

(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)

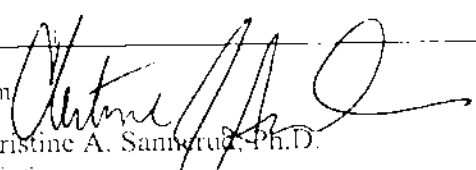
Date

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:

(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)

(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

Date Sent:

Response:

Security: A-AES

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)

(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)

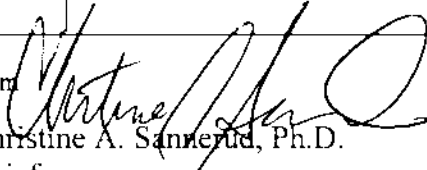
Date

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)

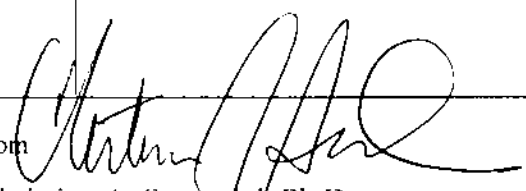
Date

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)

(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)

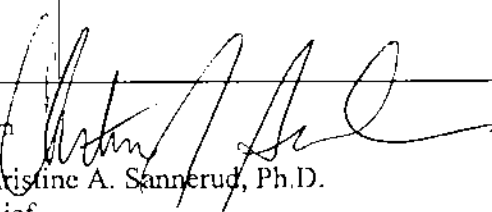
(b)(6);(b)(7)(C)

@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)

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:

Security: A-AES

Response:

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

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