

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

To: (b)(6);(b)(7)(C) Sannerud, Christine A.
Cc: Boockholdt, Barbara J. (b)(6);(b)(7)(C)
Subject: Quota Increase Request Received on February 12, 2014
Importance: High

(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)

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)

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

(b)(4);(b)(5);(b)(7)(E)

On February 12, 2014, Program Analyst (PA) [redacted] emailed Group Supervisor (GS) [redacted] 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. [redacted]

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

The Control Sheet will be returned to ODQ, with copies of PA [redacted] findings. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced [redacted]

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)

@usdoj.gov

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

From: (b)(6);(b)(7)(C)
Sent: Wednesday, February 19, 2014 9:45 AM
To: (b)(6);(b)(7)(C);(b)(7)(F)
Cc:
Subject: FW: 2014 Procurement 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)

The below listed registrant has no pending, active or ongoing investigations in the Philadelphia Field Division. (b)(6);(b)(7)(C)
Please contact the DI for further information if necessary. Thank you..... (b)(6);(b)(7)(C)

(b)(6);(b)(7)(C)
Registration Program Specialist
Drug Enforcement Administration
Phone: (b)(6);(b)(7)(C)
Fax: (b)(6);(b)(7)(C)

From: (b)(6);(b)(7)(C);(b)(7)(F)
Sent: Wednesday, February 12, 2014 5:12 PM
To: (b)(6);(b)(7)(C)
Subject: Fw: 2014 Procurement Quota INCREASE (for Oxycodone) for KVK Tech (b)(4);(b)(7)(E)
Importance: High

Please take Care of this. Thanks.

From: (b)(6);(b)(7)(C)
Sent: Wednesday, February 12, 2014 05:06 PM
To: (b)(6);(b)(7)(C);(b)(7)(F)
Subject: 2014 Procurement Quota INCREASE (for Oxycodone) for KVK Tech (b)(4);(b)(7)(E)

Good Afternoon (b)(6);(b)(7)(C);(b)(7)(F)

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 Oxycodone) to the following registrant:

KVK Tech (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)

*Program Analyst/ODGR
Regulatory Unit*

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



(b)(6);(b)(7)(C) @usdoj.gov

Memorandum



Subject

KVK Tech (b)(4);(b)(7)(E)
2014 Procurement Quota Increase Request
Oxycodone
(DFN: 630-08.2)

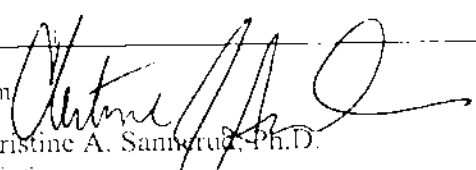
Date

FEB 12 2014

To

Barbara Boockholdt
Chief
Regulatory Section
Office of Diversion Control

From


Christine A. Sambrano, 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.

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

SBF-CM
Folder Details

Folder ID: 131411

Reg No: (b)(7)(E)

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

Addressed To:

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:

2/12/2014 10:55:17 AM

1

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

To: (b)(6);(b)(7)(C) Sannerud, Christine A.
Cc: Boockholdt, Barbara J.; (b)(6);(b)(7)(C)
Subject: 2014 Procurement Quota Increase (Hydrocodone) Request for - Vintage Pharma
(b)(4);(b)(7)(E)

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

On Wednesday, March 19, 2014 this section ODGR received your request to review one (1) quota increase application from Vintage Pharma (b)(4);(b)(7)(E) who distributes to (b)(4) registered distributors, manufacturer, and retails pharmacies, 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

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

Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for Vintage Pharma. (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)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)

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

On March 26, 2014, Program Analyst (PA) [redacted] emailed DI [redacted] of the Birmingham District Office who responded that there are no investigative actions pending that would prevent from receiving an increase in quota for Hydrocodone.

[redacted] (b)(4);(b)(7)(E)

The Control Sheet will be returned to ODQ, with copies of PA [redacted] findings. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced [redacted]

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

[redacted] (b)(6);(b)(7)(C)

*Program Analyst/ODQR
Regulatory Unit*

[redacted] (b)(6);(b)(7)(C)



[redacted] (b)(6);(b)(7)(C)

@usdoj.gov

Memorandum



Subject Vintage Pharma (b)(4);(b)(7)(E) 2014 Procurement Quota Increase Request Hydrocodone (DFN: 630-08.2)	Date MAR 18 2013
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To
Barbara Boockholdt
Chief
Regulatory Section
Office of Diversion Control

From *Stacy Della* for
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.

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

COMPLETED
3/28/2014

SBF-CM
Folder Details

Folder ID: 131887

Reg No: (b)(7)(E)

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

Addressed To:

Location: ODEQ
Due: 03/28/2014
Received: 3/18/2014

Security: A-AES

Date Sent:
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: (b)(6);(b)(7)(C) Sannerud, Christine A.
Cc: Boockholdt, Barbara J.; (b)(6);(b)(7)(C)
Subject: Procurement Quota Increase Request dated 4/9/2014 for Vintage Pharmaceuticals, LLC
(b)(4);(b)(7)(E)

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

On Thursday, April 10, 2014 this section ODGR received your request to review one (1) quota increase application from Vintage Pharmaceuticals, LLC (b)(4);(b)(7)(E) who distributes to (b)(4)

(b)(4) registered distributors, manufacturer, and retails pharmacies, 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

Vintage Pharmaceuticals, LLC (b)(4);(b)(7)(E)

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

(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);(b)(7)(F)

On April 15, 2014, Program Analyst (PA) [redacted] emailed DI [redacted] of the Birmingham District Office who responded that there are no investigative actions pending that would prevent from receiving an increase in quota for Hydrocodone.

[redacted] (b)(4);(b)(7)(E)

The Control Sheet will be returned to ODQ, with copies of PA [redacted] findings. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced [redacted]

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

[redacted] (b)(6);(b)(7)(C)

*Program Analyst/ODQR
Regulatory Unit*

Memorandum



Subject

Vintage (b)(4);(b)(7)(E)
2014 Procurement Quota Increase Request
Hydrocodone
(DFN: 630-08.2)

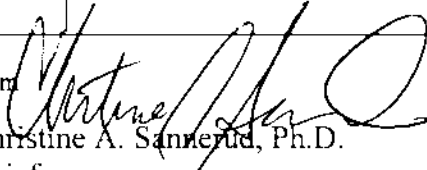
Date

APR 9 2014

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

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

COMPLETED

4/18/2014

SBF-CM
Folder Details

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:
Response:

Security: A-AES

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

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

To: (b)(6);(b)(7)(C) Sannerud, Christine A.
Cc: 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

Hello (b)(6);(b)(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 recommended 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)(5);(b)(7)(E)

On April 15, 2014, Program Analyst (PA) [redacted] emailed DI [redacted] of 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 [redacted] findings. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced [redacted]

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

[redacted]

*Program Analyst/ODQR
Regulatory Unit*

[redacted]

Memorandum



Subject

AmeriSource # (b)(4),(b)(7)(E)
2014 Procurement Quota Increase Request
Oxycodone
(DFN: 630-08.2)

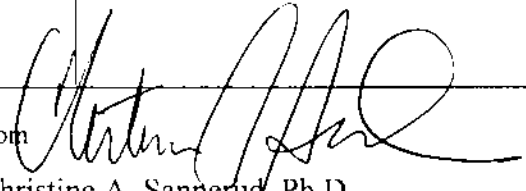
Date

APR 9 2014

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 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.

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

COMPLETED
4/18/2014
(b)(6);(b)(7)(C)

SBF-CM
Folder Details

Folder ID: 132251

Reg No: (b)(7)(E)

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

Addressed To:

Location: ODEQ
Due: 04/19/2014
Received: 4/9/2014
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: (b)(6);(b)(7)(C) Sannerud, Christine A.
Cc: Boockholdt, Barbara J.; (b)(6);(b)(7)(C)
Subject: 2014 Procurement Quota Increase request for (OXYCODONE) KVK Tech, Inc. (b)(4);(b)(7)(E)
Importance: High

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

On Friday, April 11, 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)

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 findings, it is recommended 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) (b)(6);(b)(7)(C) 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)

The Control Sheet will be returned to ODQ, with copies of PA (b)(6);(b)(7)(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)

*Program Analyst/ODQR
Regulatory Unit*

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

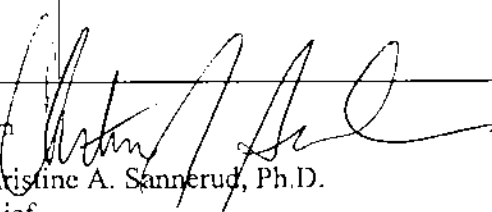
(b)(6);(b)(7)(C)

@usdoj.gov

Memorandum



<p>Subject</p> <p>KVK-Tech, Inc. (b)(4);(b)(7)(E) 2014 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)</p>	<p>Date</p> <p>APR 11 2014</p>
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<p>To</p> <p>Barbara Boockholdt Chief Regulatory Section Office of Diversion Control</p>	<p>From </p> <p>Christine A. Sannerud, Ph.D. Chief UN Reporting and Quota Section Office of Diversion Control</p>
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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.

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

SBF-CM
Folder Details

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: (b)(6);(b)(7)(C) Sannerud, Christine A.
Cc: Boockholdt, Barbara J.; (b)(6);(b)(7)(C)
Subject: 2014 Quota Increase for Fagron, Inc (b)(4);(b)(7)(E)

Importance: High

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

On Monday, April 14, 2014, this section ODGR received your request to review one (1) quota increase application from Fagron, Inc. (b)(4);(b)(7)(E) who distributes to (b)(4) registered retail pharmacies, 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

Fagron, Inc. (b)(4);(b)(7)(E)

Per consultation with the field offices, DEA does not have sufficient grounds to deny a quota increase for Fagron, Inc. However, a review of Fagron, Inc. customer list revealed no negative actions against the registrants.

On Tuesday, April 15, 2014, Program Analyst (PA) (b)(6);(b)(7)(C) emailed GS (b)(6);(b)(7)(C);(b)(7)(F) of the Minneapolis District Office who responded that there are no investigative actions pending that would prevent from receiving an increase in quota for Oxycodone. (b)(4)

The Control Sheet will be returned to ODQ, with copies of PA (b)(6);(b)(7)(C) findings. 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)



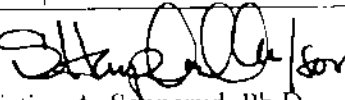
(b)(6);(b)(7)(C) @usdoj.gov

Memorandum



Subject Fagron (b)(4);(b)(7)(E) 2014 Procurement Quota Increase Request Oxycodone (DFN: 630-08.2)	Date APR 14 2014
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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 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.

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

SBF-CM
Folder Details

Folder ID: 132306

Reg No: (b)(7)(E)

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

Addressed To:

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: (b)(6);(b)(7)(C)
Sent: Thursday, May 15, 2014 1:56 PM
To: (b)(6);(b)(7)(C) Sannerud, Christine A.
Cc: Boockholdt, Barbara J. (b)(6);(b)(7)(C)
Subject: 2014 Procurement Quota Increase (Oxycodone) for Amneal Pharmaceuticals of New York, LLC - (b)(4);(b)(7)(E)

Importance: High

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

On Wednesday, May 7, 2014 this section ODGR received your request to review one (1) quota increase application from Manufacturer Amneal Pharmaceuticals of New York, LLC (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 Amneal Pharmaceuticals of New York, LLC Provided below are the results and recommendations.

QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION

Amneal Pharmaceuticals of New York, LLC (b)(4);(b)(7)(E)

Per consultation with the field office, DEA does not have sufficient grounds to deny a quota increase for Amneal 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 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)(5);(b)(7)(E)

On Friday, May 9, 2014, Program Analyst (PA) [redacted] emailed Group Supervisor (GS) [redacted] Long Island District Office who responded that there are no investigative actions pending that would prevent Amneal Pharmaceuticals of New York, LLC from receiving an increase in quota for Oxycodone.

The Control Sheet will be returned to ODQ, with copies of PA [redacted] findings. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced [redacted]

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/CDGR
Regulatory Unit*

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

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

@usdoj.gov

Memorandum



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

Steph A. Sannerud
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.

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

SBF-CM
Folder Details

Folder ID: 132663

Reg No: (b)(7)(E)

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

Addressed To:

Location: ODEQ

Due: 05/16/2014

Received: 5/6/2014

Date Sent:

Response:

Security: A-AES

Abstract: Amneal 2014 procurement quota increase request oxycodone

Signature: (b)(4);(b)(7)(E)
J. Rannazzisi

Doc Categories:

Doc Types:

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

Boockholdt, Barbara

05/13/2014

Action: Recommendation and Comments

Requested Activity:

Response Notes:

5/6/2014 10:17:30 AM

1

Memorandum



Subject

KVK Tech (b)(4);(b)(7)(E)
2014 Procurement Quota Increase Request
Oxycodone
(DFN: 630-08.2)

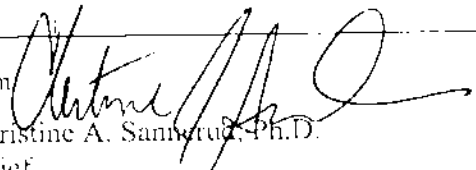
Date

FEB 12 2014

To

Barbara Boockholdt
Chief
Regulatory Section
Office of Diversion Control

From


Christine A. Sambrano, 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.

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

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

From: (b)(6);(b)(7)(C)
Sent: Thursday, May 08, 2014 2:58 PM
To: (b)(6);(b)(7)(C) Sannerud, Christine A.
Cc: (b)(6);(b)(7)(C) Boockholdt, Barbara J.
Subject: 2014 Procurement Quota Increase (Oxycodone)for Metrics (b)(4);(b)(7)(E)

Importance: High

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

On Monday, May 5, 2014, this section ODGR received your request to review one (1) quota increase application from Metrics (b)(4);(b)(7)(E) who distributes to (b)(4) 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.

The Control Sheet will be returned to ODQ, with copies of PA (b)(6);(b)(7)(C) findings. 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)@usdoj.gov

Memorandum



Subject

Metrics Inc (b)(4);(b)(7)(E)
2014 Procurement Quota Increase Request
Oxycodone
(DFN: 630-08.2)

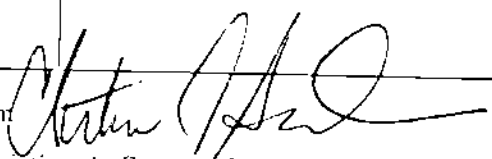
Date

MAY - 2 2014

To

Barbara Boockholdt
Chief
Regulatory Section
Office of Diversion Control

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 revising the applicant's quota allocation for oxycodone.

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

5

**SBF-CM
Folder Details**

Folder ID: 132624

Reg No: (b)(7)(E)

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

Addressed To:

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)

From: (b)(6);(b)(7)(C)
Sent: Wednesday, June 11, 2014 3:32 PM
To: (b)(6);(b)(7)(C) Sannerud, Christine A.
Cc: (b)(6);(b)(7)(C) Boockholdt, Barbara J.
Subject: 2014 Procurement Quota Increase for Generics Bidco II, LLC (b)(4);(b)(7)(E)
Hydrocodone and Oxycodone

Importance: High

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

On Tuesday, May 27, 2014 this section ODGR received your request to review one (1) quota increase application from Manufacturer Generics Bidco II, LLC (b)(4);(b)(7)(E) who distribute to (b)(4) (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 Generics Bidco II, LLC (b)(4);(b)(7)(E) Provided below are the results and recommendations.

QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION

Generics Bidco II, LLC (b)(4);(b)(7)(E)

Per consultation with the 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 the above findings, it is recommended 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)(5);(b)(7)(E)

On Tuesday, June 10, 2014, Program Analyst (PA) [redacted] emailed Acting GS [redacted] of Greensboro RO who responded that there are no investigative actions pending that would prevent Generics Bidco II, LLC [redacted] from receiving an increase in quota for Oxycodone.

The Control Sheet will be returned to ODQ, with copies of PA [redacted] findings. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced [redacted]

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

[redacted]

*Program Analyst/ODGR
Regulatory Unit*

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

From: (b)(6);(b)(7)(C)
Sent: Tuesday, June 10, 2014 4:26 PM
To: (b)(6);(b)(7)(C);(b)(7)(F)
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)(F)
Cc:
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)(F)

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:

Generics Bidco II, LLC (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)

*Program Analyst/ODGR
Regulatory Unit*

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



(b)(6),(b)(7)(C)

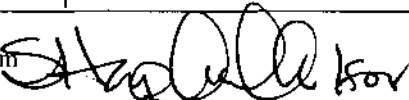
[@usdoj.gov](mailto:usdoj.gov)

Memorandum



Subject Generics Bidco II, LLC (b)(4);(b)(7)(E) 2014 Procurement Quota Increase Request Hydrocodone and Oxycodone (DFN: 630-08.2)	Date MAY 27 2014
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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 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.

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

SBF-CM
Folder Details

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:

5/27/2014 10:43:42 AM

1

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

To: (b)(6);(b)(7)(C)
Cc: (b)(6);(b)(7)(C) Boockholdt, Barbara J.; Sannerud, Christine A.
Subject: 2014 Procurement Quota Increase request for (OXYCODONE) Vintage Pharmaceuticals
(b)(4);(b)(7)(E)

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

On Thursday, June 12, 2014 this section ODGR received your request to review one (1) quota increase application from Manufacturer Vintage Pharmaceuticals (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 Vintage Pharmaceuticals (b)(4);(b)(7)(E) Provided below are the results and recommendations.

QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION

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

Per consultation with the field office, DEA does not have sufficient grounds to deny a quota increase for Vintage Pharmaceuticals (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)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)

(b)(4);(b)(5);(b)(7)(E)

On Wednesday, June 18, 2014, Program Analyst (PA) [redacted] emailed Acting GS [redacted] of Birmingham RO who responded that there are no investigative actions pending that would prevent Vintage Pharmaceuticals [redacted] from receiving an increase in quota for Oxycodone.

The Control Sheet will be returned to ODQ, with copies of PA [redacted] findings. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced [redacted]

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

[redacted]

*Program Analyst/ODQR
Regulatory Unit*

Memorandum



Subject

Vintage (b)(4);(b)(7)(E)
2014 Procurement Quota Increase Request
Oxycodone
(DFN: 630-08.2)

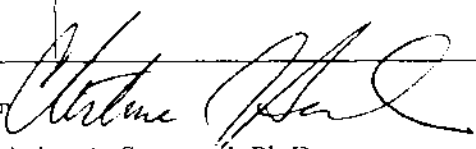
Date

JUN 10 2014

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 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.

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

SBF-CM
Folder Details

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:

Response:

Security: A-AES

Abstract: Vintage

(b)(4);(b)(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:

6/10/2014 2:50:23 PM

1

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

From: (b)(6);(b)(7)(C)
Sent: Wednesday, July 02, 2014 4:23 PM
To: (b)(6);(b)(7)(C)
Cc: Sannerud, Christine A.; Boockholdt, Barbara J.; (b)(6);(b)(7)(C)
Subject: 2014 Procurement Quota Increase request for (Hydrocodone) for Vintage Pharmaceuticals (b)(4);(b)(7)(E)

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

On Thursday, June 12, 2014 this section ODGR received your request to review one (1) quota increase application from Manufacturer Vintage Pharmaceuticals (b)(4);(b)(7)(E) who distribute to (b)(4) (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 Vintage Pharmaceuticals (b)(4);(b)(7)(E). Provided below are the results and recommendations.

QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION

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

Per consultation with the field office, DEA does not have sufficient grounds to deny a quota increase for Vintage Pharmaceuticals (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)(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) (b)(6);(b)(7)(C) emailed Acting GS (b)(6);(b)(7)(C);(b)(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)(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)

*Program Analyst/ODQR
Regulatory Unit*

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

Memorandum



Subject

Vintage (b)(4):(b)(7)(E)
2014 Procurement Quota Increase Request
Hydrocodone
(DFN: 630-08.2)

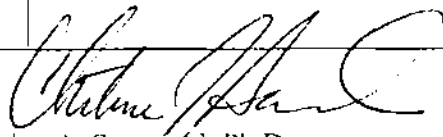
Date

JUN 10 2014

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 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.

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

**Drug Enforcement Administration
EXECUTIVE SECRETARIAT
CONTROL SHEET**

REG NO: (b)(7)(E)

<p>AUTHOR: Ms. (b)(6);(b)(7)(C) Unit Chief ODEQ ODEQ</p> <p>LOCATION: ODEQ</p> <p>TO:</p> <p>SECURITY: A-AES</p> <p>DOC CATEGORIES:</p> <p>DOC TYPE: Memo</p>	<p>DOC DATE: 7/3/2014</p> <p>DATE RECEIVED: 6/10/2014</p> <p>DATE DUE: 06/20/2014</p> <p>DATE CLOSED: 7/3/2014</p> <p>CREATED BY: (b)(6);(b)(7)(C) 6/10/2014</p> <p>MODIFIED BY: 7/3/2014</p>
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ABSTRACT: Vintage (b)(4);(b)(7)(E)
2014 Procurement Quota Increase Request for Hydrocodone.

SIGNATURE: Christine A. Sannerud

NOTES:

FYI - INFO COPIES:

FOLDER PRIORITY: High Priority

Assignments

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

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

From: (b)(6);(b)(7)(C)
Sent: Tuesday, July 01, 2014 11:48 AM
To: (b)(6);(b)(7)(C) Sannerud, Christine A.
Cc: (b)(6);(b)(7)(C) Boockholdt, Barbara J.
Subject: 2014 Procurement Quota Increase for (Oxycodone) for Norwich Pharmaceuticals, Inc.
(b)(4);(b)(7)(E)

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

*Program Analyst/ODGR
Regulatory Unit*

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

Memorandum



Subject

Norwich Pharma (b)(4);(b)(7)(E)
2014 Procurement Quota Increase Request
Oxycodone
(DFN: 630-08.2)

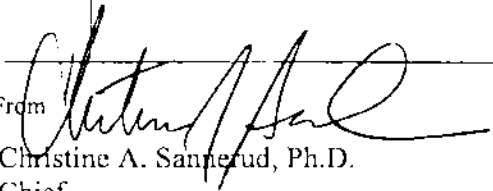
Date

JUN 13 2014

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 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.

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

SBF-CM
Folder Details

Folder ID: 133244

Reg No: (b)(7)(E)

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

Addressed To:

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)

Signature: 2014 PQ Increase Request for Oxycodone
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

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

From: (b)(6);(b)(7)(C)
Sent: Thursday, July 03, 2014 1:21 PM
To: (b)(6);(b)(7)(C) Sannerud, Christine A.
Cc: (b)(6);(b)(7)(C) Boockholdt, Barbara J.
Subject: 2014 Procurement Quota Increase for Oxycodone for Neshier Pharmaceuticals (USA) LLC
 (b)(4);(b)(7)(E)

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

On Thursday, June 18, 2014 this section ODGR received your request to review one (1) quota increase application from Manufacturer Neshier Pharmaceuticals (USA) LLC (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 office for their input and recommendation on Neshier Pharmaceuticals (USA) LLC (b)(4);(b)(7)(E). Provided below are the results and recommendations.

QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION

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

Per consultation with the field office, DEA does not have sufficient grounds to deny a quota increase for Neshier Pharmaceuticals (USA) LLC, (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)(5);(b)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)

(b)(4);(b)(5);(b)(7)(E)

On Thursday, July 3, 2014, Program Analyst (PA) [redacted] emailed GS [redacted] of St. Louis DO who responded that there are no investigative actions pending that would prevent Neshor Pharmaceuticals (USA) LLC [redacted] from receiving an increase in quota for Oxycodone.

The Control Sheet will be returned to ODQ, with copies of PA [redacted] findings. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced [redacted]

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

[redacted]

*Program Analyst/ODQR
Regulatory Unit*

[redacted]

Memorandum



Subject

Nesher Pharmaceuticals (USA) I.L.C. (b)(4);(b)(7)(E)
2014 Procurement Quota Increase Request
Oxycodone
(DFN: 630-08.2)

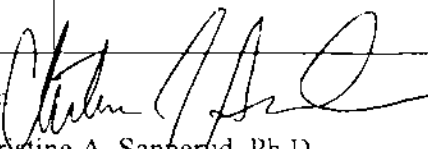
Date

JUN 17 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 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.

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

SBF-CM
Folder Details

Folder ID: 133295

Reg No: (b)(7)(E)

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

Addressed To:

Location: ODEQ
Due: 06/27/2014
Received: 6/17/2014
Date Sent: 7/3/2014

Security: A-AES

Response:

Abstract: Neshor 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: (b)(6);(b)(7)(C)
Cc: Sannerud, Christine A.; (b)(6);(b)(7)(C) Boockholdt, Barbara J.
Subject: 2014 Procurement Quota Increase for (Hydrocodone) for Mikart (b)(4);(b)(7)(E)
Importance: High

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

On Tuesday, July 1, 2014 this section ODGR received your request to review one (1) quota increase application from Manufacturer Mikart (b)(4);(b)(7)(E) 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 recommendation on Mikart (b)(4);(b)(7)(E). Provided below are the results and recommendations.

QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION

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

Per consultation with the field office, DEA does not have sufficient grounds to deny a quota increase for Mikart (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, July 3, 2014, Program Analyst (PA) (b)(6);(b)(7)(C) emailed GS (b)(6);(b)(7)(C);(b)(7)(F) of the Atlanta DO who responded that there are no investigative actions pending that would prevent Mikart (b)(4);(b)(7)(E) from receiving an increase in quota for Hydrocodone.

The Control Sheet will be returned to ODQ, with copies of PA (b)(6);(b)(7)(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)

*Program Analyst/ODGR
Regulatory Unit*

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

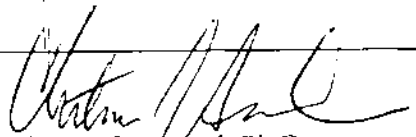
Memorandum



Subject
Mikart (b)(4);(b)(7)(E)
2014 Procurement Quota Increase Request
Hydrocodone
(DFN: 630-08.2)

Date
JUN 30 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.

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

SBF-CM
Folder Details

Folder ID: 133486

Reg No: (b)(7)(E)

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

Addressed To:

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)

Signature: 2014 PQ Increase Request for hydrocodone
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)

To: (b)(6);(b)(7)(C) Sannerud, Christine A.
Cc: (b)(6);(b)(7)(C)
Subject: Procurement Quota Increase for (Oxycodone) Sun Pharmaceutical Industries (b)(4);(b)(7)(E)

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

On Friday, August 15, 2014 this section ODGR received your request to review one (1) quota increase application from Manufacturer Sun Pharmaceutical Industries (b)(4);(b)(7)(E) who distribute to (b)(4) (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 Sun Pharmaceutical Industries (b)(4);(b)(7)(E) Provided below are the results and recommendations.

QUOTA APPLICANT WITH NO ADVERSE OR DEROGATORY INFORMATION

Sun Pharmaceutical Industries (b)(4);(b)(7)(E)

Per consultation with the field office, DEA does not have sufficient grounds to deny a quota increase for Sun Pharmaceutical Industries (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)(6);(b)(7)(C);(b)(7)(E);(b)(7)(F)

On Tuesday, August 19, 2014, Program Analyst (PA) [redacted] emailed GS [redacted] of the New Jersey DO who responded that there are no investigative actions pending that would prevent Sun Pharmaceutical Industries [redacted] from receiving an increase in quota for Oxycodone.

The Control Sheet will be returned to ODQ, with copies of PA [redacted] findings. Based on this information, ODG suggests that the increased quota be reviewed, and possibly reduced [redacted]

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

[redacted]

*Program Analyst/ODQR
Regulatory Unit*

[redacted]

Memorandum



Subject

Sun Pharmaceutical Industries, Inc. (b)(4);(b)(7)(E)
2014 Procurement Quota Increase Request
Oxycodone
(DFN: 630-08.2)

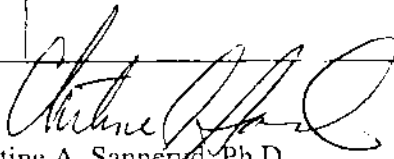
Date

AUG 13 2014

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 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 hydrocodone.

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

SBF-CM
Folder Details

Folder ID: 134119

Reg No: (b)(7)(E)

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

Addressed To:

Location: ODEQ
Due: 08/24/2014
Received: 8/14/2014
Date Sent: 8/28/2014

Security: A-AES

Response:

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