ODQ, with copies of SC [Indings. Based on this informat	ion,
Staff Coordinator Regulatory Unit - ODGR	Staff Coordinator Regulatory Unit ~ ODGR	Based on the fields respor	se, you can proceed with the completion or denial of the increase quota request.	
Regulatory Unit ~ ODGR	Regulatory Unit - ODGR)(6);(b)(7)(C)	b)(6);(b)(7)(C)		
		Regulatory Unit -	ODGR	
			Busdoj.gov	

Vol. II Page 542

Per LIE (b)(7)(E)

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		SBF-CM	
		Folder Details	ł
Polder ID: 128587		Reg No: (b)(7)(E)
Author: Ms. (b)(6);(b)(7)(C)	Addressed To:	:
ODEQ		Location:	ODEQ
		Due:	08/15/2013
		Received:	8/5/2013
		Date Sent:	4/4/2014
Security:	A-AES	Response:	
Abstract:	Vintage Pharma	ceuticals, LLC	
	(b)(4);(b)(7)(E)		
Signature:	(b)(6);(b)(7)(C)	<u>e Request for hydrocodo</u>	one and oxycodone
Doc Categories:		Doc Types:	Memo
(b)(6);(b)(7)(C)		ter and the second s ODG	08/12/2013 8/26/2013
Action:	Recomm	endation and Comments	i
Requested	Activity:		
Response M	Notes: -Automat	tically closed by system v	when folder was closed

4/16/2015 2:55:45 PM

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b)(6);(b)(7)(C)	
From:	(b)(6);(b)(7)(C)
Sent:	Thursday, August 15, 2013 1:04 PM
To:	(b)(6);(b)(7)(C) Sannerud, Christine A.
Ec:	Boockholdt, Barbara J.(^{(b)(6);(b)(7)(C)}
iubject:	RE: Quota Increase Request Received on August 7, 2013
mportance:	High
);(b)(7)(C) Chris,	
	is section received your request to review one (1) quota increase application from one (1)
	er, who distribute to (b)(4) registered
distributors, to determ dvise ODQ of the fin	nine if there are any pending administrative/legal actions against this applicant and to adings.
DCP conducted rate	iews (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input
	Provided below are the results and recommendations.
and recommendations	. Provided below are the results and recommendations.
QUOTA APPLICAN	NT WITH NO ADVERSE OR DEROGATORY INFORMATION
Vintage Pharmaccutic	(b)(4);(b)(7)(E)
Per consultation with Vintage Pharmaceutic	the field offices, DEA does not have sufficient grounds to deny a quota increase for
v intage i narmaceutie	(b)(4);(b)(7)(E)
	/Based on the above findings, it is recommended that the increased amounts be
eviewed to determine	: if they are warranted.
On August 15, 2013, 5	Staff Coordinator (SC) ^{(b)(6);(b)(7)(C)} telephonically contacted Group Supervisor
	Birmingham Resident Office, who stated that there are no investigative actions pending
	ntage from receiving an increase in quota for Oxycodone or Hydrocodone. GS (b)(6);(b)(7)(C
	very responsible company, and that she is on the telephone with them daily. It should be
oted that Vintage has	s one of the largest, if not the largest, customer base of any DEA manufacturer.
	I be returned to ODQ, with copies of SC $\binom{(b)(6);(b)(7)(C)}{(b)(7)(C)}$ findings. Based on this information,
DDG suggests that the	e increased quota be reviewed, and possibly reduced (b)(4);(b)(7)(E)
anad on the fields rea	sponse, you can proceed with the completion or denial of the increase quota request.
	sponse, you can proceed with the completion of demai of the increase quota request.
)(6);(b)(7)(C)	
staff Cooud (us at	07
Regulatory Uni	
<u>Regulatory Uni</u> b)(6);(b)(7)(C)	t - ODGR
Regulatory Uni b)(6);(b)(7)(C)	t - ODGR
Staff Coordinat <u>Regulatory Uni</u> (b)(6);(b)(7)(C) E-mail: ^{(b)(6);(b)(7)(C)}	t - ODGR



Subject Date Vintage #(b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Hydrocodone / Oxycodone AUG 5 2013 (DFN: 630-08.2) То From Barbara Boockholdt Christine A. Sannerud, Ph.D. Chief Chief **Regulatory Section** UN Reporting and Quota Section Office of Diversion Control 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 2013 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.

REF 178 (b)(7)(E)

	SBF-CM	
	Folder Details	5
Folder D: 120804	Reg No:	7)(E)
Author: Ms. (b)(6);(b)(7)(C) ODEQ	Addressed To	:
ODEQ	Location:	ODEQ
	Due:	08/17/2013
	Received:	8/7/2013
	Date Sent:	8/27/2013
Security: A-AES	S Response:	
Abstract: (b)(4)		
(b)(4);(b) 2013	<u>)(/)(⊨)</u> PQ Increase Request for hydrocod	lone (DNE 630-08-2)
Signature:		
Doc Categories:	Doc Types:	Memo
(b)(6);(b)(7)(C)	ODG	08/14/2013 8/22/2013
Action:	Recommendation and Comment	S
Requested Activity:		
Response Notes:	-Automatically closed by system	when folder was closed

<u>ШW</u> SBF Ста 4/16/2015 2:58:30 РМ

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(b)(6);(b)(7)(C)			
	(b)(6);(b)(7)(C)		
From: Sent:	Wednesday, August 21, 2013 1	1:06 PM	
To:	Sannarud Christine A		
Cc:	Boockholdt, Barbara J.; ^{(b)(6);(b)(}	(7)(C)	
	(b)(6);(b)(7)(C)		
Subject:	Review of (b)(4)		ners Per a Request from
Attachments:	(b)(4) for an Increase in Their Pr Procurement Quota Increase R	rocurement Quota Request Hydrocodone(b)(4)08 07	7 2013.pdf
Attachments.			i
Chris/ ^{(b)(6);(b)(7)(C)}			
	DDGR received the attached Memora	ndum dated August 07, 2013	, requesting a review of
(b)(4)	and their request for an increase	e in their Procurement Quota	for
Hydrocodone. ODGR	was to conduct a review to determin	e if there are any pending adr	ministrative/legal
actions against the app	licant and their proposed customers i	n order to advise ODQ of the	e findings.
ODGR conducted an i	numerican of (b)(4)	and their potential cust	amore for
Undergodone - Provide	ed below are the results and recomme		omers for
riydrocodone. riovidd	ed below are the results and recomme	indations of that inquiry.	
(b)(4)	is currently registered with DEA	A at (b)(4)	
as a Manufacturer (Re	-packager/Re-Labeler) under DEA re	gistration number (b)(4);(b)(7)(E)	expiring July 31,
2014.	paciagente nagerei) ander		
20111			
	(b)(4);(b)(7)(E	Ξ)	
THE FOLLOWING	CUSTOMERS OF (b)(4)		CURRENTLY
UNDER REVIEW A	ND INVESTIGATION BY THE F	IELD DIVISIONS WHERE	ETHESE
REGISTRANTS AR	E LOCATED:		
(b)(4);(b)(7)(E)		06/30/2	2015
(b)(4);(b)(7)(E)		01/31/20	314
(b)(4);(b)(7)(E)		06/30/	2014
(b)(4);(b)(7)(E)		06/30/20	15
(b)(4);(b)(7)(E)		03/31/2	2015
			1 4 4 4 4 4 4

At this point it does not appear that DEA has any sufficient grounds to limit, restrict, or deny quota requests from (b)(4) at this time.

Based on this information, ODG suggests that you proceed with the completion of the quota application for (b)(4)

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

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

Chief, ODGR/Regulatory Unit Drug Enforcement Administration 8701 Morrissette Drive Springfield, Virginia 22152 (b)(6);(b)(7)(C) <u>a.usdoj.gov</u> (b)(6);(b)(7)(C) (Business) (Blackberry) (Fax)



Subject	Date
(b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Hydrocodone (DFN: 630-08.2)	AUG 7 2013
То	From Stand Line / for
Barbara Boockholdt Chief Regulatory Section Office of Diversion Control	Christine A. Sanderud, Ph.D. 7007 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 2013 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.

(b)(6);(b)(7)(C	;)	
AUGIS	21	117

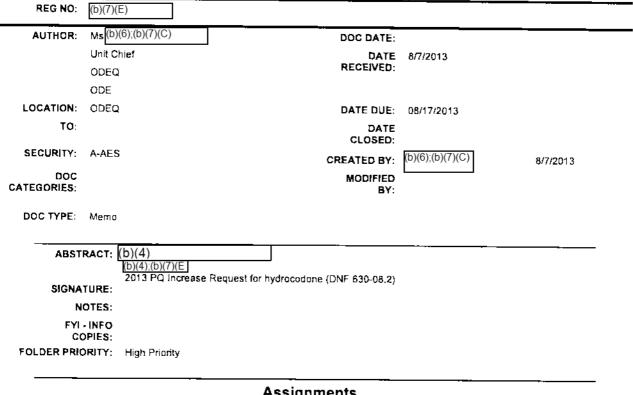
completed

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

Drug Enforcement Administration

EXECUTIVE SECRETARIAT

CONTROL SHEET



_	Assignments						
Action	Action Officer	Delegator	Status	Date Assigned	Date Due	Closed	Security
Recommendati on and Comments	ODG	(b)(6);(b)(7)(C)	Open	8/7/2013	08/14/2013		A-AES

Requested Activity:

RA 2+P (b)(7)(E)

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SBF-CM **Folder Details**

	FOI	der Details	5
Folder ID: 128818		Reg No: (b)(7)(E)
Author: Sannerud,	Christine A	Addressed To	:
		Location:	ODEQ
		Due:	08/29/2013
		Received:	8/19/2013
		Date Sent:	4/16/2015
Security:	A-AES	Response:	
Abstract:	Mikart, Inc. (b)(4);(b)(7)(E) 2013 Brocuromont Oue	ta Incrasso Pagi	last for hydrocodoso
Signature:	2013 Procurement Quo	ta increase riequ	lest for hydrocodone
Doc Categories:		Doc Types:	
(b)(6),(b)(7)(C)	ODG		08/26/2013 8/22/2013
Action:	Recommendatio	on and Comment	s
Requested A	Activity:		
Response N	otes: -Automatically c	losed by system	when folder was closed

ITH- SBF. CM 4/16/2015 3:16:28 PM

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(b)(6);(b)(7)(C)	
From:	(b)(6);(b)(7)(C)
Sent:	Wednesday, August 21, 2013 1:07 PM
To:	Sannerud, Christine A.
Cc:	Boockholdt, Barbara J.;(b)(6);(b)(7)(C)
Subject:	(b)(6);(b)(7)(C) Review of Mikart (b)(4);(b)(7)(E) and Their Customers Per a Request from MIkart for an Increase in their Procurement Quota for Hydrocodone
Attachments:	Procurement Quota Increase Request Hydrocodone Mikart 08 19 2013.pdf

Chris^{(b)(6);(b)(7)(C)}

On August 19, 2013, this section received the attached Memorandum dated August 19, 2013, requesting a review of Mikart, Inc. and their request for an increase in their Procurement Quota for the Manufacture of Hydrocodone. ODGR was to conduct a review to determine if there are any pending administrative/legal actions against the applicant and their proposed customers in order to advise ODQ of the findings.

ODGR conducted an investigation of Mikart Inc. and their potential customers for Hydrocodone. Provided below are the results and recommendations of that inquiry.

Mikart, Inc. is registered with DEA at 2090 Marietta Blvd., Atlanta, Georgia 30318, as a Dosage Form Manufacturer under DEA registration number (b)(4);(b)(7)(E) The registration is current and in good standing with no history of adverse actions. The last scheduled investigation was conducted on or about April 26, 2010, under case file (b)(7)(E)

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

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Based on this information, ODG suggests that you proceed with the completion of the quota application for Mikart.

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

Chief. ODGR/Regulatory Unit Drug Enforcement Administration 8701 Morrissette Drive Springfield, Virginia 22152 (b)(6);(b)(7)(C) (b)(6);(b)(7)(C) (Business) (Blackberry) (Fax)



	_
Subject	Date
Mikart, Inc. $(b)(4);(b)(7)(E)$	
 3 2012 Procurement Quota Increase Request Hydrocodone (DFN: 630-08.2) 	AUG 1 9 2013
	AAT
То	From Mane La
Barbara Boockholdt Chief	Christine A. Sannerug, Ph.D. Chief

Drug & Chemical Evaluation Section Office of Diversion Control

Background:

Regulatory Section

Office of Diversion Control

QC

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 2013 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.

Please feel free to contact me if I can provide further assistance in this matter.

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

PET LIP

(b)(7)(E)

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SBF-CM		
Folder	Details	

Poider ID: 128742		Reg No: (b)(/	7)(E)
Author: Sannerud,	Christine A	Addressed To	
		Location:	ODEQ
		Due:	08/23/2013
		Received:	8/13/2013
		Date Sent:	4/16/2015
Security:	A-AES	Response:	
Abstract:	Actavis (b)(4);(b)(7)(E) 2013 PQ Increase Requ	lest for oxycodor	ne
Signature:	Christine A. Sannerud	Doc Types:	
Doc Categories:	. as a partie	Doc Types.	
(b)(6),(b)(7)(C)	<u> </u>		08/20/2013 8/28/2013
Action:	Recommendatio	n and Comment	s
Requested /	Activity:		
Response N	lotes: -Automatically cl	osed by system	when folder was closed

1. R.M.

(b)(6);(b)(7)(C)	
From: Sent:	(b)(6);(b)(7)(C) Tuesday, August 27, 2013 2:45 PM
То: Сс:	Sannerud, Christine A. (b)(6);(b)(7)(C) Boockholdt, Barbara J.; (b)(6);(b)(7)(C)
Subject:	(b)(6);(b)(7)(C) Review of Activas (b)(4);(b)(7)(E) Actives to OD50 (
	Activas to ODEQ for an Increase in their Procurement Quota for Oxycodone

Chris/(b)(6);(b)(7)(C)

On August 13, 2013, ODGR received the attached Memorandum dated August 13, 2013, requesting a review of <u>two</u> Activas Manufacturing registrations and their request for an increase in Procurement Quota for Oxycodone. ODGR was to conduct a review to determine if there are any pending administrative/legal actions against the applicant and their proposed customers in order to advise ODQ of the findings.

ODGR conducted an investigation of Activas and their potential customers for Oxycodone. Provided below are the results and recommendations of that inquiry.

Activas LLC, is currently registered with DEA at 47 Brunswick Avenue, Edison, New Jersey 08817 as a Manufacturer of schedule 2, 2N, 3, 4, and 5 controlled substances under DEA registration number ^{(D)(4),(D)(7)(E)} The registration is listed in CSA as Active with no derogatory information listed. This registration has not yet been the subject of an on-site DEA scheduled investigation. The registration was just approved on October 5, 2011.

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

It does not appear that DEA has any sufficient legal grounds to limit, restrict, or deny quota requests from Activas for oxycodone products manufactured for most of their customers at this time.

(b)(4)

Based on this information, ODG suggests that you proceed with the completion of the quota application for Activas.

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

Chief, ODGR/Regulatory Unit Drug Enforcement Administration 8701 Morrissette Drive Springfield, Virginia 22152 (b)(6);(b)(7)(C) (b)(6);(b)(7)(C) (Business) (Blackberry) (Fax)



Subject Actavis ^{(b)(4);(b)(7)(E)} 2013 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)	AUG 1 3 2013
To	From L. U.
Barbara Boockholdt	Christine A. Sannerud, Ph.D.
Chief	Chief
Regulatory Section	UN Reporting and Quota Section
Office of Diversion Control	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 2013 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.

Please feel free to contact me if I can provide further assistance in this matter.

Pet LIP (b)(7)(E)

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SBF-CM Folder Details

Folder ID: 120829			((7)(E)
Author: Ms.(b)(6);(b)	(7)(C)	Addressed To) :
ODEQ			
		Location:	ODEQ
		Due:	10/31/2013
		Received:	10/21/2013
		Date Sent:	11/4/2013
Security:	A-AES	Response:	
Abstract:	KVK-Tech Inc 2013 procurement increase request oxycodone (b)(4);(b)(7)(E)		
Signature:	C. Sannerud		
Doc Categories:		Doc Types:	
(b)(6);(b)(7)(C)		odd a dae a da ODG	10/28/2013 11/4/2013
Action:	 Recomme	ndation and Commen	ts
Requested /	Activity:		
Response N	lotes: -Automatic	ally closed by system	when folder was closed

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(b)(6);(b)(7)(C)	
To: Cc:	(b)(6);(b)(7)(C) Sannerud, Christine A. (b)(6);(b)(7)(C) Boockholdt, Barbara J. ^{(b)(6);(b)(7)(C)}
Subject:	RE: Quota Increase Request Received on October 23, 2013

^{(b)(6);(b)(7)(C)} Chris,

On October 23, 2013 this section received your request to review one (1) quota increase application from one (1) registered manufacturer, who distribute 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 reviews (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input and recommendations. Provided below are the results and recommendations.

QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION

KVK-Tech, Inc. (KVK)

(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. (KVK).

(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.

On October 25, 2013, Staff Coordinator (SC)^{(b)(6);(b)(7)(C)} telephonically contacted Group Supervisor (GS)^{(b)(6);(b)(7)(C)} Philadelphia, PA. Field Division who referred him to Diversion Investigator (DI)^{(b)(6);(b)(7)(C)} o determine if KVK should receive an increase in quota for Oxycodone. DI also of the Philadelphia Field Division, sent SC ^{(b)(6);(b)(7)(} an e-mail on 10/29/2013, stating that he has no problems with KVK receiving an increase in quota for Oxycodone.

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

The Control Sheet will be returned to ODQ, with copies of $SC^{(b)(6);(b)(7)(C)}$ findings and $DI^{(b)(0),(b)(7)}_{(C)}$ e-mail. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced based on their customers.

Based on the fields response and our investigation, you can proceed with the completion or denial of the increase quota request.

(b)(6);(b)(7)(C)	
Staff Coordínator Regulatory Unit - ODGI	2
(b)(6);(b)(7)(C)	•
E-mail: (b)(6);(b)(7)(C)	@usdoj.gor

(b)(6);(b)(7)(C)	
From: Sent: To: Cc: Subject:	(b)(6);(b)(7)(C) Tuesday, October 29, 2013 1:22 PM (b)(6);(b)(7)(C) RE: KVK Tech

No, I have no problems with that.

They should be on the right track now, in regards to verifying customer's quota limits etc.

Regards,

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

 Diversion Investigator

 Drug Enforcement Administration

 Philadelphia Division

 Office:

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

 Sent:

 Tuesday, October 29, 2013 8:01 AM

 To:

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

 Subject:

 FW:

 KVK Tech

 Good Morning

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

 Do you have any problem with KVK Tech receiving additional quota?

From: (b)(6);(b)(7)(C) Sent: Friday, October 25, 2013 5:13 PM To: (b)(6);(b)(7)(C) Cc: (b)(6);(b)(7)(C) Subject: KVK Tech

Hello (b)(6);(b)(7)(

Got your msg but swamped with NTBI matters. Please contact $\binom{(b)(6);(b)(7)(C)}{and DI}$ and DI $\binom{(b)(6);(b)(7)(C)}{box}$ so that they can respond to you regarding KVK Tech. Thanks,





Subject	Date
KVK-Tech, Inc. #(b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)	OCT 2 1 2013
То	From
Barbara Boockholdt	Christine A. Sannerus, Ph.D.
Chief	Chief
Regulatory Section	UN Reporting and Quota Section
Office of Diversion Control	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 2013 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.

Please feel free to contact me if I can provide further assistance in this matter.

(b)(6);(b)(7)(C)	
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		SBF-CM	
	Fo	lder Details	5
Folder ID: 129830		Reg No:	7)(E)
Author: Ms. ^{(b)(6);(b)(7)(C)}		Addressed To	
ODEQ		Location:	ODEQ
		Due:	10/31/2013
		Received:	10/21/2013
		Date Sent:	11/4/2013
Security: A-A	ES	Response:	
οχγα	age 2013 procure codone ;(b)(7)(E)	ment quota increas	se request hydrocodone and
Signature: C. S	annerud		
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(b)(6);(b)(7)(C)	סס ך	3	10/21/2013 11/4/201
Action:	Recommenda	tion and Comment	s
Requested Activit	y:		
Response Notes:	-Automatically	closed by system	when folder was closed

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(b)(6);(b)(7)(C)	
From: Sent: To: Cc: Subject:	(b)(6);(b)(7)(C) <u>Thursday, October 31, 2013 1:12 PM</u> (b)(6);(b)(7)(C) (b)(6);(b)(7)(C) RE: Quota Increase Request Received on October 23, 2013
6);(b)(/Stacy/Chris,	
On October 23, 2013 (1) registered manufa	this section received your request to review two (2) quota increase applications from one eturer, who distribute oxycodone and hydrocodone to $\frac{(b)(4)}{(b)(4)}$ registered distributors, to any pending administrative/legal actions against this applicant and to advise ODQ of the
	iews (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their inputs. Provided below are the results and recommendations.
QUOTA APPLICA	NT WITH NO ADVERSE OR DEROGATORY INFORMATION
Vintage Pharmaceutic	cals, LLC (Vintage) (b)(4);(b)(7)(E)
Per consultation with Vintage Pharmaceutic	the field offices, DEA does not have sufficient grounds to denv a quota increase for cals, LLC (Watson).
	(b)(4);(b)(7)(E)
Base determine if they are	d on the above findings, it is recommended that the increased amounts be reviewed to warranted.
(GS) ^{(b)(b)(b)(b)(r)(C)} pending that would pr	Staff Coordinator (SC) ^{(b)(6);(b)(7)(C)} telephonically contacted Group Supervisor Birmingham, AL Resident Office who stated that there are no investigative actions revent Vintage from receiving an increase in quota for Oxycodone or Hydrocodone. GS age is always looking to receive an increase in quota, and stated "I guess it is alright if the
	(b)(4);(b)(7)(E)

(b)(4);(b)(6);(b)(7)(C);(b)(7)(E)	
The Control Sheet will be returned to ODQ, with copies of SC findings. Based on this information ODG suggests that the increased quota be reviewed, and possibly reduced	1
Based on the fields response and our investigation, you can proceed with the completion or denial of the increase quota request.	(b)(4);(b) 7)(E)
(b)(6);(b)(7)(C)	ļ
Staff Coordinator Regulatory Unit - ODGR (b)(6),(b)(7)(C)	
E-mail (b)(6);(b)(7)(C) @usdoj.gov	



Subject Date Vintage (b)(4);(b)(7)(E) 2013 Procurement Quota Increase Request OCT 2 1 2013 Hydrocodone (DFN: 630-08.2) То From Chri **, P**h.D. Barbara Boockholdt ine A. Sannerud Chief Chief UN Reporting and Quota Section **Regulatory Section** Office of Diversion Control 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 2013 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.

Please feel free to contact me if I can provide further assistance in this matter.

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Folder 10:		Reg No:	(b)(7)(E)	
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Author: Ms. (b)(6);(b)(7)(C)	Addressed	i To:	
ODEQ				
		Location:	ODEQ	
		Due:	11/18/2013	
		Received:	11/8/2013	
		Date Sent:		
Security:	A-AES	Response:	:	
Abstract:	Mikart 2013 pro	curement quota incre	ase request for hydroco	odone memo
Signature:	Christine Sanne	erud		
Doc Categories:		Doc Type:	5:	
(b)(6);(b)(7)(C)		ODG	11/29/2013	
Action:	Handle	as appropriate.	(h)(6):(h)	ā
Requested Ac	tivity: Sending	document to ODQ or	n 11/15/2013 (b)(6);(b)(7)(C)	
Response No	tes:		. /(- /	
(b)(6);(b)(7)(C)		ODG	11/15/2013	
Action:	Recommendation and Comments			
Requested Ac	tivity:			
Response No	tes:			

4/22/2015 9:45:13 AM

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From:	(b)(6);(b)(7)(C)
іелт:	Thursday, November 14, 2013 1:47 PM
Го:	(b)(6);(b)(7)(C) Sannerud, Christine A.
Cc:	Boockholdt, Barbara J.; (b)(6);(b)(7)(C)
Subject:	RE: Quota Increase Request Received on November 8, 2013
mportance:	High
);(b)(7)(C) Chris,	
(1) registered manufa	3 this section received your request to review one (1) quota increase application from one acturer, who distribute to $(b)(4)$ registered distributors, to determine if there are any ve/legal actions against this applicant and to advise ODQ of the findings.
and recommendation	views (NADDIS, CSA, etc.), as well as surveyed the responsible field offices for their input s. Provided below are the results and recommendations.
QUOTA APPLICA	NT WITH NO ADVERSE OR DEROGATORY INFORMATION
Mikart	(b)(4);(b)(7)(E)
Per consultation with Mikart.	the field offices, DEA does not have sufficient grounds to deny a quota increase for
	(b)(4);(b)(7)(E)
recommended that th	Based on the above findings, it is (b)(6);(b) (c)
(GS)(⁶ /(⁶), ⁽⁶ /(⁷), ⁽⁶))13, Staff Coordinator (SC) ^{(b)(6);(b)(7)(C)} telephonically contacted Group Supervisor Atlanta Division Office who was unavailable to return SC ^{(b)(6);(b)(7)(C)} voice message (C)
regarding Mikart, an	d an increase in quota for Hydrocodone. GS was e-mailed by SC on
November 14, 2013,	and his response stated, "he sees no issues with Mikart at this time to prevent them from $\frac{1}{2}$ and $\frac{1}{2}$ is a set of S C $\frac{(b)(0)}{(b)}$
for this investigation	rease". A copy of the above e-mail will be included with the rest of $SC_{abs}^{(b)(6);(b)(7)(C)}$ findings
5	
The Control Sheet w ODG suggests that the Mikart's volume of c	ill be returned to ODQ, with copies of $SC^{(b)(6);(b)(7)(C)}$ findings. Based on this information, he increased quota be reviewed and consideration of amounts should be assessed based on customers.
Based on the fields r	esponse, you can proceed with the completion or denial of the increase quota request.
(b)(6);(b)(7)(C)	
Staff Coordina	

(b)(6);(b)(7)(C)	
E-mail: (b)(6);(b)(7)(C)	<u>@usdoj.gov</u>



Subject

Mikart^{(b)(4);(b)(7)(E)} 2013 Procurement Quota Increase Request Hydrocodone (DFN: 630-08.2)

То

Barbara Boockholdt Chief Regulatory Section Office of Diversion Control From When Christine A. Sannerud, Ph.D.

Chief UN Reporting and Quota Section Office of Diversion Control

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 2013 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.

Please feel free to contact me if I can provide further assistance in this matter.

2013 NOV -8 PM IZ: 04

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